Regulatory Analysis Form

(Completed by Promulgating Agency)

SECTION I: PROFILE

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

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

Identification Number: **5417**

IRRC Number: 2662

(3) Short Title:
Continuing education

(4) PA Code Cite:
49 Pa. Code §§ 27.11, 27.16

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

Primary Contact: **Thomas A. Blackburn, Regulatory unit counsel, Department of State; (717)783-7200; P.O. Box 2649, Harrisburg, PA 17105-2649; (717)787-0251; tblackburn@state.pa.us**

Secondary Contact: **Joyce McKeever, Deputy Chief Counsel, Department of State (717)783-7200; P.O. Box 2649, Harrisburg, PA 17105-2649; (717)787-0251; jmckeever@state.pa.us**

(6) Primary Contact for Public Comments (List Telephone Number, Address, Fax Number and Email Address) – Complete if different from #5: **State Board of Pharmacy (717)783-7156; P.O. Box 2649, Harrisburg, PA 17105-2649; (717)787-7769; st-pharmacy@state.pa.us**

(All Comments will appear on IRRC'S website)

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

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

Regulatory Analysis Form

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

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) Include a schedule for review of the regulation including:

A. The date by which the agency must receive public comments:	Feb. 18, 2008
B. The date or dates on which public meetings or hearings will be held:	N/A
C. The expected date of promulgation of the proposed regulation as a final-form regulation:	by Dec. 31, 2009
D. The expected effective date of the final-form regulation:	upon publication as final
E. The date by which compliance with the final-form regulation will be required:	effective date
F. The date by which required permits, licenses or other approvals must be obtained:	N/A

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

The Board continually reviews the efficacy of its regulations, as part of its annual review process under Executive Order 1996-1. The Board reviews its regulatory proposals at regularly scheduled public meetings, generally the third Tuesday of each month. More information can be found on the Board's website (www.dos.state.pa.us/pharmacy).

SECTION II: STATEMENT OF NEED

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

This rulemaking is authorized by sections 3.1 and 6(k) of the Pharmacy Act (act) (63 P.S. §§ 390-3.1 and 390-6(k)).

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

The rulemaking is not mandated by any federal or state law or court order or federal regulation.

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

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

(14) If scientific data, studies, references are used to justify this regulation, please submit material with the regulatory package. Please provide full citation and/or links to internet source.

The rulemaking is not based on any scientific data, studies, or references.

(15) Describe who and how many will be adversely affected by the regulation. How are they affected?

The Board does not foresee any persons being adversely affected by the rulemaking.

(16) 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.

All pharmacists will be required to comply with the rulemaking. The Board licenses approximately 18,426 pharmacists.

SECTION III: COST AND IMPACT ANALYSIS

(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. Explain how the dollar estimates were derived.

There are no costs or savings to the regulated community associated with compliance with the rulemaking.

(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. Explain how the dollar estimates were derived.

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

(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. Explain how the dollar estimates were derived.

There are no costs or savings to state government associated with compliance with the rulemaking.

(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:	$	$	$	$	$	$
Regulated Community						
Local Government						
State Government						
Total Savings	NA	NA	NA	NA	NA	NA
COSTS:						
Regulated Community						
Local Government						
State Government						
Total Costs	NA	NA	NA	NA	NA	NA

REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses	NA	NA	NA	NA	NA	NA

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

Program	FY –3 (FY 05-06) actual	FY –2 (FY 06-07) actual	FY –1 (FY 07-08) actual	Current FY (FY 08-09) budget
Pa. State Board of Pharmacy	$1,434,730	$1,683,729	$1,751,209	$1,889,000

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

Because there are no costs or other adverse effects associated with the rulemaking, the identified benefits outweigh any costs.

(22) Describe the communications with and input from the public and any advisory council/group in the development and drafting of the regulation. List the specific persons and/or groups who were involved.

In developing and drafting the regulation, the Board obtained input from stakeholders by written correspondence and open work sessions. Additionally, the Board discussed the proposed rulemaking at public meetings of the Board, which are routinely attended by members of the regulated community and their professional associations.

