TO: The Honorable the Members of the Board of Regents

FROM: Douglas E. Lentivech

SUBJECT: Proposed Amendment of Section 29.7 of the Rules of the Board of Regents and Section 63.6 of the Regulations of the Commissioner of Education Relating to the Unprofessional Conduct Special Provisions and the Requirements for Substituting Interchangeable Biological Products for Prescribed Products in the Profession of Pharmacy

DATE: March 28, 2018

AUTHORIZATION(S):

SUMMARY

Issue for Decision (Consent Agenda)

Should the Board of Regents adopt the proposed amendment of subdivision (a) of §29.7 of the Rules of the Board of Regents and paragraph (7) of subdivision (a) and clause (c) of subparagraph (ii) of paragraph (8) of subdivision (b) of §63.6 of the Regulations of the Commissioner of Education relating to the unprofessional conduct special provisions and the requirements for substituting interchangeable biological products for prescribed products in the profession of pharmacy?

Reason for Consideration

Required by State statute (Chapter 357 of the Laws of 2017).

Proposed Handling

The proposed amendment will be presented to the Full Board for permanent adoption at the April 2018 meeting of the Board of Regents. Supporting materials are available upon request from the Secretary to the Board of Regents.

Procedural History

The proposed amendment was presented to the Professional Practice Committee for recommendation and to the Full Board for adoption as an emergency action at the December 2017 meeting of the Board of Regents, effective December 12, 2017. A Notice of Emergency Adoption and Proposed Rule Making was published in the State Register on December 27, 2017.

Because the December emergency rule was set to expire on March 11, 2018, a second emergency action was presented to the Full Board for adoption at the February 2018 meeting. The second emergency action was necessary to ensure that the emergency rule remains continuously in effect until it can be adopted at the April 9-10, 2018 Regents meeting and take effect as a permanent rule on April 25, 2018. Following the 60-day public comment period, the Department received no comments on the proposed amendment. Therefore, an Assessment of Public Comment is not required and no changes to the proposed amendment are needed. A copy of the proposed rule is attached.

Background Information

Chapter 357 of the Laws of 2017 (Chapter 357) amended the Education Law by adding definitions for the terms “biological product” and “interchangeable biological product”, effective October 23, 2017. Chapter 357 also amended the Education Law to set forth the conditions under which the substitution of a biological product is required and established the appropriate method of communication by the pharmacist to the prescriber notifying the prescriber of the substitution of the biological product dispensed.

Biological products are regulated by the United States Food and Drug Administration (FDA) and are used to diagnose, prevent, treat and cure diseases. Biological products are generally large complex molecules, produced through biotechnology in living systems such as a microorganism from plant or animal cells, making them more difficult to characterize than small molecule drugs. Currently, there are over 200 biological products approved by the FDA for use, including monoclonal antibodies, vaccines, and proteins. Biological products are used to treat patients with complex chronic disease and/or critically ill patients, including, but not limited to, cancer, heart disease, arthritis, multiple sclerosis, and HIV/AIDS.

Single biological products, already approved by FDA, are called reference products which are the products against which a proposed biosimilar product is compared. Products designated by the FDA as biosimilar are highly similar to, and have no clinically meaningful differences from, an existing FDA-approved reference product. Biosimilar products are specifically prescribed by a practitioner and should not be substituted for a reference product.

A biosimilar product may be designated by the FDA as an interchangeable biological if it is biosimilar to the reference product and has proven that it can be expected to produce the same clinical result as the reference product in any given

patient. In addition, to be determined to be an interchangeable biological product, it must be shown that for a biological product that is administered more than once to an individual, the risk, in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product, is not greater than the risk of using the reference product without such alternation or switch. An interchangeable product may be substituted for the reference product without the involvement of the prescriber.

Prior to Chapter 357, New York State law permitted and established requirements for the substitution by pharmacists of generic drugs from their branded counterparts but did not allow for the substitution of biological products. Chapter 357 updated the law to reflect the growing market of biological products and allows for the substitution of an FDA designated interchangeable biological product by a pharmacist when not prohibited by the prescriber.

The proposed amendment of subdivision (a) of §29.7 of the Rules of the Board of Regents adds the failure to identify an interchangeable biological product dispensed on a prescription by writing the name of the manufacturer and of the distributor, if different, on the prescription and on the label, except as otherwise provided in Education Law §6816-a(3)(c), to the unprofessional conduct special provisions for the profession of pharmacy. The proposed amendment also prohibits unlicensed persons from making determinations of the therapeutic equivalency as such determinations apply to interchangeable biological product substitution.

