Regulatory Analysis Form

This space for use by IRRC

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

(2) I.D. Number (Governor's Office Use)

16A-5412

IRRC Number: 2437

(3) Short Title
Drug Therapy and Injectable Medications, Biologicals and Immunizations

(4) PA Code Cite	(5) Agency Contacts & Telephone Numbers
49 Pa. Code §§ 27.1, 27 32, 27.91, 27.301 – 27.302, and 27.401-406	Primary **Contact: Carole Clarke, Counsel State Board of Pharmacy 783-7200** Secondary Contact: **Joyce McKeever, Deputy Chief Counsel Department of State 783-7200**

(6) Type of Rulemaking (check one)	(7) Is a 120-Day Emergency Certification Attached?
X Proposed Rulemaking ___ Final Order Adopting Regulation ___ Final Order, Proposed Rulemaking Omitted	X No ___ Yes: By the Attorney General ___ Yes: By the Governor

(8) Briefly explain the regulation in clear and non-technical language.

In August 2002 amendments to the Pharmacy Act became effective. These amendments changed the definition of practice of pharmacy by allowing pharmacists to perform drug therapy management and drug administration. The amendments added two sections to the Pharmacy Act that outlined the requirements for drug therapy management and administration of injectable medications, biologicals and immunizations; and required the Board to promulgate regulations to carry out those provisions.

This rulemaking package amends the Pharmacy Board's regulations at 49 Pa. Code §27.1 by adding the definition of Bureau to the Board's regulations and changing the definitions of institution and practice of pharmacy to match the new definitions in the Pharmacy Act.

This rulemaking package also amends the Pharmacy Board's regulations at 49 Pa. Code §27.32 by deleting outdated portions of this regulation and adding language that implements the continuing education requirements mandated by section 9.2 of the Pharmacy Act regarding the authority to administer injectable medications, biologicals and immunizations.

This rulemaking package amends the Board's regulations at 49 Pa. Code §27.91 by adding fees for the application for the initial authority and renewal of the authority to administer injectable medications, biologicals and immunizations.

This rulemaking package adds §27.301 that carries out the provisions of Section 9.1 of the Pharmacy Act, 63 P.S. §390-9.1, with regard to drug therapy management.

This rulemaking package adds §§27.401, 27.402, 27.403, 27.404, 27.405, and 27.406 that carry out the provisions of Section 9.2 of the Pharmacy Act, 63 P.S. §390-9.2, with regard to the administration of injectable medications, biologicals and immunizations.

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(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

The regulation is authorized under Sections 4(j), 6(k)(1) and (9), 9.1(e) and 9.2(a) of the Pharmacy Act (Act), act of September 27, 1961, P.L. 1700, (63 P.S. §§390-4(j), and 390-6(k) (1), (9), 9.1(e) and 9.2(a)).

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

This regulation is mandated by Sections 9.1 and 9.2 of the Pharmacy Act, 63 P.S. §390-9.1 and 390-9.2.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

The regulation is required by the amendments to the Pharmacy Act. Without the regulation, §§9.1 and 9.2 of the Pharmacy Act cannot be implemented.

(12) State the public health, safety, environmental or general welfare risks associated with nonregulation.

Nonregulation will prevent pharmacists from engaging in drug therapy management and administration of injectable medications, biologicals and immunizations, which the Pharmacy Act grants them the authority to do.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

Pharmacists will benefit from the regulations because they will be able to expand their scope of practice. The public will benefit by having a professional with the training and expertise in drug dosage and side effects have a hand in managing drug therapy. The public also benefits by having another professional who is able to administer vaccines and other types of injectable medications.

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(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

There are no perceived people or groups of people who will be adversely affected by the proposed regulation.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

Pharmacists who enter into written protocols for drug therapy management or who apply for and are granted the authority to administer injectable medications, biologicals and immunizations.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

In accordance with Executive Order 1996-1 the Board sent a draft of this proposed rulemaking in January 2003, to 13 pharmacy and professional associations that the Board has identified as having an interest in this rulemaking and solicited their comments. The Board considered these comments at the March 11, 2003 meeting and made revisions to the draft as a result of those comments.

