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WEST VIRGINIA LEGISLATURE

REGULAR SESSION, 1995

ENROLLED

Com. Sub. for HOUSE BILL No. 2451

(By Delegates Dallagher + Border)

Passed	march II,	1995
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COMMITTEE SUBSTITUTE

FOR

H. B. 2451

(By Delegates Gallagher and Border)

[Passed March 11, 1995; in effect ninety days from passage.]

AN ACT to repeal sections twelve-a and sixteen-a, article five, chapter thirty of the code of West Virginia, one thousand nine hundred thirty-one, as amended; to amend and reenact sections one, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, twelve-b, thirteen, fourteen, fourteen-a, fifteen, sixteen, nineteen, twenty-one and twenty-two of said article; and to further amend said article five by adding thereto nine new sections, designated sections one-a, one-b, two-a, five-a, seven-a, seven-b, sixteen-b, sixteen-c and twenty-two-a, all relating to the regulation of pharmacists, licensed interns and pharmacist technicians; repealing existing section twelve-a relating to drug and drug price listing and posting requirements and penalties for noncompliance; repealing existing section sixteen-a authorizing the manufacture of laetrile; legislative findings and statement of purpose; defining terms; filling of board vacancies; board qualifications; increasing board compensation; meetings and business of the board; clarifying public and closed meetings; records kept by the board; providing for expungement of records; examination of records; notice requirements; public information; making various technical changes; permitting licensed interns and pharmacy technicians to assist pharmacists; experience and training qualifications for pharmacists, licensed interns and pharmacy technicians; titles and terms; regulating pharmacy technicians; reciprocity; disciplinary proceedings; grounds for disciplinary action; fines and penalties; hearings and notice; confidentiality of prescription records; reporting criteria for professional malpractice, incompetence and convictions; voluntary agreements relating to alcohol or chemical dependency; confidentiality requirements; pharmacy lists; fees; license renewals and display; prohibitions; distribution of generic and brand-name drugs; prescription requirements for 'brand medically necessary' drugs; requiring ownership of USP-DI reference manual; pharmacy registration; pharmacists-in-charge; increasing fines for violations of equipment requirements; manufacturing permits; authorizing partial filling of schedule II medications under certain circumstances; limitations on application of article; increasing criminal and civil penalties; providing for immunity from civil actions for board members; limiting liability for professionals reporting to the board; required reporting of litigation results to the board; and rule-making authority.

Be it enacted by the Legislature of West Virginia:

That sections twelve-a and sixteen-a, article five, chapter thirty of the code of West Virginia, one thousand nine hundred thirty-one, as amended, be repealed; that sections one, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, twelve-b, thirteen, fourteen, fourteen-a, fifteen, sixteen, nineteen, twenty-one and twenty-two of said article be amended and reenacted; and that said article five be further amended by adding thereto nine new sections, designated sections one-a, one-b, two-a, five-a, seven-a, seven-b, sixteen-b, sixteen-c and twenty-two-a, all to read as follows:

ARTICLE 5. PHARMACISTS, PHARMACY TECHNICIANS, PHARMACY INTERNS AND PHARMACIES.

§30-5-1. Legislative findings.

- 1 The Legislature hereby finds and declares that the
- 2 practice of pharmacy is a privilege and not a natural or
- 3 fundamental right of any individual. As a matter of public
- 4 policy, it is necessary to protect the public through the
- 5 enactment of this article and to regulate the granting of
- 6 such privileges and their use. This article shall be liberally

7 construed to carry out these purposes.

§30-5-1a. Statement of purpose.

- 1 It is the purpose of this article to promote, preserve
- 2 and protect the public health, safety and welfare by the
- 3 effective regulation of the practice of pharmacy; the licen-
- 4 sure of pharmacists; the licensure, and regulation of all
- 5 sites or persons who distribute, manufacture, or sell drugs
- 6 or devices used in the dispensing and administration of drugs or devices within this state.

§30-5-1b. Definitions.

- 1 The following words and phrases as used in this article,
- 2 shall have the following meanings, unless the context oth-
- 3 erwise requires:
- 4 (a) "Administer" means the direct application of a
- 5 drug to the body of a patient or research subject by injec-
- 6 tion, inhalation, ingestion or any other means.
- 7 (b) "Board of pharmacy" or "board" means the West
- Wirginia state board of pharmacy.
- 9 (c) "Compounding" means:
- 10 (1) The preparation, mixing, assembling, packaging 11 or labeling of a drug or device:
- 12 (A) As the result of a practitioner's prescription drug
- 13 order or initiative based on the practitioner/patient/phar-
- 14 macist relationship in the course of professional practice
- 15 for sale or dispensing; or
- 16 (B) For the purpose of, or as an incident to, research,
- 17 teaching or chemical analysis and not for sale or dispens-
- 18 ing;
- 19 (2) The preparation of drugs or devices in anticipation
- 20 of prescription drug orders based on routine, regularly
- 21 observed prescribing patterns.
- 22 (d) "Confidential information" means information
- 23 maintained by the pharmacist in the patient record or
- 24 which is communicated to the patient as part of patient
- 25 counseling, or which is communicated by the patient to

- 26 the pharmacist. This information is privileged and may be
- 27 released only to the patient or to other members of the
- 28 health care team and other pharmacists where, in the
- 29 pharmacist's professional judgment, such release is neces-
- 30 sary to the patient's health and well-being; to such other
- 31 persons or governmental agencies authorized by law to
- 32 receive such privileged information; as necessary for the
- 33 limited purpose of peer review and utilization review; as
- 34 authorized by the patient or required by court order.
- 35 (e) "Deliver" or "delivery" means the actual, construc-36 tive or attempted transfer of a drug or device from one 37 person to another, whether or not for a consideration.
- 38 (f) "Device" means an instrument, apparatus, imple-39 ment or machine, contrivance, implant or other similar or 40 related article, including any component part or accessory, 41 which is required under federal law to bear the label, "Cau-42 tion: Federal or state law requires dispensing by or on the 43 order of a physician."
- 44 (g) "Dispense" or "dispensing" means the preparation 45 and delivery of a drug or device in an appropriately la-46 beled and suitable container to a patient or patient's repre-47 sentative or surrogate pursuant to a lawful order of a prac-48 titioner for subsequent administration to, or use by, a pa-49 tient.
- 50 (h) "Distribute" means the delivery of a drug or device 51 other than by administering or dispensing.
- 52 (i) "Drug" means:
- 53 (1) Articles recognized as drugs in the USP-DI, Facts 54 and Comparisons, Physicians Desk Reference or supple-55 ments thereto, for use in the diagnosis, cure, mitigation, 56 treatment or prevention of disease in human or other ani-57 mals;
- 58 (2) Articles, other than food, intended to affect the 59 structure or any function of the body of human or other 60 animals; and
- 61 (3) Articles intended for use as a component of any articles specified in subsection (1) or (2) of this section.

