



1 be amended and reenacted; and that said code be amended by adding  
2 thereto a new section, designated §30-5-35, all to read as follows:

3 **ARTICLE 5. PHARMACISTS, PHARMACY TECHNICIANS, PHARMACY INTERNS**  
4 **AND PHARMACIES.**

5 **§30-5-4. Definitions.**

6 As used in this article:

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

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

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

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

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

21 (6) "Chain Pharmacy Warehouse" means a permanent physical  
22 location for drugs and/or devices that acts as a central warehouse  
23 and performs intracompany sales and transfers of prescription drugs

1 or devices to chain pharmacies, which are members of the same  
2 affiliated group, under common ownership and control.

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

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

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

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

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

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

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

20 (A) To dispense or administer;

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

1 prescribe such drug;

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

8       (iii) Intracompany sales.

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

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

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

21       (C) The pharmacy, pharmacy warehouse or other person  
22 authorized by law to dispense or administer such drug receives  
23 delivery of the prescription drug directly from the manufacturer or

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

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

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

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

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

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

21 (I) Known allergies;

22 (ii) Rational therapy-contraindications;

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

1 (iv) Reasonable directions for use.

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

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

7 (I) Drug-drug;

8 (ii) Drug-food;

9 (iii) Drug-disease; and

10 (iv) Adverse drug reactions.

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

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

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



1 (B) Collecting and reviewing patient histories;

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

4 (D) Ordering screening laboratory tests that are dose related  
5 and specific to the patient's medication or are protocol driven and  
6 are also specifically set out in the collaborative pharmacy  
7 practice agreement between the pharmacist and physician.

8 (22) "Electronic data intermediary" means an entity that  
9 provides the infrastructure to connect a computer system, hand-held  
10 electronic device or other electronic device used by a prescribing  
11 practitioner with a computer system or other electronic device used  
12 by a pharmacy to facilitate the secure transmission of:

13 (A) An electronic prescription order;

14 (B) A refill authorization request;

15 (C) A communication; or

16 (D) Other patient care information.

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

1 "electronic prescription" or "electronic order".

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

5       (25) "Electronic transmission" means transmission of  
6 information in electronic form or the transmission of the exact  
7 visual image of a document by way of electronic equipment.

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

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

20       (A) Contracts with a manufacturer to provide or coordinate  
21 warehousing, wholesale distribution, or other services on behalf of  
22 a manufacturer and who takes title to that manufacturer's  
23 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 article.

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

7 (29) "Health care entity" means a person that provides  
8 diagnostic, medical, pharmacist care, surgical, dental treatment,  
9 or rehabilitative care but does not include a wholesale  
10 distributor.

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

13 (A) Is created or received by a health care provider, health  
14 plan, public health authority, employer, life insurer, school or  
15 university, or health care clearinghouse, and

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

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

21 (32) "Immediate container" means a container and does not  
22 include package liners.

23 (33) "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 (34) "Intracompany sales" means any transaction between a  
12 division, subsidiary, parent, and/or affiliated or related company  
13 under the common ownership and control of a corporate or other  
14 legal business entity.

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

17 (36) "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 prescription drug or device.

21 (37) "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.

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

4           (39) "Manufacturer" means any person who is engaged in  
5 manufacturing, preparing, propagating, processing, packaging,  
6 repackaging or labeling of a prescription drug, whether within or  
7 outside this state.

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

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

20           (42) "Medication therapy management" is a distinct service or  
21 group of services that optimize medication therapeutic outcomes for  
22 individual patients. Medication therapy management services are  
23 independent of, but can occur in conjunction with, the provision of

1 a medication or a medical device. Medication therapy management  
2 encompasses a broad range of professional activities and  
3 responsibilities within the licensed pharmacist's scope of  
4 practice.

5 These services may include the following, according to the  
6 individual needs of the patient:

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

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

11 (C) Developing therapeutic recommendations, to resolve  
12 medication related problems;

13 (D) Monitoring and evaluating the patient's response to  
14 medication therapy, including safety and effectiveness;

15 (E) Performing a comprehensive medication review to identify,  
16 resolve, and prevent medication-related problems, including adverse  
17 drug events;

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

20 (G) Providing verbal education and training designed to  
21 enhance patient understanding and appropriate use of his or her  
22 medications;

23 (H) Providing information, support services and resources

1 designed to enhance patient adherence with his or her medication  
2 therapeutic regimens;

3 (I) Coordinating and integrating medication therapy management  
4 services within the broader health care management services being  
5 provided to the patient; and

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

7 (43) "Misbranded" means a drug or device that has a label that  
8 is false or misleading in any particular; or the label does not  
9 bear the name and address of the manufacturer, packer, or  
10 distributor and does not have an accurate statement of the  
11 quantities of the active ingredients in the case of a drug; or the  
12 label does not show an accurate monograph for prescription drugs.

