

1 **ENGROSSED**

2 COMMITTEE SUBSTITUTE

3 for

4 **H. B. 2513**

5 (By Delegates Morgan, Stephens, Givens,
6 Hartman, Hatfield, Martin, Staggers, Swartzmiller,
7 Cowles, C. Miller and Rowan)

8 (Originating in the Committee on the Judiciary)

9 [February 24, 2011]

10

11 A BILL to repeal §30-5-1a, §30-5-1b, §30-5-2a, §30-5-3a, §30-5-5a,
12 §30-5-5b, §30-5-6a, §30-5-7a, §30-5-7b, §30-5-7c, §30-5-9a,
13 §30-5-12a, §30-5-12b, §30-5-14a, §30-5-14b, §30-5-16a, §30-5-
14 16b, §30-5-16c and §30-5-22a of the Code of West Virginia,
15 1931, as amended; to amend and reenact §16-5A-9a of said code;
16 to amend and reenact §30-5-1, §30-5-2, §30-5-3, §30-5-4, §30-
17 5-5, §30-5-6, §30-5-7, §30-5-8, §30-5-9, §30-5-10, §30-5-11,
18 §30-5-12, §30-5-13, §30-5-14, §30-5-15, §30-5-16, §30-5-17,
19 §30-5-18, §30-5-19, §30-5-20, §30-5-21, §30-5-22, §30-5-23,
20 §30-5-24 §30-5-25, §30-5-26, §30-5-27, §30-5-28, §30-5-29 and
21 §30-5-30 of said code; to amend said code by adding thereto
22 four new sections, designated §30-5-31, §30-5-32, §30-5-33 and
23 §30-5-34; and to amend and reenact §60A-10-3 of said code, all
24 relating to the practice of pharmacist care; prohibiting the
25 practice of pharmacist care without a license; permitting a
26 licensed practitioner to dispense in certain settings;
27 providing other applicable sections; providing definitions;

1 providing for board composition; setting forth the powers and
2 duties of the board; clarifying rule-making authority;
3 continuing a special revenue account; establishing license,
4 registration and permit requirements; creating a scope of
5 practice; creating a temporary permit; establishing renewal
6 requirements; providing for exemptions from licensure;
7 providing requirement to participate in collaborative pharmacy
8 practice; providing requirement for dispensing generic drugs;
9 requiring the registration of pharmacies requiring a permit
10 for mail-order pharmacies and manufacturing of drugs;
11 providing requirements of filling prescriptions; providing
12 requirements for the display of a board authorization;
13 permitting the board to file an injunction; setting forth
14 grounds for disciplinary actions; allowing for specific
15 disciplinary actions; providing procedures for investigation
16 of complaints; providing for judicial review and appeals of
17 decisions; setting forth hearing and notice requirements;
18 providing for civil causes of action; providing criminal
19 penalties; and updating references.

20 *Be it enacted by the Legislature of West Virginia:*

21 That §30-5-1a, §30-5-1b, §30-5-2a, §30-5-3a, §30-5-5a, §30-5-
22 5b, §30-5-6a, §30-5-7a, §30-5-7b, §30-5-7c, §30-5-9a, §30-5-12a,
23 §30-5-12b, §30-5-14a, §30-5-14b, §30-5-16a, §30-5-16b, §30-5-16c
24 and §30-5-22a of the Code of West Virginia, 1931, as amended, be
25 repealed; that §16-5A-9a of said code be amended and reenacted;
26 that §30-5-1, §30-5-2, §30-5-3, §30-5-4, §30-5-5, §30-5-6, §30-5-7,

1 §30-5-8, §30-5-9, §30-5-10, §30-5-11, §30-5-12, §30-5-13, §30-5-14,
2 §30-5-15, §30-5-16, §30-5-17, §30-5-18, §30-5-19, §30-5-20, §30-5-
3 21, §30-5-22, §30-5-23, §30-5-24 §30-5-25, §30-5-26, §30-5-27, §30-
4 5-28, §30-5-29 and §30-5-30 of said code be amended and reenacted;
5 that said code be amended by adding thereto four new sections,
6 designated §30-5-31, §30-5-32, §30-5-33 and §30-5-34; and that
7 §60A-10-3 of said code be amended and reenacted; all to read as
8 follows:

9 **CHAPTER 16. PUBLIC HEALTH.**

10 **ARTICLE 5A. CANCER CONTROL.**

11 **§16-5A-9a. Laetrile use; informed consent.**

12 A hospital or other health care facility may not interfere
13 with the physician-patient relationship by restricting or
14 forbidding the intravenous use of amygdalin (laetrile) as certified
15 in accordance with ~~section sixteen-a,~~ article five, chapter thirty
16 of this code, as an adjunct to recognized, customary or accepted
17 modes of therapy in the treatment of any malignancy for terminally
18 ill cancer patients when it is prescribed or administered by a
19 physician holding an unlimited license for the practice of medicine
20 in the State of West Virginia and the patient has signed the
21 "written informed request" therefor as set forth in this section:
22 *Provided,* That a parent or guardian may sign the "written informed
23 request" on a minor's behalf.

24 In the event that no recognized, customary or accepted mode of
25 therapy is available for the treatment of any malignancy for a

1 terminally ill cancer patient, the physician may prescribe or
2 administer intravenous amygdalin (laetrile), as certified in
3 accordance with ~~section sixteen-a~~, article five, chapter thirty of
4 this code, as the sole mode of therapy, providing further that said
5 patient executed the "written informed request" as set forth in
6 this section.

7 Any physician, hospital or other health care facility
8 participating in any act permitted or required by this section is
9 immune from any civil or criminal liability that otherwise might
10 result by reason of such actions. A physician may not be subjected
11 to disciplinary action by the State Board of Medicine of West
12 Virginia for prescribing or administering intravenous amygdalin
13 (laetrile), in compliance with the provisions of this section.

14 Nothing in this section shall be construed as constituting an
15 endorsement of amygdalin (laetrile), as certified in accordance
16 with ~~section sixteen-a~~, article five, chapter thirty of this code,
17 for the treatment of any malignancy, disease, illness or physical
18 condition.

19 The "written informed request" referred to in this section
20 shall be on a form prepared by and obtained from the state
21 department of health and shall be in substance as follows:

22 "WRITTEN INFORMED REQUEST" FOR PRESCRIPTION OF
23 INTRAVENOUS AMYGDALIN (LAETRILE) FOR
24 MEDICAL TREATMENT

25 Patient's name: _____

26 Address _____

1 Age _____ Sex _____

2 Name and address of prescribing physician:
3 _____

4 Nature of malignancy diagnosed for medical treatment by
5 amygdalin (laetrile):
6 _____
7 _____
8 _____

9 My physician has explained to me:

10 (a) That the manufacture and distribution of amygdalin
11 (laetrile) has not been approved by the Federal Food and Drug
12 Administration.

13 (b) That neither the American Cancer Society, the American
14 Medical Association nor the West Virginia State Medical Association
15 recommends use of amygdalin (laetrile) in the treatment of any
16 malignancy, disease, illness or physical condition.

17 (c) That there are alternative recognized treatments for the
18 malignancy, disease, illness or physical condition from which I
19 suffer which he or she has offered to provide for me including:

20 (here describe) (state "none" if applicable) _____
21 _____
22 _____

23 (d) That I have the right to refuse or terminate the
24 intravenous use of laetrile at any time.

25 I understand that physicians, hospitals or health care
26 facilities are immune from civil and criminal liability for

1 prescribing or administering amygdalin (laetrile) in compliance
2 with state statutes.

3 That notwithstanding the foregoing, I hereby request
4 prescription and use of intravenous amygdalin (laetrile) in the
5 medical treatment of the malignancy from which I suffer.

6 _____

7 Patient or person signing for patient

8 Date of execution of request _____

9 ATTEST: _____

10 Prescribing physician

11 The prescribing physician shall forward a copy of the written
12 informed request to the state registrar of vital statistics within
13 ten days of the execution of such request and shall retain a copy
14 of the request in the patient's medical file.

15 **ARTICLE 5. PHARMACISTS, PHARMACY TECHNICIANS, PHARMACY INTERNS**

16 **AND PHARMACIES.**

17 **§30-5-1. Unlawful acts.**

18 (a) It is unlawful for any person to practice or offer to
19 practice pharmacist care or practice or offer to assist in the
20 practice of pharmacist care in this state without a license or
21 registration, issued under the provisions of this article, or
22 advertise or use any title or description tending to convey or give
23 the impression that they are a pharmacist or pharmacy technician,
24 unless the person is licensed or registered under the provisions of
25 this article.

1 (b) A business entity may not render any service or engage in
2 any activity which, if rendered or engaged in by an individual,
3 would constitute the practice of pharmacist care, except through a
4 licensee.

5 (c) It is unlawful for the proprietor of a pharmacy or a
6 ambulatory health care facility to permit any person not a licensed
7 pharmacist to practice pharmacist care, Provided, That a charitable
8 clinic pharmacy may permit a licensed practitioner to act in place
9 of the pharmacist when no pharmacist is present in the charitable
10 clinic.

11 **§30-5-2. Applicable law.**

12 The practices authorized under the provisions of this article
13 and the Board of Pharmacy are subject to article one of this
14 chapter, the provisions of this article, and any rules promulgated
15 hereunder.

16 **§30-5-3. Definitions.**

17 The following words and phrases have the following meaning:

18 (1) "Ambulatory health care facility" as defined in section
19 one, article five-b, chapter sixteen of this code, that has a
20 pharmacy, offers pharmacist care, or is otherwise engaged in the
21 practice of pharmacist care.

22 (2) "Active Ingredients" means chemicals, substances, or other
23 components of articles intended for use in the diagnosis, cure,
24 mitigation, treatment, or prevention of diseases in humans or
25 animals or for use as nutritional supplements.

26 (3) "Administer" means the direct application of a drug to the

1 body of a patient or research subject by injection, inhalation,
2 ingestion or any other means.

3 (4) "Board" means the West Virginia Board of Pharmacy.

4 (5) "Board authorization" means a license, registration or
5 permit issued under this article.

6 (6) "Brand name" means the proprietary or trade name selected
7 by the manufacturer and placed upon a drug or drug product, its
8 container, label or wrapping at the time of packaging.

9 (7) "Cash Retail Sales Price" means the price paid by the
10 consumer which is not affected by contractual governmental or
11 private third party payors.

12 (8) "Chain Pharmacy Warehouse" means a permanent physical
13 location for drugs and/or devices that acts as a central warehouse
14 and performs intracompany sales and transfers of prescription drugs
15 or devices to chain pharmacies, which are members of the same
16 affiliated group, under common ownership and control.

17 (9) "Charitable clinic pharmacy" means a clinic or facility
18 organized as a not-for-profit corporation that has a pharmacy,
19 offers pharmacist care, or is otherwise engaged in the practice of
20 pharmacist care and dispenses its prescriptions free of charge to
21 appropriately screened and qualified indigent patients.

22 (10) "Collaborative pharmacy practice" is that practice of
23 pharmacist care where one or more pharmacists have jointly agreed,
24 on a voluntary basis, to work in conjunction with one or more
25 physicians under written protocol where the pharmacist or
26 pharmacists may perform certain patient care functions authorized

1 by the physician or physicians under certain specified conditions
2 and limitations.

