2018 -- S 2406

========
LC004711
========

S T A T E O F R H O D E I S L A N D

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2018

A N A C T

RELATING TO BUSINESSES AND PROFESSIONS - PHARMACIES - INSURANCE - PRESCRIPTION DRUG BENEFITS

Introduced By: Senators Sosnowski, Crowley, Miller, and Nesselbush

Date Introduced: February 15, 2018

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

SECTION 1. Section 5-19.1-2 of the General Laws in Chapter 5-19.1 entitled "Pharmacies" is hereby amended to read as follows:

5-19.1-2. Definitions.

(a) "Biological product" means a "biological product" as defined in the "Public Health Service Act", 42 U.S.C. § 262.

(b) "Board" means the Rhode Island board of pharmacy.

(c) "Change of ownership" means:

(1) In the case of a pharmacy, manufacturer, or wholesaler that is a partnership, any change that results in a new partner acquiring a controlling interest in the partnership;

(2) In the case of a pharmacy, manufacturer, or wholesaler that is a sole proprietorship, the transfer of the title and property to another person;

(3) In the case of a pharmacy, manufacturer, or wholesaler that is a corporation:

(i) A sale, lease exchange, or other disposition of all, or substantially all, of the property and assets of the corporation; or

(ii) A merger of the corporation into another corporation; or

(iii) The consolidation of two (2) or more corporations resulting in the creation of a new corporation; or

(iv) In the case of a pharmacy, manufacturer, or wholesaler that is a business corporation,

any transfer of corporate stock that results in a new person acquiring a controlling interest in the corporation; or

(v) In the case of a pharmacy, manufacturer, or wholesaler that is a non-business corporation, any change in membership that results in a new person acquiring a controlling vote in the corporation.

(d) "Compounding" means the act of combining two (2) or more ingredients as a result of a practitioner's prescription or medication order occurring in the course of professional practice based upon the individual needs of a patient and a relationship between the practitioner, patient, and pharmacist. Compounding does not mean the routine preparation, mixing, or assembling of drug products that are essentially copies of a commercially available product. Compounding shall only occur in the pharmacy where the drug or device is dispensed to the patient or caregiver and includes the preparation of drugs or devices in anticipation of prescription orders based upon routine, regularly observed prescribing patterns.

(e) "Controlled substance" means a drug or substance, or an immediate precursor of such drug or substance, so designated under, or pursuant to, the provisions of chapter 28 of title 21.

(f) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a drug or device, whether or not there is an agency relationship.

(g) "Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended:

(1) For use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or

(2) To affect the structure or any function of the body of man or other animals.

(h) "Director" means the director of the Rhode Island state department of health.

(i) "Dispense" means the interpretation of a prescription or order for a drug, biological, or device and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery or administration.

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

(k) "Drug" means:

(1) Articles recognized in the official United States Pharmacopoeia or the Official Homeopathic Pharmacopoeia of the U.S.;

(2) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, woman, or other animals;

(3) Substances (other than food) intended to affect the structure, or any function of the body, of man, woman, or other animals; or

(4) Substances intended for use as a component of any substances specified in subdivision (1), (2), or (3) of this subsection, but not including devices or their component parts or accessories.

(l) "Equivalent and interchangeable" means a drug, excluding a biological product, having the same generic name, dosage form, and labeled potency, meeting standards of the United States Pharmacopoeia or National Formulary, or their successors, if applicable, and not found in violation of the requirements of the United States Food and Drug Administration, or its successor agency, or the Rhode Island department of health.

(m) "Insured" means an individual covered by a health plan, including covered dependents.

~~(m)~~(n) "Interchangeable biological product" means a biological product that the United States Food and Drug Administration has:

(1) Licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C. § 262(k)(4) or lists of licensed, biological products with reference product exclusivity and biosimilarity or interchangeability evaluations; or

(2) Determined is therapeutically equivalent as set forth in the latest edition of or supplement to, the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations.

~~(n)~~(o) "Intern" means:

(1) A graduate of an American Council on Pharmaceutical Education (ACPE)-accredited program of pharmacy;

(2) A student who is enrolled in at least the first year of a professional ACPE-accredited program of pharmacy; or

(3) A graduate of a foreign college of pharmacy who has obtained full certification from the FPGEC (Foreign Pharmacy Graduate Equivalency Commission) administered by the National Association of Boards of Pharmacy.