- 63 (j) "Drug regimen review" includes, but is not limited 64 to, the following activities:
- 65 (1) Evaluation of the prescription drug orders and 66 patient records for:
- 67 (A) Known allergies;
- 68 (B) Rational therapy-contraindications;
- 69 (C) Reasonable dose and route of administration; and
- 70 (D) Reasonable directions for use.
- 71 (2) Evaluation of the prescription drug orders and 72 patient records for duplication of therapy.
- 73 (3) Evaluation of the prescription drug for interactions 74 and/or adverse effects which may include, but are not 75 limited to, any of the following:
- 76 (A) Drug-drug;
- 77 (B) Drug-food;
- 78 (C) Drug-disease; and
- 79 (D) Adverse drug reactions.
- 80 (4) Evaluation of the prescription drug orders and 81 patient records for proper utilization, including over utilization and under utilization and optimum therapeutic s3 outcomes.
- 84 (k) "Intern" means an individual who is:
- 85 (1) Currently registered by this state to engage in the 86 practice of pharmacy while under the supervision of a 87 licensed pharmacist and is satisfactorily progressing to-88 ward meeting the requirements for licensure as a pharma-89 cist; or
- 90 (2) A graduate of an approved college of pharmacy or 91 a graduate who has established educational equivalency by 92 obtaining a Foreign Pharmacy Graduate Examination 93 Committee (FPGEC) certificate, who is currently licensed 94 by the board for the purpose of obtaining practical expe-95 rience as a requirement for licensure as a pharmacist; or

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- 96 (3) A qualified applicant awaiting examination for 97 licensure; or
- 98 (4) An individual participating in a residency or fel-99 lowship program.
- (1) "Labeling" means the process of preparing and affixing a label 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 and state law or rule.
- 107 (m) "Mail order pharmacy" means a pharmacy, re-108 gardless of its location, which dispenses greater than ten 109 percent prescription drugs via the mail.
- (n) "Manufacturer" means a person engaged in the manufacture of drugs or devices.
 - (o) "Manufacturing" means the production, preparation, propagation or processing of a 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 and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners or other persons.
 - (p) "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.
- 127 (q) "Patient counseling" means the oral communica-128 tion by the pharmacist of information, as defined in the 129 rules of the board, to the patient, to improve therapy by 130 aiding in the proper use of drugs and devices.
- 131 (r) "Person" means an individual, corporation, partner-132 ship, association or any other legal entity, including gov-

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- (s) "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 as defined in the rules of the board.
- (t) "Pharmacist" or "registered pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacy and pharmaceutical care.
 - (u) "Pharmacist-in-charge" means a pharmacist currently licensed in this state who accepts responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy and the distribution of drugs and who is personally in full and actual charge of such pharmacy and personnel.
- (v) "Pharmacy" means any drugstore, apothecary or place within this state where drugs are dispensed and sold at retail or displayed for sale at retail and pharmaceutical care is provided; and any place outside of this state where drugs are dispensed and pharmaceutical care is provided to residents of this state.
- 155 (w) "Pharmacy technician" means registered support-156 ive personnel who work under the direct supervision of a 157 pharmacist who have passed an approved training pro-158 gram as described in this article.
- (x) "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, including allopathic and osteopathic physicians, dentists, physician's assistants, optometrists, veterinarians, podiatrists and nurse practitioners as allowed by law.
- 166 (y) "Preceptor" means an individual who is currently 167 licensed as a pharmacist by the board, meets the qualifica-168 tions as a preceptor under the rules of the board, and par-169 ticipates in the instructional training of pharmacy interns.

- (z) "Prescription drug" or "legend drug" means a drug 170 which, under federal law, is required, prior to being dis-171 172 pensed or delivered, to be labeled with either of the fol-173 lowing statements:
- 174 (1) "Caution: Federal law prohibits dispensing without 175 prescription";
- 176 (2) "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian"; or a drug 177 178 which is required by any applicable federal or state law or 179 rule to be dispensed pursuant only to a prescription drug 180 order or is restricted to use by practitioners only.
- 181 (aa) "Prescription drug order" means a lawful order of 182 a practitioner for a drug or device for a specific patient.
- 183 (bb) "Prospective drug use review" means a review of 184 the patient's drug therapy and prescription drug order, as 185 defined in the rules of the board, prior to dispensing the 186 drug as part of a drug regimen review.
- 187 (cc) "USP-DI" means the United States Pharmacopedia-Dispensing Information. 188
- 189 (dd) "Wholesale distributor" means any person en-190 gaged in wholesale distribution of drugs, including, but not limited to, manufacturers' and distributors' warehouses, 191 192 chain drug warehouses and wholesale drug warehouses; 193 independent wholesale drug trader; and retail pharmacies
- 194 that conduct wholesale distributions.

§30-5-2. Board of pharmacy; appointment, qualifications and terms of members; compensation; powers and duties generally; meetings and notices.

- 1 (a) There shall be a state board of pharmacy, known as the "West Virginia board of pharmacy," which shall consist of five practicing pharmacists and two public members, who shall be appointed by the governor by and with the 4 advice and consent of the Senate. Any vacancy which occurs in the membership of the board for any reason, 7 including expiration of term, removal, resignation, death, disability or disqualification shall be immediately filled by
- the governor as provided by this section. Nothing in this

10 section shall require the governor to change the composi-11 tion of the board prior to the usual expiration of any 12 member's term. The governor may consider the diversity 13 of pharmacy areas of practice when filling vacancies.

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- (b) Each pharmacist member of the board, at the time of his appointment, shall be a resident of this state, licensed and in good standing to engage in the practice of pharmacy in this state for a period of at least five years prior to their appointment. The public members shall be residents of this state who have attained the age of eighteen years and may not be a past or present pharmacist, the spouse of a pharmacist, a person who has ever had any material financial interest in providing pharmacy services or who has engaged in any activity directly related to the practice of pharmacy.
- (c) Each member of the board shall receive two hundred dollars for each day spent in attending to the duties of the board or of its committees, and shall be reimbursed for all actual and necessary expenses incurred in carrying out his or her duties.
- (d) The members of the board in office on the date this section takes effect shall, unless sooner removed, continue to serve until their respective terms expire and until their successors have been appointed and have qualified. Board member terms shall be for five years with at least 35 one pharmacist member's term expiring yearly. The gov-36 ernor may, with the advice and consent of the Senate, reappoint any member for additional consecutive terms. Members as of the first day of July, one thousand nine 38 39 hundred ninety-five, are eligible for reappointment to 40 additional terms regardless of the length of time they have previously served on the board.
- 42 (e) The board, in addition to the authority, powers and 43 duties granted to the board by this chapter and chapter 44 sixteen of this code, shall have the authority to:
- 45 (1) Regulate the practice of pharmacy;
- 46 (2) Regulate the employment of licensed interns in 47 pharmacy;

- 48 (3) Appoint, within the limit of appropriations, inspec-49 tors who shall be pharmacists, and investigators, to act as 50 agents of the board within the provisions of this chapter 51 and chapter sixteen of this code and rules as the board 52 shall promulgate;
- 53 (4) Adopt rules of professional conduct; and
- 54 (5) Hire an attorney, as may be necessary.
- 55 (f) A majority of the membership of the board consti-56 tutes a quorum for the transaction of business, and any 57 motion is approved by a majority vote of a quorum. All 58 board members shall be given advance notice of each 59 board meeting.
- 60 (g) Meetings of the board shall be held in public session, except that the board may hold closed sessions to 61 prepare, approve, grade or administer examinations. Disci-62 plinary proceedings, prior to a finding of probable cause, 63 64 as provided in section seven of this article shall be held in 65 closed sessions, unless the party subject to discipline re-66 quests that the hearing be held in public sessions. All discussions or meetings of the board concerning personnel 67 matters shall be held in closed session. 68

§30-5-2a. Records of board; expungement; examination notice; public information.