3 (11) "Collaborative pharmacy practice agreement" is a written
4 and signed agreement between a pharmacist, a physician and the
5 individual patient, or the patient's authorized representative who
6 has granted his or her informed consent, that provides for
7 collaborative pharmacy practice for the purpose of drug therapy
8 management of a patient, which has been approved by the board, the
9 Board of Medicine in the case of an allopathic physician or the
10 West Virginia Board of Osteopathy in the case of an osteopathic
11 physician.

12 (12) "Common Carrier" means any person or entity who
13 undertakes, whether directly or by any other arrangement, to
14 transport property including prescription drugs for compensation.

15 (13) "Component" means any active ingredient or added
16 substance intended for use in the compounding of a drug product,
17 including those that may not appear in such product.

18 (14) "Confidential information" means information maintained
19 by the pharmacist in the patient record or which is communicated to
20 the patient as part of patient counseling or which is communicated
21 by the patient to the pharmacist. This information is privileged
22 and may be released only to the patient or to other members of the
23 health care team and other pharmacists where, in the pharmacists'
24 professional judgment, the release is necessary to the patient's
25 health and well-being; to health plans, as that term is defined in
26 45 CFR §160.103, for payment; to other persons or governmental

1 agencies authorized by law to receive the privileged information;
2 as necessary for the limited purpose of peer review and utilization
3 review; as authorized by the patient or required by court order.

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

7 (16) "Device" means an instrument, apparatus, implement or
8 machine, contrivance, implant or other similar or related article,
9 including any component part or accessory, which is required under
10 federal law to bear the label, "Caution: Federal or state law
11 requires dispensing by or on the order of a physician."

12 (17) "Digital Signature" means an electronic signature based
13 upon cryptographic methods of originator authentication, and
14 computed by using a set of rules and a set of parameters so that
15 the identity of the signer and the integrity of the data can be
16 verified.

17 (18) "Dispense" or "dispensing" means the interpretation,
18 evaluation, and implementation of a prescription drug order,
19 including the preparation, verification and delivery of a drug or
20 device to a patient or patient's agent in a suitable container
21 appropriately labeled for subsequent administration to, or use by,
22 a patient.

23 (19) "Distribute" or "Distribution" means to sell, offer to
24 sell, deliver, offer to deliver, broker, give away, or transfer a
25 drug, whether by passage of title, physical movement, or both. The
26 term does not include:

1 (A) To dispense or administer;

2 (B) (i) Delivering or offering to deliver a drug by a common
3 carrier in the usual course of business as a common carrier; or
4 providing a drug sample to a patient by a practitioner licensed to
5 prescribe such drug;

6 (ii) A health care professional acting at the direction and
7 under the supervision of a practitioner; or the pharmacy of a
8 hospital or of another health care entity that is acting at the
9 direction of such a practitioner and that received such sample in
10 accordance with the Prescription Drug Marketing Act and regulations
11 to administer or dispense.

12 (20) "Drop shipment" means the sale of a prescription drug to
13 a wholesale distributor by the manufacturer of the prescription
14 drug or by that manufacturer's co-licensed product partner, that
15 manufacturer's third party logistics provider, that manufacturer's
16 exclusive distributor, or by an authorized distributor of record
17 that purchased the product directly from the manufacturer or from
18 one of these entities whereby:

19 (A) The wholesale distributor takes title to but not physical
20 possession of such prescription drug;

21 (B) The wholesale distributor invoices the pharmacy, pharmacy
22 warehouse, or other person authorized by law to dispense or
23 administer such drug; and

24 (C) The pharmacy, pharmacy warehouse or other person authorized
25 by law to dispense or administer such drug receives delivery of the
26 prescription drug directly from the manufacturer or from that

1 manufacturer's co-licensed product partner, that manufacturer's
2 third party logistics provider, that manufacturer's exclusive
3 distributor, or from an authorized distributor of record that
4 purchased the product directly from the manufacturer or from one of
5 these entities.

6 (21) "Drug" means:

7 (A) Articles recognized as drugs by the United States Food and
8 Drug Administration, or in any official compendium, or supplement
9 thereto, designated by the board for use in the diagnosis, cure,
10 mitigation, treatment, or prevention of disease in humans or other
11 animals;

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

15 (C) Articles intended for use as a component of any articles
16 specified in paragraph (A) or (B) of this subdivision.

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

19 (A) Evaluation of the prescription drug orders and patient
20 records for:

21 (i) Known allergies;

22 (ii) Rational therapy-contraindications;

23 (iii) Reasonable dose and route of administration; and

24 (iv) Reasonable directions for use.

25 (B) Evaluation of the prescription drug orders and patient
26 records for duplication of therapy.

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

- 4 (i) Drug-drug;
- 5 (ii) Drug-food;
- 6 (iii) Drug-disease; and
- 7 (iv) Adverse drug reactions.

8 (D) Evaluation of the prescription drug orders and patient
9 records for proper use, including overuse and underuse and optimum
10 therapeutic outcomes.

11 (E) All drug regimen review activities according to
12 subdivision (22).

13 (23) "Drug therapy management" means the review of drug
14 therapy regimens of patients by a pharmacist for the purpose of
15 evaluating and rendering advice to a physician regarding adjustment
16 of the regimen in accordance with the collaborative pharmacy
17 practice agreement. Decisions involving drug therapy management
18 shall be made in the best interest of the patient. Drug therapy
19 management shall be limited to:

20 (A) Implementing, modifying and managing drug therapy
21 according to the terms of the collaborative pharmacy practice
22 agreement;

23 (B) Collecting and reviewing patient histories;

24 (C) Obtaining and checking vital signs, including pulse,
25 temperature, blood pressure and respiration;

26 (D) Ordering screening laboratory tests that are dose related

1 and specific to the patient's medication or are protocol driven and
2 are also specifically set out in the collaborative pharmacy
3 practice agreement between the pharmacist and physician.

4 (24) "Electronic data intermediary" means an entity that
5 provides the infrastructure to connect a computer system, hand-held
6 electronic device or other electronic device used by a prescribing
7 practitioner with a computer system or other electronic device used
8 by a pharmacy to facilitate the secure transmission of:

9 (A) An electronic prescription order;

10 (B) A refill authorization request;

11 (C) A communication; or

12 (D) Other patient care information.

13 (25) "E-prescribing" means the transmission, using electronic
14 media, of prescription or prescription-related information between
15 a practitioner, pharmacist, pharmacy benefit manager or health plan
16 as defined in 45 CFR §160.103, either directly or through an
17 electronic data intermediary. E-prescribing includes, but is not
18 limited to, two-way transmissions between the point of care and the
19 pharmacist. E-prescribing may also be referenced by the terms
20 "electronic prescription" or "electronic order".

21 (26) "Electronic Signature" means an electronic sound, symbol,
22 or process attached to or logically associated with a record and
23 executed or adopted by a person with the intent to sign the record.

24 (27) "Electronic transmission" means transmission of
25 information in electronic form or the transmission of the exact
26 visual image of a document by way of electronic equipment.

1 (28) "Emergency medical reasons" include, but are not limited
2 to, transfers of a prescription drug by one pharmacy to another
3 pharmacy to alleviate a temporary shortage of a prescription drug;
4 sales to nearby emergency medical services, i.e., ambulance
5 companies and firefighting organizations in the same state or same
6 marketing or service area, or nearby licensed practitioners of
7 prescription drugs for use in the treatment of acutely ill or
8 injured persons; and provision of minimal emergency supplies of
9 prescription drugs to nearby nursing homes for use in emergencies
10 or during hours of the day when necessary prescription drugs cannot
11 be obtained.

12 (29) "Equivalent drug product" means a drug product which has
13 the same established name, active ingredient(s), strength or
14 concentration, dosage form, and route of administration and which
15 is formulated to contain the same amount of active ingredient(s) in
16 the same dosage form and to meet the same compendial or other
17 applicable standards (e.g., strength, quality, purity, and
18 identity) and is approved by the United States Food and Drug
19 Administration, but which may differ in characteristics, such as
20 shape, scoring, configuration, packaging, excipients (including
21 colors, flavors, and preservatives), and expiration time.

22 (30) "Exclusive distributor" means an entity that:

23 (A) Contracts with a manufacturer to provide or coordinate
24 warehousing, wholesale distribution, or other services on behalf of
25 a manufacturer and who takes title to that manufacturer's
26 prescription drug, but who does not have general responsibility to

1 direct the sale or disposition of the manufacturer's prescription
2 drug; and

3 (B) Is licensed as a wholesale distributor under this chapter.

4 (31) "FDA" means the Food and Drug Administration, a federal
5 agency within the United States Department of Health and Human
6 Services.

7 (32) "Generic name" means the official title of a drug or drug
8 combination for which a new drug application, or an abbreviated new
9 drug application, has been approved by the FDA.

10 (33) "Health care entity" means any person that provides
11 diagnostic, medical, community pharmacies, surgical, dental
12 treatment, or rehabilitative care but does not include any retail
13 pharmacy or wholesale distributor.

14 (34) "Health information" means any information, whether oral
15 or recorded in any form or medium, that:

16 (A) Is created or received by a health care provider, health
17 plan, public health authority, employer, life insurer, school or
18 university, or health care clearinghouse, and

19 (B) Relates to the past, present, or future physical or mental
20 health or condition of an individual; or the past, present, or
21 future payment for the provision of health care to an individual.

22 (35) "HIPAA" is the federal Health Insurance Portability and
23 Accountability Act of 1996 (Public Law 104-191).

24 (36) "Immediate container" means a container and does not
25 include package liners.

26 (37) "Individually identifiable health information" is

1 information that is a subset of health information, including
2 demographic information collected from an individual and is created
3 or received by a health care provider, health plan, employer, or
4 health care clearinghouse; and relates to the past, present, or
5 future physical or mental health or condition of an individual; the
6 provision of health care to an individual; or the past, present, or
7 future payment for the provision of health care to an individual;
8 and that identifies the individual; or with respect to which there
9 is a reasonable basis to believe the information can be used to
10 identify the individual.

11 (38) "Intracompany transaction" means any transaction between
12 a division, subsidiary, parent, and/or affiliated or related
13 company under the common ownership and control of a corporate or
14 other legal business entity.

15 (39) "Label" means a display of written, printed, or graphic
16 matter upon the immediate container of any drug or device.

17 (40) "Labeling" means the process of preparing and affixing a
18 label to a drug container exclusive, however, of a labeling by a
19 manufacturer, packer or distributor of a nonprescription drug or
20 commercially packaged legend drug or device.

21 (41) "Long-Term care facility" means a nursing home,
22 retirement care, mental care, or other facility or institution that
23 provides extended health care to resident patients.

24 (42) "Mail-order pharmacy" means a pharmacy, regardless of its
25 location, which dispenses greater than twenty-five percent
26 prescription drugs via the mail or other delivery services.

1 (43) "Manufacturer" means a person engaged in the manufacture
2 of drugs or devices.

3 (44) "Manufacturing" means the production, preparation,
4 propagation or processing of a drug or device, either directly or
5 indirectly, by extraction from substances of natural origin or
6 independently by means of chemical or biological synthesis and
7 includes any packaging or repackaging of the substance or
8 substances or labeling or relabeling of its contents and the
9 promotion and marketing of the drugs or devices. Manufacturing
10 also includes the preparation and promotion of commercially
11 available products from bulk compounds for resale by pharmacies,
12 practitioners or other persons.

13 (45) "Medical order" means a lawful order of a practitioner
14 that may or may not include a prescription drug order.

