Regulatory Analysis Form

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INDEPENDENT REGULATORY REVIEW COMMISSION

(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

49 Pa. Code §§ 27.1, 27.32, 27.91, 27.301, and 27.401-27.407

(5) Agency Contacts & Telephone Numbers
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)

___ Proposed Rulemaking
_X_ Final Order Adopting Regulation
___ Policy Statement

(7) Is a 120-Day Emergency Certification Attached?

_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 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 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 Code §27.32 by deleting outdated portions of this regulation and adding language that implements the continuing education requirements mandated by section 9.2 of the Pharmacy Act regarding the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 - 27.407, which 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, sections 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.)

No perceived individuals will be adversely affected by the regulations.

(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.

A notice of the proposed rulemaking was published at 34 Pa.B. 5598 (October 9, 2004) and was submitted to the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee as well as IRRC. The Board also received comments from members of the public. In preparing the final rulemaking, the Board considered the comments received from the House Professional Licensure Committee, IRRC and the public. The Senate Consumer Protection and Professional Licensure Committee did not comment on the proposed regulation.

(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. There will be 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.

(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	**$1,213,162.22**	**$1,389,369.42**	**$1,588,828.54**	**$1,655,000.00**

(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.

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(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 via a written protocol 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 as an Order of Final Rulemaking in the Pennsylvania Bulletin. Compliance will be required as of that date.

(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)

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INDEPENDENT REGULATORY REVIEW COMMISSION

2437

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

BY: _____
(DEPUTY ATTORNEY GENERAL)

_____
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: Michael J. Romano
Michael J. Romano, R.Ph.

TITLE: Chairperson
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

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

BY: David J. DeVries

MAR 10 2006
DATE OF APPROVAL

EXECUTIVE
(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.

FINAL 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) adopts amendments to §§ 27.1, 27.32 and 27.91 (relating to definitions; continuing education; and schedule of fees) and adds §§ 27.301, 27.401 - 27.407 to read as set forth in Annex A. The regulation adds definitions, updates and adds additional requirements to § 27.32, adds two new fees to § 27.91, and provides regulations relating to drug therapy management and the administration of injectable medications, biologicals and immunizations.

Notice of Proposed Rulemaking was published at 34 Pa.B. 5598 (October 9, 2004). Publication was followed by a 30-day public comment period. The Board received comments from the Pennsylvania Pharmacists Association, Louis F. Pauzano, Jr., and the Pennsylvania Academy of Family Physicians (PAFP). The House Professional Licensure Committee (HPLC) submitted fourteen comments to the proposed rulemaking on November 10, 2004. The Senate Consumer Protection and Professional Licensure Committee made no comments. The Independent Regulatory Review Commission (IRRC) submitted seven comments to the proposed rulemaking on December 10, 2004.

Summary of Comments and Responses to Proposed Rulemaking

Section 27.1. Definitions.

HPLC and IRRC commented that the Board should use the definition of "institution" in section 2 of the Pharmacy Act (act)(63 P.S. § 390-2), or reference the statutory definition. The Board declines to make this change. Section 2 defines "institution" as a "health care facility" defined in section 103 of the Health Care Facilities Act (35 P.S. § 448.103) and adds the qualifier "which offers care and medical treatment to patients who require food, board and overnight sleeping facilities". The Board included the definition of "health care facility" in section 103 of the Health Care Facilities Act with the qualifying language of the act's definition for ease of reference for pharmacists. Having the definition completely set forth in the regulations negates the necessity for pharmacists to refer to another act to understand the definition of "institution". The Board did not alter the definition as found in the Health Care Facilities Act, but included the language as referenced in the act with the qualifier. The definition is not confusing and does nothing more than clarify the definition found in the act.

HPLC and IRRC commented that the proposed regulations use the term "order" whereas "drug order" is defined and used in existing regulations. HPLC and IRRC commented that if the Board meant "drug order", that term should be used, or the Board should add the a new definition of the term "order". The term "drug order" is specific to institutions. In the proposed regulations, the Board is referring to any order from a physician within the context of management of drug therapy. Accordingly, the Board has added a definition of the term "order".

