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A11, R20, H3438

STATUS INFORMATION

General Bill

Sponsors: Reps. Henderson, G.M. Smith, Sandifer, Hiott, Loftis and Robinson-Simpson

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Companion/Similar bill(s): 299

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Last Amended on March 23, 2017

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Governor's Action: April 24, 2017, Signed

Summary: Drug substitutions

HISTORY OF LEGISLATIVE ACTIONS

Date	Body	Action Description with journal page number
1/12/2017	House	Introduced and read first time (House Journal-page 420)
1/12/2017	House	Referred to Committee on Medical, Military, Public and Municipal Affairs (House Journal-page 420)
1/18/2017	House	Member(s) request name added as sponsor: G.M.Smith
1/19/2017	House	Member(s) request name added as sponsor: Sandifer, Hiott
2/15/2017	House	Committee report: Favorable with amendment Medical, Military, Public and Municipal Affairs (House Journal-page 2)
2/21/2017	House	Member(s) request name added as sponsor: Loftis
2/21/2017	House	Amended (House Journal-page 26)
2/21/2017	House	Read second time (House Journal-page 26)
2/21/2017	House	Roll call Yeas-104 Nays-0 (House Journal-page 28)
2/21/2017	House	Member(s) request name added as sponsor: Robinson-Simpson
2/22/2017	House	Read third time and sent to Senate (House Journal-page 7)
2/22/2017	Senate	Introduced and read first time (Senate Journal-page 5)
2/22/2017	Senate	Referred to Committee on Medical Affairs (Senate Journal-page 5)
2/22/2017		Scrivener's error corrected
3/16/2017	Senate	Committee report: Favorable with amendment Medical Affairs (Senate Journal-page 11)
3/23/2017	Senate	Committee Amendment Adopted (Senate Journal-page 226)
3/23/2017	Senate	Read second time (Senate Journal-page 29)
3/23/2017	Senate	Roll call Ayes-37 Nays-0 (Senate Journal-page 29)
3/29/2017	Senate	Read third time and returned to House with amendments (Senate Journal-page 23)
4/4/2017	House	Concurred in Senate amendment and enrolled (House Journal-page 34)
4/4/2017	House	Roll call Yeas-95 Nays-0 (House Journal-page 35)
4/19/2017		Ratified R 20
4/24/2017		Signed By Governor
4/27/2017		Effective date 4/24/17
4/28/2017		Act No. 11

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VERSIONS OF THIS BILL

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(A11, R20, H3438)

AN ACT TO AMEND SECTION 39-24-20, CODE OF LAWS OF SOUTH CAROLINA, 1976, RELATING TO DEFINITIONS IN THE DRUG PRODUCT SELECTION ACT, SO AS TO CHANGE THE DEFINITION OF “SUBSTITUTE” TO INCLUDE INTERCHANGEABLE BIOLOGICAL PRODUCTS; TO AMEND SECTION 39-24-30, RELATING TO THE SUBSTITUTION OF EQUIVALENT DRUGS, SO AS TO ALLOW A PHARMACIST TO SUBSTITUTE AN INTERCHANGEABLE BIOLOGICAL PRODUCT FOR A SPECIFIC BIOLOGICAL PRODUCT; TO AMEND SECTION 39-24-40, AS AMENDED, RELATING TO THE SUBSTITUTION OF PRESCRIPTIONS BY PHARMACISTS, SO AS TO ALLOW PHARMACISTS TO SUBSTITUTE INTERCHANGEABLE BIOLOGICAL PRODUCTS WHEN APPROPRIATE; TO AMEND SECTION 40-43-30, RELATING TO DEFINITIONS IN THE PHARMACY PRACTICE ACT, SO AS TO ADD DEFINITIONS FOR “BIOLOGICAL PRODUCT” AND “INTERCHANGEABLE BIOLOGICAL PRODUCT”; AND TO AMEND SECTION 40-43-86, RELATING IN PART TO LABEL REQUIREMENTS FOR PRESCRIPTIONS, SO AS TO ADDRESS LABELING, PRESCRIBER NOTIFICATION, AND OTHER REQUIREMENTS APPLICABLE TO INTERCHANGEABLE BIOLOGICAL PRODUCTS.

