PROPOSED RULEMAKINGS

STATE BOARD OF PHARMACY

[49 PA. CODE CH. 27]

Collaborative Management of Drug Therapy

The State Board of Pharmacy (Board) proposes to amend §§ 27.1, 27.301 and 27.311 (relating to definitions; written protocol for the management of drug therapy in an institutional setting; and certification of professional liability insurance—written protocol) and add §§ 27.302 and 27.312 (relating to collaborative agreement for management of drug therapy in a non-institutional setting; and certification of professional liability insurance—collaborative agreement) to read as set forth in Annex A.

Effective Date

The proposed rulemaking will be effective upon final-form publication in the *Pennsylvania Bulletin*.

Statutory Authority

The proposed rulemaking is authorized under sections 6(k)(9) and 9.3 of the Pharmacy Act (act) (63 P. S. §§ 390-6(k)(9) and 390-9.3).

Background and Purpose

In August 2002, the act was amended to add section 9.1 (63 P. S. § 390-9.1) to authorize pharmacists practicing in an institution setting to manage drug therapy by means of a written protocol. In August 2010, section 9.3 of the act was amended to provide for collaborative drug therapy management in accordance with a written collaborative agreement between a physician and a pharmacist in a setting other than an institutional setting. This proposed rulemaking is required to implement section 9.3 of the act.

Description of Proposed Amendments

The Board proposes to amend § 27.1 by amending the definition of "practice of pharmacy" to correspond with the definition in the act. The 2010 amendments to the act changed the term "managing drug therapy" to "management of drug therapy." The Board's regulations do not define "managing drug therapy." Instead, § 27.1 defines the term "drug therapy management." The Board proposes to use the statutory term "management of drug therapy" as defined by the act throughout the proposed rulemaking. The definition will be amended to apply to the institutional and non-institutional drug therapy protocols provided in the act and recent amendments. The Board also proposes to amend §§ 27.301 and 27.311 to incorporate the amended definitions of "drug therapy management" and "practice of pharmacy."

The Board proposes to add § 27.302 to set forth the pharmacist's obligations under a non-institutional written collaborative agreement for management of drug therapy including: entering into a written collaborative agreement containing provisions required under the act with a physician who meets the qualifications in the act; maintaining appropriate professional liability insurance; complying with the prohibition against providing economic incentives to a physician; obtaining a written referral prior to initiating drug therapy management; maintaining patient records in a proper format and maintaining access to them; and handling patient records in compliance with the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191, 110 Stat. 1936), the Health Information Technology for Economic and Clinical Health Act (Pub. L. No. 111-5, Div. A, Title XIII, Div. B, Title IV, 123 Stat. 226, 467) and associated rules and regulations. Proposed § 27.302 seeks to implement the amendments to the act while, to the greatest extent possible, maintaining consistency with the regulations governing written protocols in institutional settings in § 27.301.

In the course of establishing the opportunity for pharmacists to engage in the management of drug therapy in non-institutional settings under a collaborative agreement with a physician, the most recent amendments to the act also amended several of the act's disciplinary provisions to permit pharmacists to be employed by a physician for the purpose of the management of drug therapy. These pharmacists, however, may not engage in retail dispensing while in health care practice within the context of employment. The amendments to the act also established that the act's limitations on a pharmacist's entry into an employment relationship with a physician would not prohibit entry into a collaborative agreement for the management of drug therapy. The Board sought to address the concerns that may arise in a collaborative agreement context regarding physician control over pharmacists, economic incentives and diverting or directing of prescriptions or patients from either professional to the other in subsections (c), (d) and (e).

The 2002 amendments to the act imposed the obligation that a pharmacist engaging in the management of drug therapy under a written protocol in an institutional setting maintain professional liability insurance in a minimum amount of $1 million per occurrence or claims made, which the Board implemented in § 27.311. Section 9.3 of the act also included a requirement that pharmacists engaged in the management of drug therapy under a collaborative agreement with a physician in a non-institutional setting maintain professional liability insurance in a minimum amount of $1 million per occurrence or claims made. The Board proposes to add § 27.312 to implement that provision.

Fiscal Impact and Paperwork Requirements

The proposed rulemaking will have minimal fiscal impact on the Board or the regulated community. The licensees' obligations regarding certification to the Board of professional liability insurance to practice under a collaborative agreement would be similar to those of licensees practicing in institutional settings under a written protocol.

Sunset Date

The Board reviews the effectiveness of its regulations on an ongoing basis. Therefore, a sunset date has not been assigned.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on April 22, 2013, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Board, the General Assembly and the Governor of comments, recommendations or objections raised.

Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding this proposed rulemaking to Regulatory Unit Counsel, Department of State, P. O. Box 2649, Harrisburg, PA 17105-2649, ST-PHARMACY@state.pa.us within 30 days following publication in the *Pennsylvania Bulletin*.

EDWARD J. BECHTEL, R.Ph.,
Chairperson

Fiscal Note: 16A-5425. No loss of revenue. A minimal increase in program costs to the Commonwealth or its political subdivisions is expected. These costs are associated with recordkeeping for pharmacists engaging in collaborative management of drug therapy. These costs would be assumed by the Board and offset through license fees. (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 27. STATE BOARD OF PHARMACY

GENERAL PROVISIONS

§ 27.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

* * * * *

Drug order—An oral or written order issued by a medical practitioner which is either written on or entered by computer into the medical record of a patient in an institution for the dispensing of a drug or device for administration to the patient. The term does not include an order for a drug for a patient in an institution which the patient will self-administer which will be considered a prescription.

[*Drug therapy management*—Any of the following processes performed in an institutional setting pursuant to a written agreement, protocol or order as set forth in section 9.1 of the act (63 P. S. § 390-9.1):

(i) Adjusting a drug regimen.

(ii) Adjusting drug strength, frequency of administration or route.

(iii) Administration of drugs.

(iv) Ordering laboratory tests and ordering and performing other diagnostic tests necessary in the management of drug therapy, consistent with the testing standards of the institution.]

FDLE—Federal Drug Law Examination.

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MPJE—Multistate Pharmacy Jurisprudence Examination.

Management of drug therapy—

(i) Any of the following processes performed under a written protocol as set forth in section 9.1 of the act (63 P. S. § 390-9.1) or under a collaborative agreement as set forth in section 9.3 of the act (63 P. S. § 390-9.3):

(A) Adjusting a drug regimen.

(B) Adjusting drug strength, frequency of administration or route.

(C) Administration of drugs.

(D) Ordering laboratory tests and ordering and performing other diagnostic tests necessary in the management of drug therapy.

(E) Monitoring the patient's vital signs.

(F) Providing education and training to the patient that is related to the management of the drug therapy.

(ii) The term excludes medication therapy management services in the practice of pharmacy provided under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. No. 108-173, 117 Stat. 2066)

Medical practitioner—A physician, dentist, veterinarian or other individual authorized and licensed by law to prescribe drugs.

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Practice of pharmacy—

(i) The provision of health care services by a pharmacist, which includes:

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(I) **[Managing] Management of** drug therapy **under a written collaborative agreement as set forth in section 9.3 of the act or, if** in an institutional setting**,** consistent with the institution's assignment of clinical duties **under a written protocol as set forth in section 9.1 of the act**.

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(L) Acts, services, operations or transactions necessary or incident to the provision of these health care services.

(M) Drug therapy management, including services provided under the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

(ii) The term does not include the operations of a manufacturer or distributor as defined in The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. §§ 780-101—780-144).

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[DRUG THERAPY MANAGEMENT]
MANAGEMENT OF DRUG THERAPY

§ 27.301. Written protocol **for the management of drug therapy in an institutional setting**.

(a) **The management of drug therapy under section 9.1 of the act (63 P. S. § 390-9.1) shall be performed under a written protocol consistent with the institution's assignment of clinical duties. Ordering of laboratory tests and ordering or performing other diagnostic tests necessary in the manage-**

ment of drug therapy shall be consistent with the testing standards of the institution.

(b) The written protocol for **[drug therapy]** management **of drug therapy** between **[licensed]** physicians and pharmacists must contain:

(1) A statement identifying the physician responsible for authorizing **[drug therapy]** management **of drug therapy**.

(2) A statement identifying the pharmacist authorized to perform the **[drug therapy]** management **of drug therapy**.

(3) A statement requiring that **[drug therapy]** regimens **for the management of drug therapy** be initiated by a **[licensed]** physician for patients referred to a pharmacist for **management of** drug therapy.

(4) A statement identifying the types of **[drug therapy management]** decisions **regarding the management of drug therapy** that the pharmacist is authorized to make, including a statement of the ailments or diseases involved within the physician's scope of practice, and types of **[drug therapy]** management **of drug therapy** authorized.

(5) A statement of the functions and tasks the pharmacist shall follow in the course of exercising **[drug therapy management authority] management of drug therapy**, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made. Documentation of each intervention shall occur as soon as practicable, but no later than 72 hours after the intervention in the patient medical record and shall also be recorded in the pharmacist's records.