IRRC commented that the regulatory definition of "practice of pharmacy" was practically, but not completely, identical to the statutory definition. The Board added the last sentence of the definition of "practice of pharmacy" to the regulatory definition and it is now completely identical to the statutory definition.

HPLC and IRRC recommended that the statutory definition of "drug therapy management" be added to the proposed regulations. The Board agrees and has added the definition.

Section 27.32. Continuing education.

Mr. Pauzano commented that the 2-hour continuing education requirement for the administration of injectable medications, biologicals and immunizations was not a sufficient number of hours. The Board disagrees. In drafting the regulation, the Board consulted several other states' regulations and the standard continuing education requirement for the administration of injectables was 2 hours per biennial renewal period. Pharmacists are required to complete at least a 10-hour course to apply for the authority to administer injectables, which will give sufficient knowledge to administer injectables. The Board is satisfied that the minimum 2-hour continuing education requirement is satisfactory and declines to make a change.

HPLC commented that the Board is required to establish education and training standards for the administration of injectables and noted that the proposed rulemaking was silent as to such standards. With respect to continuing education, the Board disagrees. The Board added the requirement that for renewal of the authority to administer injectables, pharmacists must complete at least 2 hours of continuing education concerning administration of injectable medications, biologicals and immunizations, including disease epidemiology, vaccine characteristics, injections technique, emergency response to adverse events, and related topics. With regard to the education needed to apply for the initial authority to administer injectables the Board added § 27.407 (relating to education requirements) to the final-form regulations. Section 27.407 lays out in detail the requirements for the course of education and training necessary to apply for the initial authority to administer injectables.

Section 27.301. Written protocol.

HPLC commented that the Board should state that drug therapy management may only take place in an institutional setting. The Board declines to make the change. The act already states in both the definition of "drug therapy management" and section 9.1 that drug therapy management can only take place in an institutional setting. Stating this again in § 27.301 would be redundant and unnecessary. Moreover, § 27.301 concerns the parameters of the written protocol, not the requirements to enter into a written protocol as these are already stated in the Pharmacy Act.

HPLC, IRRC and PAFP commented that the notification provisions for drug therapy

management under a written protocol gave a pharmacist up to 72 hours to notify a physician of a change in drug therapy and 72 hours for the pharmacist to document a change in the medical records and questioned the appropriateness of that timeframe. The Board notes that 72 hours set the outside limit for notification. The pharmacist and physician would be free to agree to a shorter timeframe in drafting the written protocol. But to address the concerns raised, the Board has added language to the final-form regulations for notification and documentation to occur as soon as practicable, but no later than 72 hours after the change or intervention. HPLC also asked for the Board's rationale for choosing the 72-hour timeframe. The Board's rationale for choosing 72 hours is twofold. First, the General Assembly already set the maximum time for notification in section 9.1(e)(9) of the act (63 P.S. §390-9.1 (e)(9)), the Board simply adopted that. Second, the 72 hours allowed for a period of time when the physician may not have been available (for example, over a weekend).

HPLC commented that the act requires that the written protocol be available to representatives of the State Board of Medicine, State Board of Osteopathic Medicine and State Board of Pharmacy and that § 27.301(b)(5) should include these entities. These entities are already covered by § 27.301(b)(5). The Board specifically chose to use the term "Bureau" instead of listing the individual boards because a specific board does not employ the inspectors and investigators. Because the Bureau of Professional and Occupational Affairs encompasses all the professional licensing boards, using the term "Bureau" covers all the boards named in the act. Use of the term "Bureau" is consistent with other collaborative practice agreement regulations. (See the CRNP regulations at 49 Pa. Code §21.285(a)(7)(relating to collaborative agreement).

Section 27.311. Professional Liability Insurance

HPLC commented that the regulations are silent as to the professional liability insurance requirement. HPLC commented that the regulations should at least require proof of insurance be submitted to the Board. The Board has added a section to the final-form regulation that requires certification of professional liability insurance to the Board when filing the written protocol.

Section 27.401. Qualifications for authority.

