WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #3

FILED

JUL 31 10 42 AM '98

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

CITE AUTHORITY WV Code Sections 29 A-3-9, 30-5-2, 30-5-19

AMENDMENT TO AN EXISTING RULE: YES X NO Repeal and Replace

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 1

TITLE OF RULE BEING AMENDED: Rules and Regulations of the Board of Pharmacy

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED:

TITLE OF RULE BEING PROPOSED:

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

William S. Douglas Jr.
Authorized Signature

$23.20

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period, Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: 7/31/98

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency Name, Address & Phone No.) West Virginia Board of Pharmacy
232 Capitol Street
Charleston, WV 25301 (304) 558-0558

LEGISLATIVE RULE TITLE: Rules and Regulations of
the Board of Pharmacy

1. Authorizing statute(s) citation WV Code § 30-5-19

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

6/22/98

b. What other notice, including advertising, did you give of the hearing?

Pharmacists Association, and various health care groups were notified and several informal meetings with reprensentatives were held.

c. Date of Public Hearing(s) *or* Public Comment Period ended:

Comment period ended on 7/23/98

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached X No comments received _____

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

7/31/98

f. **Name, title, address and phone/fax/e-mail numbers** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

William T. Douglass, Jr.

Executive Director, West Virginia Board of Pharmacy

232 Capitol Street

Charleston, WV 25301 Phone (304) 558-0558 (Fax) 558-0572

g. ***IF DIFFERENT*** **FROM ITEM 'f', please give Name, title, address and phone number(s)** of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

a. Give the date upon which you filed in the State Register a notice of the time and place of a

hearing for the taking of evidence and a general description of the issues to be decided.

_____

_____

_____

_____

b. Date of hearing or comment period:

_____

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

_____

d. Attach findings and determinations and reasons:

Attached _____

SUMMARY OF PROPOSED RULE

Title 15

Legislative Rules

Series 1

Rules and Regulations

This rule repeals and replaces the current Series 1, entitled "Rules and Regulations of the Board of Pharmacy." This rule provides definitions of many terms and establishes general provisions for Board operation. The rule establishes internship requirements. The rule provides the requirements for application as a pharmacist, including examination requirements, renewals, and reinstatement of lapsed licenses. The rule establishes the qualifications for obtaining a license by reciprocity, including requirements for a foreign pharmacy graduate. The rule establishes proceedings for disciplinary action. The rule establishes how drugs may be transferred and the restrictions on refilling and transferring of prescription orders. The rule establishes how drugs and devices may be returned. The rule states the requirements for drug product selection and substitution. The rule establishes the requirements for pharmacy permits, including the minimum requirements, security, and professional work environment. The rule states the required equipment, facilities, and record systems required by a pharmacy. The rule establishes the requirements for a permit to conduct sterile pharmaceutical compounding. The rule establishes licensure and control of nuclear pharmacies. The rule establishes the sanitary

requirements in a pharmacy. The rule establishes rules of professional conduct for pharmacists. The rule establishes the duties and responsibilities of a pharmacist-in-charge. The rule establishes the manner of issuance of a prescription. The rule states different labeling requirements. The rule establishes the requirements and responsibilities of a consultant pharmacist. The rule establishes different types of specialized dispensing systems, including the use of emergency kits. The rule states the requirement for places that need to obtain a controlled substance permit, including the fees for such permit. The rule establishes the authority of pharmacists to administer immunizations after certain training.

STATEMENT OF CIRCUMSTANCES

Title 15
Legislative Rules
Series 1
Rules and Regulations

Title 15, Series 1, Rules and Regulations of the Board of Pharmacy went into effect June 14, 1993. Since that time the practice of pharmacy has evolved and there have been dramatic changes affecting how drugs are dispensed, in what settings the drugs are dispensed, and the role of the pharmacist. The current regulations do not cover these many facets of the modern day practice of pharmacy and make it difficult to apply to current situations and enforce. Therefore, it is necessary to update the regulations so that the Board can effectively regulate the practice of pharmacy in order to protect the public.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Rules and Regulations

Type of Rule: X **Legislative** ____ **Interpretive** ____ **Procedural**

Agency West Virginia Board of Pharmacy

Address 232 Capitol Street

Charleston, WV 25301

1. Effect of Proposed Rule

	ANNUAL		FISCAL YEAR		
	INCREASE	DECREASE	CURRENT	NEXT	THEREAFTER
ESTIMATED TOTAL COST	$ N/A	$	$ N/A	$	$
PERSONAL SERVICES					
CURRENT EXPENSE					
REPAIRS & ALTERNATIONS					
EQUIPMENT					
OTHER					

2. Explanation of above estimates:

Proposed rule will not change operating costs of Board except the addition of processing authority to administer immunizations permits. The volume and costs unable to be determined.

3. Objectives of these rules:

Repeals and replaces the current Title 15.Series 1 of the Board's Legislative rules. Updates rules in order to apply to modern practice of pharmacy.

Rule Title: Rules and Regulations

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

N/A

B. Economic Impact on Political Subdivisions; Specific Industries; Specific groups of Citizens.

Only change is to add $25.00 fee for pharmacists who apply for and obtain an Authority to Administer Immunizations permit.

C. Economic Impact on Citizens/Public at Large.

N/A

Date: 6/22/98

Signature of Agency Head or Authorized Represntative

William J. Douglas Jr.

Executive Director

TITLE 15
LEGISLATIVE RULES

SERIES 1
RULES AND REGULATIONS OF THE BOARD OF PHARMACY

§15-1-1 GENERAL

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

1.2 Authority.--W. Va. Code §30-5-19.

1.3 Filing date _____.

1.4 Effective date _____.

1.5 Repeal of former rule- This legislative rule repeals and replaces WV 15CSR1 "Rules and Regulations of the Board of Pharmacy" filed June 11, 1993 and effective June 14, 1993.

§15-1-2. DEFINITIONS.

2.1 The following words and phrases as used in this Rule have the following meanings, unless the context otherwise requires:

(a) "Act" or "Uniform Controlled Substance Act" means and refers to chapter 60A of the West Virginia Code.

(b) "Administer" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion or any other means.

(c) "Automated pharmacy system" means mechanical systems which perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of medications, and which collect, control, and maintain all transaction information.

(d) "Board of Pharmacy" or "Board" means the West Virginia state board of pharmacy.

(e) "Compounding" means:

(1) The preparation, mixing, assembling, packaging, or labeling of a drug or device:

(A) As the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/ pharmacist relationship in the course of professional practice for sale or dispensing, or

(B) For the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing, or

(C) The preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(f) "Confidential information" means patient-identifiable information maintained by the pharmacist in the patient record or which is communicated to the patient as part of patient counseling, or which is communicated by the patient to the pharmacist. This information is privileged and may be released only to the patient or to other members of the health care team and other pharmacists where, in the pharmacist's professional judgement, such release is necessary to the patient's health and well-being; to such other persons or governmental agencies authorized by law to receive such privileged information; as necessary for the limited purpose of peer review and utilization review; and as authorized by the patient or required by court order.

(g) "Controlled Substance" means a drug, substance, or immediate precursor in Schedule I through Schedule V of either the Federal Controlled Substances Act or the West Virginia Uniform Controlled Substances Act.

(h) The term "Cosmetic" which shall be held to include "Dentifrice" and "Toilet articles" means:

(1) 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 temporarily altering the appearance.

(2) Articles intended for use as a component of any such articles, except that the term shall not include soap.

(i) "Deliver" or "delivery" means the actual, constructive or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

(j) "Device" means an instrument, apparatus, implement or machine, contrivance, implant or other similar or related article, including any component part or accessory, which is required under federal law to bear the label, "Caution: Federal or state law requires dispensing by or on the order of a physician" or the language or symbol as determined by the U. S. Food and Drug Administration.

(k) "Direct supervision" means that a licensed pharmacist is physically present in the pharmacy and is available to verify the accuracy of a prescription before it is dispensed.

(l) "Dispense" or "dispensing" is that aspect of the practice of pharmacy concerned with the preparation, verification, and delivery of a drug or device in an appropriately labeled and suitable container to a patient or a patient's representative or surrogate pursuant to a lawful order of a practitioner for subsequent administration to, or use by, a patient. Until actual delivery of the drug to the patient or patient's representative occurs then the drug has not been dispensed.

"Dispensing" shall not be construed to include the prescribing and administering of controlled substances as is included in the definition of "Dispensing" controlled substances found in W. Va. Code §60A-1-101(h.)

(m) "Distribute" means the delivery of a drug or device other than by administering or dispensing.

(n) Distributor" means a person licensed as a wholesaler.

(o) "Drug" means:

(1) Articles recognized as drugs by the U. S. Food and Drug Administration (FDA) and/or published in such references as the USP-NF, Facts and Comparisons, Physicians Desk Reference or supplements thereto, for use in the diagnosis, cure, mitigation, treatment or prevention of disease in human or other animals;

(2) Articles, other than food, intended to affect the structure or any function of the body of human or other animals; and

(3) Articles intended for use as a component of any articles specified in subsection (1) or (2) of this section.

(p) "Drug regimen review" includes, but is not limited to, the following activities:

(1) Evaluation of prescription orders and patient records readily available to the pharmacist for:

(A) Known significant allergies;

(B) Rational drug therapy and contraindications;

(C) Reasonable dose and route of administration; and

(D) Reasonable directions for use.

(2) Evaluation of readily available prescription drug orders and patient records for duplication of therapy.

(3) Evaluation of the prescription drug for interactions and/or adverse effects which may include, but are not limited to, any of the following:

(A) Drug-drug;

(B) Drug-food;

(C) Drug-disease; and

(D) Adverse drug reactions.

(4) Evaluation of the prescription drug orders and patient records for proper utilization, including over utilization, under utilization and optimum therapeutic outcomes.

(q) "Inpatient pharmacy" means the area within a licensed institution; i.e., a hospital, or other place where patients stay at least one night, where drugs are stored and dispensed to other areas of the institution for administration to the patients by other licensed health care providers.

(r) "Inspector" means an agent of the Board, who is a licensed pharmacist, appointed by the Board to conduct periodic inspections of permittees and perform other duties as designated by the Board.

(s) " Institutional facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, including but not limited to a(n) hospital, convalescent home, nursing home, extended care facility, mental health facility, rehabilitation center, psychiatric center, developmental disability center, drug abuse treatment center, family planning clinic, penal institution, hospice, public health facility, or athletic facility.

(t) "Institutional pharmacy" means that physical portion of an institutional facility that is engaged in the compounding, dispensing, and distribution of drugs, devices, and other materials used in the diagnosis and treatment of injury, illness, and disease and which holds a pharmacy license from the Board.

(u) "Intern" means an individual who is:

(1) Currently licensed by the Board to engage in the practice of pharmacy while under the supervision of a licensed pharmacist and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist; or

(2) A graduate of an approved college of pharmacy or a graduate who has established educational equivalency by

obtaining a Foreign Pharmacy Graduate Examination Committee certificate, who is currently licensed by the Board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist; or

(3) A qualified applicant who is licensed by the Board and is awaiting examination for licensure, or

(4) An individual participating in a residency or fellowship program.

(v) "Investigator" means an agent of the Board appointed to conduct official inquiries and perform other duties as designated by the Board.

(w) "Labeling" means the process of preparing and affixing a label and the affixing of auxiliary labels to a drug container exclusive, however, of a labeling by a manufacturer, packer or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal law or regulation or state law or rule.

(x) . "Mail order pharmacy" means a pharmacy, regardless of its location, which dispenses greater than ten percent (10%) prescription drugs via the United States Mail or otherwise.

(y) "Manufacturer" means a person engaged in the manufacturing of drugs or devices.

(z) "Manufacturing" means production, preparation, propagation or processing of any drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes any packaging or repackaging of the substance(s) or labeling or relabeling of its contents and the promotion and marketing of such drugs or devices. Manufacturing also includes the preparation or repackaging, and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners or other persons.

(aa) "Nonprescription drug" means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the requirements of the laws and rules of this state and the federal government.

(bb) "Nuclear pharmacist" means a pharmacist that has been certified in the specialty of nuclear pharmacy.

(cc) "Nuclear pharmacy" means a place where radioactive drugs are prepared and dispensed and which operates under specialized rules.

(dd) "Original License" means a license issued by the Board to an applicant when:

(1) the applicant is a new business.

(2) the applicant is an established business that is transferred to a successor.

(3) the applicant is an established business in which fifty percent (50%) ownership or more is transferred to a new owner.

(4)the applicant is an established business in which control of pharmaceutical services is transferred; not including a change in pharmacist-in-charge.

(5) the applicant is an established business which moves to a new location.

(ee) "Outpatient pharmacy" means any pharmacy, apothecary, or place within this state where drugs are dispensed and sold at retail or displayed for sale at retail and where the practice of pharmacy is conducted and pharmaceutical care is provided; and anyplace outside of this state where drugs are dispensed and the practice of pharmacy and pharmaceutical care is provided to residents of this state. The terms pharmacy, drug store, or apothecary do not include a free clinic or physician's office that dispenses drugs for free.

(ff) "Over-the counter drug" or "OTC drug" means any drug that is not a prescription drug or legend drug.

(gg) "Patient counseling" means the oral communication by the pharmacist of information, which may include supplemental media according

to the pharmacist's professional judgement, to the patient or care giver, to ensure the proper use of drugs and devices.

(hh) "Permit" means any license, registration, or other privilege granted or issued by the board to any person for the purpose of providing a business or service to individuals or the public and the holder of the permit is the "permittee". No permit will be issued unless a business is operated or a service is provided. Not more than one permit may be issued in any one name in more than one location.

(ii) "Person" means an individual, corporation, partnership, association or any other legal entity, including government.

(jj) "Person Addicted" means one who has acquired the habit of using alcoholic beverages or controlled substances or other agents to such an extent as to deprive him or her of reasonable self-control.

(kk) "Pharmaceutical care" is the provision of drug therapy and other pharmaceutical patinet care services intended to achieve outcomes related to:

(1) The cure or prevention of a disease, or

(2) Elimination or reduction of a patient's symptoms, or

(3) Arresting or slowing of a disease process.

(ll) "Pharmacist" or "registered pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacy and pharmaceutical care.

(mm) "Pharmacist-in-charge" means a pharmacist currently licensed in this state who;

1. Accepts responsibility for the operation of a pharmacy in conformance with all state and federal laws and rules pertinent to the practice of pharmacy and the distribution of drugs.

2. Is personally in full and actual charge of such pharmacy and personnel.

3. Works at least fifty percent (50%) of the time when employed in a pharmacy that is open 72 hours per week or less; including the use of any accrued annual or sick leave.

4. Works at least 36 hours a week in a pharmacy open more than 72 hours per week, including the use of any accrued annual or sick leave.

(nn) "Pharmacy technician" means registered supportive personnel who work under the direct supervision of a pharmacist, and who have passed an approved training program.

(oo) " Pharmacy technician trainee" means an individual currently engaged in a pharmacy technician training program which has been approved by the Board and who is under the direct supervision of a pharmacist.

(pp) "The practice of pharmacy" is the personal health service concerned with the preparing, compounding and dispensing of drugs and medical devices used in the diagnosis, treatment or prevention of disease, dispensed on the prescription of a practitioner, or otherwise legally dispensed or sold and shall include the proper and safe storage of drugs, the maintenance of proper records and the dissemination of information to other health care professionals and proper counseling to the patient concerning the therapeutic value and proper use of drugs and devices.

(qq) "Practitioner" means an individual currently licensed, registered or otherwise authorized by the jurisdiction in which he or she practices to prescribe and administer drugs in the course of professional practices, as allowed by law.

The term "Practitioner" shall not be construed to be persons and places, as defined in W.V. Code §60A-1-101 (v) (1) and (2), that handle controlled substances.

(rr) "Preceptor" means an individual who is currently licensed as a pharmacist by the board, meets the qualifications as a preceptor under the rules of the board, and participates in the instructional training of pharmacy interns.

(ss) "Prescription drug" or "legend drug" means a drug which, under federal law, is required, prior to being dispensed or delivered, to be labeled with any of the following statements or the language or symbol as determined by the U. S. Food and

Drug Administration.

(1) "Caution: Federal law prohibits dispensing without prescription".

(2) "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian"; or a drug which is required by any applicable federal or state law or rule to be dispensed pursuant to a prescription drug order or is restricted to use by practitioners only.

(tt) "Prescription" or "Prescription order" means a lawful order from a properly licensed practitioner to a pharmacist for a drug or device for a specific patient and transmitted by:

(1) Written order, or

(2) Oral order to a pharmacist who must immediately:

(A) Reduce it to writing which becomes the original order, and

(B) Hand initial it to identify the receiver, and

(C) Show the date, time and name of person transmitting the order, or

(3) Electronic transmission which has the capability to produce a printed copy, and shows the date, time and name of person transmitting the order.

All other methods of transmission not approved by the Board are prohibited.

(uu) "President" means the President of the West Virginia Board of Pharmacy.

(vv) "Sample" means a package of a legend drug provided by a manufacturer on the request of a practitioner to be given to a patient without charge.

(ww) An approved or recognized "School of Pharmacy" means a school of pharmacy accredited by the American Council on

Pharmaceutical Education.

(xx) The term "Secretary" means the Secretary of the West Virginia Board of Pharmacy

(yy) The term "Vice-President" means the Vice-President of the West Virginia Board of Pharmacy

(zz) A "Wholesaler" is a person or entity licensed by the Board to distribute, by sales or otherwise, prescription legend drugs to persons other than a consumer or patient.

§15-1-3 GENERAL PROVISIONS

3.1 Board in general. -- The Board of Pharmacy shall consist of five (5) practicing pharmacists and two (2) public members 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 licensed pharmacist of the State of West Virginia and actively engaged in the practice of pharmacy. The public members shall be residents of this state who have attained the age of majority and may not be a past or present member of the profession of pharmacy, the spouse of a member of the profession of pharmacy, a person who has ever had any material financial interest in providing of pharmacy service or who is engaged in any activity directly related to the practice of pharmacy.

3.2 Officers of the Board -- The members of the board shall annually elect as officers of the Board one (1) member to serve as President of the Board, one (1) to serve as Vice-president and one (1) to serve as Secretary, all to serve a one (1) year term or until their successors are elected. The election is to be held in June each year.

3.3 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 Aesculapius serpent and holding in balance a set of scales, an impression of which is affixed hereto.

3.4 Meetings of the Board -- The Board shall hold at least two (2) meetings a year for the purpose of examining applicants for licensure to practice pharmacy in West Virginia and for the transaction of such other business as may legally come before it. It may hold additional meetings for any legitimate purpose it may consider appropriate, which shall be called by the Secretary at the direction of the President or upon the written request of any three (3) members. "Roberts Rules of Order" shall control conduct of all meetings.

3.5 Quorums -- Four (4) members must be present at the time and place set for the meeting before any action can be taken by the Board. A majority vote of the members in attendance is required before any motion may be passed.

3.6 Location of Office -- The Board shall determine the location of its office.

3.7 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 article one and five, chapter thirty 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 the monies are received. He or she shall also, on the first day of January and first day of July of each year or within five (5) days thereafter, certify to the State Auditor, a detailed statement of all moneys received by him or her during the preceding six (6) months.

3.8 Every member of the board shall be paid a per diem for each day actually spent in attending sessions of the Board or of its committees and the necessary travel, as set by West Virginia Code §30-50-2(c), and shall be reimbursed for all actual and necessary expenses incurred in carrying out the provisions of chapter thirty of the West Virginia Code applicable to the Board.

3.9 Record of proceedings; registration of applicant; 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\her application, name, age, educational and other qualifications, place of residence, whether an examination was required, whether the applicant was rejected or a certificate of licensure or registration granted. the license or registration number, if required, and any suspension or revocation of any license or registration. 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, is prima facie evidence of all matters recorded therein.

3.10 Roster of licensed or registered persons. -- The Secretary of the Board shall prepare and maintain a complete roster of all persons, licensed and registered by it, alphabetically and by class or type and by whether within or without the state.

3.11 Power of Inspection and Investigation-- The duly authorized agents of the Board shall have the power to inspect and investigate in a lawful manner and during regular business hours all places or persons with permits. Such inspection and/or investigation may include, but not be limited to, all inventories, invoices for prescription drugs, selling prices, and other records required by law, acts of individuals and facilities, but shall not extend to financial data or sales data other than shipment data or pricing data; unless the owner, operator or agent in charge of the controlled premises consents in writing. Access to selling prices will be allowed only when needed for a specific investigation or inquiry regarding a particular drug.

3.12 During the course of any inspection or investigation by an agent of the Board the agent shall have the authority to temporarily close any permittee upon the discovery of any of the following:

(a) the ability of the pharmacist to practice pharmacy with reasonable skill, competency, or safety to the public is impaired because the permittee's cognitive, interpersonal, or psychomotor skills are affected by psychiatric, psychological, or emotional problems or excessive alcohol or drug use or addiction, or

(b) the absence of a valid permit issued by the Board or by the absence of an available pharmacist to be on duty.

