S T A T E O F N E W Y O R K

S. 3292 A. 6848

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S E N A T E - A S S E M B L Y

March 13, 2009

IN SENATE -- Introduced by Sens. LAVALLE, DeFRANCISCO, DIAZ, FLANAGAN, FUSCHILLO, KRUEGER, LARKIN, LITTLE, MAZIARZ, MORAHAN, ONORATO, RANZENHOFER, SEWARD, STACHOWSKI, VOLKER -- read twice and ordered printed, and when printed to be committed to the Committee on Higher Education

IN ASSEMBLY -- Introduced by M. of A. CANESTRARI, GOTTFRIED, COLTON, ENGLEBRIGHT, PAULIN, BURLING, LIFTON, PERALTA, ORTIZ -- Multi-Sponsored by -- M. of A. ALFANO, BARRA, BOYLAND, BRENNAN, CHRISTENSEN, CROUCH, CYMBROWITZ, DelMONTE, EDDINGTON, JACOBS, JOHN, KOON, MAGEE, MARKEY, McDONOUGH, McENENY, MILLER, MORELLE, PHEFFER, PRETLOW, RAIA, SAYWARD, WRIGHT -- read once and referred to the Committee on Higher Education

AN ACT to amend the education law, in relation to authorizing pharmacists to perform collaborative drug therapy management with physicians or nurse practitioners in certain settings and providing for the repeal of such provisions upon expiration thereof

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. Subdivision 1 of section 6801 of the education law, as amended by chapter 563 of the laws of 2008, is amended to read as follows:

1. The practice of the profession of pharmacy is defined as the administering, preparing, compounding, preserving, or the dispensing of drugs, medicines and therapeutic devices on the basis of prescriptions or other legal authority, INCLUDING MEDICATION REVIEW, AND COLLABORATIVE DRUG THERAPY MANAGEMENT IN ACCORDANCE WITH THE PROVISIONS OF SECTION SIXTY-EIGHT HUNDRED ONE-A OF THIS ARTICLE.

S 1-a. Section 6801 of the education law, as added by chapter 987 of the laws of 1971, is amended to read as follows:

S 6801. Definition of practice of pharmacy. The practice of the profession of pharmacy is defined as the preparing, compounding,

EXPLANATION--Matter in ITALICS (underscored) is new; matter in brackets [ ] is old law to be omitted.

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preserving, or the dispensing of drugs, medicines and therapeutic devices on the basis of prescriptions or other legal authority, INCLUDING MEDICATION REVIEW, AND COLLABORATIVE DRUG THERAPY MANAGEMENT IN ACCORDANCE WITH THE PROVISIONS OF SECTION SIXTY-EIGHT HUNDRED ONE-A OF THIS ARTICLE.

S 2. The education law is amended by adding a new section 6801-a to read as follows:

S 6801-A. COLLABORATIVE DRUG THERAPY MANAGEMENT DEMONSTRATION PROGRAM. 1. AS USED IN THIS SECTION, THE FOLLOWING TERMS SHALL HAVE THE FOLLOWING MEANINGS:

A. "COLLABORATIVE DRUG THERAPY MANAGEMENT" SHALL MEAN THE PERFORMANCE OF SERVICES BY A PHARMACIST RELATING TO THE REVIEW, EVALUATION AND MANAGEMENT OF DRUG THERAPY TO A PATIENT, WHO IS BEING TREATED BY A PHYSICIAN OR NURSE PRACTITIONER FOR A SPECIFIC DISEASE OR DISEASE STATE, IN ACCORDANCE WITH A WRITTEN AGREEMENT OR PROTOCOL WITH A VOLUNTARILY PARTICIPATING PHYSICIAN OR NURSE PRACTITIONER AND IN ACCORDANCE WITH THE POLICIES, PROCEDURES, AND PROTOCOLS OF THE FACILITY, PROVIDED THAT SUCH AGREEMENT OR PROTOCOL ENTERED INTO BY THE NURSE PRACTITIONER WITH THE PHARMACIST IS CONSISTENT WITH ALL APPLICABLE PROVISIONS OF ARTICLE ONE HUNDRED THIRTY-NINE OF THIS CHAPTER. SUCH AGREEMENT OR PROTOCOL AS ENTERED INTO BY THE PHYSICIAN OR NURSE PRACTITIONER AND A PHARMACIST, MAY INCLUDE, AND SHALL BE LIMITED TO:

(I) ADJUSTING OR MANAGING A DRUG REGIMEN OF A PATIENT, PURSUANT TO A PATIENT SPECIFIC WRITTEN ORDER OR PROTOCOL MADE BY THE PATIENT'S PHYSICIAN OR NURSE PRACTITIONER, 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 OR NURSE PRACTITIONER UNLESS SUCH SUBSTITUTION IS EXPRESSLY AUTHORIZED IN THE WRITTEN ORDER OR PROTOCOL. THE PHARMACIST SHALL BE REQUIRED TO IMMEDIATELY ENTER INTO THE PATIENT RECORD ANY CHANGE OR CHANGES MADE TO THE PATIENT'S DRUG THERAPY AND SHALL USE ANY REASONABLE MEANS OR METHOD ESTABLISHED BY THE FACILITY OR THE DEPARTMENT TO NOTIFY ANY OF THE PATIENT'S OTHER TREATING PHYSICIANS OR NURSE PRACTITIONERS WITH WHOM HE OR SHE DOES NOT HAVE A WRITTEN AGREEMENT OR PROTOCOL REGARDING SUCH CHANGES. THE PATIENT'S PHYSICIAN OR NURSE PRACTITIONER MAY PROHIBIT, BY WRITTEN INSTRUCTION, ANY ADJUSTMENT OR CHANGE IN THE PATIENT'S DRUG REGIMEN BY THE PHARMACIST;

(II) 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 CLINICAL LABORATORY TESTS RELATED TO THE DRUG THERAPY MANAGEMENT FOR THE SPECIFIC DISEASE OR DISEASE STATE SPECIFIED WITHIN THE PROTOCOL; AND

(III) ONLY IF SPECIFICALLY AUTHORIZED BY THE 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.

B. "WRITTEN AGREEMENT OR PROTOCOL" SHALL MEAN A WRITTEN DOCUMENT, PURSUANT TO AND CONSISTENT WITH ANY APPLICABLE STATE OR FEDERAL REQUIREMENTS, THAT ADDRESSES A SPECIFIC DISEASE OR DISEASE STATE AND THAT DESCRIBES THE NATURE AND SCOPE OF COLLABORATIVE DRUG THERAPY MANAGEMENT TO BE UNDERTAKEN BY THE PHARMACIST, IN COLLABORATION WITH THE PARTIC-

IPATING PHYSICIAN OR NURSE PRACTITIONER, IN ACCORDANCE WITH THE PROVISIONS OF THIS SECTION.

C. "PHYSICIAN OR NURSE PRACTITIONER" SHALL MEAN THE PHYSICIAN OR NURSE PRACTITIONER, SELECTED BY OR ASSIGNED TO A PATIENT, WHO HAS PRIMARY RESPONSIBILITY FOR THE TREATMENT AND CARE OF THE PATIENT FOR THE DISEASE OR DISEASE STATE THAT IS THE SUBJECT OF THE COLLABORATIVE DRUG THERAPY MANAGEMENT.

D. "FACILITY" SHALL MEAN A GENERAL HOSPITAL, RESIDENTIAL HEALTH CARE FACILITY, DIAGNOSTIC CENTER, TREATMENT CENTER, OR HOSPITAL-BASED OUTPATIENT DEPARTMENT, LICENSED PURSUANT TO ARTICLE TWENTY-EIGHT OF THE PUBLIC HEALTH LAW. IN ADDITION, A FACILITY MAY ALSO INCLUDE UP TO SEVEN COMMUNITY-PRACTICE SITES, SELECTED BY THE DEPARTMENT IN CONSULTATION WITH THE DEPARTMENT OF HEALTH, WHERE PHARMACISTS AND PHYSICIANS WHO ARE NOT EMPLOYED BY OR AFFILIATED WITH FACILITIES LICENSED PURSUANT TO ARTICLE TWENTY-EIGHT OF THE PUBLIC HEALTH LAW PROPOSE TO ENTER INTO COLLABORATIVE ARRANGEMENTS, PURSUANT TO THE PROVISIONS OF THIS SECTION. SUCH SITES SHALL BE SELECTED BASED UPON A REVIEW OF APPLICATIONS SUBMITTED TO THE DEPARTMENT BY SUCH PHARMACISTS AND PHYSICIANS, WHICH DEMONSTRATE THAT THE APPLICANTS CAN SATISFY THE REQUIREMENTS OF THIS SECTION.

2. A. A PHARMACIST WHO MEETS THE EXPERIENCE REQUIREMENTS OF PARAGRAPH B OF THIS SUBDIVISION AND WHO IS EMPLOYED BY OR OTHERWISE AFFILIATED WITH A FACILITY SHALL BE PERMITTED TO ENTER INTO A WRITTEN AGREEMENT OR PROTOCOL WITH A PHYSICIAN OR NURSE PRACTITIONER AUTHORIZING COLLABORATIVE DRUG THERAPY MANAGEMENT, SUBJECT TO THE LIMITATIONS SET FORTH IN THIS SECTION, WITHIN THE SCOPE OF SUCH EMPLOYMENT OR AFFILIATION.

