RULES AND REGULATIONS

Title 49—BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

STATE BOARD OF PHARMACY

[49 PA. CODE CH. 27]

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 falls 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 shall 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, for example, 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 shall 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 section 3.1 and section 6(k) of the act (63 P. S. § 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. 350, 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 November 18, 2009, the final-form rulemaking was approved by the HPLC. On December 9, 2009, the final-form rulemaking was deemed approved by the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on December 10, 2009, and 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, (717) 783-7156, or 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 (relating to notice of proposed rulemaking required; and adoption of regulations).

(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 act.

Order

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

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

(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

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 39 Pa.B. 7272 (December 26, 2009).)

Fiscal Note: Fiscal Note 16A-5417 remains valid for the final adoption of the subject regulations.

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 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, 2 of the required 30 contact hours shall be completed in courses from the ACPE topic designator "Patient Safety." 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 § 27.401 (relating to qualifications for authority), at least 2 of the required 30 hours 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. 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 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 agents. The Board will utilize a random audit of 5% of renewals to determine compliance with 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.

(c) Both live and correspondence courses will be accepted by the Board as long as they are offered by approved providers.

(d) An excess of completed contact hours in one renewal period will not be carried over into the next renewal period.

(e) A newly graduated licensee will be exempt from the requirements in subsection (a) for the license renewal immediately following licensure. A reciprocally licensed pharmacist will be required to show compliance with the requirements in subsection (a), but will have the number of hours required to be completed prorated, on a quarterly basis, from the date of licensure to the next date of renewal. For this purpose, each quarter will consist of 3 months, and will be credited for 3.75 contact hours (.375 CEU). The pharmacist will be required to begin accumulating contact hours at the beginning of the next quarter following licensure.

(f) A pharmacist whose license has been suspended or revoked for disciplinary reasons shall comply with continuing education requirements during the period of suspension or revocation, if the pharmacist wants to resume practice or petition for licensure reinstatement at the conclusion of the disciplinary period.

(g) The Board will consider renewing a license without timely filing of the required hours of continuing education on a case by case basis, upon a showing of incapacity, acute illness or other circumstances which reasonably precluded timely compliance. Pharmacists whose licenses are renewed under this subsection will be required to make up the missing hours of continuing education on a schedule determined by the Board, and to pay applicable fees and fines.

(h) Continuing education program providers which are not ACPE-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.

(i) A pharmacist who fails to comply with this section, or who submits fraudulent contact hour reports, will be subject to disciplinary action.

[Pa.B. Doc. No. 10-274. Filed for public inspection February 13, 2010, 9:00 a.m.]

Title 58—RECREATION

PENNSYLVANIA GAMING CONTROL BOARD

[58 PA. CODE CH. 529]

Temporary Table Game Licensing Regulations

The Pennsylvania Gaming Control Board (Board), under its general authority in 4 Pa.C.S. § 1303A (relating to temporary table game regulations) enacted by the act of January 7, 2010 (Act 1) and the specific authority in 4 Pa.C.S. §§ 1317 and 1317.1 (relating to supplier licensees; and manufacturer licenses), adopts temporary regulation in Chapter 529 to read as set forth in Annex A. The Board's temporary regulations will be added to Part VII (relating to Gaming Control Board) as part of a new Subpart K entitled Table Games.

Purpose of the Temporary Rulemaking

This temporary rulemaking sets forth requirements related to licensing of table game device manufacturers, manufacturer designees and suppliers and allows the issuance of temporary credentials to gaming employees.

Explanation of Chapter 529

Section 529.1 establishes the requirements related to the issuance of a conditional table game device license to entities that have applied for a table game device manufacturer, manufacturer designee or supplier license.

Act 1 authorizes the conduct of table games in this Commonwealth. As part of Act 1, entities that want to manufacture or supply table game devices are required to obtain a table game device manufacturer, manufacturer designee or supplier license. For entities that are not currently licensed by the Board, this will require the entities to file a manufacturer, manufacturer designee or supplier license application. Typically, these applications can take a year or more to process due to the extensive background investigations that are required. However, slot machine licensees who obtain a table game operation

certificate will need to be able to purchase table game devices in the coming months.

