24:6K-1 TO 24:6K-4
LEGISLATIVE HISTORY CHECKLIST
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LAWS OF: 2015 **CHAPTER:** 130

NJSA: 24:6K-1 TO 24:6K-4 (Establishes requirements for pharmacists to dispense biological products.)

BILL NO: A2477 (Substituted for S1705 (SCS))

SPONSOR(S) Lampitt, Pamela R., and others

DATE INTRODUCED: February 10, 2014

COMMITTEE: **ASSEMBLY:** Health and Senior Services

SENATE: Health, Human Services and Senior Citizens

AMENDED DURING PASSAGE: No

DATE OF PASSAGE: **ASSEMBLY:** 6/25/2015

SENATE: 6/25/2015

DATE OF APPROVAL: November 9, 2015

FOLLOWING ARE ATTACHED IF AVAILABLE:

FINAL TEXT OF BILL (First Reprint enacted) Yes

A2477

INTRODUCED BILL: (Includes sponsor(s) statement) Yes

COMMITTEE STATEMENT: **ASSEMBLY**: Yes

SENATE: Yes

(Audio archived recordings of the committee meetings, corresponding to the date of the committee statement, ***may possibly*** be found at www.njleg.state.nj.us)

FLOOR AMENDMENT STATEMENT: No

LEGISLATIVE FISCAL ESTIMATE: No

S1705 (SCS)

INTRODUCED BILL: (Includes sponsor(s) statement) Yes

COMMITTEE STATEMENT: **ASSEMBLY**: No

SENATE: Yes

(Audio archived recordings of the committee meetings, corresponding to the date of the committee statement, ***may possibly*** be found at www.njleg.state.nj.us)

FLOOR AMENDMENT STATEMENT: No

LEGISLATIVE FISCAL ESTIMATE: No

VETO MESSAGE: No

GOVERNOR'S PRESS RELEASE ON SIGNING: Yes

FOLLOWING WERE PRINTED:

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REPORTS: No

HEARINGS: No

NEWSPAPER ARTICLES: No

end

Title 24.
Subtitle 1.
Chapter 6K.
(New)
Biological
Products
§§1-3,7 -
C.24:6K-1 to
24:6K-4
§8 - Note

P.L.2015, CHAPTER 130, ***approved November 9, 2015***
Assembly Committee Substitute ***(First Reprint)*** for
Assembly, No. 2477

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

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

1. (New section) 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."

EXPLANATION – Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined thus is new matter.
Matter enclosed in superscript numerals has been adopted as follows:
[1]Senate SHH committee amendments adopted June 8, 2015.

2. (New section) The [1]**[**Commissioner of Health**]** New Jersey State Board of Pharmacy[1] 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 [1]**[**Department of Health's**]** Board of Pharmacy's[1] Internet website.

3. (New section) 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 [1]either:

(a)[1] interchangeable [1]with the product prescribed;[1] or

[1](b)[1] 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. [1]Entry into an electronic records system as described in this paragraph is presumed to provide notice to the prescriber.[1] 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:

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 <u>biological products, or</u> 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. 301 et seq.; 52 Stat. 1040 et seq.).

(cf: P.L.1966, c.74, s.1)

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

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. <u>The term "drug product" does not include "biological product" as defined in section 1 of P.L. , c. (C.) (pending before the Legislature as this bill)</u>.

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.

(cf: P.L.2012, c.17, s.87)

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

11. Every pharmacy, drug store, or drug department selling prescription drugs <u>or biological products</u> shall post a sign at the entrance and where prescription drugs <u>or biological products</u> 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 **[**his**]** 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.
(cf: P.L.1977, c.240, s.11)

7. The Commissioner of Health **[1]**and the Director of the Division of Consumer Affairs**[1]**, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), **[1][**shall**]** may**[1]** 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 **[1]**and the Director of the Division of Consumer Affairs**[1]** may take such anticipatory administrative action in advance thereof as shall be necessary for the implementation of the act.

Establishes requirements for pharmacists to dispense biological products.

ASSEMBLY, No. 2477

STATE OF NEW JERSEY

216th LEGISLATURE

INTRODUCED FEBRUARY 10, 2014

Sponsored by:
Assemblywoman PAMELA R. LAMPITT
District 6 (Burlington and Camden)
Assemblyman HERB CONAWAY, JR.
District 7 (Burlington)
Assemblyman DANIEL R. BENSON
District 14 (Mercer and Middlesex)
Assemblywoman SHAVONDA E. SUMTER
District 35 (Bergen and Passaic)
Assemblywoman NANCY F. MUNOZ
District 21 (Morris, Somerset and Union)
Assemblyman ANGEL FUENTES
District 5 (Camden and Gloucester)
Assemblywoman NANCY J. PINKIN
District 18 (Middlesex)

SYNOPSIS

Permits pharmacist to substitute biosimilar biological product under certain circumstances.

CURRENT VERSION OF TEXT

As introduced.

(Sponsorship Updated As Of: 3/17/2015)

AN ACT concerning the dispensing of certain biological products and revising various parts of the statutory law, and supplementing chapter 6 of Title 24 of the Revised Statutes.

