

PROPOSED RULEMAKING

PENNSYLVANIA GAMING CONTROL BOARD

[58 PA. CODE CH. 461a]

Slot Machine Testing and Control

The Pennsylvania Gaming Control Board (Board), under the general authority in 4 Pa.C.S. § 1202(b)(30) (relating to general and specific powers) and the specific authority in 4 Pa.C.S. § 1207 (relating to regulatory authority of board) proposes to amend Chapter 461a (relating to slot machine testing and control) to read as set forth in Annex A.

Purpose of the Proposed Amendments

These proposed amendments add provisions governing how slot machine licensees should treat unredeemed gaming vouchers.

Explanation of Amendments to Chapter 461a

The Board's current regulations require that gaming voucher systems must be in compliance with the Board's technical standards. The Board has recently amended the technical standards related to gaming vouchers to eliminate the requirement that gaming vouchers have an expiration date. The Board also revised the technical standards to clarify that Article XIII.I of The Fiscal Code (code) (72 P. S. §§ 1301.1—1301.28a) regarding the disposition of abandoned and unclaimed property applies to unredeemed gaming vouchers.

Consistent with those changes the Board is proposing to amend §§ 461a.1 and 461a.8 (relating to definitions; and gaming vouchers). In § 461a.1, the Board is adding a definition of "unredeemed gaming voucher." In § 461a.8, the Board is adding new requirements which must be addressed in each slot machine licensee's internal controls. More specifically, slot machine licensees will be required to establish procedures: to pay the value of unredeemed gaming vouchers to patrons that can be identified by the slot machine licensee; to track unredeemed gaming vouchers and forward the unredeemed gaming vouchers to the State Treasurer as required by Article XIII.I of the code; and to file copies with the Board of any reports submitted to State Treasurer related to the unredeemed vouchers.

Affected Parties

Slot machine licensees will have clearer guidance as to how they should treat unredeemed gaming vouchers.

There are currently 11 slot machine licensees.

Fiscal Impact

Commonwealth

There will be no new costs to the Board or other Commonwealth agencies as a result of this amendment. Reports filed with the State Treasurer by the slot machine licensees will be handled by existing staff.

Political Subdivisions

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

Private Sector

Slot machine licensees will be required to track unredeemed gaming vouchers and forward them to the State Treasurer as required by Article XIII.I of the code.

General Public

The Board anticipates that some patrons who did not redeem gaming vouchers issued to them will benefit by receiving the value of the unredeemed vouchers from the slot machine licensees.

Paperwork requirements

The proposed amendments will require slot machine licensees to annually prepare reports for the State Treasurer and submit copies of those reports to the Board.

Effective Date

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

Public Comments

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed rulemaking, within 30 days after the date of publication in the *Pennsylvania Bulletin* to Paul Resch, Secretary, Pennsylvania Gaming Control Board, P. O. Box 69060, Harrisburg, PA 17106-9060, Attention: Public Comment on Regulation No. 125-78.

Contact Person

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

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 the Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Gaming Oversight Committee and the Senate Community, Economic and Recreational Development 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 to 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 which 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.

MARY DIGIACOMO COLINS,
Chairperson

Fiscal Note: 125-78. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 58. RECREATION

PART VII. GAMING CONTROL BOARD

Subpart E. SLOT [MACHINE TESTING, CERTIFICATION AND CONTROL] MACHINES AND ASSOCIATED EQUIPMENT

CHAPTER 461a. SLOT MACHINE TESTING AND CONTROL

§ 461a.1. Definitions.

The following words and terms, when used in this subpart, have the following meanings, unless the context clearly indicates otherwise:

* * * * *

Unredeemed gaming voucher—A gaming voucher that has not been presented to a slot machine licensee for redemption or a gaming voucher that has been found and returned to a slot machine licensee.

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§ 461a.8. Gaming vouchers.

* * * * *

(b) The design specifications for a gaming voucher, [the expiration terms applicable thereto,] the voucher verification methodologies utilized and any limitation on the value of a gaming voucher must be in compliance with technical standards on gaming vouchers under § 461b.3 (relating to gaming vouchers).