15 (46) "Medication therapy management" is a distinct service or
16 group of services that optimize therapeutic outcomes for individual
17 patients. Medication therapy management services are independent
18 of, but can occur in conjunction with, the provision of a
19 medication or a medical device. Medication therapy management
20 encompasses a broad range of professional activities and
21 responsibilities within the licensed pharmacist's scope of
22 practice. These services may include, but are not limited to, the
23 following, according to the individual needs of the patient:

24 (A) Performing or obtaining necessary assessments of the
25 patient's health status;

26 (B) Formulating a medication treatment plan;

1 (C) Selecting, initiating, modifying, or administering
2 medication therapy;

3 (D) Monitoring and evaluating the patient's response to
4 therapy, including safety and effectiveness;

5 (E) Performing a comprehensive medication review to identify,
6 resolve, and prevent medication-related problems, including adverse
7 drug events;

8 (F) Documenting the care delivered and communicating essential
9 information to the patient's primary care providers;

10 (G) Providing verbal education and training designed to
11 enhance patient understanding and appropriate use of his or her
12 medications;

13 (H) Providing information, support services and resources
14 designed to enhance patient adherence with his or her therapeutic
15 regimens;

16 (I) Coordinating and integrating medication therapy management
17 services within the broader health care management services being
18 provided to the patient; and

19 (J) Such other patient care services as may be allowed by law.

20 (47) "Misbranded" means a drug or device that has a label that
21 is false or misleading in any particular; or the label does not
22 bear the name and address of the manufacturer, packer, or
23 distributor and does not have an accurate statement of the
24 quantities of the active ingredients in the case of a drug; or the
25 label does not show an accurate monograph for prescription drugs.

26 (48) "Nonprescription drug" means a drug which may be sold

1 without a prescription and which is labeled for use by the consumer
2 in accordance with the requirements of the laws and rules of this
3 state and the federal government.

4 (49) "Normal distribution channel" means a chain of custody
5 for a prescription drug that goes from a manufacturer of the
6 prescription drug, the manufacturer's third-party logistics
7 provider, or the manufacturer's exclusive distributor to:

8 (A) A wholesale distributor to a pharmacy to a patient or
9 other designated persons authorized by law to dispense or
10 administer such prescription drug to a patient;

11 (B) A wholesale distributor to a chain pharmacy warehouse to
12 that chain pharmacy warehouse's intracompany pharmacy to a patient
13 or other designated persons authorized by law to dispense or
14 administer such prescription drug to a patient;

15 (C) A chain pharmacy warehouse to that chain pharmacy
16 warehouse's intracompany pharmacy to a patient or other designated
17 persons authorized by law to dispense or administer such
18 prescription drug to a patient;

19 (D) A pharmacy or to other designated persons authorized by
20 law to dispense or administer such prescription drug to a patient;
21 or

22 (E) As prescribed by the board's rules.

23 (50) "Patient counseling" means the oral communication by the
24 pharmacist of information, as defined in the rules of the board, to
25 the patient to improve therapy by aiding in the proper use of drugs
26 and devices.

1 (51) "Pedigree" means a statement or record in a written form
2 or electronic form, approved by the board, that records each
3 wholesale distribution of any given prescription drug (excluding
4 veterinary prescription drugs), which leaves the normal
5 distribution channel.

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

8 (53) "Pharmacist" means an individual currently licensed by
9 this state to engage in the practice of pharmacist care.

10 (54) "Pharmacist Care" is the provision of health care by a
11 pharmacist of medication therapy management services, with or
12 without the dispensing of drugs or devices, intended to achieve
13 outcomes related to the cure or prevention of a disease,
14 elimination or reduction of a patient's symptoms, or arresting or
15 slowing of a disease process, and as provided for in section nine.

16 (55) "Pharmacist-in-charge" means a pharmacist currently
17 licensed in this state who accepts responsibility for the operation
18 of a pharmacy in conformance with all laws and legislative rules
19 pertinent to the practice of pharmacist care and the distribution
20 of drugs and who is personally in full and actual charge of the
21 pharmacy and personnel.

22 (56) "Pharmacist's scope of practice pursuant to the
23 collaborative pharmacy practice agreement" means those duties and
24 limitations of duties placed upon the pharmacist by the
25 collaborating physician, as jointly approved by the board and the
26 Board of Medicine or the Board of Osteopathy.

1 (57) "Pharmacy" means any place within this state where drugs
2 are dispensed and pharmacist care is provided and any place outside
3 of this state where drugs are dispensed and pharmacist care is
4 provided to residents of this state.

5 (58) "Pharmacy Intern" or "Intern" means an individual who is
6 currently licensed to engage in the practice of pharmacist care
7 while under the supervision of a pharmacist.

8 (59) "Pharmacy Technician" means s person registered with the
9 board to practice certain tasks related to the practice of
10 pharmacist care as permitted by the board.

11 (60) "Physician" means an individual currently licensed, in
12 good standing and without restrictions, as an allopathic physician
13 by the West Virginia Board of Medicine or an osteopathic physician
14 by the West Virginia Board of Osteopathy.

15 (61) "Practice of telepharmacy" means the provision of
16 pharmacist care by properly licensed pharmacists located within
17 United States jurisdictions through the use of telecommunications
18 or other technologies to patients or their agents at a different
19 location that are located within United States jurisdictions.

20 (62) "Practitioner" means an individual authorized by a
21 jurisdiction of the United States to prescribe drugs in the course
22 of professional practices, as allowed by law.

23 (63) "Prescription drug" or "legend drug" means a drug which,
24 under federal law, is required to be labeled with either of the
25 following statements prior to being dispensed and delivered:

26 (A) "Rx Only"; or

1 (B) "Caution: Federal law prohibits dispensing without
2 prescription"; or

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

8 (64) "Prescription or prescription drug order" means a lawful
9 order from a practitioner for a drug or device for a specific
10 patient, including orders derived from collaborative pharmacy
11 practice, where a valid patient-practitioner relationship exists,
12 that is communicated to a pharmacist in a pharmacy.

13 (65) "Primary care" is the first level of contact of
14 individuals, the family, and the community with the health care
15 delivery system, bringing health care as close as possible to where
16 people live and work, and constitutes the first element of a
17 continuing health care process. (Areas of primary care where
18 pharmacists provide pharmacist care include, but are not limited
19 to, the following: chronic disease management; smoking cessation;
20 maternal and child health; immunizations; family planning;
21 self-care consulting; Drug selection under protocol; treatment of
22 common diseases and injuries; nutrition; and general health
23 education and promotion.

24 (66) "Product Labeling" means all labels and other written,
25 printed, or graphic matter upon any article or any of its
26 containers or wrappers, or accompanying such article.

1 (67) "Repackage" means changing the container, wrapper,
2 quantity, or product labeling of a drug or device to further the
3 distribution of the drug or device.

4 (68) "Repackager" means a person who repackages.

5 (69) "Substitute" means to dispense without the prescriber's
6 express authorization a therapeutically equivalent generic drug
7 product in the place of the drug ordered or prescribed.

8 (70) "Therapeutic equivalence" mean drug products classified
9 as therapeutically equivalent can be substituted with the full
10 expectation that the substituted product will produce the same
11 clinical effect and safety profile as the prescribed product which
12 contain the same active ingredient(s); dosage form and route of
13 administration; and strength.

14 (71) "Third-Party logistics provider" means an entity that:

15 (A) Provides or coordinates warehousing, distribution, or
16 other services on behalf of a manufacturer, but does not take title
17 to the prescription drug or have general responsibility to direct
18 the prescription drug's sale or disposition; and

19 (B) Is licensed as a wholesale distributor under this article.

20 (72) "Valid patient-practitioner relationship" means the
21 following have been established:

22 (A) A patient has a medical complaint;

23 (B) A medical history has been taken;

24 (C) A face-to-face physical examination adequate to establish
25 the medical complaint has been performed by the prescribing
26 practitioner or in the instances of telemedicine through

1 telemedicine practice approved by the appropriate practitioner
2 board; and

3 (D) Some logical connection exists between the medical
4 complaint, the medical history, and the physical examination and
5 the drug prescribed.

6 (73) "Wholesale Distribution" means the distribution of
7 prescription drugs or devices by wholesale distributors to persons
8 other than consumers or patients, and includes the transfer of
9 prescription drugs by a pharmacy to another pharmacy if the value
10 of the goods transferred exceeds 5% of total prescription drug
11 sales revenue of either the transferor or transferee pharmacy
12 during any consecutive 12 month period. Wholesale distribution does
13 not include:

14 (A) The sale, purchase, or trade of a prescription drug or
15 device, an offer to sell, purchase, or trade a prescription drug or
16 device, or the dispensing of a prescription drug or device pursuant
17 to a prescription;

18 (B) The sale, purchase, or trade of a prescription drug or
19 device or an offer to sell, purchase, or trade a prescription drug
20 or device for emergency medical reasons;

21 (C) Intracompany transactions, unless in violation of own use
22 provisions;

23 (D) The sale, purchase, or trade of a prescription drug or
24 device or an offer to sell, purchase, or trade a prescription drug
25 or device among hospitals, chain pharmacy warehouses, pharmacies,
26 or other health care entities that are under common control;

1 (E) The sale, purchase, or trade of a prescription drug or
2 device or the offer to sell, purchase, or trade a prescription drug
3 or device by a charitable organization described in 503(c)(3) of
4 the Internal Revenue Code of 1954 to a nonprofit affiliate of the
5 organization to the extent otherwise permitted by law;

6 (F) The purchase or other acquisition by a hospital or other
7 similar health care entity that is a member of a group purchasing
8 organization of a prescription drug or device for its own use from
9 the group purchasing organization or from other hospitals or
10 similar health care entities that are members of these
11 organizations;

12 (G) The sale, purchase, or trade of blood and blood components
13 intended for transfusion;

14 (H) The return of recalled, expired, damaged, or otherwise
15 non-salable prescription drugs, when conducted by a hospital,
16 health care entity, pharmacy, or charitable institution in
17 accordance with the board's rules; or

18 (I) The sale, transfer, merger, or consolidation of all or
19 part of the business of a pharmacy or pharmacies from or with
20 another pharmacy or pharmacies, whether accomplished as a purchase
21 and sale of stock or business assets, in accordance with the
22 board's legislative rules.

23 (74) "Wholesale distributor" means a person engaged in
24 wholesale distribution of drugs, including, but not limited to,
25 manufacturers' and distributors' warehouses, chain drug warehouses
26 and wholesale drug warehouses, independent wholesale drug trader

1 and retail pharmacies that conduct wholesale distributions.

2 **§30-5-4. West Virginia Board of Pharmacy.**

3 (a) The West Virginia Board of Pharmacy is continued. The
4 members of the board in office on July 1, 2011, shall, unless
5 sooner removed, continue to serve until their respective terms
6 expire and until their successors have been appointed and
7 qualified.

8 (b) The Governor, by and with the advice and consent of the
9 Senate, shall appoint:

10 (1) Five members who are licensed to practice pharmacist care
11 in this state; and,

12 (2) Two citizen members, who are not licensed under the
13 provisions of this article, and who do not perform any services
14 related to the practice of the pharmacist care regulated under the
15 provisions of this article.

16 (c) After the initial appointment term, the appointment term
17 is five years. A member may not serve more than two consecutive
18 terms. A member who has served two consecutive full terms may not
19 be reappointed for at least one year after completion of his or her
20 second full term. A member may continue to serve until his or her
21 successor has been appointed and qualified.

22 (d) Each licensed member of the board, at the time of his or
23 her appointment, must have held a license in this state for a
24 period of not less than three years immediately preceding the
25 appointment.