Be it enacted by the General Assembly of the State of South Carolina:

Changing definition of substitute in Drug Product Selection Act

SECTION 1. Section 39-24-20 of the 1976 Code is amended to read:

“Section 39-24-20. As used in this chapter:

- (1) ‘Brand name’ means the proprietary or trade name placed upon a drug, its container, label or wrapping at the time of packaging;
- (2) ‘Generic name’ means the United States Adopted Name (USAN) or the official title of a drug published in the latest edition of a nationally recognized pharmacopoeia or formulary;
- (3) ‘Substitute’ means to dispense, with the practitioner’s authorization, a ‘therapeutically equivalent’ generic drug product of identical drug salt or an interchangeable biological product in place of the drug or biological product ordered or prescribed;

(4) ‘Therapeutically equivalent’ means the same efficacy and toxicity when administered to an individual in the same dosage form; and

(5) ‘Practitioner’ means a physician, osteopath, dentist, podiatrist, veterinarian, or any other person authorized to prescribe drugs under the laws of this State.”

Authority of a pharmacist to substitute interchangeable biological products

SECTION 2. Section 39-24-30 of the 1976 Code is amended to read:

“Section 39-24-30. (A) As provided in Section 39-24-40, upon receiving a prescription for a brand name product, a registered pharmacist may substitute a drug product of the same dosage form and strength which, in his professional judgment, is a therapeutically equivalent drug product.

(B) As provided in Section 39-24-40, upon receiving a prescription for a specific biological product, a registered pharmacist may substitute an interchangeable biological product.”

Prescription requirements to substitute interchangeable biological products

SECTION 3. Section 39-24-40 of the 1976 Code, as last amended by Act 314 of 2002, is further amended to read:

“Section 39-24-40. (A) An oral or written drug prescription must provide an authorization from the practitioner as to whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted.

(B) A written prescription must have two signature lines at opposite ends on the bottom of the form. Under the line at the left side must be clearly printed the words ‘DISPENSE AS WRITTEN’. Under the line at the right side shall be clearly printed the words ‘SUBSTITUTION PERMITTED’, unless the prescription is to be paid for with Medicaid funds. The practitioner shall communicate the instructions to the pharmacist by signing on the appropriate line. A written prescription is not valid without the signature of the practitioner on one of these lines.

(C) An oral prescription from the practitioner must instruct the pharmacist as to whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted, unless the prescription is to be paid for with Medicaid funds. The pharmacist shall

note the instructions on the file copy of the prescription and retain the prescription form for the period as prescribed by law.

(D) The pharmacist shall note the brand name or the manufacturer of the substituted drug or biological product dispensed on the file copy of a written or oral prescription or record this information electronically, or both.

(E) Substitution may not occur unless the pharmacist advises the patient that the practitioner has authorized substitution and the patient consents.

(F) If a pharmacist substitutes a generic drug for a name brand prescribed drug when dispensing a prescribed medication, the brand name and the name of the generic drug and its manufacturer, with an explanation of 'generic for' or similar language to indicate substitution has occurred, must appear on the prescription label and be affixed to the container or an auxiliary label, unless the prescribing practitioner indicated that the name of the drug may not appear upon the prescription label.

(G) If a pharmacist substitutes an interchangeable biological product for a specific biological product prescribed when dispensing a prescribed medication, the brand name and the name of the interchangeable biological product and its manufacturer, with an explanation of 'interchangeable with' or similar language, to indicate substitution has occurred, must appear on the prescription label and be affixed to the container or an auxiliary label unless the prescribing practitioner indicated that the name of the biological product may not appear on the prescription label."

Adding Pharmacy Practice Act definitions

SECTION 4. Section 40-43-30 of the 1976 Code is amended to read:

"Section 40-43-30. For purposes of this chapter:

(1) 'Administer' means the direct application of a drug or device pursuant to a lawful order of a practitioner to the body of a patient by injection, inhalation, ingestion, topical application, or any other means.

(2) 'Biological product' has the same meaning as defined in 42 U.S.C. Sec. 262.

(3) 'Biological safety cabinet' means a containment unit suitable for the preparation of low-to-moderate risk agents where there is a need for protection of the product, personnel, and environment, according to National Sanitation Foundation Standard 49.