(17) 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.

Any costs associated with this regulation package would be assumed voluntarily as these regulations only apply to pharmacists who choose to engage in the expanded practice of pharmacy. Costs include the initial application and renewal fees to renew the authority to administer injectable medications, biologicals and immunizations. The Board is proposing a $30 initial application and a $30 renewal fee for the authority to administer injectable medications, biologicals and immunizations. Costs also include the education and continuing education needed to apply for and renew the authority to administer injectable medications, biologicals and immunizations.

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(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures, which may be required.

This regulation does not affect local governments.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures, which may be required.

There will be some costs to the State Board of Pharmacy in developing an application and renewal form for the authority to administer injectable medications, biologicals and immunizations. The costs will be carried through to staff time needed to process the application and renewal forms. There will also be costs to the Board in staff time needed to process and file the drug therapy written protocols that must be filed with the Bureau. The Board is proposing a $30 application fee and a $30 renewal fee to cover these costs.

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(20) 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 +1	FY +2	FY +3	FY +4	FY +5
SAVINGS:	**$**	**$**	**$**	**$**	**$**	**$**
Regulated Community	N/A	N/A	N/A	N/A	N/A	N/A
Local Government						
State Government						
Total Savings						
COSTS:	**$**	**$**	**$**	**$**	**$**	**$**
Regulated Community	N/A	N/A	N/A	N/A	N/A	N/A
Local Government						
State Government						
Total Costs						
REVENUE LOSSES:	**$**	**$**	**$**	**$**	**$**	**$**
Regulated Community	N/A	N/A	N/A	N/A	N/A	N/A
Local Government						
State Government						
Total Revenue Losses						

(20a) Explain how the cost estimates listed above were derived.

It is difficult to estimate the costs involved with the regulation, as it is not known how many pharmacists will choose to apply for the authority to administer injectable medications, biologicals and immunizations.

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(20b) Provide the past three-year expenditure history for programs affected by the regulation.

Program	FY-3	FY-2	FY-1	Current FY
Pharmacy Board	**$1,197,924.91**	**$1,244,104.47**	**$1,407,589.55**	**$1,495,000.00**

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

The regulations are mandated by the amendments to the Pharmacy Act. However, the benefits of expanding the practice of pharmacy and allowing pharmacists to use the skills that are taught in pharmacy school greatly outweigh any adverse effects and costs.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

Nonregulatory alternatives were not considered because these regulations are necessary to implement the amendments to the Pharmacy Act.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

No alternative regulatory schemes were considered.

Regulatory Analysis Form

(24) 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 regulation.

Currently there are no federal regulations pertaining to the topics addressed in these regulations.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

For each section the Board looked at model acts and what other states have promulgated in their regulations. The Board first looked at the states bordering Pennsylvania to determine what, if any, regulations they had pertaining to drug therapy management and administering injectable medications, biologicals and immunizations. Delaware, Maryland, New Jersey, New York, Ohio, and West Virginia currently do not allow pharmacists to manage drug therapy. Only Ohio and Delaware allow pharmacists to administer injectable medications. The Board surveyed all the states in the nation and reviewed those states with regulations that pertain to this regulation package. The Board drew from several states in drafting the regulations for this package.

These regulations should put Pennsylvania at a competitive advantage with surrounding states. Pennsylvania is the first state to promulgate drug therapy management regulations of the states surrounding us, and the third state to promulgate regulations pertaining to the administration of injectable medications.

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

The regulations will expand on §§ 27.1 (relating to definitions) and 27.32 (relating to continuing education). The regulations may affect the Department of Health, which is the agency responsible for inspecting hospital pharmacies.