3.13 When a permittee is closed under § 15-1-3.12 (a) of this Rule they shall remain closed until an unimpaired pharmacist arrives on the premises or when closed under § 15-5-3.12 © they shall remain closed until a valid permit is obtained and on display as required by law.

3.14 Agents of the Board when acting in good faith and without malice shall enjoy immunity from individual civil liability while acting within the scope of their duties as such agents of the Board.

§15-1-4 INTERNSHIP REQUIREMENTS

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

The Board shall certify internship for an individual in this section only:

(a) When a preceptor holds a current, valid license as a pharmacist from the board and the intern has been issued an intern certificate which expires on the 30th day of June of each year and must be renewed annually up to four (4) years from the date of issue. The internship certificate shall be displayed at the place of internship, and

(b) When the intern has notified the Board within ten (10) days of the employment as an intern, and

(c) When the intern notifies the Board within ten (10) days subsequent to termination of any internship under a specific preceptor, and

(d) When the internship is certified by the submission of a "Certification by Preceptor as to Internship" form immediately after termination of the internship. (Forms are available from the board office.)

4.2 No intern shall be certified by the Board unless the intern is enrolled in or is a graduate of a recognized school of pharmacy.

4.3 An intern may receive experience credit for any period of time during which he or she is enrolled in a recognized school of pharmacy and the Board may accept up to eight hundred (800) hours credit for interns participating or enrolled in a supervised internship as part of the pharmacy curriculum.

4.4 All internship will be obtained in the practice of pharmacy and in a licensed pharmacy.

4.5 The Board may accept internship hours gained outside West Virginia on a letter of credit or certification from the Board of Pharmacy of the state in which the intern acquired internship experience. Up to one third of the internship hours may be fulfilled by an internship in a foreign country.

§15-1-5 EXAMINATION FOR LICENSURE AND REGISTRATION AND ANNUAL RENEWAL REQUIREMENTS

5.1 Application.

All applicants for examination shall apply in writing to the Board at least fifteen (15) days before the date the examination is to be conducted and shall transmit with the application the prescribed fee. The application shall be made on a form provided by the Board.

5.2 The requirements for application as a pharmacist are as follows:

(a) Age.

The applicant must be not less than eighteen (18) years of age, proof of which must be shown by birth certificate or other acceptable document.

(b) Moral Character.

Every applicant shall present to the Board satisfactory evidence that he or she is a person of good moral character and has not been convicted of a felony involving controlled substances or violent crime and has not been addicted to alcohol or controlled substances.

(c) Education.

1. The applicant for licensure as a pharmacist shall present to the Board satisfactory evidence that he or she is a graduate of an approved school of pharmacy.

(d) Internship.

The applicant shall have acquired one thousand five hundred (1500) hours of internship in a licensed pharmacy.

(e) Criminal records check

A signed waiver from the applicant allowing the Board to obtain a certified criminal records check on the applicant.

5.3 Examinations.

a. State examinations shall be held at a time and place designated by the Board. At least thirty (30) days notice shall be given by the Board prior to the holding of any examination.

b. A maximum of two (2) days shall be allowed for all portions of the state examination.

c. An applicant for licensure as a pharmacist must pass the NAPLEX examination administered by NABP and one or more state examinations in subject(s) determined by the Board as being reasonable, in testing his or her knowledge.

d. For the purpose of grading or rating, answers to the questions shall be valued by scores based upon their importance as determined by the Board. An individual test grade of seventy percent (70%) on each state examination and an average

of seventy five percent (75%) on all the state examinations created and administered by the Board is necessary for an applicant to be passed for licensure.

e. An applicant failing to achieve the required grade may repeat the state examination(s) one time with out further cost within six (6) months, but one re-examination exhausts the privilege to sit for the state examination(s) under the current application.

5.4 Certificate of licensure or registration.

a. An applicant for licensure who has successfully passed all the required examinations may receive a letter signed by the Secretary prior to preparation of a permanent certificate, or a permanent certificate evidencing that he or she is a licensed pharmacist. The permanent certificate of licensure shall bear a serial number, the full name of the applicant, the date of its issuance, the seal of the Board, and shall be signed by at least four (4) members of the Board and shall be attested by the President and Secretary. For any duplicate of this certificate the Board shall charge a fee of twenty five dollars ($25.00) paid before issuance. No certificate is assignable.

5.5 Annual license renewal.

(a) Every licensed pharmacist who desires to continue in the practice of pharmacy, shall on or before the first day of July annually apply to the Board for a renewal of his or her license, and shall transmit with the application the prescribed fee. . If the Board finds that the applicant has been legally licensed and is entitled to a renewal, it shall issue a renewal certificate attesting to that fact.

(b) Every registered pharmacy technician who desires to continue registration, shall on or before the first day of July annually apply to the Board for a renewal of his or her registration and shall transmit with the application the prescribed fee. If the Board finds that the applicant has been legally registered and is entitled to a renewal, it shall issue a renewal certificate attesting to that fact.

© Notification of the need to renew licensure shall be given by the

Board at least thirty (30) days prior to the first of July.

(d) Failure to renew.

If any pharmacist or pharmacy technician fails for a period of sixty (60) days after the first of July of each year to apply to the Board for a renewal of his or her license, the Board shall send a second notification of the required annual renewal to the last known address of the pharmacist by certified mail, return receipt requested. If the pharmacist or pharmacy technician fails to apply for renewal of licensure within thirty (30) days after receipt of the second notification, his or her name shall be erased from the register of pharmacists and pharmacy technicians.

(e) Re-instatement.

In order for any pharmacist or pharmacy technician whose name has been erased from the register of the Board pursuant to subsection (d) of this section to again become licensed, such pharmacist or pharmacy technician shall personally appear before the Board, or an authorized committee of the Board, to show cause for permitting the license to lapse.

1. If such pharmacist submits to the Board satisfactory reasons for failing to renew their license and satisfies the Board as to his or her qualifications to practice the profession by successfully passing the examinations administered by the Board such person shall be reinstated upon payment of a fee of two hundred fifty dollars ($250.00) plus the appropriate annual renewal fee.

2. If such pharmacy technician submits to the Board satisfactory reasons for failing to renew their certificate and pays an appropriate late fee plus the prescribed renewal fee and demonstrates their competency to work as a pharmacy technician by successfully passing the pharmacy technician examination they shall be reinstated.

§15-1-6 RECIPROCITY; LICENSURE OF PHARMACISTS FROM OTHER STATES OR COUNTRIES

6.1 Qualifications.

The Board may license and admit to practice pharmacists in this state, such persons that have been legally licensed or registered as pharmacists in other states or countries: PROVIDED, that;

a. The applicant is at least eighteen (18) years of age.

b. The original state in which the applicant is licensed or registered accords similar recognition to licensed pharmacists of West Virginia.

c. The applicant is in good standing in the state or country of original licensure or registration.

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 not addicted to alcohol or a controlled substance(s).

f. The applicant has not been convicted, or had his or her license suspended or revoked for violation of pharmacy, liquor, controlled substance, or food and drug laws.

g. The applicant originally passed a written examination in subjects determined by the Board as being reasonable. The applicant also originally passed a practical examination (Errors and Omissions exam) determined by the Board as being a reasonable test of the applicant's ability to translate his or her technical knowledge into terms of actual practice.

h. The applicant is familiar with West Virginia Laws and Rules and Regulations governing the practice of pharmacy and passes the state law examination.

i. An applicant may serve all or part of his or her internship in another state and up to one-third (1/3) of his or her internship in another country and shall be given credit for the same when an affidavit of such is signed by the pharmacist under whom served and when the affidavit is attested by the secretary of the board of pharmacy of the state or country where the internship was served.

j. Applicants for reciprocity and others coming into West Virginia from other states and counties shall not work as pharmacists until they receive a certificate of licensure from the state of West Virginia.

6.2 Foreign pharmacy graduate

a. A foreign pharmacy graduate whose undergraduate pharmacy degree was conferred by a recognized school of pharmacy outside of the fifty (50) United States, the District of Columbia, and Puerto Rico, may establish educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee Certificate (FPGEC) from the National Association of Boards of Pharmacy (NABP). An applicant for licensure who receives FPGEC certification meets the educational requirement for licensure and may sit for the NAPLEX and state examinations provided he or she has obtained 1500 hours of internship; of which 500 hours may have been earned in a foreign country.

6.3 Application.

a. The applicant shall complete a preliminary application form obtained from the National Association of Boards of Pharmacy and return it to that organization.

After the preliminary application data has been verified by the National Association of Boards of Pharmacy and the Board receives notification the Board shall supply the applicant who possesses the necessary qualifications with application forms. These forms must be completed and submitted with a fee of two hundred fifty-five dollars ($255.00). In the event the applicant desires to take the examination at a time other than at the next scheduled examination the applicant shall submit to the Board an additional fee of one hundred fifty dollars ($150.00).

b. The application must include the following provided by the applicant:

1. A certified copy of proof of experience, or the original pharmacist preceptor's affidavit proving experience, that was filed by the applicant when he or she took the examination in the state or country in which he or she is licensed or registered.

2. A recent head shot photograph with a statement thereon, signed by the applicant that it is a photograph of the applicant and has been made within the previous twelve (12) months.

3. A signed waiver from the applicant allowing the Board to obtain a certified criminal records check on the applicant.

6.3 Appearance before the Board.

Applicants for licensure by reciprocity are required to appear before the Board or its designated agent at such time as directed, for checking of credentials, an interview and examination as may be necessary to determine the fitness of the applicant to practice in West Virginia. Misrepresentation shall serve to void any licensure that may be granted.

§15-1-7 PROCEEDINGS FOR DISCIPLINARY ACTION

7.1 Definitions

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

(a) "Board" means the West Virginia Board of Pharmacy.

(b) The term "demanding party" means an individual, pharmacy or any other permittee of the Board who has had a license or certificate denied, suspended, or revoked by the Board and who, as a result, demands that a hearing be held before the Board on the issue of such denial.

© The term "charged Party" means an individual, pharmacy or other permittee of the Board who holds a license or certificate issued by the Board and who has been charged by the Board as described this rule.

7.2 Hearing Procedures.

(a) Any person who has had a permit denied, suspended, or revoked by the Board, and believes such action was in violation of W. Va. Code § 30-1-1, et. seq. and/or §30-5-1, et. seq., shall be entitled to a hearing on the action denying, suspending, or revoking such permit.

(b) Any person who desires a hearing for the reason described in

subsection (a) must present a written demand for the hearing to the Board.

(c) When the president of the Board or his or her authorized designee is presented with such a demand for a hearing, he or she shall schedule a hearing within thirty (30) days of receipt by him or her of such written demand, unless postponed to a later date by mutual agreement.

(d) Charges may be instituted against any person who has a permit issued by the Board when reasonable cause exists for believing that the person may have engaged in conduct or be in such condition the permit should be suspended, revoked or otherwise disciplined for one or more of the grounds set forth in W. Va. Code §30-5-1, et. seq. or the Board's legislative rules. Charges may be based upon information received by way of a verified written complaint filed with the Board and further information gathered by the Board in the process of investigating such complaint. Charges may also be based on information received solely through inspection or investigative activities undertaken by the Board.

(e) Charges instituted against a person holding a permit as described shall be set forth in a Complaint and Notice of Hearing issued in the name of the Board as the agency of the State regulating the practice of pharmacy and related activities. Such Complaint and Notice of Hearing shall designate the Board as the "Complainant" and shall designate the permittee involved in the proceedings as the "Respondent"; shall set out the substance of each offense charged with sufficient particularity to reasonably apprise the Respondent of the nature, time and place of the conduct or condition complained of therein; shall state the date, time and place for the hearing; and shall contain a statement of intention of the Board to appoint a hearing examiner.

(f) The Board may amend the charges set forth in a Complaint and Notice of Hearing as it deems proper.

(g) A Complaint and Notice of Hearing shall be served upon the demanding or charging party at least thirty (30) days prior to the date of the hearing.

(h) Upon written motion received by the Board no later than twenty (20) days prior to the date of hearing, a more definite statement of the matters charged or the reasons stated for denial of licensure shall be provided to the demanding or charged party or his or her counsel, at least fifteen (15) days prior to the hearing date.

7.3 Hearings shall be conducted as follows:

(a) Any party to the hearing shall have the right to be represented by an attorney-at-law, duly qualified to practice law in the State of West Virginia.

(b) Upon request by the Board, it shall be represented by the West Virginia Attorney General's Office.

(c) Irrelevant, immaterial, or unduly repetitious evidence shall be excluded from the hearing. Furthermore, the rules of evidence as applied in civil cases in the circuit courts of this State shall be followed. However, when necessary to ascertain facts not reasonably susceptible of proof under those rules, evidence not admissible thereunder may be admitted, except where precluded by statute, if it is of a type commonly relied upon by reasonable prudent persons in the conduct of their affairs.

(d) The rules of privilege recognized by the law of this State shall be followed.

(e) Objections to evidentiary offers shall be noted in the record. Any party to the hearing may vouch the record as to any excluded testimony or evidence.

(f) Any party to a hearing may appear with witnesses to testify on his or her behalf; may be heard in person, by counsel or both; may present such other evidence in support of his or her position as deemed appropriate by the Board or its designated hearing examiner; and, when appropriate, may cross-examine witnesses called by the Board in support of charges or in defense of its decision to deny licensure.

(g) The hearing shall be held at such time and place as is designated by the Board but no hearing shall be conducted unless and until at least thirty (30) days written notice thereof has been served upon the charged or demanding party and/or his or her attorney. Such notice shall be given either by personal delivery thereof to the person to be notified, or by depositing such notice in the United States Mail, postage prepaid. in an envelope addressed to such person at the last known address of such person.

(h)The hearing shall be open to the general public.

(I). Members of the Board and its officers, agents and employees shall be competent to testify at the hearing as to material and relevant matters: Provided, that no member of the Board who testifies at such hearing shall thereafter participate in the deliberations or decisions of the Board with respect to the case in which he or she testified.

(k). A record of the hearing, including the complaint(s), if applicable, the notice of the hearing, all pleadings, motions, rulings, stipulations, exhibits, documentary evidence, evidentiary depositions and the stenographic report of the hearing, shall be made and a transcript shall be furnished to any party at his or her expense.

(1) Documentary evidence may be received in the form of copies or excerpts or by incorporation by reference.

(m). Where a hearing is held upon instance of the Board after charges have been brought against a licensee pursuant to this rule, the board shall have the burden of proof and shall present its evidence and/or testimony in support of the charges first.

(n) Where a hearing is held upon demand under the provisions of this section, the demanding party shall have the burden of proof and shall present its evidence and/or testimony in support of the charges first..

(o) Following the conclusion of the Board's presentation of

evidence in accordance with subsection (m) of this section, the Respondent or charged party shall have the right to submit his or her evidence in defense.

(p) Following the conclusion of the demanding party's presentation of evidence in accordance with subsection (n) of this section, The Board shall have the right to submit its evidence in defense.

(q) The Board shall call witnesses to testify in support of its decision to deny a permit or in support of the charges instituted against a permittee; may present such other evidence to support its position; and, may cross-examine witnesses called by the demanding party or charged party in support of his or her position.

(r) All parties shall have the right to opening and closing arguments, not to exceed ten (10) minutes for each presentation.

(s) Hearings held by the Board as a result of charges instituted against a permittee may be continued or adjourned to a later date or to a different place by the Board or its designee by appropriate notice to all parties.

(t) Motions for a continuance of a hearing may be granted upon a showing of good cause. Motions for continuance must be in writing and received in the office of the Board no later than seven (7) days prior to the hearing date. In determining whether good cause exists, consideration will be given to the ability of the party requesting the continuance to proceed effectively without a continuance. A motion for continuance filed less than seven (7) days from the date of the hearing shall be denied unless the reason for the motion could not have been ascertained earlier. Motions for continuance filed prior to the date of the hearing may be ruled on by the officer of the Board to preside or the designated hearing examiner. All other motions for continuance shall be ruled on by the Board member (s) or the hearing examiner presiding over the hearing.

(u) All motions related to a case set for hearing before the Board, except motions for continuance shall be received in the office of the Board at least ten (10) days before the hearing.

Prehearing motions shall be heard at a prehearing conference or at the hearing prior to the commencement of testimony. The Board Member (s) or the hearing examiner presiding at the hearing shall hear the motions and the response from the non-moving party and shall rule on such motions accordingly.

7.4 Transcription of Testimony and Evidence.

(a) All testimony, evidence, arguments and rulings on the admissibility of testimony and evidence shall be recorded by stenographic notes and characters or by mechanical means.

(b) All recorded materials shall be transcribed. The Board shall have the responsibility to make arrangements for the transcription of the recorded testimony and evidence.

(c) Upon the motion of the Board or any party assigning error or omission in any part of any transcript, the Board or its appointed hearing examiner shall settle all differences arising as to whether such transcript truly discloses what occurred at the hearing and shall direct that the transcript be corrected and/or revised as appropriate so as to make it conform to the truth.

(d) A transcript of the hearing shall be provided to all members of the Board for review at least ten (10) days before the vote is taken on its decision in any licensure or licensure disciplinary matter.

7.5 Any party may submit proposed findings of fact and conclusions of law at a time and manner designated by the Board or its duly appointed hearing examiner.

7.6 Hearing Examiner

(a) The Board may appoint a hearing examiner who shall be empowered to administer oaths and affirmations, examine witnesses under oath, rule on evidentiary matters, hold conferences for the settlement or simplification of issues by consent of parties, cause to be prepared a record of the hearing so that the Board is able to discharge its functions and otherwise conduct hearings.

(b) Hearing examiners appointed by the Board are not authorized or

empowered to grant, suspend, revoke or otherwise discipline any license.

(c) The hearing examiner shall prepare recommended findings of fact and conclusions of law for submission to the Board. The Board may adopt, modify or reject such findings of fact and conclusions of law.

7.7 Conferences; Informal Disposition of Cases.

(a) At any time prior to the hearing or thereafter, the Board, its designee or its duly appointed hearing examiner may hold conferences for the following purposes:

(1)To dispose of procedural requests, prehearing motions or similar matters; or

(2)To simplify or settle issues by consent of the parties; or

(3)To provide for the informal disposition of cases by stipulation or agreement.

(b) The Board or its duly appointed hearing examiner may cause such conferences to be held on its own motion or by the request of a party.

(c) The Board may also initiate or consider stipulation or agreement proposals with regard to the informal disposition of cases and may enter into such stipulations and/or agreements without conference.

7.8 Evidentiary depositions may be taken and read or otherwise included into evidence as in civil actions in the circuit courts of this State.

7.9 Subpoenas

(a) Subpoenas to compel the attendance of witnesses and subpoenas duces tecum to compel the production of documents may be issued by any member of the Board or its executive director.

(b) Written requests by a party for the issuance of subpoenas or

subpoenas duces tecum must be received by the Board no later than ten (10) days before a scheduled hearing. Any party requesting the issuance of subpoenas or subpoenas duces tecum shall see that they are properly served in accordance with W. Va. Code §29-5-1 (b).

7.10 Orders

(a) Any final order entered by the Board following a hearing conducted pursuant to these rules shall be made pursuant to the provisions of W. Va. Code §29A-5-3 and §30-1-8 (d). Such orders shall be entered within forty-five (45) days following the submission of all documents and materials necessary for the proper disposition of the case, including transcripts, and shall contain findings of fact and conclusions of law.

(b) The findings of fact and conclusions of law must be approved by a majority of the Board either by a poll or vote at a regular meeting, before the final order is entered. A copy of the final order approved by a majority of the Board shall be served upon the demanding or charged party and/or his attorney of record, if any, within five (5) days after entry by the Board by personal service or by registered or certified mail.

7.11 Appeal.

An appeal from any final order entered in accordance with these rules shall comply with the provisions of W. Va. Code §30-1-9.

§15-1-8 REVIEW BY CIRCUIT COURT AND SUPREME COURT OF BOARD'S REFUSAL TO ISSUE, OR SUSPEND OR REVOKE PERMIT

8.1 Any person who has been refused a license for any cause other than failure to pass any examination given by the Board or whose license has been suspended or revoked, may, within thirty (30) days after the decision of the Board, present his or her petition in writing to the Circuit Court of the county in which he or she resides or to the judge of the court in vacation, praying for the review and reversal of the decision.

8.2 Before presenting his or her petition to the court or judge,

petitioner shall mail copies of the petition to the Board.

8.3 Upon receipt of the petition copy, the Secretary shall transmit to the clerk of the court, the record of the hearing proceedings.

§15-1-9 TRANSFER OF DRUGS

9.1 No legend drug may be transferred except by the following methods:

(a) Transfer of drugs without prescription.