(4) 'Board' or 'Board of Pharmacy' means the State Board of Pharmacy.

(5) 'Brand name' means the proprietary or trade name placed upon a drug, its container, label, or wrapping at the time of packaging.

(6) 'Chart order' means a lawful order from a practitioner for a drug or device for patients of a hospital or extended care facility, or such an order prepared by another person and signed by a practitioner either immediately or at another time, issued for a legitimate medical purpose within the practitioner's course of legitimate practice and including orders derived on behalf of a practitioner from a practitioner approved drug therapy management.

(7) 'Class 100 environment' means an atmospheric environment which contains less than one hundred particles 0.5 microns in diameter per cubic foot of air.

(8) 'Compounding' means the preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, or the preparation, mixing, assembling, packaging, or labeling of a drug or device as the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice, or for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns. The term compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

(9) 'Confidential information' means information maintained in a patient's records or which is communicated to a patient as part of patient counseling, which is privileged and may be released only to the patient, to those practitioners and pharmacists where, in the pharmacist's professional judgment, release is necessary to protect the patient's health and well being, and to other persons or governmental agencies authorized by law to receive such confidential information.

(10) 'Cytotoxic agent' means a drug that has the capability of killing living cells.

(11) 'Deliver' or 'delivery' means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for consideration.

(12) 'Designated agent' means a person employed by an authorized practitioner to transmit, either orally or electronically, a prescription drug order on behalf of the authorized practitioner to the pharmacist. The

authorized practitioner accepts the responsibility for the correct transmission of the prescription drug order.

(13) 'Designated pharmacist' means an individual currently licensed by the Board of Pharmacy in this State who certifies internship training.

(14) 'Device' means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is required under federal law to bear the label: 'Caution: Federal law restricts this device for sale by or on the order of a _____', the blank to be filled with the word physician, dentist, veterinarian, or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; or 'Federal law prohibits dispensing without prescription'; or any products deemed to be a public health threat after notice and public hearing as designated by the board.

(15) 'Dispense' means the transfer of possession of one or more doses of a drug or device by a licensed pharmacist or person permitted by law, to the ultimate consumer or his agent pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by, a patient. As an element of dispensing, the dispenser shall, before the actual physical transfer, interpret and assess the prescription order for potential adverse reactions or side effects, interactions, allergies, dosage, and regimen the dispenser considers appropriate in the exercise of his professional judgment, and the dispenser shall determine that the drug or device called for by the prescription is ready for dispensing. The dispenser shall also provide counseling on proper drug usage, either orally or in writing, as provided in this chapter. The actual sales transaction and delivery of a drug or device is not considered dispensing and the administration is not considered dispensing.

(16) 'Distribute' means the delivery of a drug or device other than by administering or dispensing.

(17) 'Drug' or 'medicine' means:

(a) articles recognized as drugs in an official compendium, or supplement to a compendium, including, but not limited to, USP/NF designated from time to time by the board for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

(b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

(c) articles, other than food, or nonprescription vitamins intended to affect the structure or a function of the human body or other animals; and

(d) articles intended for use as a component of any articles specified in item (a), (b), or (c) of this subsection.

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

(a) evaluation of prescription drug orders and pharmacy patient records for:

- (i) known allergies;
- (ii) rational therapy-contraindications;
- (iii) reasonable dose and route of administration; and
- (iv) reasonable directions for use.

(b) evaluation of prescription drug orders and pharmacy patient records for duplication of therapy.

(c) evaluation of prescription drug orders and pharmacy patient records for interactions:

- (i) drug-drug;
- (ii) drug-food;
- (iii) drug-disease, if available; and
- (iv) adverse drug reactions.

(d) evaluation of prescription drug orders and pharmacy patient records for proper utilization, including over-utilization or under-utilization, and optimum therapeutic outcomes.

(19) 'Drug therapy management' is that practice of pharmacy which involves the expertise of the pharmacist in a collaborative effort with the practitioner and other health care providers to ensure the highest quality health care services for patients.

(20) 'Enteral' means within or by way of the intestine.