HPLC commented that the Board had not established education and training standards for the administration of injectables. IRRC commented that the Board needed to identify the specific minimum education and training requirements that must be included in an approved course. In the proposed regulation, the Board intended to establish education and training guidelines by accepting any course that was Accreditation Council for Pharmacy Education (formerly called American Council of Pharmaceutical Education) (ACPE) approved and included the current guidelines and recommendations related to the administration of injectable medications, biologicals and immunizations of the Centers for Disease Control and Prevention and offered by providers accredited by ACPE. However, in response to these comments, the Board added § 27.407 (relating to education requirements), which lays out specific requirements for the education needed to apply

for the authority to administer injectables. With respect to the treatment guidelines, these are addressed in a new subsection added to § 27.403 (relating to conditions for administration) and in §27.404 (relating to authority and requirements), which establish the guidelines for injectable administration.

IRRC further commented that the regulations are silent as to how a course provider would apply for approval by the Board. The Board has added subsection (b) to § 27.407 that pre-approves courses offered by ACPE-accredited providers and education institutions that meet the course criteria listed in § 27.407(a). The Board will only accept ACPE-accredited courses, as ACPE is the accreditation body for pharmacy education and continuing education. With the new section added to the regulations, the Board has removed the option to approve other course providers.

Section 27.402. Application and renewal procedures.

IRRC commented that § 27.402 was silent as to the professional liability coverage required to manage drug therapy. However, § 27.402 does not pertain to managing drug therapy; it pertains to the authority to administer injectable medications, biologicals and immunizations. Professional liability insurance is not required to administer injectables. Therefore, the Board has not addressed it in this section. Professional liability insurance for managing drug therapy is addressed in section 9.1(d)(1) of the act and § 27.301 (relating to written protocol) of the regulations.

Section 27.403. Conditions for administration.

HPLC remarked in a comment concerning § 27.401 (relating to qualifications and authority) that the education and training standards and practice guidelines that the Board must establish must include a "definitive set of treatment guidelines established by a physician and approved by the board". The Board has added language to this section with respect to immunizations. Treatment guidelines are also dealt with in § 27.404 (relating to authority and requirements).

Section 27.404. Authority and requirements.

HPLC asked for an explanation with regard to subsection (c) and asked if the Board intended to address drug therapy management pursuant to section 9.1(f) of the act. In this section, the Board is detailing what must be in a written protocol for the administration of injectable medications, biologicals and immunizations. This section is unrelated to § 27.301 (relating to written protocol) or section 9.1(f) of the act, which concerns management of drug therapy in an institution pursuant to a medical order by a licensed physician approved by the medical staff of the institution. As such, §27.404(c) does not need to track the language of section 9.1(f) of the act.

Section 27.405. Recordkeeping.

HPLC recommended that the Board remove the words "or identifiable initials" from paragraph (a)(5). The Board declines to make this change. Under § 27.18 (relating to standards of practice), prescription records kept on file in the pharmacy must be identified with the name or initials of the dispensing pharmacist. The Board is being consistent with existing regulations in allowing initials to be placed on the administration records. There have been no reported problems with identifying a pharmacist by his or her initials and patient safety is not compromised with placing the pharmacist's initials on the pharmacy records. HPLC also recommended that the Board remove the words "of provision" from section (a)(6). The Board has changed the final-form regulation accordingly.

PAFP commented that the Board should adopt the 7-year recordkeeping requirement applied to medical records because the administration of injectables implicates the patient's medical condition. IRRC also commented that the Board should make this change in the final-form regulation or justify the 2-year requirement. The purpose of the 2-year requirement is to maintain the current recordkeeping standards in pharmacies. Therefore Board declines to make the suggested revision. Every administration done by a pharmacist must be reported to the patient's physician who records this information in the patient's medical file. Inasmuch as the physician is maintaining this information for 7 years, it is not necessary for the pharmacy to also maintain the record of administration for 7 years. PAFP's rationale that the administration of drugs implicates the patient's medical condition fails to consider that when pharmacists dispense any drug for the patient's consumption it implicates the patient's medical condition as well. The only difference is the route of administration. Therefore, the Board does not see the need to retain records for more than the standard 2 years.

Section 27.406. Notification requirements.