The proposed amendment of paragraph (7) of subdivision (a) of §63.6 of the Regulations of the Commissioner of Education provides that a pharmacist may, based upon his or her professional judgment, accept an electronic prescription from a prescriber, to the pharmacy of the patient's choice except when the prescriber inserts an electronic direction to dispense the drug as written, otherwise, the prescriber's electronic signature shall designate approval of substitution by a pharmacist of an interchangeable biological product. The proposed amendment further provides that notwithstanding any other provision of §63.6 or any other law to the contrary, when an interchangeable biological product is not available and the biological product originally prescribed is available and the pharmacist agrees to dispense the prescribed biological product for a price that will not exceed the price that would have been charged for the interchangeable biological substitute had it been available, substitution of an interchangeable biological product will not be required. In addition, the proposed amendment provides that if the interchangeable biological product is not available and a medical emergency exists, then the pharmacist may dispense the prescribed biological product at his or her regular price. The proposed amendment also requires that, in such instances, the pharmacist must record the date, hour and nature of the medical emergency on the back of the prescription and keep a copy of all such prescriptions.

The proposed amendment of clause (c) of subparagraph (ii) of paragraph (8) of subdivision (b) of §63.6 of the Regulations of the Commissioner of Education includes substitutions of interchangeable biological products along with generic substitutions in the off-premise counseling requirements. The proposed amendment clarifies that permitted substitution of an interchangeable biological product is not a change in

prescribed therapy and does not require the additional patient notifications and counseling that result from a prescriber approved alternative therapy.

Related Regents Items

December 2017: Proposed Amendment of §29.7 of the Rules of the Board of Regents and §63.6 of the Regulations of the Commissioner of Education Relating to the Unprofessional Conduct Special Provisions and the Requirements for Substituting Interchangeable Biological Products for Prescribed Products in the Profession of Pharmacy: Proposed Amendment of §29.7 and §63.6 December 2017 Regents Item (http://www.regents.nysed.gov/common/regents/files/1217ppca1.pdf)

February 2018: Proposed Amendment of §29.7 of the Rules of the Board of Regents and §63.6 of the Regulations of the Commissioner of Education Relating to the Unprofessional Conduct Special Provisions and the Requirements for Substituting Interchangeable Biological Products for Prescribed Products in the Profession of Pharmacy: Proposed Amendment of §29.7 and §63.6 February 2018 Regents Item (http://www.regents.nysed.gov/common/regents/files/218brca6.pdf)

Recommendation

It is recommended that the Board of Regents take the following action:

VOTED: That subdivision (a) of §29.7 of the Rules of the Board of Regents and paragraph (7) of subdivision (a) and clause (c) of subparagraph (ii) of paragraph (8) of subdivision (b) of §63.6 of the Regulations of the Commissioner of Education be amended, as submitted, effective April 25, 2018.

Timetable for Implementation

If adopted at the April 2018 Regents meeting, the proposed amendment would become effective on April 25, 2018.

AMENDMENT TO THE RULES OF THE BOARD OF REGENTS AND THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6507, 6509, 6802, 6810 and 6816-a of the Education Law and Chapter 357 of the Laws of 2017

1. Subdivision (a) of section 29.7 of the Rules of the Board of Regents is amended, as follows:

(a) The requirements of this section set forth for written prescriptions shall also be applicable to electronic prescriptions, as defined in section 63.6(a)(7)(i)(*a*) of this Title, unless otherwise indicated. For purposes of this section *signature* shall include an electronic signature, as defined in section 63.6(a)(7)(i)(*c*) of this Title, when applicable, and *sign* shall include the affixing of an electronic signature. Unprofessional conduct in the practice of pharmacy shall include all conduct prohibited by sections 29.1 and 29.2 of this Part except as provided in this section, and shall also include the following:

(1) . . .

(2) . . .

(3) . . .

(4) . . .

(5) . . .

(6) Failure to identify a generic product <u>or interchangeable biological product</u> dispensed on a prescription by writing the name of the manufacturer and of the distributor, if different, on the prescription and on the label, except as otherwise provided in Education Law, section<u>s</u> 6816-a(1)(c) <u>and 6816-a(3)(c)</u>.

(7) . . .

(8) . . .

(i) . . .

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(iii) . . .

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(ii) . . .

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(19) . . .

(20) . . .

(21) Aiding and abetting an unlicensed person to dispense drugs.

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(a) . . .

(b) . . .

(c) . . .

(d) . . .

(e) . . .