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

1. (New section) 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.

"Biosimilar" means "biosimilar" 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 biological product that is highly similar to a specific reference biological product, notwithstanding minor differences in clinically inactive compounds, such that there are no clinically meaningful differences between the reference biological product and the biological product that has been licensed as biosimilar pursuant to section 351 of the Public Health Service Act (42 U.S.C. s.262) in terms of safety, purity, and potency of the product.

"Interchangeable" means "interchangeable" as defined in subsection (i) of section 351 of the Public Health Service Act (42 U.S.C. s.262(i)).

"Reference product" means a "reference 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 the single biological product against which a biological product is evaluated in an application for a license as a biosimilar biological product.

2. (New section) The Commissioner of Health shall maintain, and make available to each pharmacy practice site in the State without charge, a list of biosimilar biological products approved by the federal Food and Drug Administration to be interchangeable with a prescribed biological reference product, pursuant to section 351 of the Public Health Service Act (42 U.S.C. s.262).

3. (New section) a. A pharmacist may substitute a biosimilar biological product for a prescribed biological product if:

EXPLANATION – Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined <u>thus</u> is new matter.

(1) the biosimilar biological product has been approved by the federal Food and Drug Administration to be interchangeable with the prescribed biological reference product; and

(2) the authorized prescriber has not indicated that there shall be no substitution by initialing the prescription blank next to "do not substitute."

b. If a pharmacist substitutes an interchangeable biosimilar biological product for a prescribed biological reference product, the pharmacist shall:

(1) notify the patient in writing that the biological product dispensed has been approved by the federal Food and Drug Administration as an interchangeable biosimilar biological product for the prescribed biological reference product;

(2) provide electronic, written, or telephonic notification of the substitution to the authorized prescriber or the authorized prescriber's staff within five business days after the dispensing of the interchangeable biosimilar biological product; and

(3) record, on the prescription label and record of dispensing, the product name of the interchangeable biosimilar biological product, followed by the words: "Substituted for" and the name of the biological reference product for which the prescription was written, and the manufacturer of the interchangeable biosimilar biological product.

c. Records of substitutions of interchangeable biosimilar biological products shall be maintained for at least five years after the dispensing date.

d. A pharmacist who substitutes an interchangeable biosimilar biological product in compliance with this section shall incur no greater liability in filling the prescription by dispensing the interchangeable biosimilar biological product than would be incurred in filling the prescription by dispensing the prescribed biological reference product.

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

24:1.1As 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 <u>biological products, or</u> 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. 301 et seq.; 52 Stat. 1040 et seq.).

(cf: P.L.1966, c.74, s.1)

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

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. <u>The term "drug product" does not include "biological product" as defined in section 1 of P.L. , c. (C.) (pending before the Legislature as this bill)</u>.

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.

(cf: P.L.2012, c.17, s.87)

6. The Commissioner of Health, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), shall adopt rules and regulations necessary to implement the provisions of this act.

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

STATEMENT

The "Patient Protection and Affordable Care Act," Pub.L.111-148, amended the federal Public Health Service Act to create an abbreviated licensure pathway for biological products demonstrated to be biosimilar to, or interchangeable with, biological products licensed by the federal Food and Drug Administration (FDA). This bill allows for the substitution of these products by pharmacists, provided the conditions set forth in the bill are met.

Specifically, the bill directs the Commissioner of Health to maintain, and make available to each pharmacy practice site in the State without charge, a list of biosimilar biological products approved by the FDA to be interchangeable with a prescribed biological reference product. A pharmacist may substitute such a product for a prescribed biological product if the prescriber has not indicated that there be no substitution by initialing the prescription blank next to "do not substitute. A pharmacist who dispenses an interchangeable biosimilar product is to notify the patient in writing that the dispensed biological product has been approved by the FDA

as an interchangeable biosimilar biological product, and notify the prescribing practitioner of the substitution within five business days after dispensing. The pharmacist is to record, on the prescription label and dispensing record, the product name of the interchangeable biosimilar biological product, followed by the words: "Substituted for" and the name of the biological reference product for which the prescription was written, as well as the manufacturer of the interchangeable biosimilar biological product. Records of substitutions are to be maintained for at least five years after the dispensing date. The bill provides immunity from liability for a pharmacist who makes such substitutions in compliance with the bill to the same extent that immunity would be provided for dispensing the prescribed biological reference product.

The bill incorporates the definitions used in relevant federal law for the terms "biological product," "biosimilar," "biological reference product," and "interchangeable." Generally, "biological products" are made from various sources, including human, animal or microorganism, and are intended to treat medical conditions, or prevent or diagnose diseases. "Biosimilar" means that data show that a product is "highly similar" to an already-approved biological product. "Reference product" refers to the single biological product against which a biological product is evaluated in an application to be licensed as biosimilar or interchangeable.

The bill also amends the definitions of "drug" in R.S.24:1-1 and "drug product" in section 5 of P.L.1977, c.240 (C.24:6E-4) to clarify that those terms do not include "biological product."

The bill takes effect on the first day of the second month next following the date of enactment.

