WEST VIRGINIA

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

Board of Pharmacy

SECRETARY
C. HERBERT TRAUBERT

December 28, 1982

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE
THIS DATE 12-29-82
Administrative Law Division

A. James Manchin
Secretary of State
State Capitol
Charleston, WV 25305

Dear Sir:

I am responding to a memo from Fredric J. George, Deputy Attorney General, regarding a requirement that a certified copy of all previously adopted or proposed rules and regulations be filed with the Secretary of State prior to January 1, 1983.

I am, therefore, forwarding you a certified copy of all adopted rules and regulations filed prior to January 1, 1983. I certify that this is a true and actual copy of the rules and regulations adopted according to Chapter 29A, Article 2, Section 5, of the West Virginia Code of 1931, as amended.

Yours very truly,

C. Herbert Traubert

C. Herbert Traubert
Secretary

CHT:dp

Enc.

Obsolete
valid ? to ~~June 12, 1985~~
May 15, 1984

Emergency rule
expired May 2, 1985
Final Filed rule June 13, 1985

Amended May 15, 1984
with Emergency Rule

WEST VIRGINIA BOARD OF PHARMACY

- SECRETARY -
C. HERBERT TRAUBERT

OFFICE LOCATED AT
150 ROCKDALE ROAD
FOLLANSBEE, W. VA. 26037

TELEPHONE 304 527-1270

February 15, 1979

James Manchin
Secretary of State
Capitol Building
Charleston, W. Va. 25305

Dear Sir:

The West Virginia Board of Pharmacy has been informed by the Office of the Attorney General that Article 14, Section 2, "Gratuities" and Article 15, Section 7, "False or Misleading Advertising" are in violation of the provision of the West Virginia Anti-Trust Act.

Therefore, the West Virginia Board of Pharmacy has taken appropriate action that the said articles, Article 14, Section 2, "Gratuities" and Article 15, Section 7, "False or Misleading Advertising" of the official regulations of the West Virginia Board of Pharmacy be repealed and proper notice be given.

Yours very truly,

Herbert Traubert

Herbert Traubert
Secretary

HT:dp

WEST VIRGINIA BOARD OF PHARMACY

- SECRETARY -
C. HERBERT TRAUBERT

OFFICE LOCATED AT
150 ROCKDALE ROAD
FOLLANSBEE, W. VA. 26037

TELEPHONE 304 527 1270

NOTICE OF REPEAL OF REGULATIONS

The West Virginia Board of Pharmacy has been informed by the office of the Attorney General, Anti-Trust Division, that Article 14, Section 2, "Gratuities" and Article 15, Section 7, "False or Misleading Advertising" are in violation of the West Virginia Anti-Trust Act.

Therefore, at a meeting of the West Virginia Board of Pharmacy, a motion was duly made that namely Article 14, Section 2, "Gratuities" and Article 15, Section 7, "False or Misleading Advertising" of the regulations of the West Virginia Board of Pharmacy be repealed.

Therefore, notice is hereby given that any person that has any objections to such action may submit their views as to this action to the West Virginia Board of Pharmacy, 150 Rockdale Road, Follansbee, West Virginia 26037, within thirty (30) days from the date of February 18, 1979.

Given under my hand this 16th day of February 1979.

C. Herbert Traubert
Secretary

WEST VIRGINIA

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

Board of Pharmacy

SECRETARY
C. HERBERT TRAUBERT

Series I & II Rules and Regulations
Filed with Secretary of State on November 15, 1971

Article II, Section 7, "Security"
Filed with Secretary of State on February 4, 1974

Article II, new section - Section 8, "List of Drugs & Prices; Posting Required; Penalties for Failure to Comply."
Filed with Secretary of State on July 14, 1976

Article 10, "Drug Product Selection Regulations"
Filed with Secretary of State on August 19, 1980

All rules were Legislative Rules.

FILED IN THE OFFICE OF
A. JAMES MANCHIN
SECRETARY OF STATE
THIS DATE 12-29-82
Administrative Law Division

SERIES ONE

AMENDED

RULES AND REGULATIONS OF THE

WEST VIRGINIA

BOARD OF PHARMACY

ADOPTED PURSUANT TO THE AUTHORITY GRANTED TO THE WEST VIRGINIA BOARD OF PHARMACY BY THE PROVISIONS OF CHAPTER 30, ARTICLE 5, SECTION 19 OF THE WEST VIRGINIA CODE OF 1961 AND FILED WITH THE SECRETARY OF THE STATE OF WEST VIRGINIA PURSUANT TO CHAPTER 29A, ARTICLE 2, SECTION 1 OF THE WEST VIRGINIA CODE

NOTE: THESE RULES AND REGULATIONS ARE DESIGNATED AS "SERIES ONE". AN ADDITIONAL SERIES TO BE DESIGNATED AS "SERIES TWO" SHALL BE PROMULGATED AND SHALL GOVERN CHAPTER 60A OF THE WEST VIRGINIA CODE AS ADOPTED IN 1971 BY THE WEST VIRGINIA LEGISLATURE; THIS CHAPTER (60A) IS ALSO KNOWN AS "THE UNIFORM CONTROLLED SUBSTANCES ACT". OCCASIONAL REFERENCE TO CHAPTER 60A OF THE WEST VIRGINIA CODE MAY BE FOUND IN SERIES ONE REGULATIONS.

SERIES ONE

AMENDED

RULES AMD REGULATIONS

of the

WEST VIRGINIA

BOARD OF PHARMACY

Adopted pursuant to the authority granted to the West Virginia Board of Pharmacy by the provisions of Chapter 30, Article 5, of the West Virginia Code of 1961 and filed with the secretary of the State of West Virginia pursuant to Chapter 29A, Article 2, Section 1 of the West Virginia Code.

INDEX

SEE PAGE 94 FOR SERIES TWO REGULATIONS AND INDEX FOR CONTROLLED SUBSTANCES ACT REGULATIONS.

ARTICLE 1. Definitions

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

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 or any function of the body of man or animals; and (d) substances 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. The term "poisonous drug" means any drug likely to be destructive to adult human life in quantities of five grains or less.

3. The term "deleterious drug" means any drug likely to be destructive to adult human life in quantities of sixty grains or less.

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.

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 U.S. 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.

6. "Controlled substance" means a drug, substance, or immediate precursor in Schedules I through V of Article 2 of Chapter 60A, West Virginia Code, (Uniform Controlled Substances Act).

7. The term "prescription" shall be held to mean an order for drugs or medicines or combinations or mixtures thereof, written or signed by a duly licensed physician, dentist, veterinarian or other medical practitioner licensed to write prescriptions intended for the treatment or prevention of disease of man or animals. The term "prescription" shall also include orders for drugs or medicines or combinations or mixtures thereof transmitted to the pharmacist by word of mouth, telephone or other means of communication and including chart orders in institutions by a duly licensed physician, dentist, veterinarian or other medical practitioner licensed to write prescriptions intended

for treatment or prevention of disease of man or animals, and such prescriptions received by word of mouth, telephone or other means of communication shall be recorded in writing by the pharmacist and the record so made by the pharmacist shall constitute the original prescription to be filed by the pharmacist. All such prescriptions shall be preserved on file for a period of five years, subject to inspection by the proper officer of the law. The above shall apply except that when controlled substance is prescribed The Uniform Controlled Substances Act and all rules and regulations adopted pursuant thereto shall govern such prescription.

8. 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.

9. 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", "pharmacist", "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.

10. 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.

11. "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 "dispensing" controlled substances found in Article 2, Chapter 60A of the Uniform Controlled Substances Act.

12. 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.

13. "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, and whose license is in good standing.

14. "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.

15. "Medical Practitioner" means an individual physician, dentist, veterinarian, podiatrist, osteopath, or other practitioner duly licensed to practice in this state by the appropriate professional licensing board and to prescribe drugs necessary in the course of professional practice intended for the treatment or prevention of disease of man or animals.

The term "practitioner" as pertains to persons and places handling controlled substances and as defined under Article 2, Chapter 60A of the Uniform Controlled Substance Act shall not be construed to have the same meaning as the definitions for medical practitioners under Chapter 30 of The West Virginia Code.

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

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

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

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

20. "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 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 or more persons.

e. A pharmacy or drug store is moved to a new location.

Only pharmacy or drug store permits issued under Chapter 30, Article 11, Section 4 of the West Virginia Code shall be considered a renewal.

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

22. "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.

23. "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.

24. The term "internship" shall be used to describe the practical experience requirement, and "one year's practical experience" ~~shall mean an average work week of~~ not less than forty hours for a period of one

shall mean an average work week of not less than forty hours for a period of one calendar year, except as herein provided for concurrent training programs.

25. "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.

26. "Person Addicted" means one 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.

27. "Act" or "uniform Controlled Substances Act" when used in these regulations shall mean and refer to Chapter 60A of the West Virginia Code as enacted by The West Virginia Legislature in 1971.

28. The term "Brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug or drug product, its container, label or wrapping at the time of packaging.

29. The term "Generic name" means the official title of a drug or drug combination for which a new drug application, or an abbreviated new drug application has been approved by the United States Food and Drug Administration and is in effect.

30. "Substitute" means to dispense with the practitioner's express authorization on a written or oral prescription or by practitioner's failure to indicate his intent to prohibit such dispensing of a therapeutically equivalent generic drug product.

31. a. "Equivalent" means drugs or drug products which are the same amounts of identical active ingredients and same dosage form, and which will provide essentially the same therapeutic efficacy and toxicity when administered to an individual.

b. Therefore, although not listed specifically in the negative formulary, pharmacists may not substitute:

1. A different drug entity or a different chemical entity than that prescribed.
2. A different salt or ester than that of the product prescribed if this changes the therapeutic equivalency and/or the disposition of the drug.
3. A different dosage form than that prescribed, unless bioavailability can be assured.

c. The words "Equivalent", "Bioequivalent" or "Therapeutically Equivalent" shall be considered synonomous and imply equal bioavailability.

ARTICLE 2. General Provisions.

1. Board in General.

The state board of pharmacy, known as the "West Virginia Board of Pharmacy" shall consist of five practicing pharmacists who shall be appointed by the governor, by and with the advice and consent of the Senate. Each member of the Board, at the time of his appointment, shall be a citizen and a registered pharmacist of the state of West Virginia and actively engaged in the practice of pharmacy.

2. Officers of the Board.

The members of the Board shall annually elect as officers of said Board, one member to serve for a period of one year as president of the said Board; one member to serve for a period of one year as Vice President of said Board; and, one member to serve for a period of one year as Secretary of said Board, all of whom shall hold their offices for one year and until their successors are elected said election to be held in the month of June each year.

The Secretary shall execute a surety bond conditioned as required by law, which bond shall be approved by the attorney general as to form, and by the auditor as to sufficiency, and when so approved, shall be filed and recorded in the office of the Secretary of State. The premium on said bond shall be regarded as a proper and necessary expense of the Board.

3. Official Seal.

The Board hereby reaffirms and readopts, as the official seal of the Board the following: the outer circle of the seal has inscribed therein "West Virginia Board of Pharmacy"; and the inner circle of the seal consists of a base upon which rests a graduate entwined about which there is an asclepius serpent and holding in balance a set of

scales, an impression of which is affixed hereto:

4. Meetings of the Board.

The Board shall hold at least two meetings each year for the purpose of examining applicants for license to practice pharmacy in West Virginia and for the transaction of such other business as may legally come before it and it may hold such other examination meetings as it might deem appropriate. In addition thereto, it may hold such additional meetings as may be necessary which shall be called by the Secretary at the direction of the President or upon the written request of any three members.

5. Quorums.

Before any action can be taken, on any matter properly in the consideration of the Board, at least three members must be in attendance at the place and time set for the meeting of the Board. A majority vote of the members in attendance is required before any motion is passed.

6. Location of Office.

The office of the Board is, unless otherwise designated by the Board located at the office of the Secretary.

7. Disposition of Moneys; Report to Auditor.

The Secretary of the Board shall receive and account for, all moneys derived by virtue of the provisions of Chapter 30, Article 1 and Article 5 of the West Virginia Code and shall pay such moneys into the state treasury monthly on or before the tenth day of the month in which such moneys are received. He shall also, on the first day of January and first day of July of each year or within five days thereafter, certify to the State Auditor, a detailed statement of all such moneys received by him during the preceding six months.

8. Compensation of Members: Expenses.

Every member of the Board shall receive Thirty-Five Dollars (35.00) for each day actually spent in attending the sessions of the Board or of its committees and the nefessary travel, and shall be reimbursed for all adtual and necessary expenses incurred in carrying out the provisions of Chapter 30 of the Code of West Virginia applicable to the Board.

The Secretary shall receive such salary as may be prescribed oy the Board but in proceedings relative to the fixing of his salary, the Secretary shall have no vote.

All authorized compensation and all expenses certified by the Board as properly and necessarily incurred in the discharge of its duties, shall be paid out of the State Treasury from funds appropriated for that purpose on warrants of the State Auditor issued on the requisition signed by the President and Secretary of the Board.