PAFP commented that the 72-hour notification requirement for injections done under an order and 14-days for injections done under a written protocol was not consistent with good medical care. IRRC echoed PAFP's comment. The Board has amended the final-form regulation to require notification as soon as practicable, but no longer than 72 hours after administration of the injectable. This change requires the pharmacist to notify the physician as soon as practicable, but allows for up to 72 hours in case the physician is unavailable, such as over a weekend when many physicians' offices are closed. HPLC and IRRC recommended that the Board change the wording to require a pharmacist to notify the physician of an adverse reaction as soon as practicable. The Board has changed the final-form regulation accordingly by adding paragraph (3) pertaining to adverse reactions and requiring notification as soon as is practicable, and in no event later than 24 hours after learning of the adverse event or reaction.

Section 27.407. Education requirements.

In response to comments from HPLC and IRRC, the Board has added this section to address the education and training requirements required to apply for the authority to administer injectable medications, biologicals and immunizations. In drafting this section, the Board looked at several other states' regulations, including North Dakota, South Dakota, Iowa, Oregon, Texas, Nevada, Ohio and Delaware, and adopted standards similar to those of these states. Pharmacists will have to complete a course within the 2-year period prior to applying for the authority to administer injectables. The course must be an evidence-based course that includes study material, includes hands-on training and techniques for administration, requires testing with a passing score, provides a minimum of 10 hours of instruction and experiential training, and complies with the current guidelines and recommendations by the Centers for Disease Control and Prevention, ACPE or a similar health authority or professional body. The course must provide instruction on basic immunology and the human immune response; mechanics of immunity, adverse effects, dose and administration schedule of available vaccines; response to an emergency situation as a result of the administration of an injectable medication, biological or immunization; administration of subcutaneous, intradermal, and intramuscular injections; disease epidemiology; standards for immunization practices; vaccine-preventable diseases; recommended immunization schedules; vaccine storage and management; biohazard waste disposal and sterile techniques; informed consent; and authority and recordkeeping requirements. The Board approves courses offered by ACPE-accredited providers and educational institutions that meet these criteria.

General Comments

Mr. Pauzano commented that the Board should address emergency situations, such as a smallpox outbreak, and promulgate regulations that would enable pharmacists to administer injectables without a physician order in such an emergency situation. The Board notes that in an emergency situation, under the appropriate emergency declaration from the Governor, the Board may suspend enforcement of its regulations. In the case of a smallpox outbreak, the Board would look at suspending the requirement of a physician order to administer injectables. However, the Board declines to promulgate specific regulations concerning emergency situations at this time.

HPLC requested an explanation from the Board regarding its discussions with the Insurance Commissioner regarding self-insurance. In late 2002/early 2003, the Board's legal counsel contacted the Insurance Department concerning what kind of regulations would be necessary for self-insurance by pharmacists. Counsel was referred to the Insurance Department's regulations for self-insurance evaluation by the Insurance Department at Title 31, Chapter 243 of the Pennsylvania Code. At that time, the decision was made to reference the Insurance Department's regulations in the Board's proposed regulations. At a later time, the issue of pharmacists not being a health care provider as defined by the Insurance Department's regulations was raised. Board counsel again contacted the Insurance Department to inquire further about self-insurance regulations. At that time, the Insurance Department identified several issues with reviewing self-insurance plans that the Board and Department must work out before regulations can be promulgated. As the Board does not anticipate

that many pharmacists who engage in drug therapy management will self-insure, the Board decided that this issue could be taken up at a future time and removed the self-insurance language from the proposed regulation.

Statutory Authority

The amendments are authorized under Sections 4(j), 6(k)(1) and (9), 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) and (9), 390-9.1(d)(3) and (e), and 390-9.2(a)).

Fiscal Impact and Paperwork Requirements

The final-form rulemaking 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.

Compliance with Executive Order 1996-1

The Board reviewed this rulemaking and considered its purpose and likely impact on the public and the regulated population under the directives of Executive Order 1996-1. This final-form rulemaking addresses a compelling public interest and otherwise complies with Executive Order 1996-1.

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 the notice of proposed rulemaking, published at 34 Pa.B. 5598 (October 9, 2004), to IRRC and the Chairpersons of the House Professional Licensure Committee (HPLC) and the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC, the HPLC and the SCP/PLC were provided with copies of the comments received during the public comment period, as well as other

documents when requested. In preparing the final-form rulemaking, the Board has considered all comments from IRRC, the HPLC, the SCP/PLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on _____, the final-form rulemaking was (deemed) approved by the HPLC. On _____, the final-form rulemaking was (deemed) approved by the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on _____, and (deemed) approved the final-form rulemaking.