ASSEMBLY HEALTH AND SENIOR SERVICES COMMITTEE

STATEMENT TO

ASSEMBLY COMMITTEE SUBSTITUTE FOR
ASSEMBLY, No. 2477

STATE OF NEW JERSEY

DATED: MAY 7, 2015

The Assembly Health and Senior Services Committee reports favorably an Assembly Committee Substitute for Assembly Bill No. 2477.

This substitute establishes certain requirements for pharmacies to dispense biological products. The term "biological product" 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.

Under the substitute, a pharmacist who dispenses a biological product, or the pharmacist's designee, will be required to communicate to the prescriber, within five business days, the specific product provided to the patient, including the name of the product and the manufacturer. The communication requirement 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. Otherwise, the communication may be conveyed using other electronic means, if available, or by facsimile. No communication would be required when: (1) there is no biological product that has been determined by the federal Food and Drug Administration (FDA) to be interchangeable or 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. The same recordkeeping requirements as apply to the dispensing of drugs would apply to the dispensing of biological products.

A pharmacist will be permitted to substitute a biological product for a prescribed biological product, provided that the prescriber does not indicate that there shall be no substitution and the biological product to be substituted has been determined by the FDA to be interchangeable with or therapeutically equivalent to the prescribed biological product. A pharmacist who substitutes a biological product

would be required to 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. A pharmacist who meets these requirements when substituting a biological product would incur no greater liability for dispensing the substituted product than would be incurred for dispensing the prescribed product.

The Commissioner of Health will be required to maintain a link to the current list of all biological products determined by the FDA to be interchangeable pursuant to section 351 of the Public Health Service Act (42 U.S.C. s.262) on the Department of Health’s Internet website.

The substitute amends the definitions of “drug” in R.S.24:1-1 and “drug product” in section 5 of P.L.1977, c.240 (C.24:6E-4) to clarify that those terms do not include “biological product,” and clarifies that pharmacies will be required to include biological products in the informational signs they are currently required to post notifying consumers that, prior to dispensing a prescription, the pharmacist must inform the consumer of the price of the medication, whether the prescribed medication is to be substituted, the cost savings of the substitution, and of the right to have the prescribed medication dispensed without substitution.

SENATE HEALTH, HUMAN SERVICES AND SENIOR CITIZENS COMMITTEE

STATEMENT TO

ASSEMBLY COMMITTEE SUBSTITUTE FOR
ASSEMBLY, No. 2477

with committee amendments

STATE OF NEW JERSEY

DATED: JUNE 8, 2015

The Senate Health, Human Services and Senior Citizens Committee reports favorably and with committee amendments Assembly Bill No. 2477 (ACS).

As amended by the committee, this substitute bill establishes certain requirements for pharmacies to dispense biological products. The term "biological product" 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.

Under the amended substitute bill, a pharmacist who dispenses a biological product, or the pharmacist's designee, will be required to communicate to the prescriber, within five business days, the specific product provided to the patient, including the name of the product and the manufacturer. The communication requirement 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. An entry made into an electronic records system would be presumed to provide notice to the prescriber. Otherwise, the communication may be conveyed using other electronic means, if available, or by facsimile. No communication would be required when: (1) there is no biological product that has been determined by the federal Food and Drug Administration (FDA) to be either interchangeable with or 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. The same recordkeeping requirements as apply to the dispensing of drugs would apply to the dispensing of biological products.

A pharmacist will be permitted to substitute a biological product for a prescribed biological product, provided that the prescriber does not indicate that there shall be no substitution and the biological product to be substituted has been determined by the FDA to be interchangeable with or therapeutically equivalent to the prescribed biological product. A pharmacist who substitutes a biological product would be required to 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. A pharmacist who meets these requirements when substituting a biological product would incur no greater liability for dispensing the substituted product than would be incurred for dispensing the prescribed product.

The Board of Pharmacy will be required to maintain a link to the current list of all biological products determined by the FDA to be interchangeable pursuant to section 351 of the Public Health Service Act (42 U.S.C. s.262) on the board's internet website.

The substitute amends the definitions of "drug" in R.S.24:1-1 and "drug product" in section 5 of P.L.1977, c.240 (C.24:6E-4) to clarify that those terms do not include "biological product," and clarifies that pharmacies will be required to include biological products in the informational signs they are currently required to post notifying consumers that, prior to dispensing a prescription, the pharmacist must inform the consumer of the price of the medication, whether the prescribed medication is to be substituted, the cost savings of the substitution, and of the right to have the prescribed medication dispensed without substitution.

The committee amended the substitute to:

- require the State Board of Pharmacy, rather than the Department of Health, to maintain the link to the current list of all biological products determined by the FDA to be interchangeable;
- clarify that a pharmacist must communicate the dispensing of a biological product to a prescriber if there exists either (1) an FDA-approved interchangeable product, or (2) a therapeutically equivalent product;
- clarify that entry by a pharmacist or designee into an electronic records system is presumed to provide the required notice to the prescriber; and
- explicitly grant the Director of the Division of Consumer Affairs authority to adopt rules and regulations and take other administrative actions to implement the substitute bill.