9. Record of Proceedings: Registration of Applicants: Certified Copies of Records Prima Facie Evidence; Report to Governor.

The Secretary of the Board shall keep a record of its proceedings and a register of all applicants for license or registration, showing for each, the date of his appliation, his name, age, educational and other qualifications, place of residence, whether an examination was required, whether the applicant was rejected or certificate of license or certificate of registration granted, the date of such action, the license or registration number, all renewals of such license or registration number, if required, and any suspension or revocation thereof. The books and register of the Board shall be open to public inspection at all reasonable times, and such books and register, or a copy of any part thereof, certified by the secretary and attested by the seal of the Board, shall be prima facie evidence of all matters recorded therein.

On or before the first day of January of each year in which the legislature meets in regular session, the Board shall submit to the governor a report of its transactions for the preceding one year, together with an itemized statement of its receipts and disbursements, and a full list of the names of all persons licensed or registered by it during such period, certified by the president and the secretary. A copy of the report shall be filed with the Secretary of State.

10. Roster of Licensed or Registered Practitioners.

The Secretary of the Board shall also prepare and maintain a complete roster of the names and office addresses of all persons licensed, or registered, and practicing within or without this state, the profession or occupation arranged alphabetically by name and also by the counties in which their offices are situated. The Board may call for and require a registration whenever it deems it necessary or expedient to secure an accurate roster.

ARTICLE 3. Internship; Requirements for certificate.

1. The principal purpose of serving an internship is to acquire practical experience under the direct supervision and instruction of a registered pharmacist preceptor in the providing of pharmaceutical services including the compounding and dispensing of prescriptions.

The Board shall certify internship, except as herein provided, only for an individual:

a. who has made application to the Board for registration as an intern and who in turn has been issued an intern certificate, which expires after three (3) years from the date of issue, by the Board. The intern certificate shall be displayed at the location of interning.

b. who notifies the Board at least ten (10) days prior to the commencement of interning of the name and location of his registered pharmacist preceptor.

c. who notifies the Board within ten (10) days subsequent to termination of any internship under a pharmacist preceptor.

d. whose internship is certified by the submission of "Certification by Pharmacist as to Internship" form executed by the pharmacist preceptor immediately after termination of the internship. (Forms are available from the Board of Pharmacy).

2. No intern shall be certified by the Board unless the individual is enrolled in the last three (3) years of the pharmacy curriculum or is a graduate of a recognized school of pharmacy.

3. No credit shall be received for experience for any period of time that is concurrent with enrollment in a recognized school of pharmacy except that the Board may grant three (3) months experience time for students participating or enrolled in supervised concurrent intern-

ship or clinical pharmacy training programs concurrent with the last year of the professional pharmacy curriculum.

4. No internship will be certified in a pharmacy or drug store in which the volume of prescription dispensing is less than 10,000 prescriptions per year, unless any particular or extenuating situation warrants deviating from this figure in the judgment and discretion of the Board as provided for in Sections II, III and V of Chapter 30.

5. Any pharmacist preceptor supervising the practical internship training shall be a qualified preceptor and employ the training concepts outlined in a "Guide for Preceptors and Interns" available through the West Virginia Board of Pharmacy.

6. The Board may accept internship experience gained outside the State of West Virginia on a letter of credit or certification from the Board of Pharmacy of the state in which the applicant acquired internship experience.

ARTICLE 4. Licensure and Annual Renewal; Requirements for

1. Application.

All applicants for examination shall apply therefor in writing to the Secretary of the Board at least 15 days before the date the examination is to be conducted and shall transmit with his application, a fee of Fifty Dollars ($50.00), which sum the Board is authorized to charge for an examination or investigation into such applicant's qualification to practice. The application shall be made on a form provided by the Board.

2. Requirements for Application.

a. Age.

The applicant must be not less than eighteen years of age, proof of which must be shown by a birth certificate, or other proof when a birth certificate is not available.

b. Citizenship

In order to be registered as a pharmacist, a person shall be a citizen of the United States, provided that a person who intends to become a citizen may satisfy all other mandatory requirements for licensing prior to being naturalized.

c. Moral Character

Every application for registration as a pharmacist shall present to the Board satisfactory evidence that he is a person of good moral character and not addicted to

drunkenness or the use of narcotic drugs and that he has not been convicted of violating the provisions of any law relating to the practice of pharmacy and that he has not been convicted of a crime involving moral turpitude. PROVIDED, that, an applicant, who has been arrested pursuant to Chapter 60A, Article 4, Section 401 of the West Virginia Code, and who has later been discharged pursuant to Section 407 of the same article, may, upon otherwise having satisfied the requirements of this section, be deemed to have fully satisfied its requirements.

d. Education

The applicant shall present to the Board satisfactory evidence that he is a graduate of a recognized school of pharmacy as defined in Article 1 of these rules and regulations.

e. Internship

The applicant shall have acquired at least nine months of internship experience under the supervision of a registered pharmacist preceptor as defined in Articles 1 and 3 of these rules and regulations.

3. Examinations.

a. Examinations shall be held at a time and place designated by the Board. At least thirty days' notice shall be given by the Board prior to the holding of any examination. Notice of such examination shall be given by mail to all

registered pharmacies or drug stores in the State of West Virginia as appearing on the roster kept by the Secretary of the Board as required under Chapter 30, Article 1, Section 13 of the Code of West Virginia, and to such other persons and schools of pharmacy as the Board may from time to time designate.

b. A maximum of three days shall be allowed for the examinations, including written, oral and laboratory.

c. An applicant must pass a written examination in subjects determined by the Board as being reasonable, in testing his technical knowledge; and an applicant must also pass a practical examination determined by the Board as being a reasonable test of the applicant's ability to translate his technical knowledge into terms of actual practice.

d. For the purpose of grading or rating, answers to the questions shall be valued by marks or points based on their importance and as determined by the judgment of the examiner. A general average of 75% with not less than 60% in any written subject except the practical examination wherein not less than 75% is required, shall be necessary for an applicant to pass the examination. An applicant failing to pass the examination satisfactorily to the Board shall at either the first or second succeeding examination conducted by the Board, be entitled to a re-

examination without further cost but one such re-examination shall exhaust his privilege under his original application.

4. Certificate of Registration.

An applicant who has successfully passed all the examinations of the Board will receive a letter signed by the Secretary of the Board, granting him the right to practice pharmacy in the State of West Virginia until such time as the permanent certificate as a registered pharmacist may be prepared for him. The permanent certificate of registration shall bear a serial number, the full name of the applicant, the date of its issuance, the seal of the Board, shall be signed by at least three members of the Board and attested by the President and Secretary. Unless otherwise provided, the Board shall charge a fee of Five Dollars ($5.00) for every such certificate and a fee of Five Dollars ($5.00) for duplicate thereof, which fee shall be paid before such certificate or duplicate is issued, No such certificate shall be assignable.

5. Annual Renewal of Registration.

a. Annual Renewal

Every registered pharmacist, who desires to continue in the practice of his profession, shall on or before the first day of July annually apply to the state Board of Pharmacy for a renewal of his registration, and shall transmit with his application a Fifteen Dollar ($15.00) fee. If the Board shall find that such applicant has

been legally registered in this State, and is entitled to a renewal of the certificate it shall issue to him a renewal certificate attesting that fact.

b. Notification.

Notification of the annual renewal shall be given by the secretary of the board at least thirty days prior to said first day of July.

c. Failure to Renew.

If any pharmacist shall fail for a period of thirty days after the first day of July to apply to the Board for a renewal of his registration, his name shall be erased from the register of registered pharmacists.

Such person, in order to again become registered, shall be required to appear personally before the Board to show cause for permitting the certificate to lapse. If such person submits to the Board satisfactory reasons for allowing the certificate to lapse, and satisfies the Board by oral, written or practical examination as to his qualifications to practice the profession, such person shall be reregistered and required to pay for renewal the same fee as in the case of examination. If necessary, the Board may charge an additional fee.

ARTICLE 5. Reciprocity; Registration of Pharmacists from Other States

1. Qualifications

The Board may register and admit to practice as pharmacists in this state without examination, such persons as have been legally registered or licensed as pharmacists in other states, provided:

a. applicant must be at least twenty-one years of age.

b. the original state in which the applicant is registered must accord similar recognition to registered pharmacists of the State of West Virginia.

c. applicant must be in good standing in the state of original licensing; a "reciprocal registration" is not recognized for reciprocity purposes.

d. the applicant is, in fact, competent and physically and mentally qualified to function as a pharmacist.

e. the applicant is of good moral character and is not addicted to the use of alcohol, or controlled substances.

f. the applicant has not been convicted, fined or had his license suspended or revoked for violation of pharmacy, liquor, narcotic or food and drug laws.

g. an applicant must have originally passed a written examination in subjects determined by the Board as being reasonable, in testing his technical knowledge, and applicant must have also passed a practical examination determined by the Board as being a reasonable test of the applicant's ability to translate his technical knowledge into terms of actual practice and the applicant must have made a general average of 75% with not less than 60% in any written subject and must have made an average of not less than 75% in the practical examination.

h. applicants who have become registered since 1945 must have graduated from a recognized school of pharmacy and in addition thereto, must have had not less than one year of practical experience as an intern and/or a registered pharmacist. Applicants who were registered prior to 1945 must have had not less than two years of practical experience requirements for registration as a pharmacist in West Virginia at the time of their registration as a pharmacist by examination.

i. ~~one year of time must have elapsed since the applicant acquired a certificate or licence by examination~~. If an applicant has not been engaged as a practicing pharmacist as evidenced by an employer's affidavit during the year immediately prior to application for reciprocity, the Board will determine competency to practice by a practical examination.

j. applicants must become familiar with the West Virginia laws and regulations governing the practice of pharmacy and the rules of professional conduct established by the Board.

k. applicants for reciprocity and others coming into West Virginia from other states are warned not to accept positions as pharmacists or to attempt to work as pharmacists until such time as they received a certificate of registration from the State of West Virginia.

2. Application.

a. A preliminary application form obtained from the Secretary of the National Association of Boards of Pharmacy shall be completed by the applicant informing him in which state or states the applicant has previously registered and in what state he wishes

to register submitted with a fee of Seventy-Five Dollars ($75.00) to the Secretary of the National Association of Boards of Pharmacy, 77 West Washington Street, Chicago, Illinois.

On receiving the application for licensing by reciprocity, the National Association of Boards of Pharmacy contacts authorities in states where the applicant may have been licensed to secure verification, and, in addition, runs a character check on all applicants. An applicant who possesses the necessary qualifications will be supplied with the application forms which must be completed and submitted with the required supporting documents to the Secretary of this Board with a fee of Fifty Dollars ($50.00) plus Five Dollars ($5.00) for the certification fee.

b. The application must include the following:

(1). a certified copy of proof of experience, or original preceptor's affidavit proving same, that were filed by applicant when he took the examination in the state from which he applies;

(2). a recent bust photograph with a statement thereon, signed by the applicant, affirming that it is a photograph of said applicant and has been made within the previous 12 months.

3. Appearance Before Board.

Applicants for registration by reciprocity are required to appear before the Board at such time as directed, for checking of credentials, interview, and such questioning and investigation as may be necessary to determine the fitness of the applicant to practice in West Virginia. Misrepresentations shall serve to void any registration that may be granted.

ARTICLE 6 Proceedings for Suspension or Revocation of License or Registration; Effective Suspension or Revocation; Transcript; Report.

(1) In all proceedings before the Board for the suspension or revocation of any license or registration, a statement of the charges against the holder thereof and a notice of the time and place of hearing shall be served upon such person as a notice is served under § 1, Article 2, Chapter 56 of the Code of West Virginia at least thirty days prior to the hearing and he may appear with witnesses and be heard in person, by counsel, or both.

(2) The Board may take such oral or written proof for or against the party charged as it may deem advisable.

(3) The Board shall have the power to compel the attendance of witnesses and to take testimony concerning any proof on matters within its jurisdiction and for such purposes, the president and secretary of the Board shall have the power to administer oath.

(4) If, upon such hearing, the Board finds that such charges are true, it may suspend, or revoke the certificate

of registration and such suspension or revocation shall take from the person, all rights and privileges acquired thereby. A stenographic report of each proceeding to suspend or revoke such certificate of registration shall be made at the expense of the Board and a transcript thereof retained in its files. The Board shall make a written report of its findings which shall constitute part of the record and copies thereof shall be filed with the secretary of state and with the appropriate office of a sister state and with the secretary of the National Association of Boards of Pharmacy if a reciprocal license is involved.

(5) The following rules of procedure shall control such hearing before the Board.

A. Hearings for the revocation, cancellation, or suspension of a license or a permit.

(a) Initiating proceedings before the Board, proceedings for revocation, cancellation or suspension of a license or permit before the Board shall be begun by filing charges with the Board in writing and under oath. Said charges may be made by any person or persons.