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

No alternative regulatory approaches were considered. Amending the regulations is the only way to revise the continuing education requirements.

(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 regulations.

This rulemaking will not be more stringent and will not overlap or conflict with any federal requirements.

Regulatory Analysis Form

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

The regulatory provisions are comparable to those of surrounding states, as 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.

This rulemaking will not put Pennsylvania at a competitive disadvantage.

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

This rulemaking will not affect other regulations of the Board or other state agencies.

(27) Submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

This rulemaking will not require any additional recordkeeping or other paperwork.

(28) 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 determined that there are no special needs of any subset of its applicants or licensees for whom special accommodations should be made.

(4) The nursing education program will be provided an opportunity to appear at a hearing to demonstrate why approval should not be withdrawn.

(5) The nursing education program and the Commonwealth will be provided an opportunity to file posthearing briefs.

(6) The Board will issue a written decision which will set forth findings of fact and conclusions of law.

(7) The Board's written decision will be a final decision of a governmental agency subject to review under 2 Pa.C.S. § 702 (relating to appeals).

(b) If a nursing education program is removed from the approved list, the controlling institution shall provide for the completion of the program for students currently enrolled by placing the students in an approved program.

(c) If a nursing education program is removed from the approved list, the controlling institution shall make provision for permanent retention of student and graduate records in conformity with §§ 21.233 and 21.234 (relating to custody or records; and access and use of records).

[Pa.B. Doc. No. 08-91. Filed for public inspection January 18, 2008, 9:00 a.m.]

STATE BOARD OF PHARMACY

[49 PA. CODE CH. 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 proposed 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 5 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 patient safety, requiring applications for program approval to be submitted at least 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 amend § 27.1 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 § 27.32to 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 pharmacists 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 shall 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 applications for approval from continuing education program providers that are not ACPE-accredited be submitted to the Board at least 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 proposed amendments will not have an adverse fiscal impact on the Commonwealth or its political subdivisions, as the Board is self-supporting. The proposed 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 (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 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 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, PA 17105-2649, within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*.

EDWARD J. BECHTEL, R.Ph.,
Chairperson

Fiscal Note: 16A-5417. 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 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 adoption of this proposed rulemaking.), 2 of the required 30 contact hours shall 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] must** 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), a 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 shall be submitted to the Board at least 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.

* * * * *

[Pa.B. Doc. No. 08-92. Filed for public inspection January 18, 2008, 9:00 a.m.]

[49 PA. CODE CH. 27]

Pharmacist Breaks

The State Board of Pharmacy (Board) proposes to amend §§ 27.11 and 27.16 (relating to pharmacy permit and pharmacist manager; and construction and equipment requirements) to read as set forth in Annex A. The proposed rulemaking would set standards for a pharma-

PENNSYLVANIA PHARMACISTS ASSOCIATION

508 North Third Street, Harrisburg, PA 17101-1199
phone: 717-234-6151 fax: 717-236-1618 website: www.PApharmacists.com

#2662

January 22, 2008

Independent Regulatory Review Commission
333 Market Street, 14th floor
Harrisburg, PA 17101

RE: ID#16A-5417 (2662)

Dear IRRC Commission:

The Pennsylvania Pharmacists Association supports the provisions contained within the regulations of #16A-5417 (2662).

We believe the clarification that CE credit is only through ACPE (Accreditation Council for Pharmacy Education) courses or courses approved in advance by the State Board of Pharmacy will alleviate any misinterpretation of this requirement. We obviously support the ACPE name change since ACPE has changed its name, and also it is accurate that ACPE does not individually approve courses but rather providers, who must approve courses against certain criteria.

In addition, we believe there should be a six month opportunity to complete insufficient CE credits is appropriate. And most importantly, we strongly support the requirement that two-hours of CE in any biennial renewal period be dedicated to "Patient safety" topics. It is crucial to have continued focus on safety and preventing medication errors. Our Association has already made a commitment to offer at least one program on a related topic at each of our annual conferences.