(1) Legend drugs without a prescription may be transferred only to a permittee or practitioner and must be kept in a record kept for that purpose and the gross dollar value of such transfers shall not exceed five percent (5%) of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any twelve (12) consecutive month period.

(2) The record showing transfers of drugs without a prescription shall contain:

(A) name of drug and quantity, and

(B) date of transaction, and

(C) permittee or practitioner to whom transferred, and

(D) selling price.

The record shall be kept in the pharmacy and be immediately accessible within one year from date of transfer, and available within forty-eight (48) hours if between one year and five years from date of transfer.

(3)Any pharmacy with transfers of prescription drugs that exceed the five percent restriction above shall obtain a permit to be a wholesaler, except that intracompany sales and transfers of drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage are not included.

(b) Transfer of drugs with a Prescription.

Legend drugs transferred by a practitioner's prescription

order are dispensed. A prescription order must contain at least the following elements:

(1) Patients name and address and the date written, and

(2) Drug name and quantity, and

(3) Directions for use.

A. If the prescription is written on a practitioner's prescription blank, the order must contain the following:

(a) The practitioner's printed name, address, professional designation and practitioner identifier number, and

(b) Signature.

B. If the prescription is written on an institutional prescription blank, the order must contain the following:

(a)The printed name of the practitioner with professional designation and DEA number with suffix, and

(b) Signature.

C. No sticker or other substance shall be allowed to obliterate or cover any of the above information.

9.2 Samples

(a) Samples are the property of a practitioner and may only be received upon a signed request from the practitioner to the manufacturer.

(b) Samples are not allowed in a pharmacy except that institutional pharmacies may receive, store, and dispense prescription drug samples without charge to patients of a practitioner that is affiliated with the institution, provided that the following requirements are met:

(1) All prescription drug samples received by the pharmacy are obtained pursuant to a written, signed request of a licensed practitioner affiliated with that institution. "Affiliated" is interpreted to mean that the requesting practitioner treats patients at that facility, and

(2) the pharmacy retains a copy of all written, signed prescription drug sample requests,

and

(3) prescription drug samples are stored separately from the prescription drug products held for sale (retail stock), and

(4) records of prescription drug sample receipt and dispensing are maintained separately from records or prescription drug products held for sale and sold (retail stock), and

(5) a relationship exists between the health care entity and the pharmacy which is evidenced by a written business or contractual agreement, or other written documentation, and

(6) prescription drug samples are dispensed by the pharmacy to patients in the manufacturer's or distributor's original packaging, and

(7) the pharmacy and its employees do not sell, purchase, or trade or offer to sell, purchase, or trade any prescription drug sample.

§15-1-10 REFILLING PRESCRIPTION ORDERS

10.1 It is unlawful to refill any prescription order containing a drug wherein the label of the original container bears the statement, "CAUTION: Federal Law Prohibits Dispensing Without Prescription", or "RX Only", unless the practitioner has authorized the refill by written notation on the original prescription order. Subsequent refill authorization shall be treated as a new prescription order.

10.2 If a prescription order is refillable, the date of the refill and the hand written initials of the pharmacist shall be recorded upon the original written prescription order or if electronic recording is used a daily printout of all prescription orders filled must be made and verified and signed by each pharmacist responsible for that days work or a log may be kept of each refill number and this log must be signed by each pharmacist.

10.3 No prescription order may be refilled after twelve (12) months from the original dispensing.

10.4 The refilling of prescription orders for controlled substances is limited by provisions of the Uniform Controlled

Substances Act, West Virginia Code Chapter 60A, article 3 section 308.

§15-1-11 TRANSFERRING PRESCRIPTION ORDERS BETWEEN PHARMACIES.

11.1 The pharmacist shall, upon the request of the patient, transfer the prescription information to the pharmacy designated by the patient.

11.2 The transfer of original prescription order information for the purpose of refilling the prescription order is permissible between pharmacies if the transfer is communicated directly between two pharmacists, and the following occurs:

a. The transferring pharmacist:

1. Writes the word "VOID" on the face of the original prescription order, and

2. Records on the reverse of the original prescription the name, address, Drug Enforcement Administration (DEA) registry number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information, and

3. Records the date and time of the transfer and the first and last name of the pharmacist transferring the information.

b. The pharmacist receiving the transferred prescription order information:

1. Writes the word "TRANSFER" on the face of the transferred prescription, and

2. Provides all the information required to be on a prescription and includes:

A. Date of issuance of the original prescription, and

B. Number of refills on the original prescription, and

C. Date of original dispensing, and

D. Number of valid refills remaining and date of last refill, and

E. Pharmacy name, address, DEA registry number and the original prescription number from which the prescription information was transferred; and

F. First and last name of transferring pharmacist.

c. Nothing in this rule shall prevent the giving of a copy of a prescription clearly marked "For Information Only" to a patient.

d. A computer record may be used if it reflects the fact that the original prescription order has been voided and shall contain all the other information required above.

11.3 No pharmacy shall refuse to transfer information about a previously dispensed prescription to another pharmacy when requested by the patient. Prescription information shall be transferred in accordance with this rule as soon as possible in order to assure that the patient's drug therapy is not interrupted.

11.4 Information on a prescription is the property of the patient and is intended to authorize the dispensing of a specific amount of medication for use by the patient. Original and transferred prescription drug orders shall be maintained for a period of five (5) years from the date of last refill; maintained on-site for a period of twelve (12) months from date of last refill, and available within 48 hours of request if date of last refill is between one (1) and five (5) years.

11.5 Pharmacies accessing a common electronic file or database used to maintain required dispensing information are not required to transfer prescription drug orders or information for dispensing purposes between or among pharmacies participating in the same common prescription file, provided, however, that any such common file shall contain complete records of each prescription drug order and refill dispensed, and, further, that the system has the capability to generate a hard copy record of each prescription drug order transferred or accessed for purposes of refilling at the pharmacy refilling the prescription drug order or to which the prescription is transferred.

§15-1-12 RETURNING DRUGS AND DEVICES.

12.1 No pharmacist or pharmacy shall accept from a patient or other person, except for the purpose of destruction, any part of any unused prescription drug unless:

(a) The returned drugs are in a manufacturer's original, sealed and visibly tamper-proof container, or

(b) The returned drugs are in extemporaneously prepared unit dose packaging, as defined in this rule, and are returned within an institution or by an institution, and

(c) all drugs are identified as to lot and control number and expiration date.

12.2 No controlled substance that has been dispensed may be returned and placed in stock for reuse or resale under any circumstances.

12.3 Any drugs returned within or by an institution must be recorded in a log which lists the name of the patient, the name and strength of the drug with name of manufacturer, prescription number (if applicable), the amount of the drug returned and the date of the return. The log shall contain the signatures of the receiving pharmacist and a registered nurse employed by the facility and the log must be retained for at least two (2) years.

§15-1-13 DRUG PRODUCT SELECTION AND SUBSTITUTION

13.1 The Board adopts the drug products in the Approved Drug Products with Therapeutic Equivalence Evaluations published by the Food and Drug Administration, Center for Drug Evaluation and Research,(commonly called the "Orange Book") with "AA", "AB", "AN", "AO", "AP" or "AT" ratings as acceptable products for generic substitution as required by West Virginia Code §30 -5- 12b. The Board may approve drug products not listed in the Orange Book as acceptable products for generic substitution upon submission of a written request to the Board.

§15-1-14. REGULATIONS GOVERNING PHARMACY PERMITS.

14.1 Pharmacy license and annual registration.

A pharmacy opening for business must first secure a license from the Board and comply fully with WV Code §30-5-14 before it may lawfully conduct a pharmacy . The annual registration for renewal of permits is effective on the first day of July of each year and expires on the thirtieth day of June of each year.

14.2 Application for permits.

The Board shall require and provide for the annual registration of every pharmacy doing business in this state. Any person desiring to operate, maintain, open or establish a pharmacy in West Virginia, shall apply to the Board for a permit to do so. Every place so registered shall be under the direct charge of a pharmacist, designated the Pharmacist-in-charge, and shall operate in compliance with state and federal laws and rules and regulations.

a. The application for a new permit shall be made on a form prescribed and furnished by the Board, which when properly executed shall indicate, but not be limited to the following;

1. identification of the owner that is applying for the permit, and

2. the name under which the business will be operated and which will be used in advertising, and

3. the physical location of the pharmacy including;

A. Street and number.

B. City and County, and

4. mailing address of the pharmacy if different from physical location, and

5. name and license number of the pharmacist-in-charge, and

6. name and license number(s) of other pharmacist(s) regularly employed at the

pharmacy, and

7. name and registration number(s) of pharmacy technician(s) regularly employed at the pharmacy, and

8. hours of operation, and

9. detailed floor plans for the pharmacy made to scale.

b. Separate applications shall be made and separate permits shall be issued for each individual pharmacy.

c. Pharmacies renewing permits must have the current edition of the three volume set of the USP-DI and its supplements or appropriate text(s) or electronic media approved by the board and shall have such equipment as may be necessary to render such service as public needs dictate, or the proper protection of the public health may require, and as required by other sections of this rule. If the United States Pharmacopeial Convention, Inc. discontinues publication of the USPDI, then the Board shall choose appropriate text(s) to replace the USPDI.

d. Each initial application for a pharmacy permit shall be accompanied by a fee of one hundred fifty dollars ($150.00), or an amount as set by statute.

e. Any pharmacy compounding parenteral, enteral or ophthalmic preparations shall first obtain a parenteral/enteral compounding permit.

14.3 Issuance of permit.

a. A permit to conduct a pharmacy will be issued to the applicant by the Board after a satisfactory inspection of the facility.

b. The permit registers the pharmacy to which it is issued and is not transferable. It is issued on the joint application of the owner and the pharmacist-in-charge, on the sworn statement that it will be conducted in accordance with the provisions of the federal and state laws and attendant Rules and Regulations.

c. Permits must be posted in a visibly conspicuous place; the permits may not be in a location that is out of sight of the dispensing area.

14.4 Renewal of permit.

a. The annual renewal of permits takes place on the

first day of July of each year. The fee for annual renewal is seventy five dollars ($75.00) or an amount as set by statute. Permits issued under this section are not transferable and expire on the thirtieth day of June of each calendar year. Renewal applications should be delivered to the Board office by the fifteenth day of June to allow time for processing.

b. If application for renewal is not made by the first day of August each year, the license becomes null and void. To renew a lapsed permit the Board must re-inspect the pharmacy and the permittee must pay a fee of one hundred fifty dollars ($150.00) or an amount as set by statute for the permit and one hundred fifty dollars ($150.00) or an amount as set by statute.

14.5 Surrender of permit.

a. When a pharmacist-in-charge in whose name a permit has been issued leaves the full time employment of that pharmacy; i.e. at least thirty -six (6) hours per week, or for any other reason ceases to be in complete and actual charge of the pharmacy, he or she is responsible to immediately notify the Board, in writing, of the termination or change of his or her services and to return the original pharmacy permit to the Board office with the date of the

change noted on the permit. A copy of the permit shall be made and posted in the pharmacy with the newly designated pharmacist-in-charge written on the permit in indelible ink. Failure by the pharmacist-in-charge to notify the Board and return the pharmacy permit shall result in disciplinary action being taken by the Board against the offending pharmacist.

b. It is the duty of a pharmacy owner to notify the Board, immediately and in writing, of the termination of the full time employment of the pharmacist-in-charge; i.e. at least thirty-six (36) hours per week, as shown on the permit, or any other action which causes the pharmacist-in-charge to cease being in complete and actual charge of the pharmacy. A new pharmacist-in-charge must immediately be designated and written on a copy of the pharmacy permit in indelible ink and posted in the pharmacy. Until a pharmacist-in-charge is designated and written in indelible ink on the pharmacy permit, the pharmacy shall not operate. The further operation of the pharmacy, in the absence of a designated pharmacist-in-charge is forbidden. Each day of operation in the absence of a designated pharmacist-in-charge is considered a separate offense. Notification of the replacement must be reported to the Board in writing within thirty (30) days upon a form provided by the Board with the appropriate fee. If an interim pharmacist-in-charge is designated who is not the

pharmacist listed upon the written form provided to the Board, then the pharmacy owner shall indicate who the interim pharmacist-in-charge was and the period of time that pharmacist served as pharmacist-in-charge. An interim pharmacist-in-charge is not required to be employed the minimum number of hours as is the permanent pharmacist-in-charge. Upon receipt of this notification, the Board will provide a newly printed permit to the pharmacy.

c. Whenever a pharmacy is moved to a new address or different location within the current building, an application for a new permit must be made with the appropriate fees being paid and the facility must be inspected before issuance of a new permit.

d. When a pharmacy changes ownership the permit becomes null and void and a new permit must be obtained from the Board.

14.6 Violations.

a. The violation of any of these rules or regulations shall be considered cause for disciplinary action.

b. All pharmacists must notify the Board immediately, in writing, of any change in employment or change of address. Failure to notify the Board shall be sufficient cause for disciplinary action.

c. It shall be the duty of any person who employs any licensed pharmacist to notify the Board within seven (7) days, in writing, of any discharge or termination of the licensed pharmacist or change in the status of the pharmacist-in-charge. Failure to notify the Board is sufficient cause for disciplinary action.

d. It shall be the duty of any person who employs any licensed pharmacist to immediately notify the Board, in writing, of any complaints registered against a pharmacist regarding the violaton of any pharmacy laws or regulations.

14.7 Security.

In the event that a pharmacy is to be operated for a period less than the regular business hours of the entire store or institution, the following requirements apply:

a. The pharmacy area shall be separated from other departments of the store or institution `by a floor to ceiling, physical barrier or partition, with entry doors that can be securely locked. The Board may approve plans, on a case by case basis, for non-physical barriers that are submitted to the Board. If the pharmacist is always present when other persons are in the store or institution, the pharmacy area need not be enclosed by a physical barrier. The barrier shall be designed so that only a

pharmacist with a key has access to the area where prescription drugs, dangerous drugs, controlled substances, and other drugs and devices restricted to sales by pharmacists are stored, compounded, prepared and/or dispensed.

b. Physical barriers may be either of solid material or movable curtain type;

1. If the barrier is of a solid material it must be of sufficient strength and thickness that it may not be easily removed and must be equipped with keyed locks.

2. If the barrier is of a movable material it must be constructed of material strong enough to prevent breakage and must have openings or interstices not large enough to permit removal of any items in the protected area and be equipped with keyed locks.

c. A device for the detection of breaking and/or entering shall be installed in each prescription department in each pharmacy. The installation and the device shall be based on accepted burglar alarm industry standards or approved by the Board, and shall be subject to the

following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or other accepted and suitable device.

2. The device shall be maintained in operating order and shall have an auxiliary source of power.

3. The device shall fully protect the prescription department and shall be capable of detecting breaking and/or entering by any means when activated.

4. Deactivation of the alarm system for the prescription department shall be restricted to the pharmacists working at the pharmacy, and the system shall be activated whenever a pharmacist is not on duty. The permit holder may deactivate the system for security or surveillance purposes as long as the reason for the deactivation, person deactivating the system, and time and date of deactivation are documented and immediately available to the Board.

5. This rule shall not apply to pharmacies which have been granted a permit prior to the effective date of this regulation provided that a previously installed security

system is in place, that no structural changes are made in the prescription department, that no changes are made in the security device, that the prescription department is not closed while the rest of the business remains open, and provided further that a breaking and loss of drugs does not occur.

6. This section does not apply to pharmacies which are open and staffed by pharmacists twenty four (24) hours a day.

d. The door keys and alarm activation and de-activation codes to the prescription areas shall be subject to the following:

1. Only pharmacists practicing at this pharmacy and authorized by the pharmacist-in-charge shall have possession of any keys to the locks on the doors of the prescription area.

2. The pharmacist may place a key and the alarm access code, if required, in a sealed envelope or other container with the pharmacist's signature across the seal in a vault or safe within the store or other secured place.

3. During such times as an institutional pharmacy may be unattended by a pharmacist, arrangements shall be made in advance by the pharmacist-in-charge for provision of drugs to the medical staff and other authorized personnel of the institution by use of night cabinets and, in emergency circumstances, by access to the pharmacy. A pharmacist must be "on call" during all absences. In the absence of a pharmacist, drugs shall be stored in a locked cabinet or other enclosure constructed and located outside the pharmacy area, to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons. The pharmacist-in-charge shall, in conjunction with the appropriate committee of the institution, develop inventory listings of those drugs to be included in such cabinets and determine who may have access, and shall ensure that:

(A) drugs are properly labeled;

(B) only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements;

(C) whenever access to the cabinet occurs, written practitioner's orders and proof-of-use are provided;

(D) all drugs therein are inventoried no less than once per week;

(E) a complete audit of all activity concerning such cabinet is conducted no less than once per month; and

(F) written policies and procedures are established to implement these requirements.

4. Whenever any drug is not available from floor supplies or night cabinets, and such drug is required to immediately treat a life-threatening situation of a patient, such drug may be obtained

from the pharmacy in accordance with these requirements. The pharmacist-in-charge shall, in conjunction with the appropriate committee of the institution, shall designate in writing one supervisory nurse in any given eight hour shift who is responsible for obtaining drugs from the pharmacy during any such emergency situation. Removal of any drug from the pharmacy by an authorized nurse must be recorded on a suitable form showing patient name, location within institution, name of drug, strength, amount, date, time, and signature of nurse. The form shall be left with the container from which the drug was removed and the pharmacist "on call" must be contacted.

e. In the absence of a pharmacist, a sign with a minimum of four

(4) inch letters shall be prominently displayed stating:

"Pharmacy Closed. No Pharmacist On Duty", and the pharmacist shall secure the pharmacy by implementing any barriers and security devices prior to leaving the pharmacy.

f. Completed prescription orders shall be bagged and kept 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(s) for the patient, or person delivering the prescription(s) to the patient at his residence or similar place. If such person is

unknown to the pharmacist then his or her identity shall be established by photo identification card.

g. Mobile pharmacy units are prohibited. Completed prescriptions must be picked up at or delivered from the same pharmacy at which they were prepared, except that this will not apply to a mail order pharmacy licensed by the Board, or to transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

h. Emergency facilities to provide pharmaceutical services during emergency conditions or natural disasters may be approved by the Board for a period not to exceed 180 days.

14.8 Professional Work Environment

a. Any pharmacy operating in excess of twelve (12) hours shall be required to operate with two (2) pharmacists working each day. No pharmacist may work more than twelve (12) hours within a twenty-four (24) hour period, except in a case of emergency when a pharmacist calls off work in a pharmacy in an acute care institution, the pharmacist on duty may work more than twelve (12) hours in order to keep the pharmacy open. The pharmacy would have to document the date, hours, and names of pharmacists that worked beyond the twelve (12) hour limit along with the reason for the extended hours of work and make it immediately available to the Board.

b. Any pharmacy dispensing more than fifteen (15) prescriptions per hour on average during a day

must have a registered pharmacy technician or pharmacy technician trainee assisting the pharmacist. The pharmacist-in-charge shall determine the work schedule for pharmacy technicians and pharmacy technician trainees based upon prior dispensing records.

§15-1-15. EQUIPMENT, FACILITIES AND RECORD SYSTEMS

15.1 The Board shall not issue a permit to operate a pharmacy unless the necessary professional, physical, and technical equipment requirements have been fulfilled.

(a) The pharmacy shall have a separate area available for patient counseling which will ensure the privacy and confidentiality of such discussions; and which has adequate space to use any equipment, visual aids, and publications, if necessary, to provide proper counseling. This rule does not apply to pharmacies which have been granted a permit prior to the effective date of this rule.

(b) All standards set by the United States Pharmacopeial Convention are the minimum standards to be followed by all licensed pharmacists and pharmacies during the course of the professional practice of pharmacy.

15.2 Every pharmacy shall continually possess the following:

a. A sanitary method of measuring and dispensing between five (5) and 250 milliliters of liquids.

b. Mortars and pestles, spatulas, ointment pads, counting trays, balance and weights, and any other equipment or supplies necessary to satisfy the requirements of this rule.

c. For pharmacies compounding ophthalmic preparations, IV additives, enteral nutritional products or other pharmaceuticals requiring more sophisticated techniques, the proper equipment and facilities to prepare sterile products and meet the requirements of good compounding practice are required.

d. Adequate facilities for the proper storage of pharmaceuticals; all areas where drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition; storage areas shall be maintained at temperatures which will ensure the integrity of the drugs prior to their dispensing as stipulated by the USP and/or the manufacturer's or distributor's labeling unless otherwise indicated by the Board.

e. Facilities for the safe storage of controlled substances if the dispersion method is not used.

f. An acceptable system of keeping records of prescriptions dispensed as required by the Uniform Controlled Substance Act.

and any Rules and Regulations pertaining thereto.

g. A system of keeping patient profiles which allows immediate review of at least the following data about individuals which may be reasonably obtained by the pharmacist;

1. Patient biographical data, and

2. Patient medications, and

3. Patient disease state(s) and drug allergies, and

4. Pharmacist's notes, and

5. Any other data necessary to make rational judgements about pharmaceutical care.

h. The most currently available Pharmacy Law Book and book of Rules and Regulations as published by this Board.