(21) 'Equivalent drug product' means a drug product which has the same established name and active ingredients to meet the same compendia or other applicable standards, but which may differ in characteristics such as shape, scoring configuration, packaging, excipient (including colors, flavors, preservatives), and expiration time. Pharmacists may utilize as a basis for the determination of generic equivalency Approved Drug Products with Therapeutic Equivalence Evaluations and current supplements published by the federal Food and Drug Administration, within the limitations stipulated in that publication.

(22) 'Extern' means an individual currently enrolled in an approved college or school of pharmacy who is on required rotations for obtaining a degree in pharmacy.

(23) 'Generic names' mean the official compendia names or United States Adopted Names (USAN).

(24) 'Health care provider' includes a pharmacist who provides health care services within the pharmacist's scope of practice pursuant to state law and regulation.

(25) 'Institutional facility' means an organization whose primary purpose is to provide a physical environment for patients to obtain health care services and shall not include those places where physicians, dentists, veterinarians, or other practitioners, who are duly licensed, engage in private practice.

(26) 'Institutional pharmacy' means the physical portion of an institutional facility that is engaged in the compounding, dispensing, and distribution of drugs, devices, and other materials, hereinafter referred to as 'drugs', used in the diagnosis and treatment of injury, illness, and disease and which is permitted by the State Board of Pharmacy.

(27) 'Institutional consultant pharmacist' means a pharmacist licensed in this State who acts as a consultant for institutional facilities.

(28) 'Interchangeable biological product' means a biological product that the federal Food and Drug Administration has:

(a) licensed and determined to meet the standards of 'interchangeability' pursuant to 42 U.S.C. Section 262(k)(4); or

(b) determined to be therapeutically equivalent by the federal Food and Drug Administration.

(29) 'Intern' means an individual who is currently registered by certificate in this State to engage in the practice of pharmacy while under the personal supervision of a pharmacist and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist.

(30) 'Labeling' means the process of preparing and affixing a label which includes all information required by federal and state law to a drug container exclusive of the labeling by a manufacturer, packer, or distributor of a nonprescription drug or commercially packaged legend drug or device.

(31) 'Manufacturing of products' means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, or from bulk chemicals, and includes any packaging or repackaging of the substances or labeling or relabeling of its container, if these actions are followed by the promotion and marketing of the drugs or devices for resale to pharmacies, practitioners, or other persons.

(32) 'Manufacturer' means a person engaged in the manufacture of prescription drugs or devices.

(33) 'Medical order' means a lawful order of a practitioner which may or may not include a prescription drug order.

(34) 'Nonprescription drug' means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the requirements of the laws of this State and the federal government.

(35) 'Nonresident pharmacy' means a pharmacy located outside this State.

(36) 'Parenteral' means a sterile preparation of drugs for injection through one or more layers of the skin.

(37) 'Patient counseling' means the oral or written communication by the pharmacist to a patient or caregiver providing information on the proper use of drugs and devices.

(38) 'Permit consultant pharmacist' means a pharmacist licensed in this State who acts as a consultant for a permit holder other than a pharmacy or institution.

(39) 'Person' means an individual, sole-proprietorship, corporation, partnership, association, or any other legal entity including government.

(40) 'Pharmacy care' is the direct provision of drug therapy and other pharmacy patient care services through which pharmacists, in cooperation with the patient and other health care providers, design, implement, monitor, and manage therapeutic plans for the purpose of improving a patient's quality of life. Objectives include cure of disease, elimination or reduction of a patient's symptomatology, arresting or slowing a disease process, or prevention of a disease or symptomatology. The process includes three primary functions:

- (a) identifying potential and actual drug-related problems;
- (b) resolving actual drug-related problems; and
- (c) preventing potential drug-related problems.

(41) 'Pharmacist' means an individual health care provider licensed by this State to engage in the practice of pharmacy. A pharmacist is a learned professional authorized to provide patient care services within the scope of his knowledge and skills.

(42) 'Pharmacist-in-charge' means a pharmacist currently licensed in this State who accepts responsibility for the operation of a pharmacy in conformance with all laws pertinent to the practice of pharmacy and the distribution of drugs and who is in full and actual charge of the pharmacy and personnel.

(43) 'Pharmacy' means a location for which a pharmacy permit is required and in which prescription drugs and devices are maintained, compounded, and dispensed for patients by a pharmacist. This definition includes a location where pharmacy-related services are provided by a pharmacist.