* * * * *

(d) Prior to issuing a gaming voucher, a slot machine licensee shall establish a system of internal controls for the issuance and redemption of gaming vouchers. The internal controls shall be submitted and approved by the Board under § 465a.2 (relating to internal control systems and audit protocols) and address:

* * * * *

(9) Procedures for the payment of the value of unredeemed gaming vouchers to patrons whose identity can be determined by the slot machine licensee.

(10) Procedures for the retention, tracking and payment of the value of unredeemed gaming vouchers to the State Treasurer as required under Article XIII.I of The Fiscal Code (72 P. S. §§ 1301.1—1301.28a) regarding the disposition of abandoned and unclaimed property.

(11) Procedures for filing with the Board a copy of any report submitted to the State Treasurer as required by Article XIII.I of The Fiscal Code.

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[Pa.B. Doc. No. 08-90. Filed for public inspection January 18, 2008, 9:00 a.m.]

STATE BOARD OF NURSING

[49 PA. CODE CH. 21]

Nursing Education Programs Examination Pass Rates

The State Board of Nursing (Board) proposes to amend §§ 21.1, 21.26, 21.33, 21.34, 21.141 and 21.162 and to add §§ 21.33a, 21.33b, 21.162a, 21.162b and 21.166, to read as set forth in Annex A. The proposed amendments set forth requirements and procedures for registered and practical nursing education programs on provisional approval status or subject to removal from approved lists and sets new minimum pass rates of program graduates on the licensing examination.

Effective Date

The proposed amendments will be effective upon publication of the final-form rulemaking in the *Pennsylvania Bulletin*.

Statutory Authority

Section 6.1 of The Professional Nursing Law (RN act) (63 P. S. § 216.1) requires the Board to establish standards for the operation and approval of nursing education programs for the preparation of registered professional nurses. Section 9 of the Practical Nurse Law (LPN act) (63 P. S. § 659) authorizes the Board to approve all schools and institutions that educate practical nurses. The Board is further authorized to establish rules and regulations for the practice of professional nursing and the administration of the RN act under section 2.1(k) of the RN act (63 P. S. § 212.1(k)) and for the practice of practical nursing and the administration of the LPN act under section 17.6 of the LPN act (63 P. S. § 667.6).

Background and Purpose

The proposed amendments result from the Board's ongoing review of nursing education programs and the regulations that govern the programs. The Board published a proposed rulemaking at 31 Pa.B. 809 (February 10, 2001) representing a systematic revision of its registered nursing education program approval regulations. The proposed rulemaking included new requirements for continuing approval of registered nursing programs, including the pass rates of first-time examinees on the licensing examination. The Board withdrew the proposed rulemaking on March 12, 2003, with the intention of republishing the proposal as proposed with a new public comment period.

On April 23, 2004, a draft of the current proposal was sent to 29 agencies, associations, health care entities and individuals who have been identified as interested parties or who have expressed an interest in proposed rulemaking by the Board and to all 128 precicensure nursing education programs (78 RN and 50 LPN programs) which were on the Board's approved list as of December 22, 2003. The Board received three comments, which it reviewed at its meeting on May 27 and 28, 2004.

The Hospital and Healthsystem Association of Pennsylvania (HAP) supported the rulemaking and noted that percentages established by the Board were consistent with HAP's recommendations. HAP suggested that the Board clarify what actions a nursing education program would be required to take with regard to its enrolled students if a program were removed from the approved

list. The Board has addressed this issue in §§ 21.34(b) and (c) and 21.166(b) and (c) (relating to removal from approved list).

A nurse from Avoca, Pennsylvania commented that the draft rulemaking was sound and reasonable.

The practical nursing education program at Wilson College expressed concern for schools that currently calculate pass rates on a quarterly, rather than annual, basis. The commentator also suggested that any program with a pass rate lower than the State average be forbidden from having flexible scheduling of classes and be required to use standard daytime programming. In response to the concerns of Wilson College, the Board defined "examination year" in §§ 21.1 and 21.141 (relating to definitions). Proposed §§ 21.33a(d) and 21.162a(d) (relating to failure to comply with standards; and minimum rate for graduates of nursing education programs to pass the National licensure examination) would authorize the Board to place restrictions on nursing education programs that are on provisional approval status. One restriction might be to restrict the school to standard daytime programming, if such a restriction appeared to advance the objective of bringing the school into compliance with the regulations.