As reported, this substitute is identical to the Senate Committee Substitute for Senate Bill No. 1705 (Vitale/Singer), which the committee also reported favorably on this date.

SENATE, No. 1705

STATE OF NEW JERSEY

216th LEGISLATURE

INTRODUCED MARCH 17, 2014

Sponsored by:
Senator JOSEPH F. VITALE
District 19 (Middlesex)
Senator ROBERT W. SINGER
District 30 (Monmouth and Ocean)

SYNOPSIS

Permits pharmacist to substitute biosimilar biological product under certain circumstances.

CURRENT VERSION OF TEXT

As introduced.

(Sponsorship Updated As Of: 2/25/2015)

AN ACT concerning the dispensing of certain biological products and revising various parts of the statutory law, and supplementing chapter 6 of Title 24 of the Revised Statutes

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

1. (New section) 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.

"Biosimilar" means "biosimilar" 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 biological product that is highly similar to a specific reference biological product, notwithstanding minor differences in clinically inactive compounds, such that there are no clinically meaningful differences between the reference biological product and the biological product that has been licensed as biosimilar pursuant to section 351 of the Public Health Service Act (42 U.S.C. s.262) in terms of safety, purity, and potency of the product.

"Interchangeable" means "interchangeable" as defined in subsection (i) of section 351 of the Public Health Service Act (42 U.S.C. s.262(i)).

"Reference product" means a "reference 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 the single biological product against which a biological product is evaluated in an application for a license as a biosimilar biological product.

2. (New section) The Commissioner of Health shall maintain, and make available to each pharmacy practice site in the State without charge, a list of biosimilar biological products approved by the federal Food and Drug Administration to be interchangeable with a prescribed biological reference product, pursuant to section 351 of the Public Health Service Act (42 U.S.C. s.262).

3. (New section) a. A pharmacist may substitute a biosimilar biological product for a prescribed biological product if:

EXPLANATION – Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined <u>thus</u> is new matter.

(1) the biosimilar biological product has been approved by the federal Food and Drug Administration to be interchangeable with the prescribed biological reference product; and

(2) the authorized prescriber has not indicated that there shall be no substitution by initialing the prescription blank next to "do not substitute."

b. If a pharmacist substitutes an interchangeable biosimilar biological product for a prescribed biological reference product, the pharmacist shall:

(1) notify the patient in writing that the biological product dispensed has been approved by the federal Food and Drug Administration as an interchangeable biosimilar biological product for the prescribed biological reference product;

(2) provide electronic, written, or telephonic notification of the substitution to the authorized prescriber or the authorized prescriber's staff within five business days after the dispensing of the interchangeable biosimilar biological product; and

(3) record, on the prescription label and record of dispensing, the product name of the interchangeable biosimilar biological product, followed by the words: "Substituted for" and the name of the biological reference product for which the prescription was written, and the manufacturer of the interchangeable biosimilar biological product.

c. Records of substitutions of interchangeable biosimilar biological products shall be maintained for at least five years after the dispensing date.

d. A pharmacist who substitutes an interchangeable biosimilar biological product in compliance with this section shall incur no greater liability in filling the prescription by dispensing the interchangeable biosimilar biological product than would be incurred in filling the prescription by dispensing the prescribed biological reference product.

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

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 <u>biological products, or</u> 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. 301 et seq.; 52 Stat. 1040 et seq.).

(cf: P.L.1966, c.74, s.1)

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

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. <u>The term “drug product” does not include “biological product” as defined in section 1 of P.L. , c. (C.) (pending before the Legislature as this bill)</u>.

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.

(cf: P.L.2012, c.17, s.87)

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

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

STATEMENT

The “Patient Protection and Affordable Care Act,” Pub.L.111-148, amended the federal Public Health Service Act to create an abbreviated licensure pathway for biological products demonstrated to be biosimilar to, or interchangeable with, biological products licensed by the federal Food and Drug Administration (FDA). This bill allows for the substitution of these products by pharmacists, provided the conditions set forth in the bill are met.

Specifically, the bill directs the Commissioner of Health to maintain, and make available to each pharmacy practice site in the State without charge, a list of biosimilar biological products approved by the FDA to be interchangeable with a prescribed biological reference product. A pharmacist may substitute such a product for a prescribed biological product if the prescriber has not indicated that there be no substitution by initialing the prescription blank next to “do not substitute. A pharmacist who dispenses an interchangeable biosimilar product is to notify the patient in writing that the dispensed biological product has been approved by the FDA as an interchangeable biosimilar biological product, and notify the

prescribing practitioner of the substitution within five business days after dispensing. The pharmacist is to record, on the prescription label and dispensing record, the product name of the interchangeable biosimilar biological product, followed by the words: "Substituted for" and the name of the biological reference product for which the prescription was written, as well as the manufacturer of the interchangeable biosimilar biological product. Records of substitutions are to be maintained for at least five years after the dispensing date. The bill provides immunity from liability for a pharmacist who makes such substitutions in compliance with the bill to the same extent that immunity would be provided for dispensing the prescribed biological reference product.