(f) . . .

(g) . . .

(h) . . .

(i) . . .

(j) . . .

(ii) . . .

(a) . . .

(b) Unlicensed persons shall not be authorized to:

(1) . . .

(2) . . .

(3) make determinations of the therapeutic equivalency as such determinations apply to generic substitution or interchangeable biological product substitution;

(4) . . .

(5) . . .

(6) . . .

(7) . . .

(c) . . .

2. Paragraph (7) of subdivision (a) of section 63.6 of the Regulations of the Commissioner of Education is amended, as follows:

(a) General provisions.

(1) . . .

(2) . . .

(3) . . .

(4) . . .

(5) . . .

(6) . . .

(7) Electronic prescriptions.

(i) . . .

(a) . . .

(b) . . .

(c) . . .

(ii) A pharmacist may, based upon his or her professional judgment, accept an electronic prescription from a prescriber, to the pharmacy of the patient's choice, subject to the following requirements:

(a) . . .

(b) . . .

(c) . . .

(d) . . .

(e) [such prescriptions shall be processed in accordance with the requirements of section 29.7 of this Title, provided, however, that prescriptions for controlled substances shall be filled in accordance with the requirements of article 33 of the Public Health Law; and] except when the prescriber inserts an electronic direction to dispense the drug as written, the prescriber's electronic signature shall designate approval of an interchangeable biological product by a pharmacist. Notwithstanding any other provision of this section or any other law to the contrary, when an interchangeable biological product is not available and the biological product originally prescribed is available and the pharmacist agrees to dispense the prescribed biological product for a price that will not exceed the price that would have been charged for the interchangeable biological substitute had it been available, substitution of an interchangeable biological product will not be required. If the interchangeable biological product is not available and a medical emergency situation, which for purposes of this section is defined as any condition requiring alleviation of severe pain or which threatens to cause disability or take life if not promptly treated, exists, then the pharmacist may dispense the prescribed biological product at his or her regular price. In such instances, the pharmacist must record the date, hour and nature of the medical emergency on the back of the prescription and keep a copy of all such prescriptions;

(f) [in accepting an electronic prescription, the pharmacist shall be subject to the applicable requirements of Part 29 of this Title relating to unprofessional conduct, including but not limited to section 29.1(b)(2) and (3) of this Title.] such prescriptions shall be processed in accordance with the requirements of section 29.7 of this Title,

provided, however, that prescriptions for controlled substances shall be filled in accordance with the requirements of article 33 of the Public Health Law; and

(g) in accepting an electronic prescription, the pharmacist shall be subject to the applicable requirements of Part 29 of this Title relating to unprofessional conduct, including but not limited to section 29.1(b)(2) and (3) of this Title.

(iii) . . .

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(b) . . .

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(d) . . .

(e) . . .

(ii) . . .

(a) . . .

(b) . . .

(c) . . .

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(iv) . . .

(9) . . .

3. Clause (c) of subparagraph (ii) of paragraph (8) of subdivision (b) of section 63.6 of the Regulations of the Commissioner of Education is amended, as follows:

(b) Pharmacies.

(1) . . .

(i) . . .

(ii) . . .

(iii) . . .

(iv) . . .

(2) . . .

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(4) . . .

(5) . . .

(6)...

(i) . . .

(a) . . .

(b) . . .

(1) . . .

(2) . . .

(ii) . . .

(a) . . .

(b) . . .

(c) . . .

(d) . . .

(e)...

(f) ...

(g)...

(iii)...

(7)...

(8) Counseling.

(i) . . .

(a) . . .

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(5) . . .

(6) . . .

(7) . . .

(8) . . .

(b) . . .

(c) . . .

(d) . . .

(e) . . .

(ii) Off-premises delivery. For a prescription that is delivered to the patient or the person authorized to act on behalf of the patient off the premises of the pharmacy through mail delivery, a delivery service or otherwise, the pharmacist or pharmacy intern shall meet the requirements of this subparagraph.

(a) . . .

(b) . . .

(c) Except for instances covered by clause (*d*) of this subparagraph, which applies in those cases, if upon presentation of the prescription, the pharmacist or pharmacy intern determines that the prescription is a prescriber approved alternative drug, meaning a change in the drug originally prescribed exclusive of generic substitutions or interchangeable biological product substitutions, the pharmacist or pharmacy intern shall meet the following requirements in addition to the requirements of clauses (*a*) and (*b*) of this subparagraph:

(1) …

(2) …

(3) …

(4) …

(5) …

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(7) …

(d) . . .

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