The Board intends to revise the requirements for all nursing education programs regarding the pass rates of program graduates on the National licensure examination. Under existing § 21.26 (relating to failing rate of a school in examination), an approved school for registered nurses is placed on provisional status if less than 60% of its first-time examinees pass the examination. A nursing program which fails to correct deficiencies within 2 years may be removed from the Board's list of approved programs under existing § 21.33(c) (relating to types of approval). The regulations pertaining to the approval of practical nursing education programs in § 21.162 (relating to types of approval) do not currently provide for placement on provisional approval status of a licensed practical nursing school based on failure rates of first-time examinees. The proposed rulemaking would standardize requirements for both registered and practical nursing education programs. In addition, the Board proposes to increase the minimum pass rate over a 2-year period. The pass rate to be initiated in the second year is consistent with the minimum pass rates in other states.

Description of Amendments

The Board is charged with the responsibility of approving and regulating nursing education programs in this Commonwealth. The Board has a three-category approval system—a new program is on initial approval status until it has graduated its first class and demonstrated an acceptable pass rate on the National licensure examination. At that time, the program is placed on full approval status. A program may be placed on provisional approval status if it fails to meet the standards in this chapter. Examples of reasons a program may be placed on provisional approval status include unacceptable student-faculty ratio, inability to conduct clinical educational experiences or failure to meet the minimum pass rate standards. The Board proposes to add a new subsection (b) to § 21.33 that requires a program to notify applicants for admission and students of the program's approval status.

One of the criteria used by the Board, as well as by many other state boards of nursing, in approving a nursing education program is the pass rate of graduates of the program who take the National licensure examination (NCLEX-RN and NCLEX-PN) for the first time.

Under existing § 21.26, the Board will downgrade a registered nursing (RN) education program from fully approved to provisionally approved status if 40% or more of its first time examinees fail the NCLEX. The Board proposes to rescind § 21.26 and move the minimum pass rate to § 21.33b (relating to minimum rate for graduates of nursing education programs to pass the National licensure examination). The Board also proposes to create the same requirements for LPN education programs by the addition of § 21.162b (relating to minimum rate for graduates of nursing education programs to pass the National licensure examination).

Under the proposal, the existing 60% minimum pass rate will continue in effect and will apply to practical nursing education programs on the effective date of this rulemaking. Beginning 1 year after final rulemaking is implemented, a nursing education program will be downgraded from full approval status to provisional approval status if less than 70% of its graduates pass the NCLEX when they take it the first time. Beginning 2 years after final-form rulemaking is implemented, a nursing education program will be downgraded from full approval status to provisional approval status if less than 80% of its graduates pass the NCLEX when they take it the first time.

The Board proposes this change for the following reasons. This Commonwealth's minimum pass rate is the least stringent standard in the Nation when compared with the 32 other states that use the NCLEX pass rate as a criterion for approving a nursing education program. At least seven states have established 75% as the minimum pass rate, at least eight states have established 80% as the minimum and at least four states have established 85% or greater as the minimum. Other states have established a percentage of the National pass rate as the minimum standard for program approval, but in no case less than 10% of the National pass rate. (Source: National Council of State Boards of Nursing Member Board Profiles.)

For the examination year October 1, 2005, to September 30, 2006, 21 of 56 jurisdictions had NCLEX-RN pass rates below that of this Commonwealth. The overall pass rate for first time examinees applying for RN licensure in this Commonwealth who were educated in programs in this Commonwealth during the examination year October 1, 2005, to September 30, 2006, was 87.00%. The overall pass rate for the United States in the same period was 88.11%.

For the examination year October 1, 2005, to September 30, 2006, 20 of 56 jurisdictions had NCLEX-PN pass rates below that of this Commonwealth. The overall pass rate for first time examinees applying for practical nursing licensure in this Commonwealth who were educated in the programs in this Commonwealth during the examination year October 1, 2005, to September 30, 2006, was 90.53%. The overall pass rate for the United States in the same period was 88.22%.