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

The Board reviews its regulatory proposals at regularly scheduled public meetings. The Board meets each month at 2601 North Third Street, Harrisburg and the meeting schedule can be obtained from the Department of State's website at www.dos.state.pa.us.

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(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports, which will be required as a result of implementation, if available.

Pharmacists who engage in drug therapy management through a written protocol will have to file a copy of the written protocol with the Bureau as well as keep the written protocol on file at the practice sites of the pharmacist and physician who are the parties to the agreement and the institution where the written agreement or protocol is in place. Pharmacists will be responsible for maintaining a record of the changes made to any patient's drug therapy. Pharmacists who engage in drug therapy management will also have to carry professional liability insurance. With regard to the administration of injectable medications, biologicals and immunizations the regulations add several record keeping requirements.

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

There are no perceived special groups of affected people.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The regulation will be effective upon publication in the *Pennsylvania Bulletin* as final rulemaking.

(31) Provide the schedule for continual review of the regulation.

The Board reviews the effectiveness of its regulations on a regular basis pursuant to Executive Order 1996-1.

CDL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

#2437 DO NOT WRITE IN THIS SPACE

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

BY: _____
(DEPUTY ATTORNEY GENERAL)

SEP 01 2004
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-5412

DATE OF ADOPTION: _____

BY: _____

TITLE: Chairperson
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

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

BY: _____

7.27.04
DATE OF APPROVAL

(Deputy General Counsel
(Chief Counsel,
Independent Agency
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.

PROPOSED RULEMAKING
COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF PHARMACY
49 PA. CODE, CHAPTER 27
Drug Therapy and Injectable Medications, Biologicals and Immunizations

The State Board of Pharmacy (Board) proposes to amend §§27.1, 27.32, and 27.91 (relating to definitions; continuing education; and fees) and to add §§27.301, 27.302, and 27.401-27.406 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 4(j), 6(k)(1) and (9), 8.2(a), 9.1(d)(3) and (e), and 9.2(a) of the Pharmacy Act (act) (63 P.S. §§ 390-(4)(j), 390-6(k)(1), 390-8.2(a), and (9), 390-9.1(d)(3) and (e), and 390-9.2(a)).

Background and Purpose

In August 2002, the Pharmacy Act was amended to add §§9.1 and 9.2 to the act, as well as to modify and to add several definitions to the act. The additional sections authorize pharmacists to manage drug therapy via a written protocol as well as administer injectable medications, biologicals and immunizations. These regulations are required to implement the new provisions of the Pharmacy Act.

Description of Proposed Amendments

The Board proposes to amend §27.1 (relating to definitions) by adding the definition of Bureau to define the term as it is used in the regulations. The Board also proposes to amend §27.1 by changing the definitions of institution and practice of pharmacy to correspond with the definitions in the Pharmacy Act.

The Board proposes to amend §27.32 (relating to continuing education) to remove obsolete portions of the regulation and add the continuing education requirements necessary to renew the authority to administer injectable medications, biologicals and immunizations.

The Board proposes to amend §27.91 (relating to fees) to add the fees necessary for pharmacists to apply for and renewal the approval to administer injectable medications, biologicals and immunizations.

Proposed §27.301 (relating to written protocol) sets out the requirements for the drug therapy management written protocol. Proposed §27.301 incorporates the requirements under §9.1 of the act and adds a section that requires the protocol to identify the types of drug therapy management decisions that the pharmacist is authorized to make, the ailments or diseases involved in the physician's scope of practice, and types of drug therapy management authorized. The act also requires the Board to promulgate

regulations with regard to self-insurance for pharmacists engaging in drug therapy management via a written protocol. The Board has deferred proposing regulations for self-insurance until the details of such regulations can be worked out with the Insurance Commissioner.

Proposed §27.401 (relating to qualifications for authority) lists the qualifications that a pharmacist must have to be granted the authority to administer injectable medications, biologicals and immunizations. A pharmacist must hold an active license to practice pharmacy in the Commonwealth; complete a course of education and training related to the administration of injectable medications, biologicals and immunizations offered by an approved provider; and hold a current basic cardiopulmonary resuscitation (CPR) certificate from an approved provider.