(6) A statement that requires notification to the authorizing physician of any changes in dose, duration or frequency of medication prescribed as soon as practicable but not longer than 72 hours after the change.

(7) **[A provision for execution of the agreement when any licensed physician or licensed pharmacist may be temporarily absent from a practice setting or temporarily unavailable to participate in its execution.] A provision for implementation of the written protocol when a physician or pharmacist who is a party to the protocol is temporarily unavailable to participate in its implementation.**

(8) A provision for notification of the role of the pharmacist by a **[licensed]** physician to each referred patient **the management of** whose drug therapy **[management]** may be affected by the **[agreement] written protocol** and providing an opportunity for the patient to refuse **[drug therapy]** management **of drug therapy** by a pharmacist.

(9) The signatures of the **[licensed]** physicians and **[licensed]** pharmacists who are entering into the written protocol, and the dates signed.

(10) A statement allowing for the termination of the **[agreement] written protocol** at the request of any party to it at any time.

[(b)] (c) The written protocol must be available as follows:

(1) At the practice site of **[any licensed] each** physician who is a party to the **[agreement] written protocol**.

(2) At the practice site of **[any licensed] each** pharmacist who is a party to the **[agreement] written protocol**.

(3) At the institution where a written **[agreement or]** protocol is in place.

(4) To any patient **the management of** whose drug therapy **[management]** is affected by the **[agreement] written protocol, upon request of the patient**.

(5) Upon request, to representatives of the Bureau and the Department of Health.

[(c)] (d) The written protocol shall be filed with **the** Bureau.

[(d)] (e) The written protocol must be effective for a period not to exceed 2 years from the date of execution. At the end of the 2-year period, or sooner, the parties shall review the **[agreement] written protocol** and make a determination as to its renewal, necessary modifications or termination.

(*Editor's Note*: The following section is new and printed in regular type to enhance readability.)

§ 27.302. Collaborative agreement for management of drug therapy in a non-institutional setting.

(a) Before practicing the management of drug therapy in a non-institutional setting, a pharmacist shall enter into a written collaborative agreement with a physician authorizing the management of drug therapy for diseases or for conditions or symptoms of diseases.

(b) The collaborative agreement shall be between a physician and a pharmacist.

(c) A pharmacist may not provide economic or other incentives, inducements or benefits to a physician for the purpose of entering into a collaborative agreement for the management of drug therapy.

(d) A pharmacist who is employed by a physician under a collaborative agreement for the purpose of management of drug therapy may not engage in retail dispensing while in the health care practice or within the context of employment.

(e) Participation in a collaborative agreement authorizing the management of drug therapy is voluntary. A physician or pharmacist is not required to participate.

(f) The collaborative agreement must contain:

(1) A statement identifying the physician responsible for authorizing the management of drug therapy.

(2) A statement identifying the pharmacist authorized to perform the management of drug therapy.

(3) A statement requiring that regimens for the management of drug therapy be initiated by a physician for patients referred to a pharmacist for management of drug therapy.

(4) A statement identifying the types of decisions regarding the management of drug therapy that the pharmacist is authorized to make within the physician's scope of practice and the types of management of drug therapy authorized.

(5) A statement identifying the terms under which a pharmacist providing the management of drug therapy is permitted to: adjust the drug regimen, the drug strength and the frequency of administration; adjust the route of administration; administer drugs; order laboratory tests and order and perform other diagnostic tests necessary in the management of drug therapy without prior written or oral consent by the collaborating physician. This paragraph does not provide prescriptive authority to a pharmacist.

(6) A statement of the functions and tasks the pharmacist shall follow in the course of exercising management of drug therapy, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made. Documentation of each intervention shall occur as soon as practicable, but no later than 72 hours after the intervention, and be recorded in the pharmacist's records.

(7) A statement that requires notification to the authorizing physician of changes in dose, duration or frequency of medication prescribed as soon as practicable but no longer than 72 hours after the change.

(8) A provision for implementation of the collaborative agreement when a physician or pharmacist who is a party to the agreement is temporarily unavailable to participate in its implementation.

(9) A provision for notification of the role of the pharmacist by a physician to each referred patient the management of whose drug therapy may be affected by the collaborative agreement and providing an opportunity for the patient to refuse management of drug therapy by a pharmacist.

(10) The signatures of the physicians and pharmacists who are entering into the collaborative agreement and the dates signed.

(11) A statement allowing for the termination of the collaborative agreement at the request of a party to it at any time.