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

17 (45) "Normal distribution channel" means a chain of custody  
18 for a prescription drug that goes directly or by drop shipment,  
19 from a manufacturer of the prescription drug, the manufacturer's  
20 third-party logistics provider, or the manufacturer's exclusive  
21 distributor to:

22 (A) A wholesale distributor to a pharmacy to a patient or  
23 other designated persons authorized by law to dispense or

1 administer such prescription drug to a patient;

2 (B) A wholesale distributor to a chain pharmacy warehouse to  
3 that chain pharmacy warehouse's intracompany pharmacy to a patient  
4 or other designated persons authorized by law to dispense or  
5 administer such prescription drug to a patient;

6 (C) A chain pharmacy warehouse to that chain pharmacy  
7 warehouse's intracompany pharmacy to a patient or other designated  
8 persons authorized by law to dispense or administer such  
9 prescription drug to a patient;

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

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

14 (46) "Patient counseling" means the communication by the  
15 pharmacist of information, as prescribed further in the rules of  
16 the board, to the patient to improve therapy by aiding in the  
17 proper use of drugs and devices.

18 (47) "Pedigree" means a statement or record in a written form  
19 or electronic form, approved by the board, that records each  
20 wholesale distribution of any given prescription drug (excluding  
21 veterinary prescription drugs), which leaves the normal  
22 distribution channel.

23 (48) "Person" means an individual, corporation, partnership,



1 association or any other legal entity, including government.

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

4       (50) "Pharmacist Care" means the provision by a pharmacist of  
5 patient care activities, with or without the dispensing of drugs or  
6 devices, intended to achieve outcomes related to the cure or  
7 prevention of a disease, elimination or reduction of a patient's  
8 symptoms, or arresting or slowing of a disease process and as  
9 provided for in section ten.

10       (51) "Pharmacist-in-charge" means a pharmacist currently  
11 licensed in this state who accepts responsibility for the operation  
12 of a pharmacy in conformance with all laws and legislative rules  
13 pertinent to the practice of pharmacist care and the distribution  
14 of drugs and who is personally in full charge of the pharmacy and  
15 pharmacy personnel.

16       (52) "Pharmacist's scope of practice pursuant to the  
17 collaborative pharmacy practice agreement" means those duties and  
18 limitations of duties placed upon the pharmacist by the  
19 collaborating physician, as jointly approved by the board and the  
20 Board of Medicine or the West Virginia Board of Osteopathic  
21 Medicine.

22       (53) "Pharmacy" means any place within this state where drugs  
23 are dispensed and pharmacist care is provided and any place outside

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

3 (54) "Pharmacy benefits manager" means an entity that performs  
4 pharmacy benefits management and includes a person or entity acting  
5 for another pharmacy benefits manager in a contractual or  
6 employment relationship in the performance of pharmacy benefits  
7 management services, including mail order pharmacy.

8 (55) "Pharmacy benefits management" means the procurement of  
9 prescription drugs at a negotiated rate for dispensation within  
10 this state to covered individuals, the administration or management  
11 of prescription drug benefits provided by a covered entity for the  
12 benefit of covered individuals or any of the following services  
13 provided with regard to the administration of pharmacy benefits:

14 (A) Mail-order pharmacy;

15 (B) Claims processing retail network management and payment of  
16 claims to pharmacies for prescription drugs dispensed to covered  
17 individuals;

18 (C) Clinical formulary development and management services;

19 (D) Rebate contracting and administration;

20 (E) Patient compliance, therapeutic intervention and generic  
21 substitution programs; and

22 (F) Disease management programs.

23 ~~(54)~~ (56) "Pharmacy Intern" or "Intern" means an individual

1 who is currently licensed to engage in the practice of pharmacist  
2 care while under the supervision of a pharmacist.

3 ~~(55)~~ (57) "Pharmacy related primary care" means the  
4 pharmacist's activities in patient education, health promotion,  
5 selection and use of over the counter drugs and appliances and  
6 referral or assistance with the prevention and treatment of health  
7 related issues and diseases.

8 ~~(56)~~ (58) "Pharmacy Technician" means a person registered with  
9 the board to practice certain tasks related to the practice of  
10 pharmacist care as permitted by the board.

11 ~~(57)~~ (59) "Physician" means an individual currently licensed,  
12 in good standing and without restrictions, as an allopathic  
13 physician by the West Virginia Board of Medicine or an osteopathic  
14 physician by the West Virginia Board of Osteopathic Medicine.

15 ~~(58)~~ (60) "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 ~~(59)~~ (61) "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 ~~(60)~~ (62) "Prescription drug" means any human drug required by

1 federal law or regulation to be dispensed only by prescription,  
2 including finished dosage forms and active ingredients subject to  
3 section 503(b) of the federal food, drug and cosmetic act.

4 ~~(61)~~ (63) "Prescription or prescription drug order" means a  
5 lawful order from a practitioner for a drug or device for a  
6 specific patient, including orders derived from collaborative  
7 pharmacy practice, where a valid patient-practitioner relationship  
8 exists, that is communicated to a pharmacist in a pharmacy.

9 ~~(62)~~ (64) "Product Labeling" means all labels and other  
10 written, printed, or graphic matter upon any article or any of its  
11 containers or wrappers, or accompanying such article.