(b) Settings: The president of the Board shall set a time and a place for hearings on the revocation, cancellation or suspension of a license or a permit.

(c) Representation: At any hearing the respondent shall have the right to appear either personally or by counsel, or both, to produce witnesses or evidence in his behalf, to cross examine witnesses and to have subpoenas issued by the

Board.

(d) Recording of Hearings: A record of proceedings at hearings may be made in shorthand or by mechanical or electronic recordings at the discretion of the president of the Board or other person presiding over the hearing.

(e) The Board may deputize an employee to conduct the questioning at any hearing. It shall be the duty of such appointee to require an orderly presentation in accordance with these rules.

B. Order of Presentation.

(a) When any licensee or permittee shall be served with charges previously filed before the Board as provided in these rules, he shall appear before the Board on the day and at the time specified in the notice of hearing.

(b) The absence of a licensee will in no way affect the power of the Board to act, provided proper notice has been given.

(c) At any hearing based upon charges previously filed with the Board as provided in these rules, the president of said Board or the Board's appointee shall commence such hearing by causing said charges to be read, and thereafter receiving the answer of the respondent to such charges, if any. The answer may be given either guilty or not guilty.

(d) The Board shall then proceed to hear evidence, both written and oral, in support of the charges. Each witness appearing in support of the charges shall first give direct testimony and immediately thereafter be available for cross-examination by the respondent or his attorney. Such testimony shall be given under oath.

(e) After the presentation of evidence in support of the charges, the respondent or his attorney shall then proceed with the presentation of evidence in opposition to the charges. The evidence may be written or oral. Witnesses appearing in behalf of the respondent shall give direct testimony and immediately thereafter, be subject to cross-examination by the Board or its duly authorized appointee. All such testimony shall be given under oath.

(f) Any member of the Board may examine any witness or the respondent during their presentation of direct testimony or upon cross-examination.

(g) At the close of the presentation of evidence in support of the complaint and evidence in opposition of the complaint, respondent or his attorney may be permitted oral argument before the Board.

(h) Evidence: All oral testimony shall be given under the oath of the witness. Evidence, both oral and written, which has probative value shall be received by the Board. Such evidence may be received even though the evidence is not presented in a form which would make it admissible if offered in court of law. However, evidence which is irrelevant to the issue shall be excluded. The president of the Board or other persons presiding over the hearing shall rule on the admissibility of the evidence.

(i) Effective date of official acts or orders: All official acts or orders of the Board shall be evidenced by a written record, and the date of the order or act unless some other effective date is stated in the writing itself. An

appeal from the action of the Board shall not operate as a stay of the Board's action unless specifically directed as such by the Board.

C. Application for Re-Issuance of License or Registration.

Upon application, the Board may re-issue a license or registration to a person whose license or registration has been cancelled or revoked. Such application, in the case of cancellation or revocation, shall not be made prior to one year after the cancellation or revocation.

Upon application, the Board may reinstate a license which has been suspended. Such application for reinstatement of a license shall be in a manner and form that the Board may require.

D. Appearances Before the Board by Invitation of the Board.

(a) Appearances by invitation: When any licensee, permittee or other person shall receive an invitation to appear before the Board, such invitation shall in no manner be considered a subpoena or a demand to appear, but shall only be considered a request, to be complied with at the discretion of the person so invited.

(b) Representation at such hearings: Such person so invited, should he so desire, may have legal counsel accompany him to said hearing before the Board.

(c) Appearances by invitation shall be informal: All hearings before the Board based upon invitation by the Board shall be informal. No record of such proceedings shall be made.

E. Hearings By Board Upon Complaint.

(1) Any person aggrieved by the rules and regulations promulgated by the Board shall be entitled to have his complaint set down for hearing by said Board.

(2) Requests for such hearings must be filed with the Board in accordance with the following requirements:

(a) Complaint, depositions, briefs and other papers of importance, shall be printed or typewritten and only one side of the paper shall be used.

(b) Requests for such hearings shall specify in detail the basis for complaint.

(c) Complaint shall specify reasonable evidence that such rule or regulation is inconsistent with the law governing the practice of pharmacy in West Virginia.

(3) Hearings for such complaint shall be held in ten days from the date of receipt of said request by the Board, unless postponed by mutual agreement.

ARTICLE 7 Review by Circuit Court and Supreme Court of Board's Refusal to Issue Suspension or Revocation of License or Registration.

(1) Any person who has been refused a license or registration for any cause other than failure to pass the examination given by the Board or whose certificate of registration has been suspended or revoked, may, within thirty days after the decision of the Board, present his petition in writing to the Circuit Court of the county in which he resides or to the judge of such court in vacation, praying for the review and reversal of such decision.

(2) Before presenting his petition to the court or judge, petitioner shall mail copies thereof to the president and secretary, respectively, of the Board.

(3) Upon receipt of such copy, the secretary shall forthwith transmit to the clerk of such court, the record of the proceedings before the Board.

(4) The court or judge shall affix a time for review of said proceedings at its earliest convenience.

(5) Notice of the time and place, in writing, of such hearing, shall be given by the clerk of the court, to the president and secretary of the Board, at least ten days before the date set therefore.

(6) The court or judge may enter an order affirming, revising or reversing the decision of the Board if it appears that the decision was clearly wrong.

(7) Prior to the entry of such order by the court or judge, no order shall be made or entered by the court or

judge to stay or supersede said suspension, revocation or cancellation of any such certificate of registration.

(8) The judgment of the Circuit Court or the judge thereof, may be reviewed upon appeal in the Supreme Court of Appeal.

ARTICLE 8 Prescription Requirements and Pharmacist's Dispensing Responsibilities.

1. Issuance of Prescription. A prescription to be valid must be issued for a legitimate medical purpose by a duly licensed medical practitioner acting in the usual course of professional practice.

All written prescription orders shall be dated and signed by the medical practitioner on the day when issued. Every drug prescription order shall contain an instruction on whether or not an equivalent generic name drug or drug product may be substituted. No prescription, either new or presented for refill, shall be dispensed after the death of the practitioner.

2. Oral Prescriptions. Where an oral prescription is permitted, the pharmacist shall reduce the practitioner's order for the drug or drug product to writing and this record shall constitute the original prescription filed by the pharmacist. The pharmacist shall indicate substitution permitted if so ordered by the practitioner or his agent.

3. Refilling of Prescriptions. It shall be unlawful for a pharmacist to refill any prescription containing a drug wherein the label of the original container of such drug bears the statement, "Caution: Federal Law prohibits dispensing without prescription," unless the licensed practitioner has authorized such by written notation on the original prescription, or has authorized such by oral order which is reduced promptly to writing and filed by the pharmacist.

~~2. If a prescription is refillable, the date of such refill and the initials of the pharmacist refilling said prescription shall be recorded upon the original written prescription, or upon the oral prescription which has been reduced to writing and filed by the pharmacist.~~

4. Controlled Substances. The refilling of prescriptions shall be limited by the provisions of the Uniform Controlled Substances Act (60A-3-308, West Virginia Code) applicable to prescriptions and any rules and regulations adopted pursuant thereto.

a. No prescription for a schedule II Controlled Substance may be refilled.

b. The prescription for a Schedule III or IV Controlled Substance shall not be filled or refilled more than six months after the date written or be refilled more than five times unless renewed by the practitioner.

5. Prescription Records. Records of all prescriptions dispensed shall be maintained on file for a period of at least 5 years and upon request made available for inspection. Such prescription records on file shall bear the following information on the original prescription order form:

a. The date dispensed and the initials of the dispensing pharmacist.
b. The brand name or generic equivalent name of the drug product dispensed, and the manufacturer's name; or its national drug code number.
c. If a prescription for a drug product is refilled, a record of (1) the date of each refill, (2) the quantity dispensed if different from original prescription, (3) the initials of the dispensing pharmacist, and (4) the name of the practitioner authorizing the refill or his agent who communicated his authorization to refill.

6. Confidentiality of Records. Records of dispensed or administered drugs are not public records. Prescription and patient medication records shall be deemed confidential and may not be released to anyone other than patient or prescriber without the written consent of the patient or pursuant to other statutory authority.

7. Prescription Containers. A drug product dispensed to a patient shall be placed in a new container which conforms with the drug's monograph standards specified in the Official United States Compendia, and current state and federal safety container regulations. Federal safety package containers must be used unless otherwise requested by patient or practitioner.

8. Prescription Label Requirements. Any drug dispensed pursuant to a valid prescription order or dispensed directly by a duly licensed medical practitioner, shall have affixed to the immediate container in which the drug product is dispensed or sold a label bearing the following information:

a. The directions for the use of the drug with cautions or warnings.
b. Unless the prescribing practitioner directs otherwise, the generic name of the drug product and the name of the original manufacturer. Commonly used abbreviations may be used for the manufacturer and for the active ingredient(s) and for the generic name.
c. The name of the patient.
d. The name of the prescribing practitioner.
e. The date originally dispensed.
f. The name, address and prescription number of the provider.

g. The strength of the dosage form prescribed.

h. The prescribing, dispensing and labeling of a drug product which is a controlled substance shall be subject to additional requirements as provided in Chapter 60A and Series Two regulations of the West Virginia Code.

ARTICLE 9. Prohibitions on Resale

1. No controlled substance, drug, chemical or medicine after leaving the pharmacy shall be accepted for return and placed in stock for reuse or resale.

~~ARTICLE-10;--Prohibitions-on-Substitutions;~~

~~1. The-substitution-or-dispensing-of-a-different-drug-in-lieu-of-any-drug-prescribed-in-a-prescription-without-the-approval of-the-practitioner-authorizing-the-original-prescription-as-prohibited-in-Chapter-38;-Article-5;-Section-12-shall-be-deemed-to include-the-substitution-or-dispensing-of-a-different-brand-of drug-in-lieu-of-any-brand-of-drug-prescribed;~~

ARTICLE 10, Drug Product Selection Regulations.

1. Negative Formulary

(a)

1. Aminophylline
2. Dicumarol
3. Digoxin
4. Digitoxin
5. Furosemide
6. Isosorbide Dinitrate
7. Nitroglycerin
8. Phenytoin
9. Prednisone
10. Prednisolline
11. Quinidine
12. Tolbutamide
13. Warfarin

The pharmacist may not substitute:

(b)

1. an erythromycin base when an erythromycin salt or ester is prescribed;

2. an erythromycin salt or ester when an erythromycin base is prescribed;

3. a different erythromycin salt or ester from the salt or ester, or base is prescribed,

(c) - Exceptions to Negative Formulary

Any product not in violation of F,D,A, requirements and holding a valid NDA or ANDA approved applications, and determined by the F,D,A, to be acceptable in both bio-equivalency and bioavailability, and so published as approved by the F,D,A, shall be interchangeable for the purpose of generic substitution, not withstanding the products listing on the Negative Formulary (part a and b above), A list of F,D,A, and Board approved exceptions to the Negative Formulary shall be published annually by theBoard, on July 1st of every year or as soon there after as practical, and bulletins will be issued periodically during the year as such products meet F,D,A, approval. This list shall be the only accepted list by which products on the Negative Formulary may be substituted.

(d) - Procedure for Revisions

Any manufacturer or person aggrieved by the exclusion or inclusion of any product on the Negative Formulary (part

a and b) or on the list of exceptions to the Negative Formulary (part c), may petition the Board for a determination of bioequivalency/bioavailability and possible revision of said formulary or list. The expense of any such determination shall, if the Board so decides, be born by the party seeking said determination, and the burden of proof shall also be on said party.

(e)

Any pharmacist, or other person, firm corporation, or copartnership who after public notice of Article 17, Section (e) shall be subject to the provisions of sub section (L) of Section 12b of Article 5, Chapter 30 of the West Virginia Code of 1931 as amended.

ARTICLE 10. Prohibitions on Substitutions.

1. The substitution or dispensing of a different drug in lieu of any drug prescribed in a prescription without the approval of the practitioner authorizing the original prescription as prohibited in Chapter 30, Article 5, Section 12 shall be deemed to include the substitution or dispensing of a different brand of drug in lieu of any brand of drug prescribed.

ARTICLE 11. Regulation Governing Pharmacy Permits.

1. Pharmacy Permits and Annual Registration.

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

2. Applications for Permits.

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

a. The application for such permit shall be made on a form prescribed and furnished by the Board of Pharmacy, which when properly executed, shall indicate the owner, manager, trustee, lessee, receiver, or other person or persons desiring such permit, as well as the location of such pharmacy or drug store, including street and number, the name and registration number of the pharmacist-in-charge, the names and registration numbers of all other pharmacists providing pharmaceutical services and the times when the pharmacy or drug store is open for service. Said applications should be delivered to the Secretary by the 15th

day of June to allow matriculation.

b. Separate applications shall be made and separate permits shall be issued for each pharmacy or drug store.

c. Any pharmacy or drug store operating more than twelve hours a day will be required to operate with not less than two registered pharmacists.

d. All pharmacies or drug stores, as defined, must have on file a recent edition of the United States Pharmacopoeia and the National Formulary, or other publications embodying these texts, and also shall have such equipment, as may be required to render such service as public needs may dictate, or the proper protection of the public health may indicate. The minimum Board requirements are found in Articles 12 and 13 of these regulations.

e. Each initial application for a permit shall be accompanied by the required fee of Fifty Dollars ($50.00). The fee for renewal of such permit shall be Twenty-Five Dollars annually.

