TO: The Honorable the Members of the Board of Regents

FROM: Douglas E. Lentivech

SUBJECT: Proposed Amendment to Section 63.10 of the Regulations of the Commissioner of Education Relating to Collaborative Drug Therapy Management for Pharmacists

DATE: February 16, 2016

AUTHORIZATION(S):

SUMMARY

Issue for Decision (Consent Agenda)

Should the Board of Regents amend section 63.10 of the Regulations of the Commissioner of Education relating to collaborative drug therapy management (CDTM) for pharmacists?

Reason(s) for Consideration

Required by State statute (L. 2015, Ch. 238).

Proposed Handling

The proposed amendment will be presented to the Full Board for adoption as a permanent rule at the February 2016 Regents meeting. A copy of the proposed amendment is attached. Supporting materials are available upon request from the Secretary to the Board of Regents.

Procedural History

The proposed amendment was discussed by the Professional Practice Committee and adopted by the Full Board as an emergency action at the November 2015 Regents meeting, effective December 13, 2015. A Notice of Emergency Adoption and Proposed Rule Making was published in the State Register on December 2, 2015 for a 45 day public comment period.

Because the November emergency rule will expire on February 14, 2016, it was necessary to adopt a second emergency action at the January 2016 Regents meeting, effective February 15, 2016, to ensure that the rule remains continuously in effect until it can be presented for adoption and take effect as a permanent rule.

Subsequent to the above-referenced publication of the Notice of Emergency Adoption and Proposed Rule Making in the State Register, 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.

Background Information

At least 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. This law, which was scheduled to sunset three years from its effective date, restricted collaboration to pharmacists who meet specified education and experience requirements. In addition, this law provided that pharmacists participating in CDTM complete five hours of relevant continuing education and required the Department, in consultation with the Department of Health, to prepare a report to the legislature on the implementation of the CDTM. The report reviewed the extent to which CDTM was implemented, and examined 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 report, which has previously been shared with the Board of Regents, confirmed the positive impact of physician pharmacist collaboration for those states included in the report. Further, there was widespread support for continuation and expansion by physicians and patients alike. The full report may be accessed at

http://www.op.nysed.gov/news/cdtmreportmay2014final.pdf.

In 2011, the Board of Regents added section 63.10 to the Regulations of the Commissioner of Education to implement this law by establishing the standards for the experience required for a pharmacist to participate in CDTM and amended section 63.7 of the Regulations of the Commissioner of Education to revise the continuing education requirements to reflect the statutory provisions of Chapter 21 of 2011 for pharmacists engaging in CDTM.

On September 14, 2015, Governor Cuomo signed into law Chapter 238 of the Laws of 2015, which extends and expands the provisions that were enacted in 2011 by

extending the CDTM program for an additional three year period and expanding CDTM to general hospitals and nursing homes with an on-site pharmacy staffed by a licensed pharmacist. This law further authorizes the Department to develop regulations necessary to implement it. Chapter 238 of 2015 also directs the Department to prepare a report on the expanded CDTM program within four months of the program's expiration.

The proposed amendment establishes the experience and education requirements for pharmacists seeking to participate in CDTM. It requires such pharmacists to submit an application to the Department for approval to participate in CDTM. The proposed amendment further establishes the requirements for CDTM written agreements and protocols.

Recommendation

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

VOTED: That section 63.10 of the Regulations of the Commissioner of Education be amended, as submitted, effective March 9, 2016.

Timetable for Implementation

If adopted at the February 2016 Regents meeting, the proposed amendment will become effective on March 9, 2016.

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6507 and 6801-a of the Education Law and Chapter 238 of the Laws of 2015

Section 63.10 of the Regulations of the Commissioner of Education is amended, effective March 9, 2016, to read as follows:

(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.]

(b) Definitions. As used in this section:

(1) Board means the State Board of Pharmacy as established by section 6804 of the Education Law.

(2) Clinical services means the collection and interpretation of patient data for the purpose of initiating, modifying and monitoring drug therapy with associated accountability and responsibility for outcomes in a direct patient care setting.

(3) Collaborative drug therapy management means the performance of clinical services by a pharmacist relating to the review, evaluation and management of drug therapy to a patient, who is being treated by a physician for a specific disease or associated disease states, in accordance with a written agreement or protocol with a voluntarily participating physician and in accordance with the policies, procedures, and protocols of the facility.

(4) Facility means:

(i) a teaching hospital or general hospital, including any diagnostic center, treatment center, or hospital-based out-patient department as defined in section 2801 of the Public Health Law; or

(ii) a nursing home with an on-site pharmacy staffed by a licensed pharmacist; provided, however, for the purposes of this section the term facility shall not include dental clinics, dental dispensaries, residential health care facilities and rehabilitation centers.

(5) Teaching hospital means a hospital licensed pursuant to Article 28 of the Public Health Law that is eligible to receive direct or indirect graduate medical education payments pursuant to Article 28 of the Public Health Law.

(6) Physician means the physician selected by or assigned to a patient, who has primary responsibility for the treatment and care of the patient for the disease and associated disease states that are the subject of the collaborative drug therapy management.

