

1 COMMITTEE SUBSTITUTE

2 FOR

3 **Senate Bill No. 492**

4 (By Senators Stollings, Laird, Miller, Cookman, Snyder and
5 Prezioso)

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7 [Originating in the Committee on Health and Human Resources;
8 reported February 12, 2014.]
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11
12 A BILL to amend and reenact §30-5-4 of the Code of West Virginia,
13 1931, as amended; and to amend said code by adding thereto a
14 new section, designated §30-5-35, all relating to specialty
15 drugs; defining terms; requiring Board of Pharmacy to develop
16 a list of specialty drugs; requiring consultation with state
17 pharmacy schools; requiring publication of the list of
18 specialty drugs in the state register; establishing criteria
19 to select speciality drugs; requiring pharmacy benefits
20 managers to follow list developed by the Board of Pharmacy;
21 providing certain pharmacies and pharmacists with the
22 opportunity to dispense specialty drugs; and specifying
23 reimbursement requirements for pharmacy benefits managers for
24 specialty drugs.

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

2 That §30-5-4 of the Code of West Virginia, 1931, as amended,
3 be amended and reenacted; and that said code be amended by adding
4 thereto a new section, designated §30-5-35, all to read as follows:

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

7 **§30-5-4. Definitions.**

8 As used in this article:

9 (1) "Ambulatory health care facility" includes any facility
10 defined in section one, article five-b, chapter sixteen of this
11 code, that also has a pharmacy, offers pharmacist care, or is
12 otherwise engaged in the practice of pharmacist care.

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

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

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

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

23 (6) "Chain Pharmacy Warehouse" means a permanent physical
24 location for drugs and/or devices that acts as a central warehouse

1 and performs intracompany sales and transfers of prescription drugs
2 or devices to chain pharmacies, which are members of the same
3 affiliated group, under common ownership and control.

4 (7) "Charitable clinic pharmacy" means a clinic or facility
5 organized as a not-for-profit corporation that has a pharmacy,
6 offers pharmacist care, or is otherwise engaged in the practice of
7 pharmacist care and dispenses its prescriptions free of charge to
8 appropriately screened and qualified indigent patients.

9 (8) "Collaborative pharmacy practice" is that practice of
10 pharmacist care where one or more pharmacists have jointly agreed,
11 on a voluntary basis, to work in conjunction with one or more
12 physicians under written protocol where the pharmacist or
13 pharmacists may perform certain patient care functions authorized
14 by the physician or physicians under certain specified conditions
15 and limitations.

16 (9) "Collaborative pharmacy practice agreement" is a written
17 and signed agreement, which is a physician directed approach, that
18 is entered into between an individual physician or physician group,
19 an individual pharmacist or pharmacists and an individual patient
20 or the patient's authorized representative who has given informed
21 consent that provides for collaborative pharmacy practice for the
22 purpose of drug therapy management of a patient, which has been
23 approved by the board, the Board of Medicine in the case of an
24 allopathic physician or the West Virginia Board of Osteopathic

1 Medicine in the case of an osteopathic physician.

2 (10) "Common Carrier" means any person or entity who
3 undertakes, whether directly or by any other arrangement, to
4 transport property including prescription drugs for compensation.

5 (11) "Component" means any active ingredient or added
6 substance intended for use in the compounding of a drug product,
7 including those that may not appear in such product.

8 (12) "Compounding" means:

9 (A) The preparation, mixing, assembling, packaging or labeling
10 of a drug or device:

11 (I) As the result of a practitioner's prescription drug order
12 or initiative based on the practitioner/patient/pharmacist
13 relationship in the course of professional practice for sale or
14 dispensing; or

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

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

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

23 (14) "Device" means an instrument, apparatus, implement or
24 machine, contrivance, implant or other similar or related article,

1 including any component part or accessory, which is required under
2 federal law to bear the label, "Caution: Federal or state law
3 requires dispensing by or on the order of a physician."