Proposed §27.402 (relating to application and renewal procedures) outlines the application and renewal process for the authority to administer injectable medications, biologicals and immunizations. An applicant for the initial authority must certify that the applicant has completed the educational requirement and that the applicant holds an acceptable CPR certificate. A pharmacist may renew the authority along with the biennial pharmacist license renewal. In order to renew the authority, the pharmacist must certify that a minimum of 2 continuing education hours in the administration of injectable medications, biologicals and immunizations were completed. Lastly, the pharmacist must submit proof of a current CPR certificate.

Proposed §27.403 (relating to conditions for administration) details the conditions for administration of injectable medications, biologicals and immunizations. Pharmacists may only administer injectable medications, biologicals and immunizations to persons who are more than 18 years of age. The proposed regulation defines what "more than 18 years of age" means. The proposed regulation also mandates that the administration of injectable medications, biologicals and immunizations shall not be delegated to another person.

Proposed §27.404 (relating to authority and requirements) sets forth the scope of authority and requirements for administering injectable medications, biologicals and immunizations. A pharmacist with the authority to administer injectable medications, biologicals and immunizations may do so only under an order or written protocol. This section details the requirements for the order and written protocol.

Proposed §27.405 (relating to recordkeeping) sets forth the recordkeeping requirements for pharmacists who administer injectable medications, biologicals, or immunizations. All of the records must be kept for a minimum of 2 years. Additionally, the proposed regulation lists the additional information that must be maintained when an immunization is administered.

Proposed §27.406 (relating to notification requirements) details the notification requirements when a pharmacist administers an injection. The notification requirements are different depending on whether the administration is done under an order or a written

protocol. The notification requirement when the administration is done under an order places a shorter timeframe within which the pharmacist must notify the prescriber. When the administration is done under a written protocol the pharmacist has a longer period of time to notify the prescriber.

Compliance with Executive Order 1996-1

In compliance with Executive Order 1996-1, the Board extended an invitation to boards, associations, and interested licensees and educators to preliminarily review and comment on the Board's draft regulatory proposal.

The Board reviewed and considered all comments and suggestions received from these and other interested parties during the regulatory development process.

Fiscal Impact and Paperwork Requirements

The proposed regulations would have a fiscal impact on the Board in that there would be revenue to the Board through the licensure and renewal fees for the authority to administer injectable medications, biologicals and immunizations. The regulations would require the Board to develop an application for the authority to administer injectable medications, biologicals and immunizations. The Board would also have to revise the pharmacist license renewal form to allow for the renewal of the authority to administer injectable medications, biologicals and immunizations.

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 September 29, 2004, 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 Carole Clarke, Counsel, State Board of Pharmacy, P.O. Box 2649, Harrisburg, PA 17105-2649, within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin.*

Michael J. Romano, R.Ph.
Chairperson

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:

* * *

Bureau – The Bureau of Professional and Occupational Affairs of the Department of State of the Commonwealth.

* * *

Institutions – [Extended care facilities, nursing homes, nursing care facilities, convalescent homes, resident care facilities, hospitals or another place which offers medical treatment to patients who require food, board and overnight sleeping facilities and care.] Any health care facility that offers care and medical treatment to patients who require food, board and overnight sleeping facilities and provides clinically related services including, a general or special hospital, including psychiatric hospitals, rehabilitation hospitals, ambulatory surgical facilities, long term care nursing facilities, cancer treatment centers using radiation therapy on an ambulatory basis, and inpatient drug and alcohol treatment facilities, both profit and nonprofit and including those operated by an agency or State or local government. The term also includes a hospice

that offers care and medical treatment to patients who require food, board and overnight sleeping facilities. The term does not include an office used primarily for the private or group practice by health care practitioners where no reviewable clinically related health service is offered, a facility providing treatment solely on the basis of prayer or spiritual means in accordance with the tenets of any church or religious denomination or a facility conducted by a religious organization for the purpose of providing health care services exclusively to clergy or other persons in a religious profession who are members of the religious denominations conducting the facility.