To address this need, the Board has decided that it may issue conditional licenses to table game device manufacturer, manufacturer designee or supplier applicants who meet the requirements contained in § 529.1 (relating to table game devices—conditional licenses). More specifically, these applicants will have to: have submitted a complete licensing application; be licensed in good standing in a jurisdiction that has licensing standards which provide similar safeguards to those in this Commonwealth; have an expression of interest in acquiring the equipment they manufacture or supply from a slot machine applicant or licensee or a manufacturer designee or supplier licensee; have successfully completed a preliminary screening, including a criminal background check; and have paid the applicable application and licensing fee. To date, the Board has determined that New Jersey, Nevada, Mississippi and Louisiana have licensing standards that are equivalent to this Commonwealth.

Table game device manufacturer, manufacturer designee or supplier applicants who meet these requirements will be able to begin to provide table game devices while the review of their license application continues. If however, as part of the continuing investigation, the Office of Enforcement Counsel issues a Notice of Recommendation of Denial, the Bureau of Licensing may rescind the conditional license. If this occurs, the Bureau of Licensing will notify the applicant and all slot machine applicants and licensees and manufacturers, manufacturer designee and supplier licensees that the applicant is no longer authorized to provide table game devices in this Commonwealth. This notice will be sent by registered mail and contain a date after which the applicant will no longer be able to provide table game devices.

Under § 529.2 (relating to temporary credentials for gaming employees), gaming employees who are required to obtain an occupation permit will be able to obtain a temporary credential. This will allow gaming employees in critical positions to work in a licensed facility before their permit is issued.

Affected Parties

Slot machine licensees will benefit from this rulemaking because they will have more sources from whom they may obtain table game devices in a shorter period of time. Applicants for table game device manufacturer, manufacturer designee or supplier licenses will benefit by being able to offer their products in this Commonwealth sooner.

Employees who are required to obtain an occupation permit will be able to obtain a temporary credential which will allow them to work in a licensed facility before their permit is issued.

Fiscal Impact

Commonwealth

The Board does not anticipate that there will be any significant net costs or savings to the Board or any other Commonwealth agency as a result of this rulemaking. This is because the costs associated with the review of applications are recovered from the applicants.

Political Subdivisions

This rulemaking will have no direct fiscal impact on political subdivisions of this Commonwealth.

Private Sector

This rulemaking will make it easier for slot machine applicants and licensees to obtain table game devices in the coming months. It will also allow table game device manufacturer, manufacturer designee or supplier applicants to offer their products in this Commonwealth sooner.

Table game device manufacturer, manufacturer designee and supplier applicants will have to complete the applicable existing Board license application forms and pay all of the associated application, investigation and licensing fees. However, there will be no additional forms required or fees imposed in connection with the conditional licenses.

General Public

This rulemaking will have no fiscal impact on the general public.

Paperwork requirements

This rulemaking will not require applicants to file any separate or additional application forms or materials to be considered for a conditional license. These applicants will however be required to file the normal applications and related materials for a manufacturer, manufacturer designee or supplier license.

Effective Date

This temporary rulemaking will become effective upon publication in the *Pennsylvania Bulletin*.

Public Comments

While this rulemaking will be effective upon publication, the Board is seeking comments from the public and affected parties as to how these temporary regulations might be improved. Interested persons are invited to submit written comments, suggestions or objections regarding this temporary rulemaking, within 30 days after the date of publication in the *Pennsylvania Bulletin* to Richard Sandusky, Director of Regulatory Review, Pennsylvania Gaming Control Board, P. O. Box 69060, Harrisburg, PA 17106-9060, Attention: Public Comment on Regulation #125-111.

Contact Person

The contact person for questions about this rulemaking is Richard Sandusky, Director of Regulatory Review, at (717) 214-8111.

Regulatory Review

Under 4 Pa.C.S. § 1303A, the Board is authorized to adopt temporary regulations which are not subject to the provisions of: sections 201, 202, 203, 204 and 205 of the act of July 31, 1968 (P. L. 769, No. 240), referred to as the Commonwealth Documents Law; the Regulatory Review Act (71 P.S. §§ 745.1—745.12); and sections 204(b) and 301(10) of the Commonwealth Attorneys Act (71 P. S. §§ 732-204(b) and 732-301(10)). These temporary regulations shall expire 2 years after publication in the *Pennsylvania Bulletin*.