26 (e) Each member of the board must be a resident of this state

1 during the appointment term.

2 (f) A vacancy on the board shall be filled by appointment by
3 the Governor for the unexpired term of the member whose office is
4 vacant.

5 (g) The Governor may remove any member from the board for
6 neglect of duty, incompetency or official misconduct.

7 (h) A licensed member of the board immediately and
8 automatically forfeits membership to the board if his or her
9 license to practice is suspended or revoked in any jurisdiction.

10 (i) A member of the board immediately and automatically
11 forfeits membership to the board if he or she is convicted of a
12 felony under the laws of any jurisdiction or becomes a nonresident
13 of this state.

14 (j) The board shall elect annually one of its members as
15 president, one member as vice-president and one member as treasurer
16 who shall serve at the will and pleasure of the board.

17 (k) Each member of the board is entitled to receive
18 compensation and expense reimbursement in accordance with article
19 one of this chapter.

20 (l) A simple majority of the membership serving on the board
21 at a given time is a quorum for the transaction of business.

22 (m) The board shall hold at least two meetings annually.
23 Other meetings shall be held at the call of the chairperson or upon
24 the written request of three members, at the time and place as
25 designated in the call or request.

26 (n) Prior to commencing his or her duties as a member of the

1 board, each member shall take and subscribe to the oath required by
2 section five, article four of the Constitution of this state.

3 (o) The members of the board when acting in good faith and
4 without malice shall enjoy immunity from individual civil liability
5 while acting within the scope of their duties as board members.

6 **§30-5-5. Powers and duties of the board.**

7 The board has all the powers and duties set forth in this
8 article, by rule, in article one of this chapter and elsewhere in
9 law, including:

10 (1) Hold meetings;

11 (2) Establish additional requirements for a license, permit
12 and registration;

13 (3) Establish procedures for submitting, approving and
14 rejecting applications for a license, permit and registration;

15 (4) Determine the qualifications of any applicant for a
16 license, permit and registration;

17 (5) Establish the fees charged under the provisions of this
18 article;

19 (6) Issue, renew, deny, suspend, revoke or reinstate a
20 license, permit, and registration;

21 (7) Prepare, conduct, administer and grade written, oral or
22 written and oral examinations for a license and registration;

23 (9) Contract with third parties to administer the examinations
24 required under the provisions of this article;

25 (10) Maintain records of the examinations the board or a third
26 party administers, including the number of persons taking the

1 examination and the pass and fail rate;
2 (11) Maintain an office, and hire, discharge, establish the
3 job requirements and fix the compensation of employees and contract
4 with persons necessary to enforce the provisions of this article.
5 Inspectors shall be licensed pharmacists;
6 (12) Investigate alleged violations of the provisions of this
7 article, legislative rules, orders and final decisions of the
8 board;
9 (13) Conduct disciplinary hearings of persons regulated by the
10 board;
11 (14) Determine disciplinary action and issue orders;
12 (15) Institute appropriate legal action for the enforcement of
13 the provisions of this article;
14 (16) Maintain an accurate registry of names and addresses of
15 all persons regulated by the board;
16 (17) Keep accurate and complete records of its proceedings,
17 and certify the same as may be necessary and appropriate;
18 (18) Propose rules in accordance with the provisions of
19 article three, chapter twenty-nine-a of this code to implement the
20 provisions of this article;
21 (19) Sue and be sued in its official name as an agency of this
22 state;
23 (20) Confer with the Attorney General or his or her assistant
24 in connection with legal matters and questions; and
25 (21) Take all other actions necessary and proper to effectuate
26 the purposes of this article.

1 §30-5-6. Rule-making authority.

2 (a) The board shall propose rules for legislative approval, in
3 accordance with the provisions of article three, chapter twenty-
4 nine-a of this code, to implement the provisions of this article,
5 and articles two, three, eight, nine and ten of chapter sixty-A
6 including:

7 (1) Standards and requirements for a license, permit and
8 registration;

9 (2) Educational and experience requirements;

10 (3) Procedures for examinations and reexaminations;

11 (4) Requirements for third parties to prepare, administer or
12 prepare and administer examinations and reexaminations;

13 (5) The passing grade on the examination;

14 (6) Procedures for the issuance and renewal of a license,
15 permit and registration;

16 (7) A fee schedule;

17 (8) Continuing education requirements;

18 (9) Set standards for professional conduct;

19 (10) Establish equipment and facility standards for
20 pharmacies;

21 (11) Approve courses and standards for training pharmacist
22 technicians;

23 (12) Regulation of charitable clinic pharmacies;

24 (13) Regulation of mail order pharmacies;

25 (14) Agreements with organizations to form pharmacist recovery
26 networks;

1 (15) Creating an alcohol or chemical dependency treatment
2 program;

3 (16) A ratio of pharmacy technicians to on-duty pharmacist
4 operating in any outpatient, mail order or institutional pharmacy;

5 (17) Regulation of telepharmacy;

6 (18) The minimum standards for a charitable clinic pharmacy
7 and rules regarding the applicable definition of a pharmacist-in-
8 charge, who may be a volunteer, at charitable clinic pharmacies:

9 Provided, A charitable clinic pharmacy may not be charged any
10 applicable licensing fees and such clinics may receive donated
11 drugs.

12 (19) Establish standards for substituted drug products;

13 (20) Establish the regulations for E-prescribing;

14 (21) Establish the proper use of the automated data processing
15 system;

16 (22) Registration and control of the manufacture and
17 distribution of controlled substances within this state.

18 (23) Regulation of pharmacies;

19 (24) Sanitation and equipment requirements for wholesalers,
20 distributers and pharmacies.

21 (25) The procedures for denying, suspending, revoking,
22 reinstating or limiting the practice of a licensee, permittee or
23 registrant;

24 (26) Regulations on prescription paper as provided in article
25 section five article five-w, chapter sixteen;

26 (27) Regulations on controlled substances as provided in

1 article two, chapter sixty-A;

2 (28) Regulations on manufacturing, distributing, or dispensing
3 any controlled substance as provided in article three, chapter
4 sixty-A;

5 (29) Regulations on wholesale drug distribution as provided in
6 article eight, chapter sixty-A;

7 (30) Regulations on controlled substances monitoring as
8 provided in article nine, chapter sixty-A;

9 (31) Regulations on Methamphetamine Laboratory Eradication Act
10 as provided in article ten, chapter sixty-A; and

11 (32) Any other rules necessary to effectuate the provisions of
12 this article.

13 (b) The board may provide an exemption to the pharmacist-in-
14 charge requirement for the opening of a new retail pharmacy or
15 during a declared emergency;

16 (c) The board, the Board of Medicine and the Board of
17 Osteopathy shall jointly agree and propose rules concerning
18 collaborative pharmacy practice for legislative approval in
19 accordance with the provisions of article three, chapter twenty-
20 nine-a of the code;

21 (d) The Board with the advice of the Board of Medicine and the
22 Board of Osteopathy shall propose rules for legislative approval in
23 accordance with the provisions of article three, chapter twenty-
24 nine-a of this code to perform influenza and pneumonia
25 immunizations, on a person of eighteen years of age or older.

26 These rules shall provide, at a minimum, for the following:

1 (1) Establishment of a course, or provide a list of approved
2 courses, in immunization administration. The courses must be based
3 on the standards established for such courses by the Centers for
4 Disease Control and Prevention in the public health service of the
5 United States Department of Health and Human Services;

6 (2) Definitive treatment guidelines which shall include, but
7 not be limited to, appropriate observation for an adverse reaction
8 of an individual following an immunization;

9 (3) Prior to administration of immunizations, a pharmacist
10 shall have completed a board approved immunization administration
11 course and completed an American Red Cross or American Heart
12 Association basic life-support training, and maintain certification
13 in the same.

14 (4) Continuing education requirements for this area of
15 practice;

16 (5) Reporting requirements for pharmacists administering
17 immunizations to report to the primary care physician or other
18 licensed health care provider as identified by the person receiving
19 the immunization;

20 (6) Reporting requirements for pharmacists administering
21 immunizations to report to the West Virginia Statewide Immunization
22 Information (WVSII);

23 (7) That a pharmacist may not delegate the authority to
24 administer immunizations to any other person; unless administered
25 by a licensed pharmacy intern under the direct supervision of a
26 pharmacist of whom both pharmacist and intern have successfully

1 completed all board required training.

2 (8) Any other provisions necessary to implement the provisions
3 of this section.

4 (e) The board, the Board of Medicine and the Board of
5 Osteopathy shall propose joint rules for legislative approval in
6 accordance with the provisions of article three, chapter twenty-
7 nine-a of this code to permit licensed pharmacists to administer
8 other immunizations such as Hepatitis A, Hepatitis B, Herpes Zoster
9 and Tetanus. These rules shall provide, at a minimum, the same
10 provisions contained in subsection (d)(1) through (d)(8) of this
11 section

12 (f) All of the board's rules in effect on July 1, 2011, shall
13 remain in effect until they are amended, modified, repealed or
14 replaced.

15 **§30-5-7. Fees; special revenue account; administrative fines.**

16 (a) All fees and other moneys, except fines, received by the
17 board shall be deposited in a separate special revenue fund in the
18 State Treasury designated the "Board of Pharmacy Fund", which fund
19 is continued. The fund is used by the board for the administration
20 of this article. Except as may be provided in article one of this
21 chapter, the board shall retain the amounts in the special revenue
22 account from year to year. Any compensation or expense incurred
23 under this article is not a charge against the General Revenue
24 Fund.

25 (b) The board shall deposit any amounts received as
26 administrative fines imposed pursuant to this article into the

1 General Revenue Fund of the State Treasury.

2 **§30-5-8. Qualifications for licensure as pharmacist;**

3 (a) To be eligible for a license to practice pharmacist care
4 under the provisions of this article, the applicant must:

5 (1) Submit a written application to the board;

6 (2) Be eighteen years of age or older;

7 (3) Pay all applicable fees;

8 (4) Graduate from a recognized school of pharmacy;

9 (5) Complete at least fifteen hundred hours of internship in
10 a pharmacy under the instruction and supervision of a pharmacist;

11 (6) Pass an examination or examinations approved by the board;

12 (7) Not be an alcohol or drug abuser, as these terms are
13 defined in section eleven, article one-a, chapter twenty-seven of
14 this code: *Provided, That an applicant in an active recovery*
15 *process, which may, in the discretion of the board, be evidenced by*
16 *participation in a twelve-step program or other similar group or*
17 *process, may be considered;*

18 (8) Present to the board satisfactory evidence that he or she
19 is a person of good moral character, has not been convicted of a
20 felony involving controlled substances or violent crime;

21 (9) Not been convicted in any jurisdiction of a felony or any
22 crime which bears a rational nexus to the individual's ability to
23 practice pharmacist care; and

24 (10) Has fulfilled any other requirement specified by the
25 board in rule.

26 (b) An applicant from another jurisdiction shall comply with

1 all the requirements of this article.

2 **§30-5-9. Scope practice for licensed pharmacist;**

3 (a) A licensed pharmacist may:

4 (1) Provide care related to the interpretation, evaluation,
5 and implementation of medical orders;

6 (2) Dispense of prescription drug orders; participation in
7 drug and device selection;

8 (3) Provide drug administration;

9 (4) Provide drug regimen review;

10 (5) Provide drug or drug-related research;

11 (6) Perform patient counseling;

12 (7) Provide pharmacist care in all areas of patient care,
13 including collaborative pharmacy practice;

14 (8) May compound and label drugs and drug devices;

15 (9) Proper and safe storage of drugs and devices;

16 (10) Maintain of proper records;

17 (11) Provide patient counseling concerning the therapeutic
18 value and proper use of drugs and devices;

19 (12) Order laboratory tests in accordance with drug therapy
20 management and medication therapy management; and

21 (13) Medication therapy management.