~~(o)~~(p) "Legend drugs" means any drugs that are required by any applicable federal or state law or regulation to be dispensed on prescription only or are restricted to use by practitioners only.

~~(p)~~(q) "Limited-function test" means those tests listed in the federal register under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as waived tests. For the purposes of this chapter, limited-function test shall include only the following: blood glucose, hemoglobin

Alc, cholesterol tests, and/or other tests that are classified as waived under CLIA and are approved by the United States Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit.

~~(q)~~(r) "Manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance or device or the packaging or repackaging.

~~(r)~~(s) "Non-legend" or "non-prescription drugs" means any drugs that may be lawfully sold without a prescription.

~~(s)~~(t) "Person" means an individual, corporation, government, subdivision, or agency, business trust, estate, trust, partnership or association, or any other legal entity.

~~(t)~~(u) "Pharmaceutical care" is the provision of drugs and other pharmaceutical services intended to achieve outcomes related to cure or prevention of a disease elimination or reduction of a patient's symptoms or arresting or slowing of a disease process. "Pharmaceutical care" includes the judgment of a pharmacist in dispensing an equivalent and interchangeable drug or device in response to a prescription after appropriate communication with the prescriber and the patient.

(v) "Pharmacist" means a person licensed to practice pharmacy in the state.

~~(u)~~(w) "Pharmacist in charge" means a pharmacist licensed in this state as designated by the owner as the person responsible for the operation of a pharmacy in conformance with all laws and regulations pertinent to the practice of pharmacy and who is personally in full and actual charge of such pharmacy and personnel.

~~(v)~~(x) "Pharmacy" means that portion or part of a premise where prescriptions are compounded and dispensed, including that portion utilized for the storage of prescription or legend drugs.

(y) "Pharmacy benefit manager" means a person or entity who contracts with a pharmacy on behalf of an insurer, health plan, or third party administrator to administer or manage prescription drug benefits.

~~(w)~~(z) "Pharmacy technician" means an individual who meets minimum qualifications established by the board, that are less than those established by this chapter as necessary for licensing as a pharmacist, and who works under the direction and supervision of a licensed pharmacist.

~~(x)~~(aa) "Practice of pharmacy" means the interpretation, evaluation, and implementation of medical orders; the dispensing of prescription drug orders; participation in drug and device selection; the compounding of prescription drugs; drug regimen reviews and drug or drug-related research; the administration of adult immunizations pursuant to a valid prescription or physician-

approved protocol and in accordance with regulations, to include training requirements as promulgated by the department of health; the administration of all forms of influenza immunizations to individuals between the ages of nine (9) years and eighteen (18) years, inclusive, pursuant to a valid prescription or prescriber-approved protocol, in accordance with the provisions of § 5-19.1-31 and in accordance with regulations, to include necessary training requirements specific to the administration of influenza immunizations to individuals between the ages of nine (9) years and eighteen (18) years, inclusive, as promulgated by the department of health; provision of patient counseling and the provision of those acts or services necessary to provide pharmaceutical care; and/or the responsibility for the supervision for compounding and labeling of drugs and devices (except labeling by a manufacturer, repackager, or distributor of non-prescription drugs and commercially packaged legend drugs and devices), proper and safe storage of drugs and devices, and maintenance of proper records for them; and the performance of clinical laboratory tests, provided such testing is limited to limited-function tests as defined herein. Nothing in this definition shall be construed to limit or otherwise affect the scope of practice of any other profession.

~~(y)~~(bb) "Practitioner" means a physician, dentist, veterinarian, nurse, or other person duly authorized by law in the state in which they practice to prescribe drugs.

~~(z)~~(cc) "Preceptor" means a pharmacist registered to engage in the practice of pharmacy in this state who has the responsibility for training interns.

~~(aa)~~(dd) "Prescription" means an order for drugs or devices issued by the practitioner duly authorized by law in the state in which he or she practices to prescribe drugs or devices in the course of his or her professional practice for a legitimate medical purpose.

~~(bb)~~(ee) "Wholesaler" means a person who buys drugs or devices for resale and distribution to corporations, individuals, or entities other than consumers.

