THE STATE EDUCATION DEPARTMENT / THE UNIVERSITY OF THE STATE OF NEW YORK / ALBANY, NY 12234

TO: The Professional Practice Committee

FROM: Douglas E. Lentivech

SUBJECT: Proposed Amendment of Section 29.7 of the Rules of the Board of Regents Relating to Customized Patient Packaging of Medications for Patients on Complex Medication Regimens

DATE: October 7, 2011

AUTHORIZATION(S):

SUMMARY

Issue for Decision

Should the Board of Regents amend section 29.7 of the Rules of the Board of Regents relating to customized patient packaging of medications for patients on complex medication therapies?

Reason(s) for Consideration

Review of Policy.

Proposed Handling

The proposed amendment will be presented to the Professional Practice Committee for recommendation and to the Full Board for adoption at the October 2011 Regents Meeting.

Procedural History

The proposed amendment was discussed by the Professional Practice Committee at the May Regents meeting. A Notice of Proposed Rule Making was published in the State Register on June 1, 2011. An Assessment of Public Comment is attached. The proposed amendment has been revised in response to public comment

to require that pharmacists maintain a record of the lot number for each medication contained in a customized patient medication package. A Notice of Revised Rule Making was published in the State Register on August 31, 2011. Supporting materials are available upon request from the Secretary to the Board of Regents.

Background Information

The proposed amendment to the Rules of the Board of Regents concerns a method of packaging drugs that is referred to as customized patient packaging by the United States Pharmacopeia (USP), the official compendium of standards for drugs in the United States.

In traditional packaging for tablets and capsules, each drug is placed in a vial with a label. An alternative method is unit-dose packaging, in which each capsule or tablet is packaged separately. Customized patient medication packaging is different in that several different drugs are packaged together for administration at the same time of day. Specific labeling would still be required, and certain drugs, such as those that are controlled substances or those that are known to be chemically unstable, would not be permitted in this type of packaging. Likewise, to assure the chemical and therapeutic viability of these medications, once packaged, repackaging would be prohibited, and the customized patient medication packages would have an expiration period of not more than 60 days. The proposed rule also sets forth additional requirements to assure that customized patient packaging is used in a safe manner.

Customized patient medication packaging would not be appropriate for all patients. It has been proven, however, to increase compliance with complex therapeutic regimens, such as those required for patients with end-stage renal disease or HIV/AIDS. In all cases, it is anticipated that providers, patients, and care-givers will be familiarized with the process and the packaging itself. Customized patient medication packaging may reduce reliance on daily and weekly “pill-minders” that are often packed by patients themselves or by caregivers, with a potential for error that this customized patient packaging would avoid.

Recommendation

VOTED: That paragraph (15) of subdivision (a) of section 29.7 of the Rules of the Board of Regents be amended, as submitted, effective November 9, 2011.

Timetable for Implementation

If adopted at the October meeting, the proposed amendment will become effective November 9, 2011.

Attachment

ASSESSMENT OF PUBLIC COMMENT

Since publication of a Notice of Proposed Rule making in the June 1, 2011 State Register, the State Education Department received the following comments:

1. COMMENT:

Support was expressed for the proposed rule as a means to ensure that patients are able to adhere to their prescribed medication schedules and thereby improve their health outcomes and lower overall health care costs. Medication adherence is of utmost importance when trying to treat and monitor a patient's drug therapy and overall health. Many patients, especially those with chronic disease such as hypertension, diabetes and asthma (and others) do not take their medications on schedule. This is compounded in patients who have multiple diseases/conditions and patients who are elderly, debilitated or have critically important conditions such as HIV/AIDS. Many of these patients are treated with several medications creating a monumental task for some patients to stay on schedule. The costs to the health care system for this rule are minimal and are far outweighed by the improved benefits to patients and the health care system.

DEPARTMENT RESPONSE:

The Department concurs with the comment.

2. COMMENT:

While generally supporting the proposal to authorize the use of customized patient medication packages, one comment urged the Department to include in the records a pharmacist must maintain the lot number of each medication contained in

each such package. The comment indicates that “ready access to this product information can literally be a life-saver in the event of a recall of contaminated or mislabeled medications.”