22 (b) A licensee meeting the requirements as promulgated by
23 legislative rule may administer immunizations.

24 **§30-5-10. Registration of pharmacy technicians;**

25 (a) To be eligible for a registration as a pharmacy technician
26 to assist in the practice of pharmacist care, the applicant must:

- 1 (1) Submit a written application to the board;
- 2 (2) Be at least eighteen years of age;
- 3 (3) Pay the applicable fees;
- 4 (4) Have graduated from high school or obtained a Certificate
5 of General Educational Development (GED) or equivalent;
- 6 (5) Have:
- 7 (A) Graduated from a competency-based pharmacy technician
8 education and training program as approved by legislative rule of
9 the board; or
- 10 (B) Completed a pharmacy provided, competency-based education
11 and training program approved by the board;
- 12 (6) Effective July 1, 2012, have successfully passed an
13 examination developed using nationally recognized and validated
14 psychometric and pharmacy practice standards approved by the board;
- 15 (7) Not be an alcohol or drug abuser, as these terms are
16 defined in section eleven, article one-a, chapter twenty-seven of
17 this code: *Provided*, That an applicant in an active recovery
18 process, which may, in the discretion of the board, be evidenced by
19 participation in a twelve-step program or other similar group or
20 process, may be considered;
- 21 (8) Not have been convicted of a felony in any jurisdiction
22 within ten years preceding the date of application for license
23 which conviction remains unreversed;
- 24 (9) Not have been convicted of a misdemeanor or felony in any
25 jurisdiction if the offense for which he or she was convicted
26 bearing a rational nexus to the practice of pharmacist care, which

1 conviction remains unreversed; and

2 (10) Has fulfilled any other requirement specified by the
3 board in rule.

4 (b) A person whose license to practice pharmacist care has
5 been denied, revoked, suspended, or restricted for disciplinary
6 purposes in any jurisdiction is not eligible to be registered as a
7 pharmacy technician.

8 (c) A person registered to assist in the practice pharmacist
9 care issued by the board prior to July 1, 2011, shall for all
10 purposes be considered registered under this article and may renew
11 pursuant to the provisions of this article.

12 **§30-5-11. Scope practice for registered pharmacy technician;**

13 (a) A registered pharmacy technician shall, under the direct
14 supervision of the licensed pharmacist, but is not limited to,
15 perform the following:

16 (1) Assist in the dispensing process;

17 (2) Receive new written or electronic prescription drug
18 orders;

19 (3) Compound; and

20 (4) Stock of medications.

21 (b) A registered pharmacy technician may perform the following
22 under indirect supervision:

23 (1) Process medical coverage claims; and

24 (2) Cashier.

25 (c) A registered pharmacy technician may not perform the
26 following:

- 1 (1) Drug regimen review;
- 2 (2) Clinical conflict resolution;
- 3 (3) Contact a prescriber concerning prescription drug order
- 4 clarification or therapy modification;
- 5 (4) Patient counseling;
- 6 (5) Dispense process validation;
- 7 (6) Prescription transfer; and
- 8 (7) Receive new oral prescription drug orders.

9 (d) Indirect supervision of a registered pharmacy technician
10 is permitted to allow a pharmacist to take one break of no more
11 than thirty minutes during any contiguous eight hour period. The
12 pharmacist may leave the pharmacy area but may not leave the
13 building during the break. When a pharmacist is on break, a
14 pharmacy technician may continue to prepare prescriptions for the
15 pharmacist's verification. A prescription may not be delivered
16 until the pharmacist has verified the accuracy of the prescription,
17 and counseling, if required, has been provided to or refused by the
18 patient.

19 (e) A pharmacy that permits indirect supervision of pharmacy
20 technician during a pharmacist's break shall have either an
21 interactive voice response system or a voice mail system installed
22 on the pharmacy phone line in order to receive new prescription
23 orders and refill authorizations during the break.

24 (f) The pharmacy shall establish protocols that require a
25 registered pharmacy technician to interrupt the pharmacist's break
26 if an emergency arises.

1 **§30-5-12. Pharmacist interns.**

2 (a) To be eligible for a license to assist in the practice of
3 pharmacist care as a pharmacy intern, the applicant must be:

4 (1) Enrolled in a professional degree program of a school or
5 college of pharmacy that has been approved by the board, is in good
6 standing and is satisfactorily progressing toward meeting the
7 requirements for licensure as a pharmacist; or

8 (2) A graduate of an approved professional degree program of
9 a school or college of pharmacy or a graduate who has established
10 educational equivalency by obtaining a Foreign Pharmacy Graduate
11 Examination Committee Certificate, who is currently licensed by the
12 board for the purpose of obtaining practical experience as a
13 requirement for licensure as a pharmacist; or

14 (3) A qualified applicant awaiting examination for licensure
15 or meeting board requirements for re-licensure; or

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

18 **§30-5-13. Prohibiting the dispensing of prescription orders in**
19 **absence of practitioner-patient relationship.**

20 A pharmacist may not compound or dispense any prescription
21 order when he or she has knowledge that the prescription was issued
22 by a practitioner without establishing an ongoing
23 practitioner-patient relationship. An online or telephonic
24 evaluation by questionnaire is inadequate to establish an
25 appropriate practitioner-patient relationship: Provided, That this

1 prohibition does not apply:

2 (1) In a documented emergency;

3 (2) In an on-call or cross-coverage situation; or

4 (3) Where patient care is rendered in consultation with
5 another practitioner who has an ongoing relationship with the
6 patient and who has agreed to supervise the patient's treatment,
7 including the use of any prescribed medications.

8 **§30-5-14. Reciprocal licensure of pharmacists from other states or**
9 **countries.**

10 (a) The board may by reciprocity license pharmacists in this
11 state who have been authorized to practice pharmacist care in
12 another state: *Provided,* That the applicant for licensure meets
13 the requirements of the rules for reciprocity promulgated by the
14 board in accordance with the provisions of chapter twenty-nine-a of
15 this code: *Provided, however,* That reciprocity is not authorized
16 for pharmacists from another state where that state does not permit
17 reciprocity to pharmacists licensed in West Virginia.

18 (b) The board may refuse reciprocity to pharmacists from
19 another country unless the applicant qualifies under the
20 legislative rules as may be promulgated by the board for licensure
21 of foreign applicants.

22 **§30-5-15. Renewal requirements.**

23 (a) All persons regulated by this article shall annually or
24 biannually, renew his or her board authorization by completing a
25 form prescribed by the board and submitting any other information

1 required by the board.

2 (b) The board shall charge a fee for each renewal of an board
3 authorization and shall charge a late fee for any renewal not paid
4 by the due date.

5 (c) The board shall require as a condition of renewal that
6 each licensee or registrant complete continuing education.

7 (d) The board may deny an application for renewal for any
8 reason which would justify the denial of an original application.

9 (e) After July 1, 2013, a previously registered pharmacist
10 technician may renew his or her current registration without having
11 successfully completed subdivision six, subsection (a), of section
12 ten. The previously registered pharmacist may continue to renew his
13 or her registration under this provision.

14 **§30-5-16. Special volunteer pharmacist license; civil immunity for**
15 **voluntary services rendered to indigents.**

16 (a) There is a special volunteer pharmacist license for
17 pharmacists retired or retiring from the active practice of
18 pharmacist care who wish to donate their expertise for the
19 pharmacist care and treatment of indigent and needy patients in the
20 clinic setting of clinics organized, in whole or in part, for the
21 delivery of health care services without charge. The special
22 volunteer pharmacist license shall be issued by the board to
23 pharmacists licensed or otherwise eligible for licensure under this
24 article and the legislative rules promulgated hereunder without the
25 payment of an application fee, license fee or renewal fee, and the
26 initial license shall be issued for the remainder of the licensing

1 period, and renewed consistent with the boards other licensing
2 requirements. The board shall develop application forms for the
3 special license provided in this subsection which shall contain the
4 pharmacist's acknowledgment that:

5 (1) The pharmacist's practice under the special volunteer
6 pharmacist license shall be exclusively devoted to providing
7 pharmacist care to needy and indigent persons in West Virginia;

8 (2) The pharmacist may not receive any payment or
9 compensation, either direct or indirect, or have the expectation of
10 any payment or compensation, for any pharmacist care rendered under
11 the special volunteer pharmacist license;

12 (3) The pharmacist will supply any supporting documentation
13 that the board may reasonably require; and

14 (4) The pharmacist agrees to continue to participate in
15 continuing professional education as required by the board for the
16 special volunteer pharmacist license.

17 (b) Any pharmacist who renders any pharmaceutical service to
18 indigent and needy patients of a clinic organized, in whole or in
19 part, for the delivery of health care services without charge under
20 a special volunteer pharmacist license authorized under subsection
21 (a) of this section without payment or compensation or the
22 expectation or promise of payment or compensation is immune from
23 liability for any civil action arising out of any act or omission
24 resulting from the rendering of the pharmacist care at the clinic
25 unless the act or omission was the result of the pharmacist's gross
26 negligence or willful misconduct. In order for the immunity under

1 this subsection to apply, there must be a written agreement between
2 the pharmacist and the clinic pursuant to which the pharmacist
3 provides voluntary uncompensated pharmacist care under the control
4 of the clinic to patients of the clinic before the rendering of any
5 services by the pharmacist at the clinic: *Provided, That any*
6 clinic entering into such written agreement is required to maintain
7 liability coverage of not less than one million dollars per
8 occurrence.

9 (c) Notwithstanding the provisions of subsection (b) of this
10 section, a clinic organized, in whole or in part, for the delivery
11 of health care services without charge is not relieved from imputed
12 liability for the negligent acts of a pharmacist rendering
13 voluntary pharmaceutical services at or for the clinic under a
14 special volunteer pharmacist license authorized under subsection
15 (a) of this section.

16 (d) For purposes of this section, "otherwise eligible for
17 licensure" means the satisfaction of all the requirements for
18 licensure as listed in section eight of this article and in the
19 legislative rules promulgated thereunder, except the fee
20 requirements of that section and of the legislative rules
21 promulgated by the board relating to fees.

22 (e) Nothing in this section may be construed as requiring the
23 board to issue a special volunteer pharmacist license to any
24 pharmacist whose license is or has been subject to any disciplinary
25 action or to any pharmacist who has surrendered a license or caused
26 such license to lapse, expire and become invalid in lieu of having

1 a complaint initiated or other action taken against his or her
2 license, or who has elected to place a pharmacist license in
3 inactive status in lieu of having a complaint initiated or other
4 action taken against his or her license, or who has been denied a
5 pharmacist license.

6 (f) Any policy or contract of liability insurance providing
7 coverage for liability sold, issued or delivered in this state to
8 any pharmacist covered under the provisions of this article shall
9 be read so as to contain a provision or endorsement whereby the
10 company issuing such policy waives or agrees not to assert as a
11 defense on behalf of the policyholder or any beneficiary thereof,
12 to any claim covered by the terms of such policy within the policy
13 limits, the immunity from liability of the insured by reason of the
14 care and treatment of needy and indigent patients by a pharmacist
15 who holds a special volunteer pharmacist license.