- 1 (a) The board shall maintain a permanent record of 2 the names of all pharmacists, interns and pharmacy techni-3 cians lawfully practicing in this state, and of all persons 4 applying for licensure to practice, along with an individual 5 historical record for each such individual containing re-6 ports and all other information furnished to the board 7 concerning any applicant, pharmacist, intern or pharmacy 8 technician.
- 9 (b) Upon a determination by the board that any information submitted to it is without merit, the report shall be expunged from the individual's historical record.
- 12 (c) Any licensee or registrant of the board or autho-13 rized representative thereof, has the right, upon request, to 14 examine his or her own individual historical record main-

- 15 tained by the board pursuant to this article and to place
- 16 into such record a statement regarding the correctness or
- 17 relevance of any information in the historical record.
- 18 These statements shall at all times be appended to and
- 19 accompany any request for review or copies made of the
- 20 portion of the record to which they refer.
- 21 (d) Orders of the board relating to disciplinary action
- 22 against a pharmacist, pharmacy technician, or other license
- 23 or registrant of the board are public information.
- §30-5-3. When licensed pharmacist required; person not licensed pharmacist, pharmacy technician or licensed intern not to compound prescriptions or dispense poisons or narcotics; licensure of interns.
 - 1 (a) It is unlawful for any person not a pharmacist, or 2 who does not employ a pharmacist to conduct any phar-3 macy, or store for the purpose of retailing, compounding 4 or dispensing prescription drugs or prescription devices.
 - 5 (b) It is unlawful for the proprietor of any store or 6 pharmacy to permit any person not a pharmacist to compound or dispense prescriptions or prescription refills, or to retail or dispense the poisons and narcotic drugs named in sections two, three and six, article eight, chapter sixteen 10 of this code: Provided, That a licensed intern may com-11 pound and dispense prescriptions or prescription refills under the direct supervision of a pharmacist: Provided, 13 however, That registered pharmacy technicians may assist 14 in the preparation and dispensing of prescriptions or pre-15 scription refills including, but not limited to, reconstitution 16 of liquid medications, typing and affixing labels under the 17 direct supervision of a licensed pharmacist.
 - (c) It is the duty of a pharmacist or employer who employs an intern, to license the intern with the board within ninety days after employment. The board shall furnish proper forms for this purpose and shall issue a certificate to the intern upon licensure.

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23 (d) The experience requirement for licensure as a 24 pharmacist shall be computed from the date certified by

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- the supervising pharmacist as the date of entering the 26 internship. If the internship is not registered with the 27 board of pharmacy, then the intern shall receive no credit for such experience when he or she makes application for examination for licensure as a pharmacist: Provided, That 30 credit may be given for such unregistered experience if an 31 appeal is made and evidence produced showing experience was obtained but not registered and that failure to 33 register the internship experience was not the fault of the intern.
- (e) An intern having served part or all of his or her internship in a pharmacy in another state or foreign coun-37 try shall be given credit for the same when the affidavit of his or her internship is signed by the pharmacist under whom he or she served, and it shows the dates and number of hours served in the internship and when the affidavit is attested by the secretary of the state board of pharmacy of the state or country where the internship was served.
- 43 (f) Up to one third of the experience requirement for licensure as a pharmacist may be fulfilled by an internship in a foreign country.

§30-5-4. Use of titles or terms; penalties and fines.

- (a) It is unlawful for any person not legally licensed as a pharmacist, unless he or she employs a licensed pharmacist, to take, use or exhibit the title of pharmacist, or li-4 censed or registered pharmacist, or the title of druggist or apothecary, or any other title or description of like import, or to label, mark, or advertise his or her or any other place 7 of business as a pharmacy or drugstore or by the use of the words drug or medicines or any other compound or derivative of the same, or by any other word or sign indi-10 cating or intended to indicate that drugs or pharmaceutical 11 supplies are either sold or offered for sale.
- 12 (b) It is unlawful for any person not legally registered 13 as a pharmacy technician to take, use or exhibit the title of 14 pharmacy technician, or any title or description of like 15 import.
- 16 (c) Any person violating this section shall, upon con-

- 17 viction, be deemed guilty of a misdemeanor and fined not
- 18 less than five hundred nor more than one thousand dol-
- 19 lars.

§30-5-5. Qualifications for licensure as pharmacist; fees; certificates of licensure; rules for licensure; reciprocity; minimum standards.

- 1 (a) In order to be licensed as a pharmacist within the 2 meaning of this article, a person shall:
- 3 (1) Be eighteen years of age or older;
- 4 (2) Present to the board satisfactory evidence that he 5 or she is a graduate of a recognized school of pharmacy 6 as defined by the board of pharmacy.
- 7 (3) Present to the board satisfactory evidence that he 8 or she has completed at least fifteen hundred hours of 9 internship in a pharmacy under the instruction and super- vision of a pharmacist;
- 11 (4) Pass an examination approved by the board of 12 pharmacy; and
- 13 (5) Present to the board satisfactory evidence that he 14 or she is a person of good moral character, has not been 15 convicted of a felony involving controlled substances or 16 violent crime, and is not addicted to alcohol or the use of 17 controlled substances.
- 18 (b) An applicant for examination shall pay to the 19 board a fee of one hundred twenty-five dollars with his or 20 her application.
- 21 (c) The board shall issue certificates of licensure to all persons who successfully pass the required examination and are otherwise qualified and to all those whose certificates or licenses the board shall accept in lieu of an examination as provided in section six of this article.
- 26 (d) The board shall by rule stipulate the forms to be 27 used for licensure application, the requirements for reci-28 procity and the required minimum score for passing of 29 the licensure examination.

§30-5-5a. Legislative findings; registration of pharmacy technicians; qualifications; training programs; rules and restrictions.

- 1 (a) The Legislature finds that it is in the best interests
 2 of the public health, safety and welfare that licensed phar3 macists in this state be assisted with or relieved of certain
 4 tasks so that the pharmacist may counsel patients, improve
 5 pharmaceutical care and therapeutic outcomes. To achieve
 6 this aim, the board shall recognize and register pharmacy
 7 technicians.
- 8 (b) On or after the first day of July, one thousand nine 9 hundred ninety-six, any person practicing as a pharmacy 0 technician in this state shall be registered with the board of 1 pharmacy pursuant to the provisions of this section.
- 12 (c) In order to become registered as pharmacy techni-13 cians in this state, individuals shall:
- 14 (1) Be at least eighteen years old;
- 15 (2) Be a high school graduate or its equivalent;
- 16 (3) Present to the board satisfactory evidence that he 17 or she is of good moral character, is not addicted to alco-18 hol or controlled substances and is free of any felony 19 convictions; and
- 20 (4) Satisfactorily complete a board-approved pharma-21 cy technician training program.
- 22 (d) The pharmacy technician training program and its 23 curriculum shall be designed to train individuals to per-24 form nonprofessional functions as described in legislative 25 rules promulgated in accordance with the provisions of 26 article three, chapter twenty-nine-a of this code.
- (e) Pharmacy technicians shall be identified by a name tag and designation as pharmacy technician while working in a pharmacy within this state. A ratio of no more than four pharmacy technicians per on-duty pharmacist operating in any outpatient, mail order or institutional pharmacy shall be maintained.

§30-5-6. Reciprocal licensure of pharmacists from other states or countries.

- 1 (a) The board of pharmacy may by reciprocity license 2 pharmacists in this state persons who have been legally 3 registered or licensed pharmacists in another state: *Provid-*4 *ed*, That the applicant for such licensure shall meet the 5 requirements of the rules for reciprocity promulgated by 6 the board in accordance with the provisions of chapter 7 twenty-nine-a of this code: *Provided*, *however*, That reciprocity is not authorized for pharmacists from another 9 state where that state does not permit reciprocity to pharmacists licensed in West Virginia.
- 11 (b) The board may refuse reciprocity to pharmacists 12 from another country unless the applicant qualifies under 13 such rules as may be promulgated by the board for licen-14 sure of foreign applicants.
- 15 (c) Applicants for licensure under this section shall, 16 with their application, forward to the secretary of the 17 board of pharmacy a fee of two hundred fifty dollars. In 18 the event the applicant desires to be examined other than 19 at a regular meeting of the board the applicant shall sub-20 mit to the board an additional fee of one hundred fifty 21 dollars.

§30-5-7. Grounds for suspension or revocation of license or disciplinary proceedings; penalties and procedures; temporary suspensions; reporting of disciplinary action.