B. A PARTICIPATING PHARMACIST MUST:

(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 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 OR NURSE PRACTITIONERS WITH RESPECT TO DRUG THERAPY AND MAY INCLUDE A RESIDENCY AT A FACILITY INVOLVING SUCH CONSULTATION; 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 FIVE YEARS EXPERIENCE, OF WHICH AT LEAST ONE YEAR OF SUCH EXPERIENCE SHALL INCLUDE CLINICAL EXPERIENCE IN A HEALTH FACILITY, WHICH INVOLVES CONSULTATION WITH PHYSICIANS OR NURSE PRACTITIONERS WITH RESPECT TO DRUG THERAPY AND MAY INCLUDE A RESIDENCY AT A FACILITY INVOLVING SUCH CONSULTATION.

C. NOTWITHSTANDING ANY PROVISION OF THIS SECTION, NOTHING HEREIN SHALL AUTHORIZE THE PHARMACIST TO DIAGNOSE DISEASE. IN THE EVENT THAT A TREATING PHYSICIAN OR NURSE PRACTITIONER MAY DISAGREE WITH THE EXERCISE OF PROFESSIONAL JUDGMENT BY THE PHARMACIST, THE JUDGMENT OF THE TREATING PHYSICIAN OR NURSE PRACTITIONER SHALL PREVAIL.

3. THE PHYSICIAN OR NURSE PRACTITIONER WHO IS A PARTY TO A WRITTEN AGREEMENT OR PROTOCOL AUTHORIZING COLLABORATIVE DRUG THERAPY MANAGEMENT SHALL BE EMPLOYED BY OR OTHERWISE AFFILIATED WITH THE SAME FACILITY WITH WHICH THE PHARMACIST IS ALSO EMPLOYED OR AFFILIATED.

4. 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. 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 PHYSICIAN OR NURSE PRACTITIONER AND ANY OTHER TREATING PHYSICIAN, NURSE PRACTITIONER OR HEALTHCARE PROVIDER.

5. PARTICIPATION IN A WRITTEN AGREEMENT OR PROTOCOL AUTHORIZING COLLABORATIVE DRUG THERAPY MANAGEMENT SHALL BE VOLUNTARY, AND NO PATIENT, PHYSICIAN, NURSE PRACTITIONER, PHARMACIST, OR FACILITY SHALL BE REQUIRED TO PARTICIPATE.

S 3. Subdivision 2 of section 6827 of the education law, as added by chapter 311 of the laws of 1996, is amended to read as follows:

2. During each triennial registration period an applicant for registration shall complete a minimum of forty-five hours of acceptable formal continuing education, as specified in subdivision four of this section, provided that no more than twenty-two hours of such continuing education shall consist of self-study courses. ANY PHARMACIST PARTICIPATING IN COLLABORATIVE DRUG THERAPY MANAGEMENT PURSUANT TO SECTION SIX THOUSAND EIGHT HUNDRED ONE OF THIS ARTICLE SHALL COMPLETE AT LEAST FIVE HOURS OF ACCEPTABLE FORMAL CONTINUING EDUCATION IN THE AREA OR AREAS OF PRACTICE GENERALLY RELATED TO ANY COLLABORATIVE DRUG THERAPY MANAGEMENT PROTOCOLS TO WHICH THE PHARMACIST MAY BE SUBJECT. Any pharmacist whose first registration date following the effective date of this section occurs less than three years from such effective date, but on or after January first, nineteen hundred ninety-eight, shall complete continuing education hours on a prorated basis at the rate of one and one-quarter hours per month for the period beginning January first, nineteen hundred ninety-seven up to the first registration date thereafter. A licensee who has not satisfied the mandatory continuing education requirements shall not be issued a triennial registration certificate by the department and shall not practice unless and until a conditional registration certificate is issued as provided for in subdivision three of this section. Continuing education hours taken during one triennium may not be transferred to a subsequent triennium.

S 4. The department of education, in consultation with the department of health, shall prepare or shall arrange for the preparation of a report on the implementation of collaborative drug therapy management (CDTM) in New York state. The report shall be submitted to the speaker of the assembly and the temporary president of the senate and the chairs of the senate and assembly higher education committees at least four months prior to the expiration of this act. The report shall review the extent to which CDTM was implemented in New York state and shall examine whether and the extent to which CDTM contributed to the 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 may make recommendations regarding the extension, alteration and/or expansion of these provisions and make any other recommendations related to the implementation of CDTM pursuant to this act.

S 5. This act shall take effect on the one hundred twentieth day after it shall have become a law and shall expire 4 years after such effective date when upon such date the provisions of this act shall be deemed repealed; provided, however, that the amendments to subdivision 1 of section 6801 of the education law made by section one of this act shall be subject to the expiration and reversion of such subdivision pursuant to section 8 of chapter 563 of the laws of 2008, when upon such date the

provisions of section one-a of this act shall take effect; provided, further, that effective immediately, the addition, amendment and/or repeal of any rule or regulation necessary for the implementation of this act on its effective date is authorized and directed to be made and completed on or before such effective date.