Findings

The Board finds that:

(1) Under 4 Pa.C.S. § 1303A, the temporary regulations are exempt from the requirements of the Regulatory Review Act, sections 201—205 of the Commonwealth Documents Law and sections 204(b) and 301(10) of the Commonwealth Attorney Act.

(2) The adoption of the temporary regulations is necessary and appropriate for the administration and enforcement of 4 Pa.C.S. Part II (relating to gaming).

Order

The Board, acting under 4 Pa.C.S. Part II, orders that:

(1) The regulations of the Board, 58 Pa. Code, are amended by adding temporary §§ 529.1 and 529.2 to read as set forth in Annex A.

(2) The temporary regulations are effective February 13, 2010.

(3) The temporary regulations will be posted on the Board's web site and published in the *Pennsylvania Bulletin*.

(4) The temporary regulations shall be subject to amendment as deemed necessary by the Board.

(5) The Chairperson of the Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

GREGORY C. FAJT,
Chairperson

Fiscal Note: 125-111. No fiscal impact; (8) recommends adoption.

Annex A

Title 58. RECREATION

PART VII. GAMING CONTROL BOARD

Subpart K. TABLE GAMES

CHAPTER 529. GENERAL LICENSING REQUIREMENTS

Sec.
529.1. Table game devices—conditional licenses.
529.2. Temporary credentials for gaming employees.

§ 529.1. Table game devices—conditional licenses.

(a) The Board may grant an applicant for a table game device manufacturer, manufacturer designee or supplier license a conditional license to conduct table game business in this Commonwealth, prior to licensure.

(b) To be eligible to obtain a conditional table game device license, the applicant for a table game device manufacturer, manufacturer designee or supplier license shall:

(1) Submit a completed manufacturer, manufacturer designee or supplier license application.

(2) Be licensed in good standing to manufacture or provide table game devices in another jurisdiction in the United States or Canada that the Board has determined has licensing standards that are comprehensive and thorough and provide similar adequate safeguards as those required by the act.

(3) Submit a written statement from a slot machine licensee or applicant, a supplier licensee or a manufacturer designee licensee that the slot machine licensee or applicant, the supplier licensee or the manufacturer designee licensee may do business with the applicant for the purpose of purchasing, selling or marketing table game devices.

(4) Pass a preliminary review of the application and criminal history investigation.

(5) Submit full payment for the table game device manufacturer, manufacturer designee or supplier license prior to the issuance of the conditional license.

(c) An applicant for a table game device manufacturer, manufacturer designee or supplier license that has received a conditional license shall provide monthly transaction reports to the Bureau of Licensing by the 20th calendar day of the following month during the period of conditional licensure. The monthly transaction reports must include:

(1) The date table game devices were provided to an applicant or licensee.

(2) A description of the table game devices provided.

(3) The amount paid by the applicant or licensee for the table game devices.

(4) A copy of the invoice for the table game devices.

(d) If the Office of Enforcement Counsel issues a Notice of Recommendation for Denial to an applicant for a table game device manufacturer, manufacturer designee or supplier license that has received a conditional license, the Bureau of Licensing may rescind the conditional license issued to the applicant. If the conditional license is rescinded, the applicant shall cease conducting business by the date specified in the notice of the rescission sent to the applicant by the Bureau of Licensing under subsection (e).

(e) When the Bureau of Licensing rescinds a conditional license, the Bureau of Licensing will notify the holder of the conditional license and all slot machine licensees or applicants, supplier licensees and manufacturer designee licensees by registered mail that:

(1) Permission for the applicant to conduct business under subsection (a) has been rescinded.

(2) Slot machine licensees or applicants, supplier licensees and manufacturer designee licensees shall cease conducting business with the applicant by the date specified in the notice.

(f) Pending a hearing on the Notice of Recommendation for Denial, the applicant may not seek or conduct any new business in this Commonwealth and may only complete transactions that were commenced prior to the date specified in the notice of rescission.

§ 529.2. Temporary credentials for gaming employees.

(a) A temporary credential may be issued by the Board to a gaming employee whose investigation for a permit is pending but whose presence is necessary in the licensed facility.

(b) A temporary credential issued under this section shall be void 180 days after the date of issuance.

(c) The Board may extend the expiration date of a temporary credential if the Board determines additional time is needed to complete the investigation for the permit.

[Pa.B. Doc. No. 10-275. Filed for public inspection February 12, 2010, 9:00 a.m.]