3. Issuance of Permit.

a. If an applicant is found satisfactory, the secretary of the board of pharmacy shall issue to the applicant a permit for each pharmacy or drug store for which application is made.

b. The permit registers the pharmacy or drug store to which it is issued and is not transferable. It is issued on the application of the owner and the registered pharmacist in charge, on the sworn statement that it will be conducted in accordance with the provisions of law.

c. In the case where a pharmacy or drug store is owned by a person not himself a registered pharmacist, the permit will be issued

jointly to the registered pharmacist in charge and to the person owning said pharmacy, as defined in the definitions under these regulations.

d. Permits must be posted in a conspicuous place. This requirement is not met when a permit is locked in a safe, placed in a desk drawer, or otherwise concealed.

4. Renewal of Permit

The annual registration for renewal of permit takes place on July 1, each year. The fee for annual renewal shall be Twenty-Five Dollars ($25.00).

Permits issued under this section shall not be transferable and shall expire on the thirtieth day of June of each calendar year, and if application for renewal of permit is not made on or before the first day of August [illegible], the permit shall lapse and become null and void.

5. Surrender of Permit

a. Where a registered pharmacist in whose name a permit has been issued leaves the employment of such pharmacy or drug store he will be held responsible for proper notification of such termination of his services, and also for the surrender of the permit in his name. Neglect on the part of the pharmacist to so notify the Board will operate to prevent his securing a permit to take charge or operate another pharmacy or drug store at a subsequent date.

b. Whenever a pharmacy or a drug store is to be moved to a new location or when a pharmacy or a drug store changes ownership, the original permit becomes void and must be surrendered to the Board and a new permit secured by the new owners.

c. When the registered pharmacist in whose name a pharmacy permit has been issued for any reason ceases to be actually the registered

pharmacist who has responsible supervision over said pharmacy or drug store, the permit becomes void, and must be surrendered to the Board. A duplicate permit may be issued by the Board for the same pharmacy under a new pharmacist in charge. A fee of Five Dollars ($5.00) is charged for issuing such permit.

d. Pharmacists employed and in charge of pharmacies or drug stores, owned by persons not registered pharmacists, are required to notify the Board and surrender for cancellation the permit issued immediately upon the termination of such employment. It shall also be the duty of the owner of such pharmacies or drug stores, who are not registered pharmacists, to immediately notify the Board upon the termination of employment of registered pharmacists and to cause the surrender of permit as indicated. The further operation of the pharmacy or drug store, in the absence of a replacement and the issuance of a new permit is forbidden by law and each day so operated will be considered a separate offense.

6. Violations

a. The violation of these regulations may be considered cause for suspension of permits or the refusal to grant new ones.

b. All registered pharmacists must notify the Board immediately of any change in employment and change of address. Not to do so may be considered sufficient cause for suspension.

c. It shall be the duty of any person who employs any registered pharmacist to immediately notify the Board of any discharge, termination or change of place of employment of said registered pharmacist. Failure to so notify the Board may be deemed sufficient cause for suspension of any permit or license held by such person.

Article II

7. SECURITY

In the event that a prescription department is to be operated for a period less than the regular business hours of the entire store, the following rules and regulations shall be observed.

(a) The prescription area shall be separated from other departments of the store by a floor to ceiling, permanent barrier or partition, with entry doors that can be securely locked. If the pharmacy area is continually attended by a pharmacist when other people are in the store, the pharmacy area need not be enclosed by the permanent barrier. The barrier shall be so designed that only a pharmacist with a key shall have access to the area where prescription drugs, dangerous drugs, controlled substances, and other drugs and devices restricted to sales by pharmacists are stored, compounded, and dispensed.

(b) Types of permanent barriers: The permanent barrier may be constructed of other than a solid material. If constructed of a material other than a solid barrier, the openings or interstices in the material shall not be large enough to permit removal of items in the pharmacy area, by any means. Any material used in the construction must be of sufficient strength and thickness that it can not be readily or easily removed, penetrated or bent. The plans and specifications of the permanent barrier shall be submitted to the Board for approval showing that it affords adequate security. Plans shall be submitted prior to proceeding with any construction, which plan shall indicate, the pharmacy area which shall be of adequate space. Before a pharmacy permit shall be issued, the plans submitted must meet the approval of the Board.

(c) Signs. In the absence of a pharmacist, a sign with a minimum of four inch letters shall be prominently displayed stating: "PHARMACY CLOSED, NO PHARMACIST ON DUTY."

(d) Telephone. Separate phone (listing) answered only in pharmacy area. No telephone extensions of this listing are permitted outside the pharmacy area.

(e) Receipt and Delivery. Written prescription orders and refill requests can be delivered to a pharmacy at any time. But if no pharmacist is present then the prescription order(s) must be deposited, by the patient or his agent delivering the prescription order or refill request to the establishment, into a "mail slot" or "drug box" so that the prescription orders are stored in the pharmacy area. The times that the pharmacy is open for business must be displayed so that they are prominently visible to the person depositing the prescription orders(s).

(f) Completed prescription orders shall be stored in the pharmacy and cannot be removed from the pharmacy unless the pharmacist is present and the removal is for the immediate delivery to the patient, person picking up the prescription for the patient, or person delivering the prescription to the patient at his residence or similar place.

(g) Adequate working space shall be allotted to the pharmacy area subject to the approval of the Board.

(h) Mobile pharmacy units are prohibited.

PUBLIC INFORMATION

AS TO

PRICE POSTING REGULATIONS

1. This list is to be posted in every pharmacy licensed in West Virginia. It is intended to provide the public with information about the prices of prescription drugs.
2. This list includes the one-hundred most commonly prescribed drugs in the most frequently prescribed quantities. If your prescribed drug, quantity or strength is not listed here, you can obtain price information by asking the pharmacist.
3. This is not a price control system. Each pharmacy establishes its own prices. The current selling price and the posting of such price may change at any time. Prices may differ among pharmacies. Of course, price is only one of several factors in selecting a pharmacy because service is also important. Services provided by the pharmacy are listed on page 3 prior to the listing of prescription drug prices.
4. If you do not know the name or identity of your prescription drug, ask the pharmacist so that you may locate it on this listing. The name of your prescription drug might also be very similar to a completely different drug. Consult your pharmacist if you have any doubt.

5. This list must be located near the dispensing area. It must be placed so that the public can easily see it.

List of Professional and Convenience Services Provided by this Pharmacy.

The "current selling" price means the price above which the listed drug may not be sold to the purchaser by the pharmacist, and includes all professional services as so indicated.

Yes	No		
____	____	1.	Patient Profiles
____	____	2.	Consultation on Prescription Medication
____	____	3.	Emergency Services after Hours
____	____	4.	Provide Health Care Information
____	____	5.	Charge Privileges
____	____	6.	Delivery
____	____	7.	Tax Records
____	____		_____
____	____		_____
____	____		_____
____	____		_____
____	____		_____
____	____		_____

~~RULES & REGULATIONS~~

of

WEST VIRGINIA BOARD OF PHARMACY

Series One

Amended ~~rules and regulations~~ of the West Virginia Board ~~of Pharmacy, adopted pursuant to the~~ authority ~~granted to the~~ West Virginia Board of Pharmacy, by Chapter 30, Article 5, Section 19.

~~ARTICLE II. Regulation Governing Pharmacy Permits.~~

Section 8. List of Drugs and Prices; Posting Required; Penalties for Failure to Comply.

(a) The Board of Pharmacy shall annually in the month of August distribute to all pharmacies licensed by the Board such forms as adopted and the same shall be publicly displayed for the convenience of the public.

(b) The official forms will contain not less than 100 most commonly prescribed prescription drugs by brand name and approved generic equivalent name (established name). The Board of Pharmacy has deemed that an approved generic equivalent shall mean the established name of a prescription drug or drug product designated by an official compendium of the United States and recognized by this Board in the list of prescription drugs or drug products to be posted by price, strength, manufacture, and quantity in every licensed pharmacy.

(c) Such forms shall bear a title across the top portion reading, "Prescription Price List and Services."

The pharmacist shall designate the prices, and such prices shall reflect all of the services and conveniences that are included. A pharmacy may change the current posted selling price at any time. No prices shall be erased or crossed out. Price overlay stickers shall be used to effect any price change. Where the established or generic name is so designated, the pharmacy shall also list the name of the manufacturer.

(d) The price as shown shall indicate the current selling price and which professional and convenience services are included.

(e) Each pharmacy shall place in a prominent location which can be seen by the public, a sign furnished by the Board to read: "This pharmacy has for your information a list of drugs so priced as required by Chapter 30, Article 5, Section 12 (a)."

(f) The owner of the Pharmacy, member of firm, or officer of corporation shall certify on the forms provided by the Board that a list of current prices and other information as required by Chapter 30, Article 5, Section 12 (a) is available to the public as required by appropriate rules and regulations.

(g) Any pharmacy that does not comply with Chapter 30, Article 5, Section 12 (a) or Article II of the regulations of this Board is subject to the penalties as

prescribed in Chapter 30, Article 5, Section 19, Revocation of Permits.

(h) The rules and regulations so adopted shall be distributed along with the required forms to each pharmacy registered with this Board.

CERTIFICATION OF COMPLIANCE

WITH CHAPTER 30, ARTICLE 5, SECTION 12-a

CODE OF WEST VIRGINIA

List of drugs and prices, strengths, and quantity prescribed and manufacturer.

The Board hereby submits the following list of drugs, which list is final.

The "current selling" price means the price above which the listed drug may not be sold to the purchaser by the pharmacist.

The posted price shall include the professional and convenience service performed by the pharmacy.

Pursuant to Section Nineteen of this Article, the Board of Pharmacy shall establish and require compliance with all rules and regulations necessary to implement this section.

Firm Name_____

By_____

(State whether owner, member of firm or officer of corporation)

do hereby certify that this is a list of the current prices and other information as required by Chapter 30, Article 5, Section 12-a Code of West Virginia.

_____

Authorized Signature

ARTICLE 12. Professional and Technical Equipment

1. No permit shall be issued to operate a pharmacy or drug store, unless the minimum professional and technical equipment requirements have been fulfilled.

2. Every pharmacy or drug store shall at all times possess the following minimum professional and technical equipment:

a. The current editions of the United States Pharmacopoeia and the National Formulary, or the equivalent thereof in pharmaceutic and therapeutic reference books.

b. Class "A" prescription balance accurate to 12 milligrams.

c. A set of accurate prescription weights ranging from 10 milligrams to 50 grams.

d. A set of graduates ranging from 5 ml to 250 ml.

e. Mortars and pestles, spatulas, ointment pads, funnels, stirring rods, etc., to meet the current needs for extemporaneous compounding.

f. Pharmacies compounding opthalmic preparations, IV additives or other pharmaceuticals requiring more sophisticated techniques must have the proper equipment to prepare sterile products or to meet other requirements of good compounding practices.

g. Adequate facilities for the proper storage of pharmaceuticals which require refrigeration or protection from heat, light, or high humidity.

h. Facilities for the safe storage of "Controlled Substances."

i. An acceptable system for keeping records of prescriptions dispensed as required by The Uniform Controlled Substances Act and any rules and regulations adopted pursuant thereto.

j. A record book for the disposition of "Schedule V Controlled Substances".

k. Current copies of laws, rules and regulations pertaining to the practice of pharmacy in West Virginia.

ARTICLE 13. Sanitary Regulation of Pharmacies.

(1) The pharmacist in charge of a pharmacy, drug store, or apothecary shop in which prescriptions are compounded shall maintain such place and the equipment therein in a clean and orderly condition.

(2) All such places shall comply with the sanitation laws of this state pertaining to any business conducted within a licensed pharmacy or drug store.

(3) The prescription counter upon which prescriptions are compounded shall be used for no other purpose than for the compounding of prescriptions.

(4) Upon the completion of compounding a prescription the prescription counter shall be cleaned and the refuse or waste materials shall be placed in a closed receptacle, and all instruments used in the compounding of such prescriptions shall be thoroughly cleaned and placed in a clean cabinet or storage space.

(5) The sink or wash basin in the prescription room shall be used for no other purpose than for the cleansing of instruments and articles in the preparation of prescriptions or the cleansing of the hands of those preparing and compounding prescriptions.

(6) All pharmacists when compounding prescriptions or working in the prescription room shall wear clean linen, either apron or coat, and shall be required to keep themselves and their apparel in a clean and sanitary condition.