4 (15) "Digital Signature" means an electronic signature based
5 upon cryptographic methods of originator authentication, and
6 computed by using a set of rules and a set of parameters so that
7 the identity of the signer and the integrity of the data can be
8 verified.

9 (16) "Dispense" or "dispensing" means the interpretation,
10 evaluation, and implementation of a prescription drug order,
11 including the preparation, verification and delivery of a drug or
12 device to a patient or patient's agent in a suitable container
13 appropriately labeled for subsequent administration to, or use by,
14 a patient.

15 (17) "Distribute" or "Distribution" means to sell, offer to
16 sell, deliver, offer to deliver, broker, give away, or transfer a
17 drug, whether by passage of title, physical movement, or both. The
18 term does not include:

19 (A) To dispense or administer;

20 (B) (I) Delivering or offering to deliver a drug by a common
21 carrier in the usual course of business as a common carrier; or
22 providing a drug sample to a patient by a practitioner licensed to
23 prescribe such drug;

24 (ii) A health care professional acting at the direction and

1 under the supervision of a practitioner; or the pharmacy of a
2 hospital or of another health care entity that is acting at the
3 direction of such a practitioner and that received such sample in
4 accordance with the Prescription Drug Marketing Act and regulations
5 to administer or dispense;

6 (iii) Intracompany sales.

7 (18) "Drop shipment" means the sale of a prescription drug to
8 a wholesale distributor by the manufacturer of the prescription
9 drug or by that manufacturer's colicensed product partner, that
10 manufacturer's third party logistics provider, that manufacturer's
11 exclusive distributor, or by an authorized distributor of record
12 that purchased the product directly from the manufacturer or from
13 one of these entities whereby:

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

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

19 (C) The pharmacy, pharmacy warehouse or other person
20 authorized by law to dispense or administer such drug receives
21 delivery of the prescription drug directly from the manufacturer or
22 from that manufacturer's colicensed product partner, that
23 manufacturer's third party logistics provider, that manufacturer's
24 exclusive distributor, or from an authorized distributor of record

1 that purchased the product directly from the manufacturer or from
2 one of these entities.

3 (19) "Drug" means:

4 (A) Articles recognized as drugs by the United States Food and
5 Drug Administration, or in any official compendium, or supplement;

6 (B) An article, designated by the board, for use in the
7 diagnosis, cure, mitigation, treatment, or prevention of disease in
8 humans or other animals;

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

12 (D) Articles intended for use as a component of any articles
13 specified in paragraph (A), (B) or (C) of this subdivision.

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

16 (A) Evaluation of the prescription drug orders and if
17 available, patient records for:

- 18 (i) Known allergies;
- 19 (ii) Rational therapy-contraindications;
- 20 (iii) Reasonable dose and route of administration; and
- 21 (iv) Reasonable directions for use.

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

24 (C) Evaluation of the prescription drug for interactions

1 and/or adverse effects which may include, but are not limited to,
2 any of the following:

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

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

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

17 (A) Implementing, modifying and managing drug therapy
18 according to the terms of the collaborative pharmacy practice
19 agreement;

20 (B) Collecting and reviewing patient histories;

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

23 (D) Ordering screening laboratory tests that are dose related
24 and specific to the patient's medication or are protocol driven and

1 are also specifically set out in the collaborative pharmacy
2 practice agreement between the pharmacist and physician.

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

8 (A) An electronic prescription order;

9 (B) A refill authorization request;

10 (C) A communication; or

11 (D) Other patient care information.

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

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

23 (25) "Electronic transmission" means transmission of
24 information in electronic form or the transmission of the exact

1 visual image of a document by way of electronic equipment.

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

13 (27) "Exclusive distributor" means an entity that:

14 (A) Contracts with a manufacturer to provide or coordinate
15 warehousing, wholesale distribution, or other services on behalf of
16 a manufacturer and who takes title to that manufacturer's
17 prescription drug, but who does not have general responsibility to
18 direct the sale or disposition of the manufacturer's prescription
19 drug; and

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

21 (28) "FDA" means the Food and Drug Administration, a federal
22 agency within the United States Department of Health and Human
23 Services.

