Regulatory Analysis Form

(Completed by Promulgating Agency)

(All Comments submitted on this regulation will appear on IRRC's website)

INDEPENDENT REGULATORY REVIEW COMMISSION

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IRRC

(1) Agency
Department of State, Bureau of Professional and Occupational Affairs, State Board of Pharmacy

(2) Agency Number: **16A**
Identification Number: **5425**

IRRC Number: 3006

(3) PA Code Cite: **49 Pa. Code §§ 27.1, 27.301, 27.302, 27.311 and 27.312**

(4) Short Title: **Collaborative Management of Drug Therapy**

(5) Agency Contacts (List Telephone Number and Email Address):

Primary Contact: **Kerry Maloney, Board Counsel, State Board of Pharmacy; (717) 783-7200; kmaloney@pa.gov**

Secondary Contact: **Cynthia K. Montgomery, Regulatory Counsel, Department of State; (717) 783-7200; cymontgome@pa.gov**

(6) Type of Rulemaking (check applicable box):

- **X Proposed Regulation**
- ☐ Final Regulation
- ☐ Final Omitted Regulation
- ☐ Emergency Certification Regulation;
  - ☐ Certification by the Governor
  - ☐ Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

The proposed rulemaking would amend existing regulations at §§ 27.1, 27.301 and 27.311 (relating to definitions; written protocols; and certification of professional liability insurance) and would 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). The main objectives of the proposed rulemaking are: (1) to implement regulations mandated by Act 29 of 2010, which amended the Pharmacy Act to provide for collaborative management of drug therapy between a physician and a pharmacist in a setting other than an institutional setting, without conferring prescriptive authority upon the pharmacist; (2) to utilize with consistency the statutory terms; and (3) to clarify and update the liability insurance obligations for pharmacists engaging in the collaborative management of drug therapy in any setting.

(8) State the statutory authority for the regulation. Include specific statutory citation.

This rulemaking is authorized by sections 6(k)(9) and 9.3 of the Pharmacy act (63 P.S. §§ 390-6(k)(9) and 390-9.3).

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

The proposed rulemaking is mandated by section 5 of Act 29 of 2010, which requires the Board to promulgate regulations to implement the addition of section 9.3 of the act.

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

The regulation is needed to implement the addition of section 9.3 of the Pharmacy Act. Pharmacists will benefit from the regulations because they will be able to expand their scope of practice to include collaborative management of drug therapy. The public will benefit by having a health-care professional with training and experience in drug dosage and side effects involved in the management of the patient's drug therapy. The regulations will effectuate the act's provisions, the amendments of which broadened the class of potential beneficiaries of these services beyond patients of institutional pharmacies.

(11) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

The proposed rulemaking is not more stringent and does not overlap or conflict with any federal requirements.

(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?

In 2006, Pennsylvania was among the first states in its region, including those contiguous states, to promulgate drug therapy management regulations, however they were restricted to institutional settings only. By expanding the collaborative role of the pharmacist in the management of drug therapy to non-institutional contexts, these regulations should put Pennsylvania at a competitive advantage as compared to surrounding states. All surrounding states permit collaborative management of drug therapy to some degree, except Delaware.

In 2011, the State of New York adopted a law establishing a "collaborative drug therapy management demonstration program" which expires as of September 14, 2014, and permits collaborative drug therapy management by pharmacists in teaching hospitals only. (NY Education Law § 6801-a). West Virginia has permitted collaborative management of drug therapy since 2005, but only in the hospital setting, the nursing home setting, the medical school setting and the hospital community and ambulatory care clinics. (W. Va. Code § 30-5-27(d)). Virginia permits collaborative management of drug therapy for certain conditions in accordance with protocols approved by the State Board of Pharmacy and Medicine. (VA Code Ann. § 54.1-3300.1) In New Jersey, collaborative management of drug therapy is permitted, but only for the treatment of a disease identified jointly by the New Jersey Board of Pharmacy and Board of Medical Examiners as subject to collaborative drug therapy management. (N.J.S.A. 45:14-41). In Maryland, the Drug Therapy Management Program was created in 2002 (MD Health Occupations Title 12 §§ 12-6a-01 – 12-6a-10) and was originally set to expire in 2008, but was subsequently extended, and ultimately made permanent, however, participation is low due to the onerous administrative process (in 2011, there were only 9 approved collaborative agreements in that state according to the Maryland Department of Legislative Services' Sunset Review of the State Board of Pharmacy.)

