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 63.7 and Addition of Section 63.10 of the Regulations of the Commissioner of Education Relating to Collaborative Drug Therapy Management and Continuing Education for Pharmacists

DATE: December 2, 2011

AUTHORIZATION(S):

Summary

Issue for Action

Should the Board of Regents amend the Regulations of the Commissioner of Education relating to collaborative drug therapy management (CDTM) and continuing education for pharmacists?

Reason(s) for Consideration

Required by State statute.

Proposed Handling

The proposed amendment is presented to the Professional Practice Committee for recommendation and to the Full Board for adoption as an emergency action and as a permanent rule at the December 2011 Regents meeting. A Statement of the Facts and Circumstances Which Necessitate Emergency Action is attached.

Procedural History

The concept of collaborative drug therapy management was discussed briefly with the Professional Practice Committee prior to passage of legislation. The Professional Practice Committee then adopted the proposed amendment as an

emergency rule at its September 2011 meeting. Supporting materials are available upon request from the Secretary to the Board of Regents.

Background Information

To date, 46 other states have already authorized collaboration between medication prescribers and pharmacists for the purpose of improving therapeutic outcomes from medication therapies. The purpose of such collaboration is to reduce morbidity and mortality, reduce emergency room visits and hospital admissions, and otherwise reduce health care spending. Included among the many disease states in which such improvements have been documented are asthma, diabetes, and clotting disorders or other indications for anticoagulation.

On May 17, 2011 Governor Cuomo signed into law Chapter 21 of the Laws of 2011, which added a new section 6801-a of the Education Law authorizing the Collaborative Drug Therapy Management Demonstration Program for physicians and pharmacists working under the auspices of a teaching hospital. The new law, which sunsets three years from its effective date, restricts collaboration to pharmacists who meet specified education and experience requirements. In addition, the statute provides that pharmacists participating in CDTM complete five hours of relevant continuing education, and requires the Department, in consultation with the Department of Health, to prepare a report to the legislature on the implementation of the CDTM. The report will review the extent to which CDTM was implemented, and will examine whether, and the extent to which, it contributed to improvement of quality of care for patients, reduced the risk of medication error, reduced unnecessary health care expenditures, and was otherwise in the public interest.

The legislation authorizes the Department to develop regulations necessary to implement the new law. The proposed amendment establishes standards for the experience required for a pharmacist to participate in CDTM, and revises continuing education requirements to reflect the new statutory provisions for pharmacists engaging in CDTM.

Concurrently, the proposed amendment updates the continuing education regulations for pharmacists by deleting out-dated references.

A Notice of Emergency Adoption and Proposed Rule Making was published in the State Register on October 5, 2011. Upon expiration of the 45-day public comment period under the State Administrative Procedure Act, the Department received no comments on the proposed amendment.

Recommendation

VOTED: That subparagraph (i) of paragraph (2) of subdivision (b) and paragraph (1) of subdivision (c) of section 63.7 of the Regulations of the Commissioner of Education be amended and that section 63.10 of the Regulations of the Commissioner

of Education be added, as submitted, effective December 13, 2011, 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 to ensure that the emergency rule remains continuously in effect until it can be adopted as a permanent rule.

VOTED: That subparagraph (i) of paragraph (2) of subdivision (b) and paragraph (1) of subdivision (c) of section 63.7 of the Regulations of the Commissioner of Education be amended and that section 63.10 of the Regulations of the Commissioner of Education be added, as submitted, effective January 4, 2012.

Timetable for Implementation

The proposed amendment, if approved as an emergency action, will be effective December 13, 2011 and the permanent rule will become effective on January 4, 2012.

Attachment

STATEMENT OF FACTS AND CIRCUMSTANCES WHICH NECESSITATE EMERGENCY ACTION

The proposed amendment of section 63.7 and addition of section 63.10 of the Commissioner's regulations is necessary to conform the Commissioner's regulations to Chapter 21 of the Laws of 2011. The legislation was signed by the Governor on May 17, 2011, and adds a new section 6801-a of the Education Law authorizing the Collaborative Drug Management Therapy Demonstration Program for physicians and pharmacists working under the auspices of a teaching hospital. The new law, which sunsets three years from its effective date, restricts collaboration to pharmacists who meet specified education and experience requirements. In addition, the statute provides that pharmacists participating in CDTM complete five hours of relevant continuing education. The legislation authorizes the Commissioner to develop regulations necessary to implement the new law.