§15-1-16. STERILE PHARMACEUTICAL COMPOUNDING

16.1 Permitting and control.

a. A pharmacy compounding or mixing prescription orders for sterile solutions or suspensions to be administered parenterally, enterally, by irrigation or ophthalmic drops shall obtain a Sterile Pharmaceutical Compounding Permit from the Board in addition to a pharmacy license. The permit will be issued after a satisfactory inspection of the completed facilities.

b. The compounding and preparation of sterile prescription orders shall be accomplished in a pharmacy environment subject to the West Virginia Code and the Rules and Regulations of this Board and all Federal laws and regulations.

c. Sterile compounding or mixing shall be under the supervision and control of a pharmacist who shall be present on duty during all hours of prescription preparation.

d. This rule shall not apply to pharmacies which have been granted a parenteral-enteral compounding permit prior to the effective date of this rule; provided that the current compounding environment meets the requirements of the regulations in effect prior to this rule and the public health, safety, and welfare is not jeopardized.

16.2 Application for permit

An applicant for a Sterile Pharmaceutical Compounding Permit shall provide the Board with the following:

a. A completed Board application form, and

b. A copy of the Policy and Procedure Manual, and

c. Statement and plans showing how the applicant meets the minimum requirements regarding space, equipment, supplies and publications.

16.3 Compounding environment.

The environment for this practice shall be separate rooms set apart from all other activities. The environment shall facilitate controlled aseptic conditions and meet all standards of the United States Pharmacopeial Convention (USP) including:

a. Separation from other areas by a 'clean' entry room or vestibule, and

b. Adequate space for at least one certified air flow hood in each sterile admixture compounding room along with other necessary equipment and supplies, and

c. Sufficient space to allow pharmacists and other employees room to work to safely and accurately fulfill their duties.

16.4 General requirements.

a. Special handling and packaging shall be available to maintain stability of the prepared prescription orders during delivery to the patient.

b. All prescriptions shall include labeling, in addition to that required by other state or federal law or rule, showing:

1. Expiration date, and

2. Date of preparation, and

3. Control number.

c. A pharmacy with a Sterile Pharmaceutical Compounding Permit shall provide a twenty four (24) hour telephone number to contact its pharmacist(s) for use by its patients or other health care providers who may be administering its prescriptions.

16.5 Operating requirements.

A pharmacy with a Sterile Pharmaceutical Compounding Permit shall comply with the following requirements;

a. A Policy and Procedure Manual shall be maintained either separately or as a section of the Pharmacy Policy and Procedure Manual, and shall contain at least the following:

1. A statement in detail of the objectives and operational guidelines of the permittee, and

2. A Description of a Quality Assurance Program which monitors:

A. personnel qualifications,

B. Continuing training and performance of staff,

C. Equipment and facilities requirements,

D. Standards for compounding and dispensing, and

E. Any other requirements of this Board or the USP.

b. The pharmacy shall provide protection for its personnel involved in the handling of cytotoxic agents by:

1. Utilizing the proper equipment and supplies, and

2. Having a special section of the Policy and Procedure Manual devoted to handling procedures, including:

A. Statement that Compounding shall be conducted within a properly certified vertical airflow hood,

B. Discussion of the proper use of protective garb,

C. Description of proper techniques to prevent all contamination of the prescription and chemical contamination

of the person preparing the prescription, and

D. Disposal procedures of cytotoxic agents in accordance with accepted professional standards and applicable law.

16.5 Space, Equipment, Supplies and Reference Works.

The minimum requirements for space, equipment, supplies and reference works, which are in addition to those required for a regular pharmacy permit, shall be met by a pharmacy operating under a Sterile Pharmaceutical Compounding Permit and include the following:

a. Space.

1. The area for preparing sterile preparations, as provided for in this rule and referred to as the sterile admixture room, shall be set apart from general work and storage areas.

2. Adequate air conditioning or positive air pressure must be maintained to prevent easy entry of outside air.

3. An operating sink with hot and cold running water must be located in the "clean" anteroom adjoining the buffer room according to USP standards.

4. The compounding area must be large enough to allow working room for all personnel to be in the room at one time without interference with each other.

5. The buffer room must contain at least one certified airflow hood, vented if necessary.

b. Equipment.

At least the following equipment shall be available and shall be maintained in working order:

1. Properly certified airflow hood(s),

2. Adequate refrigerator and freezer space,

3. Sink and wash area in the anteroom as provided in this section, and

4. Appropriate waste containers for:

A. Used needles and syringes, and

B. All cytotoxic waste including disposable apparel used in its preparation.

c. Supplies

Minimum supplies on hand shall include but not be limited to:

1. Gloves, masks, and disposable gowns,

2. Disposable syringes and needles in necessary sizes,

3. Disinfectant cleaning material for equipment surfaces,

4. Disposable towels,

5. Liquid bactericidal cleanser for hand washing, and

6. Spill kits for cytotoxic agent spills.

d. Reference works.

Minimum reference works required in a pharmacy with a Sterile Pharmaceutical

Compounding permit shall be:

1. A current edition of the three volume set of the USP-DI with supplements, or referenced text(s) designated by the Board.

2. Handbook of Injectable Drugs published by the American Society of Hospital Pharmacists, or its equivalent, and

3. Procedures for Handling Cytotoxic Drugs by the American Society of Hospital Pharmacists, or its equivalent.

§15-1-17. LICENSURE AND CONTROL OF NUCLEAR PHARMACIES

17.1 General Requirements.

a. A pharmacy providing radiopharmaceutical services, and compounding or mixing prescription orders for radiopharmaceuticals shall obtain a Nuclear Pharmacy license from the Board. The license will be issued after satisfactory inspection of the completed facilities. The license will be issued only when the pharmacist-in-charge is a qualified nuclear pharmacist and the pharmacy has been approved by the appropriate

federal agency.

b. Pharmacies providing regular pharmaceutical care in addition to radiopharmaceutical services shall comply with all regulations applicable to pharmacies in general. Pharmacies providing only radiopharmaceutical services shall comply with all regulations relating to sanitary conditions, security, record keeping, and pharmaceutical care not directly related to dispensing non-radioactive drugs.

17.3 Space.

a. The nuclear pharmacy area shall be separate from all other pharmacy areas for non-radioactive drugs and shall be secured from unauthorized personnel.

b. A pharmacy handling radiopharmaceuticals shall provide a radioactive storage and product decay area which meets the requirements of the appropriate federal agency.

17.4 Dispensing and labeling.

a. A prescription order for a radiopharmaceutical shall be dispensed in a package that is properly labeled.. A pharmacy may furnish radiopharmaceuticals only to practitioners for administration to patients and for the occasional transfer to another pharmacist.

b in addition to any label requirements of the Board for nonradioactive drugs, the immediate outside container of a radiopharmaceutical to be dispensed shall also be labeled with:

1. the standard radiation symbol,

2. The words "CAUTION--Radioactive Material",

3. the name of the radio nucleotide,

4. the chemical form,

5. The amount of radioactive material contained, in millicuries or microcuries,

6. The volume in milliliters, if the material is a liquid,

7. The requested calibration time for the amount of radioactivity contained, and

8. The practitioner's name and the assigned lot number.

c. The immediate inner container shall be labeled with:

1. The standard radiation symbol,

2. The words "CAUTION--Radioactive Material", and

3. The prescription number.

d. The amount of radioactivity shall be determined by radiometric methods for each dose immediately prior to dispensing.

17.5 Distribution.

Nuclear pharmacies may distribute approved radioactive drugs to any receiving pharmacy if the receiving pharmacy does not process the radioactive drugs in any manner nor violate or change the product packaging except dividing the product

into individual doses by a licensed pharmacist.

§15-1-18. SANITARY REGULATION OF PHARMACIES.

18.1 The pharmacist-in-charge of a pharmacy is responsible to maintain the prescription room and equipment therein in a clean and orderly condition and in good operating order at all times.

18.2 The prescription counter shall be used for no other purpose than for the compounding and dispensing of prescriptions and shall be maintained free from dust and in orderly condition.

18.3 The sink, with hot and cold running water, in the pharmacy shall be used for no other purpose than the cleaning of equipment and articles used in the preparation of prescriptions and the cleaning of hands of those preparing and dispensing prescriptions.

18.4 All pharmacists and interns, when providing pharmaceutical care, shall wear a clean white coat or jacket with a name tag identifying the individual and showing job designation, and are required to keep themselves and their apparel in a clean condition. All pharmacy

technicians and pharmacy technician trainees shall wear a name tag identifying the individual and showing job designation and shall wear clean attire and a coat, jacket, or apron of a color other than white.

18.5 Any area used for providing pharmaceutical care shall be maintained in an orderly and clean condition. All instruments, articles, stock bottles, containers, shelving, cabinets and other equipment and fixtures shall be free from dust, insects, rodents or any other foreign material.

18.6 The prescription room and anywhere drugs are stored shall be well ventilated, temperature controlled, free from obnoxious odors and equipped with adequate lighting.

18.7 Only persons who are licensed or registered by the Board or are pharmacy technician trainees, except agents of the Board, may be present in the prescription area when dispensing and pharmaceutical care is being provided, unless the pharmacist on duty deems the presence of another individual appropriate. The permit holder may enter the pharmacy without a pharmacist present for immediate security or surveillance purposes as long as the reason for the entry, name of person entering, and time and date of entry are documented and immediately available to the Board.

§15-1-19 RULES OF PROFESSIONAL CONDUCT.

19.1 Statement of purpose.

a .The practice of pharmacy is a profession dedicated to the service of public health which requires knowledge, skill and integrity. The practice of pharmacy is restricted to persons who possess special education and qualifications and licenses to practice pharmacy. The pharmacist recognizes his or her responsibility to the public in providing pharmaceutical care, providing safe storage and handling of drugs, in dispensing drugs and devises and the dissemination of information on drugs and devices to other health care specialists. For these reasons he or she is obligated to the highest standards of professional conduct.

b. In order that the citizens of West Virginia shall receive the best possible pharmaceutical care, and that the public health, welfare and safety be fully protected, the following rules of professional conduct shall be followed at all times..

19.2 Freedom of practice.

a. No pharmacist shall engage in conduct, in the practice of pharmacy or the operation 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 or she interfere in the provision of pharmaceutical care or offer pharmaceutical services under any terms or conditions which tend to impair the free and complete exercise of the professional skill and judgement of another pharmacist. He or she shall at all times practice this profession in conformity with federal and state laws and regulations and the rules of this Board.

b. Every pharmacist, when practicing the profession of pharmacy, shall provide pharmaceutical care as defined in this rule.

19.3 Uncertain Prescription orders.

a. No pharmacist shall compound or dispense any prescription order which, in his or her judgement and/or professional opinion, contains any error, irregularity or ambiguity. A conference with the

prescriber is mandatory before dispensing, if there is any doubt that the prescription order is not legal or correct or issued for a legitimate medical purpose.

19.4 Professional services.

a. It is the duty of a practicing pharmacist to make his or her professional services available to the public. Every licensed pharmacy, except for a nuclear pharmacy, shall provide pharmaceutical care, including the compounding and dispensing of all prescription orders which may reasonably be expected to be compounded or dispensed by pharmacists.

19.5 Confidential information.

a. No pharmacist shall exhibit, discuss or reveal any patient-specific confidential information as defined in this rule with any person other than:

1. Agents of the Board engaged in the performance of their official duties,

2. Another pharmacist or pharmacy technician when necessary,

3. The patient or his or her authorized representative,

4 The prescriber or other members of the health care team treating the patient,

5. Any person authorized by law to receive the information.

19.6 Diagnosis or treatment.

a. No pharmacist shall attempt to diagnose any disease, illness or organic disorder. This does not preclude evaluation after a diagnosis is made by a practitioner. A pharmacist may advise individuals on the merits and quality of over-the-counter (OTC) products.

19.7 Coded prescription orders.

a. No pharmacist shall 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 use, other than those normal letters, numbers, words or symbols recognized by the profession of pharmacy as a means of conveying information by prescription order.

19.8 False or misleading advertising.

a. No pharmacist or pharmacy shall make, permit to be made,

conduct or otherwise participate in any false, misleading or fraudulent advertising.

19.9 Promotion of and reliability of drugs.

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

b. No pharmacist shall purchase, accept, compound or dispense any medicinal preparation, whether by prescription order or otherwise, which in his or her professional judgement is not therapeutically reliable.

19.10 Prescription order forms.

No pharmacist shall provide any practitioner with prescription order forms imprinted with any reference to a pharmacy or pharmacist.

19.11 Place of practice.

No place of practice or location shall be maintained to dispense prescription orders other than a pharmacy for which a permit has been issued by the Board.

19.12 Physician agreements.

No pharmacist shall enter into or engage in any agreement or arrangement with any practitioner which may tend to exploit the patient, nor shall he or she enter into an agreement of any kind whereby in any way a patient's free choice of pharmacist or pharmacy is limited.

19.13 Duties and responsibilities.

It is the duty and responsibility of a pharmacist in every pharmacy to perform, at the minimum, the following duties:

a. To accept all new prescription orders from authorized prescribers transmitted by oral communication, immediately reduce them to writing and document the same by entering on the prescription order form:

1. the name of the caller,

2. the time and date of transmission, and

3. the hand -written initials of the receiver.

b. To dispense, deliver, or distribute a prescription drug order accurately as prescribed; accurately as prescribed meaning:

1. To the correct patient (or agent of the patient) for whom the drug or device was prescribed,

2. with the correct drug in the correct strength, quantity, and dosage form ordered by the practitioner, and

3. With correct labeling (including directions for use) as ordered by the practitioner; provided, however, that nothing herein shall prohibit generic substitution by the pharmacist.

c. To ensure that his or her initials are on all prescription labels dispensed while he or she is on duty, whether prepared by him or her or prepared by a pharmacy technician under his or her supervision.

d. To ensure that his or her initials are on all prescription

order forms dispensed while he or she is on duty, whether prepared by him or her or prepared by a pharmacy technician under his or her supervision.

e. To possess a list of the drugs which may be prescribed by a physician's assistant with prescriptive privileges and also to possess the written list of drugs excluded from the prescriptive authority of nurse practitioners prior to dispensing prescription orders from such prescribers.

f. To counsel or inform patients about their drug(s). An offer to counsel shall be made by the pharmacist or designee in an oral communication with the patient, care giver or agent who presents a new prescription order, unless in the professional judgement of the pharmacist it is considered inappropriate. In such instances, it is permissible for the offer to counsel to be made in a written communication, by telephone, in person, or in a manner determined by the pharmacist to be appropriate. The exercise of and reasons for such judgement shall be documented including the hand- written pharmacist's initials. An offer to counsel has not been made by a mere question of whether the patient has any questions.

1. In those cases, when the offer to counsel, as described in

this subsection, has been accepted, a pharmacist who provides pharmaceutical care to patients shall discuss with the patient or care giver or agent who presents a new prescription order, any matter which in the exercise of the pharmacist's professional judgement the pharmacist considers significant, which may or may not include the following:

A. The name of and a description of the medication,

B. the dosage form, route of administration, dosage, and duration of drug therapy,

C. Special directions and precautions for preparation, administration, and use by the patient,

D. Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance and the actions required if they occur,

E. Techniques for self-monitoring drug therapy,

F. Proper storage and handling,

G. Prescription refill information; and

H. Any action to take in the event of a missed dose.

2. Nothing in this sub-section requires a pharmacist to provide consultation if the patient, care giver, or agent does not accept the offer to counsel. If counseling is refused it shall be documented, followed by the initials of the recording pharmacist. Patient counseling is not required for inpatients of a hospital or institution where other licensed health care workers are authorized to administer the drug(s).

g. To make a reasonable effort to obtain, record, and maintain at least the following information at the individual pharmacy:

1. The patients name, address, telephone number, date of birth or age, and gender,

2. The patient's individual history including disease state and states, known allergies and drug

reactions, and a comprehensive list of medications and relevant devices; and

3. The pharmacist's comments regarding the patient's drug therapy.

h. To perform all of the functions in this section,

I. To adequately supervise all interns, registered pharmacy technicians and pharmacy technician trainees,

j. To perform any other functions of any nature or kind which:

1. Require the knowledge, ability or skill of a licensed pharmacist, and

2. Attempt to improve the therapeutic outcome to the patient of the pharmaceutical care provided by the pharmacist.

19.14 Violation of the rules of professional conduct.

a. These rules of professional conduct are intended to govern all pharmacists licensed by this Board and improve the pharmaceutical care provided to the citizens of West Virginia.

b. The violation of any of the parts of this rule by a licensed pharmacist or person with a permit to operate a pharmacy shall result in disciplinary action.

c. Any pharmacist who knowingly accepts and continues employment with any permittee who violates this rule is guilty of a violation of the rule the same as if he or she had personally engaged in the violation.

19.15 Publication and posting of rules.

The Board shall make a copy of these Rules of Professional Conduct available to every pharmacy and pharmacist licensed by the Board. A copy of the rules shall be visibly posted in the prescription area of every pharmacy.

§15-1-20 Duties and Responsibilities of the Pharmacist-in-Charge

20.1 (a) A pharmacy may not operate without a pharmacist-in-charge(PIC), who shall be designated on the application for a pharmacy license, and in each renewal thereof. A pharmacist may not serve as PIC unless he or she is physically present in the pharmacy a sufficient amount of time to provide supervision and control. A pharmacist may not serve as PIC for more than one pharmacy at any one time.

(b) The pharmacist-in-charge has the following responsibilities:

1. Implementing quality assurance programs for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems. Quality assurance programs shall be designed to prevent and detect drug diversion.

2. The PIC shall develop or adopt, implement, and maintain a Pharmacy Technician Training Manual for the specific practice setting of which he or she is in charge. He or she shall supervise a training program conducted pursuant to the training manual for all individuals employed by thepharmacyy who will assist in the practice of pharmacy. The PIC shall be responsible for maintaining a record of all technicians successfully completing the pharmacy's technician training program and shall attest to the Board, in a timely manner, those persons who, from time to time, have met the training requirements necessary for registration with the Board.

3. Establishing policies and procedures for the procurement, storage, security, and disposition of drugs and devices.

4. Assuring that all pharmacists and interns employed at the pharmacy are currently licensed and that all pharmacy technicians employed at the pharmacy are currently registered with the board.

5. Notifying the board immediately of any of the following changes:

A. Change of employment or responsibility as the PIC,

B. Change of ownership of the pharmacy,

C. Change of address of the pharmacy, or

D. Permanent closing of the pharmacy.

6. Making or filing any reports required by state or federal laws and rules.

7. Responding to the board regarding any warning notice issued by the Board; the Board shall provide notification of the issuance of the warning notice to the permit holder.

8. Implementing policies and procedures for maintaining the integrity and confidentiality of prescription information and patient health care information, or verifying the existence thereof and ensuring that all employees of the pharmacy read, sign, and comply with the established policies and procedures.

9. Providing the board with prior written notice of the installation or removal of an Automated Pharmacy System. Such notice must include, but is not limited to:

A. The name and address of the pharmacy,

B. The location of the automated equipment, and

C. The identification of the responsible pharmacist.

c. The PIC shall be assisted by a sufficient number of pharmacists and pharmacy technicians as may be required to competently and safely provide pharmacy services.

1. The PIC shall maintain and file with the Board, on a form provided by the Board, a current list of all pharmacy technicians assisting in the provision of pharmacy services.

2. The PIC shall implement written policies and procedures to specify the duties to be performed by pharmacy technicians. The duties and responsibilities of these personnel shall be consistent with their training and experience. These policies and procedures shall specify that pharmacy technicians are to be personally and directly supervised by a pharmacist stationed within the same work area who has the ability to control and who is responsible for the activities of pharmacy technicians, and that pharmacy technicians are not assigned duties that may be performed only by a pharmacist.

§15-1-21 Manner of Issuance of a Prescription

21.1 A prescription, to be valid, must be issued for a legitimate medical purpose by a practitioner acting within the course of legitimate professional practice.

(a) A prescription must be communicated to a pharmacist. A prescription, including that for a controlled substance listed in Schedules II through V, may be communicated in written form. A prescription, including that for a controlled substance listed in Schedules III through V, and, in certain situations, that for a controlled substance listed in Schedule II, may be communicated orally (including telephone voice communication) or by way of electronic transmission.

(b) If communicated orally or by way of electronic transmission, the prescription shall be immediately reduced to a form by the pharmacist that may be maintained for the time required by laws and rules.

(c) A prescription for a Schedule II controlled substance may be communicated orally and/or by way of electronic transmission only in the following situations and/or with the following restrictions. Otherwise, a prescription for a Schedule II controlled substance must be communicated in written form.