(7) Written agreement or protocol means a written document, pursuant to and consistent with an applicable state or federal requirements, that addresses a specific disease or associated disease states and that describes the nature and scope of collaborative drug therapy management to be undertaken by the pharmacists, in

collaboration with the participating physician in accordance with the requirements of this section.

(c) Requirements. A pharmacist seeking to engage in collaborative drug therapy management shall submit his or her credentials, in a form determined by the department, to the department for review. Those pharmacists who the department determines to meet the requirements of paragraph (3) of this subdivision and who are employed by or otherwise affiliated with a facility shall be permitted to enter into a written agreement or protocol with a physician authorizing collaborative drug therapy management, subject to the limitations set forth in this section, within the scope of such employment or affiliation, and shall be identified as being so authorized by a designation determined by the department.

(1) As used in section 6801-a(2)(b) of the Education Law, 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 with which the pharmacist is employed or affiliated.

(3) A participating pharmacist shall:

(i)(a) have been awarded either a master of science in clinical pharmacy or a doctor of pharmacy degree;

(b) maintain a current unrestricted license; and

(c) have a minimum of two years experience, of which at least one year of such experience shall include clinical experience in a health facility, which involves

consultation with physicians with respect to drug therapy and may include a residency at a facility involving such consultation, and such clinical experience shall be gained within the three years immediately preceding the pharmacist's submission of his or her credentials to the department for review;

or

(ii) (a) have been awarded a bachelor of science in pharmacy;

(b) maintain a current unrestricted license; and

(c) within the last seven years, have a minimum of three years experience, of which at least one year of such experience shall include clinical experience in a health facility, which involves consultation with physicians with respect to drug therapy and may include a residency at a facility involving such consultation, and such clinical experience shall be gained within the three years immediately preceding the pharmacist's submission of his or her credentials to the department for review;

and

(iii) (a) have residency training in a program accredited or accreditation-pending by a nationally recognized accreditation body acceptable the department; or

(b) have board certification awarded by a certification body acceptable to the department and shall include baseline and ongoing competency assessments;

and

(iv) meet additional experience provisions as follows:

(a) for pharmacists seeking to engage in collaborative drug therapy management by satisfying the requirements of clauses (a) though (c) of subparagraph (i) of this paragraph, if he or she seeks to utilize residency training to satisfy the one year of clinical experience requirement, the second year of required experience shall also be

clinical experience, unless such pharmacist possesses board certification that satisfies the requirements of clause (b) of subparagraph (iii) of this paragraph.

(b) for pharmacists seeking to engage in collaborative drug therapy by satisfying the requirements of clauses (a) through (c) of subparagraph (ii) of this paragraph, if he or she seeks to utilize residency training to satisfy the one year of clinical experience requirement, an additional year's experience of the three years required shall also be clinical experience, unless such pharmacist possesses board certification that satisfies the requirements of clause (b) of subparagraph (iii) of this paragraph.

(d) Requirements for collaborative drug therapy management written agreements or protocols. A physician who is a party to a written agreement or protocol to authorize collaborative drug treatment shall be employed by or otherwise affiliated with the same facility with which the pharmacist is also employed or affiliated and their written agreement or protocol may include, and shall be limited to, the following:

(1) Adjusting or managing a drug regimen of a patient, pursuant to a patient specific order or protocol made by the patient's physician, which may include adjusting drug strength, frequency of administration or route of administration. Adjusting the drug regimen shall not include substituting or selecting a different drug which differs from that initially prescribed by the patient's physician unless such substitution is expressly authorized in the written order or protocol. The pharmacist shall be required to immediately document in the patient's medical record changes made to the patient's drug therapy and shall use any reasonable means or method established by the facility to notify the patient's other treating physicians with whom he or she does not have a written agreement or protocol regarding such changes. The patient's physician may prohibit, by written instruction, any adjustment or change in the patient's drug regiment by the pharmacist;

(2) Evaluating and, only if specifically authorized by the protocol and only to the extent necessary to discharge the responsibilities set forth in this section, ordering disease state laboratory tests related to the drug therapy management for the specific disease or disease state specified within the written agreement or protocol; and

(3) Only if specifically authorized by the written agreement or protocol and only to the extent necessary to discharge the responsibilities set forth in this section, ordering or performing routine patient monitoring functions as may be necessary in the drug therapy management, including the collecting and reviewing of patient histories, and ordering or checking patient vital signs, including pulse, temperature, blood pressure and respiration.

(e) Additional provisions relating to collaborative drug therapy management written agreements and protocols.

(1) The existence of a written agreement or protocol on collaborative drug therapy management and the patient's right to choose to not participate in collaborative drug therapy management shall be disclosed to any patient who is eligible to receive collaborative drug therapy management. Collaborative drug therapy management shall not be utilized unless the patient or the patient's authorized representative consents, in writing, to such management. If the patient or the patient's authorized representative consents, it shall be noted on the patient's medical record. If the patient or the patient's authorized representative who consented to collaborative drug therapy management chooses to no longer participate in such management, at any time, it shall be noted in the patient's medical record. In addition, the existence of the written agreement or protocol and the patient's consent to such management shall be disclosed to the patient's primary care physician and any other treating physician or healthcare provider.

(2) Participation in a written agreement or protocol authorizing collaborative drug therapy management shall be voluntary, and no patient, physician, pharmacist, or facility shall be required to participate.