16 **§30-5-17. Pharmacist requirements to participate in a collaborative**
17 **pharmacy practice agreement.**

18 For a pharmacist to participate in a collaborative pharmacy
19 practice agreement, the pharmacist shall:

20 (a) Have an unrestricted and current license to practice as a
21 pharmacist in West Virginia;

22 (b) Have at least one million dollars of professional
23 liability insurance coverage;

24 (c) Meet one of the following qualifications, at a minimum:

25 (1) Earned a Certification from the Board of Pharmaceutical
26 Specialties, is a Certified Geriatric Practitioner, or has

1 completed an American Society of Health System Pharmacists (ASHP)
2 accredited residency program, which includes two years of clinical
3 experience approved by the boards;

4 (2) Successfully completed the course of study and holds the
5 academic degree of Doctor of Pharmacy and has three years of
6 clinical experience approved by the board and has completed an
7 Accreditation Council for Pharmacy Education (ACPE) approved
8 certificate program in the area of practice covered by the
9 collaborative pharmacy practice agreement; or

10 (3) Successfully completed the course of study and hold the
11 academic degree of Bachelor of Science in Pharmacy and has five
12 years of clinical experience approved by the boards and has
13 completed two ACPE approved certificate programs with at least one
14 program in the area of practice covered by a collaborative pharmacy
15 practice agreement.

16 **§30-5-18. Collaborative pharmacy practice agreement.**

17 (a) A pharmacist engaging in collaborative pharmacy practice
18 shall have on file at his or her place of practice the
19 collaborative pharmacy practice agreement. The existence and
20 subsequent termination of the agreement and any additional
21 information the rules may require concerning the agreement,
22 including the agreement itself, shall be made available to the
23 appropriate licensing board for review upon request. The agreement
24 may allow the pharmacist, within the pharmacist's scope of practice
25 pursuant to the collaborative pharmacy practice agreement, to
26 conduct drug therapy management activities approved by the

1 collaborating physician. The collaborative pharmacy practice
2 agreement must be a voluntary process, which is a physician
3 directed approach, that is entered into between an individual
4 physician, an individual pharmacist and an individual patient or
5 the patient's authorized representative who has given informed
6 consent.

7 (b) A collaborative pharmacy practice agreement may authorize
8 a pharmacist to provide drug therapy management. In instances
9 where drug therapy is discontinued, the pharmacist shall notify the
10 treating physician of the discontinuance in the time frame and in
11 the manner established by joint legislative rules. Each protocol
12 developed, pursuant to the collaborative pharmacy practice
13 agreement, shall contain detailed direction concerning the services
14 that the pharmacists may perform for that patient. The protocol
15 shall include, but need not be limited to:

16 (1) The specific drug or drugs to be managed by the
17 pharmacist;

18 (2) The terms and conditions under which drug therapy may be
19 implemented, modified or discontinued;

20 (3) The conditions and events upon which the pharmacist is
21 required to notify the physician; and

22 (4) The laboratory tests that may be ordered in accordance
23 with drug therapy management.

24 (c) All activities performed by the pharmacist in conjunction
25 with the protocol shall be documented in the patient's medical
26 record. The pharmacists shall report at least every thirty days to

1 the physician regarding the patient's drug therapy management. The
2 collaborative pharmacy practice agreement and protocols shall be
3 available for inspection by the board, the West Virginia Board of
4 Medicine, or the West Virginia Board of Osteopathy, depending on
5 the licensing board of the participating physician. A copy of the
6 protocol shall be filed in the patient's medical record.

7 (d) Collaborative pharmacy agreements may not include the
8 management of controlled substances.

9 (e) A collaborative pharmacy practice agreement, meeting the
10 requirements herein established and in accordance with joint rules,
11 shall be allowed in the hospital setting, the nursing home setting,
12 the medical school setting and the hospital, community-based
13 pharmacy setting and ambulatory care clinics. The pharmacist shall
14 be employed by or under contract to provide services to the
15 hospital, pharmacy, nursing home or medical school, or hold a
16 faculty appointment with one of the schools of pharmacy or medicine
17 in this state.

18 (f) Nothing pertaining to collaborative pharmacy practice
19 shall be interpreted to permit a pharmacist to accept delegation of
20 a physician's authority outside the limits included in the
21 appropriate board's statute and rules.

22 **§30-5-19. Board authorizations shall be displayed.**

23 (a) The board shall prescribe the form for an board
24 authorization, and may issue a duplicate upon payment of a fee.

25 (b) Any person regulated by the article shall conspicuously
26 display his or her board authorization at his or her principal

1 business location.

2 **§30-5-20. Responsibility for quality of drugs dispensed;**
3 **exception; falsification of labels; deviation from**
4 **prescription.**

5 (a) All persons, whether licensed pharmacists or not, shall be
6 responsible for the quality of all drugs, chemicals and medicines
7 they may sell or dispense, with the exception of those sold in or
8 dispensed unchanged from the original retail package of the
9 manufacturer, in which event the manufacturer shall be responsible.

10 (b) Except as provided in section twenty-one of this article,
11 the following acts shall be prohibited:

12 (1) The falsification of any label upon the immediate
13 container, box and/or package containing a drug;

14 (2) The substitution or the dispensing of a different drug in
15 lieu of any drug prescribed in a prescription without the approval
16 of the practitioner authorizing the original prescription:
17 Provided, That this may not be construed to interfere with the art
18 of prescription compounding which does not alter the therapeutic
19 properties of the prescription or appropriate generic substitute;

20 (3) The filling or refilling of any prescription for a greater
21 quantity of any drug or drug product than that prescribed in the
22 original prescription without a written or electronic order or an
23 oral order reduced to writing, or the refilling of a prescription
24 without the verbal, written or electronic consent of the
25 practitioner authorizing the original prescription.

26 **§30-5-21. Generic drug products.**

1 (a) A pharmacist who receives a prescription for a brand name
2 drug or drug product shall substitute the least expensive
3 therapeutic equivalent generic drug or drug product based on the
4 cash retail sales price of the respective products at the time it
5 is dispensed unless otherwise required by a third party payor, the
6 patient or in the exercise of his or her professional judgment the
7 pharmacist affirmatively indicates that the least expensive
8 therapeutic equivalent drug is not suitable for the particular
9 patient: *Provided*, That no substitution may be made by the
10 pharmacist where the prescribing practitioner indicates that, in
11 his or her professional judgment, a specific brand name drug is
12 medically necessary for a particular patient.

13 (b) A written prescription order shall permit the pharmacist
14 to substitute an equivalent generic name drug or drug product
15 except where the prescribing practitioner has indicated in his or
16 her own handwriting, the words "Brand Necessary" or "Brand
17 Medically Necessary". The following sentence shall be printed on
18 the prescription form. "This prescription may be filled with a
19 generically equivalent drug product unless the words 'Brand
20 Necessary' or 'Brand Medically Necessary' are written, in the
21 practitioner's own handwriting, indicated by the prescribing
22 practitioner on this prescription form."

23 (c) A verbal prescription order shall permit the pharmacist to
24 substitute an equivalent generic name drug or drug product except
25 where the prescribing practitioner shall indicate to the pharmacist
26 that the prescription is "Brand Necessary" or "Brand Medically

1 Necessary". The pharmacist shall note the instructions on the file
2 copy of the prescription or electronic chart.

3 (d) An electronic prescription order shall permit the
4 pharmacist to substitute an equivalent generic name drug or drug
5 product except where the prescribing practitioner shall indicate to
6 the pharmacist that the prescription is "Brand Necessary" or "Brand
7 Medically Necessary". The pharmacist shall note the instructions
8 on the file copy of the prescription or electronic chart.

9 (e) No person may by trade rule, work rule, contract or in any
10 other way prohibit, restrict, limit or attempt to prohibit,
11 restrict or limit the making of a generic name drug or other
12 product substitution under the provisions of this section. No
13 employer or his or her agent may use coercion or other means to
14 interfere with the professional judgment of the pharmacist in
15 deciding which generic name drugs or drug products shall be stocked
16 or substituted: *Provided*, That this section may not be construed
17 to permit the pharmacist to generally refuse to substitute less
18 expensive therapeutically equivalent generic drugs for brand name
19 drugs and that any pharmacist so refusing shall be subject to the
20 penalties prescribed in this article.

21 (f) A pharmacist may substitute a drug pursuant to the
22 provisions of this section only if the drug is a lower cash retail
23 sales price than the prescribed drug. Where substitution is proper,
24 pursuant to this section, or where the practitioner prescribes the
25 drug by generic name, the pharmacist shall, consistent with his or
26 her professional judgment, dispense an equivalent generic drug

1 product with the lowest cash retail sales price which is available
2 in the pharmacy at the time of dispensing: *Provided*, That all
3 savings in the retail price of the prescription shall be passed on
4 to the purchaser and shall be equal to the difference between the
5 retail price of the brand name product and the customary and usual
6 price of the generic product substituted therefor: *Provided*,
7 however, That in no event shall such savings be less than the
8 difference in acquisition cost of the brand name product prescribed
9 and the acquisition cost of the substituted product.

10 (g) Each pharmacy shall maintain a record of any substitution
11 of an equivalent generic name drug product for a prescribed brand
12 name drug product on the file copy of a written, electronic or
13 verbal prescription or chart order. The record shall include the
14 manufacturer and generic name of the drug product selected.

15 (h) All drugs shall be labeled in accordance with the
16 instructions of the practitioner.

17 (i) Unless the practitioner directs otherwise, the
18 prescription label on all drugs dispensed by the pharmacist shall
19 indicate the generic name using abbreviations, if necessary, and
20 either the name of the manufacturer or packager, whichever is
21 applicable in the pharmacist's discretion. The same notation will
22 be made on the original prescription retained by the pharmacist.

23 (j) A pharmacist may not dispense a product under the
24 provisions of this section unless the manufacturer has shown that
25 the drug has been manufactured with the following minimum good
26 manufacturing standards and practices by:

1 (1) Labeling products with the name of the original
2 manufacturer and control number;

3 (2) Maintaining quality control standards equal to or greater
4 than those of the FDA;

5 (3) Marking products with identification code or monogram; and

6 (4) Labeling products with an expiration date.

7 (k) A pharmacist may not substitute a generic-named
8 therapeutically equivalent drug product for a prescribed brand name
9 drug product if the brand name drug product or the generic drug
10 type is listed on the formulary established by the board pursuant
11 to this article or is found to be in violation of the requirements
12 of the FDA.

13 (l) A pharmacist who substitutes any drug shall, either
14 personally or through his or her agent, assistant or employee,
15 notify the person presenting the prescription of the substitution.
16 The person presenting the prescription shall have the right to
17 refuse the substitution. Upon request the pharmacist shall relate
18 the cash retail sales price difference between the brand name and
19 the drug substituted for it.

20 (m) A pharmacist complying with the provisions of this section
21 may not be liable in any way for the dispensing of a generic-named
22 therapeutically equivalent drug, substituted under the provisions
23 of this section, unless the generic-named therapeutically
24 equivalent drug was incorrectly substituted.

25 (n) In no event where the pharmacist substitutes a drug under
26 the provisions of this section shall the prescribing physician be

1 liable in any action for loss, damage, injury or death of any
2 person occasioned by or arising from the use of the substitute drug
3 unless the original drug was incorrectly prescribed.

4 (o) Failure of a practitioner to specify that a specific brand
5 name is necessary for a particular patient does not constitute
6 evidence of negligence unless the practitioner had reasonable cause
7 to believe that the health of the patient required the use of a
8 certain product and no other.