(7) The prescription room shall be maintained in an

orderly and clean condition. All instruments, articles, stock bottles, containers, shelving, cabinets and equipment shall be free from dust, insects, rodents, or any other foreign material.

(8) The prescription room shall be well ventilated, free from obnoxious odors and equipped with adequate lighting facilities.

ARTICLE 14 - Sale of Drugs by Mechanical Devices; Gratuities; Sharing Compensation.

(1) Sale of drugs and medicines by mechanical devices or vending machines prohibited. The use of any mechanical device or vending machine in connection with the sales or disposition of drugs and/or medicines is unlawful.

(2) Gratuities. No person, firm, corporation or co-partnership operating and maintaining a pharmacy or drug store as defined in Article 1 shall give any trading stamps, commission, gratuity or rebate in any manner or form whatever on any fees for professional services rendered to a patient of a duly licensed physician.

(3) Sharing Compensation. The independent judgment of a pharmacist is a public trust, and his first allegiance is to the patient whom he serves. No pharmacist shall, except with a person licensed to practice pharmacy, or in the course of his employment with a duly licensed institution, clinic or foundation, directly or indirectly share compensation arising out of or incidental to his professional employment with, or accept professional employment from any person or persons who for compensation prescribe drugs used in the compounding or dispensing of prescriptions.

As used in this rule, the words 'person or persons' includes firms, associations, partnerships or corporations in which an individual who for compensation prescribes drugs used in the compounding or dispensing of prescriptions has a proprietary interest sufficient to permit him to exercise a substantial degree of supervision, direction or control over the pharmacist.

ARTICLE 15 Rules of Professional Conduct.

The practice of pharmacy is a profession dedicated to the service of public health which requires knowledge, skill, and integrity. The state law restricts the practice of pharmacy to persons who possess special training and qualifications and licenses to them privileges which are denied to others. The pharmacist recognizing his responsibility to the public in safeguarding the preparation, compounding and dispensing of drugs, the storage and handling of drugs and medical supplies, and the dissemination of information on medicinal agents obligates himself to the highest standards of professional conduct.

In order that the citizens of West Virginia shall receive the best possible pharmaceutical services, and that the public health, welfare and safety be fully protected, the following rules of professional conduct have been adopted by the West Virginia Board of Pharmacy as authorized by Chapter 30, Article 5, Section 7, of the Code of West Virginia, 1931, as amended

1. Professional Responsibilities. No pharmacist shall engage in conduct, in the practice of pharmacy or the operation of

of a pharmacy which tends to reduce the public confidence in the ability and integrity of the profession of pharmacy, or endangers the public health, safety and welfare; nor shall he engage in pharmaceutical practice or offer pharmaceutical services under any terms or conditions which tend to interfere with or impair the free and complete exercise of professional judgment and skill of a pharmacist. He shall at all times practice his profession in conformity with federal and state laws and regulations and the regulations of the West Virginia State Board of Pharmacy.

2. Uncertain Prescription Orders. No pharmacist shall compound or dispense any prescription which, in his professional opinion, contains any error, omission, irregularity or ambiguity, but upon the receipt of such prescription order he shall contact the prescriber and confer with him before dispensing the prescription. No pharmacist shall dispense any medication by virtue of a prescription order if he has any doubt existing in his mind that such prescription order is not legitimate.

3. Refusal of Prescriptions. It is the duty of a pharmacist to make his professional services available to the public. Every pharmacy offering pharmaceutical services to the general public shall provide complete pharmaceutical service,

including the compounding or dispensing of all prescription orders which may be reasonably expected to be compounded or dispensed by pharmacists. No pharmacist shall refuse to accept and fill, or cause to be filled, for payment thereof any prescription order presented to him unless there is a valid reason for his inability to fill such prescription order.

4. Betrayal of Confidence. No pharmacist shall exhibit, discuss or reveal the contents of any prescription, the therapeutic effect thereof, or the nature, extent, or degree of illness suffered by a patient served by him with any person other than (1) another pharmacist when necessary for the proper fulfillment of duties devolving upon the pharmacist, (2) the patient or his authorized representative, (3) the prescriber, or (4) any persons authorized by law to receive such information. He shall not, however, discuss with the patient or his authorized representative such matters that should be discussed with the prescriber only.

5. Diagnosis or Treatment. No pharmacist shall attempt to diagnose, treat, or prescribe for any disease, illness, or organic disorder. This prohibition shall not be construed so as to prevent any pharmacist from advising individuals on matters concerning simple ailments, first aid measures, sanitary measures, or the merits and quality of preparations which may be distributed legally without a prescription order.

6. Coded Prescription Orders. No pharmacist shall compound or dispense any prescription order which is coded. A "coded" prescription order is one which bears letters, numbers, words or symbols, or any other device used in lieu of the name, quantity, strength, and directions for its use, other than those normal letters, numbers, words or symbols recognized by the profession of pharmacy as a means for conveying information by prescription order.

7. False or Misleading Advertising. No pharmacist or pharmacy shall make, permit to be made, conduct or otherwise participate in any false, misleading, or fraudulent advertising, or any claim of superiority in compounding and filling prescription orders through advertising, nor shall any pharmacist or pharmacy make, permit to be made, conduct or otherwise participate in any advertising which may reduce the public confidence in the ability, character, or integrity of the pharmacist.

8. Promotion of Drugs. No pharmacist or pharmacy shall promote to the public by any means a narcotic drug or any other drug which may only be dispensed pursuant to a prescription order, which promotion tends to cause such drugs to be used in excess of the requirements established in a legitimate physician-patient relationship.

9. Unreliable Drugs. No pharmacist shall purchase, accept, compound, or dispense any medicinal preparation, whether by prescription order or otherwise, which in his professional opinion is not therapeutically reliable. Drugs shall be obtained only in original containers and only for

authentic sources. No pharmacist shall accept from a patron, except for the purpose of destruction, any part of any unused prescription.

10. Changes in Prescriptions. No pharmacist shall dispense medication or devices which differ in any manner from the medication or device which is prescribed unless prior approval has been obtained ~~only in original~~ containers and only from authentic sources. No pharmacist shall accept from a patron, except for the purpose of destruction, any part of an unused prescription.

11. Prescription Order Forms. No pharmacist shall solicit professional practice by means of providing physicians or other medical practitioners with prescription order forms imprinted with any reference to a pharmacy or pharmacist.

12. Place of Practice. No pharmacist shall maintain a place of practice or location from which to solicit, accept or dispense prescriptions other than a pharmacy for which a permit has been issued by the West Virginia Board of Pharmacy.

13. Physician Agreements. No pharmacist shall enter into or engage in any agreement or arrangement with any physician or other practitioner which may tend to exploit the sick or for the payment or acceptance of compensation in any form or type for the recommending of the professional services of either; nor shall he enter into an agreement of any kind whereby in any way a patient's free choice of a pharmacist or pharmacy is or may be limited.

14. Duties. It shall be the duty of a registered pharmacist

in every pharmacy to perform the following duties:

a. Accept all new prescriptions transmitted by oral communication.

b. Affix typed prescription labels to prescription containers.

c. Measure, pour, count, weigh, reconstitute, subtract from or add to prescription medications.

d. Record date and dispensing pharmacist's initials on original or refilled prescriptions.

e. Deliver completed prescription to patient when instructions regarding its use are to be imparted to the patient.

f. Discuss with patient matters pertaining to the drug, its reasons for usage, contraindications or answer questions regarding the practitioner's intent.

g. Perform any of the above functions except, nothing shall restrict registered interns from performing any or all of the above functions under the supervision of a registered pharmacist.

h. Perform any other function of any nature or kind which requires the knowledge, judgment, ability or skill of a registered pharmacist.

15. Evasion or Violation of the Rules of Professional Conduct. These rules of professional conduct are intended to govern all pharmacists licensed to practice in West Virginia by the State Board of Pharmacy, their employees or agents, as well as their operation of pharmacies and their consultantships in West Virginia. No pharmacist or any other person subject to these

rules shall act in any way to evade the rules and regulations of the West Virginia Board of Pharmacy and the laws applying to them, and they shall assist the West Virginia Board of Pharmacy in the enforcement thereof and compliance with said laws, rules and regulations.

A violation of any of the provisions of these rules shall constitute unprofessional conduct.

Any pharmacist who knowingly accepts professional employment from any person, firm, or corporation who violates or evades these rules or regulations shall be deemed guilty of violation of the rules the same as if he had personally engaged in such evasion or violation.

16. Publication and Posting of Rules. The Secretary of the West Virginia Board of Pharmacy shall make a copy of these Rules of Professional Conduct available to every pharmacy and pharmacist licensed by the West Virginia Board of Pharmacy. A copy of said rules shall be posted in the prescription department of every such establishment where it can be seen by all persons entering said department.

ARTICLE 16. Pharmacist Consultants and Coordinators of Pharmaceutical Services.

Whereas, increasing numbers of pharmacists are serving as pharmacy consultants to, or serving as coordinators of pharmaceutical services in hospitals, skilled nursing facilities and intermediate care facilities, nursing homes, clinics, rest homes, homes for the aged, governmental agencies, and other places where a pharmacy permit is not held, and the Board of Pharmacy has the responsibility to maintain standards of professional conduct and to regulate professional practice, the Board of Pharmacy hereby promulgates the following rules and regulations:

1. Requirements.

a. The Board of Pharmacy shall maintain a roster of all pharmacist consultants and coordinators of pharmaceutical services. All persons serving as consultants or coordinators shall be licensed and registered to practice pharmacy in West Virginia.

b. Any pharmacist consultant to hospitals, skilled nursing facilities, intermediate care facilities, nursing homes, clinics, rest homes, homes for the aged, governmental agencies, and any other pharmaceutical consultation practice, shall register initially and annually in each instance such practice and place with the West Virginia Board of Pharmacy on forms provided by the Board.

c. Any pharmacist providing pharmaceutical consultation to, or coordinating pharmaceutical services in hospitals, skilled nursing facilities, intermediate care facilities, nursing homes, clinics, rest homes, homes for the aged, governmental agencies, and any other place where a pharmacy permit is not held shall register initially and annually in each instance such practice and place with the West Virginia Board of Pharmacy on forms provided by the Board and signed by the consultant and the administrator of such facility.

d. All applicants certified as consultant pharmacists shall meet such additional educational and experienced backgrounds as required by the Board, and comply with the regulation as set forth by the Board.

e. Consultants shall document by time and date his activities consistent with the level of institutional care requirements.

2. Responsibilities.

a. The pharmacist consultant or coordinator shall be responsible to initiate and maintain in each instance appropriate records and procedures for the receipt, labeling, storage and disposition of all drugs, including investigational drugs, medication samples, and emergency kits.

b. The pharmacist consultant or coordinator shall cause to be developed, issued and implimented a "Policy and Procedures" manual for pharmaceutical services. This manual shall be open to inquiry by all authorized governmental agencies including the Board of Pharmacy. This manual shall enumerate provisions for, but not limited to the following:

1. Drug recall
2. Separate reconcilitations for controlled substances
3. Automatic stop orders
4. Systematic review of drug orders
5. Formulary or minimum standards for drug quality
6. Assist in in-service drug education
7. Outline the procedure which shall spell out How drug orders are to be taken from the patient's chart and transcribed to drug orders

c. The pharmacist consultant or coordinator shall be responsible for maintaining an adequate professional library of pharmaceutical references within the facility.

d. The pharmacist consultant or coordinator shall insure compliance with Rules of Professional Conduct as adopted by the Board of Pharmacy under Chapter 30, Article 5, Section 2.

e. The pharmacist consultant or coordinator shall insure compliance with all federal, state, and local laws concerning drugs and pharmaceutical services.

f. Nothing under these regulations shall preclude a patient in a skilled nursing facility or intermediate care facility from fee choice of pharmaceutical supplies and drugs.

ARTICLE 17. List of Controlled Substances.

WHEREAS, the West Virginia Legislature of 1971 did adopt certain schedules of controlled substances;

WHEREAS, Chapter 60A, Article 2, Section 201 of The West Virginia Code as adopted in 1971 defines certain drugs as schedule one controlled substances, and

WHEREAS, Chapter 60A, Article 2, Section 206 of The West Virginia Code as adopted in 1971 defines certain drugs as schedule two controlled substances, and

WHEREAS, Chapter 60A, Article 2, Section 208 of The West Virginia Code as adopted in 1971 defines certain drugs as schedule three controlled substances, and

WHEREAS, Chapter 60A, Article 2, Section 210 of The West Virginia Code as adopted in 1971 defines certain drugs as schedule four controlled substances, and

WHEREAS, Chapter 60A, Article 2, Section 212 of The West Virginia Code as adopted in 1971 defines certain drugs as schedule five controlled substances,

WHEREAS, the West Virginia Ligislature of 1971 enacted Chapter 60A, of The West Virginia Code which includes the same five schedules of controlled substances as are found in the Federal Controlled Substances Act, and

WHEREAS, Chapter 60A, Article 2 of The West Virginia Code classifies substances according to substantially the same criteria as the Federal Controlled Substances Act.