24 (29) "Health care entity" means a person that provides

1 diagnostic, medical, pharmacist care, surgical, dental treatment,
2 or rehabilitative care but does not include a wholesale
3 distributor.

4 (30) "Health information" means any information, whether oral
5 or recorded in a form or medium, that:

6 (A) Is created or received by a health care provider, health
7 plan, public health authority, employer, life insurer, school or
8 university, or health care clearinghouse, and

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

12 (31) "HIPAA" is the federal Health Insurance Portability and
13 Accountability Act of 1996 (Public Law 104-191).

14 (32) "Immediate container" means a container and does not
15 include package liners.

16 (33) "Individually identifiable health information" is
17 information that is a subset of health information, including
18 demographic information collected from an individual and is created
19 or received by a health care provider, health plan, employer, or
20 health care clearinghouse; and relates to the past, present, or
21 future physical or mental health or condition of an individual; the
22 provision of health care to an individual; or the past, present, or
23 future payment for the provision of health care to an individual;
24 and that identifies the individual; or with respect to which there

1 is a reasonable basis to believe the information can be used to
2 identify the individual.

3 (34) "Intracompany sales" means any transaction between a
4 division, subsidiary, parent, and/or affiliated or related company
5 under the common ownership and control of a corporate or other
6 legal business entity.

7 (35) "Label" means a display of written, printed, or graphic
8 matter upon the immediate container of any drug or device.

9 (36) "Labeling" means the process of preparing and affixing a
10 label to a drug container exclusive, however, of a labeling by a
11 manufacturer, packer or distributor of a nonprescription drug or
12 commercially packaged prescription drug or device.

13 (37) "Long-Term care facility" means a nursing home,
14 retirement care, mental care, or other facility or institution that
15 provides extended health care to resident patients.

16 (38) "Mail-order pharmacy" means a pharmacy, regardless of its
17 location, which dispenses greater than twenty-five percent
18 prescription drugs via the mail or other delivery services.

19 (39) "Manufacturer" means any person who is engaged in
20 manufacturing, preparing, propagating, processing, packaging,
21 repackaging or labeling of a prescription drug, whether within or
22 outside this state.

23 (40) "Manufacturing" means the production, preparation,
24 propagation or processing of a drug or device, either directly or

1 indirectly, by extraction from substances of natural origin or
2 independently by means of chemical or biological synthesis and
3 includes any packaging or repackaging of the substance or
4 substances or labeling or relabeling of its contents and the
5 promotion and marketing of the drugs or devices. Manufacturing
6 also includes the preparation and promotion of commercially
7 available products from bulk compounds for resale by pharmacies,
8 practitioners or other persons.

9 (41) "Medical order" means a lawful order of a practitioner
10 that may or may not include a prescription drug order.

11 (42) "Medication therapy management" is a distinct service or
12 group of services that optimize medication therapeutic outcomes for
13 individual patients. Medication therapy management services are
14 independent of, but can occur in conjunction with, the provision of
15 a medication or a medical device. Medication therapy management
16 encompasses a broad range of professional activities and
17 responsibilities within the licensed pharmacist's scope of
18 practice.

19 These services may include the following, according to the
20 individual needs of the patient:

21 (A) Performing or obtaining necessary assessments of the
22 patient's health status pertinent to medication therapy management;

23 (B) Optimize medication use, performing medication therapy,
24 and formulating recommendations for patient medication care plans;

1 (C) Developing therapeutic recommendations, to resolve
2 medication related problems;

3 (D) Monitoring and evaluating the patient's response to
4 medication 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 medication
15 therapeutic 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 (43) "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

1 label does not show an accurate monograph for prescription drugs.