Additional Information

Individuals who need information about the regulation may contact Melanie Zimmerman, R.Ph., Executive Secretary, State Board of Pharmacy, P.O. Box 2649, Harrisburg, PA 17105-2649.

Findings

The State Board of Pharmacy finds that:

(1) Public notice of intention to adopt a regulation at 49 Pa.Code, Chapter 27, was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202) and the regulations promulgated under those sections at 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments were considered.

(3) This final rulemaking of the State Board of Pharmacy is necessary and appropriate for the administration of the Pharmacy Act.

(4) The amendments to this final rulemaking do not enlarge the original purpose of the proposed regulation published at 34 Pa.B. 5598 (October 9, 2004).

Order

The Board therefore ORDERS that:

(A) The regulations of the Board, 49 Pa.Code Chapter 27, are amended to read as set

forth in Annex A.

(B) The Board shall submit this Order and a copy of Annex A to the Office of Attorney General and the Office of General Counsel for approval as required by law.

(C) The Board shall certify this Order and Annex and shall deposit them with the Legislative Reference Bureau as required by law.

(D) This Order shall take effect upon publication in the Pennsylvania Bulletin.

Michael J. Romano, 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:

* * *

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

* * *

DRUG THERAPY MANAGEMENT – ANY OF THE FOLLOWING PROCESSES PERFORMED IN AN INSTITUTIONAL SETTING PURSUANT TO A WRITTEN AGREEMENT, PROTOCOL OR ORDER AS SET FORTH IN SECTION 9.1 OF THE ACT:

(i) ADJUSTING A DRUG REGIMEN.

(ii) ADJUSTING DRUG STRENGTH, FREQUENCY OF ADMINISTRATION OR ROUTE.

(iii) ADMINISTRATION OF DRUGS.

(iv) ORDERING LABORATORY TESTS AND ORDERING AND PERFORMING OTHER DIAGNOSTIC TESTS NECESSARY IN THE MANAGEMENT OF DRUG

THERAPY, CONSISTENT WITH THE TESTING STANDARDS OF THE INSTITUTION.

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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.]

(i) A health care facility that offers care and medical treatment to patients who require food, board and overnight sleeping facilities and provides clinically related health 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.

(ii) The term also includes a hospice that offers care and medical treatment to patients who require food, board and overnight sleeping facilities.

(iii) 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.

* * *

ORDER – ANY DIRECTIVE FROM A MEDICAL PRACTITIONER.

* * *

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.]

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

(i) The interpretation, evaluation and implementation of medical orders for the provision of pharmacy services or prescription drug orders.

(ii) The delivery, dispensing or distribution of prescription drugs.

(iii) Participation in drug and device selection.

(iv) Drug administration.

(v) Drug regimen review.

(vi) Drug or drug-related research.

(vii) Compounding.

(viii) Proper and safe storage of drugs and devices.

(ix) Managing drug therapy in an institutional setting consistent with the institution's assignment of clinical duties.

(x) Maintaining proper records.

(xi) Patient counseling.

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

(xiii)THE TERM DOES NOT INCLUDE THE OPERATIONS OF A MANUFACTURER OR DISTRIBUTOR AS DEFINED IN THE CONTROLLED SUBSTANCE, DRUG, DEVICE AND COSMETIC ACT (35 P.S. §§780-101 – 780-144).

* * *

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~~ PRECEDING 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 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 must occur ~~within~~ 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 ~~establishes an appropriate time frame, not to exceed~~ REQUIRES NOTIFICATION TO THE AUTHORIZING PHYSICIAN ~~within which the licensed pharmacist must notify the licensed 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 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 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 at the request of any party to it at any time.

(b) The written protocol must 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 must be filed with Bureau.

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

PROFESSIONAL LIABILITY INSURANCE

§27.311. CERTIFICATION OF PROFESSIONAL LIABILITY INSURANCE.

(A) A LICENSEE WHO ENGAGES IN DRUG THERAPY MANAGEMENT UNDER A WRITTEN PROTOCOL SHALL MAINTAIN PROFESSIONAL LIABILITY INSURANCE IN THE MINIMUM AMOUNT OF $1,000,000 PER OCCURRENCE OR CLAIMS MADE.