Thank you for your consideration of our comments on this regulation package. We urge the final adoption of this.

Sincerely,

Patricia A. Epple, CAE
Executive Director

P. MICHAEL STURLA, MEMBER
MAJORITY DEPUTY WHIP
333 MAIN CAPITOL BUILDING
P.O. BOX 202096
HARRISBURG, PENNSYLVANIA 17120-2096
PHONE: (717) 787-3555
FAX: (717) 705-1923

THE GRIEST BUILDING
8 NORTH QUEEN STREET
SUITE 1100
LANCASTER, PENNSYLVANIA 17603
PHONE: (717) 295-3157
FAX: (717) 295-7816

#2662

House of Representatives
COMMONWEALTH OF PENNSYLVANIA
HARRISBURG

COMMITTEES

PROFESSIONAL LICENSURE – MAJORITY CHAIRMAN
FINANCE
RULES
MAJORITY POLICY
CAPITOL PRESERVATION

February 13, 2008

Mr. Kim Kaufman
Executive Director
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

RECEIVED
2008 FEB 14 AM 11:06
INDEPENDENT REGULATORY
REVIEW COMMISSION

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

Dear Mr. Kaufman:

The House Professional Licensure Committee on this date voted to take no formal action on Regulation 16A-5417 until final regulation is promulgated and submit the following comment:

1. The Committee suggests spelling out the word two instead of using the number "2" in the two places in §27.32 where it refers to "2 years" and "2 of the required 30."

Sincerely,

P. Michael Sturla
Chairman, House Professional Licensure Committee

PHONE: (717) 783-5417
FAX: (717) 783-2664
irrc@irrc.state.pa.us
http://www.irrc.state.pa.us

INDEPENDENT REGULATORY REVIEW COMMISSION
333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

March 20, 2008

Edward J. Bechtel, R.Ph., Chairperson
State Board of Pharmacy
2601 North 3rd Street
Harrisburg, PA 17110

Re: Regulation #16A-5417 (IRRC #2662)
State Board of Pharmacy
Continuing Education

Dear Chairperson Bechtel:

Enclosed are the Commission's comments for consideration when you prepare the final version of this regulation. These comments are not a formal approval or disapproval of the regulation. However, they specify the regulatory review criteria that have not been met.

The comments will be available on our website at www.irrc.state.pa.us. If you would like to discuss them, please contact me.

Sincerely,

Kim Kaufman
Executive Director
wbg
Enclosure
cc: Honorable Robert M. Tomlinson, Chairman, Senate Consumer Protection and Professional Licensure Committee
Honorable Lisa M. Boscola, Minority Chairman, Senate Consumer Protection and Professional Licensure Committee
Honorable P. Michael Sturla, Majority Chairman, House Professional Licensure Committee
Honorable William F. Adolph, Jr., Minority Chairman, House Professional Licensure Committee
Honorable Pedro A. Cortes, Secretary, Department of State

Comments of the Independent Regulatory Review Commission

on

State Board of Pharmacy Regulation #16A-5417 (IRRC #2662)

Continuing Education

March 20, 2008

We submit for your consideration the following comments on the proposed rulemaking published in the January 19, 2008 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b). Section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)) directs the State Board of Pharmacy (Board) to respond to all comments received from us or any other source.

1. Section 27.32. Continuing education. - Implementation procedures.

This Section concerns continuing education for pharmacists. We raise one issue.

Subsection (b) states that: "[a] 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." What are the consequences for failure to meet the 6-month deadline? Has the Board considered including penalties in the regulation?

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE

DATE: **May 15, 2009**

SUBJECT: **Final Rulemaking:**
State Board of Pharmacy
Continuing education (16A-5417)

TO: **Andrew C. Clark, Deputy General Counsel**
Office of General Counsel

FROM: **Thomas A. Blackburn, Regulatory Unit Counsel**
Department of State

There are no significant legal and policy issues presented by this amendment to the regulations of the State Board of Pharmacy concerning continuing education.