(1) A prescription for a Schedule II controlled substance may be communicated by the practitioner or the practitioner's agent by way of electronic transmission, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except the hard copy of the electronic transmission may serve as the original, written prescription in the following instances:

(A) the prescription for a Schedule II narcotic substance is to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion, or

(B) the prescription for a Schedule II controlled substance is for a resident of a Long Term Care Facility, or

(C) the prescription for a Schedule II controlled substance is for a patient under the care of a hospice certified by Medicare or licensed by the state. The practitioner or Practitioner's agent must note on the prescription that the patient is a hospice patient.

(d) In the case of an emergency situation, a prescription for a Schedule II controlled substance may be communicated by the practitioner orally or by way of electronic transmission, 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 practitioner);

(2) the orally communicated prescription shall be immediately reduced to writing by the pharmacist, or, if necessary, the prescription communicated by way of electronic transmission shall be immediately reduced to a hard copy;

(3) if the prescribing practitioner is not known to the pharmacist, he or she must make a reasonable effort to determine that the oral authorization came from a registered practitioner, which may include a callback to the practitioner using the

practitioner's phone number as listed in the telephone directory and/or other good faith efforts to insure his identity; and

(4) within seven (7) days after authorizing an emergency oral prescription, the practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. The prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the orally or electronically transmitted prescription. 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 seven (7) day period. Upon receipt, the dispensing pharmacist shall attach this written prescription to the emergency oral prescription which had earlier been reduced to writing or to the hard copy of the electronically transmitted prescription. The pharmacist shall notify the nearest office of the U.S. Drug Enforcement Administration if the prescribing practitioner fails to deliver a written prescription.

(e) A prescribing practitioner may authorize his or her agent to communicate a prescription orally or by way of electronic transmission to a pharmacist in a licensed pharmacy, provided:

(1) the identity of the transmitting agent is included in the order,

(2) the prescription is transmitted directly to a pharmacist in a licensed pharmacy of the patient's choice with no intervening person having access to the prescription,

(3) the prescription shall identify the transmitter's phone number for

verbal confirmation, the time and date of transmission, and the identity of the pharmacy intended to receive the transmission, as well as any other information required by federal or state law,

(4) the pharmacist shall exercise professional judgement regarding the accuracy, validity, and authenticity of the prescription communicated by way of electronic transmission, and

(5) all electronic equipment for receipt of prescriptions communicated by way of electronic transmission shall be maintained so as to ensure against unauthorized access.

§15-1-22 Labeling

22.1 All drugs dispensed by a licensed pharmacy shall be labeled according to the requirements of this rule.

(a) All drugs dispensed for use by inpatients of a hospital or other health care facility, whereby the drug is not in the possession of the ultimate user prior to administration, shall meet the following requirements:

(1) the label of a single-unit package of an individual-dose or unit-dose system of packaging of drugs shall include:

(A) the name of the drug;

(B) the route of administration, if other than oral;

(C) the strength and volume, where appropriate, expressed in the

metric system whenever possible;

(D) the control number and expiration date;

(E) identification of the repackager by name or by license number shall be clearly distinguishable from the rest of the label; and

(F) special storage conditions, if required.

(2) When a multiple-dose drug distribution system is utilized, including dispensing of single unit packages, the drugs shall be dispensed in a container to which is affixed a label containing the following information:

(A) identification of the dispensing pharmacy;

(B) the patient's name;

(C) the date of dispensing;

(D) the name of the drug dispensed; and

(E) the strength, expressed in the metric system whenever possible.

(b) All drugs dispensed to inpatients for self-administration shall be labeled in accordance with subsection (d) of this rule.

(c) Whenever any drugs are added to parenteral solutions, such admixtures shall bear a distinctive label indicating:

(1) name of solution, lot number, and volume of solution;

(2) patient's name;

(3) infusion rate;

(4) bottle sequence number or other system control number:

(5) name and quantity of each additive;

(6) date of preparation;

(7) beyond-use date and time of parenteral admixture; and

(8) ancillary precaution labels.

(d) All drugs dispensed to ambulatory or outpatients shall contain a label affixed to the container in which such drug is dispensed including:

(1) the name and address of the pharmacy dispensing the drug;

(2) the name of the patient for whom the drug is prescribed; or, if the patient is an animal, the name of the owner and species of the animal;

(3) the name of the prescribing practitioner;

(4) such directions as may be stated on the prescription;

(5) the date of dispensing;

(6) any cautions which may be required by federal or state law;

(7) the serial number of the prescription drug order;

(8) the name or initials of the dispensing pharmacist;

(9) the proprietary or generic name of the drug dispensed and its strength, if more than one strength of the drug is marketed;

(A) when dispensing an equivalent drug product, the word "substitution" or letters "sub" must appear on the label affixed to the container in which such drug is dispensed, followed by the generic name and manufacturer, or reasonable abbreviation, and/or distributor of the chosen product; provided this only applies to

single-entity, multiple-source drugs;

(B) when dispensing a single-entity, single-source drug, the trade name of the prescribed drug may also appear on the label, and the generic name of the prescribed drug may also appear on the label;

(C) when dispensing a fixed combination product, the United States Pharmacopeia's publication of Pharmacy Equivalent Names (PEN) for fixed combination products is the official list of abbreviations for such labeling, and will be the approved abbreviation for identifying the combination product dispensed.

(10) the name of the manufacturer or distributor of the drug; and

(11) the beyond- use date.

(e) No radiopharmaceutical may be dispensed unless a label is affixed to the immediate container bearing the following information:

(1) the standard radiation symbol,

(2) the words "Caution- Radioactive Material", and

(3) the prescription number.

(f) No radiopharmaceutical may be dispensed unless a label is affixed to the outer or delivery container bearing the following information:

(1) the standard radiation symbol,

(2) the words "Caution - Radioactive Material",

(3) the radionuclide and chemical form;

(4) the activity and date and time of assay,

(5) the volume, if in liquid form,

(6) the requested activity and the calibrated activity,

(7) the prescription number,

(8) patient name or space for patient name; where the patient's name is not available at the time of dispensing, a 72 hour exemption is allowed to obtain the name of the patient; no later than 72 hours after dispensing the radiopharmaceutical, the patient's name shall become a part of the prescription to be retained for a period of five years;

(9) the name and address of the nuclear pharmacy,

(10) the name of the practitioner, and

(11) the lot number of the prescription.

§15-1-23 Pharmacist Consultants.

23.1 Places needing consultants.

The requirements of this section apply to pharmacists serving as pharmacy consultants to, hospitals, skilled nursing facilities, intermediate nursing facilities, nursing homes, rest homes, personal care centers, governmental agencies, jails, correctional facilities, clinics; and any other place where a pharmacy permit is not held, but a controlled substance permit is required; or any place

where a pharmacist's expertise is needed to increase or improve patient care and safety in the use of drugs and devices or where the expertise is needed to ensure proper storage conditions and safeguards.

23.2 Requirements and registration.

a. A pharmacist providing consulting services shall be registered as a consultant pharmacist with the Board and shall be licensed to practice pharmacy in West Virginia.

b. Every pharmacist providing pharmacy consulting services to any of the facilities mentioned in this rule, or to any other type of place or person, shall make application annually on the prescribed form, to register with the Board as follows:

1. An application must be filed with the Board, by the consultant pharmacist, for each institution, place or person to whom consulting services are provided.

2. The application shall contain, but is not limited to:

A. Name, address and phone number of applying consultant and

license number,

B. Name, address, phone number and type of institution, entity or person receiving the consulting services,

C. A description of the services to be provided by the consultant, and

D. The name and signature of the facility administrator.

c. Any change in the data previously placed on the application for registration as a consultant shall be immediately reported to the Board. If the consulting arrangement is discontinued the consulting permit shall be immediately returned to the Board.

d. The fee for registration as a consultant is twenty dollars ($20.00) for each registration.

23.3 Education

All pharmacists registered as consultants shall have three (3) hours of continuing education in the subjects of consulting practice each year. These three (3) hours may be included in the mandatory

fifteen (15) hours of continuing education required for license renewal as a pharmacist.

23.4 Responsibilities.

a. A pharmacist consultant shall document by date and time, in a permanent log book, his or her activities for each place where he or she is registered.

1. This log book must be present in each facility for which the consultant pharmacist is registered and must be available for inspection by the Board at any time.

b. The pharmacist consultant shall initiate and maintain, in each facility, appropriate records and procedures for the receipt, storage and disposition of all drugs including but not limited to:

1. Prescriptions,

2. Floor stock,

3. Emergency boxes or kits,

4. Investigational drugs,

5. Samples, and

6. Outdated or discontinued drugs.

c. The pharmacist consultant shall maintain a Policy and Procedures Manual for pharmaceutical services. The Manual shall be available to all inspectors and available to patient care providers for their guidance in drug handling. The manual shall include, but not be limited to, provisions for the following:

1. Transcribing drug orders and prescription ordering,

2. Prescription delivery system and in-house verification,

3. Drug recall,

4. Automatic stop orders,

5. Formulary or standards for drug quality,

6. Systematic review of drug orders,

7. Reconciliation of controlled substances,

8. Disposition by the following means of prescriptions not totally consumed by the patient:

A. Return to pharmacy for credit; and

B. Destruction by pharmacist in presence of a registered nurse.

9. In-service drug education of other personnel.

c. The pharmacist consultant shall be responsible for maintaining an appropriate drug reference library for use by other health care personnel.

d. The pharmacist consultant shall insure compliance with all applicable laws and regulations, both state and federal.

e. The pharmacist consultant shall make every effort to separate consulting duties from dispensing duties. Remuneration shall be comparable to that charged by a pharmacist consultant not

associated with the supplier of drugs or devices.

1. Remuneration must be received by the pharmacist directly from the facility to which he or she is providing the service.

2. If the pharmacist consultant has any financial interest in the pharmacy providing drugs and/or devices to the facility he or she may not provide the consulting service in order to obtain an agreement to be the supplier.

f. Nothing in this rule precludes a patient in a skilled or intermediate nursing facility, or other voluntarily entered facility, from free choice of pharmacy services.

§15-1-24 Specialized dispensing systems.

24.1 Definition.

a. Specialized dispensing systems are those systems used to provide controlled administration of drugs, for oral administration, to patients and residents of health institutions

other than traditional bottle systems.

24.2 Types.

a. A unit dose dispensing system is a system in which each individual unit of medication dosage form is in a separate container, which is intended to be placed in a larger prescription container which is complete with prescription labeling and contains several unit doses. Each individual unit-dose container must be labeled with the following:

1. Name and strength of drug,

2. Name of manufacturer or packager,

3. Lot number, and

4. Expiration date.

b. A unit of use system; is a system in which all doses containing different medications to be administered at a given time are placed together in a single package, or packet, which are intended to be placed in a larger prescription container which is complete with prescription labeling and

contains several unit of use packets. Each unit of use packet must be labeled with the following:

1. Name and strength of each drug contained therein,

2. Name of manufacturer or packager of each drug therein,

3. Lot number of each drug therein, and

4. Expiration date of each drug therein.

c. Punch card packaging is a system, which does not constitute unit dose packaging, in which several doses of the same drug are packaged in a card, which is a prescription container, in which each dose has its own space and may be removed without disturbing the packaging for the remaining doses. A Punch card must be labeled with the following:

1. Name and strength of the drug contained therein,

2. Name of manufacturer or packager of the drug therein,

3. Lot number of the drug therein,

4. Expiration date of the drug therein, and

5. All other information required to be on the label of a completed prescription order.

24.3 Preparation.

a. All extemporaneous unit dose, unit of use, punch card or any other specialized packaging must be done by pharmacists, interns or pharmacy technicians or pharmacy technician trainees under the direct supervision of a pharmacist.

b. Expiration dates must be no more than twenty five percent (25%) of the time between the day of packaging and the expiration date on the stock bottle, not to exceed twelve (12) months in any case.

c. These specialized packaging systems may not be used without the required prescription labeling being on the package that is intended to hold several doses for an individual patient.

24.4 Methods of supplying drugs and devices.

a. Drugs may not be supplied to institutions in floor stock quantities unless a controlled substance permit is held by the institution.

b. Drugs may be supplied by prescription for individual patients.

c. Drugs, other than by prescription, may be stocked in emergency kits when the following conditions are met:

1. Drugs in emergency kits are to be administered only by those persons licensed to administer drugs,

2. The drugs in the emergency kit shall be of such nature that their absence would threaten the survival of the patient(s) or intended recipients,

3. The contents of the emergency kit shall be determined by the pharmacist consultant and the medical director and the nursing director,.

4. The emergency kit shall be sealed so that it is obvious if it has been opened and it shall be stored under secure conditions,

5. Administration of drugs from the kit must be ordered by a practitioner and a record kept of administration,

6. Drugs stocked in the emergency kit shall be unit dose packaged,

7. Any drug used from the kit shall be replaced only upon a prescription or physician institution order form for the patient to which the dose was administered, and

8. Any emergency kit containing controlled substances may only be kept at a facility holding a controlled substance permit from the Board.

§15-1-25. PRESCRIBING BY PRACTITIONERS WITH PRESCRIPTIVE AUTHORITY.

25.1 All practitioners are authorized to prescribe within their medical specialty only for a legitimate medical purpose where a practitioner-patient relationship exists. Licensing boards, by

statute and legislative rule, have defined and limited prescriptive authority of individuals licensed by those boards and the Board of Pharmacy requires all its permit holders to adhere to those limitations placed by other licensing boards.

§15-1-26. INSTITUTIONS AND OTHER PLACES NEEDING A CONTROLLED SUBSTANCE PERMIT.

26.1 Any Institution (which means any hospital, skilled nursing facility, intermediate nursing facility, personal care home, jail, correctional institution, emergency organization, clinic or any other place which is responsible to administer drugs to in-patients or out-patients which, may or may not, hold a permit from this Board to operate a pharmacy) must have a permit to handle controlled substances from the Board of Pharmacy if the institution keeps controlled substances on hand at the facility. A practitioner's office that is his or her primary place of practice is not required to obtain this permit but any satellite offices or clinics with controlled substances on the premises must obtain the permit.

b. The Board shall issue a controlled substance permit to those persons required by West Virginia Code §§60A-3-301, 302 to possess such a permit.

26.2 FEES.

The fees for a controlled substance permit are as follows unless changed by statute:

a. Manufacturer and wholesaler----------$50.00

b. Hospital or clinic----------$50.00

c. Extended care facility or nursing home-----$25.00

d. Non-government training institution--------$25.00

e. Non-government researcher----------$25.00

f. Pharmacy----------$10.00

g. Jails and correctional facilities----------$25.00

h. Non-government rescue or emergency squads--$25.00

I. Non-government humane societies-------$25.00

j. All government agencies or employees are exempt from paying the fee.

§15-1-27 ADMINISTRATION OF IMMUNIZATIONS BY PHARMACISTS

27.1 Pharmacists registered in the state of West Virginia may administer vaccines after receiving an Authority to Administer Immunizations from the Board and being properly trained in the following:

(a) disease epidemiology,

(b) vaccine characteristics,

(c) injection technique, and

(d) emergency responses to adverse events.

27.2 Pharmacists may administer vaccines only in settings equipped with epinephrine and related supplies. Prior to immunization, a pharmacist shall question patients and/or their families about contraindications and inform them in specific terms about the risks and benefits of immunization and document any patient education provided.

27.3 An applicant for an Authority to Administer Immunizations permit shall:

(a) successfully complete an immunization training program recognized by the Board. The course of study must include current guidelines and recommendations of the Center for Disease Control and Prevention for pediatric, adolescent and

adult patients and the American Pharmaceutical Association Guidelines for Pharmacy-based Immunization Advocacy. The training program shall include, at a minimum, the following:

1. basic immunology, including the human immune response;

2. the mechanism of immunity, adverse effects, dose, administration schedule of available vaccines, and approved medications for immunizations;

3. how to handle an emergency situation in the event one should occur as a result of the administration of the immunization;

4. how to persuade patients to be immunized and options for record-keeping for patients immunized;

5. how to administer subcutaneous, intradermal, and intramuscular injections;

6. record-keeping requirements for immunizations;

7. mechanisms of action for vaccines, contraindications, drug interactions, and monitoring after vaccine administration;

8. vaccine storage;

9. biohazard waste disposal and sterile techniques;

10. immunization coalitions and other community resources available;

11. mechanism for reporting adverse events to the Vaccine Adverse Event Reporting System (VAERS).

(b) obtain supervised instructions on the physical administration of immunizations during the course of study; and

(c) obtain and maintain current certification in Cardiopulmonary Resuscitation (CPR) or Basic Cardiac Life Support (BCLS).

27.4 Upon completion of a recognized immunization training program the Board may issue an Authority to Administer Immunizations permit to a licensed pharmacist who submits an application with a fee of twenty-five ($25) dollars. The permit shall contain the following:

(a) name of the pharmacist to whom the permit is issued;

(b) the West Virginia license number of the pharmacist;

(c) date of issue; and

(d) expiration date.

27.5 The Authority to Administer Immunizations permit shall be renewed annually by the pharmacist with a renewal fee of twenty-five ($25) dollars.

27.6 Pharmacists authorized by the West Virginia Board of Pharmacy to administer immunizations must maintain continuing competency by completing a minimum of three (3) contact hours of continuing education dedicated to the subject of immunization and/or vaccination. Those three (3) hours may be included in the mandatory fifteen (15) hours of continuing education required for license renewal as a pharmacist. Failure to comply with continuing competency shall be reason for revoking the Authority to Administer Immunizations

permit.

27.7 Pharmacists authorized to administer immunizations shall maintain perpetual immunization records and offer a personal immunization record to each patient and their primary care provider whenever possible.

§15-1-28 EMERGENCY DISPENSING BY PHARMACISTS

28.1 A pharmacist shall be allowed to dispense an emergency supply refill of life-sustaining prescription drugs to a patient without a prescription when, in the professional judgement of the pharmacist, the emergency supply is appropriate and the prescribing practitioner is not available. The emergency supply may not be more than a ten (10) days supply and the pharmacist must immediately document the dispensing indicating the patient name , drug, strength, amount, date filled, name of dispensing pharmacist, and reasons for emergency dispensing. The prescribing practitioner must be contacted as soon as possible subsequent to the drugs being dispensed.

WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #2

FILED

JUN 22 2 41 PM '98

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

RULE TYPE: Legislative ; CITE AUTHORITY Sections 29A-3-9,30-5-2

AMENDMENT TO AN EXISTING RULE: YES X NO ___ Repeal and Replace

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 1

TITLE OF RULE BEING AMENDED: Rules and Regulations of the Board of Pharmacy

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED: ___

TITLE OF RULE BEING PROPOSED: ___

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON July 23, 1998 AT 4:00 P.M.

ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS.

West Virginia Board of pharmacy
232 Capitol Street
Charleston, West Virginia 25301

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.

William J. Douglass Jr.
Authorized Signature Executive Director

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

West Virginia University
Department of Clinical Pharmacy
1124 Health Sciences North
PO Box 9520
Morgantown WV 26506-9520

Phone 304 293-5104
FAX 304 293-5483

July 21, 1998

William Douglas
West Virginia Board of Pharmacy
232 Capitol Street
Charleston, WV 25301

Dear Doug:

It was a pleasure to be able to meet with you last week and discuss new rules and regulations that may impact pharmacy education. Both Ginger Scott and I felt the discussions were quite positive and mutually beneficial.

In regard to the hours of internship credit to be derived from student clerkship experiences, we propose that up to 1120 hours of clerkship experience be eligible for internship credit. The figure of 1120 hours is based upon seven clerkship blocks of 160 hours each. Although this figure falls short of the 1760 hours that will be completed during the students fourth year, we feel that this lower amount will serve both of our needs. From the School of Pharmacy perspective, it will enable us to utilize sites and preceptors currently not qualified for state board approval (e.g. federally operated facilities). From the Board's perspective, this lower level will still require that the student obtain approximately one summers worth of internship in practical training (e.g. community pharmacy dispensing) in order to meet the 1500 hour internship requirement. This two-thirds clerkship/one-third dispensing experience balance follows guidelines we have seen proposed by the National Association Boards of Pharmacy and is being incorporated in many of our surrounding states (e.g. Virginia).

We thank the Board for the opportunity to provide input into the revision of internship regulations and we look forward to continually working with the Board to optimize student education.

Sincerely,

W. Clarke Ridgway blh
W. Clarke Ridgway, R.Ph.
Clinical Assistant Professor of Pharmacy
Coordinator, Externship/Clerkship Programs

WCR/blh

cc: Dean Spratto
Art Jacknowitz, PharmD

State of West Virginia
Board of Pharmacy

Phone (304) 558-0558
Fax (304) 558-0572

Office
232 Capitol Street
Charleston, West Virginia 25301

July 30, 1998

W. Clarke Ridgway, R.Ph.
Clinical Assistant Professor of Pharmacy
West Virginia University
Department of Clinical Pharmacy
1124 Health Sciences North
P.O. Box 9520
Morgantown, West Virginia 26506-9520

Dear Mr. Ridgeway:

The Board considered the comments you made regarding the proposed Legislative Rules and decided to increase the internship hours accepted from the pharmacy curriculum to eight hundred (800) hours. Thank you for your comments and input during this process.