(13) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

The proposed rulemaking does not affect other regulations of the Board or other state agencies.

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

In accordance with Executive Order 1996-1, the Board sent a draft of this proposed rulemaking in January 2011 to pharmacy and professional associations, hospitals, pharmacy schools and other stakeholders that the Board has identified as having an interest in this rulemaking and solicited their comments. The Board considered those comments at the February 5, 2011, and March 15, 2011, meetings and made revisions to the draft as a result of those comments. The proposal was further discussed by the Board at the December 20, 2011, meeting and additional revisions made as a result of those discussions. Public meetings of the Board are routinely attended by interested parties and stakeholders, including representatives from the Pennsylvania Pharmacists' Association.

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

All pharmacists who elect to enter into collaborative agreements for the management of drug therapy will be impacted by the regulations. There are currently approximately 21,575 pharmacists and 3,380 pharmacies licensed by the Board.

According to the Pennsylvania Department of Labor in 2008, most pharmacists work in health and personal care stores (48.7%) and general medical and surgical hospitals (23.5%), while a minority of pharmacists work in grocery stores (6.9%), druggists' goods merchant wholesalers (2.4%), other hospitals (2.0%), the Federal government (1.7%), home health care services (0.7%), and 0.4% are self-employed.

According to the Small Business Administration (SBA), there are approximately 982,692 businesses in Pennsylvania; of which 978,831 are small businesses; and 3,861 are large businesses. Of the 978,831 small businesses, 236,775 are small employers (those with fewer than 500 employees) and the remaining 772,056 are non-employers. Thus, the vast majority of businesses in Pennsylvania are considered small businesses.

Small businesses are defined in Section 3 of the Regulatory Review Act, (71 P.S. § 745.3) which provides that a small business is defined by the SBA's Small Business Size Regulations under 13 CFR Ch. 1 Part 121. These size standards have been established for types of businesses under the North American Industry Classification System (NAICS). In applying the NAICS standards to the places where pharmacists work, a small business for pharmacies and drug stores is $25.5 million or less in average annual receipts. For general medical and surgical hospitals, a small business is $35.5 million or less in average annual receipts. Grocery stores consisting of supermarkets and other grocery stores (except convenience stores) have a small business threshold of $30.0 million or less in average annual receipts. The small business threshold for home health care services is $14.0 million or less in average annual receipts. For all other health and personal care stores, the small business threshold is $7.0 million or less in average annual receipts. Finally, in terms of wholesalers, medical, dental and hospital equipment and supplies merchant wholesalers are considered small businesses if they have 100 or less employees.

In Pennsylvania, some of the 3,380 licensed pharmacies are small businesses owned and operated by individuals, however, many pharmacies would not qualify as "small businesses" under the SBA definition (large retail chains, for example). Whether or not pharmacists work in small or large businesses, this regulation will affect only those who elect to enter into collaborative agreements for the management of drug therapy. And the Board expects the effects to be positive for those businesses.

(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.

All pharmacists who elect to participate in the collaborative management of drug therapy with a physician would be required to comply with the provisions of this rulemaking. There are approximately 21,575 pharmacists and 3,380 pharmacies currently licensed by the Board. The Board has no way of knowing how many pharmacists will elect to enter into collaborative agreements with physicians for the management of drug therapy in non-institutional settings.

(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

The only costs to pharmacists associated with the regulation relate to the maintenance of records regarding the collaborative agreement /written protocol and with obtaining the professional liability insurance required by the regulations.

According to the Alliance of Pharmaceutical care, a consortium of nine national organizations (including the American Association of Colleges of Pharmacy (AACP); the American College of Clinical Pharmacy (ACCP); the Academy of Managed Care Pharmacy (AMCP); the American Pharmacists Association (APhA); the American Society of Consultant Pharmacists (ASCP); the American Society of Health-System Pharmacists (ASHP); the National Alliance of State Pharmacy Associations (NASPA); the National Association of Chain Drug Stores (NACDS); and the National Community Pharmacists Association (NCPA)), collaborative drug therapy management maximizes the expertise of pharmacists and physicians or other prescribers to achieve optimal patient care outcomes through appropriate medication use and enhanced patient care services. Collaborative drug therapy management reduces delays in modifying drug regimens and unnecessary physician office visits, and increases patient compliance and adherence to drug therapy plans, all of which increases the likelihood that drug therapy problems will be averted.