9 **§30-5-22. Pharmacies to be registered.**

10 (a) A pharmacy, an ambulatory health care facility, and a
11 charitable clinic pharmacy shall register with the board.

12 (b) A person desiring to operate, maintain, open or establish
13 a pharmacy shall register with the board.

14 (c) To be eligible for a registration to operate, maintain,
15 open or establish a pharmacy the applicant shall:

16 (1) Submit a written application to the board;

17 (2) Pay all applicable fees;

18 (3) Designate a pharmacist-in-charge;

19 (4) Successfully complete an inspection by the board;

20 (d) A separate application shall be made and separate permits
21 issued for each location.

22 (e) Permits are not transferable.

23 (f) Permits expire and shall be renewed annually.

24 (g) If a permit expires, the pharmacy shall be reinspected and
25 an inspection fee is required.

26 (h) A registrant shall employ a pharmacist-in-charge and

1 operate in compliance with the legislative rules governing the
2 practice of pharmacist care and the operation of a pharmacy.

3 (i) The provisions of this section do not apply to the sale of
4 nonprescription drugs which are not required to be dispensed
5 pursuant to a practitioner's prescription.

6 **§30-5-23. Pharmacist-in-charge.**

7 (a) A pharmacy shall be under the direction and supervision of
8 a licensed pharmacist who shall be designated by the owner of the
9 pharmacy as the pharmacist-in-charge. This designation shall be
10 filed with the board within thirty days of the designation.

11 (b) The pharmacist-in-charge is responsible for the pharmacy's
12 compliance with state and federal pharmacy laws and regulations and
13 for maintaining records and inventory.

14 (c) A pharmacist-in-charge may not hold the designated
15 position at more than one pharmacy, whether within or outside the
16 state, except as provided in legislative rule.

17 (d) An interim pharmacist-in-charge may be designated for a
18 period not to exceed sixty days. The request for an interim
19 pharmacist-in-charge shall detail the circumstances which warrant
20 the change. This change in designation shall be filed with the
21 board within thirty days of the designation.

22 **§30-5-24. Permits for mail-order pharmacy.**

23 (a) A mail-order pharmacy which dispenses drugs shall register
24 with the board.

25 (b) A mail-order pharmacy shall submit an application for a
26 permit to the board. The application shall require the following

1 information:

2 (1) The owner of the mail-order pharmacy, whether an
3 individual, a partnership, or a corporation.

4 (2) The names and titles of all individual owners, partners or
5 corporate officers.

6 (3) The pharmacy manager.

7 (4) The pharmacist-in-charge.

8 (5) The complete address, telephone number and fax number of
9 the mail-order pharmacy.

10 (c) This section does not apply to any mail-order pharmacy
11 which operates solely as a wholesale distributor.

12 **§30-5-25. Permit for manufacture and packaging of drugs,**
13 **medicines, distribution of legend drugs.**

14 (a) Drugs may not be manufactured, made, produced, packed,
15 packaged or prepared within the state, except under the personal
16 supervision of a pharmacist or other qualified person as may be
17 approved by the board;

18 (b) A person may not manufacture, package or prepare a drug
19 without obtaining a permit from the board.

20 (c) A person, who offers for sale, sells, offers for sale
21 through the method of distribution any legend drugs is subject to
22 this article.

23 (d) The application for a permit shall be made on a form to be
24 prescribed and furnished by the board and shall be accompanied by
25 an application fee.

26 (e) The board shall promulgate rules on permit requirements

1 and sanitation requirements.

2 (f) Separate applications shall be made and separate permits
3 issued for each place of manufacture, distribution, making,
4 producing, packing, packaging or preparation.

5 **§30-5-26. Filling of prescriptions more than one year after**
6 **issuance.**

7 A prescription order may not be dispensed after twelve months
8 from the date of issuance by the practitioner. A pharmacist may
9 fill the prescription after twelve months if the prescriber
10 confirms to the pharmacist that he or she still wants the
11 prescription filled and the pharmacist documents upon the
12 prescription that the confirmation was obtained.

13 **§30-5-27. Partial filling of prescriptions.**

14 (a) The partial filling of a prescription is permissible for
15 any prescription if the pharmacist is unable to supply, or the
16 patient requests less than the full quantity called for in a
17 written, electronic, or oral prescription, provided the pharmacist
18 makes a notation of the quantity supplied on either the written
19 prescription or in the electronic record.

20 (b) The partial filling of a prescription for a controlled
21 substance listed in Schedule II is permissible if the pharmacist is
22 unable to supply or the patient requests less than the full
23 quantity called for in the prescription. The remaining portion of
24 the prescription may be filled within seventy-two hours of the
25 first partial filling: *Provided*, That if the remaining portion is
26 not or cannot be filled within the seventy-two hour period, the

1 pharmacist shall notify the prescribing individual practitioner.
2 Further quantity may not be supplied beyond seventy-two hours
3 without a new prescription.

4 **§30-5-28. Partial filling of prescriptions for long-term care**
5 **facility or terminally ill patients; requirements; records;**
6 **violations.**

7 (a) As used in this section, "long-term care facility" or
8 "LTCF" means any nursing home, personal care home, or residential
9 board and care home as defined in section two, article five-c,
10 chapter sixteen of this code which provides extended health care to
11 resident patients: *Provided*, That the care or treatment in a
12 household, whether for compensation or not, of any person related
13 by blood or marriage, within the degree of consanguinity of second
14 cousin to the head of the household, or his or her spouse, may not
15 be deemed to constitute a nursing home, personal care home or
16 residential board and care home within the meaning of this article.
17 This section does not apply to:

18 (1) Hospitals, as defined under section one, article five-b,
19 chapter sixteen of this article or to extended care facilities
20 operated in conjunction with a hospital;

21 (2) State institutions as defined in section six, article one,
22 chapter twenty-seven or in section three, article one, chapter
23 twenty-five, all of this code;

24 (3) Nursing homes operated by the federal government;

25 (4) Facilities owned or operated by the state government;

26 (5) Institutions operated for the treatment and care of

1 alcoholic patients;

2 (6) Offices of physicians; or

3 (7) Hotels, boarding homes or other similar places that
4 furnish to their guests only a room and board.

5 (b) As used in this section, "terminally ill" means that an
6 individual has a medical prognosis that his or her life expectancy
7 is six months or less.

8 (c) Schedule II prescriptions for patients in a LTCF and for
9 terminally ill patients shall be valid for a period of sixty days
10 from the date of issue unless terminated within a shorter period by
11 the discontinuance of the medication.

12 (d) A prescription for a Schedule II controlled substance
13 written for a patient in a LTCF or for a terminally ill patient may
14 be filled in partial quantities, including, but not limited to,
15 individual dosage units. The total quantity of Schedule II
16 controlled substances dispensed in all partial filling may not
17 exceed the total quantity prescribed.

18 (1) If there is any question whether a patient may be
19 classified as having a terminal illness, the pharmacist shall
20 contact the prescribing practitioner prior to partially filling the
21 prescription.

22 (2) Both the pharmacist and the prescribing practitioner have
23 a corresponding responsibility to assure that the controlled
24 substance is for a terminally ill patient.

25 (e) The pharmacist shall record on the prescription that the
26 patient is "terminally ill" or a "LTCF patient". A prescription

1 that is partially filled and does not contain the notation
2 "terminally ill" or "LTCF patient" shall be deemed to have been
3 filled in violation of section three hundred eight, article three,
4 chapter sixty-a of this code.

5 (f) For each partial filling, the dispensing pharmacist shall
6 record on the back of the prescription, or on another appropriate
7 record which is readily retrievable, the following information:

8 (1) The date of the partial filling;

9 (2) The quantity dispensed;

10 (3) The remaining quantity authorized to be dispensed; and

11 (4) The identification of the dispensing pharmacist.

12 (g) Information pertaining to current Schedule II
13 prescriptions for terminally ill and LTCF patients may be
14 maintained in a computerized system if such a system has the
15 capability to permit either by display or printout, for each
16 patient and each medication, all of the information required by
17 this section as well as the patient's name and address, the name of
18 each medication, original prescription number, date of issue, and
19 prescribing practitioner information. The system shall also allow
20 immediate updating of the prescription record each time a partial
21 filling of the prescription is performed and immediate retrieval of
22 all information required under this section.

23 **§30-5-29. Limitations of article.**

24 (a) This article may not be construed to prevent, restrict or
25 in any manner interfere with the sale of nonnarcotic
26 nonprescription drugs which may be lawfully sold without a

1 prescription in accordance with the United States Food, Drug and
2 Cosmetic Act or the laws of this state, nor may any legislative
3 rule be adopted by the board which shall require the sale of
4 nonprescription drugs by a licensed pharmacist or in a pharmacy or
5 which shall prevent, restrict or otherwise interfere with the sale
6 or distribution of such drugs by any retail merchant. The sale or
7 distribution of nonprescription drugs may not be deemed to be
8 improperly engaging in the practice of pharmacist care.

9 (b) This article may not be construed to interfere with any
10 legally qualified practitioner of medicine, dentistry or veterinary
11 medicine, who is not the proprietor of the store for the dispensing
12 or retailing of drugs and who is not in the employ of such
13 proprietor, in the compounding of his or her own prescriptions or
14 to prevent him or her from supplying to his or her patients such
15 medicines as he or she may deem proper, if such supply is not made
16 as a sale.

17 (c) The exception provided in subsection (b) of this section
18 does not apply to an ambulatory health care facility: *Provided,*
19 That a legally licensed and qualified practitioner of medicine or
20 dentistry may supply medicines to patients that he or she treats in
21 a free clinic and that he or she deems appropriate.

22 **§30-5-30. Actions to enjoin violations.**

23 (a) If the board obtains information that any person has
24 engaged in, is engaging in or is about to engage in any act which
25 constitutes or will constitute a violation of the provisions of
26 this article, the rules promulgated pursuant to this article, or a

1 final order or decision of the board, it may issue a notice to the
2 person to cease and desist in engaging in the act and/or apply to
3 the circuit court in the county of the alleged violation for an
4 order enjoining the act.

5 (b) The circuit court may issue a temporary injunction pending
6 a decision on the merits, and may issue a permanent injunction
7 based on its findings in the case.

8 (c) The judgment of the circuit court on an application
9 permitted by the provisions of this section is final unless
10 reversed, vacated or modified on appeal to the West Virginia
11 Supreme Court of Appeals.

12 **§30-5-31. Complaints; investigations; due process procedure;**
13 **grounds for disciplinary action.**

14 (a) The board may initiate a complaint upon receipt of
15 credible information, and shall upon the receipt of a written
16 complaint of any person, cause an investigation to be made to
17 determine whether grounds exist for disciplinary action under this
18 article or the legislative rules promulgated pursuant to this
19 article.

20 (b) After reviewing any information obtained through an
21 investigation, the board shall determine if probable cause exists
22 that the licensee, registrant or permittee has violated subsection
23 (g) of this section or rules promulgated pursuant to this article.

24 (c) Upon a finding of probable cause to go forward with a
25 complaint, the board shall provide a copy of the complaint to the
26 licensee, registrant or permittee.

1 (d) Upon a finding that probable cause exists that the
2 licensee, registrant or permittee has violated subsection (g) of
3 this section or rules promulgated pursuant to this article, the
4 board may enter into a consent decree or hold a hearing for
5 disciplinary action against the licensee, registrant or permittee.
6 Any hearing shall be held in accordance with the provisions of this
7 article, and shall require a violation to be proven by a
8 preponderance of the evidence.