The bill incorporates the definitions used in relevant federal law for the terms "biological product," "biosimilar," "biological reference product," and "interchangeable." Generally, "biological products" are made from various sources, including human, animal or microorganism, and are intended to treat medical conditions, or prevent or diagnose diseases. "Biosimilar" means that data show that a product is "highly similar" to an already-approved biological product. "Reference product" refers to the single biological product against which a biological product is evaluated in an application to be licensed as biosimilar or interchangeable.

The bill also amends the definitions of "drug" in R.S.24:1-1 and "drug product" in section 5 of P.L.1977, c.240 (C.24:6E-4) to clarify that those terms do not include "biological product."

The bill takes effect on the first day of the second month next following the date of enactment.

SENATE HEALTH, HUMAN SERVICES AND SENIOR CITIZENS COMMITTEE

STATEMENT TO

SENATE COMMITTEE SUBSTITUTE FOR
SENATE, No. 1705

STATE OF NEW JERSEY

DATED: JUNE 8, 2015

The Senate Health, Human Services and Senior Citizens Committee reports favorably Senate Committee Substitute for Senate Bill No. 1705.

This substitute bill establishes certain requirements for pharmacies to dispense biological products. The term "biological product" 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.

Under the substitute bill, a pharmacist who dispenses a biological product, or the pharmacist's designee, will be required to communicate to the prescriber, within five business days, the specific product provided to the patient, including the name of the product and the manufacturer. The communication requirement 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. An entry made into an electronic records system would be presumed to provide notice to the prescriber. Otherwise, the communication may be conveyed using other electronic means, if available, or by facsimile. No communication would be required when: (1) there is no biological product that has been determined by the federal Food and Drug Administration (FDA) to be either interchangeable with or 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. The same recordkeeping requirements as apply to the dispensing of drugs would apply to the dispensing of biological products.

A pharmacist will be permitted to substitute a biological product for a prescribed biological product, provided that the prescriber does not indicate that there shall be no substitution and the biological

product to be substituted has been determined by the FDA to be interchangeable with or therapeutically equivalent to the prescribed biological product. A pharmacist who substitutes a biological product would be required to 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. A pharmacist who meets these requirements when substituting a biological product would incur no greater liability for dispensing the substituted product than would be incurred for dispensing the prescribed product.

The Board of Pharmacy will be required to maintain a link to the current list of all biological products determined by the FDA to be interchangeable pursuant to section 351 of the Public Health Service Act (42 U.S.C. s.262) on the board's internet website.

The substitute amends the definitions of "drug" in R.S.24:1-1 and "drug product" in section 5 of P.L.1977, c.240 (C.24:6E-4) to clarify that those terms do not include "biological product," and clarifies that pharmacies will be required to include biological products in the informational signs they are currently required to post notifying consumers that, prior to dispensing a prescription, the pharmacist must inform the consumer of the price of the medication, whether the prescribed medication is to be substituted, the cost savings of the substitution, and of the right to have the prescribed medication dispensed without substitution.

This substitute is identical to Assembly Bill No. 2477 (ACS) (1R) (Lampitt/Conaway/Benson/Sumter/Munoz/Fuentes/Pinkin), which the committee also reported favorably on this date.

Governor Christie Takes Action On Pending Legislation

Monday, November 9, 2015 Tags: Bill Action

Trenton, NJ – Governor Chris Christie today took action on legislation, including a package of five bills intended to address the fiscal stability of Atlantic City.

Understanding both the immediate and long-term obstacles facing Atlantic City and its stabilization, the Governor has consistently highlighted the need for comprehensive reform efforts to confront the city's challenges – both from State and local leaders. The Governor remains committed to bringing about the necessary reforms to stabilize Atlantic City and continue an effective long-term transition to an economy that is diversified beyond its traditional gaming industry.

Continuing in that effort, Governor Christie conditionally vetoed A-3981, establishing a payment-in-lieu-of-taxes (PILOT) program for casinos operating in the City, A-3984, reallocating revenue derived from the casino investment alternative tax from the Casino Reinvestment Development Authority to the City to pay debt service on municipal bonds, and A-3985, repealing the Atlantic City Alliance.

"While I commend the Legislature for attempting to devise measures to stabilize the City's budget and finances, I am concerned that the bills, in their present form, fail to recognize the true path to economic revitalization and fiscal stability in the City," Governor Christie said. "While these bills represent the bipartisan efforts of many to provide important, near-term support to the City's immediate challenges, I do not believe they meet the goal of setting a course toward renewed, long-term prosperity and economic growth. To achieve these goals, we must continue our work and go further to ensure that the next step leads to that economically vibrant future for Atlantic City."

In addition, the Governor signed A- 3983, authorizing supplemental school aid to the Atlantic City school district, and vetoed the fifth bill, A-3982, which would add a costly and unjustified new mandate for casino business operation in the City by requiring each casino, as a condition of licensure, to provide to its full time employees "suitable" health care benefits and "suitable" retirement benefits.

"A-3982 would do nothing to enhance the financial condition of Atlantic City," Governor Christie wrote. "To be sure, this bill would make it more costly for casinos to operate in Atlantic City, thereby impeding the industry's ability to grow and expand."

