

4857

2015-2016 Regular Sessions

I N S E N A T E

April 22, 2015

Introduced by Sen. LAVALLE -- read twice and ordered printed, and when printed to be committed to the Committee on Higher Education

AN ACT to amend the education law, in relation to authorizing pharmacists to perform collaborative drug therapy management, and to amend chapter 21 of the laws of 2011 amending the education law relating to authorizing pharmacists to perform collaborative drug therapy management with physicians in certain settings, in relation to making such provisions permanent

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

1 Section 1. Section 6801-a of the education law, as added by chapter 21
2 of the laws of 2011, is amended to read as follows:
3 S 6801-a. Collaborative drug therapy management [demonstration
4 program]. 1. As used in this section, the following terms shall have
5 the following meanings:
6 a. "CLINICAL SERVICES" SHALL MEAN THE COLLECTION AND INTERPRETATION
7 OF PATIENT DATA FOR THE PURPOSE OF INITIATING, MODIFYING AND MONITORING
8 DRUG THERAPY WITH ASSOCIATED ACCOUNTABILITY AND RESPONSIBILITY FOR
9 OUTCOMES IN A DIRECT PATIENT CARE SETTING.
10 B. "Collaborative drug therapy management" shall mean the performance
11 of CLINICAL services by [a pharmacist] PHARMACISTS relating to the
12 review, evaluation and management of drug therapy to a patient, who is
13 being treated by a physician, PHYSICIAN ASSISTANT OR NURSE PRACTITIONER
14 for a specific disease or disease [state] STATES, in accordance with a
15 written agreement or protocol with a voluntarily participating
16 physician, PHYSICIAN ASSISTANT OR NURSE PRACTITIONER and in accordance
17 with the policies, procedures, and protocols of [the] A facility OR
18 MEDICAL PRACTICE. Such agreement or protocol as entered into by the
19 physician, PHYSICIAN ASSISTANT OR NURSE PRACTITIONER and [a pharmacist]
20 PHARMACISTS, may include[, and shall be limited to]:

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

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1 (i) [adjusting or managing] PRESCRIBING IN ORDER TO ADJUST OR MANAGE a
2 drug regimen of a patient, pursuant to a patient specific [written]
3 order, or NON-PATIENT-SPECIFIC protocol made by the patient's physician,
4 PHYSICIAN ASSISTANT OR NURSE PRACTITIONER, which may include adjusting
5 drug strength, frequency of administration or route of administration[.
6 Adjusting the drug regimen shall not include substituting or selecting a
7 different] OR SELECTING A drug which differs from that initially
8 prescribed by the patient's physician [unless such substitution is
9 expressly], PHYSICIAN ASSISTANT OR NURSE PRACTITIONER AS authorized in
10 the written order or protocol. [The pharmacist] PHARMACISTS shall be
11 required to [immediately enter into] DOCUMENT IN the patient record [any
12 change or] changes made to the patient's drug therapy and shall use any
13 reasonable means or method established by the facility or [the depart-
14 ment] MEDICAL PRACTICE to notify [any of] the patient's other treating
15 physicians [with whom he or she does not have a written agreement or
16 protocol regarding such changes. The patient's physician may prohibit,
17 by written instruction, any adjustment or change in the patient's drug
18 regimen by the pharmacist], PHYSICIAN ASSISTANTS, NURSE PRACTITIONERS
19 AND OTHER PROFESSIONALS AS REQUIRED BY THE WRITTEN AGREEMENT OR
20 PROTOCOL;

21 (ii) evaluating and, [only if specifically] AS authorized by the NEW
22 WRITTEN AGREEMENT OR protocol and only to the extent necessary to
23 discharge the responsibilities set forth in this section, ordering
24 [clinical] DISEASE STATE laboratory tests related to the drug therapy
25 management for the specific disease or disease [state] STATES specified
26 within the WRITTEN AGREEMENT OR protocol; and

27 (iii) [only if specifically] AS authorized by the WRITTEN AGREEMENT OR
28 protocol and only to the extent necessary to discharge the responsibil-
29 ities set forth in this section, ordering or performing routine patient
30 monitoring functions as may be necessary in the drug therapy manage-
31 ment[, including the collecting and reviewing of patient histories, and
32 ordering or checking patient vital signs, including pulse, temperature,
33 blood pressure and respiration].

34 [b. "Written agreement or protocol" shall mean a written document,
35 pursuant to and consistent with any applicable state or federal require-
36 ments, that addresses a specific disease or disease state and that
37 describes the nature and scope of collaborative drug therapy management
38 to be undertaken by the pharmacist, in collaboration with the partic-
39 ipating physician, in accordance with the provisions of this section.