I certify that I have reviewed this regulation for form and legality, that I have discussed any legal and policy issues with the administrative officers responsible for the program, and that all information contained in the Preamble and Annex is correct and accurate.

TAB

COMMENTATOR'S LIST FOR
Regulation 16A-5417

STEVE MAVROS PRESIDENT
APA
3863-900 UNION DEPOSIT ROAD
HARRISBURG PA 17109

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)

_____
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: Michael A. Podgurski
Michael A. Podgurski, RPh

TITLE: Chairperson
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

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

BY: Andrew C. Clark

OCT 9 2008
DATE OF APPROVAL

(Deputy General Counsel
~~(Chief Counsel~~,
~~Independent Agency~~
(Strike inapplicable title)

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

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

FINAL RULEMAKING

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF PHARMACY

49 Pa. Code §§ 27.1, 27.32
CONTINUING EDUCATION

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

Description and Need for the Rulemaking

Section 3.1 of the Pharmacy Act (Act) (63 P.S. § 390-3.1) authorizes the Board to require licensees to complete continuing education and to promulgate regulations to enforce that requirement. The Board has done so by promulgating § 27.32 (relating to continuing education). However, the Board determined that its regulation should be updated and in January of 2008, the Board published proposed rulemaking to make certain updates.

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 5 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, this rulemaking amends the current regulation to make it clear that, in general, only ACPE-accredited providers of continuing education are acceptable. In addition, the Board reviewed the regulation and determined that other updates are needed, specifically with regard to requiring continuing education in the area of 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.

This rulemaking amends § 27.1 to reflect the change of name for ACPE from the American Council of Pharmaceutical Education to the Accreditation Council for Pharmacy Education. The rulemaking also amends § 27.32 to clarify that, with limited exceptions, the Board only accepts ACPE-accredited providers of continuing education. The rulemaking further amends § 27.32 to delete the term "approved" after ACPE, as ACPE accredits providers instead of approving them.

This rulemaking adds a requirement that 2 of the required 30 hours of continuing education be completed in courses under the ACPE topic designator "Patient Safety." This change will go into effect beginning with the license period commencing on October 1, 2011. 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 pharmacists aware of common errors and ways to prevent them. Recently ACPE introduced new topic designators, which make it easier for licensees and the auditing agents to determine if a course fills under a certain topic. 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 rulemaking codifies the Board's 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 will 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, will 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. The Board cannot simply let licensees make up deficient continuing education in place of disciplinary action, for that would encourage licensees to avoid the continuing education obligation until being discovered in an after-the-fact audit and then complete the required continuing education without consequence.

Finally, the rulemaking requires that any application for approval from a continuing education program provider that is not ACPE-accredited be submitted to the Board no less than 60 days prior to the start of the program. This requirement is necessary to give the Board ample time to review a program for equivalency to ACPE standards before the program takes place.

Summary of Comments and Responses to Proposed Rulemaking

The Board published notice of proposed rulemaking at 38 Pa.B. 350 (January 19, 2008) with a 30-day public comment period. The Board received comments from the Pennsylvania Pharmacists Association (PPA), but from no other members of the public. The Board received comments from the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC) as part of their review of proposed rulemaking under the Regulatory Review Act (71 P.S. §§ 745.1-745.12). The Board did not receive any comments from the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC).

The PPA supported the proposed rulemaking. Other than a language format question that has been resolved by the Legislative Reference Bureau in accordance with standards of the Pennsylvania Code & Bulletin *Style Manual*, the HPLC had no comment.