Governor Christie also vetoed legislation designed to revise certain laws concerning domestic violence and firearms. The Christie Administration has made protecting our most vulnerable residents one of its main priorities and has enacted some of the toughest measures to combat domestic violence. Governor Christie has supported a comprehensive approach to addressing the level of violence within our society and recently signed legislation to further penalize aggravated assault perpetuated against domestic violence victims. This legislation, A-4218 (Mosquera, Greenwald, Lagana, Benson, Lampitt, Vainieri Huttle, Danielsen/Weinberg, Gill, Cruz-Perez), substantially restates New Jersey's existing laws that govern firearms and domestic violence and does not offer new and sensible improvements to those current laws. For that reason, rather than restate existing laws, the Governor is proposing significant amendments that will meaningfully deter future acts of violence.

- **Enhanced Penalties For Domestic Violence.** Governor Christie is proposing enhanced criminal penalties imposed against those who are convicted of domestic violence. To demonstrate society's unconditional condemnation of this conduct, perpetrators would receive the maximum available prison sentence under New Jersey law.

- **Tighter Restrictions On Parole Eligibility For Perpetrators Of Domestic Violence.** The Governor's recommended changes will strengthen penalties for perpetrators of domestic abuse by lengthening periods of parole

ineligibility.

• **Prioritizing Victims Who Seek Firearms For Protection.** The Governor is also recommending an immediate codification in statute of new rules currently being processed, giving expedited processing of firearm license applications for victims of domestic violence so that the victims may better defend themselves against future instances of abuse.

“I urge the Legislature to join with me in a bipartisan manner to broaden this bill’s approach to reducing domestic violence while simultaneously empowering victims to protect themselves through lawful means,” Governor Christie said. “Together, we can enact a more comprehensive approach and reduce the harm that domestic violence inflicts on victims, families, and our society.”

The Governor also took the following action on other pending legislation:

BILL SIGNINGS:

S-2174/A-3364 (Barnes, Holzapfel/Quijano, Mainor, Pinkin) - Prohibits manufacture, sale, or installation of counterfeit or nonfunctional air bags in motor vehicles

A-815/S-852 (Coughlin, Ciattarelli, Diegnan, Pinkin, Giblin/Vitale) - Requires municipalities which license peddlers and solicitors to accept certain background check results from other municipalities

A-1029/S-274 (Benson, Vainieri Huttle, Jasey, Tucker, Wimberly/Greenstein, Ruiz) - Requires training program for school bus drivers and school bus aides on interacting with students with special needs, and requires development and use of student information cards

A-1041/S-2676 (Schaer, Johnson, Vainieri Huttle, Eustace, Mazzeo,/Rumana, Gordon, Weinberg) - Exempts Holocaust reparations payments from legal process, and from estate recovery under Medicaid program

A-1102/S-1145 (Vainieri Huttle, Sumter, Spencer, Schaer, Wimberly/Weinberg, Cruz-Perez) - Provides for licensure of dementia care homes by DOH

ACS for A-1662/S-2856 (Johnson, Lagana, Wimberly/Weinberg) - Authorizes the court to order the deletion, sealing, labeling, or correction of certain personal information in government records involving certain victims of identity theft

AS for A-1678/SS for S-1365 (Johnson, Mainor, O'Scanlon, Wilson, Wimberly/ Weinberg) - Authorizes court to order submission of DNA evidence to national database to determine whether evidence matches known individual or DNA profile from an unsolved crime

AS for ACS for A-2073/SCS for S-712 (Handlin, Space, Garcia, Pintor Marin/Cruz-Perez, Kyrillos, Lesniak) - Exempts certain offers and sales of securities from registration

A-2385/S-944 (McKeon, Diegnan, Jasey, Andrzejczak/Smith, Codey) - Authorizes rural electric cooperative and certain municipalities to establish municipal shared services authority

ACS for A-2477/SCS for S-1705 (Lampitt, Conaway, Benson, Sumter, Munoz, Pinkin/Vitale, Singer) - Establishes requirements for pharmacists to dispense biological products

A-2714/S-1993 (Giblin, Sumter/Barnes) - Requires continuing education for licensed practicing psychologists

A-2936/S-1957 (Mosquera, Lampitt, Singleton, Wimberly/Singer, Connors) - Requires complaint for guardianship of person receiving services from Division of Developmental Disabilities to include one of documents identified in bill

A-3012/S-2296 (Ciattarelli, Dancer/Bateman) - Criminalizes bestiality

A-3079/S-2766 (Jasey, Diegnan, Mainor, Wimberly, Oliver, DeCroce/Turner, Ruiz) - Prohibits administration of standardized assessments in kindergarten through second grade

A-3153/S-2415 (DeAngelo, Mosquera/Madden, Beach) - Requires UI employer contribution reports and remittances be submitted to the Division of Revenue

A-3248/S-2459 (Conaway, Sumter, Pintor Marin/Singer) - Establishes the Task Force on Chronic Obstructive Pulmonary Disease in DOH

A-3580/S-2846 (Moriarty, Dancer, Coughlin, Mainor, Pinkin, Munoz, Danielsen, Wimberly/Madden, Turner) - Prohibits sale of powdered alcohol