40 c. "Physician" shall mean the physician, selected by or assigned to a
41 patient, who has primary responsibility for the treatment and care of
42 the patient for the disease or disease state that is the subject of the
43 collaborative drug therapy management.

44 d.] C. "Facility" shall mean a [teaching] hospital, [including any]
45 diagnostic center, treatment center, or hospital-based outpatient
46 department, [however, for the purposes of this section,] residential
47 health care facilities [and] OR nursing [homes shall be excluded] HOME
48 OR ANY FACILITY AS DEFINED IN SECTION TWENTY-EIGHT HUNDRED ONE OF THE
49 PUBLIC HEALTH LAW OR OTHER ENTITY THAT PROVIDES DIRECT PATIENT CARE
50 UNDER THE AUSPICES OF A MEDICAL DIRECTOR.

51 D. "MEDICAL PRACTICE" SHALL MEAN A PLACE OR SITUATION IN WHICH PHYSI-
52 CIANS, PHYSICIAN ASSISTANTS AND NURSE PRACTITIONERS EITHER ALONE OR IN
53 GROUP PRACTICES PROVIDE DIAGNOSTIC AND TREATMENT CARE FOR PATIENTS. [For
54 the purposes of this section, a "teaching hospital" shall mean a hospi-
55 tal licensed pursuant to article twenty-eight of the public health law
56 that is eligible to receive direct or indirect graduate medical educa-

tion payments pursuant to article twenty-eight of the public health law.]

E. "PHYSICIAN, PHYSICIAN ASSISTANT OR NURSE PRACTITIONER" SHALL MEAN THE PHYSICIAN, PHYSICIAN ASSISTANT 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.

F. "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 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, PHYSICIAN ASSISTANT, NURSE PRACTITIONER OR FACILITY, IN ACCORDANCE WITH THE PROVISIONS 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 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] PARTICIPATING PHARMACISTS must:

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

(B)] (I) 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; 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.

c.] (II) SATISFY ANY TWO OF THE FOLLOWING CRITERIA:

(A) BOARD CERTIFICATION FROM A NATIONAL ACCREDITING BODY AS APPROVED BY THE DEPARTMENT IN CONSULTATION WITH THE STATE BOARD OF PHARMACY OR OTHER CREDENTIAL OR PROGRAM IN PHARMACY CLINICAL SERVICES AS APPROVED BY THE DEPARTMENT, IN CONSULTATION WITH THE STATE BOARD OF PHARMACY;

(B) POSTGRADUATE RESIDENCY THROUGH AN ACCREDITED POSTGRADUATE PROGRAM REQUIRING AT LEAST FIFTY PERCENT OF THE EXPERIENCE BE IN DIRECT PATIENT CARE SERVICES WITH INTERDISCIPLINARY TERMS; OR

(C) HAVE PROVIDED CLINICAL SERVICES TO PATIENTS FOR AT LEAST ONE YEAR EITHER:

(1) UNDER A COLLABORATIVE PRACTICE AGREEMENT OR PROTOCOL WITH A PHYSICIAN, PHYSICIAN ASSISTANT, NURSE PRACTITIONER OR FACILITY; OR

(2) HAS DOCUMENTED EXPERIENCE IN THE PROVISION OF CLINICAL SERVICES TO PATIENTS FOR AT LEAST ONE YEAR OR ONE THOUSAND HOURS, OR AS APPROVED BY THE DEPARTMENT, IN CONSULTATION WITH THE STATE BOARD OF PHARMACY.

B. NOTWITHSTANDING ANY PROVISION OF LAW, NOTHING IN THIS SECTION SHALL PROHIBIT A LICENSED PHARMACIST FROM ENGAGING IN CLINICAL SERVICES ASSOCIATED WITH COLLABORATIVE DRUG THERAPY MANAGEMENT, IN ORDER TO GAIN EXPERIENCE NECESSARY TO QUALIFY UNDER ITEM TWO OF CLAUSE (C) OF SUBPARAGRAPH (II) OF PARAGRAPH A OF THIS SUBDIVISION, PROVIDED THAT SUCH PRAC-

1 TICE IS UNDER THE SUPERVISION OF A PHARMACIST THAT CURRENTLY MEETS THE
2 REFERENCED REQUIREMENT, AND THAT SUCH PRACTICE IS AUTHORIZED UNDER THE
3 COLLABORATIVE DRUG THERAPY MANAGEMENT PROTOCOL WITH THE INVOLVED PHYSI-
4 CIAN, PHYSICIAN ASSISTANT, NURSE PRACTITIONER OR FACILITY.