THEREFORE, these controlled substances are more particularly set forth hereafter;

THE SAID CONTROLLED SUBSTANCES ARE FILED WITH THE SECRETARY OF STATE OF WEST VIRGINIA IN SERIES TWO RULES AND REGULATIONS UNDER THE HEADING OF CLASSIFICATIONS OF CONTROLLED SUBSTANCES, SECTION 201.

THIS LIST DOES NOT REFLECT THE NAMES OF ALL CONTROLLED SUBSTANCES. IT DOESNOT INDICATE THAT THESE ARE THE ONLY DRUGS SUBJECT TO CONTROL.

SERIES TWO

RULES AND REGULATIONS OF THE

WEST VIRGINIA BOARD OF PHARMACY FOR THE

UNIFORM CONTROLLED SUBSTANCES ACT

ADOPTED PURSUANT TO THE AUTHORITY GRANTED TO THE WEST VIRGINIA BOARD OF PHARMACY BY THE PROVISIONS OF CHAPTER 60A OF THE WEST VIRGINIA CODE AS FOLLOWS:

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I.

GENERAL DEFINITIONS

§101

ARTICLE 1. Definitions

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

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 or any function of the body of man or animals; and (d) substances 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. The term "poisonous drug" means any drug likely to be destructive to adult human life in quantities of five grains or less.

3. The term "deleterious drug" means any drug likely to be destructive to adult human life in quantities of sixty grains or less.

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.

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 U.S. 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.

6. "Controlled substance" means a drug, substance, or immediate precursor in Schedules I through V of Article 2 of Chapter 60A, West Virginia Code, (Uniform Controlled Substances Act).

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.

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.

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, and 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.

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 201, Article 2 of The Uniform Controlled Substances Act, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

11. "Opium poppy" means the plant of the species "Papaver somniferum L.", except its seeds.

12. "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

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 maufacturer, distributor, or dispenser other than the person who in fact manufactured, distributed, or dispensed the substance.

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.

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.

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.

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 Article 1, Chapter 60A of the Uniform Controlled Substances Act.

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

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.

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, and whose license is in good standing.

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.

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.

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

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

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

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

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 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 or more persons.

Only pharmacy or drug store permits issued under Chapter 30, Article 11, Section 4 of the West Virginia Code shall be considered a renewal.

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.

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.

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.

31. The term "internship" shall be used to describe the practical experience requirement, and "one year's practical experience" shall mean an average work week of not less than forty hours for a period of one calendar year, except as herein provided for concurrent training programs.

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.

33. "Person Addicted" means one 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.

34. "Act" or "Uniform Controlled Substances Act" when used in these regulations shall mean and refer to Chapter 60A of The West Virginia Code as enacted by The West Virginia Legislature in 1971.

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:

(1). a practitioner (or, in his presence, by his authorized agent),

or

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

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:

(1). by a practitioner as an incident to his administering or dispensing of a controlled substance in the course of his professional practice, or

(2). 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.

II.

CLASSIFICATION

OF CONTROLLED SUBSTANCES

§201 - Schedules

The following is a list of controlled substances as adopted by the West Virginia Boards of Pharmacy September 20, 1971. This list shall be revised January 1, 1972; June 15, 1972; January 1, 1973; June 15, 1973; and June 15, of each and every year subsequent to the year 1973. This list is comprised of official, common, usual, chemical or trade name designations of the controlled substances in the various classes. (See Section 308.11 et seq. for a classification of controlled substances according to schedules).

ARTICLE 2. STANDARDS AND SCHEDULES.

§60A-2-201. Authority of state board of pharmacy; recommendations to Legislature.—(a) The state board of pharmacy shall administer the provisions of this chapter. It shall also, on the first day of each regular legislative session, recommend to the Legislature which substances should be added to or deleted from the schedules of controlled substances contained in this article or reschedule therein.

In making any such recommendation regarding a substance, the state board of pharmacy shall consider the following factors:

(1) The actual or relative potential for abuse;

(2) The scientific evidence of its pharmacological effect, if known;

(3) The state of current scientific knowledge regarding the substance;

(4) The history and current pattern of abuse;

(5) The scope, duration, and significance of abuse;

(6) The potential of the substance to produce psychic or physiological dependence liability; and

(7) Whether the substance is an immediate precursor of a substance already controlled under this article.

(b) After considering the factors enumerated in subsection (b), the state board of pharmacy shall make findings with respect to the substance under consideration. If it finds that any substance not already controlled under any schedule has a potential for abuse, it shall recommend to the Legislature that the substance be added to the appropriate schedule. If it finds that any substance already controlled under any schedule should be rescheduled or deleted, it shall so recommend to the Legislature.

(c) If the state board of pharmacy designates a substance as an immediate precursor, substances which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.

(d) If any substance is designated rescheduled or deleted as a controlled substance under federal laws and notice thereof is given to the state board of pharmacy, the board shall recommend similar control of such substance to the Legislature, specifically stating that such recommendation is based on federal action and the reasons why the federal government deemed such action necessary and proper.

(e) The authority vested in the board by subsection (a) of this section shall not extend to distilled spirits, wine, malt beverages or tobacco as those terms are defined or used in other chapters of this code nor to any nonnarcotic substance if such substance may under the "Federal Food, Drug and Cosmetic Act" and the law of this state lawfully be sold over the counter without a prescription.

§60A-2-202. Nomenclature.—The controlled substances listed in the schedules in this article are included by whatever official, common usual, chemical or trade name designated.

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§60-a-203. **Schedule I criteria.**—The state board of pharmacy shall recommend to the Legislature that a substance be included in Schedule I if it finds that the substance:

(1) Has high potential for abuse; and

(2) Has no accepted medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision.

§60A-2-204. **Schedule I.**—(a) The controlled substances listed in this section are included in Schedule I.

(b) Unless specifically excepted or unless listed in another schedule, any of the following 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:

(1) Acetylmethadol;
(2) Allylprodine;
(3) Alphacetylmethadol;
(4) Alphameprodine;
(5) Alphamethadol;
(6) Benzethidine;
(7) Betacetylmethadol
(8) Betameprodine;
(9) Betamethadol;
(10) Betaprodine;
(11) Clonitazene;
(12) Dextromoramide;
(13) Diampromide;
(14) Diethylthiambutene;
(15) Difenoxin;
(16) Dimemoxadol;
(17) Dimepheptanol;
(18) Dimethylthiambutene;
(19) Dioxaphetyl butyrate;
(20) Dipipanone;
(21) Ethylmethylthiambutene;
(22) Etonitazene;
(23) Etoxeridine;
(24) Furethidine;
(25) Hydroxypethidine;
(26) Ketobemidone;
(27) Levomoramide;

(28) Levophenacylmorphan;
(29) Morpheridine;
(30) Noracymethadol;
(31) Norlevorphanol;
(32) Normethadone;
(33) Norpipanone;
(34) Phenadoxone;
(35) Phenampromide;
(36) Phenomorphan;
(37) Phenoperidine;
(38) Piritramide;
(39) Proheptazine;
(40) Properidine;
(41) Propiram;
(42) Racemoramide;
(43) Sufentanil;
(44) Tilidine;
(45) Trimeperidine.

(c) Unless specifically expected or unless listed in another schedule, any of the following opium derivativers, 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:

(1) Acetorphine;
(2) Acetyldihydrocodeine;
(3) Benzylmorphine;
(4) Codeine methylbromide;
(5) Codeine-N-Oxide;
(6) Cyrenorphine;
(7) Desomorphine;
(8) Dihydromorphine;
(9) Drotebanol;
(10) Etorphine (except HC1 Salt);
(11) Heroin;
(12) Hydromorphinol;
(13) Methyldesorphine;
(14) Methyldihydromorphine;
(15) Morphine methylbromide;
(16) Morphinemethylsulfonate;
(17) Morphine-N-Oxide;
(18) Myrophine;
(19) Nicocodeine;

(20) Nicomorphine;
(21) Normorphine;
(22) Phoclodine;
(23) Thebacon.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of the salts, isomers and salts of isomers of any thereof whenever the existence of such salts, isomers and salts of isomers if possible within the specific chemical designation and for the purposes of this subsection only, "isomer" includes the optical position and geometric isomers;

(1) 2,5-dimethoxyamphetamine; also known by these trade or other names: 2, 5-dimethoxy-a-methylphenethylamine; 2, 5-DMA;

(2) 3, 4-methylenedioxy amphetamine;

(3) 4-bormo-2, 5-dimethoxyamphetamine or 4-bromo-2, 5-dimethoxy-a-methylphenethylamine, or 4-bromo-2, 5-DMA;

(4) 5-methyloxy-3, 4-methylenedioxy amphetamine;

(5) 4-methoxyamphetamine; also known by these trade or other names; 4-methoxy-a-methylphenethylamine; paramethoxyamphetamine; PMA;

(6) 3, 4, 5-trimethoxy amphetamine;

(7) Bufoteinine; known also by these trade and other names; 3-(B-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylamino-ethyl)-5) idolol; N-N-dimethylserotonin; 5-hydroxy-N-dimethyltryptamine; mappine;

(8) Diethyltryptamine; known also by these trade and other names; N-N-Diethyltryptamine; "DET";

(9) Dimethyltryptamine; known also by the name "DMT";

(10) d-methyl-2, 5e-dimethoxy amphetamine; known also by these trade and other names: 4-methyl-2, 5-dimethoxy-a-methylphenethylamine; "DOM"; "STP";

(11) Iboqaine; known also by these trade and other names: 7-Ethyl-6, 6a, 7, 8, 9, 10, 12, 13-joctahydro-2-methoxy-6, 9-methano-5H-pyrido (1', 2': 1, 2 azepino 4, 5b) indole; tabernanthe iboga;

(12) Lysergic acid diethylamide;

(13) Marihuana;

(14) Mescaline;

(15) Peyote; meaning all parts of the plant presently classified botanically as Lophophora Williamsii Lematre, whether growing or not; the seeds thereof; any extrat from any part of such plant; and every compound, manufacture, salt, derivative, mixture or preparation of such plant, its seeds or extracts;

(16) N-ethyl-3-piperidyl benzilate;

(17) N-methyl-3-piperidyl benzilate;

(18) Psilocybin;

(19) Psilocyn;

(20) Tetrahydrocannabinols; including synthetic equivalents of the substances contained in the plant or in the resinous extractives of Cannabis or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity such as the following:

Delta 1
Cis or trans tetrahydrocannabinol, and their optical isomers;

Delta 6
Cis or trans tetrahydrocannabinol, and their optical isomers;

Delta 3, 4
Cis or trans tetrahydrocannabinil tetrahydrocannabinol, and their optical isomers;

(21) Thiophene analog of phencyclidine; also known by these trade or other names: (A) (1-(2-thienyl) (1-(1-thieyl) cyclohexyl) piperidine; (B) Thienyl analog of phencyclidine; TPCP;

(22) Ethylamine analog of phencyclidine. . . Some trade or other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl) ethylamine, cyclohexamine, PCE;

(23) Pyrrolidine analog of phencyclidine . . . Some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine, PCYy, PHP.

(e) Unless specifically excepted or unless listed in another schedule, any of the following depressants, its salts, isomers and salts of isomers is possible within the specific chemical designation:

(1) Mecloqualone.

§60A-2-205. Schedule II criteria.—The state board of pharmacy shall recommend to the Legislature that a substance be placed in Schedule II if it finds that: (1) The substance has a high potential for abuse;

(2) The substance has currently accepted medical use in treatment in the United States or currently accepted medical use with severe restrictions;

(3) Abuse of the substance may lead to severe psychic or physical dependence.

§60A-2-206. Schedule II.—(a) The controlled substances listed in this section are included in Schedule II.

(b) Unless specifically excepted or unless listed in another schedule, any 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:

(1) Opium and opiate, and any salt, compound, derivative or preparation of opium or opiate excluding nalorphine, naxolone and naltrexone and their respective salts, but including the following:

(A) Raw opium;
(B) Opioum extracts;
(C) Opium fluid extracts;
(D) Powdered opium;
(E) Granulated opium;
(F) Tincture of opium;
(G) Codeine;
(H) Ethylmorphine;
(I) Ethrophine HCL;
(J) Hydrocodone;
(K) Hydromorphone;
(L) Metopon;
(M) Morphine;
(N) Oxycodone;
(O) Oxymorphone;
(P) Thebaine;

(2) Any salt, compound, isomer derivative or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subdivision (1) of this subsection, except that these substances shall not include the isoquinoline alkaloids of opium;

(3) Opium poppy and poppy straw;

(4) Coca leaves and any salt, compound, derivative or preparation of coca leaves, and any salt, compound, derivative or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extractions of coca leaves, which extractions do not contain cocaine or ecgonine;

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(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenathrine alkaloids of the opium poppy).