Sincerely yours,

William T. Douglass, Jr.
Executive Director and
General Counsel

WTD/bjk
ltr1

University Eye Center
Department of Ophthalmology
West Virginia University
Office: (304) 293-3757 Appointments 1-800-248-3393 FAX: (304) 293-7139

July 18, 1998

George Rider
4307 MacCorkle Ave., SE
Charleston, WV 25304
FAX: (304) 925-0345

Dear George:

I welcome the opportunity to respond to the West Virginia State Medical Association as to my views on the proposed legislation to allow administration of immunizations by pharmacists. As I am a pharmacist, physician, and recently have undergone the immunization process with my three young children, I wish to offer the following comments.

1) In the traditional model of family physicians and pediatricians administering immunizations, the schedules are timed with well child visits. These well child screenings insure that the children are growing and developing in the proper manner. It also helps to screen for illnesses which may be subtle in onset and allow for earlier intervention. The advantage of combining these two is that it is a definite marker for parents to bring their children in for these very important examinations. Should the immunizations be moved to the pharmacies, it may mean that a few more children are receiving immunizations, however it is more likely that many more children will abandon the very important well child visits. Parents would now be expected to keep two separate appointments.

2) To evaluate a child thoroughly to make sure it is appropriate to administer immunizations requires measurements such as height, weight, temperature, and physical exam looking for early otitis media and other health problems. The height and weight measurements should be correlated as to the child's previous performance on standardized charts, as well as comparison to age matched controls. There has been more one occasion when one of my seemingly healthy children had a delay in their immunizations because of things detected on the physical assessment. A pharmacist would not be able to perform this function.

3) There are many recommendations as to appropriate vaccinations. The CDC, American Academy of Pediatrics, and drug companies sometimes have deferring recommendations. Specifically there is no wide-spread acceptance as to the administration of vaccinations for Varicella, hepatitis, and pneumococcus in the pediatric population. Not only is it not widely

accepted that each child should receive these types of vaccinations, but the dosing schedule is also not widely agreed upon. I am not sure that pharmacy training will allow pharmacists to make specific recommendations pertinent for each individual child and their environment as to if they should proceed, how many vaccinations they should receive at one time, and at how early an age.

4) Immunization schedules often need to be altered according to patient illnesses. If the pediatrician or family physician is monitoring the illness, I am not sure how that would easily be transmitted to the pharmacist to know when the schedule may be resumed and how to alter it accordingly.

5) Physicians who offer immunization services standardly offer 24-hour on call service to not only address possible complications of immunizations, but to at a minimum offer information to the emergency room as to what vaccination was administered. Pharmacies must be available to give 24 hour service at least for providing information to emergency rooms. Their liability insurance coverage will also increase accordingly.

6) In the case of extreme adverse events such as an anaphylactic reaction, having epinephrine on site is not adequate. There should be ready access to a crash cart and resuscitation equipment. The epinephrine that was specified in the legislation to be kept on site is best administered IV or through the intratracheal tube. I doubt that pharmacists will receive training in establishing IV access and intubating patients.

7) Part of receiving immunizations also involve counseling on appropriate fever prophylaxis for the children. A child's medical history needs to be thorough enough so that the practitioner can direct the parents to either use acetaminophen or nonsteroidal anti-inflammatory drugs. It also needs to be established if the oral vs. suppository route is better.

While the goal of the American Pharmaceutical Association is to provide more ready access of immunizations, there are several other factors which means we would be compromising the overall health and welfare of those receiving the immunizations. Specifically, well child visits would likely fall in frequency, and evaluations as to which immunizations and their frequency would also be compromised.

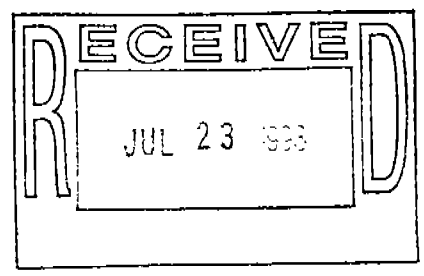
Sincerely,

Judie Charlton/slc

Judie Charlton, M.D.
Professor in Ophthalmology

JC/slc
Dictated and proofed, but not signed, by Dr. Charlton

West Virginia State Medical Association



July 22, 1998

William J. Douglass, Jr.
Executive Director
West Virginia Board of Pharmacy
232 Capitol Street
Charleston, WV 25301

Dear Mr. Douglass:

Enclosed are the comments of the West Virginia State Medical Association addressing proposed rules of the Board of Pharmacy recommending that Pharmacists be given the authority to administer vaccines to their customers.

Sincerely,

George Rider
George Rider
Executive Director

GR/ta
Enclosures

Phone: 304-925-0342 • Toll Free: 800-257-4747 • Fax: 304-925-0345
E-mail: WVSMA@AOL.Com

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West Virginia State Medical Association

Comments from the West Virginia State Medical Association on the Proposed Legislative Rules from the West Virginia Board of Pharmacy, Title Number 15

submitted July 22, 1998

In proposed legislative rules dated June 22, 1998, the West Virginia Board of Pharmacy is requesting that West Virginia pharmacists be permitted to administer vaccinations to the public. They suggest that after submitting a **twenty five dollar fee** and **receiving a three hour course**, pharmacists would then receive an "Authority to Administer Immunizations" Board-issued permit. Their rules would require that pharmacists "may administer vaccines only in settings equipped with epinephrine and related supplies. Prior to immunization, a pharmacist shall question patients and/or their families about contraindications and inform them in specific terms about the risks and benefits of immunization and document any patient education provided."

One can only hope that good intentions, though seriously misguided, were behind such a colossally reckless approach to public health. For those who may think that administering immunizations involves a mere injection or administration of an oral dosage, such ignorance will prove to be less than bliss for the unsuspecting public! Though providing no evidence of a mandate (we have yet to hear from any West Virginian demanding this change), we believe that the Board of Pharmacy is advocating a standard of care that is so low that it essentially constitutes "sanctioned negligence."

The development of vaccines has been one of mankind's most significant achievements advancing the cause of human health. Since 1798, with the introduction of the small pox vaccine, many new vaccines have been developed for the control of a wide range of diseases: rabies, the plague, diphtheria, pertussis, tuberculosis, tetanus, polio, measles, mumps, rubella, hepatitis B and influenza. In 1956, the World Health Organization declared war on smallpox via a massive worldwide vaccination and containment effort. By 1980, having met their goal, the WHO proclaimed the world finally free of smallpox - truly an incredible feat.

Clearly, there can be no question that vaccination is one of the more powerful, cost effective tools at the disposal of medicine in controlling and eradicating serious human illness.

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However, with all vaccines, there are contraindications. Although small in number, serious and possibly fatal reactions to vaccines can and do occur. In order to avoid civil litigation and to ensure the continued availability of immunizations, the National Vaccine Injury Compensation Program was established by the U.S. Congress. The National Childhood Vaccine Injury Act of 1986 requires physicians and other health care providers to maintain permanent vaccination records and mandates the reporting of occurrences and adverse events. Why?

To quote the World Health Organization,

> "Vaccines are designed to provoke a reaction in the body. If it were not so, they would not produce a reaction in the immune system that provides the protection from disease which is sought. In addition to the desired reaction, all vaccines produce some degree of unwanted reaction. The vast majority of these are trivial and harmless. Some are more noticeable and annoying. **A very small number are serious and potentially life threatening."**

The WHO cautions that adverse events following immunization (AEFIs) are:

> *"AEFIs due to programmatic errors in the storage, handling, or administration of vaccine are more common than AEFIs due to the properties of the vaccine."*

The WHO details the factors contributing to AEFIs. Among them: **too much vaccine given in one dose; improper immunization site or route; syringes and needles improperly sterilized; vaccine reconstituted with incorrect diluent; drug inadvertently substituted for vaccine or diluent; vaccine prepared incorrectly for the use; vaccine or diluent contaminated; vaccine stored incorrectly; reconstituted vaccine not thrown out at the end of an immunization session and used at a subsequent one; and contraindications ignored, e.g. child who experienced a severe reaction after a previous dose of DTP is immunized with the same vaccine.**

Even today policy changes are occuring relative to some of the most well established vaccines. In 1996, the CDC's ACIP voted "to move away from use of the live oral polio vaccine (OPV) and toward increased use of the injectable inactivated polio vaccine (IPV) in order to cut down on the number of cases of polio disease caused by OPV in the U.S. each year."

More well known, perhaps, have been the problems associated with the pertussis (whooping cough) vaccine and rare occurrences of brain damage in young children.

The flu vaccine, though widely popular and effective, likewise carries risk. According to the CDC's ACIR, it should not be given to persons "with a history of any signs or symptoms of an anaphylactic reaction (hives, swelling of the mouth or throat, difficulty breathing, hypotension, or shock) after eating eggs should not be given inactivated

influenza vaccine."

The importance of a good medical history cannot be overemphasized in determining the appropriateness of vaccination for particular individuals. For example, a variety of factors should be considered:

- occupation;
- age;
- international travel;
- sexual preference;
- pregnancy;
- conditions which compromise the immune system;
- renal transplant patients;
- renal disease;
- alcoholism;
- intravenous drug use.

Again, according to the ACIR:

> "A systematic approach to vaccination is necessary to ensure that every adult is appropriately protected against vaccine-preventable diseases. Every visit by an adult to a health care provider should be an opportunity to provide this protection. However, several factors need to be considered before any patient is vaccinated. These include susceptibility of the patient, the risk of exposure to disease, the risk from the disease, and the benefits and risks of the immunizing agent."

Are pharmacists equipped to make these kinds of determinations?

Judie Charlton, M.D., Associate Professor of the WVU School of Medicine, who is both a pharmacist and a physician, suggests yet another unfortunate scenario:

> "In the traditional model of family physicians and pediatricians administering immunizations, the schedules are timed with well child visits. These well child screenings insure that the children are growing and developing in the proper manner. It also helps to screen for illnesses which may be subtle in onset and allow for earlier intervention. The advantage of combining these two is that it is a definite marker for parents to bring their children in for these very important examinations. Should the immunizations be moved to the pharmacies, it may mean that a few more children are receiving the immunizations, however, it is more likely that many more children will abandon the very important well child visits. Parents would now be expected to keep two separate appointments." (Dr. Charlton's full comments are provided as an attachment.)

Pregnancy poses particular issues relative to benefits/risks and timing related to the

appropriate administration of certain vaccines. The ACIR emphatically states that due to a risk to the developing fetus, "the measles vaccine should not be given to pregnant women." In yet another example, ACIR cautions that "the safety of pneumococcal polysaccharide vaccine among pregnant women has not been evaluated. Women at high risk of pneumococcal disease ideally should be vaccinated before pregnancy.

For those pregnant women considering international travel, cholera presents a more troubling choice. ACIR says that "because cholera disease during pregnancy is a serious illness, whether to use cholera vaccine should be determined in individual circumstances based on the actual risk of disease and the probable benefits of the vaccine." **Should pharmacists be offering what is clearly MEDICAL ADVICE?**

Lest there may be those who may be confusing "administration" with "dispensation", the Board of Pharmacy currently has no authority to create or regulate the practice of medicine. Though they may covet expanding their scope of authority and the scope of practice for those they regulate, <u>they are only authorized to regulate the dispensers, i.e. the pharmacists.</u>

Jim Helsley, M.D., Associate Professor of the WVU School of Medicine and a Family Practice Physician, raises the fundamental question, "how will this create better immunization rates and what scientific evidence exists to prove it?

We hope the committee will heed the warning of Dr. Helsley who advises, **"there is more to resuscitation of anaphylaxis than just giving epinephrine. Clinical treatment of this kind of emergency is beyond any pharmacist, particularly one who has taken a three hour course once a year."**

State of West Virginia
Board of Pharmacy

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July 30, 1998

West Virginia State Medical Association
George Rider
Executive Director
P.O. Box 4106
Charleston, West Virginia 25364

Dear Mr. Rider:

The Board considered the comments you made regarding the proposed Legislative Rules and decided that no changes were necessary to the section regarding pharmacist's authority to administer immunizations. You stated that the pharmacist would only receive a three (3) hour course and they would be allowed to administer immunizations but that is incorrect. Rule 28.3 on page 102 states that the pharmacist must successfully complete an immunization training program which would include the current guidelines and recommendations of the Center for Disease Control and Prevention for pediatric adolescents, and adult patients and the American Pharmaceutical Association guidelines for pharmacy based immunization advocacy. The training program is required to include a minimum of eleven (11) components listed on page 102 and 103 of the proposed rules. The three (3) hours that you reference in your comments would be listed in Rule 28.6 on page 104 which requires that a pharmacist with such a permit obtain three (3) contract hours of Continuing Education each year dedicated to the subject of immunization and or vaccine. Considering the fact that twenty three (23) other States currently allow pharmacists to administer immunizations the Board feels that such training is appropriate and would not in any manner jeopardize the health and welfare of the public. Thank you for your comments and input during this process.

Sincerely yours,
with J. Doug.
William T. Douglass, Jr.
Executive Director and
General Counsel

West Virginia Pharmacists Association
2003 Quarrier Street, Charleston, West Virginia 25311
Telephone (304) 344-5302 • FAX: (304) 344-5316

July 21, 1998

West Virginia Board of Pharmacy
232 Capitol Street
Charleston, WV 25301

Dear Members of the Board:

The West Virginia Pharmacists Association respectfully submits its comments regarding your Board's proposed rules, Title Number 15, Series 1, filed with the West Virginia Secretary of State on June 22, 1998.

The following officers of this Association met July 11, 1998, and conducted a thorough review of your proposed rules and approved the comments contained herein: Bill McFarland, President; J. J. Bernabei, President Elect; Amy Wayne-Brabbin, Secretary; Steve Judy, Immediate Past President; Carl Malanga, Director; Charles Selby, Director; David Drennen, Director; Maribeth Nobles, Director; John DeMary, Director; George Spratto, Dean of WVU School of Pharmacy; and Richard D. Stevens, Executive Director.

The following comments are respectfully submitted for your consideration in adoption:

Page 6 — Definitions. (aa) - Change definition of "Pharmaceutical care" to definition stated in WV Code §30-5-1b(s) and in NABP's Model Practice Act:

"Pharmaceutical care" is the provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process."

Page 13 — General Provisions. 3.11 - Delete "selling price".

Pages 13/14 — General Provisions. 3.12 - Delete "psychiatric, psychological, or emotional problems or".

Page 29 — Transfer of Drugs. 9.1.(a).(1) and (3) - Amend "five thousand dollars ($5,000)" to "five percent (5%) of annual prescription drug purchases" and delete "two thousand five hundred (2,500) doses for the year, whichever is greater".

(more)

Page 31	Refilling Prescription Orders. 10.3 - Amend "original dispensing" to "date of original prescription".
Page 35	Drug Product Selection and Substitution. 13.2 - Delete "13.2".
Page 50	Equipment, Facilities and Record Systems. 15.2. g. - Add "drug allergies" to data in patient profiles.
Page 64	Sanitary Regulation of Pharmacies. 18.7 - Add "unless voluntarily accompanied by a licensed pharmacist" at the end of the sentence.
Page 74	Rules of Professional Conduct. 20.13.(f).(F) - Add "and handling" to "Proper storage".
Page 80	Manner of Issuance of a Prescription. 22.1.(a) - Delete "in a licensed pharmacy".
Page 90	Pharmacist Consultants. 24.3 Education - Amend continuing education requirement to "three (3) hours of the fifteen (15) hours required each year".
Page 95	Specialized Dispensing Systems. 25.2.(b) - Insert the following "containing different medications" between the words "doses" and "to".

No Page	The Board of Pharmacy is respectfully requested to include in the appropriate section of their proposed rules the authority of a licensed pharmacist to dispense an emergency supply of life sustaining prescription drugs when in their professional judgement an emergency supply is appropriate and the prescribing practitioner is not available.

The West Virginia Pharmacists Association considers the following as major provisions of the proposed rules, and considers each in the interest of protecting the public as well as improving health care provided the public by pharmacists:

Rules of Professional Conduct. §15-1-20 with above amendment.
Duties and Responsibilities of the PIC. §15-1-21.

(more)

Manner of Issuance of a Prescription. §15-1-22 with above amendment.
Labeling. §15-1-23 which complies with NABP language.
Pharmacist Consultants. §15-1-24 with the above amendment.
Specialized Dispensing Systems. §15-1-25 with the above amendment.
Administration of Immunizations by Pharmacists. §15-1-28

The Board is commended for undertaking major and much-needed revisions to the rules regulating the profession of pharmacy in the interest of the public's health, safety and welfare. The West Virginia Pharmacists Association offers its approval and support of the proposed rules with amendments described above.

Very truly yours,

Richard D. Stevens
Executive Director

RDS:msf

xc: WVPA Officers and Directors

State of West Virginia
Board of Pharmacy

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July 30, 1998

Richard Stevens
Pharmacist Association
2003 Quarrier Street
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Dear Mr. Stevens:

The Board considered your written comments regarding the proposed Legislative Rules and has agreed to make the changes listed within your comments. The Board thanks you for providing your comments and helping to clarify and clean up the language of the proposed rules.

Sincerely yours,

William T. Douglass, Jr.
Executive Director and
General Counsel

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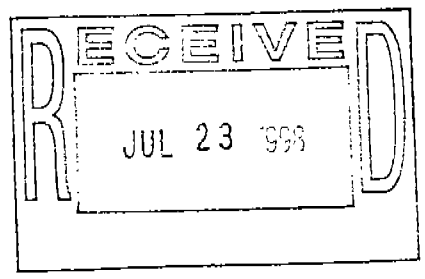
July 22, 1998



William J. Douglas, Jr.
Executive Director
West Virginia Board of Pharmacy
232 Capitol Street
Charleston, WV 25301

Re: Rules and Regulations of the Board of Pharmacy

Dear Mr. Douglas:

The purpose of this letter is to provide comments concerning the proposed amendments to Series I of the Rules and Regulations of the Board of Pharmacy. On behalf of its 65 member hospitals, the West Virginia Hospital Association is providing you with these comments pertaining to the proposed rules. We have four areas of concern, they are:

§15-1-12 Returning drugs and devices

Specifically Section 12.2, "No controlled substance may be returned and placed in stock for reuse or resale under any circumstances." There has been some concern over the intent of this statement regarding controlled substances in hospitals, i.e., three units of Valium are checked out to the endoscopy lab to perform a colonoscopy. Only one unit is used for the procedure. Can the two sealed unused unit dose packages be returned to the lockbox for use on a future case? Section 12.2 would seem to indicate that this could not be done.

The unit-dose system of medication distribution is routinely utilized in hospitals. This system typically dispenses medications in unit-of-use packaging in individual patient bins on medication carts in amounts for a 24 hour supply. The records maintained for this system create audit trails for all medications dispensed, administered, and returned to the pharmacy on a daily basis. Upon discontinuation of the medications or discharge of the patient, these medications are returned to stock and appropriate credit made to the patient's bill. Controlled drugs, usually those in schedule III-V, are commonly dispensed in this system. If controlled substances cannot be dispensed and re-issued as part of this or similar systems, the expense incurred by hospitals and other facilities with similar dispensing systems will be enormous and will increase the cost of care provided to patients. If this is correct, then Appendix B 'Fiscal Note For Proposed Rules', would be incorrect. There will be significant economic impact on both the industry and on citizens.

§15-1-16 Sterile pharmaceutical compounding

Specifically Section 16.3, Compounding Environment, states that each sterile admixture compounding room must be separate from other areas and have a clean entry room. Would this

require existing pharmacies without a clean room to build one, or are existing pharmacies grandfathered under these proposed regulations?

In many small rural facilities, as well as many larger facilities, current physical plant may not provide the ability for expansion of this area. In addition, the cost of building such a room would be in the $50,000 to $100,000 range. Again, this economic impact is not noted in Appendix B. If not already the intent of the Board, we would recommend that existing pharmacies be grandfathered and that these standards be adopted for all new pharmacies, or any pharmacy undergoing renovation or location change.

§15-1-14 Regulations governing pharmacy permits

Specifically Section 14.7, Security. In Section 6.d.1., it states that no one is permitted access to an institutional pharmacy after hours except a pharmacist. In a hospital, and more specifically in the rural setting, the pharmacist on call often lives a great distance from the institution, and in an emergency situation, this time delay would likely have a dramatic impact on the patient's care. We would request the Board to consider changing the regulation so that entrance to the pharmacy could occur by a nursing supervisor, but only after a phone call is made to the on-call pharmacist.