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

6 (45) "Normal distribution channel" means a chain of custody
7 for a prescription drug that goes directly or by drop shipment,
8 from a manufacturer of the prescription drug, the manufacturer's
9 third-party logistics provider, or the manufacturer's exclusive
10 distributor to:

11 (A) A wholesale distributor to a pharmacy to a patient or
12 other designated persons authorized by law to dispense or
13 administer such prescription drug to a patient;

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

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

22 (D) A pharmacy or to other designated persons authorized by
23 law to dispense or administer such prescription drug to a patient;
24 or

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

2 (46) "Patient counseling" means the communication by the
3 pharmacist of information, as prescribed further in the rules of
4 the board, to the patient to improve therapy by aiding in the
5 proper use of drugs and devices.

6 (47) "Pedigree" means a statement or record in a written form
7 or electronic form, approved by the board, that records each
8 wholesale distribution of any given prescription drug (excluding
9 veterinary prescription drugs), which leaves the normal
10 distribution channel.

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

13 (49) "Pharmacist" means an individual currently licensed by
14 this state to engage in the practice of pharmacist care.

15 (50) "Pharmacist Care" means the provision by a pharmacist of
16 patient care activities, with or without the dispensing of drugs or
17 devices, intended to achieve outcomes related to the cure or
18 prevention of a disease, elimination or reduction of a patient's
19 symptoms, or arresting or slowing of a disease process and as
20 provided for in section ten.

21 (51) "Pharmacist-in-charge" means a pharmacist currently
22 licensed in this state who accepts responsibility for the operation
23 of a pharmacy in conformance with all laws and legislative rules
24 pertinent to the practice of pharmacist care and the distribution

1 of drugs and who is personally in full charge of the pharmacy and
2 pharmacy personnel.

3 (52) "Pharmacist's scope of practice pursuant to the
4 collaborative pharmacy practice agreement" means those duties and
5 limitations of duties placed upon the pharmacist by the
6 collaborating physician, as jointly approved by the board and the
7 Board of Medicine or the West Virginia Board of Osteopathic
8 Medicine.

9 (53) "Pharmacy" means any place within this state where drugs
10 are dispensed and pharmacist care is provided and any place outside
11 of this state where drugs are dispensed and pharmacist care is
12 provided to residents of this state.

13 (54) "Pharmacy benefits management" means obtaining
14 prescription drugs at a negotiated rate to dispense in this state
15 to persons covered by the pharmacy benefit manager, the
16 administration or management of prescription drug benefits provided
17 by a covered entity for the benefit of persons covered by the
18 pharmacy benefit manager or any of the following services offered
19 as part of the administration of pharmacy benefits:

20 (A) Mail-order pharmacy;

21 (B) Claims processing retail network management and payment of
22 claims to pharmacies for prescription drugs dispensed to persons
23 covered by the pharmacy benefit manager;

24 (C) Clinical formulary development and management services;

1 (D) Rebate contracting and administration;
2 (E) Patient compliance, therapeutic intervention and generic
3 substitution programs; and
4 (F) Disease management programs.
5 (55) "Pharmacy benefits manager" means an entity performing
6 pharmacy benefits management including a person or entity acting
7 for another pharmacy benefits manager in a contractual or
8 employment relationship performing pharmacy benefits management
9 services.
10 ~~(54)~~ (56) "Pharmacy Intern" or "Intern" means an individual
11 who is currently licensed to engage in the practice of pharmacist
12 care while under the supervision of a pharmacist.
13 ~~(55)~~ (57) "Pharmacy related primary care" means the
14 pharmacist's activities in patient education, health promotion,
15 selection and use of over the counter drugs and appliances and
16 referral or assistance with the prevention and treatment of health
17 related issues and diseases.
18 ~~(56)~~ (58) "Pharmacy Technician" means a person registered with
19 the board to practice certain tasks related to the practice of
20 pharmacist care as permitted by the board.
21 ~~(57)~~ (59) "Physician" means an individual currently licensed,
22 in good standing and without restrictions, as an allopathic
23 physician by the West Virginia Board of Medicine or an osteopathic
24 physician by the West Virginia Board of Osteopathic Medicine.

1 ~~(58)~~ (60) "Practice of telepharmacy" means the provision of
2 pharmacist care by properly licensed pharmacists located within
3 United States jurisdictions through the use of telecommunications
4 or other technologies to patients or their agents at a different
5 location that are located within United States jurisdictions.

