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-5417

IRRC Number: 2662

(3) Short Title

Continuing Education

(4) PA Code Cite

49 Pa. Code, §§ 27.1, 27.32

(5) Agency Contacts & Telephone Numbers

Primary Contact: **Carole L. Clarke, Counsel**
State Board of Pharmacy (717) 783-7200
Secondary Contact: **Joyce McKeever, Deputy Chief Counsel, Department of State (717) 783-7200**

(6) Type of Rulemaking (check one)

_X_ Proposed Rulemaking
___ 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 nontechnical language.

The proposed rulemaking would correct the definition of the acronym ACPE (Accreditation Council for Pharmacy Education), require 2 hours of the 30-hour continuing education requirement be completed in courses from the ACPE topic designator "Patient Safety," require that any deficiencies in continuing education be made up within 6 months of notification by the Board, require that any providers seeking program approval apply no less than 60 days prior to the start date of the program, and clear up confusing language regarding continuing education.

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

The amendments are authorized under Sections 3.1, 4(j) and 6(k)(1) and (9) of the Pharmacy Act (act) (63 P.S. §§ 390-3.1, 390-4(j) and 390-6(k)(1) and (9)).

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(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.

The proposed amendments to the regulation are not mandated, however the Board is required to adopt rules and regulations pertaining to continuing education.

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

There is a compelling public interest in revising and updating regulations on a periodic basis. The public also benefits by having pharmacists complete continuing education that helps them become better practitioners. Therefore, the Board proposes to add a requirement that during each biennial renewal period pharmacists must complete 2 hours of continuing education related to patient safety. This specific type of continuing education will help pharmacists become aware of issues relating to patient safety, including medication errors.

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

Nonregulation perpetuates the risk that many pharmacists will never complete continuing education pertaining to patient safety. The Board believes that requiring this specific type of continuing education benefits practitioners and the public alike.

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

The public and regulated community will benefit from pharmacists becoming more knowledgeable about patient safety issues.

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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.)

Approximately 18,426 pharmacists and 3,264 pharmacies apply for licenses and permits biennially.

(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 developing and drafting the regulation, the Board obtained input from stakeholders by written correspondence and open work sessions.

(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.

There are no costs and/or savings associated with compliance with the proposed regulation.

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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.

Local governments would not be affected by this regulation.

(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 are no costs or savings to the Board associated with implementation of this regulation.

Regulatory Analysis Form

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

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

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

Regulatory Analysis Form

(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	**$1,532,884.94**	**$1, 433,964.55**	**$1,652,516.51**	**$1,862,000.00**

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

There are no adverse effects and costs associated with this regulation.

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

No nonregulatory approaches were considered. Amending the existing regulations is the only way to change the continuing education requirements.

(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. Amending the regulations is the only way to change the continuing education requirements.

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.

There are no federal standards that apply.

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

The proposed regulations are comparable to those of surrounding states; there should be no competitive disadvantage. The requirements are summarized below.

New York: 45 hours of continuing education over 3 years. 3 hours in strategies and techniques to reduce medication and prescription errors.
New Jersey: 30 hours over 2 years. 10 hours must be live.
Delaware: 30 hours over 2 years.
Maryland: 30 hours over 2 years.
West Virginia: 30 hours over 2 years. 2 hours must be in end of life care.
Ohio: 60 hours over 3 years. 3 hours must be in jurisprudence.

(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 regulation amends current §§ 27.1 and 27.32. No other agency's regulations are affected.

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

The Board provides an opportunity for public input into its activities, including its rulemaking proposals, at its regularly scheduled monthly meetings. The dates times and places of the Board's meetings are available at the Department of State's Website, www.dos.state.pa.us.

Regulatory Analysis Form

(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.

Yes, pharmacists would be required to certify compliance with the requirement that 2 hours of continuing education were obtained in patient safety. Other record keeping requirements would not change.

(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.

The Board has not identified particular needs for which special provisions need to be developed or anticipated.