A-3636/SCS for S-2393, 2408, 2411 (McKeon, Lagana, Spencer/Scutari, O'Toole, Holzapfel) - Establishes crime-fraud exception to marital and civil union partnership privilege

A-3669/S-2655 (Mazzeo, Burzichelli/Whelan) - Prohibits eligibility for certain sign programs from being conditioned on availability of free drinking water or public telephone

A-3807/S-2619 (Eustace, Greenwald/Whelan) - Permits educational research and services corporations to act as lead procurement agencies for local units and publically supported educational institutions; permits Council of County Colleges to act as lead procurement agency for county colleges

A-3841/S-2540 (Munoz, Gusciora, Angelini, DeCroce/O'Toole, Weinberg) – Upgrades violation of a stalking restraining order to a crime of the third degree

A-3843/S-2735 (Caputo, Giblin, Tucker, Johnson, Mainor, Sumter/Rice) - Permits municipality to enact ordinance allowing voluntary registration of private outdoor video surveillance cameras

A-3983/S-2574 (Mazzeo, Burzichelli, Giblin/Sweeney, Whelan) - Authorizes supplemental State aid to school districts in municipality with significant decrease in commercial property valuation; makes appropriation

A-4008/SCS for S-2334 (Singleton, Mukherji, Pintor Marin, Wimberly, Sumter/Cunningham, Ruiz) - Requires DOC to make reports containing information concerning treatment and reentry initiative participation; requires AOC to establish program that collects recidivism data and make reports concerning adults sentenced to period of probation

A-4013/S-2497 (Greenwald, Lagana, Coughlin/Oroho) - Eliminates mortgage guaranty insurance coverage cap of 25% of outstanding balance of insured loan

A-4073/S-2687 (Schaer, Prieto, Caride, Lagana, Giblin, Wimberly, Rumana/Sarlo, Gill) - Requires installation of carbon monoxide detectors in certain structures; designated as "Korman and Park's Law"

A-4078/S-2686 (Vainieri Huttle, Mosquera, McKeon, Munoz, Benson, Sumter/Pou, Beck) - "Sexual Assault Survivor Protection Act of 2015"; authorizes the court to issue protective orders for victims of certain nonconsensual sexual conduct

A-4089/S-2693 (Coughlin, Ciattarelli/Beach, Singer) - Revises certain provisions of dental service corporation law

A-4143/S-2514 (Lagana, Spencer, Mukherji, Johnson, Rumana, Rodriquez-Gregg, Gusciora, Mazzeo/Barnes, Addiego) - Permits holders of certain alcoholic beverage licenses to be issued amusement game license and updates definition of recognized amusement park

A-4144/S-2755 (Pintor Marin, Spencer, Caride, Quijano, Mukherji/Ruiz, Stack) – Requires insurance producer licensing examination and registration materials to be offered in English and Spanish, and examination instructional materials to be available in Spanish

A-4167/S-2751 (Lagana, Mazzeo, Eustace, Andrzejczak, Vainieri Huttle/Barnes) - Requires DHS to notify enrollees in Programs of All-Inclusive Care for the Elderly of Medicare eligibility

A-4168/S-2750 (Lagana, Mazzeo, Eustace, Andrzejczak, Vainieri Huttle/Barnes) - Requires providers to submit to DHS expenditure details of enrollees in Program of All-Inclusive Care for the Elderly

A-4169/S-2752 (Lagana, Mazzeo, Eustace, Andrzejczak, Vainieri Huttle/Barnes) - Requires DHS to monitor utilization and billing of services for Medicaid home and community-based long-term care

A-4333/S-3020 (Singleton, Gill) - Exempts certain activities of alarm businesses from statutes governing practice of locksmithing

A-4361/S-2891 (Johnson, A.M. Bucco, Garcia, S. Kean/Barnes, A.R. Bucco) - Revises definition of all-terrain vehicles

A-4375/S-3011 (Moriarty, Andrzejczak, Mazzeo, Mosquera, Quijano, Ciattarelli, Wimberly/Van Drew, Bateman) - Upgrades crimes of false public alarm under certain circumstances and establishes reporting requirements concerning crime

A-4485/S-2881 (Diegnan, Jasey, Wimberly, McKeon, Lagana/Gill, Turner) - Prohibits withholding of State school aid based on student participation rate on State assessments

A-4587/S-3049 (Greenwald, Lampitt, McKeon, Holley/Scutari, Cruz-Perez) – Requires facilities providing services to persons with developmental disabilities and schools to adopt policies permitting administration of medical marijuana to qualifying patients

AJR-64/SJR-82 (Schaer, Eustace, Lagana, Spencer, Caride, Mukherji/Pou, Ruiz) - Declares August 16 of each year as "Dominican Restoration Day" in New Jersey

BILLS VETOED:

S-929/A-1908 (Sweeney, Madden/Burzichelli, Riley, Moriarty) – **ABSOLUTE** -Concerns certain workers' compensation supplemental benefits