And finally, Section 14.8, Professional Work Environment, states, "No pharmacist may work more than 12 hours within a 24 hour period." Again, we would request the Board to consider some exception to this rule in the hospital environment. For example, a hospital pharmacy operates 16 hours a day using two 8 hour shifts, however, the evening shift pharmacist calls in sick which could require the day pharmacist to work 16 hours. Shutting down the pharmacy in an acute care institution would not be a viable alternative. A possible alternative which the Board could consider would be for the pharmacy to have a log book which shows all pharmacists, the dates and hours which they worked beyond 12 and the reason for the extended hours of work. This log book could be available for review by the Board inspectors.

Summary:

The West Virginia Hospital Association recognizes the important role the Board of Pharmacy plays in the health care delivery system in West Virginia; to ensure all West Virginians receive quality, competent health care. We recognize that the needs of institutional pharmacies are not always the same as retail pharmacies. Thank you for reading and addressing our concerns. We would hope the Board will continue to recognize some of the unique needs of institutional pharmacies.

Sincerely,

James A. Kranz
Vice President, Professional Activities

JAK/nal

State of West Virginia
Board of Pharmacy

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July 30, 1998

James A. Kranz
Vice President Professional Activities
West Virginia Hospital Association
100 Association Drive
Charleston, West Virginia 25311

Dear Mr. Kranz:

The Board considered the written comments you made regarding the proposed Legislative Rules and agreed to make amendments to the rules in order to better address the practice of pharmacy in the institutional settings. Also please be advised that the section regarding the issuance of pharmaceutical compounding permits will have additional language clearly stating that existing permit holders will not be expected to comply with the requirements listed for new applicants. Thank you for your comments and input during this process.

Sincerely yours,

William T. Douglass, Jr.
Executive Director and
General Counsel

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WEST VIRGINIA SOCIETY OF HEALTH-SYSTEM PHARMACISTS

WVSHP

July 17, 1998

Dear Members of the West Virginia Board of Pharmacy,

Recently the Board of Directors of the West Virginia Health System Pharmacists met to review the revisions proposed for the practice of pharmacy in the State of West Virginia. Our suggestions are as given.

15-1-2.(m)(2) change food to "food supplement"

(w) suggest rewriting section to include oral and written communications of patient information

(aa) definition of pharmaceutical care should follow NABP guidelines

(cc)3. Delete

(dd)change United States Mail to U.S.Postal System. Mail order systems within the state are not addressed.

(ee/ff/gg/hh) definitions are unclear. Suggest using the NABP guidelines.

(jj) Delete current definition . Suggest using the NABP guidelines.

(ll) The definition for preceptor should be redefined to include Pharm.D, instructors etc.

(nn) add properly licensed practitioner or THEIR AGENT

Electronic orders are not addressed especially for institutional pharmacies.

(oo/pp) Why are the terms deleterious and poisonous drugs defined?

15-1-4 The WVSHP Board members felt this section dealing with interships requirements be discussed with the Dean of the WVU School of Pharmacy, George Spratto

15-1-4 section 4.4 contradicts section 4.3.

4.4 Why 10,000 prescriptions per year would this exclude rural health care sites as internship sites?

4.6 Are internship hours from other states considered for a WV license?

15-1-5- 5.2(b)Who is responsible for the evidence of good moral standing?

5.2c 2 Would the Board consider using the words pharmacist and technician instead of licensed and registered.?

Should this be a separate statement for technicians?

15-1-14 14.8b How is the need for a technician defined in a hospital situation?

15-1-15 15.1b Sterile drug product productions should be consistant to include retail and hospital
Please see attached article.

15-1-16 How will this statement impact hospitals that already prepared sterile products?

16.3 What are the cost impacts for current facilities? What are the concerns for nurses that prepare intravenous solutions at their nursing station?

16.4 Is the phone number a requirement for retail and hospital ?

16.5 a.2D Sampling is an unnecessary expense unless quality control is required.

2E Please consider deleting this statement.

16.5 The space for preparation/equipment/buffer room/gloves etc should be defined on an individual basis.

The American Society of Hospital Pharmacists is now call The American Society of Health System Pharmacists.

15-1-17 Must each institution have a Nuclear Pharmacy?

15-1-18 18.4 Please consider a change in wording to include hospital dress codes especially in in patient care areas. Suggest a change that includes that in some institutions the pharmacist wears "scrub suits" to complete their work.

18.7Definition will change when the term pharmaceutical care changes. Does this statement Allow pharmaceutical representives and "Shadow Students" in the pharmacy area ?

15-1-20 20.4 Will need to be changed when the definition of pharmaceutical care changes.

20.6 What about protocol changes in a clinic or hospital? Suggest deleting 20.6.a.

20.11 This statement does not permit volunteer work such as at Health Right in the State of West Virginia as does other professions.

20.12 This statement does not address pharmacist monitoring patients.

20.13 f The Board was unclear of the intent of this statement.

j 2 The Board was unclear of the intent of the therapeutic outcomes expected.

15-1-21 21.1b1Who will define the guidelines for the quality assurance program?

2 What about training requirements for technicians who have sucessfully passsed the National Certification Test?

9 How is an Automated Pharmacy System defined for an institutional setting? Night cabinet? Pyxis? Robotic system?

15-1-5 5.3b A maximum of 2 days shall be allowed for all portions of the examination- does this include computerized exam?

d. How are the weighted questions decided? Should the percentages be the same?

15-1-6 6.1 "sates" should be states

15-1-9 9.1(a)(1) This statement does not address the lending or borrowing necessary or emergency medications between hospitals that may exceed this amount

(b)(3)B(a) Should DEA numers be required to be preprinted on prescription blanks?

9.2 This section addressing samples needs redefined. What is a clinic pharmacy? The pharmaceutical Representatives retain copies of sample requests that must be signed by a physician.

15-1-10 10.3 No prescription order may be refilled after 14 months from the original dispensing. Other states limit refills to 12 months. Does this apply to PRN medications also?

15-1-11 Transferring prescriptionorder section the Board Deferred to WVPA.

15-1-12 12.1/2/3 Needs to be redefined to include institutional practices especially narcotic usage.

15-1-13 13.1 Most hospitals are required to have a Pharmacy and Therapeutic Committee to review medication selections. How can this process be addressed in this statement?

13.2 The medications indicated have generic equivalents.

15-1-14 14.2 9. Why is a detailed scale needed? Would square footage be appropriate?

5 a/b/c Surrender of permit sections are confusing.

Is a fee necessary for a move of the pharmacy within a building, not a new entity?

6.c Is this section being enforced?

7.2.c What about hospitals that area have security systems?

c.4 Would the Board consider adding health care designee for hospital emergencies?

Should a mandated panic alarm also be included?

e. What about hospitals?

14.8 What pharmacists in a hospital situation in an emergency working 14 to 16 hours? Would a log showing this information and reason for the extended hours of work be appropriate to be reviewed by the Board Inspectors?

15-1-23 23.1(d)(9)(A)How is the manufacturer defined? Should it be theoriginal manufacturer or the repackager? Is The PEN still being utilized nationally?

15-1-24 24.3 Why should consultant pharmacists be required to have additional hours when no other speciality has additional continuing education requirements?

Please consider also changing the regulation regarding no one permitted access to an institutional pharmacy after hours. In an emergeny not all needs can be met for a patient with a night cabinet or code cart. Many institutional small pharmacies are not open 24 hours a day. If the pharmacist on call lives a distance from the institution the time delay may have a dramatic impact on the patient's care. Entrance to the pharmacy would not be use as grounds to close a pharmacy earlier than already stated. Entrance would only be permitted after a phone call is made to the pharmacist on call.

Thank you for reviewing WVSHP concerns about the law change.

Sincerely,

Carol A Hudachek RPh,MA

Carol A.Hudachek RPh,MA
President,WVSHP

Carol A. Hudachek, RPh., MA.
Clinical Pharmacist
Weirton Medical Center - Pharm. Dept.
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Weirton WV 26062

State of West Virginia
Board of Pharmacy

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July 30, 1998

Carol A. Hudachek
President
West Virginia Society of Health Systems Pharmacists
Weirton Medical Center Pharmacy Department
601 Colliers Way
Weirton, West Virginia 26062

Dear Ms. Hudachek:

The West Virginia Board of Pharmacy considered your comments to the proposed Legislative Rules and has agreed to make changes to the rules to address your various concerns. After meeting with Mr. Jeff Hess from your organization, many of your questions were answered to his satisfaction and any additional concerns have been addressed by the Amendments to the proposed rules. Thank you for your comments and input during this process.

Sincerely yours,

William T. Douglass, Jr.
Executive Director and
General Counsel

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State of West Virginia
Board of Pharmacy

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July 30, 1998

Tracy L. Baroni
Manager State Pharmacy Affairs
National Association of Chain Drug Stores
413 North Lee Street
P.O. Box 1417-D49
Alexandria, VA 22313-1417

Dear Ms. Baroni:

After meeting with representatives from your organization on two different occasions I believe we came to a consensus on many of our differences regarding the proposed Legislative Rules and narrowed them down to a few concerns. The Board agreed to make many of your suggested changes by amendments to the proposed rules. However the Board did not agree to make changes to the sections regarding the minimum hours a pharmacist-in-charge must be employed in a pharmacy; i.e. at least thirty six (36) hours in a pharmacy open more than seventy two (72) hours per week or 50% of time when a pharmacy is open less then 72 hours per week. The Board also decided not to change the restriction that a pharmacist may not work more then twelve (12) hours within a 24 hour period. The Board felt strongly that both of these provisions needed to retain the current wording in order to best protect the public. The Board did agree to Amend Rule 14.8 (b) on page 48 to state that technician help would be required when a pharmacy was dispensing more than an average of 15 prescriptions per hour throughout the day. I would like to thank you for your comments which helped to clarify some of the language in the Rules and I appreciate your input during this process.

Sincerely yours,
William T. Douglass, Jr.
Executive Director and
General Counsel

WTD/bjk
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SUMMARY OF RULE BEING REPEALED AND REPLACED

The current Series 1 has provisions covering many aspects of the practice of pharmacy. It includes definitions, application process, examination provisions, rules of professional conduct, minimum requirements in a pharmacy, security, internship, etc.

TITLE 15
LEGISLATIVE RULES
BOARD OF PHARMACY

SERIES 1
RULES AND REGULATIONS OF THE BOARD OF PHARMACY

§15-1-1. General.

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

1.2. Authority. -- W. Va. Code §30-5-19

1.3. Filing Date. -- June 11, 1993

1.4. Effective Date. -- June 14, 1993

§15-1-2. Definitions.

The following words and phrases as used in this Rule have the following meanings, unless the context otherwise requires:

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

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

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

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

2.5. "Patent or Proprietary Preparation" means a medicinal preparation which is intended for use in the cure, mitigation, treatment or prevention of disease in man or other animal pursuant to self-diagnosis; when the same is identified by and sold under a trademark, trade name or other trade symbol, privately owned or registered with the 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.

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

2.7. The term "Prescription" means an order for drugs or medicines or combinations or mixtures thereof, written or signed by a duly licensed physician, an authorized physician assistant at the direction of his or her supervising physician in accordance with the provisions of section sixteen, article three of this chapter, dentist, optometrist, as authorized by section two, article eight of this chapter, veterinarian or other medical practitioner licensed to write prescriptions intended for the treatment or prevention of disease of man or animals. Any prescription written or signed by an authorized physician assistant shall be printed with the name of the physician assistant, and a list of drugs approved under the physician assistant's job description, in accordance with the provision of section sixteen, article three of this chapter. 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 by a duly licensed physician, an authorized physician assistant, dentist, optometrist, 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 constitutes the original prescription to be filed by the pharmacist. A pharmacist receiving a prescription by word of mouth, telephone or other means of communication from an authorized physician assistant shall require a copy of the list of drugs approved under the job description of the physician assistant prior to accepting such orders. All such descriptions shall be preserved on file for a period of five (5) years, subject to inspection by the proper officer of the law. The requirements of this subsection apply except for narcotic prescriptions, when all narcotic laws and regulations must be complied with.

2.8. 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 the term shall not include soap.

2.9. The term "Pharmacy" or "Drug Store" or "Apothecary" means any place where the practice of pharmacy is conducted and includes 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) with respect to which any of the above words are used in any advertisement.

2.10. 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 of the drugs, the maintenance of proper records regarding dispensing and the dissemination of information concerning the therapeutic values and uses of such drugs and medicines.

2.11. "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 W. Va. Code §60A-2.

2.12. "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.

2.13. "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 the first day of January, one thousand nine hundred thirty-nine, and whose license is in good standing.

2.14. "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 of prevention of disease of man or animals.

The term "Practitioner" as pertains to persons and places handling controlled substances and as defined under article two, chapter sixty-a of the Uniform Controlled Substances Act shall not be construed to have the same meaning as the definitions for medical practitioners under chapter thirty of the West Virginia Code.

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

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

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

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

2.19. "Original Drug Store Permit" means a permit issued for a pharmacy, drug store or apothecary where:

a. The pharmacy, drug store or apothecary is a new business;

b. An established business is transferred to a successor;

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

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

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

Only pharmacy or drug store permits issued under W. Va. Code §30-11-14 are considered a renewal.

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

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

2.22. "Intern" means an individual working in a pharmacy or drug store under the

instruction and supervision of a licensed 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. In this rule the word "apprentice" to refer to individuals registered with the Board to obtain the practical experience required under W. Va. Code §15-1-2.

2.23. The term "Internship" describes the practical experience requirement, and "Nine (9) months practical experience" shall mean an average work week of not less than forty (40) hours for a period of one (1) calendar year, except as provided in this rule for concurrent training programs.

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

2.25. "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.

2.26. "Act" or "Uniform Controlled Substances Act" when used in these regulations shall mean and refer to chapter sixty-a of the West Virginia Code.

§15-1-3. General Provisions.

3.1. Board in general. -- The state Board of Pharmacy, known as the "West Virginia Board of Pharmacy" shall consist of five (5) practicing pharmacists and two (2) public members 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 licensed pharmacist of the State of West Virginia and actively engaged in the practice of pharmacy. The public members shall be residents of this state who have attained the age of majority and may not be a past or present member of the profession of pharmecy, the spouse of a member of the profession of pharmacy, a person who has ever has any material financial interest in the providing of pharmecy service or who is engaged in any activity directly related to the practice of pharmacy.

3.2. Officers of the Board. -- The members of the board shall annually elect as officers of the Board one (1) member to serve for a period of one (1) year as President of the Board; one (1) member to serve for a period on one (1) year as vice president of the Board; and, one (1) member to serve for a period of one (1) year as Secretary of the Board, all of whom shall hold their offices for one (1) 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 the bond shall be regarded as a proper and necessary expense of the Board.

3.3. 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 Aesculapius serpent and holding in balance a set of scales, an impression of which is affixed hereto.

3.4. Meeting of the Board. -- The Board shall hold at least two (2) 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 consider 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 (3) members.

3.5. Quorums. -- Before any action can be taken, on any matter properly in the consideration of the board, at least four (4) 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.

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

3.7. 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 article one and five, chapter thirty 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 the moneys are received. He shall also, on the first day of January and first day of July of each year or within five (5) days thereafter, certify to the State Auditor, a detailed statement of all moneys received by him or her during the preceding six (6) months.

3.8. Compensation of members; expenses. -- Every member of the Board shall receive one hundred fifty dollars ($150.00) for each day actually spent in attending the sessions of the Board or of its committees and the necessary travel, and shall be reimbursed for all actual and necessary expenses incurred in carrying out the provisions of chapter thirty of the West Virginia Code applicable to the Board.

The Board shall prescribe the Secretary's salary and in proceedings relative to the fixing of his salary, the Secretary has 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.

3.9. Record of proceedings; registration of applicant; certified copies of records prima facie evidence, report to governor. -- The Secretary of the Board shall keep a record of its precedings and a register of all applicants for license or registration, showing for each, the date of his application, his or her name, age, educational and other qualifications, place of residence, whether an examination was required, whether the applicant was rejected or a certificate of license or certificate of registration granted, the date of the action, the license or registration number, if required, and any suspension or revocation of a license or registration. 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, is 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.

3.10. Roster of licensed or registered practitioners. -- The Secretary of the Board shall also prepare and maintain a complete roster of licensed pharmacies within this State and licensed pharmacists practicing within or without this State. The pharmacy and pharmacists names must be arranged alphabetically. The Board may call for and require a registration whenever it considers it necessary or expedient to secure an accurate roster.

§15-1-4. Apprenticeship; Requirements For Certificate.

4.1. The principal purpose of serving an apprenticeship 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. An apprenticeship is required under W. Va. Code §30-5-5 for licensure.

The Board shall certify apprenticeship, except as provided in this subsection only for an individual:

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

b. For whom the licensed pharmacist or other employer has notified the Board within ninety (90) days of the employment of the apprentice.

c. Who notifies the Board within ten (10) days subsequent to termination of any apprenticeship under a pharmacist preceptor; and

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

4.2. No apprentice 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.

4.3. Apprentice receives experience for any period of time that is concurrent with enrollment in a recognized school of pharmacy. The Board may grant an additional four (4) months experience time for apprentices participating or enrolled in a supervised apprenticeship or clinical pharmacy concurrent with the last year of the professional pharmacy curriculum.

4.4. No apprenticeship will be certified in a pharmacy or drug store in which the volume of prescription dispensing is less than ten thousand (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 W. Va. Code §30-5-2.

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

4.6. The Board may accept apprenticeship 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 apprenticeship experience.

§15-1-5. Licensure And Annual Renewal; Requirement For.

5.1. Application.

All applicants for examination shall apply in writing to the Secretary of the Board at least fifteen (15) days before the date the examination is to be conducted and shall transmit with his or her application a fee of one hundred twenty-five dollars ($125) 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.

5.2. Requirements for application.

a. Age.

The applicant must be not less than eighteen (18) years of age, proof of which must be shown by a birth certificate or other proof when a birth certificate is not available.

b. Moral character.

Every application for registration as a pharmacist shall present to the Board satisfactory evidence that he or she is a person of good moral character and not addicted to drunkenness or the use of controlled substances and that he or she has not been convicted of violating the provisions of any law relating to the practice of pharmacy and that he or she has not been convicted of a crime involving moral turpitude: **Provided,** That an applicant, who has been arrested pursuant to W. Va. Code §30A-4-401, and who has later been discharged pursuant to W. Va. Code §60A-4-407 may, upon otherwise having satisfied the requirements of this section, be considered by the Board to have fully satisfied its requirements.

c. Education.

The applicant shall present to the board satisfactory evidence that he or she is a graduate of a recognized school of pharmacy as defined in section one of this rule.

d. Apprenticeship.

The applicant shall have acquired at least nine (9) months of apprenticeship experience under the supervision of a licenced pharmacist preceptor as defined in Sections 2.22 and 4 of this Rule.

5.3. Examinations.

a. Examinations shall be held at a time and place designated by the Board. At least thirty (30) days' notice shall be given by the Board prior to the holding of any examination. The Board shall give notice of such examination 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 W. Va. Code §30-1-13, and to such other persons and schools of pharmacy as the Board may from time to time designate.

b. A maximum of three (3) days shall be allowed for the examination, including the written, oral and practical portions of the examination.

c. An applicant must pass a written examination in subjects determined by the Board as being reasonable, in testing his or her 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 seventy-five percent (75%) is necessary for an applicant to pass the examination.

An applicant failing to pass the examination satisfactorily to the Board is entitled at either the first or second succeeding examination conducted by the Board, to a reexamination without further cost but one reexamination exhausts his or her privilege for examination under his or her original application.

5.4. 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 or her the right to practice pharmacy in the State of West Virginia until such time as the permanent certificate as a licenced pharmacist may be prepared for him or her. The permanent certificate of registration which 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 (3) 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 duplicate thereof, which fee shall be paid before such certificate or duplicate is issued. No such certificate shall be assignable.

5.5. Annual renewal of registration.

a. Annual renewal.

Every licensed pharmacist, who desires to continue in the practice of his or her profession, shall on or before the first day of July annually apply to the State Board of Pharmacy for a renewal of his or her registration, and shall transmit with his or her application a thirty dollar ($30.00) fee. If the Board finds that the applicant has been legally registered in this State, and is entitled to a renewal of the certificate it shall issue to him or her 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 (30) days prior to said first day of July.

c. Failure to renew.

If any pharmacist fails for a period of thirty (30) days after the first day of July to apply to the Board for a renewal of his or her registration, the Board shall erase his or her name from the register of registered pharmacists.

Such person, in order to again become registered, shall 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 or her qualifications to practice the profession, the Board shall reinstate him or her upon payment of a reinstatement fee of two hundred fifty dollars ($250.00) plus the renewal fee of thirty dollars ($30.00).

§15-1-6. Reciprocity; Registration of Pharmacists From Other States.

6.1. 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,** That

a. The applicant is at least eighteen (18) years of age.

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

c. The applicant is in good standing in the state of original licensing.