* * *

Practice of pharmacy – The [practice of that profession concerned with the art and science of preparing, compounding and dispensing drugs and devices, whether dispensed on the prescription of a medical practitioner or legally dispensed or sold directly to the ultimate consumer. The term includes the proper and safe storage and distribution of drugs, the maintenance of proper records therefor and the responsibility of relating information as required concerning the drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease.] provision of health care services by a pharmacist, which includes the interpretation, evaluation and implementation of medical orders for the provision of pharmacy services or prescription drug orders; the delivery, dispensing or distribution of prescription drugs; participation in drug and device selection; drug administration; drug regimen review; drug or drug-related research; compounding; proper and safe storage of drugs and devices; managing drug therapy in an institutional setting consistent with the institution's assignment of clinical duties;

maintaining proper records; patient counseling; and such acts, services, operations or transactions necessary or incident to the provision of these health care services.

* * *

RENEWAL OF PHARMACIST LICENSE AND PHARMACY PERMIT

* * *

§27.32. Continuing education.

(a) [Beginning with 1988 renewals, the]The Board will renew the license of a pharmacist who has completed [the required hours of continuing professional education.

(1) For 1988 renewals, a pharmacist shall have completed a minimum of 25 contact hours (2.5 CEU) of programs offered by providers approved by the ACPE.

(2) For 1990 renewals and thereafter, a pharmacist shall have completed] a minimum of 30 contact hours (3 CEU) of continuing education during the proceeding biennial renewal period. For licensees with authority to administer injectable medications, biologicals and immunizations in accordance with section 9.2 of the act (63 P.S. §390-9.2) and §§ 27.301 and 27.302 (relating to qualifications for authority; and application and renewal procedures), at least 2 of the required 30 hours shall concern the administration of injectable medications, biologicals and immunizations, including, but not limited to, disease epidemiology, vaccine characteristics, injection technique, emergency response to adverse events, and related topics. Programs offered by providers accredited by the ACPE are approved by the Board.

* * *

FEES

§ 27.91. Schedule of fees.

An applicant for a license, certificate, permit or service shall pay the following fees at the time of application:

* * *

Application for approval to administer injectables $30

Biennial renewal of approval to administer injectables.....$30

DRUG THERAPY MANAGEMENT

§ 27.301. Written protocol.

(a) The written protocol for drug therapy management between licensed physicians and pharmacists shall contain:

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

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

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

(4) A statement identifying the types of drug therapy management decisions 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 authorized.

(5) A statement of the functions and tasks the pharmacist shall follow in the course of exercising drug therapy management authority, 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 within 72 hours in the patient medical record and shall also be recorded in the pharmacist's records.

(6) A statement that establishes an appropriate time frame, not to exceed 72 hours, within which the licensed pharmacist must notify the licensed physician of any changes in dose, duration or frequency of medication prescribed.

(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.

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

(9) The signatures of the licensed physician(s) and licensed pharmacist(s) who are entering into the written protocol, and the dates signed.

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

(b) The written protocol shall be available as follows:

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

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

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

(4) To any patient whose drug therapy management is affected by the agreement.

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

(c) The written protocol shall be filed with Bureau.

(d) The written protocol shall 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 and make a determination as to its renewal, necessary modifications or termination.

ADMINISTRATION OF INJECTABLE MEDICATIONS, BIOLOGICALS AND IMMUNIZATIONS

§ 27.401. Qualifications for authority.

A candidate for authority to administer injectable medications, biologicals and immunizations shall meet the following requirements:

(a) The pharmacist holds an active license to practice pharmacy in this Commonwealth.

