

Senate Bill No. 16

(By Senators Stollings, Facemire and Romano)

[Introduced January 14, 2015; referred to the Committee on Health and Human Resources; and

then to the Committee on the Judiciary.]

**FISCAL
NOTE**

A BILL to amend and reenact §30-5-4 of the Code of West Virginia, 1931, as amended; and to amend said code by adding thereto a new section, designated §30-5-35, all relating to specialty drugs; defining “specialty drug”, “pharmacy benefits manager” and “pharmacy benefits management”; requiring State Board of Pharmacy to develop a list of specialty drugs; requiring pharmacy benefits managers to follow list developed by the Board of Pharmacy; providing certain pharmacies and pharmacists with the opportunity to dispense specialty drugs; and specifying reimbursement requirements for pharmacy benefits managers for specialty drugs.

Be it enacted by the Legislature of West Virginia:

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

ARTICLE 5. PHARMACISTS, PHARMACY TECHNICIANS, PHARMACY INTERNS

1 **AND PHARMACIES.**

2 **§30-5-4. Definitions.**

3 As used in this article:

4 (1) “Ambulatory health care facility” includes any facility defined in section one, article
5 five-b, chapter sixteen of this code, that also has a pharmacy, offers pharmacist care, or is otherwise
6 engaged in the practice of pharmacist care.

7 (2) “Active Ingredients” means chemicals, substances, or other components of articles
8 intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans
9 or animals or for use as nutritional supplements.

10 (3) “Administer” means the direct application of a drug to the body of a patient or research
11 subject by injection, inhalation, ingestion or any other means.

12 (4) “Board” means the West Virginia Board of Pharmacy.

13 (5) “Board authorization” means a license, registration or permit issued under this article.

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

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

22 (8) “Collaborative pharmacy practice” is that practice of pharmacist care where one or more

1 pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more
2 physicians under written protocol where the pharmacist or pharmacists may perform certain patient
3 care functions authorized by the physician or physicians under certain specified conditions and
4 limitations.

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

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

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

16 (12) "Compounding" means:

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

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

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

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

3 (13) “Deliver” or “delivery” means the actual, constructive or attempted transfer of a drug
4 or device from one person to another, whether or not for a consideration.

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

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

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

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

19 (A) To dispense or administer;

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

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

5 (iii) Intracompany sales.

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

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

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

15 (C) The pharmacy, pharmacy warehouse or other person authorized by law to dispense or
16 administer such drug receives delivery of the prescription drug directly from the manufacturer or
17 from that manufacturer’s colicensed product partner, that manufacturer’s third party logistics
18 provider, that manufacturer’s exclusive distributor, or from an authorized distributor of record that
19 purchased the product directly from the manufacturer or from one of these entities.

20 (19) “Drug” means:

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

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

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

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

7 (20) “Drug regimen review” includes, but is not limited to, the following activities:

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

9 (i) Known allergies;

10 (ii) Rational therapy-contraindications;

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

12 (iv) Reasonable directions for use.

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

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

16 (i) Drug-drug;

17 (ii) Drug-food;

18 (iii) Drug-disease; and

19 (iv) Adverse drug reactions.

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

22 (21) “Drug therapy management” means the review of drug therapy regimens of patients by

1 a pharmacist for the purpose of evaluating and rendering advice to a physician regarding adjustment
2 of the regimen in accordance with the collaborative pharmacy practice agreement. Decisions
3 involving drug therapy management shall be made in the best interest of the patient. Drug therapy
4 management is limited to:

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

7 (B) Collecting and reviewing patient histories;

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

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

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

17 (A) An electronic prescription order;

18 (B) A refill authorization request;

19 (C) A communication; or

20 (D) Other patient care information.

21 (23) "E-prescribing" means the transmission, using electronic media, of prescription or
22 prescription-related information between a practitioner, pharmacist, pharmacy benefit manager or

1 health plan as defined in 45 CFR §160.103, either directly or through an electronic data intermediary.
2 E-prescribing includes, but is not limited to, two-way transmissions between the point of care and
3 the pharmacist. E-prescribing may also be referenced by the terms “electronic prescription” or
4 “electronic order”.