- **When pharmacists and physicians work closely together, patients consistently achieve better results from their drug therapies, in part because they are more likely to take their medicines – and take them correctly.**
- **When physicians and pharmacists work together to monitor a patient's reaction to a particular drug therapy, they are able to detect adverse reactions more quickly, which ultimately saves lives and unnecessary costs.**
- **By informing patients and prescribers of possible adverse effects and/or drug interactions, pharmacists keep their patients healthy and safe – as well as avoid unnecessary costs from complications or hospitalizations.**

Thus, the regulation has benefits for physicians, pharmacists and patients throughout the Commonwealth.

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

The regulations are mandated by the amendments to the Pharmacy Act. The benefits of expanding the practice of pharmacy to allow pharmacists to engage in collaborative management of drug therapy as set forth above, greatly outweigh the minimal costs of compliance and recordkeeping.

(19) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

There are minimal additional costs to the regulated community associated with compliance. Pharmacists who elect to participate in collaborative management of drug therapy with a physician would be required to obtain and maintain professional liability insurance. Any prudent pharmacist would already have professional liability insurance, but for those that do not, there would be a cost associated with the premium for this coverage. The only other costs associated with the regulations relates to the paperwork requirements: to maintain a collaborative agreement/written protocol, execute a certification/affidavit; and provide copies of the agreement/protocol and affidavit/certification to the Board Also, participation in collaborative management of drug therapy is not mandatory, therefore a pharmacist could avoid any additional costs by simply electing not to participate. However, the Board believes the benefits of this expansion in the scope of practice of qualified pharmacists greatly outweighs the minimal costs involved.

(20) Provide a specific estimate of the costs and/or savings to the **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

There are no costs or savings to local governments associated with the proposed rulemaking.

(21) Provide a specific estimate of the costs and/or savings to the **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

There are minimal costs associated with recordkeeping associated with additional pharmacists engaging in collaborative management of drug therapy and filing collaborative agreements/written protocols and affidavits/certifications relating to professional liability insurance with the Board. These costs would be assumed by the Board and borne by the licensees through their license fees. Because the Board has no way of knowing how many pharmacists will elect to participate in collaborative management of drug therapy in non-institutional settings, any estimate of such costs would be speculative.

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

Pharmacists who engage in collaborative management of drug therapy will have to maintain a copy of the collaborative agreement on file at the pharmacist's practice site and on the pharmacy premises. Any physician who is a party to a collaborative agreement bears the same obligation. Pharmacists who engage in collaborative management of drug therapy will also have to carry professional liability insurance. The Board will be required to maintain copies of the collaborative agreements/written protocols and affidavits/certifications of professional liability insurance on file.

(23) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY FY 12-13	FY +1 FY 13-14	FY +2 FY 14-15	FY +3 FY 15-16	FY +4 FY 16-17	FY +5 FY 17-18
SAVINGS:	$	$	$	$	$	$
Regulated Community						
Local Government						
State Government						
Total Savings	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
COSTS:						
Regulated Community						
Local Government						
State Government						
Total Costs	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**

(23a) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3 FY 2009-2010	FY -2 FY 2010-2011	FY -1 FY 2011-2012	Current FY FY 2012-2013
State Board of Pharmacy	**$1,742,656**	**$1,695,150**	**$1,748,926**	**$2,226,000 (budgeted)**

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

(a) An identification and estimate of the number of small businesses subject to the regulation.
(b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.
(c) A statement of probable effect on impacted small businesses.
(d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

As outlined above, the Board does not expect this regulation to have an adverse impact on small businesses. In fact, the benefits of this expansion to the scope of practice of many qualified pharmacists should vastly outweigh the minimal costs involved. As most pharmacists already maintain professional liability insurance in the amounts defined in the act and regulations, costs associated with the regulations are likely limited to the recordkeeping requirements.

(25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.

The Board has determined that there are no special needs of any subset of its licensees for whom special accommodations should be made.

