WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE

AGENCY: Pharmacy TITLE-SERIES: 15-17

RULE TYPE: Legislative Amendment to Existing Rule: No Repeal of existing rule: No

RULE NAME: SUBSTITUTION OF BIOLOGICAL PHARMACEUTICALS

CITE STATUTORY AUTHORITY: §§ 30-5-7 and 30-5-12c

The above rule has been authorized by the West Virginia Legislature.

Authorization is cited in (house or senate bill number) HB 2577

Section § 30-5-7 Passed On 4/17/2013 12:00:00 AM

This rule is filed with the Secretary of State. This rule becomes effective on the following date:

April 25, 2024

This rule shall terminate and have no further force or effect from the following date:

August 01, 2034

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Krista Capehart -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 17
BOARD OF PHARMACY RULES FOR THE SUBSTITUTION OF BIOLOGICAL PHARMACEUTICALS

§15-17-1. General.

1.1. Scope. -- To establish standards for the substitution of biological pharmaceuticals.

1.2. Authority. -- W. Va. Code§§ 30-5-7 and 30-5-12c.

1.3. Filing Date. -- April 25, 2024

1.4. Effective Date. -- April 25, 2024

1.5. Sunset Date -- This rule shall terminate and have no further force or effect upon August 1, 2034.

§15-17-2. Definitions.

2.1. "Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative or arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

2.2. "Biosimilar" means a biological product that has been licensed as a biosimilar pursuant to 42 U.S.C. § 262(k), reflecting that it is highly similar to the specific reference biological product notwithstanding minor differences in clinically inactive components, and that there are no clinically meaningful differences between the reference biological product in terms of safety, purity, and potency of the product.

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

2.4. "Interchangeable biological product" means a biological product that the federal Food and Drug Administration has licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C § 262(k)(4) or determined is therapeutically equivalent as set forth in the latest edition of or supplement of the federal Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations.

2.5. "Original prescription" means either the original written prescription drug order, or the original verbal or electronic prescription drug orders reduced to writing either manually or electronically by the pharmacist.

2.6. "Proper name" means the nonproprietary name of a biological product.

2.7. "Reference biological product" means the single biological product licensed pursuant to 42 U.S.C. § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food and Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to 42 U.S.C. § 262(k).

2.8. "Substitute" means to dispense without the prescriber's express authorization an interchangeable biological product in the place of the drug ordered or prescribed.

2.9. "Therapeutically equivalent" means pharmaceutically equivalent drug products that, if administered in the same amounts, will provide the same therapeutic effect, identical in duration and intensity.

§15-17-3. Substitution Requirements.

3.1. A pharmacist may dispense an interchangeable biological product if:

3.1.1. The interchangeable biological product costs the patient less than or the same amount as the prescribed drug
product;

3.1.2. The patient does not refuse the substitution; and

3.1.3. The practitioner does not certify on the prescription form that a specific prescribed brand is medically necessary as specified in a dispensing directive described in subsection (c) of this section.

3.2. Dispensing directive.

3.2.1. General requirements. The following is applicable to the dispensing directive outlined in this subsection.

3.2.1.a. When a prescription is issued for a brand name product that has no interchangeable biological equivalent, the pharmacist must dispense the brand name product. If an interchangeable biological product becomes available, a pharmacist may substitute the interchangeable biological product unless the practitioner has specified on the initial prescription that the brand name product is medically necessary.

3.2.1.b. If the practitioner has prohibited substitution through a dispensing directive in compliance with this subsection, a pharmacist shall not substitute an interchangeable biological product unless the pharmacist obtains verbal or written authorization from the practitioner, notes such authorization on the original prescription drug order, and notifies the patient.

3.2.2 Written prescriptions.

3.2.2.a A practitioner may prohibit the substitution of an interchangeable biological product for a brand name drug product by writing across the face of the written prescription, in the practitioner's own handwriting, the phrase "brand necessary" or "brand medically necessary."

3.2.2.b. The dispensing directive shall comply with federal and state law, including rules, with regard to formatting and security requirements

3.2.2.c. The dispensing directive specified in this section may not be preprinted, rubber stamped, or otherwise reproduced on the prescription form.

3.2.2.d. A practitioner may prohibit substitution on a written prescription only by following the dispensing directive specified in this section. Two-line prescription forms, check boxes, or other notations

on an original prescription drug order which indicate "substitution instructions" are not valid methods to prohibit substitution, and a pharmacist may substitute on these types of written prescriptions.

3.2.3. Verbal prescription.

3.2.3.a. If a prescription drug order is transmitted to a pharmacist orally, the practitioner or practitioner's agent shall prohibit substitution by specifying "brand necessary" or "brand medically necessary." The pharmacist shall note any substitution instructions by the practitioner or practitioner's agent, on the file copy of the prescription drug order.

3.2.3.b. If the practitioner's or practitioner's agent does not clearly indicate that the brand name is medically necessary, the pharmacist may substitute a generically equivalent drug or interchangeable biological product.