(b) The pharmacist has completed a course of education and training which includes the current guidelines and recommendations related to the administration of injectable medications, biologicals and immunizations of the Centers for Disease Control and Prevention or a similar health authority or professional body approved by the Board offered by providers accredited by the ACPE or a similar health authority or professional body approved by the Board.

(c) The pharmacist holds a current basic cardiopulmonary resuscitation (CPR) certificate issued by the American Heart Association, American Red Cross or a similar health authority or professional body approved by the Board.

§27.402. Application and renewal procedures.

(a) An applicant for authority to administer injectable medications, biologicals and immunizations shall submit the following to the Board:

(1) An application obtained from the Board along with the fee required by §27.91 (relating to schedule of fees).

(2) Certification that the pharmacist has completed the required education and training.

(3) Certification that the pharmacist holds an acceptable, current CPR certificate.

(b) A holder of the authority to administer injectable medications, biologicals and immunizations shall renew the authority every 2 years along with the license to practice pharmacy. Renewal requires completion of a form provided to the pharmacist by the Board in advance of the renewal period, payment of the fee specified by §27.91, certification of completion of 2 hours of continuing education required by section 9.2 of the act (63 P.S. §390-9.2) and §27.32 (relating to continuing education), and proof of a current CPR certificate.

§27.403. Conditions for administration.

(a) A pharmacist who is granted authority may administer injectable medications, biologicals and immunizations to persons who are more than 18 years of age. A person is more than 18 years of age on the day following the person's 18th birthday.

(b) No pharmacist may delegate the administration of injectable medications, biologicals and immunizations to another person.

§ 27.404. Authority and requirements.

(a) A pharmacist authorized by the Board to administer injectable medications, biologicals and immunizations may only do so under either an order or written protocol.

(b) The order from a licensed prescriber shall be written, received electronically or if received orally be reduced to writing, and must contain at a minimum the following:

(1) Identity of the licensed prescriber issuing the order.

(2) Identity of the patient to receive the injection.

(3) Identity of the medication, immunization or vaccine, and dose, to be administered.

(4) Date of the original order and the date or schedule, if any, of each subsequent administration.

(c) An authorized pharmacist may enter into a written protocol, either approved by a physician or authorized by the medical staff of an institution, governing the administration of injectable medications, biologicals and immunizations for a specific period of time or purpose. The written protocol may be valid for a time period not to exceed 2 years. The protocol must include the following:

(1) Identity of the participating pharmacist and physician or institution.

(2) Identification of the medication, biological or immunization, which may be administered.

(3) Identity of the patient or groups of patients to receive the authorized injectable medication, biological or immunization.

(4) Identity of the authorized routes and sites of administration allowed.

(5) A provision establishing a course of action the pharmacist shall follow to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks.

(6) A provision establishing a length of time the pharmacist must observe an individual for adverse events following an injection.

(7) Identity of the location at which the pharmacist may administer the authorized medication, biological or immunization.

(8) Recordkeeping requirements and procedures for notification of administration.

(9) A provision that allows for termination of the protocol at the request of any party to it at any time.

§ 27.405. Recordkeeping.

(a) A pharmacist who administers an injectable medication, biological or immunization shall maintain the following records regarding each administration for a minimum of 2 years:

(1) The name, address, and date of birth of the patient.

(2) The date of the administration and site of the injection.

(3) The name, dose, manufacturer, lot number, and expiration date of the medication, biological or immunization.

(4) The name and address of the patient's primary health care provider, as identified by the patient.

(5) The name or identifiable initials of the administering pharmacist.

(6) Documentation of provision of informed consent for administration of injectable medications, biologicals and immunizations.

(7) The nature of an adverse reaction and who was notified.

(b) A pharmacist who administers an immunization shall also maintain the following records regarding each such administration for a minimum of 2 years:

(1) Identification of the Vaccine Information Statement (VIS) that was provided.

(2) The date of publication of the VIS.

(3) The date and to whom the VIS was provided.

(c) In an institution, the information required to be maintained in subsections (a) and (b) may be maintained in the patients' medical records.