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 or her license suspended or revoked for violation of pharmacy, liquor, narcotic or food and drug laws.

g. The applicant originally passed a written examination in subjects determined by the Board as being reasonable, in testing his or her technical knowledge, the applicant also passed a practical examination determined by the Board as being a reasonable test of the applicant's ability to translate his or her technical knowledge into terms of actual practice and the applicant made a general average of not less than seventy-five percent (75%) in the practical examination.

h. Applicants who registered since 1945 must have graduated from a recognized school of pharmacy and in addition thereto, had not less than nine (9) months 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 (2) 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. 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 shall not accept positions as pharmacists or attempt to work as pharmacists until such time as they received a certificate of registration from the State of West Virginia.

6.2. Application.

a. The applicant shall complete a preliminary application form obtained from the Secretary of the National Association of Boards of Pharmacy informing the Secretary which state or states the applicant has previously registered and in what state he wishes to register and submit the form with a required fee of one hundred twenty-five dollars ($125) to the Secretary of the National Association of Boards of Pharmacy, O'Hare Corporate Center, 1300 Higgins Road, Suite 103, Park Ridge, Illinois, 60068.

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. The Board shall supply an applicant who possesses the necessary qualifications 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 two hundred fifty dollars ($250) unless the applicant desires to be examined other than at a regular meeting of the Board. In that case, the applicant shall pay an additional fee of one hundred fifty dollars ($150).

b. The application must include the following:

A. A certified copy of proof of experience, or the original pharmacist preceptor's affidavit proving experience, that were filed by applicant when he or she took the examination in the state from which he or she is registered.

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

6.3. Appearance before the Board.

Applicants for registration by reciprocity are required to appear before the Board at such time as directed, for checking of credentials, an interview, and such questions 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.

§15-1-7. Proceedings for Suspension or Revocation of License or Registration; Effective Suspension or Revocation; Transcript; Report.

7.1. In all proceedings before the Board for the suspension or revocation of any license or registration, a statement of the charges against the licensee and a notice of the time and place of hearing shall be served upon the licensee as a notice is served under W. Va. Code §56-2-1 at least thirty (30) days prior to the hearing and he or she may appear with witnesses and be heard in person, by counsel, or both.

7.2. The Board may take such oral or written proof for or against the licensee charged as it may deem advisable.

7.3. 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 oaths.

7.4. If after a hearing, the Board finds that the charges are true, it may suspend, or revoke the license and the suspension or revocation takes from the person, all attendant rights and privileges. A stenographic report of each proceeding to suspend or revoke the license shall be made at the expense of the Board and a transcript of the hearing retained in its files. The Board shall make a written report of its findings which shall constitute part of the record and copies of the report shall be filed with the Secretary of State and with the appropriate office of the state of original licensure with the Secretary of the National Association of Boards of Pharmacy if a reciprocal license is involved.

7.5. The following rules of procedure shall control a hearing before the Board:

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

A. Any person may initiate proceedings before the Board, for the revocation, cancellation or suspension of a license or permit before the Board by filing charges with the Board in writing and under oath.

B. Settings: The President of the Board shall set a time and a place for a hearing on the revocation, cancellation or suspension of a license or a permit.

C. Representation: At any hearing the licensee or permittee has the right to appear either personally or by counsel, or both, to produce witnesses or evidence in his or her 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 is the duty of the deputy to require an orderly presentation in accordance with this rule.

b. Order of presentation.

A. When any licensee or permittee is served with charges previously filed before the Board as provided in this rule, he or she shall appear before the Board on the day at the time specified in the notice of hearing.

B. The absence of a licensee or permittee in no way affects 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 this rule, the President of said Board or the Board's appointee shall commence the hearing by causing the charges to be read, and thereafter receiving the answer of the licensee or permitteent to the charges, if any. The licensee or permittee may plead either guilty or not guilty to the charges.

D. The Board shall then proceed to hear evidence, both written or 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 or her attorney. The testimony shall be given under oath.

E. After the presentation of evidence in support of the charges, the licensee or permittee or his or her 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 licensee or permittee shall give direct testimony and immediately thereafter, be subject to cross-examination by the Board or its duly authorized appointee. All testimony shall be given under oath.

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

G. At the close of the presentation of evidence in support of the charges and evidence in opposition of the charges, the licensee or permittee or his or her attorney may present an 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. The 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 order or act. An appeal from the action of the Board does not stay of the Board's action unless specifically directed as such by the Board.

c. Application for reissuance of license.

Upon application, the Board may reissue a license to a person whose license has been suspended or revoked. Such application, the case of suspension or revocation, shall not be made prior to one (1) year after the suspension 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 receives an invitation to appear before the Board, the 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 invited.

B. Representation at such hearings: The person invited, should he or she so desire, may have legal counsel accompany him or her to the hearing before the Board.

C. Appearances by invitation are 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.

A. Any person aggrieved by the Rules and Regulations promulgated by the Board is entitled to have his or her complaint set down for hearing by the Board.

B. Requests for hearings must be filed with the Board in accordance with the following requirements:

(a) The 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 hearings shall specify in detail the basis for the complaint.

(c) The complaint shall specify reasonable evidence that the rule is inconsistent with the law governing the practice of pharmacy in West Virginia.

C. The Board shall hold hearings for the complaint ten (10) days from the date of receipt of the request by the Board, unless postponed by mutual agreement.

§15-1-8. Review by Circuit Court and Supreme Court of Board's Refusal to Issue Suspension or Revocation of License.

8.1. Any person who has been refused a license for any cause other than failure to pass the examination given by the Board or whose license has been suspended or revoked, may,

within thirty (30) days after the decision of the Board, present his or her petition in writing to the Circuit Court of the county in which he or she resides or to the judge of the court in vacation, praying for the review and reversal of the decision.

8.2. Before presenting his or her petition to the court or judge, petitioner shall mail copies to the petition to the President and Secretary of the Board.

8.3. Upon receipt of the petition, the Secretary shall transmit to the clerk of the court, the record of the proceedings before the Board.

§15-1-9. Refilling Prescriptions.

9.1. It is unlawful for a pharmacist to refill any prescription containing a drug wherein the label of the original container of the drug bears the statement, "Caution: Federal Law Prohibits Dispensing Without Prescription," unless the medical practitioner has authorized the refill by written notation on the original prescription, or has authorized the refill by oral order which is reduced promptly to writing and filled by the pharmacist.

9.2. If a prescription is refillable, the date of the 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.

9.3. The refilling of prescriptions is limited by the provisions of the Uniform Controlled Substances Act, W. Va. Code §60A-3-308.

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 (6) months after the date written or be efilled more than five (5) times unless renewed by the practitioner.

§15-1-10. Prohibitions on Resale.

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

§15-1-11. Drug Product Selection Regulations.

11.1. The Board of Pharmacy of the State of West Virginia adopts the Food and Drug Administration's approved Drug Products and Legal Requirements Publication, the 1989 Ninth Edition and its supplements, as published by the United States Pharmacopeia Drug Product.

§15-1-12. Regulation Governing Pharmacy Permits.

12.1. 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 is effective on the first day of July of each year.

12.2. 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 partnership 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 place of business 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 a 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 the 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. The applications should be delivered to the Secretary by the fifteenth 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 (12) hours a day will be required to operate with not less than two (2) licensed 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 Sections 13 and 14 of this rule.

e. Each initial application for a permit shall be accompanied by the required fee of one hundred fifty dollars ($150). The fee for renewal of such permit shall be seventy-five dollars ($75.00) annually.

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

12.3. 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 an 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 licensed pharmacist in charge, on the sworn statement that it will be conducted in accordance with the provisions of the law.

c. In the case where a pharmacy or drug store is owned by a person who is not a licensed pharmacist, the Board will issue a permit jointly to the licensed pharmacist in charge and to the person owning said pharmacy, as defined in Section 1 of this rule.

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.

12.4. Renewal of permit.

The annual registration for renewal of permit takes place on the first day of July of each year. The fee for annual renewal is seventy-five dollars ($75.00). Permits issued under this section are not transferable and 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 each year, the permit lapses and becomes null and void. To renew a lapsed permit the Board must inspect the pharmacy and the permittee must pay a fee of one hundred fifty dollars ($150) and one hundred fifty dollars ($150) for the inspection.

12.5. Surrender of permit.

a. Where a licensed pharmacist in whose name a permit has been issued leaves the employment of the pharmacy or drug store he or she is responsible for notifying the Board of the termination of his or her services, and also for the surrender of the permit in his or her name. Neglect on the part of the pharmacist to notify the Board may prevent his or her from 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 licensed pharmacist who has responsible supervision over the 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 the permit.

d. Pharmacists employed and in charge of pharmacies or drug stores, owned by persons not licensed pharmacists, are required to notify the Board and surrender for cancellation the permit issued immediately upon the termination of the employment. It also is the duty of the owner of such pharmacies or drug stores, who are not licensed pharmacists, to immediately notify the Board upon the termination of employment of licensed 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 of operation considered a separate offense.

12.6. Violations.

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

b. All licensed pharmacists must notify the Board immediately of any change in employment and change of address. Failure to notify the Board is sufficient cause for suspension.

c. It shall be the duty of any person who employs any licensed pharmacist to immediately notify the Board of any discharge, termination or change of place of employment of the licensed pharmacist. Failure to notify the Board is sufficient cause for suspension of any permit or license held by that person.

12.7. Security.

In the event that a prescription area is to be operated for a period less than the regular business hours of the entire store, the following requirements apply:

a. The pharmacy 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 designed so that only a pharmacist with a key has 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 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 cannot be readily or easily removed. The owner of the pharmacy shall submit the plans and specifications of the permanent barrier to the Board for approval showing that it affords adequate security. Plans shall be submitted prior to proceedings with any construction, which plan shall indicate the pharmacy area which shall be of adequate space. Before a pharmacy permit is 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 (4) inch letters shall be prominently displayed stating: "Pharmacy Closed, No Pharmacist On Duty."

d. Telephone: Each pharmacy area shall have a separate phone (listing) which may be answered only in the 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. If no pharmacist is present when the prescription order(s) must be deposited the patient or his or her agent shall deliver the prescription order into a "Mail Slot" or "Drug Box". The times that the pharmacy is open for business must be displayed so that they are prominently visible to the person depositing the prescription order(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 patient, person picking up the prescription for the patient, or person delivering the prescription to the patient at his or her 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.

12.8. 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 the forms adopted by the Boardand the pharmacy shall publicly display the forms for the convenience of the public.

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

c. The forms shall bear a title across the top portion reading, "Prescription Price List and Services." The pharmacist shall designate the prices, and the 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 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 priced as required by W. Va. Code §30-5-12a."

f. The owner of the pharmacy, a member of firm, or an officer of corporation shall certify on the forms provided by the Board that a list of current prices and other information as required by W. Va. Code §30-5-12a is available to the public as required by this rule.

g. Any pharmacy that does not comply with the W. Va. Code §30-5-12a and this rule is subject to the penalties as prescribed in the W. Va. Code §30-5-19 on revocation of permits.

h. The Rules adopted by the Board shall be distributed along with the required forms to each pharmacy registered with this Board.

§15-1-13. Professional And Technical Equipment.

13.1. The Board will not issue a permit to operate a pharmacy or drug store, unless the minimum professional and technical equipment requirements have been fulfilled.

13.2. 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 balances and weights shall meet the minimum standards adopted by the National Bureau of Standards as outlined in Handbook 44.

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

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

e. For pharmacies compounding opthalmic preparations, IV additives or other pharmaceuticals requiring more sophisticated techniques, the proper equipment to prepare sterile products or to meet other requirements of good compounding practices.

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

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

h. 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.

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

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

§15-1-14. Parenteral/Enteral Compounding.

14.1. A pharmacy engaged in the practice of parenteral/enteral compounding shall comply with the following regulations:

a. A parenteral/enteral compounding pharmacy is a type of special pharmacy which is limited in scope of pharmacy practice to render parenteral/enteral compounding functions. The is pharmacy practice facilitates the utilization of certain institutional therapeutic measures by patients in the home environment, by patients in an institutional environment where such pharmacy service is unavailable or by patients in a hospital. Pharmacy services and parenteral/enteral products provided be a parenteral/enteral compounding pharmacy pursuant to prescription as defined in W. Va. Code §30-5-1(6), shall be limited to the compounding and/or dispensing of: All sterile preparations for parenteral therapy and parenteral nutrition, including but not limited to:

A. Sterile preparations for jejunostomy feeding and sterile irrigation solutions; and/or

B. Sterile preparations of parenteral cytotoxic, antineoplastic, anti-infective and analgesic agents.

b. Pharmacy environment.

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

c. General requirements.

A. Parenteral/enteral compounding shall be under the control and supervision of a licensed pharmacist, who shall be designated pharmacist manager on the application for a parenteral/enteral compounding permit. The pharmacist manager or other licensed qualified pharmacist shall be present on duty during all

hours of product preparation. Changes in the pharmacist manager shall be reported to the Board of Pharmacy office within ten (10) days by the permit holder and pharmacist manager of record. A pharmacist manager of a partneral/enteral compounding pharmacy shall not be designated pharmacist manager of record of more than one parenteral/enteral compounding pharmacy.

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

C. The pharmacy shall maintian a patient profile for each patient. The profile must contain available medical information consistent with prevailing pharmacy standards.

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

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

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

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

(c) Proper aseptic procedures must be used at all times to prevent bacterial contamination of the product as well as chemical contamination of the operator.

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

F. An applicant for a parenteral/enteral compounding pharmacy permit shall provide the Board of Pharmacy with the following:

(a) A completed Board of Pharmacy permit application form.

(b) A copy of the Policy and Procedure Manual.

(c) The minimum requirements for space, equipment, supplies and publications.

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

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

(B) Space:

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

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

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

(C) Equipment:

1. Laminar air flow hood(s).

(1) Vertical.

2. Refrigerator/ freezer

3. Sink and wash area as provided in this section.

4. Appropriate waste containers for:

(1) Used needles and syringes.

(2) All cytotoxic waste including disposal apparel used in its preparation.

(D) Supplies:

1. Gloves, masks and gowns.

2. Disposable needles and syringes of various standard sizes.

3. Disinfenctant cleaning agents.

4. Clean towels.

5. Liquid handwashing materials with bactericidal properties.

6. Vacuum containers and various transfer sets.

7. "Spill Kits" for cytotoxic agent spills.

(E) Current references:

1. United States Pharmacopeia and National Formulary.

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

3. Procedures for handling cytotoxic drugs by American Society of Hospital Pharmacists, Inc.

§15-1-15. Sanitary Regulation of Pharmacies.

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

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

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

15.4. Upon the completion of compounding a prescription the pharmacist shall clean the prescription counter and place the refuse or waste materials 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.

15.5. 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 cleaning of the hands of those preparing and compounding prescriptions.

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

15.7. 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.

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

§15-1-16. Sale of Drugs by Mechanical Devices; Sharing Compensation.

16.1. The sale of drugs and medicines by mechanical devices or vending machines is prohibited.

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

§15-1-17. 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 or her 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 or herself 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 W. Va. Code §30-5-2.

17.1. Professional responsibilities.

No pharmacist shall engage in conduct, in the practice of pharmacy or the operation 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 or she 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 the professional judgment and skill of a pharmacist. He or she shall at all times practice his or her profession in conformity with federal and state laws and regulations and the regulations of the West Virginia State Board of Pharmacy.

17.2. Uncertain prescription orders.

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

17.3. Refusal of prescription.

It is the duty of a pharmacist to make his or her 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 or her unless there is a valid reason for his or her inability to fill the prescription order.

17.4. 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 or her 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 or her authorized representative; (3) the prescriber; or (4) any person authorized by law to receive the information. He or she shall not, however, discuss with the patient or his or her authorized representative matters that should be discussed with the prescriber only.

17.5. Diagnosis or treatment.

No pharmacist shall attempt to diagnose, treat or prescribe for any disease, illness or organic disorder. A pharmacist may advise 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.

17.6. 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.

17.7. 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.

17.8. Promotion of drugs.

No pharmacist or pharmacy shall promote to the public by any means a controlled substance 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.

No pharmacist shall purchase, accept, compound or dispense any medicinal preparation, whether by prescription order or otherwise, which in his or her professional opinion is not therapeutically reliable. Drugs shall be 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 any unused prescription.

17.9. Changes in prescription.

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 from the prescriber, except when professional judgment requires the use of pharmaceutical adjuncts which do not compromise the therapeutic properties but are necessary for proper compounding. Any approved change in the prescription order shall immediately be recorded upon the order with the date, time and method of ascertaining the approval.

17.10. 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.

17.11. 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.

17.12. 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 or she 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.

17.13. Duties.

It is the duty of a registered pharmacist in every pharmacy to perform the following duties:

a. To accept all new prescriptions transmitted by oral communication.

b. To affix typed prescription labels to prescription containers.

c. To reconstitute, subtract from, or add to prescription medications.

d. To record the date and dispensing pharmacist's initials on original or refilled prescriptions.

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

f. To counsel patients. An offer to counsel shall be made by the pharmacist or the pharmacist's designee in an oral communication with the patient or caregiver or agent who presents a new prescription, unless, in the professional judgement of the pharmacist it is considered inappropriate. In such instances, it is permissible for the offer to counsel to be made in a written communication, by telephone, inperson, or in a manner determined by the pharmacist to be appropriate. The requirements in this section constitute an acceptable offer to provide counseling to all parties including recipients of Medicaid and other third party programs or plans in the state.

A. In those cases, when the offer to counsel, as described in this sub-section, has been accepted, a pharmacist who provides prescription services to patients, shall discuss with the patient or caregiver or agent who presents a new prescription, any matter which in the exercise of the pharmacist's professional judgement the pharmacist considers significant, which may or may not include any othe the following:

(a) The name and description of the medication;

(b) The route, dosage form, dosage, route of administration, and duration of drug therapy;

(c) Special directions and precautions for preparation, adminstration, and use by the patient;

(d) Common severe side or adverse effects or interactions and therapeutic

contraindications that may be encountered, including their avoidance and the action required if they occur;

(e) Techniques for self-monitoring drug therapy;

(f) Proper storage;

(g) Prescription refill information; and

(h) Any action to be taken in the event of a missed dose.

B. Nothing in this sub-section requires a pharmacist to provide consultation if the patient or caregiver or agent does not accept the offer to counsel. The refusal may be noted whether manually or electronically in the patient's profile.

C. To make a reasonable effort to obtain, record, and maintain at least the following information at the individual pharmacy:

(a) The patient's name, address, telephone number, date of birth or age, and gender.

(b) The patient's individual history when significant, including disease state and states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and

(c) The pharmacist's comments relevant to the patient's drug therapy.

D. Patient counseling, is not required for inpatients of a hospital or institution where other licensed health care practitioners are authorized to administer the drug(s).

g. To perform any of the functions in this seciton except, nothing shall restrict registered interns from performing any and all of the functions in this section under the supervision of a registered pharmacist.

h. To perform any other functions of any nature or kind which require the knowledge, ability or skill of a registered pharmacist.

17.14. Evasion or violation of the rules of professional conduct.

These rules of professional conduct are intended to govern all pharmacist licensed to practice in West Virginia by the State Board of Pharmacy and their employees or agents. A violation of any provision of this rule constitutes unprofessional conduct.

Any pharmacist who knowingly accepts professional employment from any person, firm or corporation who violates or evades this rule is guilty of a violation of the rule the same as if he or she had personally engaged in the evasion or violation.

17.15. 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 the rules shall be posted in the prescription department of every such establishment where it can be seen by all persons entering said department.

§15-1-18. Pharmacist Consultants and Coordinators of Pharmaceutical Services.

The requirements in this section apply to pharmacists who 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.

18.1. Requirements.

a. The Board of Pharmacy shall maintain a roster of all pharmacist consultants and coordinators of pharmaceutical services. All pharmacists serving as consultants or

coordinators shall be licensed 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 with the West Virginia Board of Pharmacy on forms provided by the Board. The forms shall specify the service which the pharmacist is providing and the location where the service in being provided. The forms must be signed by the pharmacist and the administrator of the facility. The pharmacist must register annually with the West Virginia Board of Pharmacy.

d. All applicants certified as pharmacist consultants or coordinators of pharmaceutical services shall meet such additional educational and experienced backgrounds as required by the Board and comply with this rule.

e. Pharmacist consultants or coordinators of pharmaceutical services shall document by time and date his or her activities consistent with the level of institutional care requirements.

18.2. Responsibilities.

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

A. Drug recall.

B. Separate reconciliation for controlled substances.

C. Automatic stop orders.

D. Systematic review of drug orders.

E. Formulary or minimum standards for drug quality.

F. In-service drug education.

G. Procedures 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 W. Va. Code §30-5-2.

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

f. Nothing under this rule precludes a patient in a skilled nursing facility or intermediate care facility from free choice of pharmaceutical supplies and drugs.