(26) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

No alternative regulatory schemes were considered. The Board believes that the regulations represent the least burdensome acceptable manner of implementing the amendments to the act.

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

a) The establishment of less stringent compliance or reporting requirements for small businesses;
b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
c) The consolidation or simplification of compliance or reporting requirements for small businesses;
d) The establishment of performing standards for small businesses to replace design or operational standards required in the regulation; and
e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

a) The only reporting requirements required of any business, including small businesses, is the requirement to maintain copies of the written protocol/collaborative agreement at the practice site of the pharmacist and in the pharmacy. The physician who is a party to the agreement/protocol would have similar responsibilities. The Board did not consider making any exceptions for small businesses.
b) The regulations establish no schedules or deadlines for which small businesses need to be accommodated.
c) The Board does not believe the minimal reporting requirements need to be simplified for small businesses.
d) The regulations do not contain any design or operational standards for which small businesses need to be accommodated.
e) **The Board did not consider exempting small businesses from any part of the regulation. It would not be consistent with the public health, safety or welfare to make exceptions to the regulations.**

(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

No data was the basis for this regulation. The regulation was statutorily mandated by Act 29 of 2010.

(29) Include a schedule for review of the regulation including:

A. The date by which the agency must receive public comments: **Within 30 days of publication of the proposed rulemaking.**

B. The date or dates on which public meetings or hearings will be held: **The Board will review all comments on the proposed rulemaking at regularly scheduled board meetings. The Board generally meets on the third Tuesday of each month.**

C. The expected date of promulgation of the proposed regulation as a final-form regulation: **Fall 2013.**

D. The expected effective date of the final-form regulation: **Upon publication as final.**

E. The date by which compliance with the final-form regulation will be required: **Upon the effective date.**

F. The date by which required permits, licenses or other approvals must be obtained: **N/A**

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

The Board continually reviews the efficacy of its regulations, as part of its annual review process under Executive Order 1996-1. The Board reviews its regulatory proposals at regularly scheduled monthly public meetings, generally the third Tuesday of each month.

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FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

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Copy below is hereby approved as to form and legality. Attorney General

BY: _____
(DEPUTY ATTORNEY GENERAL)

APR 11 2013
DATE OF APPROVAL

Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:

State Board of Pharmacy
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-5425

DATE OF ADOPTION: _____

BY: _____
Edward J. Bechtel, R.Ph.

TITLE: Chairman
(EXECUTIVE OFFICER, CHAIRMAN)

Copy below is approved as to form and legality Executive or Independent Agencies.

BY: _____
SHAWN E. SMITH

MAR 21 2013
DATE OF APPROVAL

(Deputy General Counsel
(Strike inapplicable title)

[ ] Check if applicable
Copy not approved.
Objections attached.

[ ] Check if applicable. No Attorney General approval or objection within 30 day after submission.

NOTICE OF PROPOSED RULEMAKING

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF PHARMACY
49 PA CODE, CHAPTER 27
§§ 27.1, 27.301, 27.302, 27.311 and 27.312

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; and certification of professional liability insurance); and to adopt §§ 27.302 and 27.312 (relating to collaborative agreement between pharmacist and physician in a non-institutional setting; and certification of professional liability insurance – collaborative agreement), to read as set forth in Annex A.

Effective Date

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

Statutory Authority

The amendments are 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 via a written protocol. In August 2010, the act was further amended to add section 9.3, which provides 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. These proposed amendments are required to implement section 9.3.

Description of Proposed Amendments

The Board proposes to amend § 27.1 by changing 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 current regulations contain no definition for the term "managing drug therapy." Instead, § 27.1 defines the term "drug therapy management." The Board proposes to use the new statutory term "management of drug therapy" as defined by the act throughout the proposed amendments. The revised definitions will update them to apply to the institutional and non-institutional drug therapy protocols provided in the act and its 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 by the act with a physician who meets the act's qualifications; 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 (HIPAA) (HIPAA, Pub. L. 104-191, 110 Stat. 1936) and the Health Information Technology for Economic and Clinical Health Act (HITECH Act) (Pub. L. 111-5, Div. A, Title XII, 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 at § 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 such employment. The amendments 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 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 $1,000,000 per occurrence or claims made, which the board implemented at § 27.311. Section 9.3 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 $1,000,000 per occurrence or claims made. The Board proposes to add § 27.312 to implement that provision.