A-801/S-861 (Coughlin, Wisniewski, Mazzeo/Vitale, Sacco) - **CONDITIONAL** - Directs New Jersey Turnpike Authority and South Jersey Transportation Authority to study and report on potential revenue generating services of rest areas and service plazas

A-947/S-2216 (Singleton, Lagana, Diegnan/Pennacchio, Rice) – CONDITIONAL - Requires release of bid list prior to bid date under "Local Public Contracts Law"

A-1468/S-2513 (Diegnan, Lampitt, Caride/Barnes, Ruiz) – CONDITIONAL -Establishes Task Force on Engineering Curriculum and Instruction

A-1726/S-308 (Eustace, Lagana, Mosquera, Vainieri Huttle, Wimberly/Gordon) – **CONDITIONAL -** Amends "Flood Hazard Area Control Act" to require DEP to take certain actions concerning delineations of flood hazard areas and

floodplains

A-2579/S-1510 (Mukherji, Pintor Marin, Eustace/Smith, Bateman) – CONDITIONAL - Authorizes municipalities to facilitate private financing of water conservation, storm shelter construction, and flood and hurricane resistance projects through use of voluntary special assessments

A-2771/S-452 (Johnson, Burzichelli, Pintor Marin, Mosquera/Ruiz, Cruz-Perez) – CONDITIONAL - "The New Jersey Social Innovation Act"; establishes social innovation loan pilot program and study commission within EDA

A-2906/S-2926 (Stender, Pinkin, Mazzeo/Whelan, Scutari) – ABSOLUTE - Excludes from gross income compensation paid to members of district boards of election for services rendered in elections

A-3223/S-2056 (Singleton, Lampitt, Quijano, Pintor Marin, Wimberly/Sarlo, Ruiz) – CONDITIONAL - Requires Division of Local Government Services to include certain property tax information on division's web page

A-3393/S-2167 (Spencer, Pintor Marin, Caputo, Tucker/Rice, Ruiz) – CONDITIONAL - Permits Newark to use rental car tax proceeds over three-year period to help reduce its "cash deficit for preceding year" appropriation and operational deficit

A-3421/S-2220 (Dancer, Mukherji/Singer) – CONDITIONAL - Revises the "Self-Funded Multiple Employer Welfare Arrangement Regulation Act"

A-3435/S-2503 (Garcia, Mukherji, Vainieri Huttle, Mainor, Eustace, Mosquera/Stack, Gordon) - CONDITIONAL - "Boys & Girls Clubs Keystone Law"; permits minors to give consent for behavioral health care

A-3500/S-1973 (Andrzejczak, Pinkin, Quijano/Van Drew, Beach) – ABSOLUTE - Requires local recreation departments and youth serving organizations to have defibrillators for youth athletic events

A-3954/S-2981 (Conaway, Singleton, Spencer, McKeon/Greenstein) – CONDITIONAL - Requires maximum contaminant level to be established for 1,2,3-trichloropropane in drinking water

A-3981/S-2572 (Mazzeo, Burzichelli, Andrzejczak/Sweeney, Whelan) - CONDITIONAL - "Casino Property Taxation Stabilization Act"

A-3982/S-2573 (Mazzeo, Burzichelli, Andrzejczak/Sweeney, Whelan) – **ABSOLUTE -** Requires holder of casino license to provide certain employees with certain health care and retirement benefits

A-3984/S-2575 (Mazzeo, Burzichelli, Giblin/Sweeney, Whelan) – **CONDITIONAL** - Reallocates casino investment alternative tax to Atlantic City to pay debt service on municipal bonds issued

A-3985/S-2576 (Mazzeo, Burzichelli, Andrzejczak, Giblin/Sweeney, Whelan) – **CONDITIONAL -** Removes provisions of law relating to Atlantic City Alliance

A-4018/S-2843 (Burzichelli, Caputo, Mazzeo/Sarlo, Whelan) – ABSOLUTE - Authorizes operation of lottery courier services

A-4218/S-2786 (Mosquera, Greenwald, Lagana, Benson, Lampitt, Vainieri Huttle, Danielsen/Weinberg, Gill, Cruz-Perez) - **CONDITIONAL** - Revises certain laws concerning domestic violence and firearms

A-4265/S-2783 (McKeon, Pintor Marin, Jasey, Caputo, Giblin, Tucker, Spencer, Oliver, Gusciora, Danielson/Codey, Ruiz, Rice) – ABSOLUTE - Permits municipal, county, and regional police and fire forces to establish five-year residency requirement for police officers and firefighters; allows exceptions to requirement under certain circumstances

A-4337/S-3008 (Schaer, Danielsen, Dancer, Sumter/Barnes) – ABSOLUTE - Expands eligibility of inmates for medical parole and requires inmate's enrollment in Medicaid under certain circumstances

A-4476/S-2876 (Conaway/Codey) - **CONDITIONAL** - Requires certain surgical practices and ambulatory care facilities licensed in this State to be owned by hospital or medical school located in the State

A-4607/S-3106 (Pintor Marin, Schaer, Oliver, Lagana, Johnson, Singleton/Ruiz, Cunningham) – ABSOLUTE - Makes FY 2016 supplemental appropriations of $6,500,000 and adds language provision

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