IRRC questioned what the penalty would be for a licensee who failed within 6 months to make up delinquent contact hours of continuing education, as required in proposed § 27.32(b), and whether such a penalty should be included in the rulemaking. Existing § 27.32(i) provides that a pharmacist who fails to comply with the continuing education requirements, e.g., upon request failing to provide proof of completion of the required amount of continuing education during the biennial period, is subject to disciplinary action. Under § 27.32(b), a licensee who failed to complete the required amount of continuing education must make up the deficiency within 6 months, regardless of any other sanction imposed. The Board may revoke or suspend the license of a pharmacist who has violated the act or regulations of the Board. Section 5(a)(6) of the act (63 P.S. § 390-5(a)(6)). The Board may impose a civil penalty of up to $1,000 on any licensee who has violated the act. Section 8(15.1) of the act (63 P.S. § 390-8(15.1)). The result is that a pharmacist who does not complete continuing education when required or does not make up the deficiency timely will be subject to disciplinary action, with the possibility of a suspension of the pharmacist's

license and the imposition of a civil penalty. The Board is considering whether it should standardize the amount of a civil penalty for failure to complete continuing education timely. Because a civil penalty may be levied through issuance of a citation under a schedule promulgated by the Commissioner of Professional and Occupational Affairs, the Board will consider doing so in a separate rulemaking.

The Board has not found a need to revise its rulemaking in response to the comments. However, in the course of reviewing these comments, the Board noticed that § 27.32(b) referred to producing certificates upon demand of its "auditing agents" and determined that this should be upon demand simply of the Board's "agents."

Fiscal Impact and Paperwork Requirements

The final-form rulemaking will have no adverse fiscal impact on the Commonwealth or its political subdivisions and will impose no additional paperwork requirements upon the Commonwealth, political subdivisions or the private sector.

Effective date

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

Statutory Authority

The final rulemaking is authorized under sections 3.1 and 6(k) of the act (63 P.S. §§ 390-3.1 and 390-6(k)).

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 the notice of proposed rulemaking, published at 38 Pa.B. 351, to IRRC and the chairpersons of the HPLC and the 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 received 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 _____ ___, 2009, the final-form rulemaking was approved by the HPLC. On _____ ___, 2009, the final-form rulemaking was deemed approved by the SCP/PLC. Under section 5(g) of the Regulatory Review Act, IRRC was deemed to have approved the final-form rulemaking.

Additional Information

Persons who require additional information about the final-form rulemaking should submit inquiries to Regulatory Unit Counsel, Department of State, by mail to P.O. Box 2649, Harrisburg, PA 17105-2649, by telephone at (717) 783-7156, or by e-mail at st-pharmacy@state.pa.us.

Findings

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) and regulations promulgated thereunder, 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) The amendments to this final-form rulemaking do not enlarge the scope of proposed rulemaking published at 38 Pa.B. 350.

(4) The final-form rulemaking adopted by this order is necessary and appropriate for the administration of the Pharmacy Act.

Order

The Board, acting under its authorizing statute, orders that:

(a) The regulations of the Board at 49 Pa. Code Chapter 27 are amended, by amending §§ 27.1 and 27.32, to read as set forth in Annex A.

(b) The Board shall submit this order and 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 A and deposit them with the Legislative Reference Bureau as required by law.

(d) The final-form rulemaking shall take effect upon publication in the *Pennsylvania Bulletin*.

Michael A. Podgurski, RPh, Chairperson
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:

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 OCTOBER 1, 2011 ~~*(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 adoption of this proposed rulemaking)*~~, 2 of the required 30 contact hours shall 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] must 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), a 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 at least 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

November 2, 2009

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

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

Dear Chairman Coccodrilli:

Enclosed is a copy of a final 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,

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

MAP/TAB:rs
Enclosure
cc: Basil L. Merenda, Commissioner
Bureau of Professional and Occupational Affairs
Peter V. Marks, Executive Deputy Chief Counsel
Department of State
Joyce McKeever, Deputy Chief Counsel
Department of State
Cynthia Montgomery, Regulatory Counsel & Senior Counsel in Charge
Department of State
Thomas A. Blackburn, 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

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

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
		HOUSE COMMITTEE ON PROFESSIONAL LICENSURE
11/2	K. Lutz	MAJORITY CHAIRMAN Michael P. McGeehan
		SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE
11/2	D.H	MAJORITY CHAIRMAN Robt. M. Tomlinson
11/2	N Schnee	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

October 13, 2009