- 1 (a) The board shall have the power to withhold, revoke 2 or suspend any license or any certificate issued under this 3 article or to penalize or discipline any pharmacist or phar-4 macy after giving reasonable notice and an opportunity to 5 be heard pursuant to the provisions of section one, article 6 five, chapter twenty-nine-a of this code, any person who 7 has:
- 8 (1) Become unfit or incompetent to practice pharmacy 9 by reason of: (A) alcohol or substance abuse; (B) insanity; 10 or (C) any abnormal physical or mental condition which 11 threatens the safety of persons to whom such person might

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- sell or dispense prescriptions, drugs, or devices, or for whom he might manufacture, prepare or package, or supervise the manufacturing, preparation, or packaging of prescriptions, drugs or devices;
- 16 (2) Been convicted in any of the courts of this state, 17 the United States of America, or any other state, of a felo-18 ny or any crime involving moral turpitude which bears a 19 rational nexus to the individual's ability to practice as a 20 pharmacist or pharmacist technician;
- 21 (3) Violated any of the provisions of this chapter or chapter sixteen of the code;
 - (4) Failed to comply with the rules of professional conduct adopted by the board pursuant to section two of this article:
- 26 (5) Knowledge or suspicion that a pharmacist, pharmacy technician or pharmacy intern is incapable of engaging in the practice of pharmacy with reasonable skill, competence and safety and has failed to report this information to the board;
- 31 (6) Committed fraud as a licensee in connection with 32 the practice of pharmacy;
- 33 (7) Performed an act outside this state which would 34 constitute a violation within this state; or
- 35 (8) Agreed to participate in a legend drug product 36 conversion program promoted or offered by a manufac-37 turer, wholesaler or distributor of such product for which 38 the pharmacist or pharmacy received any form of finan-39 cial remuneration, or agreed to participate in a legend 40 drug program in which the pharmacist or pharmacy is 41 promoted or offered as the exclusive provider of legend 42 drug products or whereby in any way the public is denied. limited or influenced in selecting pharmaceutical service 43 44 or counseling.
 - (b) Upon a finding of a violation of one or more of the above grounds for discipline by a pharmacist, intern or pharmacy technician, the board may impose one or more of the following penalties:

- 49 (1) Suspension of the offender's license or registration 50 for a term to be determined by the board;
- 51 (2) Revocation of the offender's license or registration;
- 52 (3) Restriction of the offender's license or registration 53 to prohibit the offender from performing certain acts or 54 from engaging in the practice of pharmacy in a particular 55 manner for a term to be determined by the board;
- 56 (4) Imposition of a fine not to exceed one thousand 57 dollars for each offense;
- 58 (5) Refusal to renew the offender's license or registra-59 tion:

- (6) Placement of the offender on probation and supervision by the board for a period to be determined by the board.
- (c) All final decisions of the board shall be subject to judicial review pursuant to the procedures of article five, chapter twenty-nine-a of this code.
- (d) In the case of a pharmacy or wholesale distributor, the disciplinary order may be entered as to the corporate owner, if any, as well as to the pharmacist, officer, owner or partner of the pharmacy or wholesale distributor if it is found that such person or entity had knowledge of or knowingly participated in one or more of the violations set forth in this article or of article three, chapter sixty-a of this code.
- (e) Notwithstanding the provisions of section eight, article one, chapter thirty of this code, if the board determines that the evidence in its possession indicates that a pharmacist's continuation in practice or unrestricted practice constitutes an immediate danger to the public, the board may, on a temporary basis and without a hearing, take any of the actions provided for in this section if proceedings for a hearing before the board are initiated simultaneously with the temporary action and begin within fifteen days of such action. The board shall render its decision within five days of the conclusion of a hearing conducted pursuant to the provisions of this section.

- 86 (f) In every disciplinary or licensure case considered 87 by the board pursuant to this article, whether initiated by 88 the board or upon complaint or information from any 89 person or organization, the board shall make a prelimi-90 nary determination as to whether probable cause exists to 91 substantiate charges of disqualification due to any reason 92 set forth in this section. If such probable cause is found to 93 exist, all proceedings on such charges shall be open to the 94 public, who shall be entitled to all reports, records and 95 nondeliberative materials introduced at such hearing, in-96 cluding the record of any final action taken: Provided, 97 That any medical records pertaining to a person who has 98 not expressly waived his or her right to the confidentiality 99 of such records shall not be open to the public.
- 100 (g) All disciplinary actions taken by the board shall be 101 reported to the national board of pharmacy, appropriate 102 federal agencies and to any other state boards with which 103 the disciplined licensee may also be registered or licensed.

§30-5-7a. Required reporting of information to board pertaining to professional malpractice and convictions; complaints of professional incompetence; reporting forms.

- 1 (a) Every person, partnership, corporation, association,
 2 insurance company, professional society or other organi3 zation providing professional liability insurance to a phar4 macist, pharmacist technician or intern in this state shall
 5 submit to the board the following information within thir6 ty days from any judgment, dismissal or settlement of a
 7 civil action or of any claim involving the insured: The date
 8 of any judgment or settlement; the amount of any settle9 ment or judgment against the insured; and such other
 1 information as the board may require.
- 11 (b) Within thirty days after a person known to be a
 12 pharmacist, pharmacy intern, or pharmacy technician
 13 licensed or otherwise lawfully practicing pharmacy in this
 14 state or applying to be so licensed is convicted of any
 15 crime under the laws of this state, or the laws of the United
 16 States which involves drugs in any way, including any
 17 controlled substance under state or federal law, the clerk
 18 of the court of record in which the conviction was entered

- 19 shall forward to the board a certified true and correct
- 20 abstract of record of the convicting court. The abstract
- 21 shall include the name and address of such licensee, the
- 22 nature of the offense committed and the final judgment
- 23 and sentence of the court.
- 24 (c) Any person may report to the board relevant facts 25 about the conduct of a licensee of the board which in the 26 opinion of such person amounts to professional malprac-
- 27 tice or professional incompetence.
- 28 (d) The board shall provide forms for filing reports
- 29 pursuant to this section. Reports submitted in other forms
- 30 shall be accepted by the board.

§30-5-7b. Voluntary agreements relating to alcohol or chemical dependency; confidentiality of same.

- 1 (a) In order to encourage voluntary reporting of alco-2 hol or other chemical dependency impairment and in
- 3 recognition of the fact that alcoholism and chemical de-
- 4 pendency are illnesses, a pharmacist or pharmacy techni-
- 5 cian or other licensee or registrant or the board may enter
- 6 into a voluntary agreement with the board reporting his or
- 7 her participation in an alcohol or chemical dependency
- 8 treatment program or reporting an alcohol or chemical
- 9 dependency impairment to the board and seek treatment
- 10 for his or her dependency. Pursuant to said agreement, the
- board shall impose limitations on the practice of said
- 12 pharmacist, pharmacy technician or other licensee or reg-
- 13 istrant of the board.
- 14 (b) Any voluntary agreement entered into pursuant to 15 this subsection may not be considered a disciplinary ac-16 tion or order by the board and shall not be public infor-
- 17 mation if:
- 18 (1) Such voluntary agreement is the result of the phar-19 macist, pharmacy technician, or other licensee or registrant
- 20 of the board reporting his or her participation in an alco-
- 21 hol or chemical dependency treatment program or report-
- 22 ing to the board his or her alcohol or chemical dependen-
- 23 cy impairment and requesting such an agreement for the
- 24 purpose of seeking treatment; and

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- 25 (2) The board has not received nor filed any written 26 complaints regarding said pharmacist, pharmacy techni-27 cian or other licensee or registrant of the board relating to 28 an alcohol or chemical dependency impairment affecting 29 the care and treatment of patients or customers, nor re-30 ceived any reports pursuant to section seven of this article 31 relating to an alcohol or chemical dependency impair-32 ment.
- (c) If any pharmacist, pharmacy technician or other 34 licensee or registrant enters into a voluntary agreement 35 with the board pursuant to this subsection and then fails to 36 comply with or fulfill the terms of said agreement, the 37 board shall initiate disciplinary proceedings pursuant to section seven of this article.
 - (d) If the board has not instituted any disciplinary proceedings as provided for in this article, any information received, maintained or developed by the board relating to the alcohol or chemical dependency impairment of any pharmacist or pharmacy technician, other licensee or registrant of the board and any voluntary agreement made pursuant to this subsection shall be confidential and not available for public information, discovery or court subpoena nor for introduction into evidence in any professional liability action or other action for damages arising out of the provision of or failure to provide health care services.
- 51 (e) In the board's annual report of its activities to the 52 Legislature required under section eight of this article, the 53 board shall include information regarding the success of 54 the voluntary agreement mechanism established therein: 55 Provided, That in making such report the board shall not 56 disclose any personally identifiable information relating to 57 any pharmacist or other licensee or registrant of the board participating in a voluntary agreement as provided herein. 58
 - (f) Notwithstanding any of the foregoing provisions, the board may cooperate with and provide documentation of any voluntary agreement entered into pursuant to this subsection to licensing boards in other jurisdictions, as may be appropriate.