For the examination year October 1, 2005, to September 30, 2006, 16 of the Commonwealth's 80 RN education programs had examination pass rates below 80%. Of these, four were associate degree programs, seven were baccalaureate programs and four were hospital-based diploma programs. For the examination year October 1, 2005, to September 30, 2006, five of this 50 LPN education programs in this Commonwealth had examination pass rates below 80%. Of these, three were vocational-technical schools and two were private licensed schools. If the amendments were in effect and pass rates were

raised to 80% as proposed, these 21 programs would be placed on provisional status. These programs would be required to correct the deficiencies in the program that hinder the program's graduates from satisfactory performance on the NCLEX. If a program fails to achieve the minimum pass rate by a date specified, removal proceedings would commence in accordance with §§ 21.34 and 21.166. Removal proceedings include notice to the program and an opportunity for the program to show why it should not be removed. The Board considered lowering the proposed pass rates, but after consultation with the Board's education advisors, the Board believes that the schools are ready to meet the challenge of the higher pass rate and that the higher pass rate will benefit students in nursing education programs by ensuring the best chance of passing the examination and obtaining licensure. In addition, none of the schools of nursing provided negative comments regarding the proposed amendment to the minimum pass rate.

The proposed amendments will bring this Commonwealth's nursing education programs in line with Nationwide standards and will motivate any marginal programs to improve to the benefit of the students and the general public. A nursing education program unable to prepare at least 80% of its graduates to pass the entrance examination to the profession does its students, recipients of nursing care, and the resources of this Commonwealth, a great disservice. The Board believes that a number of programs are not providing sufficient support services for students which results in lower pass rates for their graduates. It is the Board's understanding that programs with higher pass rates do not necessarily have more resources available to them than programs with lower pass rates; these schools are simply more effective in using their resources. Programs will be given 2 years from the effective date of the amendments to improve pass rates to 80%, so that existing program approval will not be affected. For these reasons, the Board does not anticipate that any programs will necessarily be removed from the approved list based on these increased requirements.

The Board also proposes to clarify the requirements for a nursing education program on provisional approval status in §§ 21.33a and 21.162a. Sections §§ 21.34 and 21.166 will be amended to provide the detailed procedure the Board will follow in removal proceedings. Under the current § 21.34, the Board gives "sufficient" notice of its intent to remove a program. The LPN regulations are silent on the procedure. The proposed amendments will expand and clarify the Board's procedure for RN education programs and create a parallel section for LPN education programs. The proposed amendments will provide the nursing education program 45 days notice of the Board's intent to remove the program. The proposed amendments will specify that the program may appear at a hearing and that posthearing briefs may be filed. The proposal also clarifies that the Board will issue a written decision that may be appealed according to the Pennsylvania Rules of Appellate Procedure. Finally in §§ 21.34(b) and (c) and 21.166(b) and (c), the Board proposes amendments to set forth a program's responsibilities to students if the program is removed from the approved list.

Fiscal Impact and Paperwork Requirements.

The proposed amendments may have a fiscal impact on nursing education programs that fall below the minimum requirements and will impose no additional paperwork on those programs beyond what is already required for the maintenance of the nursing education program. The

amendments will not otherwise have any fiscal impact nor impose additional paperwork on the private sector, the general public and the Commonwealth and its political subdivisions.

Sunset Date

The Board continuously monitors its regulations. 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 to the proposed rulemaking within 30 days from 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 and objections raised.

Public Comment

Interested persons are invited to submit written comments, recommendations or objections regarding this proposed rulemaking to Ann Steffanic, Board Administrator, State Board of Nursing, P. O. Box 2649, Harrisburg, Pennsylvania 17105-2649 within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Please reference (16A-5123) Nursing Education Programs Examination Pass Rates when submitting comments.

MARY E. BOWEN, RN, DNS, CNAA,
Chairperson

Fiscal Note: 16A-5123. 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 21. STATE BOARD OF NURSING

Subchapter A. REGISTERED NURSES

GENERAL PROVISIONS

§ 21.1. Definitions.

The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise:

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Examination year—The period beginning on October 1st of a year through September 30th of the following year.