(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 final-form publication in the Pennsylvania Bulletin. The requirement that 2 hours of continuing education be completed in patient safety will be effective with the first biennial renewal period that occurs at least 2 years from the effective date of the proposed rulemaking.

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

The Board will review the effectiveness of this regulation as part of its annual review of its fiscal operations.

CDL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

DO NOT WRITE IN THIS SPACE

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

BY: _____
(DEPUTY ATTORNEY GENERAL)

DEC 18 2007
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-5417

DATE OF ADOPTION: _____

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

TITLE: Chairman
(EXECUTIVE OFFICER, CHAIRMAN OR SE

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

BY: _____
Andrew C. Clark

DEC 3 2007
DATE OF APPROVAL

(Deputy General Counsel (~~Strike inapplicable title~~)

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

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

NOTICE OF PROPOSED RULEMAKING

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF PHARMACY
49 PA. CODE, CHAPTER 27
CONTINUING EDUCATION

The State Board of Pharmacy (Board) proposes to amend §§ 27.1 and 27.32 (relating to definitions; and continuing education) to read as set forth in Annex A.

Effective Date

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

Statutory Authority

The amendments are authorized under Sections 3.1, 4(j) and 6(k)(1) and (9) of the Pharmacy Act (act) (63 P.S. §§ 390-3.1, 390-4(j) and 390-6(k)(1) and (9)).

Background and Need for Amendment

Pharmacists are required to certify proof of completion of continuing education hours on their biennial renewal forms. Every biennial renewal period the Board performs an audit of 5% of the licensee population. Through the course of past audits and resulting disciplinary actions for noncompliance with the regulations, it has come to the Board's attention that not all licensees understand that only courses offered by ACPE-accredited continuing education providers are acceptable continuing education. While § 27.32(h) does permit other non-ACPE accredited providers to apply to the Board for approval, to date the Board has not approved any other continuing education providers. In the past five years, the Board has not received an application for approval from a non-ACPE accredited provider of continuing education. Because ACPE is the national accrediting body for pharmacy-related continuing education, a vast majority of providers are ACPE-accredited. Therefore, the Board proposes to amend the current regulation to make it clear that, in general, only ACPE-accredited providers of continuing education are acceptable. In addition, the Board has reviewed the regulation and determined that other updates are needed, specifically with regard to requiring continuing education in the area of to patient safety, requiring applications for program approval to be submitted no less than 60 days prior to the start of the program, and requiring any deficiencies in continuing education hours to be made up within 6 months of notification by the Board.

Description of Proposed Amendments

The proposed amendments would amend § 27.1 (relating to definitions) to reflect the change of name for ACPE from the American Council of Pharmaceutical Education to the Accreditation Council for Pharmacy Education. The proposal would also amend § 27.32 (relating to continuing education) to clarify that, with limited exceptions, the Board only accepts ACPE-accredited providers of continuing education. The proposal would further amend § 27.32 to delete the term "approved" after ACPE, as ACPE accredits providers instead of approving them.

The Board also proposes to add a requirement that 2 of the required 30 hours of continuing education be completed in courses under the ACPE topic designator "Patient Safety." Recently ACPE introduced new topic designators, which will make it easier for licensees and the auditing agents to determine if a continuing education course falls under a certain topic. The Board is concerned about medication errors and believes that pharmacists benefit from completing continuing education specific to these types of errors. The public benefits from having pharmacist aware of common errors and ways to prevent them. ACPE has indicated that the topic designator "Patient Safety" includes the prevention of healthcare errors, and the elimination or mitigation of patient injury caused by healthcare errors.

The Board proposes to codify in this rulemaking its current practice that any pharmacist found to be in noncompliance with the continuing education requirement must make up the deficiency within 6 months. This provision would not apply to licensees who indicate on the renewal form that they have not met the continuing education requirements, as their licenses would not be renewed until 30 hours of continuing education can be verified. Any pharmacist found to be noncompliant with the continuing education requirements, either through the audit or some other means, would be required to make up the deficiency within 6 months from the notice of deficiency from the Board, notwithstanding any disciplinary action taken for the violation of the continuing education requirements.