64 (g) Any restrictions on the disclosure of confidential 65 information does not apply to any investigation or pro-66 ceeding by the board or by a hospital governing board or 67 committee with respect to relevant medical records, while 68 any of the aforesaid are acting within the scope of their 69 authority as stated in law or in the hospital bylaws, rules, 70 regulations or policies and procedures: *Provided*, That the disclosure of any information pursuant to this provision 72 shall not be considered a waiver of any such privilege in 73 any other proceeding.

§30-5-8. Reports by secretary of board to secretary of state; "list of pharmacists."

1 The secretary of the board of pharmacy shall provide the secretary of state with a list of all pharmacists, pharma-3 cy technicians and pharmacy interns in this state, giving 4 the name of the person, his or her business address, and the date of his or her licensure registration. On or before 6 the fifteenth day of September each year, the secretary of the board shall certify to the secretary of state all changes in said list required by the addition of new licensures, 9 registrations, renewals, reported deaths, forfeitures of li-10 censes or registrations or for other causes, occurring dur-11 ing the preceding year. The secretary of state shall enter in an appropriate book, known as "List of Pharmacists" the 12 13 facts shown by such reports, which reports shall be filed and preserved in his or her office.

§30-5-9. Fees.

1 The board of pharmacy shall charge and collect the following fees, in addition to those provided in article one of this chapter and in sections five, fourteen and sixteen of 4 this article: For renewing the licensure of a pharmacist, thirty dollars; to license an intern pharmacist, ten dollars 5 6 plus five dollars for each of the remaining periods of his or her internship; to register a consultant pharmacist, twenty dollars for the initial application and ten dollars for each additional application; and to register a pharmacy 10 technician, twenty-five dollars and ten dollars for each renewal.

§30-5-10. Annual renewal of license; fees and notices.

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- (a) Every licensed pharmacist, intern or pharmacy 2 technician who desires to renew his or her license shall on or before the first day of July, one thousand nine hundred ninety-one, and annually thereafter apply to the state 5 board of pharmacy for a renewal of his or her license, and shall transmit with his or her application the fee prescribed 7 in the preceding section of this article. Notification of the annual renewal shall be given by the board at least thirty days prior to said first day of July. Such notification shall 10 be mailed to the last known address of each pharmacist or 11 pharmacy technician as shown on record with the board.
- (b) If any pharmacist or pharmacy technician fails for a period of sixty days after the first day of July of each 14 year to apply to the board for a renewal of his or her li-15 cense, the board shall send a second notification of the 16 required annual renewal to the last known address of the pharmacist or pharmacy technician by certified mail, re-18 turn receipt requested. If the pharmacist or pharmacy technician fails to apply to the board for a renewal of his or her license within thirty days after receipt of the second notification, his or her name shall be erased from the register of pharmacists and pharmacy technicians.
- 23 (c) In order for any pharmacist or pharmacy techni-24 cian whose name has been erased from the register of the 25 board pursuant to subsection (b) of this section to again 26 become licensed, such pharmacist or pharmacy technician 27 shall appear personally before the board, or an authorized 28 committee of the board, to show cause for permitting the 29 license to lapse. If such person submits to the board satis-30 factory reasons for allowing the license to lapse and satis-31 fies the board as to his or her qualifications to practice the profession, such person shall be reinstated upon payment of a reinstatement fee of two hundred fifty dollars plus the renewal fee of thirty dollars.

§30-5-11. Certificate of licensure or permit shall be displayed.

1 Every certificate of registration or licensure to practice 2 as a pharmacist, intern or pharmacy technician, and every renewal of such certificate or permit, shall be conspicuously displayed in the pharmacy or place of business of which the pharmacist, intern or pharmacy technician or

- 6 other person to whom it is issued is the owner or manager, 7 or in which he or she is employed.
- §30-5-12. Responsibility for quality of drugs dispensed; exception; falsification of labels; deviation from prescription.
 - 1 (a) All persons, whether licensed pharmacists or not, 2 shall be responsible for the quality of all drugs, chemicals 3 and medicines they may sell or dispense, with the excep-4 tion of those sold in or dispensed unchanged from the 5 original retail package of the manufacturer, in which event 6 the manufacturer shall be responsible.
- 7 (b) Except as provided in section twelve-b of this article, the following acts shall be prohibited: (1) The falsification of any label upon the immediate container, box and/or package containing a drug; (2) the substitution or 10 the dispensing of a different drug in lieu of any drug 11 12 prescribed in a prescription without the approval of the 13 practitioner authorizing the original prescription: Provided, That this shall not be construed to interfere with the art 14 15 of prescription compounding which does not alter the 16 therapeutic properties of the prescription or appropriate generic substitute; (3) the filling or refilling of any pre-17 scription for a greater quantity of any drug or drug prod-18 19 uct than that prescribed in the original prescription with-20 out a written order or an oral order reduced to writing, or 21 the refilling of a prescription without the verbal or written 22 consent of the practitioner authorizing the original pre-23 scription.
- §30-5-12b. Definitions; selection of generic drug products; exceptions; records; labels; manufacturing standards; rules; notice of substitution; complaints; notice and hearing; immunity.
 - 1 (a) As used in this section:
 - 2 (1) "Brand name" means the proprietary or trade name 3 selected by the manufacturer and placed upon a drug or 4 drug product, its container, label or wrapping at the time 5 of packaging.
 - 6 (2) "Generic name" means the official title of a drug

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or drug combination for which a new drug application, or an abbreviated new drug application, has been approved by the United States food and drug administration and is 10 in effect.

- (3) "Substitute" means to dispense without the 12 prescriber's express authorization a therapeutically equiva-13 lent generic drug product in the place of the drug ordered or prescribed.
 - (4) "Equivalent" means drugs or drug products which are the same amounts of identical active ingredients and same dosage form, and which will provide the same therapeutic efficacy and toxicity when administered to an individual and is approved by the United States food and drug administration.
 - (5) "Practitioner" means a physician, an authorized Type A physician assistant at the direction of his or her supervising physician in accordance with the provisions of section sixteen, article three of this chapter, osteopath, dentist, veterinarian, podiatrist, optometrist or any other person duly licensed to practice and to prescribe drugs under the laws of this state.
- (b) A pharmacist who receives a prescription for a 29 brand name drug or drug product shall substitute a less 30 expensive equivalent generic name drug or drug product 31 unless in the exercise of his or her professional judgment 32 the pharmacist believes that the less expensive drug is not 33 suitable for the particular patient: Provided, That no sub-34 stitution may be made by the pharmacist where the pre-35 scribing practitioner indicates that, in his or her profes-36 sional judgment, a specific brand name drug is medically necessary for a particular patient.
- 38 (c) A written prescription order shall permit the phar-39 macist to substitute an equivalent generic name drug or 40 drug product except where the prescribing practitioner has 41 indicated in his or her own handwriting the words "Brand 42 Medically Necessary." The following sentence shall be 43 printed on the prescription form: "This prescription may 44 be filled with a generically equivalent drug product unless 45 the words 'Brand Medically Necessary' are written, in the 46 practitioner's own handwriting, on this prescription form.": Provided, That "Brand Medically Necessary" may be indi-

48 cated on the prescription order other than in the prescrib-49 ing practitioners own handwriting unless otherwise re-50 quired by federal mandate.