6 ~~(59)~~ (61) "Practitioner" means an individual authorized by a
7 jurisdiction of the United States to prescribe drugs in the course
8 of professional practices, as allowed by law.

9 ~~(60)~~ (62) "Prescription drug" means any human drug required by
10 federal law or regulation to be dispensed only by prescription,
11 including finished dosage forms and active ingredients subject to
12 section 503(b) of the federal food, drug and cosmetic act.

13 ~~(61)~~ (63) "Prescription or prescription drug order" means a
14 lawful order from a practitioner for a drug or device for a
15 specific patient, including orders derived from collaborative
16 pharmacy practice, where a valid patient-practitioner relationship
17 exists, that is communicated to a pharmacist in a pharmacy.

18 ~~(62)~~ (64) "Product Labeling" means all labels and other
19 written, printed, or graphic matter upon any article or any of its
20 containers or wrappers, or accompanying such article.

21 ~~(63)~~ (65) "Repackage" means changing the container, wrapper,
22 quantity, or product labeling of a drug or device to further the
23 distribution of the drug or device.

24 ~~(64)~~ (66) "Repackager" means a person who repackages.

1 (67) "Specialty drug" means a prescription drug requiring
2 special handling, special administration, unique inventory
3 management, a high level of patient monitoring, or more intense
4 patient support than conventional drug therapies.

5 ~~(65)~~ (68) "Therapeutic equivalence" mean drug products
6 classified as therapeutically equivalent can be substituted with
7 the full expectation that the substituted product will produce the
8 same clinical effect and safety profile as the prescribed product
9 which contain the same active ingredient(s); dosage form and route
10 of administration; and strength.

11 ~~(66)~~ (69) "Third-party logistics provider" means a person who
12 contracts with a prescription drug manufacturer to provide or
13 coordinate warehousing, distribution or other services on behalf of
14 a manufacturer, but does not take title to the prescription drug or
15 have general responsibility to direct the prescription drug's sale
16 or disposition. A third-party logistics provider shall be licensed
17 as a wholesale distributor under this article and, in order to be
18 considered part of the normal distribution channel, shall also be
19 an authorized distributor of record.

20 ~~(67)~~ (70) "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

1 the medical complaint has been performed by the prescribing
2 practitioner or in the instances of telemedicine through
3 telemedicine practice approved by the appropriate practitioner
4 board; and

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

8 ~~(68)~~ (71) "Wholesale distribution" and "wholesale
9 distributions" mean distribution of prescription drugs, including
10 directly or through the use of a third-party logistics provider or
11 any other situation in which title, ownership or control over the
12 prescription drug remains with one person or entity but the
13 prescription drug is brought into this state by another person or
14 entity on his, her or its behalf, to persons other than a consumer
15 or patient, but does not include:

16 (A) Intracompany sales, as defined in subdivision thirty-four
17 of this subsection;

18 (B) The purchase or other acquisition by a hospital or other
19 health care entity that is a member of a group purchasing
20 organization of a drug for its own use from the group purchasing
21 organization or from other hospitals or health care entities that
22 are members of such organizations;

23 (C) The sale, purchase or trade of a drug or an offer to sell,
24 purchase or trade a drug by a charitable organization described in

1 section 501(c)(3) of the United States Internal Revenue Code of
2 1986 to a nonprofit affiliate of the organization to the extent
3 otherwise permitted by law;

4 (D) The sale, purchase or trade of a drug or an offer to sell,
5 purchase or trade a drug among hospitals or other health care
6 entities that are under common control. For purposes of this
7 article, "common control" means the power to direct or cause the
8 direction of the management and policies of a person or an
9 organization, whether by ownership of stock, voting rights, by
10 contract, or otherwise;

