

## CHAPTER 130

AN ACT concerning the dispensing of certain biological products, supplementing Title 45 of the Revised Statutes, and amending R.S.24:1-1 and P.L.1977, c.240.

**BE IT ENACTED** by the Senate and General Assembly of the State of New Jersey:

C.24:6K-1 Definitions relative to dispensing certain biological products.

1. As used in this act:

“Biological product” means a “biological product” as defined in subsection (i) of section 351 of the Public Health Service Act (42 U.S.C. s.262(i)), and refers to a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or any derivative of arsphenamine or any other trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human beings.

“Interchangeable” means “interchangeable” as defined in subsection (i) of section 351 of the Public Health Service Act (42 U.S.C. s.262(i)) and indicated as interchangeable by the federal Food and Drug Administration in the “Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations,” sometimes referred to as the “Purple Book.”

“Therapeutically equivalent” means a therapeutic equivalence rating of “A” has been listed by the federal Food and Drug Administration in the “Approved Drug Products with Therapeutic Equivalence Evaluations,” sometimes referred to as the “Orange Book.”

C.24:6K-2 Link to current lists of all biological products.

2. The New Jersey State Board of Pharmacy shall maintain a link to the current list of all biological products determined by the federal Food and Drug Administration to be interchangeable pursuant to section 351 of the Public Health Service Act (42 U.S.C. s.262) on the Board of Pharmacy’s Internet website.

C.24:6K-3 Conditions for substitution.

3. a. A pharmacist may substitute a biological product for a prescribed biological product, provided that the following conditions are met:

(1) the authorized prescriber has not indicated that there shall be no substitution as set forth in section 8 of P.L.1977, c.240 (C.24:6E-7); and

(2) the biological product to be substituted has been determined by the federal Food and Drug Administration to be:

(a) interchangeable with the prescribed biological product; or

(b) therapeutically equivalent to the prescribed biological product.

b. If a pharmacist dispenses a biological product, the pharmacist or the pharmacist’s designee shall, within five business days following the dispensing of the biological product, communicate to the prescriber the specific product provided to the patient, including the name of the product and the manufacturer. No communication shall be required under this subsection when:

(1) there is no biological product that has been determined by the federal Food and Drug Administration to be either:

(a) interchangeable with the product prescribed; or

(b) therapeutically equivalent to the product prescribed; or

(2) a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

c. The communication requirement under subsection b. of this section may be satisfied by making an entry in an interoperable electronic medical records system or an electronic pharmacy record that can be accessed electronically by the prescriber, or through the use of another electronic prescribing technology that can be accessed electronically by the prescriber. Entry into an electronic records system as described in this paragraph is presumed to provide notice to the prescriber. Otherwise, the communication may be conveyed using other electronic means, if available, or by facsimile.

d. A pharmacist who substitutes a biological product in compliance with this section shall record, on the prescription label and record of dispensing, the product name and manufacturer of the biological product dispensed, followed by the words: "Substituted for" and the name of the biological product for which the prescription was written.

e. The same recordkeeping requirements as apply to the dispensing of drugs shall apply to the dispensing of biological products.

f. A pharmacist who substitutes a biological product in compliance with this section shall incur no greater liability in filling the prescription by dispensing the biological product than would be incurred in filling the prescription by dispensing the prescribed biological product.

4. R.S.24:1-1 is amended to read as follows:

Definitions.

As used in this Title:

a. "State department," "department of health" and "department" mean the "State Department of Health."

b. "Council" means the Public Health Council in the State Department of Health.

c. "Local board" or "local board of health" means the board of health of any municipality, or the boards, bodies, or officers in such municipality lawfully exercising the powers of a local board of health under the laws governing such municipality, and includes any consolidated local board of health or county local board of health created and established pursuant to law.

d. "Food" means (1) articles used for food or drink for man or other animals (2) chewing gum and (3) articles used for components of any such article.

e. "Drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include biological products, or devices or their components, parts, or accessories.

f. "Package" or "container" means wrapper, case, basket, hamper, can, bottle, jar, tube, cask, vessel, tub, firkin, keg, jug, barrel, or other receptacles, but the word, "package" shall not include open containers which permit a visual and physical inspection by the purchaser at retail, nor bags and other receptacles which are filled in the presence of the purchaser at retail.

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. “Cosmetic” means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

i. “New drug” means (1) any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, and (2) any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

j. “Label” means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this subtitle that any word, statement or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper. The term “immediate container” does not include package liners.

k. “Labeling” means all labels and other written, printed or graphic matter (1) upon an article or any of its containers or wrappers, or (2) accompanying such article.

l. “Official compendium” means the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.

m. If an article is alleged to be misbranded because the labeling is misleading, then in determining whether such labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, or any combination thereof, but also the extent to which such labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which such labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

n. The representation of a drug as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

o. The provisions of this act regarding the selling of food, drugs, devices, or cosmetics, shall be considered to include the manufacture, production, processing, packing, exposure, offer, possession, and holding of any such article for sale; and the sale, dispensing, and giving away of any such article and the supplying or applying of any such articles in the conduct of any food, drug or cosmetic establishment.

p. The term “Federal Act” means the Federal Food, Drug and Cosmetic Act (Title 21, U.S.C. s.301 et seq.; 52 Stat. 1040 et seq.).