- (d) A verbal prescription order shall permit the pharmacist to substitute an equivalent generic name drug or drug product except where the prescribing practitioner shall indicate to the pharmacist that the prescription is "Brand Necessary" or "Brand Medically Necessary." The pharmacist shall note the instructions on the file copy of the prescription or chart order form.
- (e) No person may by trade rule, work rule, contract, or in any other way prohibit, restrict, limit or attempt to prohibit, restrict or limit the making of a generic name substitution under the provisions of this section. No employer or his or her agent may use coercion or other means to interfere with the professional judgment of the pharmacist in deciding which generic name drugs or drug products shall be stocked or substituted: *Provided*, That this section shall not be construed to permit the pharmacist to generally refuse to substitute less expensive therapeutically equivalent generic drugs for brand name drugs, and that any pharmacist so refusing shall be subject to the penalties prescribed in section twenty-two, article five, chapter thirty of this code.
- (f) A pharmacist may substitute a drug pursuant to the provisions of this section only where there will be a savings to the buyer. Where substitution is proper pursuant to this section, or where the practitioner prescribes the drug by generic name, the pharmacist shall, consistent with his or her professional judgment, dispense the lowest retail cost, effective brand which is in stock.
- (g) All savings in the retail price of the prescription shall be passed on to the purchaser; these savings shall be equal to the difference between the retail price of the brand name product and the customary and usual price of the generic product substituted therefor: *Provided*, That in no event shall such savings be less than the difference in acquisition cost of the brand name product prescribed and the acquisition cost of the substituted product.

- 87 (h) Each pharmacy shall maintain a record of any 88 substitution of an equivalent generic name drug product for a prescribed brand name drug product on the file copy of a written or verbal prescription or chart order. 90 Such record shall include the manufacturer and generic 92 name of the drug product selected.
- 93 (i) All drugs shall be labeled in accordance with the 94 instructions of the practitioner.
- 95 (j) Unless the practitioner directs otherwise, the pre-96 scription label on all drugs dispensed by the pharmacist 97 shall indicate the generic name using abbreviations if 98 necessary and either the name of the manufacturer or 99 packager, whichever is applicable in the pharmacist's discretion. The same notation will be made on the original 100 prescription retained by the pharmacist. 101
- 102 (k) A pharmacist may not dispense a product under 103 the provisions of this section unless the manufacturer has 104 shown that the drug has been manufactured with the fol-105 lowing minimum good manufacturing standards and prac-106 tices by:
- 107 (1) Labeling products with the name of the original 108 manufacturer and control number;
- 109 (2) Maintaining quality control standards equal to or 110 greater than those of the United States Food and Drug 111 Administration:
- 112 (3) Marking products with identification code or 113 monogram; and
- 114 (4) Labeling products with an expiration date.
- 115 (1) The West Virginia board of pharmacy shall pro-116 mulgate rules in accordance with the provisions of chapter 117 twenty-nine-a of this code which establish a formulary of 118 generic type and brand name drug products which are 119 determined by the board to demonstrate significant bio-120 logical or therapeutic inequivalence and which, if substi-121 tuted, would pose a threat to the health and safety of pa-122 tients receiving prescription medication. The formulary 123

shall be promulgated by the board within ninety days of

the date of passage of this section, and may be amended in accordance with the provisions of chapter twenty-nine-a of this code.

- (m) No pharmacist shall substitute a generic named therapeutically equivalent drug product for a prescribed brand name drug product if the brand name drug product or the generic drug type is listed on the formulary established by the West Virginia board of pharmacy pursuant to this article, or is found to be in violation of the requirements of the United States Food and Drug Administration.
- (n) Any pharmacist who substitutes any drug shall, either personally or through his or her agent, assistant or employee, notify the person presenting the prescription of such substitution. The person presenting the prescription shall have the right to refuse the substitution. Upon request the pharmacist shall relate the retail price difference between the brand name and the drug substituted for it.
- (o) Every pharmacy shall post in a prominent place that is in clear and unobstructed public view, at or near the place where prescriptions are dispensed, a sign which shall read: "West Virginia law requires pharmacists to substitute a less expensive generic named therapeutically equivalent drug for a brand name drug, if available, unless you or your physician direct otherwise." The sign shall be printed with lettering of at least one and one-half inches in height with appropriate margins and spacing as prescribed by the West Virginia board of pharmacy.
- (p) The West Virginia board of pharmacy shall promulgate rules in accordance with the provisions of chapter twenty-nine-a of this code setting standards for substituted drug products, obtaining compliance with the provisions of this section and enforcing the provisions of this section.
- (q) Any person shall have the right to file a complaint with the West Virginia board of pharmacy regarding any violation of the provisions of this article. Such complaints shall be investigated by the board of pharmacy.
- (r) Fifteen days after the board has notified, by registered mail, a person, firm, corporation or copartnership

- that such person, firm, corporation or copartnership is 162 163 suspected of being in violation of a provision of this sec-164 tion, the board shall hold a hearing on the matter. If, as a 165 result of the hearing, the board determines that a person, 166 firm, corporation or copartnership is violating any of the 167 provisions of this section, it may, in addition to any penal-168 ties prescribed by section twenty-two of this article, sus-169 pend or revoke the permit of any person, firm, corpora-170 tion or copartnership to operate a pharmacy.
- 171 (s) No pharmacist complying with the provisions of 172 this section shall be liable in any way for the dispensing of 173 a generic named therapeutically equivalent drug, substitut-174 ed under the provisions of this section, unless the generic 175 named therapeutically equivalent drug was incorrectly 176 substituted.
- (t) In no event where the pharmacist substitutes a drug under the provisions of this section shall the prescribing physician be liable in any action for loss, damage, injury or death of any person occasioned by or arising from the use of the substitute drug unless the original drug was incorrectly prescribed.
- 183 (u) Failure of a practitioner to specify that a specific 184 brand name is necessary for a particular patient shall not 185 constitute evidence of negligence unless the practitioner 186 had reasonable cause to believe that the health of the pa-187 tient required the use of a certain product and no other.

§30-5-13. Each pharmacy to have USP-DI.

- Every pharmacy as defined in this article, shall own and have in the pharmacy at all times in text or electronic
- 3 form, a recent edition of the USP-DI and any supple-
- 4 ments. No license or renewal shall be issued until a
- 5 USP-DI is in the pharmacy.

§30-5-14. Pharmacies to be registered; permit to operate; fees; pharmacist to conduct business.

- 1 (a) The board of pharmacy shall require and provide 2 for the annual registration of every pharmacy doing busi-
- 3 ness in this state. Any person, firm, corporation or partner-
- 4 ship desiring to operate, maintain, open or establish a

- 5 pharmacy in this state shall apply to the board of pharma6 cy for a permit to do so. The application for such permit
 7 shall be made on a form prescribed and furnished by the
 8 board of pharmacy, which, when properly executed, shall
 9 indicate the owner, manager, trustee, lessee, receiver, or
 10 other person or persons desiring such permit, as well as the
 11 location of such pharmacy, including street and number,
 12 and such other information as the board of pharmacy may
 13 require. If it is desired to operate, maintain, open or estab14 lish more than one pharmacy, separate application shall be
 15 made and separate permits or licenses shall be issued for
- 17 (b) Every initial application for a permit shall be ac-18 companied by the required fee of one hundred fifty dol-19 lars. The fee for renewal of such permit or license shall be 20 seventy-five dollars annually.
- 21 (c) If an application is approved, the secretary of the 22 board of pharmacy shall issue to the applicant a permit or 23 license for each pharmacy for which application is made. Permits or licenses issued under this section shall not be 24 25 transferable and shall expire on the thirtieth day of June of each calendar year, and if application for renewal of 27 permit or license is not made on or before that date, or a 28 new one granted on or before the first day of August, following, the old permit or license shall lapse and become 30 null and void and shall require an inspection of the phar-31 macy and a fee of one hundred fifty dollars plus one 32 hundred fifty dollars for the inspection.
- 33 (d) Every such place of business so registered shall 34 employ a pharmacist in charge and operate in compliance 35 with the general provisions governing the practice of phar-36 macy and the operation of a pharmacy.
- 37 (e) The provisions of this section shall have no appli-38 cation to the sale of nonprescriptive drugs which are not 39 required to be dispensed pursuant to a practitioner's pre-40 scription.