(B) A LICENSEE WHO ENGAGES IN DRUG THERAPY MANAGEMENT UNDER A WRITTEN PROTOCOL SHALL CERTIFY COMPLIANCE WITH SUBSECTION (A) ON A FORM PROVIDED BY THE BOARD. THE FORM SHALL BE PROVIDED WITH THE WRITTEN PROTOCOL.

(C) A LICENSEE WHO ENGAGES IN DRUG THERAPY MANAGEMENT UNDER A WRITTEN PROTOCOL SHALL UPON REQUEST MAKE AVAILABLE TO THE BOARD OR ITS AGENTS ALL RECORDS, RELATING TO THE LICENSEE'S MAINTENANCE OF PROFESSIONAL LIABILITY INSURANCE, INCLUDING POLICIES, CANCELLED CHECKS, RECEIPTS OR OTHER PROOFS OF PREMIUM PAYMENT.

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:

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

(2) 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.~~ MEETS THE REQUIREMENTS OF §27.407 (RELATING TO EDUCATION REQUIREMENTS).

(3) 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 AS SET FORTH IN §27.407 (RELATING TO EDUCATION REQUIREMENTS).

(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) A pharmacist may not delegate the administration of injectable medications, biologicals and immunizations to another person.

(c) THE BOARD APPROVES THE TREATMENT GUIDELINES FOR IMMUNIZATIONS ESTABLISHED BY THE CENTERS FOR DISEASE CONTROL AND PREVENTION. A PHARMACIST SHALL ADMINISTER INJECTABLE IMMUNIZATIONS IN ACCORDANCE WITH THESE TREATMENT GUIDELINES.

§ 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 must be written, received electronically or if received orally be reduced to writing, and contain at a minimum the following:

(1) The identity of the licensed prescriber issuing the order.

(2) The identity of the patient to receive the injection.

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

(4) The 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) The identity of the participating pharmacist and physician or institution.

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

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

(4) The 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 shall observe an individual for adverse events following an injection.

(7) The 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 administration for a minimum of 2 years:

(1) An 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~~ AS SOON AS PRACTICABLE, BUT NO LONGER THAN 72 hours AFTER ADMINISTRATION of the following:

(i) The identity of the patient.

(ii) ~~Identity~~ THE IDENTITY of the medication.

~~(iii) Biological~~ , BIOLOGICAL or immunization administered.

~~(iv)~~ (iii) The route of administration.

~~(v)~~ (iv) The site of the administration.

~~(vi)~~ (v) The dose administered.

~~(vii)~~ (vi) The date of administration.

~~(viii) 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~~ AS SOON AS PRACTICABLE, BUT NO LONGER THAN 72 HOURS AFTER ADMINISTRATION of the following:

(i) The identity of the patient.

(ii) The identity of the medication.

~~(iii) The~~ , biological or immunization administered.

~~(iv)~~ (iii) The site of the administration.

~~(v)~~ (iv) The dose administered.

~~(vi)~~ (v) The date of administration.

~~(vii) The nature of any adverse events or reactions experienced by the patient.~~

(3) IN THE EVENT OF ANY ADVERSE EVENT OR REACTION EXPERIENCED BY THE PATIENT EITHER PURSUANT TO AN ORDER OR A WRITTEN PROTOCOL, THE PHARMACIST SHALL NOTIFY THE PATIENT'S PHYSICIAN AS SOON AS IS PRACTICABLE, AND IN NO EVENT LATER THAN 24 HOURS AFTER LEARNING OF THE ADVERSE EVENT OR REACTION.

§27.407. EDUCATION REQUIREMENTS.

(a) TO APPLY FOR THE AUTHORITY TO ADMINISTER INJECTABLE MEDICATIONS, BIOLOGICALS AND IMMUNIZATIONS, A PHARMACIST MUST MEET THE FOLLOWING EDUCATION REQUIREMENTS:

(1) COMPLETE WITHIN THE 2-YEAR PERIOD PRIOR TO APPLICATION AN EVIDENCE-BASED COURSE THAT MEETS THE FOLLOWING CRITERIA:

(i) INCLUDES STUDY MATERIAL.