5. Section 5 of P.L.1977, c.240 (C.24:6E-4) is amended to read as follows:

C.24:6E-4 Definitions.

5. As used in this act unless the context clearly indicates otherwise:

a. “Drug product” means a dosage form containing one or more active therapeutic ingredients along with other substances included during the manufacturing process. The term “drug product” does not include “biological product” as defined in section 1 of P.L.2015, c.130 (C.24:6K-1).

b. “Brand name” means the proprietary name assigned to a drug by the manufacturer thereof.

c. “Established name” with respect to a drug or ingredient thereof, means (1) the applicable official name designated pursuant to the Federal Food, Drug and Cosmetic Act (Title 21, U.S.C. s.301 et seq.), or (2) if there is no such official name and such drug or ingredient is recognized in an official compendium, then the official title thereof in such compendium, except that where a drug or ingredient is recognized in the United States Pharmacopoeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopoeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia shall apply, or (3) if neither (1) nor (2) is applicable, then the common or usual name, if any, of such drug or ingredient.

d. “Prescription” means an order for drugs or combinations or mixtures thereof, written or signed by a duly licensed physician, dentist, veterinarian, or other medical practitioner licensed to write prescriptions intended for the treatment or prevention of disease in man or animals, and includes orders for drugs or medicines or combinations or mixtures thereof transmitted to pharmacists through word of mouth, telephone, telegraph, or other means of communication by a duly licensed physician, dentist, veterinarian, or other medical practitioner licensed to write prescriptions intended for the treatment or prevention of disease in man or animals.

e. “Department” means the Department of Health.

f. “Chemical equivalents” means those drug products that contain the same amounts of the same therapeutically active ingredients in the same dosage forms and that meet present compendial standards.

g. “Reference drug product” means the product which is adopted by the department as the standard for other chemically equivalent drugs in terms of testing for the therapeutic equivalence. In all cases, the reference drug product shall be a currently marketed drug which is the subject of a full (not abbreviated) new drug application approved by the Federal Food and Drug Administration.

h. “Therapeutic equivalents” means chemical equivalents which, when administered to the same individuals in the same dosage regimen, will provide essentially the same efficacy or toxicity as their respective reference drug products.

i. “Bioavailability” means the extent and rate of absorption from a dosage form as reflected by the time-concentration curve of the administered drug in the systemic circulation.

j. “Bioequivalents” means chemical equivalents which, when administered to the same individuals in the same dosage regimen, will result in comparable bioavailability.

k. “Pharmaceutical equivalents” means those drug products that contain the same amounts of the same therapeutically active ingredients in the same dosage form and that meet established standards.

l. “Interchangeable drug products” means pharmaceutical equivalents or bioequivalents that are determined to be therapeutic equivalents by the department.

m. “Present compendial standards” means the official standards for drug excipients and drug products listed in the latest revision of the United States Pharmacopoeia (USP) and the National Formulary (NF).

n. “Dosage form” means the physical formulation or medium in which the product is intended, manufactured and made available for use, including, but not limited to: tablets, capsules, oral solutions, aerosols, inhalers, gels, lotions, creams, ointments, transdermals and suppositories, and the particular form of the above which utilizes a specific technology or mechanism to control, enhance, or direct the release, targeting, systemic absorption, or other delivery of a dosage regimen in the body.

6. Section 11 of P.L.1977, c.240 (C.24:6E-10) is amended to read as follows:

C.24:6E-10 Signs, information to be disclosed relative to drugs, biological products to be dispensed.

11. Every pharmacy, drug store, or drug department selling prescription drugs or biological products shall post a sign at the entrance and where prescription drugs or biological products are sold disclosing the fact that upon request, before a prescription drug or biological product is dispensed, a consumer shall be told the price of such drug or biological product, whether such drug or biological product is to be substituted from a list of interchangeable drug or biological products, and of the consumer’s right to be informed of the price savings resulting from substitution for such drug or biological product and to be dispensed the drug or biological product as prescribed by the physician, if not satisfied with said price savings. Such sign shall not be less than 12 inches by 12 inches.

C.24:6K-4 Rules, regulations.

7. The Commissioner of Health and the Director of the Division of Consumer Affairs, pursuant to the “Administrative Procedure Act,” P.L.1968, c.410 (C.52:14B-1 et seq.), may adopt rules and regulations necessary to implement the provisions of this act.

8. This act shall take effect on the first day of the second month next following the date of enactment, but the Commissioner of Health and the Director of the Division of Consumer Affairs may take such anticipatory administrative action in advance thereof as shall be necessary for the implementation of the act.

Approved November 9, 2015.