9 (e) Any member of the board or the executive director of the
10 board may issue subpoenas and subpoenas duces tecum to obtain
11 testimony and documents to aid in the investigation of allegations
12 against any person regulated by the article.

13 (f) Any member of the board or its executive director may sign
14 a consent decree or other legal document on behalf of the board.

15 (g) The board may, after notice and opportunity for hearing,
16 deny or refuse to renew, suspend, restrict or revoke the license,
17 registration or permit of, or impose probationary conditions upon
18 or take disciplinary action against, any licensee, registrant or
19 permittee for any of the following reasons:

20 (1) Obtaining a board authorization by fraud,
21 misrepresentation or concealment of material facts;

22 (2) Being convicted of a felony or other crime involving
23 drugs, violent crime, or moral turpitude, or engaging in any act
24 involving moral turpitude or gross immorality;

25 (3) Being guilty of unprofessional conduct which placed the
26 public at risk, as defined by legislative rule of the board;

1 (4) Intentional violation of a lawful order or legislative
2 rule of the board;

3 (5) Having had a board authorization revoked or suspended,
4 other disciplinary action taken, or an application for a board
5 authorization revoked or suspended by the proper authorities of
6 another jurisdiction;

7 (6) Aiding or abetting unlicensed practice;

8 (7) Engaging in an act while acting in a professional capacity
9 which has endangered or is likely to endanger the health, welfare
10 or safety of the public;

11 (8) Incapacity that prevents a licensee or registrant from
12 engaging in the practice of pharmacist care or assisting in the
13 practice of pharmacist care, with reasonable skill, competence, and
14 safety to the public;

15 (9) Violation of any laws, including rules pertaining thereto,
16 of this or any other jurisdiction, relating to the practice of
17 pharmacist care, drug samples, drug manufacturing, wholesale or
18 retail drug or device distribution, or controlled substances;

19 (10) Committing fraud in connection with the practice of
20 pharmacist care;

21 (11) Disciplinary action taken by another state or
22 jurisdiction against an board authorization to practice pharmacist
23 care based upon conduct by the licensee, registrant or permittee
24 similar to conduct that would constitute grounds for actions as
25 defined in this section;

26 (12) Failure to report to the board any adverse action taken

1 by another licensing jurisdiction, government agency, law
2 enforcement agency, or court for conduct that would constitute
3 grounds for action as defined in this section;

4 (13) Failure to report to the board one's surrender of a
5 license or authorization to practice pharmacist care in another
6 jurisdiction while under disciplinary investigation by any of those
7 authorities or bodies for conduct that would constitute grounds for
8 action as defined in this section;

9 (14) Failure to report to the board any adverse judgment,
10 settlement, or award arising from a malpractice claim arising
11 related to conduct that would constitute grounds for action as
12 defined in this section;

13 (15) Knowing or suspecting that a licensee or registrant is
14 incapable of engaging in the practice of pharmacist care or
15 assisting in the practice of pharmacist care, with reasonable
16 skill, competence, and safety to the public, and failing to report
17 any relevant information to the board;

18 (16) Illegal use or disclosure of protected health
19 information;

20 (17) Engaging in any conduct that subverts or attempts to
21 subvert any licensing examination or the administration of any
22 licensing examination;

23 (18) Failure to furnish to the board or its representatives
24 any information legally requested by the board, or failure to
25 cooperate with or engaging in any conduct which obstructs an
26 investigation being conducted by the board;

1 (19) Agree to participate in a legend drug product conversion
2 program promoted or offered by a manufacturer, wholesaler or
3 distributor of such product for which the pharmacist or pharmacy
4 received any form of financial remuneration, or agreed to
5 participate in a legend drug program in which the pharmacist or
6 pharmacy is promoted or offered as the exclusive provider of legend
7 drug products or whereby in any way the public is denied, limited
8 or influenced in selecting pharmaceutical service or counseling.

9 (20) Violation of any of the terms or conditions of any order
10 entered in any disciplinary action.

11 (h) For the purposes of subsection (g) of this section,
12 effective July 1, 2011, disciplinary action may include:

13 (1) Reprimand;

14 (2) Probation;

15 (3) Restrictions;

16 (4) Suspension;

17 (5) Revocation;

18 (6) Administrative fine, not to exceed \$1,000 per day per
19 violation;

20 (7) Mandatory attendance at continuing education seminars or
21 other training;

22 (8) Practicing under supervision or other restriction; or

23 (9) Requiring the licensee, registrant or permittee to report
24 to the board for periodic interviews for a specified period of
25 time.

26 (i) In addition to any other sanction imposed, the board may

1 require a licensee, registrant or permittee to pay the costs of the
2 proceeding.

3 (j) The board may defer disciplinary action with regard to an
4 impaired licensee or registrant who voluntarily signs an agreement,
5 in a form satisfactory to the board, agreeing not to practice
6 pharmacist care and to enter an approved treatment and monitoring
7 program in accordance with the board's legislative rule. This
8 subsection, provided that this section should not apply to a
9 licensee or registrant who has been convicted of, pleads guilty to,
10 or enters a plea of nolo contendere or a conviction relating to a
11 controlled substance in any jurisdiction.

12 (k) Nothing shall be construed as barring criminal
13 prosecutions for violations of this article.

14 (l) A person authorized to practice under this article, who
15 reports or otherwise provides evidence of the negligence,
16 impairment or incompetence of another member of this profession to
17 the board or to any peer review organization, is not liable to any
18 person for making such a report if such report is made without
19 actual malice and in the reasonable belief that such report is
20 warranted by the facts known to him or her at the time.

21 **§30-5-32. Procedures for hearing; right of appeal.**

22 (a) Hearings are governed by the provisions of section eight,
23 article one of this chapter.

24 (b) The board may conduct the hearing or elect to have an
25 administrative law judge conduct the hearing.

26 (c) If the hearing is conducted by an administrative law

1 judge, at the conclusion of a hearing he or she shall prepare a
2 proposed written order containing findings of fact and conclusions
3 of law. The proposed order may contain proposed disciplinary
4 actions if the board so directs. The board may accept, reject or
5 modify the decision of the administrative law judge.

6 (d) Any member or the executive director of the board has the
7 authority to administer oaths, examine any person under oath and
8 issue subpoenas and subpoenas duces tecum.

9 (e) If, after a hearing, the board determines the licensee,
10 registrant or permittee has violated provisions of this article or
11 the board's rules, a formal written decision shall be prepared
12 which contains findings of fact, conclusions of law and a specific
13 description of the disciplinary actions imposed.

14 **§30-5-33. Judicial review.**

15 Any person adversely affected by a decision of the board
16 entered after a hearing may obtain judicial review of the decision
17 in accordance with section four, article five, chapter twenty-nine-
18 a of this code, and may appeal any ruling resulting from judicial
19 review in accordance with article six, chapter twenty-nine-a of
20 this code.

21 **§30-5-34. Criminal proceedings; penalties.**

22 (a) When, as a result of an investigation under this article
23 or otherwise, the board has reason to believe that a person
24 authorized under this article has committed a criminal offense
25 under this article, the board may bring its information to the
26 attention of an appropriate law-enforcement official.

1 (b) Any person, who violates any of the provisions of this
2 article is guilty of a misdemeanor, and, upon conviction, shall be
3 fined not to exceed \$50 for the first offense, and upon conviction
4 of a second offense shall be fined not less than \$50 nor more than
5 \$500, or shall be imprisoned in the county jail not to exceed 30
6 days, or both fined and imprisoned. Each and every day that the
7 violation continues shall constitute a separate offense.

8 **CHAPTER 60A. UNIFORM CONTROLLED SUBSTANCES ACT.**

9 **ARTICLE 10. METHAMPHETAMINE LABORATORY ERADICATION ACT.**

10 **§60A-10-3. Definitions.**

11 In this article:

12 (a) "Board of Pharmacy" or "board" means the West Virginia
13 Board of Pharmacy established by the provisions of article five,
14 chapter thirty of this code.

15 (b) "Designated precursor" means any drug product made subject
16 to the requirements of this article by the provisions of section
17 seven of this article.

18 (c) "Distributor" means any person within this state or
19 another state, other than a manufacturer or wholesaler, who sells,
20 delivers, transfers or in any manner furnishes a drug product to
21 any person who is not the ultimate user or consumer of the product;

22 (d) "Drug product" means a pharmaceutical product that
23 contains as its single active ingredient ephedrine, pseudoephedrine
24 or phenylpropanolamine or a substance identified on the
25 supplemental list provided for in section seven of this article
26 which may be sold without a prescription and which is labeled for

1 use by a consumer in accordance with the requirements of the laws
2 and rules of this state and the federal government.

3 (e) "Ephedrine " means ephedrine, its salts or optical isomers
4 or salts of optical isomers.

5 (f) "Manufacturer" means any person within this state who
6 produces, compounds, packages or in any manner initially prepares
7 for sale or use any drug product or any such person in another
8 state if they cause the products to be compounded, packaged or
9 transported into this state.

10 (g) "Phenylpropanolamine" means phenylpropanolamine, its
11 salts, optical isomers and salts of optical isomers.

12 (h) "Pseudoephedrine" means pseudoephedrine, its salts,
13 optical isomers and salts of optical isomers.

14 (i) "Precursor" means any substance which may be used along
15 with other substances as a component in the production and
16 distribution of illegal methamphetamine.

17 (j) "Pharmacist" means an individual currently licensed by
18 this state to engage in the practice of ~~pharmacy and pharmaceutical~~
19 ~~care~~ pharmacist care as defined in ~~subsection (t), section one-b,~~
20 article ~~fifty~~ five, chapter thirty of this code.

21 (k) "Pharmacy intern" has the same meaning as the term
22 "intern" as set forth in ~~section one-b,~~ article five, chapter
23 thirty of this code.

24 (l) "Pharmacy" means any drugstore, apothecary or place within
25 this state where drugs are dispensed and sold at retail or display
26 for sale at retail and ~~pharmaceutical~~ pharmacist care is provided

1 outside of this state where drugs are dispensed and ~~pharmaceutical~~
2 pharmacist care is provided to residents of this state.

3 (m) "Pharmacy counter" means an area in the pharmacy
4 restricted to the public where controlled substances are stored and
5 housed and where controlled substances may only be sold,
6 transferred or dispensed by a pharmacist or pharmacy technician.

7 (n) "Pharmacy technician" means a registered technician who
8 meets the requirements for registration as set forth in article
9 five, chapter thirty of this code.

10 (o) "Retail establishment" means any entity or person within
11 this state who sells, transfers or distributes goods, including
12 over-the-counter drug products, to an ultimate consumer.

13 (p) "Schedule V" means the schedule of controlled substances
14 set out in section two hundred twelve, section two of this chapter.

15 (q) "Single active ingredient" means those ingredients listed
16 on a drug product package as the only active ingredient in
17 over-the-counter medication or identified on the Schedule
18 maintained by the Board of Pharmacy as being primarily used in the
19 illegal production and distribution of methamphetamine.

20 (r) "Superintendent of the State Police" or "Superintendent"
21 means the Superintendent of the West Virginia State Police as set
22 forth in section five, article two, chapter fifteen of this code.

23 (s) "Wholesaler" means any person within this state or another
24 state, other than a manufacturer, who sells, transfers or in any
25 manner furnishes a drug product to any other person in this state
26 for the purpose of being resold.