(g) The collaborative agreement must be available:

(1) At the practice site of each physician who is a party to the collaborative agreement.

(2) At the practice site of each pharmacist who is a party to the collaborative agreement.

(3) To a patient the management of whose drug therapy is affected by the agreement, upon request of the patient.

(4) Upon request, to representatives of the Bureau and the Department of Health.

(h) The collaborative agreement must be maintained on the premises of the pharmacy for review during inspection by or by request of representatives of the Bureau and the Department of Health.

(i) The collaborative agreement must be effective for no more than 2 years from the date of execution. At the end of the 2-year period, or sooner, the parties shall review the collaborative agreement and make a determination as to its renewal, necessary modifications or termination.

(j) A pharmacist who is party to a collaborative agreement authorizing the management of drug therapy shall:

(1) Utilize an area for in-person, telephonic or other approved electronic consultations regarding the management of drug therapy that ensures the confidentiality of the patient information being discussed.

(2) Initiate the management of drug therapy only upon a written referral to the pharmacist from the physician. The written referral must include the minimum frequency in which the pharmacist shall conduct the management of the drug therapy in person.

(3) Confirm that the physician who is a party to the collaborative agreement holds an active and unrestricted license and that the terms of the collaborative agreement are within the scope of the physician's current practice at the time of the execution of the collaborative agreement.

(k) Patient records regarding the management of drug therapy may be maintained in a computerized recordkeeping system which meets the requirements for Federal and State-certified electronic health care records, subject to the following:

(1) The pharmacist who is a party to the collaborative agreement shall have access to the records of the patient who is the recipient of the management of drug therapy.

(2) The handling of patient records by the pharmacist providing the management of drug therapy shall comply with the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191, 110 Stat. 1936), the Health Information Technology for Economic and Clinical Health Act (Pub. L. No. 111-5, Div. A, Title XIII, Div. B, Title IV, 123 Stat. 226, 467) and associated rules and regulations.

PROFESSIONAL LIABILITY INSURANCE

§ 27.311. Certification of professional liability insurance**—written protocol**.

(a) A licensee who engages in **[drug therapy]** management **of drug therapy** under a written protocol shall maintain professional liability insurance in the minimum amount of **[$1,000,000] $1 million** per occurrence or claims made. **The Board will accept from a licensee as satisfactory evidence of insurance coverage any of the following:**

(1) Personally purchased professional liability insurance.

(2) Professional liability insurance coverage provided by the individual licensee's employer.

(3) Similar insurance coverage acceptable to the Board.

(b) A licensee who engages in **[drug therapy]** management **of drug therapy** under a written protocol shall certify compliance with subsection (a) on a form **[provided by] available from** the Board. The **[form shall be provided] licensee shall submit the completed certification form to the Board** with the written protocol.

(c) A licensee who engages in **[drug therapy]** management **of drug therapy** under a written protocol shall**,** upon request**,** make available to the Board or its agents **[all records, relating to] a certificate of insurance regarding** the licensee's maintenance of professional liability insurance**[, including policies, cancelled checks, receipts or other proofs of premium payment]**.

(d) Failure to maintain insurance coverage as required under the act and this section will subject the licensee to disciplinary action under section 5(a)(6) of the act (63 P. S. § 390-5(a)(6)).

(*Editor's Note*: The following section is new and printed in regular type to enhance readability.)

§ 27.312. Certification of professional liability insurance—collaborative agreement.

(a) A licensee who is a party to a collaborative agreement authorizing the management of drug therapy shall obtain and maintain a level of professional liability insurance coverage in the minimum amount of $1 million per occurrence or claims made. The Board will accept from a licensee as satisfactory evidence of insurance coverage any of the following:

(1) Personally purchased liability insurance.

(2) Professional liability insurance coverage provided by the individual licensee's employer.

(3) Similar insurance coverage acceptable to the Board.

(b) A licensee who engages in the management of drug therapy under a collaborative agreement shall provide an affidavit to the Board that the licensee has obtained professional liability insurance in accordance with subsection (a) on a form available from the Board. The licensee shall submit the completed affidavit form to the Board with the collaborative agreement.

(c) A licensee who engages in the management of drug therapy under a collaborative agreement shall, upon request, make available to the Board or its agents a certificate of insurance regarding the licensee's maintenance of professional liability insurance.

(d) Failure to maintain insurance coverage as required under the act and this section will subject the licensee to disciplinary action under section 5(a)(6) of the act (63 P. S. § 390-5(a)(6)).

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