Consistent with the statute, the proposed amendment will add a new section 63.10 and amend section 63.7 of the Commissioner's Regulations to establish requirements necessary for implementation of Chapter 21 of the Laws of 2011. Because the Board of Regents meets at scheduled intervals, the earliest the proposed amendment could be presented for regular adoption, after publication of a Notice of Proposed Rule Making in the State Register and expiration of the 45-day public comment period prescribed in the State Administrative Procedure Act (SAPA), is at the December 12-13, 2011 meeting of the Board of Regents. If adopted at the December Regents meeting, the earliest the amendment could become effective pursuant to SAPA is December 28, 2011, the date of publication of the Notice of Adoption in the State

Register. However, Chapter 21 of the Laws of 2011 takes effect on September 14, 2011, and directs that any rule or regulation necessary for the law's implementation be made and completed on or before such effective date.

Emergency action is necessary for the preservation of the public health and general welfare to immediately conform the Commissioner's regulations to Chapter 21 of the Laws of 2011, and thereby ensure that the Collaborative Drug Management Therapy Demonstration Program is implemented in a timely manner and consistent with statutory requirements.

Emergency action is also necessary to ensure that the emergency rule that was adopted at the September Regents meeting remains continuously in effect until it can be adopted as a permanent rule. The proposed rule was adopted as an emergency action at the September 2011 Regents meeting, effective September 14, 2011. A Notice of Proposed and Emergency Rule Making was published in the State Register on October 5, 2011. The September emergency rule will expire on December 12, 2011 and the permanent rule will not become effective until January 4, 2012. Therefore, emergency action is necessary to ensure that the emergency rule remains continuously in effect until such time as it can be adopted as a permanent rule.

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6507, 6801-a and 6827 of the Education Law and Chapter 21 of the Laws of 2011.

1. Subparagraph (i) of paragraph (2) of subdivision (b) of section 63.7 of the Regulations of the Commissioner of Education is amended, effective December 13, 2011, as follows:

(i) [Exemptions. The following licensees shall be exempt from the continuing education requirements, as prescribed in subdivision (c) of this section:

(a) licensees for the triennial registration period during which they are first licensed to practice pharmacy in New York State, exclusive of those first licensed to practice pharmacy in New York State pursuant to an endorsement of a license of another jurisdiction;

(b) licensees whose first registration date following January 1, 1997 occurs prior to January 1, 1998, for periods prior to such registration date; and

(c) licensees] Exemption. Licensees who are not engaged in the practice of pharmacy, as evidenced by not being registered to practice in New York State, shall be exempt from the continuing education requirements, as prescribed in subdivision (c) of this section, except as otherwise provided in paragraph (c)(2) of this section to meet the education requirements for the resumption of practice after a lapse in practice for a licensee who has not lawfully practiced continuously in another jurisdiction throughout such lapse period.

2. Paragraph (1) of subdivision (c) of section 63.7 of the Regulations of the Commissioner of Education is amended, effective December 13, 2011, as follows:

(1) During each triennial registration period, meaning a registration period of three years' duration, an applicant for registration shall complete at least 45 hours of formal continuing education acceptable to the department, as defined in paragraph (4) of this subdivision, provided that no more than 22 hours of such continuing education shall consist of self-study courses. During registration periods beginning on or after September 1, 2003, a licensee shall complete as part of the 45 hours of formal continuing education, or pro-ration thereof, at least three hours of formal continuing education acceptable to the department in the processes and strategies that may be used to reduce medication and/or prescription errors. Any licensee participating in collaborative drug therapy management pursuant to Education Law section 6801-a, shall complete as part of the 45 hours of formal continuing education, or pro-ration thereof, at least five hours of formal continuing education acceptable to the department in the area or areas of practice generally related to any collaborative drug therapy management protocols to which the pharmacist may be subject, provided that such continuing education shall not be completed as self-study. [Any licensed pharmacist whose first registration date following January 1, 1997 occurs less than three years from that date, but on or after January 1, 1998, shall complete continuing education hours on a prorated basis at the rate of one and one-quarter hours of acceptable formal continuing education per month for the period beginning January 1, 1997 up to the first registration date thereafter. Such continuing education shall be completed during the period beginning January 1, 1997 and ending before the first day of the new registration period or at the option of the licensee during any time in the previous registration period.]

3. Section 63.10 of the Regulations of the Commissioner of Education is added, effective December 13, 2011, to read as follows:

§63.10 Collaborative drug therapy management.

(a) Applicability. This section shall apply only to the extent that the applicable provisions in Education Law sections 6801 and 6801-a, authorizing certain pharmacists to participate in collaborative drug therapy management, have not expired or been repealed.

(b) Experience requirement for participating pharmacists.

(1) As used in Education Law section 6801-a(2)(b), a year of experience shall mean not less than 1,680 hours of work as a pharmacist within a period of one calendar year.

(2) In order to be counted as a year of experience that includes clinical experience in a health facility, such experience shall include, on average, not less than 15 hours per week of clinical experience which involves consultation with physicians with respect to drug therapy, as determined by the facility that employs or is affiliated with the pharmacist.