12 ~~(63)~~ (65) "Repackage" means changing the container, wrapper,  
13 quantity, or product labeling of a drug or device to further the  
14 distribution of the drug or device.

15 ~~(64)~~ (66) "Repackager" means a person who repackages.

16 (67) "Specialty drug" means a prescription drug that requires  
17 special handling, special administration, unique inventory  
18 management, a high level of patient monitoring, or more intense  
19 patient support than conventional therapies.

20 ~~(65)~~ (68) "Therapeutic equivalence" mean drug products  
21 classified as therapeutically equivalent can be substituted with  
22 the full expectation that the substituted product will produce the  
23 same clinical effect and safety profile as the prescribed product

1 which contain the same active ingredient(s); dosage form and route  
2 of administration; and strength.

3       ~~(66)~~ (69) "Third-party logistics provider" means a person who  
4 contracts with a prescription drug manufacturer to provide or  
5 coordinate warehousing, distribution or other services on behalf of  
6 a manufacturer, but does not take title to the prescription drug or  
7 have general responsibility to direct the prescription drug's sale  
8 or disposition. A third-party logistics provider shall be licensed  
9 as a wholesale distributor under this article and, in order to be  
10 considered part of the normal distribution channel, shall also be  
11 an authorized distributor of record.

12       ~~(67)~~ (70) "Valid patient-practitioner relationship" means the  
13 following have been established:

14       (A) A patient has a medical complaint;

15       (B) A medical history has been taken;

16       (C) A face-to-face physical examination adequate to establish  
17 the medical complaint has been performed by the prescribing  
18 practitioner or in the instances of telemedicine through  
19 telemedicine practice approved by the appropriate practitioner  
20 board; and

21       (D) Some logical connection exists between the medical  
22 complaint, the medical history, and the physical examination and  
23 the drug prescribed.

1       ~~(68)~~ (71) "Wholesale distribution" and "wholesale  
2 distributions" mean distribution of prescription drugs, including  
3 directly or through the use of a third-party logistics provider or  
4 any other situation in which title, ownership or control over the  
5 prescription drug remains with one person or entity but the  
6 prescription drug is brought into this state by another person or  
7 entity on his, her or its behalf, to persons other than a consumer  
8 or patient, but does not include:

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

11           (B) The purchase or other acquisition by a hospital or other  
12 health care entity that is a member of a group purchasing  
13 organization of a drug for its own use from the group purchasing  
14 organization or from other hospitals or health care entities that  
15 are members of such organizations;

16           (C) The sale, purchase or trade of a drug or an offer to sell,  
17 purchase or trade a drug by a charitable organization described in  
18 section 501(c)(3) of the United States Internal Revenue Code of  
19 1986 to a nonprofit affiliate of the organization to the extent  
20 otherwise permitted by law;

21           (D) The sale, purchase or trade of a drug or an offer to sell,  
22 purchase or trade a drug among hospitals or other health care  
23 entities that are under common control. For purposes of this

1 article, "common control" means the power to direct or cause the  
2 direction of the management and policies of a person or an  
3 organization, whether by ownership of stock, voting rights, by  
4 contract, or otherwise;

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

13 (F) The sale, purchase or trade of a drug, an offer to sell,  
14 purchase, or trade a drug or the dispensing of a drug pursuant to  
15 a prescription;

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

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

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

23 ~~(69)~~ (72) "Wholesale drug distributor" or "wholesale

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

15 **30-5-35. Determinations regarding specialty drugs.**

16 (a) The board, in consultation with the West Virginia  
17 University School of Pharmacy and the Marshall University School of  
18 Pharmacy, shall, beginning on January 1, 2015, and every six months  
19 thereafter, publish in the State Register a list of prescription  
20 drugs that may be considered specialty drugs by a pharmacy benefits  
21 manager.

22 (b) In specifying the prescription drugs that may be  
23 considered specialty drugs, the board shall consider whether:



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

7           (2) The prescription drug is not generally stocked at  
8 community retail pharmacies;

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

11           (4) Patients receiving the prescription drug require complex  
12 education and treatment maintenance, including: complex dosing,  
13 intensive monitoring, and clinical oversight.

14           (c) If a pharmacy benefits manager intends to designate a  
15 certain prescription drug as a specialty drug on a formulary, the  
16 pharmacy benefits manager may designate only a prescription drug  
17 listed as a specialty drug in the State Register by the board.

18           (d) A pharmacy benefits manager:

19           (1) Shall allow any licensed pharmacy or licensed pharmacist  
20 in the State to fill a prescription for a specialty drug, if the  
21 licensed pharmacist:

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

23           (B) Has the specialty drug in inventory or has ready access to

1 the specialty drug; and

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

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

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

NOTE: The purpose of this bill is to require the State Board of Pharmacy to specify which prescription drugs may be considered specialty drugs by a pharmacy benefits manager and provide licensed pharmacists who meet specified requirements with the opportunity to dispense specialty drugs.

Strike-throughs indicate language that would be stricken from the present law, and underscoring indicates new language that would be added.

Section 30-5-35 is new; therefore, strike-throughs and underscoring have been omitted.