(c) Unless specifically excepted or unless in another schedule, any of the following 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;

(1) Alphaprodine;
(2) Anileridine;
(3) Bezitramide;
(4) Dihydrocodeine;
(5) Diphenoxylate;
(6) Fentanyl;
(7) Isomethadone;
(8) Levomethorphan;
(9) Levorphanol;
(10) Metazocine;
(11) Methadone;
(12) Methadone-Itermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane;
(13) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-carboxylic acid;
(14) Pethidine; (meperidine);
(15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine;
(16) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate;
(17) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-car-
(18) Phenazocine;
(19) Piminodine;
(20) Racemethorphan;
(21) Racemorphan;

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Methamphetamine, including its salts, isomers and salts of isomers;

(2) Amphetamine, its salts, optical isomers and salts of its optical isomers;

(3) Phenmetrazine and its salts;

(4) Methylphenidate and its salts;

(e) Unless specifically excepted or unless listed in another schedule, any

material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, 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:

(1) Methaqualone;
(2) Amobarbital;
(3) Secobarbital;
(4) Pentobarbital;
(5) Phencyclidine.

(f) Immediate precursors. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

(1) Immediate precursor to amphetamine and methamphetamine;

(i) Phenylacetone
Some trade or other names: phenyl-2-propanone; P2P; benzylymethyl ketone; methyl benzyl ketone.

(2) Immediate precursors to phencyclidine (PCP):

(i) 1-phenylclohexylamine

(ii) 1-piperidinocyclohexanecarbonitrile (PCC)

§60A-2-207. Schedule III criteria.— The state board of pharmacy shall recommend to the Legislature that a substance be placed in Schedule III if it finds that:

(1) The substance has a potential for abuse less than the substances listed in Schedules I and II;

(2) The substance has currently accepted medical use in treatment in the United States; and

(3) Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

§60A-2-208. Schedule III.—(a) The controlled substances listed in this section are included in Schedule III.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Benzphetamine;
(2) Chlorphentermine;

(3) Clortermine;
(4) Mazindol;
(5) Phendimetrazine.

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid;
(2) Chlorhexadol;
(3) Glutethimide;
(4) Lysergic acid;
(5) Lysergic acid amide;
(6) Methyprylon;
(7) Sulfondiethylmethane;
(8) Sulfonethylmethane;
(9) Sulfonmethane;
(10) Any compound, mixture, or preparation containing:
(i) Amobarbital;
(ii) Secobarbital;
(iii) Pentobarbutal or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule;
(12) Any suppository dosage form containing:
(i) Amobarbital;
(ii) Secobarbital;
(iii) Pentobarbital.

(d) Nalorphine.

(e) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation containing limited quantities of any of the following narcotic drugs or any salts thereof:

(1) Not more than 1.8 grams of codeine per 100 milliliters and not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;

(2) Not more than 1.8 grams of codeine per 100 milliliters and not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters and not more than 15 milligrams per dosage unit, with a fourfold of greater quantity of an isoquinoline alkaloid of opium;

(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters and not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amount;

(5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters and not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amount;

(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters and not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams and not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams and not more than 2.5 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

§60A-2-209. Schedule IV criteria.—The state board of pharmacy shall recommend to the Legislature that a substance be placed in Schedule IV if it finds that:

(1) The substance has a low potential for abuse relative to substances in Schedule III;

(2) The substance has currently accepted medical use in treatment in the United States; and

(3) Abuse of the substance may lead to limited physical dependence or psychological dependence relative to the substances in Schedule III.

§60A-2-210. Schedule IV.—(a) The controlled substances listed in this section are included in Schedule IV.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following 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:

(1) Barbital;
(2) Chloral betaine;
(3) Chloral hydrate;
(4) Ethchlorvynol;
(5) Ethinamate;
(6) Methohexital;

(7) Meprobamate;
(8) Methylphenobarbital, as methobarbital;
(9) Paraldehyde;
(10) Petrichloral;
(11) Phenobarbital;
(12) Lorazepam;
(13) Mebutamate;
(14) Clorazepate;
(15) Chlordiazepoxide;
(16) Clonazepam;
(17) Diazepam;
(18) Flurazepam;
(19) Oxazepam;
(20) Prazepam.
(21) Pentazocine.

(c) Any material, compound, mixture or preparation which contains any quantity of the following substance, including its salts, isomers (whether optical, position or geometric) and salts of such isomers whenever the existence of such salts, isomers and salts of isomers is possible: Fenfluramine.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position or geometric) and salts of such isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

(1) Diethylpropion;

(2) Phentermine;

(3) Pemoline (including organometallic complexes and chelates thereof);

(4) Pipradrol:

(5) SPA ((-)-1-dimethylamino-1, 2-diphenylethane).

(e) Other substances, Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts:

(1) Dextropropoxyhene (alpha-(+)-4-dimethylamino-1, 2-diphenyl-3-methyl-2-propionoxybutane).

(f) Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

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§60A-2-211. Schedule V criteria.—The state board of pharmacy shall recommend to the Legislature that a substance be placed in Schedule V if it finds that:

(1) The substance has a low potential for abuse relative to the controlled substances listed in Schedule IV;

(2) The substance has currently accepted medical use in treatment in the United States; and

(3) The substance has limited physical dependence or psychological dependence liability relative to the controlled substances listed in Schedule IV.

§60A-2-212. Schedule V.—(a) The controlled substances listed in this section are included in Schedule V.

(b) Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture or preparation containing any of the following limited quantities of narcotic drugs or salts thereof, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams and not more than 100 milligrams per dosage unit;

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams and not more than 5 milligrams per dosage unit;

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams and not more than 5 milligrams per dosage unit;

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams;

(6) Not more than 0.5 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(c) Loperamide.

(d) Amyl Nitrite, isobutyl nitrite and the other organic nitrites are controlled substances and no product containing these compounds as a significant component shall be possessed, bought or sold other than pursuant to a bona fide prescription, or for industrial or manufacturing purposes.

§60A-2-213. Review and printing of schedules by board; public information.—The state board of pharmacy shall annually review and

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cause to be printed the schedules contained in this article, which printed schedules shall be made available to the public.

III.

REGISTRATION OF MANUFACTURERS, DISTRIBUTORS AND DISPENSERS OF CONTROLLED SUBSTANCES

ARTICLE 1

GENERAL INFORMATION

§301.01 - Scope of Part 301

Procedures governing the registration of manufacturers, distributors, and dispensers of controlled substances pursuant to sections 301 through 305 of the Uniform Controlled Substances Act (Chapter 60A, 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 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 Article 1, Section 101 of the Act (Chapter 60A, 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.

§301.02 - 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 60A 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, etheres, 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 §308.11(b) 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 §308.11(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 §308.11(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:

(i) opium, including raw opium, opium extracts, opium fluid extracts, powdered opium, granulated opium, deodorized opium and tincture of opium;

(ii) Apomorphine;

(iii) Codeine;

(iv) Ethylmorphine;

(v) Hydrocodone;

(vi) Hydromorphone;

(vii) Metopon;

(viii) Morphine;

(ix) Oxycodone;

(x) Oxymorphone;

(xi) Thebaine;

(xii) Mixed alkaloids of opium listed in §308.12 (b) (2) of this chapter;

(xiii) Cocaine; and

(xiv) 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 §308.12 (c) of this chapter;

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

(7) Amphetomines 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 Article 3, §305 of the Uniform Controlled Substances Act (Chapter 60A 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 Article 3, Section 303 of the Uniform Controlled Substances Act (Chapter 60A West Virginia Code).

(g) The term "registrant" means any person who is registered pursuant to Article 3, Section 303 of the Uniform Controlled Substances Act (Chapter 60A West Virginia Code).

(h) Any term not defined in this Section shall have the definition set forth in Section 1-101 these regulations or in Section 1-101 of the Act.

§301.03 - 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.

ARTICLE 2

FEES FOR REGISTRATION
AND REREGISTRATION

§301.11 - Fee amounts.

(a) For each registration or reregistration to manufacture controlled substances, the registrant shall pay a fee of $50.

(b) For each registration or reregistration to distribute controlled substances, the registrant shall pay a fee of $25.

(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 $5.

(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 $5.

(e) For each registration or reregistration to conduct chemical analysis with controlled substances listed in any schedule, the registrant shall pay a fee of $5.

§301.12 - 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.

§301.13 - 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 U.S. 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 preclinical research (including quality 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.

ARTICLE 3

REQUIREMENTS OF REGISTRATION

§301.21 - Persons required to register.

(1) 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 Article 2 § 301.13. 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)

§301.22 - Separate registration for independent activities.

(2)(a) The following eight 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 IV.

(b) Every person who engages in more than one 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 obtained 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 Article 2 § 301.13, 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 (1) one or more controlled substances listed in schedules II through V or (2) one basis class of controlled substance listed in schedule I, except that a registration to conduct chemical analysis may include more than one basic class of controlled substance

listed in schedule I and also include one or more controlled substances listed in schedules II through V.

§301.23 - Separate registrations for separate locations.

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

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

(1) A warehouse where controlled substances are stored by 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 302(c)(2) of the Uniform Controlled Substances Act (Chapter 60A 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.

§301.26 - 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 U.S. 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; and

(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.

(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.

§301.27 - 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, it 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 U.S. General Services Administration and in accordance with the rules of the U.S. Office of Emergency Prepardedness.

(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 U.S. 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 filled by any person registered under the Uniform Controlled Substance Act. The organization shall, upon the execution of a Civil Defense Emergency Order Form, be deemed to be registered under the Uniform Controlled Substance Act, for purposes of recordkeeping pursuant to Part 304 of this chapter.

ARTICLE 4

APPLICATIONS FOR REGISTRATION

§301.31 - 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 30 days before the expiration date of his registration.

§301.32 - 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 manufacutre 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 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 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 substance 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 308 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 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 1.101, 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 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.

301.34 - 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 registration may submit all applications in one package. Each application must be complete and should not refer to accompanying application for required information.

§301.35 - 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. Applications 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 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 §301.36 and has no bearing on whether the application will be granted.

§301.36 - 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.

§301.37 - 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 §301.48, or before the date on which a notice of hearing on the application is published pursuant to Chapter 60A, Article 3, Section 305 of the Act, 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.

ARTICLE 5

ACTION ON APPLICATIONS FOR REGISTRATION:
REVOCATION OR SUSPENSION OF REGISTRATION

§301.41 - 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 5 of the Uniform Controlled Substance Act, Chapter 60A 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 303 of the Uniform Controlled Substance Act (Chapter 60A West Virginia Code), have been met by the applicant.

§301.42 - 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 adquately safeguarded, it shall register the applicant unless it finds registration should be denied for reasons set forth in Article 3, Section 303 of the Uniform Controlled Substance Act (Chapter 60A, 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 §301.48 and, if requested by the applicant, hold a hearing on the application.

§301.44 - 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 303 of the Uniform Controlled Substance Act (Chapter 60A 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 §301.48 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.

§301.45 - Suspension or revocation of registration.

(a). The West Virginia Board of Pharmacy may suspend any registration pursuant to section 304 (a) of the Uniform Controlled Substance Act (Chapter 60A West Virginia Code)

(b). The West Virginia Board of Pharmacy may revoke any registration pursuant to section 304 (a) of the Uniform Controlled Substance Act (Chapter 60A West Virginia Code).

(c). Before revoking or suspending any registration, the West Virginia Board of Pharmacy shall issue order to show cause pursuant to §301.48 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 304 (c) of the Uniform Controlled Substance Act (Chapter 60A 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 303 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 Pharmacy all of the particular controlled substances 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 304 (c) of the Uniform Controlled Substance Act (Chapter 60A West Virginia Code).

§301.46 - 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 §301.48 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 304(c) of the Uniform Controlled Substance Act (Chapter 60A 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 §301.48, 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.

§301.47 - 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 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 re registration at least 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.

§301.48 - 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 Article 3, Section 303 of the Uniform Controlled Substance Act (Chapter 60A West Virginia Code), to register the applicant, the West Virginia Board of Pharmacy shall serve upon the applicant an order to show casue 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 Article 3 Section 304 Uniform Controlled Substance Act (Chapter 60A 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 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 Article 3 §305 of the Uniform Controlled Substance Act (West Virginia Code Chapter 60A).

(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.

ARTICLE 6

HEARINGS

§301.51 - 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 29A, West Virginia Code), and by the procedures for hearings under the Act set forth in §§304-305 of this chapter and article.

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

§301.52 - 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.

§ 301.53 - 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.

§301.55 - Burden of proof.

(a) At any hearing on an application to manufacutre 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 303(a) of the Act (Chapter 60A West Virginia Code) are satisfied. Any other person participating in the hearing shall have the burden of proving any propositions of fact or 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 303 of the Act (Chapter 60A 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 304(a) of the Act (Chapter 60A West Virginia Code) are satisfied.

§301.56 - 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 §301.46 (c) 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.