(44) 'Pharmacy technician' means an individual other than an intern or extern, who assists in preparing, compounding, and dispensing

medicines under the personal supervision of a licensed pharmacist and who is required to register as a pharmacy technician.

(45) 'Poison' means:

(a) a drug, chemical, substance, or preparation which, according to standard works on medicine, materia medica, or toxicology, is liable to be destructive to adult human life in doses of sixty grains or less; or

(b) a substance recognized by standard authorities on medicine, materia medica, or toxicology as poisonous; or

(c) any other item enumerated in this chapter; or

(d) a drug, chemical, substance, or preparation which is labeled 'Poison'.

(46) 'Practice of pharmacy' means the interpretation, evaluation, and dispensing of prescription drug orders in the patient's best interest; participation in drug and device selection, drug administration, prospective drug reviews, and drug or drug-related research; provision of patient counseling and the provision of those acts or services necessary to provide pharmacy care and drug therapy management; and responsibility for compounding and labeling of drugs and devices, (except labeling by a manufacturer, repackager, or distributor or nonprescription drugs and commercially packaged legend drugs and devices) proper and safe storage of drugs and devices and maintenance of proper records for them; or the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, education, management, and control of pharmacy.

(47) 'Practitioner' means a physician, dentist, optometrist, podiatrist, veterinarian, or other health care provider authorized by law to diagnose and prescribe drugs and devices.

(48) 'Prescription drug' or 'legend drug' means:

(a) a drug which, under federal law, is required, prior to being dispensed or delivered, to be labeled with any of the following statements:

(i) 'Caution: Federal law prohibits dispensing without prescription';

(ii) 'Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian';

(iii) 'Rx only'; or

(b) a drug which is required by any applicable federal or state law to be dispensed pursuant only to a prescription drug order or is restricted to use by practitioners only;

(c) any drug products considered to be a public health threat, after notice and public hearing as designated by the board; or

(d) any prescribed compounded prescription is a prescription drug within the meaning of this act.

(49) 'Prescription drug order' means a lawful order from a practitioner for a drug or device for a specific patient, issued for a legitimate medical purpose within the prescriber's course of legitimate practice and including orders derived from collaborative pharmacy practice.

(50) 'Prospective drug use review' means a review of the patient's drug therapy and prescription drug order before dispensing the drug as part of a drug regimen review.

(51) 'Significant adverse drug reaction' means a drug-related incident that may result in serious harm, injury, or death to the patient.

(52) 'Sterile pharmaceutical' means a dosage form devoid of viable microorganisms.

(53) 'Therapeutically equivalent' means a drug product with the same efficacy and toxicity when administered to an individual as the originally prescribed drug as provided for in Section 39-24-40.

(54) 'Wholesale distributor' means a person engaged in wholesale distribution of prescription drugs or devices including, but not limited to, manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions. 'Wholesale distributor' does not include:

(a) intracompany sales, being defined as a transaction or transfer between a division, subsidiary, parent, or affiliated or related company under the common ownership and control of a corporate entity;

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

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

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

(e) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For purposes of this section, 'emergency medical reasons' includes the transfer of legend drugs by a licensed pharmacy to another licensed pharmacy or a

practitioner licensed to possess prescription drugs to alleviate a temporary shortage, except that the gross dollar value of the transfers may not exceed five percent of the total legend drug sales revenue of either the transferor or the transferee pharmacy during a consecutive twelve-month period;

(f) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription; or

(g) the sale, purchase, or trade of blood and blood components intended for transfusion.

(55) 'Revocation' means the cancellation or withdrawal of a license, permit, or other authorization issued by the board either permanently or for a period specified by the board before the person shall be eligible to apply anew. A person whose license, permit, or other authorization has been permanently revoked by the board shall never again be eligible for a license or permit of any kind from the board.

(56) 'Certified pharmacy technician' means an individual who is a registered pharmacy technician and who has completed the requirements provided for in Section 40-43-82(B)."