DEPARTMENT RESPONSE:

The Department concurs that requiring pharmacists to maintain records of the lot numbers of medications contained in customized patient packages will enhance public safety. The proposed rule has been revised accordingly.

AMENDMENT TO THE RULES OF THE BOARD OF REGENTS

Pursuant to sections 207, 6504, 6506, and 6509 of the Education Law.

Paragraph (15) of subdivision (a) of section 29.7 of the Rules of the Board of Regents is amended, effective November 9, 2011, as follows**:**

(15)(i) Repacking of drugs in a pharmacy, except by a pharmacist or under his/her immediate and personal supervision. Labels on repacked drugs shall bear sufficient information for proper identification and safety. A repacking record shall be maintained, including the name, strength, lot number, quantity and name of the manufacturer and/or distributor of the drug repacked, the date of the repacking, the number of packages prepared, the number of dosage units in each package, the signature of the person performing the packaging operation, the signature of the pharmacist who supervised the repacking, and such other identifying marks added by the pharmacy for internal recordkeeping purposes. Drugs repacked for in-house use only shall have an expiration date of 12 months, or 50 percent of the time remaining to the manufacturer's expiration date, whichever is less, from the date of repacking. For the repacking of drugs by manufacturers and wholesalers, the provisions of parts 210 and 211 of title 21, Code of Federal Regulations (1984 edition, Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402: 1984, available at New York State Board of Pharmacy, [Room 3035, Cultural Education Center, Albany, NY 12230] 89 Washington Avenue, 2nd Floor, Albany, NY 12234), shall apply. Repacking records shall be maintained for five years and shall be made available to the department for review and copying.

(ii) Repacking drugs in customized patient medication packages (patient med-pak or patient medication package) unless the following conditions are complied with:

(a) medications are packaged in moisture-proof containers that are either non-reclosable or are designed to show evidence of having been opened;

(b) medications are dispensed in containers that bear a label affixed to the immediate container in which the medications are dispensed in accordance with section 6810(1) of the Education Law. Such label shall include:

(1) all information required by Education Law section 6810(1);

(2) the name, strength, physical description or identification, and quantity of each medication;

(3) the address and telephone number of the dispenser;

(4) an expiration date for the customized patient medication package, which shall not be longer than the shortest recommended expiration date of the medications included therein, provided that in no event shall the expiration date be more than 60 days from the date of preparation of the package and shall not exceed the shortest expiration date on the original manufacturer’s bulk containers for the dosage forms included therein;

(5) a separate identifying serial number for each of the prescription orders for each of the drug products contained in the customized patient medication package and, unless such number provides complete information about the customized patient medication package, a serial number for the customized patient medication package itself; and

(6) any other information, including storage instructions or any statements, or warnings required for the medications contained in the package.

(c) medications shall not be repackaged for or reissued to any patient other than to the patient for whom they are originally dispensed;

(d) medications shall not be dispensed in customized patient medication packages, without the consent of the patient, the patient's caregiver, or the prescriber, and the patient or caregiver shall be properly instructed in the use of such packages, in how to identify each medication, and in the steps to be taken in the event one of the medications is discontinued or the therapy otherwise altered;

(e) controlled substances shall not be dispensed in customized patient medication packages;

(f) medications that are unstable or therapeutically incompatible shall not be dispensed in customized patient medication packages; and

(g) a record of each customized patient medication package shall be maintained by the pharmacist. Each record shall contain:

(1) the name and address of the patient;

(2) the serial number of the prescription order for each medication contained therein, or other means of individualized tracking system acceptable to the Department;

(3) the name of the manufacturer or labeler and the lot number for each medication contained therein;

(4) information identifying or describing the design, characteristics, or specifications of the customized patient medication package sufficient to allow

subsequent preparation of an identical customized patient medication package for the patient;

(5) the date of preparation of the customized patient medication package and the expiration date that was assigned;

(6) any special labeling instructions; and

(7) the name or initials of the pharmacist who prepared the customized patient medication package.