(ii) INCLUDES HANDS-ON TRAINING AND TECHNIQUES FOR ADMINISTRATION.

(iii) REQUIRES TESTING WITH A PASSING SCORE.

(iv) PROVIDES A MINIMUM OF 10 HOURS OF INSTRUCTION AND EXPERIENTIAL TRAINING.

(v) COMPLIES WITH CURRENT GUIDELINES AND RECOMMENDATIONS BY THE CENTERS FOR DISEASE CONTROL AND PREVENTION, ACPE OR A SIMILAR HEALTH AUTHORITY OR PROFESSIONAL BODY.

(2) THE COURSE MUST PROVIDE INSTRUCTION ON THE FOLLOWING TOPICS:

(i) BASIC IMMUNOLOGY AND THE HUMAN IMMUNE RESPONSE.

(ii) MECHANICS OF IMMUNITY, ADVERSE EFFECTS, DOSE, AND ADMINISTRATION SCHEDULE OF AVAILABLE VACCINES.

(iii) RESPONSE TO AN EMERGENCY SITUATION AS A RESULT OF THE ADMINISTRATION OF AN INJECTABLE MEDICATION, BIOLOGICAL OR IMMUNIZATION.

(iv) ADMINISTRATION OF SUBCUTANEOUS, INTRADERMAL, AND INTRAMUSCULAR INJECTIONS.

(v) DISEASE EPIDEMIOLOGY.

(vi) STANDARDS FOR IMMUNIZATION PRACTICES.

(vii) VACCINE-PREVENTABLE DISEASES.

(viii) RECOMMENDED IMMUNIZATION SCHEDULES

(ix) VACCINE STORAGE AND MANAGEMENT.

(x) BIOHAZARD WASTE DISPOSAL AND STERILE TECHNIQUES.

(xi) INFORMED CONSENT.

(xii) AUTHORITY AND RECORDKEEPING REQUIREMENTS AS PROVIDED IN THIS CHAPTER.

(b) THE BOARD APPROVES COURSES OFFERED BY ACPE-ACCREDITED PROVIDERS AND EDUCATIONAL INSTITUTIONS THAT MEET THE CRITERIA AND PROVIDE INSTRUCTION ON THE TOPICS LISTED IN PARAGRAPH (A).

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 Lisa Burns, Administrator, State Board of Dentistry, P. O. Box 2649, Harrisburg, PA 17105-2649 within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*.

VEASEY B. COLLEN, Jr., D.M.D.,
Chairperson

Fiscal Note: 16A-4615. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 33. STATE BOARD OF DENTISTRY

Subchapter A. GENERAL PROVISIONS

§ 33.3. Fees.

Following is the schedule of fees charged by the Board:

* * * * *

Biennial renewal fee—dentists.....**$[100]250**

* * * * *

[Biennial renewal fee—unrestricted or restricted anesthesia permit.....$25]

* * * * *

For fees related to anesthesia permits, refer to § 33.339 (relating to fees for issuance of permits).

Subchapter E. ADMINISTRATION OF GENERAL ANESTHESIA, CONSCIOUS SEDATION AND NITROUS OXIDE/OXYGEN ANALGESIA

§ 33.339. Fees for issuance of permits.

The following fees are charged for the issuance of permits under this subchapter:

(1) *Unrestricted permit.*

(i) **[Issuance under § 33.335(a)(1) or (2)]**
Initial.....$[15]100

(ii) **[Issuance under § 33.335(a)(3)]**
Renewal.....$[300]200

(iii) Temporary.....$100

(2) *Restricted permit I.*

(i) **[Issuance under § 33.336(a)(1)]**
Initial.....$[15] 100

(ii) **[Issuance under § 33.336(a)(2)]**
Renewal.....$[300] 200

(iii) Temporary.....$100

(3) *Restricted permit II.*

(i) **[Issuance under § 33.337(a)(1)] Initial.....** $15

(ii) **[Issuance under § 33.337(a)(2)]**
Renewal.....$[15]50

(iii) Temporary.....$15

[Pa.B. Doc. No. 04-1854. Filed for public inspection October 8, 2004, 9:00 a.m.]