5 (24) “Electronic Signature” means an electronic sound, symbol, or process attached to or
6 logically associated with a record and executed or adopted by a person with the intent to sign the
7 record.

8 (25) “Electronic transmission” means transmission of information in electronic form or the
9 transmission of the exact visual image of a document by way of electronic equipment.

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

17 (27) “Exclusive distributor” means an entity that:

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

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

1 (28) “FDA” means the Food and Drug Administration, a federal agency within the United
2 States Department of Health and Human Services.

3 (29) “Health care entity” means a person that provides diagnostic, medical, pharmacist care,
4 surgical, dental treatment, or rehabilitative care but does not include a wholesale distributor.

5 (30) “Health information” means any information, whether oral or recorded in a form or
6 medium, that:

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

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

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

13 (32) “Immediate container” means a container and does not include package liners.

14 (33) “Individually identifiable health information” is information that is a subset of health
15 information, including demographic information collected from an individual and is created or
16 received by a health care provider, health plan, employer, or health care clearinghouse; and relates
17 to the past, present, or future physical or mental health or condition of an individual; the provision
18 of health care to an individual; or the past, present, or future payment for the provision of health care
19 to an individual; and that identifies the individual; or with respect to which there is a reasonable
20 basis to believe the information can be used to identify the individual.

21 (34) “Intracompany sales” means any transaction between a division, subsidiary, parent,
22 and/or affiliated or related company under the common ownership and control of a corporate or other

1 legal business entity.

2 (35) “Label” means a display of written, printed, or graphic matter upon the immediate
3 container of any drug or device.

4 (36) “Labeling” means the process of preparing and affixing a label to a drug container
5 exclusive, however, of a labeling by a manufacturer, packer or distributor of a nonprescription drug
6 or commercially packaged prescription drug or device.

7 (37) “Long-Term care facility” means a nursing home, retirement care, mental care, or other
8 facility or institution that provides extended health care to resident patients.

9 (38) “Mail-order pharmacy” means a pharmacy, regardless of its location, which dispenses
10 greater than twenty-five percent prescription drugs via the mail or other delivery services.

11 (39) “Manufacturer” means any person who is engaged in manufacturing, preparing,
12 propagating, processing, packaging, repackaging or labeling of a prescription drug, whether within
13 or outside this state.

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

21 (41) “Medical order” means a lawful order of a practitioner that may or may not include a
22 prescription drug order.

1 (42) “Medication therapy management” is a distinct service or group of services that optimize
2 medication therapeutic outcomes for individual patients. Medication therapy management services
3 are independent of, but can occur in conjunction with, the provision of a medication or a medical
4 device. Medication therapy management encompasses a broad range of professional activities and
5 responsibilities within the licensed pharmacist’s scope of practice.

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

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

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

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

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

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

16 (F) Documenting the care delivered and communicating essential information to the patient’s
17 primary care providers;

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

20 (H) Providing information, support services and resources designed to enhance patient
21 adherence with his or her medication therapeutic regimens;

22 (I) Coordinating and integrating medication therapy management services within the broader

1 health care management services being provided to the patient; and

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

3 (43) “Misbranded” means a drug or device that has a label that is false or misleading in any
4 particular; or the label does not bear the name and address of the manufacturer, packer, or distributor
5 and does not have an accurate statement of the quantities of the active ingredients in the case of a
6 drug; or the label does not show an accurate monograph for prescription drugs.

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

10 (45) “Normal distribution channel” means a chain of custody for a prescription drug that goes
11 directly or by drop shipment, from a manufacturer of the prescription drug, the manufacturer’s
12 third-party logistics provider, or the manufacturer’s exclusive distributor to:

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

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

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

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

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

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

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

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

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

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

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

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

1 Virginia Board of Osteopathic Medicine.

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

5 (54) "Pharmacy benefits management" means obtaining prescription drugs at a negotiated
6 rate to dispense in this state to persons covered by the pharmacy benefit manager, the administration
7 or management of prescription drug benefits provided by a covered entity for the benefit of persons
8 covered by the pharmacy benefit manager or any of the following services offered as part of the
9 administration of pharmacy benefits:

10 (A) Mail-order pharmacy;

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

13 (C) Clinical formulary development and management services;

14 (D) Rebate contracting and administration;

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

16 (F) Disease management programs.