5 3. Notwithstanding any provision of this section, nothing herein shall
6 authorize [the pharmacist] PHARMACISTS to diagnose disease. In the event
7 that a treating physician, PHYSICIAN ASSISTANT OR NURSE PRACTITIONER may
8 disagree with the exercise of professional judgment by [the] A pharma-
9 cist, the judgment of the treating physician, PHYSICIAN ASSISTANT OR
10 NURSE PRACTITIONER shall prevail.

11 [3. The physician who is a party to a written agreement or protocol
12 authorizing collaborative drug therapy management shall be employed by
13 or otherwise affiliated with the same facility with which the pharmacist
14 is also employed or affiliated.

15 4. The existence of a written agreement or protocol on collaborative
16 drug therapy management and the patient's right to choose to not partic-
17 ipate in collaborative drug therapy management shall be disclosed to any
18 patient who is eligible to receive collaborative drug therapy manage-
19 ment. Collaborative drug therapy management shall not be utilized unless
20 the patient or the patient's authorized representative consents, in
21 writing, to such management. If the patient or the patient's authorized
22 representative consents, it shall be noted on the patient's medical
23 record. If the patient or the patient's authorized representative who
24 consented to collaborative drug therapy management chooses to no longer
25 participate in such management, at any time, it shall be noted on the
26 patient's medical record. In addition, the existence of the written
27 agreement or protocol and the patient's consent to such management shall
28 be disclosed to the patient's primary physician and any other treating
29 physician or healthcare provider.]

30 4. PHARMACISTS WHO ARE CERTIFIED BY THE DEPARTMENT TO ENGAGE IN COLLA-
31 BORATIVE DRUG THERAPY MANAGEMENT MAY ENTER INTO A WRITTEN AGREEMENT OR
32 PROTOCOL WITH A PHYSICIAN, PHYSICIAN ASSISTANT OR NURSE PRACTITIONER AS
33 AN INDEPENDENT HEALTH CARE PROVIDER OR AS AN EMPLOYEE OF A PHARMACY OR
34 OTHER HEALTH CARE PROVIDER. IN A FACILITY, THE PHYSICIAN, PHYSICIAN
35 ASSISTANT OR NURSE PRACTITIONER AND THE PHARMACIST WHO ARE PARTIES TO A
36 WRITTEN AGREEMENT OR PROTOCOL AUTHORIZING COLLABORATIVE DRUG THERAPY
37 MANAGEMENT SHALL BE EMPLOYED BY OR BE OTHERWISE AFFILIATED WITH THE
38 FACILITY.

39 5. Participation in a written agreement or protocol authorizing colla-
40 borative drug therapy management shall be voluntary, and no patient,
41 physician, [pharmacist, or facility] PHYSICIAN ASSISTANT, NURSE PRACTI-
42 TIONER OR PHARMACIST shall be required to participate.

43 [6. Nothing in this section shall be deemed to limit the scope of
44 practice of pharmacy nor be deemed to limit the authority of pharmacists
45 and physicians to engage in medication management prior to the effective
46 date of this section and to the extent authorized by law.]

47 S 2. Section 5 of chapter 21 of the laws of 2011, amending the educa-
48 tion law relating to authorizing pharmacists to perform collaborative
49 drug therapy management with physicians in certain settings, as amended
50 by chapter 125 of the laws of 2014, is amended to read as follows:

51 S 5. This act shall take effect on the one hundred twentieth day after
52 it shall have become a law [and shall expire 4 years after such effec-
53 tive date when upon such date the provisions of this act shall be deemed
54 repealed]; provided, however, that the amendments to subdivision 1 of
55 section 6801 of the education law made by section one of this act shall
56 be subject to the expiration and reversion of such subdivision pursuant

1 to section 8 of chapter 563 of the laws of 2008, when upon such date the
2 provisions of section one-a of this act shall take effect; provided,
3 further, that effective immediately, the addition, amendment and/or
4 repeal of any rule or regulation necessary for the implementation of
5 this act on its effective date is authorized and directed to be made and
6 completed on or before such effective date.
7 S 3. This act shall take effect immediately, provided that section one
8 of this act shall take effect on the one hundred twentieth day after it
9 shall have become a law; provided, further, that, effective immediately,
10 the addition, amendment and/or repeal of any rule or regulation neces-
11 sary for the implementation of this act on its effective date is author-
12 ized and directed to be made and completed on or before such effective
13 date.