§27.406. Notification requirements.

A pharmacist administering injectable medications, biologicals or immunizations shall meet the following notification requirements:

(1) When administration has occurred under an order, the pharmacist shall notify the ordering prescriber within 72 hours of the identity of the patient, identity of the medication, biological or immunization administered, route of administration, site of the

administration, dose administered, and date of administration and the nature of any adverse events or reactions experienced by the patient.

(2) When the administration has occurred under a written protocol, the pharmacist shall notify the participating physician within 14 days of the identity of the patient, identity of the medication, biological or immunization administered, site of the administration, dose administered, and date of administration and the nature of any adverse events or reactions experienced by the patient.

FEE REPORT FORM

Agency: State - BPOA **Date:** December 03, 2003

Contact: Scott Messing

Phone No. 783-7193

Fee Title, Rate and Estimated Collections: $30.00

Application Fee For Registration To Administer Injectable Medications:
Estimated Initial Application Revenue: $17,580.00 (5,860 applications x $30.00)

Fee Description:

The fee will be charged to each applicant for registration to administer injectable medications

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Pharmacy to review and process an application to administer injectable medications and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time - review and process examination application (.50 hr)		$10.73
Administrative Overhead:		16.57
	Total Estimated Cost:	$27.30
	Proposed Fee:	$30.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of $30.00 be established to evaluate the application for Registration to Administer Injectable Medications.

Application For Registration To Administer Injectable Medications:

Board Staff: Reviews application for completeness, verifies that supporting documents are attached, contacts candidate to request any missing information. Issues approval through computer or prepares letter of rejection.

FEE REPORT FORM

Agency: State - BPOA **Date:** December 3, 2003

Contact: Scott Messing

Phone No. 783-7193

Fee Title, Rate and Estimated Collections: $30.00

Biennial Renewal Fee – Registration To Administer Injectable Medications

Estimated Biennial Revenue: $19,080.00 (6,360 applications x $30.00)

Fee Description:

The fee will be charged biennially to every Pharmacist who renews their Registration To Administer Injectable Medications.

Fee Objective:

The fee should defray a portion of the State Board of Pharmacy's administrative overhead.

Analysis, Comment, and Recommendation:

It is recommended that a renewal fee of $30.00 be established for Registration To Administer Injectable Medications, thereby causing those licensees to contribute to the operational costs of the Sate Board of Pharmacy.

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

September 29, 2004

The Honorable John R. McGinley, Jr., Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Proposed Regulation
State Board of Pharmacy
16A-5412: Drug Therapy and Injectable Medications, Biologicals and Immunizations

Dear Chairman McGinley:

Enclosed is a copy of a proposed rulemaking package of the State Board of Pharmacy pertaining to Drug Therapy and Injectable Medications, Biologicals and Immunizations.

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

Sincerely,

Michael J. Romano RPh

Michael J. Romano, R. Ph., Chairperson
State Board of Pharmacy

MJR/CLC:lm
Enclosure
c: Basil L. Merenda, Commissioner
Bureau of Professional and Occupational Affairs
Linda C. Barrett, Chief Counsel
Department of State
Joyce McKeever, Deputy Chief Counsel
Department of State
Cynthia Montgomery, Regulatory Counsel
Department of State
Gerald S. Smith, Senior Counsel in Charge
Department of State
Carole L. Clarke, Counsel
State Board of Pharmacy
State Board of Pharmacy

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	16A-5412
SUBJECT:	State Board of Pharmacy - Bureau of Professional and Occupational Affairs Drug Therapy and Injectable Medications, Biologicals and Immunizations
AGENCY:	DEPARTMENT OF STATE #2437

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

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
9/29/04	N Baumgroff	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
9/29/04	Mary Walmer	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
9/24/04	Gayle S. Huff	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
9/29/04	C. Lee Barnes	LEGISLATIVE REFERENCE BUREAU (for Proposed only)