Labeling and other pharmacy requirements for interchangeable biological products

SECTION 5. Section 40-43-86(B)(4)(b) and (H) of the 1976 Code is amended to read:

“(b) The pharmacist-in-charge shall develop and implement written policies and procedures to specify the duties to be performed by pharmacy technicians. The duties and responsibilities of these personnel shall be consistent with their training and experience. These policies and procedures shall, at a minimum, specify that pharmacy technicians are to be personally supervised by a licensed pharmacist who has the ability to control and who is responsible for the activities of pharmacy technicians and that pharmacy technicians are not assigned duties that may be performed only by a licensed pharmacist. One pharmacist may not supervise more than three pharmacy technicians at a time; through June 30, 2006, at least one of these three technicians must be state-certified, and after June 30, 2006, at least two of these three technicians must be state-certified. If a pharmacist supervises only one or two pharmacy technicians, these technicians are not required to be state-certified. Pharmacy technicians do not include personnel in the prescription area performing only clerical functions, including data entry up to the point of dispensing, as defined in Section 40-43-30 (15).

(H)(1) Upon receiving a prescription for a brand name drug or for a specific biological product, a registered pharmacist may in his professional judgment substitute an equivalent drug or interchangeable biological product as provided in this subsection.

(2) Every oral or written drug prescription shall provide an authorization from the practitioner as to whether or not an equivalent drug or interchangeable biological product may be substituted.

(3) A written prescription shall have two signature lines at opposite ends on the bottom of the form. Under the line at the left side shall be clearly printed the words 'DISPENSE AS WRITTEN'. Under the line at the right side shall be clearly printed the words 'SUBSTITUTION PERMITTED'. The practitioner shall communicate the instructions to the pharmacist by signing on the appropriate line. No written prescription is valid without the signature of the practitioner on one of these lines.

(4) An oral prescription from the practitioner shall instruct the pharmacist as to whether or not an equivalent drug product or interchangeable biological product may be substituted. The pharmacist shall note the instructions on the file copy of the prescription and retain the prescription form for the period as prescribed by law.

(5) The pharmacist shall note the brand name or the manufacturer of the substituted drug or brand or proper name and manufacturer of the biological product dispensed on the file copy of a written or oral prescription or record this information electronically, or both. If a pharmacist substitutes a generic drug or interchangeable biological product for a name brand prescribed drug or specific biological product prescribed:

(a) In the case of a drug product described, when dispensing a prescribed medication, the brand name and the generic name of the drug and its manufacturer or brand name, if any, with an explanation of 'generic for' or similar language in the case of a drug dispensed, to indicate substitution has occurred, must appear on the prescription label and be affixed to the container or an auxiliary label, unless in the case of a drug product prescribed, the prescribing practitioner indicated that the name of the drug may not appear upon the prescription label.

(b) In the case of a biological product described, when dispensing a prescribed medication, the brand name, if any, and the proper name of the biological product and its manufacturer, with an explanation of 'interchangeable with' or similar language, in the case of a biological product dispensed, to indicate substitution has occurred, must appear on the prescription label and be affixed to the container or an auxiliary label, unless in the case of a drug product prescribed, the

prescribing practitioner indicated that the name of the drug may not appear upon the prescription label.

(6) Substitution may not occur unless the pharmacist advises the patient or the patient's agent that the practitioner has authorized substitution and the patient, or patient's agent, consents. A Medicaid recipient whose prescription is reimbursed by the South Carolina Medicaid Program is deemed to have consented to the substitution of a less costly equivalent generic drug product or interchangeable biological product.

(7) Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific biological product provided to the patient, including the name of the biological product and the manufacturer. The communication must be conveyed by making an entry that is electronically accessible to the prescriber through: (i) an interoperable electronic medical records system; (ii) an electronic prescribing technology; (iii) a pharmacy benefit management system; or (iv) a pharmacy record. Entry into an electronic records system as described in this section is presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication is not required when:

(a) there is no federal Food and Drug Administration approved interchangeable biological product for the product prescribed; or

(b) a refill prescription is not changed from the product dispensed on the prior filling of the prescription; or

(c) a biological product is dispensed for inpatient hospital services or is a hospital-administered biological product for outpatients.”

Time effective

SECTION 6. This act takes effect upon approval by the Governor.

Ratified the 19th day of April, 2017.

Approved the 24th day of April, 2017.