§30-5-14a. Pharmacist-in-charge.

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each.

1 (a) Every pharmacy at all times, shall be under the

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- direction and supervision of a licensed pharmacist who shall be designated by the owner of the pharmacy as the pharmacist-in-charge. This designation must be filed with the board within thirty days of the designation.
- 6 (b) The pharmacist-in-charge is responsible for the 7 pharmacy's compliance with state and federal pharmacy 8 laws and regulations and for maintaining records and 9 inventory.
 - (c) It is a violation of this section if the owner of a pharmacy fails to designate a pharmacist-in-charge or permits the practice of pharmacy without having designated a pharmacist-in-charge, or fails to notify the board of pharmacy if the designated pharmacist-in-charge leaves the employ of the pharmacy.
 - (d) Before a permit is issued to operate a pharmacy, or renewed, the application shall designate the pharmacist-in-charge. The designated pharmacist-in-charge shall be present when a new store is to be inspected.
 - (e) A pharmacist-in-charge shall not hold such designated position at more than one pharmacy, whether within or without the state of West Virginia. The board of pharmacy shall promulgate rules in accordance with the provisions of chapter twenty-nine-a of this code relative to pharmacies which are operated over forty hours a week.
- 26 (f) An interim pharmacist-in-charge may be designat-27 ed for a period not to exceed sixty days. The request for 28 an interim pharmacist-in-charge shall detail the circum-29 stances which warrant such a change. This change in des-30 ignation shall be filed with the board within thirty days of 31 the designation.
- 32 (g) The board of pharmacy shall furnish the form 33 which designates a change of the pharmacist-in-charge 34 and every such application shall be subject to a fee of ten 35 dollars.

§30-5-15. Professional and technical equipment required for pharmacy or drugstore; penalties and fines.

(a) Every pharmacy shall be equipped with proper

- pharmaceutical utensils so that prescriptions can be properly filled and compounded. The board of pharmacy shall by rule prescribe the minimum equipment which a phar-5 macy shall possess.
- 6 (b) Any person violating this section is guilty of a misdemeanor and shall be fined not less than two hundred fifty dollars nor more than one thousand dollars, and no permit shall be issued or renewed for any pharmacy which has not complied with the provisions of this section. 10

§30-5-16. Permit for manufacture and packaging of drugs, medicines, cosmetics; distribution of legend drugs; regulations as to sanitation and equipment; penalties; revocation of permit.

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- (a) No drugs or medicines, or toilet articles, dentifrices, or cosmetics, shall be manufactured, made, produced, packed, packaged or prepared within the state, except under the personal supervision of a pharmacist or such other person as may be approved by the board of pharmacy, after an investigation and determination by the board that they are qualified by scientific or technical training and/or experience to perform such duties of supervision as may be necessary to protect the public health and safety.
- 10 (b) No person shall manufacture, make, produce, pack, 11 package or prepare any such articles without first obtain-12 ing a permit to do so from the board of pharmacy. The 13 permit shall be subject to such rules with respect to sanita-14 tion and/or equipment, as the board of pharmacy may 15 from time to time adopt for the protection of the public 16 health and safety.
- (c) Any person, firm, corporation, partnership, company, cooperative society or organization who offers for sale, sells, offers or exposes for sale through the method of 20 distribution any legend drugs shall be subject to this article.
- 22 (d) The application for any permit required by this 23 section shall be made on a form to be prescribed and 24 furnished by the board of pharmacy and shall be accompanied by the following fees: For a distributor, one hun-25

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- dred fifty dollars, for a manufacturer, five hundred dollars, 27 which amounts shall also be paid as the fees for each an-28 nual renewal of such permits. Separate applications shall 29 be made and separate permits issued for each separate 30 place of manufacture, distribution, making, producing, 31 packing, packaging or preparation.
- 32 (e) The following fees shall be charged for a permit to 33 handle controlled substances: For a hospital or clinic, fifty dollars; for extended care facilities, twenty-five dollars; for 35 a nursing home, twenty-five dollars; for a teaching institu-36 tion, twenty-five dollars; for a researcher, twenty-five dol-37 lars; for a medical examiner, twenty-five dollars; and for a 38 pharmacy or drug store, fifteen dollars, which amounts 39 shall also be paid for each annual renewal of such permits.
 - (f) Permits issued under the provisions of this section shall be posted in a conspicuous place in the factory or place for which issued; such permits shall not be transferable, and shall expire on the thirtieth day of June following the day of issue and shall be renewed annually. Nothing in this section shall be construed to apply to those operating registered pharmacies.
- (g) Any person, firm, corporation, partnership, compa-48 ny, cooperative society or organization violating any of the provisions of this section and any permittee hereunder who shall violate any of the conditions of this permit or any of the rules adopted by the board of pharmacy shall, upon conviction, be deemed guilty of a misdemeanor and fined not more than fifty dollars for each offense. Each and every day such violation continues shall constitute a separate and distinct offense. Upon conviction of a permittee, his permit shall also immediately be revoked and become null and void.
- 58 (h) Any person, firm, corporation, partnership, compa-59 ny, cooperative society, organization or any permittee who 60 is convicted of two or more successive violations of the 61 provisions of this section or of the rules adopted by the 62 board of pharmacy shall at the discretion of the board of 63 pharmacy have such permit permanently revoked, and the 64 board of pharmacy shall refuse to issue further permits to such person, firm, corporation, partnership, company,

66 cooperative society, organization or permittee.

§30-5-16b. Partial filling of prescriptions.

The partial filling of a prescription for a controlled substance listed in Schedule II is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written 5 prescription or on the written record of the emergency oral prescription. The remaining portion of the prescription may be filled within seventy-two hours of the first partial filling: Provided, That if the remaining portion is 10 not or cannot be filled within the seventy-two hour period, 11 the pharmacist shall so notify the prescribing individual 12 practitioner. No further quantity may be supplied beyond seventy-two hours without a new prescription.

§30-5-16c. Partial filling of prescriptions for long-term care facility or terminally ill patients; requirements; records; violations.