Finally, the Board proposes to require any applications for approval from continuing education program providers that are not ACPE-accredited be submitted to the Board no less than 60 days prior to the start of the program. The Board proposes to add this requirement to the regulation to give the Board ample time to review a program for equivalency to ACPE standards before the program takes place.

Fiscal Impact and Paperwork Requirements

The amendments will not have an adverse fiscal impact on the Commonwealth or its political subdivisions, as the Board is self-supporting. The amendments will not impose any additional paperwork requirements upon the Commonwealth or its political subdivisions.

Sunset Date

The Board monitors 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 January 9, 2008, 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 any comments, recommendations or objections regarding the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria that 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, recommendations or objections regarding this proposed rulemaking to Melanie Zimmerman, Executive Secretary, State Board of Pharmacy, P.O. Box 2649, Harrisburg, Pennsylvania 17105-2649, within 30 days following publication of this proposed rulemaking in the Pennsylvania Bulletin.

Edward J. Bechtel, 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:

ACPE – The [American Council of Pharmaceutical Education] Accreditation Council for Pharmacy Education.

* * * * *

RENEWAL OF PHARMACIST LICENSE AND PHARMACY PERMIT

* * * * *

§ 27.32. Continuing education.

(a) The Board will renew the license of a pharmacist who has completed a minimum of 30 contact hours (3 CEU) of continuing education during the preceding biennial renewal period. Beginning with the license period commencing on _____ (Editor's note: The blank refers to the date of the first biennial renewal that occurs at least 2 years from the effective date of this amendment), 2 of the required 30 contact hours must be completed in courses from the ACPE topic designator "Patient Safety." [For] In addition, 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] § 27.401 (relating to qualifications for authority), 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.] Except as provided in subsection (h), only continuing education programs offered by ACPE-accredited providers of continuing pharmaceutical education targeted toward pharmacists are acceptable to the Board.

(b) A pharmacist shall prove compliance with the requirements of subsection (a) by completing and submitting a form provided to the pharmacist by the Board for that purpose with the renewal application. The certificates provided upon completion of an approved program shall be retained by a pharmacist for 2 years after renewal, and shall be produced upon demand by the board or its auditing agents. The Board will utilize a random audit of 5% of renewals to determine compliance with the requirements of subsection (a), and may expand the audit if rates of noncompliance at 20% or more of the sample are revealed by the initial audit. Individuals selected for the audit will be required to produce certificates proving the information they provided to the Board on the form submitted with the renewal application. Notwithstanding any disciplinary action taken under subsection (i), any pharmacist found to be in noncompliance with the continuing education requirements shall make up the delinquent contact hours within 6 months of the notice of deficiency from the Board.

* * * * *

(h) Continuing education program providers which are not ACPE [approved] accredited may apply to the Board for approval, and shall make a showing of program accreditation substantially similar to ACPE accreditation standards. Requests for approval must be submitted to the Board no less than 60 days prior to the start date of the program. Retroactive requests for approval will not be considered. The Board will maintain a list of programs approved under this subsection.

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

January 9, 2008

The Honorable Arthur Coccodrilli, Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Proposed Regulation
State Board of Pharmacy
16A-5417: Continuing Education

Dear Chairman Coccodrilli:

Enclosed is a copy of a proposed rulemaking package of the State Board of Pharmacy pertaining to continuing education.

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

Sincerely,

for Michael A. Podgurski, R.Ph., Chairperson
State Board of Pharmacy

MAP/CLC:klh
Enclosure
cc: Basil L. Merenda, Commissioner
Bureau of Professional and Occupational Affairs
Albert H. 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-5417
SUBJECT:	CONTINUING EDUCATION
AGENCY:	DEPARTMENT OF STATE STATE BOARD OF PHARMACY

TYPE OF REGULATION

X Proposed Regulation

Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

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

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
1-9-08		HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
		MAJORITY CHAIRMAN Sturla
1/9/08		SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
		MAJORITY CHAIRMAN Tomlinson
1/9/08		INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
1/9/08		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

December 19, 2007