§ 301.57 - 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 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.

ARTICLE 7

MODIFICATION, TRANSFER AND TERMINATION OF REGISTRATION

§301.61 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.

§301.62 - 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.

§ 301.63 - 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.

IV.

SECURITY REQUIRMENTS

ARTICLE 8

SECURITY REQUIREMENTS

§301.71 - 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 §§301.74-301.76 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 opera-

tions 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 §§301.71 et seq.: PROVIDED, that the West Virginia Board of Pharmacy has previously approved them. All such persons shall notify the Board before November 1, 1971, 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 §§301.71 et seq., notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved by the Board.

§301.74 - 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.

&301.75 - Physical security controls for practitioners.

(a) Controlled substances listed in schedules 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 substances.

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

§301.76 - Other security controls for practitioners.

(a). The registrant shall not employee 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 form may be obtained from the office of the Secretary.

V.

LABELING AND PACKAGING REQUIREMENTS FOR CONTROLLED SUBSTANCES

ARTICLE 9

LABELING AND PACKAGING REQUIREMENTS
FOR CONTROLLED SUBSTANCES

§302.01 - Scope of Article.

Requirements governing the labeling and packaging of controlled substances pursuant to section 305 of the Uniform Controlled Substance Act (Chapter 60A West Virginia Code) are set forth generally by that section and specifically by the sections of this part.

§302.02 - 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 "manufacturer" 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 102 of the Act (Article 1 of the regulations West Virginia Code Chapter 60, Article 3).

§302.03 - Symbol required; exceptions.

(a) Each commercial container of a controlled substance excepted by the West Virginia Board of Pharmacy (pursuant to §308 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	Symbol
Schedule I----------	(I) or C-I.
Schedule II----------	(II) or C-II.
Schedule III----------	(III) or C-III.
Schedule IV----------	(IV) or C-IV.
Schedule V----------	(V) 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 labelling, of, a controlled substance intended for export from the United States.

§302.04 - 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 schedules I through V. The symbol must be at least two 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 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.

§302.05 - Location and size of symbol on labeling.

The symbol shall be prominently located on all labeling other than labels covered by §302.04. In all cases the symbol shall be clear and large enough to afford prompt identification of the controlled substance upon inspection of the labeling.

§302.06 - 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 302.03.

(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 180 days following the date on which the transfer or addition becomes effective, shall comply with the requirements of 302.03.

(c). The West Virginia Board of Pharmacy may, in the case of any controlled substance, require compliance with the requirements of 302.03 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.

§ 302.07 - 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.

VI.

QUOTAS - RESERVED

VII.

RECORDS AND REPORTS OF REGISTRANTS

ARTICLE 11

GENERAL INFORMATION

§304.01 Scope of Part 304

Inventory and other records and reports required under Article 3, § 306 of the Act (Chapter 60A, West Virginia Code) shall be in accordance with, and contain the information required by, those sections and by the sections of this Part.

§304.02 - 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 60A, 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 of 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 pharmacist 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, redlined, 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 sections 101 of the Uniform Controlled Substances Act (Chapter 60A, West Virginia Code).

§304.03 - 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.

§304.04 - 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 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 one inch high and filed in the usual consecutively numbered prescription file for noncontrolled substances.

ARTICLE 12
INVENTORY REQUIREMENTS

§304.11 - 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 §304.18.

(d). A registrant may take an inventory on a date that is within four days of his biennial inventory date pursuant to 304.13 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.

§304.12 - 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 §§304.15-304.18, 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 §§304.15-304.18, as applicable.

§304.13 - Biennial inventory date.

Every two years following the date on which the initial inventory is taken by a registrant pursuant to §304.12, the registrant shall take a new inventory of all stocks of controlled substances on hand. The biennnial 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 months from the biennial date that would otherwise apply or (c) on any other fixed date which does not vary by more than six 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.

§304.14 Inventory date for New Controlled Substances

On the effective date of a rule by the West Virginia Board of Pharmacy pursuant to Article 2, §201 (a) of the Act (Chapter 60A, 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 §304.13.

§304.15 - 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 non-controlled 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;

(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., 10-milligram tablet or 10-milligram concentration per fluid ounce of milliliter) and the number or volume thereof; and

(c) For each controlled substance in finished form:

(1) The name of the substance;

(2) Each finished form of the substance (e.g., 10-milligram tablet or 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., 100-tablet bottle or 3-milliliter vial); and

(4) The number of commercial containers of each such finished form (e.g., four 100-tablet bottles or six 3-milliliter vials).

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

(d) For each controlled substance not included in paragraphs (a), (b) or (c) or 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.

§304.16 - Inventories of distributors.

Each registered distributor shall include in his inventory the same information required of manufacturers pursuant to §304.15 (c) and (d).

§304.17 - Inventories of dispensers and researchers.

Each person registered to dispense or conduct research with controlled substances and required to keep records pursuant to §304.03 shall include in his inventory the same information required of manufacturers pursuant to §304.15(c) and (d). 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 contents; 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 1,000 tablets or capsules in which case he must make an exact count of the contents.

§304.18 - Inventories of importers and exporters.

Each registered importer or exporter shall include in his inventory the same information required of manufacturers pursuant to §304.15 (a), (c), and (d). 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).

§304.19 - 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 §305.15 (a), (c), and (d) as to substances which have been manufactured, imported, or received by the laboratory conducting the inventory, If less than 1 kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in schedule I), or less than 20 grams of a hallucinogenic substance listed in schedule I, (other than lysergic acid diethylamide), or less than 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 150 grams of any hallucinogenic substance in schedule I without regard to a need for an inventory of those substances.

ARTICLE 13

CONTINUING RECORDS

§304.21 - General requirements for continuing records.

(a) On and after June 15, 1971, every registrant required to keep records pursuant to §304.03 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 §304.04(a). 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 transfers, 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).

§304.22 - 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:

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

(ii) The quantity used in the manufacture;

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

(iv) The number of units of finished form manufactured;

(v) The quantity used in quality control;

(vi) The quantity lost during manufacturing and the causes therefor, if known;

(vii) The total quantity of the substance contained in the finished form;

(viii) The theoretical and actual yields; and

(ix) 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 whome 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., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 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;

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

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

(iii) The number of units of finished form used in the manufacture, the number manufactured and the number lost during manufactured and the ~~number lost during manufacture~~, with the causes therefor, if known; and

(iv) 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.

§304.23 - 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., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 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.

§304.24 - Records for dispensers and researchers.

Each person registered to dispense or conduct research with controlled substances and required to keep records pursuant to §304.03 shall maintain records with the following information for each controlled substance:

(a) The name of the substance;

(b) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 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 dateof 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.

§304.25 - 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 §304.22 (a)(4) or (b) (5), including the date and manner of disposal and the quantity disposed.

§304.27 - 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., US.P., N.F., 10-milligram tablet or 10-milligram concentration per milliliter);

(3) The total number of the forms received, imported or manufactured (e.g., 100 tablets, thirty 1-milliliter vials, or 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 and 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 sub-

stances 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.

VIII.

ORDER FORMS

RESERVED.

IX.

PRESCRIPTIONS

ARTICLE 15

GENERAL INFORMATION

§306.01 - Scope of Part 306.

Rules governing the issuance, filling and filing of prescriptions pursuant to Article 3 §308 of the Act (Chapter 60A - West Virginia Code) are set forth generally in that section and specifically by the sections of this part.

§306.02 - 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 60A, 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 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 Article 1 §101 of the Act (Chapter 60A, West Virginia Code).

§306.03 - 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.

§306.04 - 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 Article 3 §308 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.

§306.05 - 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 the 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.

§ 306.06 - 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 30 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.

§306.07 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.

ARTICLE 16

CONTROLLED SUBSTANCES LISTED IN SCHEDULE II

306.11 - 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 306.07.

(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 §306.05, except for the signature of the prescribing individual practitioner;

(3) If the prescribing individual 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 callback 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 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 § 306.05, 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 72 hour period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had 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.

306.12 - Refilling prescriptions.

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

306.13 - 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 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72 hour period, the pharmacist shall so notify prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

306.14 - 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.

306.15 - Filing of prescriptions.

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

ARTICLE 17

CONTROLLED SUBSTANCES LISTED IN SCHEDULES III AND IV

§306.21 - 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 §306.05, 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 §306.07.

(c). An institutional practitioner, as described in §303.06, may administer or dispense directly (but not prescribe) a controlled substance listed in schedules III or 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 §306.05 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 §306.07.

§306.22 Refilling of Prescriptions

No prescription for a controlled substance listed in schedule III or IV shall be filled or refilled more than 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 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 §306.21 which shall be a new and separate prescription.

§306.23 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.

§306.24 Filing Prescriptions

All prescriptions for controlled substances listed in schedules III and IV shall be kept in accordance with §304.04(d) of this chapter.

ARTICLE 18

CONTROLLED SUBSTANCES LISTED
IN SCHEDULE V

§306.31 - 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 §306.21. 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 §306.23 and file the prescription in accordand with §306.24.

(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 §306.07.

(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 §306.05 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 §306.07.

§306.32 - 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 his 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 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 48-hour period;

(c). The purchaser is at least 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 sub-

stance to the purchaser (the book shall be maintained in accordance with the recordkeeping requirement of § 304.04 of this chapter); and

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

X.

MISCELLANEOUS

§307.11 - 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 305 of this chapter.

(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.

§307.12 - Distribution of Aqueous or 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 ounce at any one time, containing a narcotic controlled substance in a proportion not exceeding 20 percent 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.

§307.13 - Distribution to Supplier.

Any 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.

§307.14 - 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 307.14 of the regulations implementing the Federal Controlled Substances Act be complied with.

§307.15 - Disposal of Controlled Substances.

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

§307.16 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. A copy of the report to be filed is attached hereto.

U.S. DEPARTMENT OF JUSTICE / DRUG ENFORCEMENT ADMINISTRATION

REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

OMB APPROVAL
No 43 RO464

Federal Regulations require registrants to submit a detailed report of any theft or loss of Controlled Substances to the Drug Enforcement Administration
Complete this form in triplicate. Forward the original and duplicate copies to the nearest DEA Regional Office. Retain the triplicate copy for your records.

1 NAME AND ADDRESS OF REGISTRANT (Include ZIP Code) | ZIP Code | PHONE NO. (Include Area Code)

2 PRINCIPAL BUSINESS OF REGISTRANT (Check one)
1 ☐ Pharmacy 3 ☐ Manufacturer/Distributor
2 ☐ Practitioner 4 ☐ Other _____

3 DEA REGISTRATION NUMBER
2 ltr. prefix | 7 digit suffix

4 COUNTY IN WHICH REGISTRANT IS LOCATED

5 DATE OF THEFT OR LOSS

6. NUMBER OF THEFTS OR LOSSES REGISTRANT EXPERIENCED IN LAST 12 MONTHS

7. WAS THEFT OR LOSS REPORTED TO POLICE
☐ YES ☐ NO

8 NAME AND ADDRESS OF POLICE DEPARTMENT

9 TYPE OF THEFT OR LOSS (Check one)
1 ☐ Night Break In (complete Item 10 below)
2 ☐ Armed Robbery (complete Item 11 below)
3 ☐ Employee Theft
4 ☐ Customer Pilferage
5 ☐ Other (specify) _____
6 ☐ Lost in Transit (complete Item 12 below)

10 IF NIGHT BREAK IN, WHAT WAS THE POINT OF ENTRY ?

11 IF ARMED ROBBERY, WAS ANYONE INJURED ?
☐ NO ☐ YES (If Yes, HOW ?)

12 IF LOST IN TRANSIT, COMPLETE THE FOLLOWING
A. Name of Common Carrier | B. Name of Consignee | C. Consignee's DEA Registration Number

13 IF OFFICIAL CONTROLLED SUBSTANCES ORDER FORMS WERE STOLEN, GIVE NUMBERS.

14 WHAT IDENTIFYING MARKS, SYMBOLS OR PRICE CODES WERE ON THE LABELS OF THESE CONTAINERS ?
(Insert your pricing codes)

15A IF CASH WAS TAKEN, WHAT AMOUNT ?

15B IF MERCHANDISE WAS TAKEN, VALUE ?

16 WHAT SECURITY MEASURES HAVE BEEN TAKEN TO PREVENT FUTURE THEFTS OR LOSSES ?

PRIVACY ACT INFORMATION

AUTHORITY Section 301 of the Controlled Substances Act of 1970 (PL 91-513)

PURPOSE Report theft or loss of Controlled Substances

ROUTINE USES. The Controlled Substances Act Registration Records produces special reports as required for statistical analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated.

A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes

B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes

C Persons registered under the Controlled Substances Act (Public Law 91-513) for the purpose of verifying the registration of customers and practitioners

EFFECT Failure to report theft or loss of controlled substances may result in penalties under Section 402 and 403 of the Controlled Substances Act.

DEA Form 106 – 106

Previous edition dated 9-75 is Obsolete

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