- (a) As used in this section, "long-term care facility" or 1 "LTCF" means any nursing home, personal care home, or residential board and care home as defined in section two, article five-c, chapter sixteen of this code which provides 5 extended health care to resident patients: Provided, That the care or treatment in a household, whether for compensation or not, of any person related by blood or marriage, within the degree of consanguinity of second cousin to the head of the household, or his or her spouse, may not be 10 deemed to constitute a nursing home, personal care home or residential board and care home within the meaning of 11 12 this article. This section shall not apply to:
- 13 (1) Hospitals, as defined under section one, article 14 five-b, chapter sixteen of this code or to extended care 15 facilities operated in conjunction with a hospital;
- 16 (2) State institutions as defined in section six, article 17 one, chapter twenty-seven or in section three, article one, 18 chapter twenty-five, all of this code;
- 19 (3) Nursing homes operated by the federal govern-20 ment;

- 21 (4) Facilities owned or operated by the state govern-22 ment;
- 23 (5) Institutions operated for the treatment and care of 24 alcoholic patients;
- 25 (6) Offices of physicians; or
- 26 (7) Hotels, boarding homes or other similar places that furnish to their guests only a room and board.
- 28 (b) As used in this section, "terminally ill" means that 29 an individual has a medical prognosis that his life expectancy is six months or less.
- 31 (c) Schedule II prescriptions for patients in a LTCF 32 and for terminally ill patients shall be valid for a period of 33 sixty days from the date of issue unless terminated within 34 a shorter period by the discontinuance of the medication.
- 35 (d) A prescription for a Schedule II controlled sub-36 stance written for a patient in a LTCF or for a terminally 37 ill patient may be filled in partial quantities, including, but 38 not limited to, individual dosage units. The total quantity 39 of Schedule II controlled substances dispensed in all par-40 tial filling shall not exceed the total quantity prescribed.
- 41 (1) If there is any question whether a patient may be 42 classified as having a terminal illness, the pharmacist shall 43 contact the prescribing practitioner prior to partially fill-44 ing the prescription.
- 45 (2) Both the pharmacist and the prescribing practitio-46 ner have a corresponding responsibility to assure that the 47 controlled substance is for a terminally ill patient.
- 48 (e) The pharmacist shall record on the prescription 49 that the patient is "terminally ill" or a "LTCF patient". A 50 prescription that is partially filled and does not contain the 51 notation "terminally ill" or "LTCF patient" shall be deemed 52 to have been filled in violation of section three hundred 53 eight, article three, chapter sixty-a of this code.
- 54 (f) For each partial filling, the dispensing pharmacist 55 shall record on the back of the prescription, or on another 56 appropriate record which is readily retrievable, the follow-

- 57 ing information:
- 58 (1) The date of the partial filling;
- 59 (2) The quantity dispensed;
- 60 (3) The remaining quantity authorized to be dis-61 pensed; and
- 62 (4) The identification of the dispensing pharmacist.
- 63 (g) Information pertaining to current Schedule II 64 prescriptions for terminally ill and LTCF patients may be 65 maintained in a computerized system if such a system has 66 the capability to permit either by display or printout, for 67 each patient and each medication, all of the information 68 required by this section as well as the patient's name and 69 address, the name of each medication, original prescrip-70 tion number, date of issue, and prescribing practitioner 71 information. The system shall also allow immediate updat-72 ing of the prescription record each time a partial filling of 73 the prescription is performed and immediate retrieval of 74 all information required under this section.

§30-5-19. Rules of board of pharmacy; revocation of permits; employment of field agents, chemists, clerical and other qualified personnel.

- 1 (a) The board of pharmacy shall promulgate rules in accordance with the provisions of chapter twenty-nine-a of this code not inconsistent with law, as are necessary to carry out the purposes and enforce the provisions of this article. The board may revoke any permit or license issued under the provisions of this article at any time when examination or inspection of the pharmacy discloses that such place of business is not being conducted according to law.
- 9 (b) The board of pharmacy shall have the power and authority to employ field agents, chemists, clerical help, 11 hearing examiners and other qualified personnel, as may 12 be necessary to carry out the purposes and enforce the provisions of this article.
- 14 §30-5-21. Limitations of article.
- 15 (a) Nothing in this article shall be construed to pre-

- vent, restrict or in any manner interfere with the sale of 17 non-narcotic nonprescription drugs which may be lawful-18 ly sold without a prescription in accordance with the Unit-19 ed States food, drug, and cosmetic act, or the laws of this state, nor shall any rule be adopted by the board which 21 shall require the sale of nonprescription drugs by a li-22 censed pharmacist or in a pharmacy, or which shall pre-23 vent, restrict, or otherwise interfere with the sale or distribution of such drugs by any retail merchant. The sale or 24 25 distribution of nonprescription drugs shall not be deemed 26 to be improperly engaging in the practice of pharmacy.
- (b) Nothing in this article shall be construed to interfere with any legally qualified practitioner of medicine, dentistry or veterinary medicine, who is not the proprietor of the store for the dispensing or retailing of drugs, and who is not in the employ of such proprietor, in the compounding of his own prescriptions, or to prevent him from supplying to his patients such medicines as he may deem proper, if such supply is not made as a sale.

§30-5-22. Offenses; penalties.

- 1 (a) Any person who violates any of the provisions of 2 section three of this article is guilty of a misdemeanor, 3 and, upon conviction, shall, for each offense, be fined not 4 less than two hundred fifty dollars nor more than one 5 thousand dollars, or confined in the county jail not to 6 exceed six months, or both fined and imprisoned, in the 7 discretion of the court, and each day such violation shall 8 continue shall be deemed a separate offense.
- 9 (b) Any person who violates any of the provisions of 10 section twelve is guilty of a misdemeanor, and, upon con11 viction, shall be punished by a fine of not less than fifty 12 nor more than one hundred fifty dollars for each offense.
- 13 (c) Any person, except for the board of pharmacy or 14 board member acting within the scope of his or her re-15 sponsibilities or duties as such member, who violates any 16 of the provisions of section twelve-b is guilty of a misde-17 meanor, and, upon conviction, shall be punished by a fine 18 of not less than fifty nor more than one thousand dollars 19 for each offense.

- 20 (d) Any person, firm, partnership or corporation who violates any of the provisions of section fourteen is guilty of a misdemeanor, and, upon conviction, for the first offense shall be fined not to exceed one hundred dollars, or shall be imprisoned in the county jail not to exceed six months, or both fined and imprisoned, in the discretion of the court. Each and every day that the violation continues shall constitute a separate offense.
- 28 (e) Any person, firm, partnership or corporation who 29 violates any of the provisions of section eighteen is guilty 30 of a misdemeanor, and, upon conviction, shall be fined not 31 to exceed fifty dollars for the first offense, and upon con-32 viction of a second offense shall be fined not less than 33 fifty nor more than five hundred dollars, or shall be imprisoned in the county jail not to exceed thirty days, or 35 both fined and imprisoned. Each and every day that the 36 violation continues shall constitute a separate offense.

§30-5-22a. Civil immunity for board members; liability limitations of professionals reporting to board; reporting results of litigation to the board; rules.

- 1 (a) The members of the board when acting in good 2 faith and without malice shall enjoy immunity from indi-3 vidual civil liability while acting within the scope of their 4 duties as board members.
- 5 (b) Any licensee of this board who reports or other6 wise provides evidence of the negligence, impairment or
 7 incompetence of another member of this profession to the
 8 board or to any peer review organization, shall not be
 9 liable to any person for making such a report if such re10 port is made without actual malice and in the reasonable
 11 belief that such report is warranted by the facts known to
 12 him or her at the time.
- 13 (c) Within thirty days of the dismissal, settlement, adju-14 dication or other termination of any claim or cause of 15 action asserted against any professional reporting under 16 the provisions of this article the person or persons filing 17 such claim or cause of actions shall submit to the board 18 the following information:

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- 19 (1) The names of the parties involved;
- 20 (2) The name of the court in which the action was 21 filed, if applicable;
- 22 (3) The basis and nature of the claim or cause of ac-23 tion; and
- 24 (4) The results of such claim or cause of action, in-25 cluding dismissal, settlement, court or jury verdict or other 26 means of termination.
- 27 (e) The board shall promulgate legislative rules in accordance with the provisions of chapter twenty-nine-a of this code establishing procedures for imposing sanctions and penalties against any licensee who fails to submit to the board the information required by this section.

The Joint Committee on Enrolled Bills hereby certifies that the foregoing bill is correctly enrolled.
Chairman Senate Committee
Chairman House Committee
Originating in the House.
Takes effect ninety days from passage Clerk of the Senate Clerk of the House of Delegates President of the Senate
Speaker of the House of Delegates
The within this the
day of, 1995.
Governor

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PRESENTED TO THE

GOVERNOR
Date 32895
Time 8:55 aux