TO: The Professional Practice Committee

FROM: Douglas E. Lentivech

SUBJECT: 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

DATE: November 30, 2017

AUTHORIZATION(S):

SUMMARY

Issue for Decision

Should the Board of Regents adopt, as an emergency action, 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 (L. 2017, Chapter 357).

Proposed Handling

The proposed amendment will be 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. A copy of the proposed rule and Statement of Facts and Circumstances Which Necessitate Emergency Action are attached.

Procedural History

A Notice of Emergency Adoption and Proposed Rule Marking will be published in the State Register on December 27, 2017. Supporting materials are available upon request from the Secretary to the Board of Regents.

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

None.

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 December 12, 2017, as an emergency action upon a finding by the Board of Regents that such action is necessary for the preservation of the public health and general welfare in order to timely implement the requirements of Chapter 357 of the Laws of 2017, which defined the terms “biological product” and “interchangeable biological product” and established the requirements for the substitution of a biological product, as well as the appropriate method of communication by the pharmacist to the prescriber notifying the prescriber of the substitution of the biological product dispensed.

Timetable for Implementation

If adopted at the December 2017 Regents meeting, the emergency rule will become effective on December 12, 2017 and expire on March 11, 2018. It is anticipated that an additional emergency action will be presented for adoption at the February 2018 Regents meeting to keep the rule continuously in effect until it can be adopted as a permanent rule, effective March 28, 2018.

It is further anticipated that the proposed rule will be presented to the Board of Regents for permanent adoption at the March 12-13, 2018 Regents meeting, after publication of the proposed amendment in the State Register and expiration of the 45-day public comment period required under the State Administrative Procedure Act.

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 or 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, sections 6816-a(1)(c) and 6816-a(3)(c).

(7) . . .

(8) . . .

(i) . . .

(ii) . . .

(iii) . . .

(iv) . . .

(v) . . .

(a) . . .

(b) . . .

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(7) . . .

(16) . . .

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(ii) . . .

(17) . . .

(i) . . .

(ii) . . .

(18) . . .

(19) . . .

(20) . . .

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

(i) . . .

(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) . . .

(8) . . .

(i) . . .

(a) . . .

(b) . . .

(c) . . .

(d) . . .

(e) . . .

(ii) . . .

(a) . . .

(b) . . .

(c) . . .

(iii) . . .

(iv) . . .

(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) . . .

(3) . . .

(4) . . .

(5) . . .

(6)...

(i) . . .

(a) . . .

(b) . . .

(1) . . .

(2) . . .

(ii) . . .

(a) . . .

(b) . . .

(c) . . .

(d) . . .

(e)...

(f) ...

(g)...

(iii)...

(7)...

(8) Counseling.

(i) . . .

(a) . . .

(1) . . .

(2) . . .

(3) . . .

(4) . . .

(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) …

(6) …

(7) …

(d) . . .

(1) . . .

(2) . . .

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(9)…

8 NYCRR §§29.7 and 63.6

STATEMENT OF FACTS AND CIRCUMSTANCES

WHICH NECESSITATE EMERGENCY ACTION

The proposed amendment is necessary to implement Chapter 357 of the Laws of 2017 (Chapter 357), which amended the Education Law by defining the terms “biological product” and “interchangeable biological product” and establishing the requirements for both the substitution of a biological product and the appropriate method of communication by the pharmacist to the prescriber to notify him or her of the substitution of the biological product dispensed, effective October 23, 2017. Pursuant to Chapter 357, a “biological product” means a biological product as defined in subsection (i) of section 351 of the Public Health Service Act, 42 U.S.C. section 262(i) and an “interchangeable biological product” means a biological product licensed by the United States Food and Drug Administration (FDA) pursuant to 42 U.S.C. section 262(k)(4) as set forth in the latest edition or supplement of the United States Food and Drug Administration Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, sometimes referred to as the “Purple Book,” or a biological product determined by the United States Food and Drug Administration to be therapeutically equivalent as set forth in the latest edition or supplement of the United States Food and Drug Administration Approved Drug Products with Therapeutic Equivalence Evaluations, sometimes referred to as the “Orange Book.”

Chapter 357 further requires that, notwithstanding any other law, 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 Chapter 357 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.

Chapter 357 also requires that the prescriber inform the patient whether he or she has prescribed a brand name or its generic equivalent drug product or interchangeable biological product.

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. By permitting the substitution of biological products, when the specified requirements for such substitutions are met, Chapter 357 furthers the public health by improving access to these products. Therefore, it is imperative that the requirements for these biological products substitutions be implemented as soon as possible.

Since the Board of Regents meets at fixed intervals, the earliest the proposed rule can be presented for adoption, after expiration of the required 45-day public comment period provided for in the State Administrative Procedure Act (SAPA) sections 201(1) and (5), would be the March 12-13, 2018 Regents meeting. Furthermore, pursuant to SAPA

section 203(1), the earliest effective date of the proposed rule, if adopted at the March meeting, would be March 28, 2018, the date the Notice of Adoption would be published in the State Register.

Therefore, emergency action is necessary at the December 2017 Regents meeting for the preservation of the public health and the general welfare in order to enable the State Education Department to immediately establish requirements to timely implement Chapter 357, which is already in effect, so that pharmacists will be able to substitute FDA designated biological products, unless prohibited from doing so by the prescriber.

It is anticipated that the proposed rule will be presented for permanent adoption as a permanent rule at the March 12-13, 2018 Regents meeting, which is the first scheduled meeting after expiration of the 45-day public comment period prescribed in the State Administrative Procedure Act for State agency rule makings.