17 (55) "Pharmacy benefits manager" means an entity performing pharmacy benefits
18 management including a person or entity acting for another pharmacy benefits manager in a
19 contractual or employment relationship performing pharmacy benefits management services.

20 ~~(54)~~ (56) "Pharmacy Intern" or "Intern" means an individual who is currently licensed to
21 engage in the practice of pharmacist care while under the supervision of a pharmacist.

22 ~~(55)~~ (57) "Pharmacy related primary care" means the pharmacist's activities in patient

1 education, health promotion, selection and use of over the counter drugs and appliances and referral
2 or assistance with the prevention and treatment of health related issues and diseases.

3 ~~(56)~~ (58) "Pharmacy Technician" means a person registered with the board to practice certain
4 tasks related to the practice of pharmacist care as permitted by the board.

5 ~~(57)~~ (59) "Physician" means an individual currently licensed, in good standing and without
6 restrictions, as an allopathic physician by the West Virginia Board of Medicine or an osteopathic
7 physician by the West Virginia Board of Osteopathic Medicine.

8 ~~(58)~~ (60) "Practice of telepharmacy" means the provision of pharmacist care by properly
9 licensed pharmacists located within United States jurisdictions through the use of
10 telecommunications or other technologies to patients or their agents at a different location that are
11 located within United States jurisdictions.

12 ~~(59)~~ (61) "Practitioner" means an individual authorized by a jurisdiction of the United States
13 to prescribe drugs in the course of professional practices, as allowed by law.

14 ~~(60)~~ (62) "Prescription drug" means any human drug required by federal law or regulation
15 to be dispensed only by prescription, including finished dosage forms and active ingredients subject
16 to section 503(b) of the federal food, drug and cosmetic act.

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

21 ~~(62)~~ (64) "Product Labeling" means all labels and other written, printed, or graphic matter
22 upon any article or any of its containers or wrappers, or accompanying such article.

1 ~~(63)~~ (65) "Repackage" means changing the container, wrapper, quantity, or product labeling
2 of a drug or device to further the distribution of the drug or device.

3 ~~(64)~~ (66) "Repackager" means a person who repackages.

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

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

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

17 ~~(67)~~ (70) "Valid patient-practitioner relationship" means the following have been established:

18 (A) A patient has a medical complaint;

19 (B) A medical history has been taken;

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

1 (D) Some logical connection exists between the medical complaint, the medical history, and
2 the physical examination and the drug prescribed.

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

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

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

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

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

20 (E) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug for
21 "emergency medical reasons" for purposes of this article includes transfers of prescription drugs by
22 a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, except that the gross

1 dollar value of such transfers shall not exceed five percent of the total prescription drug sales revenue
2 of either the transferor or transferee pharmacy during any twelve consecutive month period;

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

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

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

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

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

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

21 (a) Beginning on January 1, 2016, and every six months thereafter, the board, after
22 consultation with the West Virginia University School of Pharmacy, the Marshall University School

1 of Pharmacy and the University of Charleston School of Pharmacy shall publish in the State Register
2 a list of prescription drugs that may be considered specialty drugs by a pharmacy benefits manager.

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

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

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

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

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

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

17 (d) A pharmacy benefits manager:

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

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

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

22 (C) Is capable of complying with any special handling, special administration, inventory

1 management, patient monitoring, or patient support requirements for the specialty drug; and

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

3 (e) A pharmacy benefits manager shall reimburse a retail pharmacy for a specialty drug on

4 a formulary of the pharmacy benefits manager and dispensed by the pharmacy at the current

5 preferred brand tier reimbursement rate specified in the contract between the pharmacy benefits

6 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.