STATE BOARD OF PHARMACY

[49 PA. CODE CH. 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 schedule of fees) and to add §§ 27.301 and 27.401—27.406 to read as set forth in Annex A.

Effective Date

This proposed rulemaking will be effective upon publication as 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) and (9), 390-8.2(a), 390-9.1(d)(3) and (e) and 390-9.2(a)).

Background and Purpose

In August 2002, the act was amended to add sections 9.1 and 9.2, as well as to modify and add several definitions to the act. The additional sections authorize pharmacists to manage drug therapy by means of a written protocol as well as administer injectable medications, biologicals and immunizations. This proposed rulemaking is required to implement the new provisions of the act.

Description of Proposed Rulemaking

The Board proposes to amend § 27.1 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 act.

The Board proposes to amend § 27.32 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 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 section 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 by means of a written protocol. The Board has deferred proposing regulations for self-insurance until the details of the 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 this 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 shall 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. 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 rulemaking defines what "more than 18 years of age" means. The proposed rulemaking 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 shall be kept for a minimum of 2 years. Additionally, the proposed rulemaking lists the additional information that shall 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 shall notify the prescriber. When the administration is done under a written protocol the pharmacist has a longer period of time to notify the prescriber.

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

Fiscal Impact and Paperwork Requirements

The proposed rulemaking 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 proposed rulemaking 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 rulemaking 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

Fiscal Note: 16A-5412. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

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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:

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(i) A 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.

(ii) The term also includes a hospice that offers care and medical treatment to patients who require food, board and overnight sleeping facilities.

(iii) 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.] The provision of health care services by a pharmacist, which includes:

(i) The interpretation, evaluation and implementation of medical orders for the provision of pharmacy services or prescription drug orders.

(ii) The delivery, dispensing or distribution of prescription drugs.

(iii) Participation in drug and device selection.

(iv) Drug administration.

(v) Drug regimen review.

(vi) Drug or drug-related research.

(vii) Compounding.

(viii) Proper and safe storage of drugs and devices.

(ix) Managing drug therapy in an institutional setting consistent with the institution's assignment of clinical duties.

(x) Maintaining proper records.

(xi) Patient counseling.

(xii) 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 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.

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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:

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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 must occur within 72 hours in the patient medical record and must 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 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 at the request of any party to it at any time.

(b) The written protocol must 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 must be filed with Bureau.

(d) 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 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:

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

(2) 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.

(3) 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) A pharmacist may not 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 must be written, received electronically or if received orally be reduced to writing, and contain at a minimum the following:

(1) The identity of the licensed prescriber issuing the order.

(2) The identity of the patient to receive the injection.

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

(4) The 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) The identity of the participating pharmacist and physician or institution.

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

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

(4) The 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 adverse reactions, anaphylactic reactions and accidental needle sticks.

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

(7) The 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 administration for a minimum of 2 years:

(1) An 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 following:

(i) The identity of the patient.

(ii) Identity of the medication.

(iii) Biological or immunization administered.

(iv) The route of administration.

(v) The site of the administration.

(vi) The dose administered.

(vii) The date of administration.

(viii) 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 following:

(i) The identity of the patient.

(ii) The identity of the medication.

(iii) The biological or immunization administered.

(iv) The site of the administration.

(v) The dose administered.

(vi) The date of administration.

(vii) The nature of any adverse events or reactions experienced by the patient.

[Pa.B. Doc. No. 04-1855. Filed for public inspection October 8, 2004, 9:00 a.m.]

Commentator List
Regulation 16A-5412
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April 13, 2006

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

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

Dear Chairman McGinley:

Enclosed is a copy of a final 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,

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

EJB/CLC:sb
Enclosure
c: Basil L. Merenda, Commissioner
Bureau of Professional and Occupational Affairs
Albert Masland, 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: Drug Therapy & Injectable Medications, Biologicals and Immunizations
AGENCY:	DEPARTMENT OF STATE

TYPE OF REGULATION

Proposed Regulation

X 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
2006 APR 13 AM 10: 24
INDEPENDENT REGULATORY REVIEW COMMISSION

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
4/13/06	Sandra J Harper	HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
4/13/06	Mary Walmer	SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
4/13/06	Kathy Cooper	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

March 13, 2006