3.2.4. Electronic prescription drug orders.

3.2.4.a. To prohibit substitution, the practitioner or practitioner's agent shall clearly indicate substitution instructions in the electronic prescription drug order.

3.2.4.b. If the practitioner or practitioner's agent does not indicate or does not clearly indicate in the electronic prescription drug order that the brand is necessary, the pharmacist may substitute an interchangeable biological product.

3.2.5. Refills. All refills shall follow the original substitution instructions unless otherwise indicated by the practitioner or practitioner's agent.

§15-17-4. Patient Notification.

4.1. Substitution notification. Before delivery of a prescription for an interchangeable biological product, a pharmacist must personally, or through his or her agent or employee inform the patient or the patient's agent that a less expensive interchangeable biological product is available for the brand prescribed; and ask the patient or the patient's agent to choose between the interchangeable biological product and the brand prescribed.

4.2. Exceptions. A pharmacy is not required to comply with the provisions of subsection 4.1. of this section:

4.2.1. in the case of the refill of a prescription for which the pharmacy previously complied with subsection 4.1. of this section with regard to the same patient or patient's agent; or

4.2.2. if the patient's physician or physician's agent advises the pharmacy that:

4.2.2.a. the physician has informed the patient or the patient's agent that a less expensive interchangeable biological product is available for the brand prescribed; and

4.2.2.b. the patient or the patient's agent has chosen either the brand prescribed or the less interchangeable biological product.

4.3. Notification by pharmacies delivering prescriptions by mail.

4.3.1. A pharmacy that supplies a prescription by mail is considered to have complied with the provision of subsection 4.1. of this section if the pharmacy includes on the prescription order form completed by the patient or the patient's agent language that clearly and conspicuously:

4.3.1.a. states that if a less expensive generically equivalent drug or interchangeable biological product is available for the brand prescribed, the patient or the patient's agent may choose between the generically equivalent drug or interchangeable biological product and the brand prescribed; and

4.3.1.b. allows the patient or the patient's agent to indicate the choice of the generically equivalent drug or interchangeable biological product or the brand prescribed.

4.3.2. If the patient or patient's agent fails to indicate otherwise to a pharmacy on the prescription order form under 4.1.a. of this subsection, the pharmacy may dispense an interchangeable biological product.

§15-17-5. Communication with prescriber.

5.1. Not later than the fifth business day after the date of dispensing a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing practitioner the specific product provided to the patient, including the name of the product and the manufacturer or national drug code number.

5.2. The communication must be conveyed by making an entry into an interoperable electronic medical records system or through electronic prescribing technology or a pharmacy benefit management system or a pharmacy record, which may include information submitted for the payment of claims, that a pharmacist reasonably concludes is electronically accessible by the prescribing practitioner. Otherwise, the pharmacist or the pharmacist's designee shall communicate the biological product dispensed to the prescribing practitioner, using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication is not required if:

5.2.1. there is no interchangeable biological product approved by the United States Food and Drug Administration for the product prescribed; or

5.2.2. a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

§15-17-6. Records.

6.1. When a pharmacist dispenses an interchangeable biological product, the following information shall be noted on the original prescription or in the pharmacy's data processing system:

6.1.1. any substitution instructions communicated orally to the pharmacist by the practitioner or practitioner's agent; and

6.1.2. the name and strength of the actual drug product dispensed shall be noted on the original or hard-copy prescription drug order. The name shall be either:

6.1.2.a. the brand name and strength; or

6.1.2.b. the name of the interchangeable biological product, strength, and name of the manufacturer or distributor of such generic drug or interchangeable biological product. (The name of the manufacturer or distributor may be reduced to an abbreviation or initials, provided the abbreviation or initials are sufficient to identify the manufacturer or distributor. For combination drug products having no brand name, the principal active ingredients shall be indicated on the prescription.)

6.2. If a pharmacist refills a prescription drug order with a generically equivalent product or interchangeable biological product from a different manufacturer or distributor than previously dispensed, the pharmacist shall record on the prescription drug order the information required in subsection 6.1 of this section for the product dispensed on the refill.

6.3. If a pharmacy utilized patient medication records for recording prescription information, the information required in subsections 6.1. and 6.2. of this section shall be recorded on the patient medication records.

6.4. The National Drug Code (NDC) of a drug or any other code may be indicated on the prescription drug order at the discretion of the pharmacist, but such code shall not be used in place of subsections 6.1. and 6.2.

§15-17-7. Dispensing Responsibilities.

7.1. The determination of the drug product to be substituted as authorized by West Virginia Code of State Rules §15-17 et seq. is the professional responsibility of the pharmacist, and the pharmacist may not dispense any product that does not meet the requirements of the West Virginia Code of State Rules §15-17 et seq.

7.2. Pharmacists shall use as a basis for the determination of interchangeability as defined in West Virginia Code of State Rules §15-17 et seq., most recent edition or supplement of the United States Food and Drug Administration's references (e.g. the Purple Book).

7.3. Pharmacists shall use Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book) and current supplements published by the Federal Food and Drug Administration, within the limitations stipulated in that publication, to determine biosimilarity to or interchangeability with a reference biological product.