11 (E) The sale, purchase or trade of a drug or an offer to sell,
12 purchase or trade a drug for "emergency medical reasons" for
13 purposes of this article includes transfers of prescription drugs
14 by a retail pharmacy to another retail pharmacy to alleviate a
15 temporary shortage, except that the gross dollar value of such
16 transfers shall not exceed five percent of the total prescription
17 drug sales revenue of either the transferor or transferee pharmacy
18 during any twelve consecutive month period;

19 (F) The sale, purchase or trade of a drug, an offer to sell,
20 purchase, or trade a drug or the dispensing of a drug pursuant to
21 a prescription;

22 (G) The distribution of drug samples by manufacturers'
23 representatives or distributors' representatives, if the
24 distribution is permitted under federal law [21 U. S. C. 353(d)];

1 (H) Drug returns by a pharmacy or chain drug warehouse to
2 wholesale drug distributor or the drug's manufacturer; or

3 (I) The sale, purchase or trade of blood and blood components
4 intended for transfusion.

5 ~~(69)~~ (72) "Wholesale drug distributor" or "wholesale
6 distributor" means any person or entity engaged in wholesale
7 distribution of prescription drugs, including, but not limited to,
8 manufacturers, repackers, own-label distributors, jobbers, private-
9 label distributors, brokers, warehouses, including manufacturers'
10 and distributors' warehouses, chain drug warehouses and wholesale
11 drug warehouses, independent wholesale drug traders, prescription
12 drug repackagers, physicians, dentists, veterinarians, birth
13 control and other clinics, individuals, hospitals, nursing homes
14 and/or their providers, health maintenance organizations and other
15 health care providers, and retail and hospital pharmacies that
16 conduct wholesale distributions, including, but not limited to, any
17 pharmacy distributor as defined in this section. A wholesale drug
18 distributor shall not include any for hire carrier or person or
19 entity hired solely to transport prescription drugs.

20 **30-5-35. Determinations regarding specialty drugs.**

21 (a) Beginning on January 1, 2015, and every six months
22 thereafter, the Board, after consultation with the West Virginia
23 University School of Pharmacy, the Marshall University School of
24 Pharmacy and the University of Charleston School of Pharmacy shall

1 publish in the State Register a list of prescription drugs that may
2 be considered specialty drugs by a pharmacy benefits manager.

3 (b) In specifying the prescription drugs that may be
4 considered specialty drugs, the Board shall consider whether:

5 (1) The prescription drug is used to treat a patient with a
6 complex; chronic; or rare medical condition that is progressive,
7 can be debilitating or fatal if left untreated or undertreated, or
8 for which there is no known cure. These include, but are not
9 limited to, multiple sclerosis, hepatitis c, cystic fibrosis,
10 hemophilia, and rheumatoid arthritis;

11 (2) The prescription drug is not generally stocked at retail
12 pharmacies;

13 (3) The prescription drug has special handling, storage,
14 inventory, or distribution requirements; or

15 (4) Patients receiving the prescription drug require complex
16 education and treatment maintenance. This may include complex
17 dosing, intensive monitoring, and clinical oversight.

18 (c) If a pharmacy benefits manager intends to designate a
19 certain prescription drug as a specialty drug on a formulary, the
20 pharmacy benefits manager may designate only a prescription drug
21 listed as a specialty drug in the State Register by the Board.

22 (d) A pharmacy benefits manager:

23 (1) Shall allow any licensed pharmacy or licensed pharmacist
24 in the State to fill a prescription for a specialty drug, if the

1 licensed pharmacist:

2 (A) Has a contract with the pharmacy benefits manager;

3 (B) Has the specialty drug in inventory or has ready access to
4 the specialty drug; and

5 (C) Is capable of complying with any special handling, special
6 administration, inventory management, patient monitoring, or
7 patient support requirements for the specialty drug; and

8 (2) May not require a specialty drug to be dispensed by mail
9 order.

10 (e) A pharmacy benefits manager shall reimburse a retail
11 pharmacy for a specialty drug on a formulary of the pharmacy
12 benefits manager and dispensed by the pharmacy at the current
13 preferred brand tier reimbursement rate specified in the contract
14 between the pharmacy benefits manager and the pharmacy.