SECTION 2. Chapter 5-19.1 of the General Laws entitled "Pharmacies" is hereby amended by adding thereto the following section:

5-19.1-33. Pharmacist - Patient relationship.

(a) A pharmacy benefits manager shall not prohibit a pharmacist or pharmacy from providing an insured information regarding the amount of the insured's cost share for a prescription drug and the clinical efficacy of a lower-priced alternative drug, if one is available. Neither a pharmacy nor a pharmacist shall be penalized by a pharmacy benefits manager for discussing any information described in this section or for selling a lower-priced drug to the insured if one is available.

(b) A pharmacy or pharmacist shall have the right to provide the insured individual with

any relevant information pertaining to the acquisition of a prescription medication. A pharmacist may disclose any and all relevant information pertaining to the clinical efficacy, or the availability of any therapeutically equivalent alternative prescription medications, or any alternative methods to the purchasing of a prescription medication, including, but not limited to, paying a cash price, that is less expensive than the cost of the prescription medication to the insured individual.

(c) Communication by and between a pharmacist and patient shall be confidential health care communication and disclosed only pursuant to the provisions of § 5-37.3-4.

SECTION 3. Sections 27-20.8-1 and 27-20.8-2 of the General Laws in Chapter 27-20.8 entitled "Prescription Drug Benefits" are hereby amended to read as follows:

27-20.8-1. Definitions.

For the purposes of this chapter, the following terms shall mean:

(1) "Director" shall mean the director of the department of business regulation.

(2) "Health plan" shall mean an insurance carrier as defined in chapters 18, 19, 20 and 41 of this title, and any plan by which health benefits are paid by an insurer, the state, or the United States.

(3) "Insured" shall mean any person who is entitled to have pharmacy services paid by a health plan pursuant to a policy, certificate, contract or agreement of insurance or coverage including those administered for the health plan under a contract with a third-party administrator that manages pharmacy benefits or pharmacy network contracts.

27-20.8-2. Pharmacy benefit, limits and co-payments.

Any health plan that offers pharmacy benefits shall comply with the following:

(a) When a health plan's pharmacy benefit has a dollar limit, the insured's use of such benefit shall be determined based on the health plan's contracted rate to purchase the drug minus the enrollee's applicable co-payment for covered drugs. The balance will apply towards the enrollee's dollars limit.

(b) When a health plan charges a co-payment for covered prescription drugs that is based on a percent of the drug cost, the health plan shall disclose within the group policy or individual policy benefits description statement whether the co-payment is based on the plan's contracted rate to purchase the drug or some other cost basis such as retail price.

(c) No insured shall be required to make a payment for a prescription drug at point of sale in an amount greater than the lesser of the pharmacy's usual and customary price of filling the prescription or the contracted copayment.

(d) The amount reimbursed to the pharmacy in connection with the claims associated to

the co-payment from the insured shall be retained by the pharmacy. The amount that is credited to the insured's account in the pre-coverage gap shall be no more than the amount that the pharmacy was reimbursed by the health plan payor from the corresponding co-payment made by the insured. The pharmacy benefits manager or health plan may not apply an amount greater than the actual amount reimbursed to the pharmacy by the health plan payor per prescription from the corresponding co-payment to an insured's account or to determine when an insured falls into a coverage gap.

(e) A pharmacy benefits manager may not charge a fee, or otherwise hold a pharmacist or pharmacy responsible, for costs relating to the adjudication of a claim.

(f) No pharmacy benefits manager shall act as a proponent for any pharmacy or pharmacy chain nor shall any pharmacy benefits manager prescribe, direct, or cause any pharmacy or pharmacy chain name or logo to appear on any employer base health plan card or prescription savings card.

SECTION 4. This act shall take effect upon passage.

========
LC004711
========

EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

A N A C T

RELATING TO BUSINESSES AND PROFESSIONS - PHARMACIES - INSURANCE - PRESCRIPTION DRUG BENEFITS

***

This act would allow a pharmacist to provide information to patients including less expensive prescription alternatives. This act would also limit charges for drugs to the lesser of usual price or co-pay, provide restrictions on credit for insurance coverage gaps, and prohibit pharmacy benefit managers from placing a pharmacy logo to be placed on an insurance or savings cards.

This act would take effect upon passage.

========
LC004711
========