Fiscal Impact and Paperwork Requirements

The proposed amendments 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, no sunset date has been assigned.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on _____ __, 2013, the Board submitted a copy of this proposed regulation and a copy of a Regulatory Analysis form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee and the House 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 shall 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 or by e-mail to the State Board of Pharmacy at ST-PHARMACY@state.pa.us, within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin.*

Edward J. Bechtel, R.Ph.
Chairman
State Board of Pharmacy

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 therapy management]Management of drug therapy –

(i) Any of the following processes performed [in an institutional setting pursuant to] under a written [agreement, or] protocol [or order] 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):

[(i)] (A) Adjusting a drug regimen.

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

[(iii)] (C) Administration of drugs.

[(iv)] (D) 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].

(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 (MTM) services in the practice of pharmacy provided under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173, 117 Stat. 2066)

* * * * *

Practice of pharmacy –

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

* * * * *

(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.

* * * * *

(M) Drug therapy management, including such services provided under the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub.L. 108-172, 117 stat. 2066).

* * * * *

[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 must 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 management of drug therapy must 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 [shall] 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 [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 relating to 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] 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 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 must occur as soon as practicable, but no

later than 72 hours after the intervention in the patient medical record and must 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 no longer than 72 hours after the change.

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

§ 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 must 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 such employment.

(e) Participation in a collaborative agreement authorizing the management of drug therapy must be voluntary, and no physician or pharmacist may be 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 relating to the management of drug therapy that the pharmacist is authorized to make within the physician's scope of practice, and 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 or 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. Nothing in this section may be construed to 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 must occur as soon as practicable, but no later than 72 hours after the intervention, and must be recorded in the pharmacist's records.

(7) 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 no longer than 72 hours after the change.

(8) A provision for implementation of the collaborative agreement when any 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 any party to it at any time.

(g) The collaborative agreement must be available as follows:

(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 any 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 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 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 relating to 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) At the time of the execution of the collaborative agreement, 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.

(k) Patient records relating to the management of drug therapy may be maintained in a computerized recordkeeping system which meets all 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 all patient records by the pharmacist providing the management of drug therapy must comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA, Pub. L. 104-191, 110 Stat. 1936), the Health Information Technology for Economic and Clinical Health Act (HITECH Act) (Pub. L. 111-5, Div. A, Title XII, 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 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,] a certificate of insurance relating to 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 by 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)).

§ 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 $1,000,000 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 relating to the licensee's maintenance of professional liability insurance.

(d) Failure to maintain insurance coverage as required by 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).

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF PHARMACY
Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
(717) 783-7156

April 22, 2013

The Honorable Silvan B. Lutkewitte, III, Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Proposed Regulation
State Board of Pharmacy
16A-5425: COLLABORATIVE MANAGEMENT OF DRUG THERAPY

Dear Chairman Lutkewitte:

Enclosed is a copy of a proposed rulemaking package of the State Board of Pharmacy pertaining to Collaborative Management of Drug Therapy.

The Board will be pleased to provide whatever information the Commission may require during the course of its review of the rulemaking.

Sincerely,

Edward J. Bechtel, RPh, Chairperson
State Board of Pharmacy

EJB/KEM:rs
Enclosure
cc: Katie True, Commissioner
Bureau of Professional and Occupational Affairs
Rebecca Oyler, Director of Policy, Department of State
Steven V. Turner, Chief Counsel
Department of State
Cynthia Montgomery, Regulatory Counsel
Department of State
Kerry E. Maloney, Counsel
State Board of Pharmacy
State Board of Pharmacy

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	16A-5425
SUBJECT:	COLLABORATIVE MANAGEMENT OF DRUG THERAPY
AGENCY:	DEPARTMENT OF STATE BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS STATE BOARD OF PHARMACY

TYPE OF REGULATION

X Proposed Regulation

Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

RECEIVED
2013 APR 22 AM 10:49
IRRC

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
4/22/13	Michele Warren	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE MAJORITY CHAIR Julie Harhart
4-22-13		SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE MAJORITY CHAIR Robt. M. Tomlinson
4/22/13		INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
4-22-13		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

April 11, 2013