* * * * *

LICENSES

§ 21.26. [Failing rate of a school in examination] (Reserved).

[If 40% or more of the first-time examinees of a school of nursing writing the examination in this Commonwealth fail the examination, the school will be placed on provisional approval status. The Board may consider additional documented statistics concerning the examination scores received in other states by Commonwealth graduates in determining the status of the school.]

APPROVAL OF [SCHOOLS OF] NURSING EDUCATION PROGRAMS

§ 21.31. Surveys; list of approved schools.

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(d) For purposes of activities relating to the approval and status of nursing education programs, the term "Board" used in this subchapter may mean the Board's educational advisors appointed under section 2.1(j) of the act (63 P. S. § 212.1(j)). Only the Board may confer initial approval status on a proposed nursing education program and only the Board may remove a program from the approved list.

§ 21.33. Types of approval.

(a) The Board grants the following types of approval to nursing education programs:

(1) *Initial.* The Board may grant initial approval to a new [schools] nursing education program, with evidence that [acceptable] the standards of this subchapter are being met, for a period of time necessary to evaluate the results of the licensing examination taken by the [first] graduates from the program's first examination year. A program will not be placed on full approval status until it has graduated its first class and the class has achieved an acceptable rate of passing the National licensure examination, as set forth in § 21.33b (relating to minimum rate for graduates of nursing education programs to pass the National licensure examination). A program on initial approval status that fails to achieve an acceptable rate of passing the National licensure examination upon graduation of its first class will be placed on provisional approval status.

[(b)] (2) *Full.* The Board will place on full approval [those schools] a nursing education program which [attain] attains and [maintain the acceptable] maintains the standards [and adhere to the policies and regulations of the Board considered essential for a sound program of nursing education] of this subchapter.

[(c)] (3) *Provisional.* The Board may place on provisional approval a [school] nursing education program not meeting the [acceptable] standards of this subchapter. A nursing education program on full approval status will be placed on provisional approval status if the program fails to meet the provisions of § 21.33b. [A period of 2 years will be the maximum time allowed for the correction of deficiencies resulting in provisional approval. If the standards are not met within this designated time, the school will be removed from the approved list.]

(b) A nursing education program shall notify applicants for admission of the program's approval status and notify applicants and students whenever the program's approval status changes. The program shall provide the Board with a copy of the notice sent to applicants and students. A program shall provide additional notice to applicants and students at the direction of the Board.

§ 21.33a. Failure to comply with standards.

(a) Whenever the Board receives information suggesting that a nursing education program has not maintained the standards of this subchapter, the Board may request information from the program or conduct a site visit and may informally resolve any deficiency. The failure of a program to cooperate will be considered a violation of this section and may result in immediate referral of the program for removal from the approved list as provided in § 21.34 (relating to removal from approved list).

(b) If the Board determines that a nursing education program should be placed on provisional approval status, the Board will notify the program, in writing, that the program has been placed on provisional approval status.

(c) If the Board places a nursing education program on provisional approval status, the Board will notify the program, in writing, of the deficiencies and the amount of time that will be allowed for correction of the deficiencies that resulted in the program's placement on provisional approval status. The Board may extend the time period for correction of deficiencies at its discretion if the program is making demonstrable progress toward the correction of deficiencies. If additional deficiencies are identified, the existing provisional period may be extended at the discretion of the Board.

(d) The Board may place restrictions on a nursing education program on provisional approval status as deemed necessary by the Board to bring the program into compliance with this subchapter. The failure of a program to adhere to the restrictions mandated by the Board will be considered a violation of this section and may result in immediate referral of the program for removal from the approved list as provided in § 21.34.

(e) The Board may require that a nursing education program on provisional approval status prepare and submit additional reports. The failure of a program to timely provide reports required by the Board will be considered a violation of this section and may result in immediate referral of the program for removal from the approved list as provided in § 21.34.

(f) The Board may make announced or unannounced site visits to a nursing education program on provisional approval status.

(g) Two years will be the maximum time allowed for the correction of deficiencies resulting in provisional approval status.

(h) If the standards of this subchapter are met within the designated time, the nursing education program will be removed from provisional approval status and returned to the approved list. The Board will notify the program in writing of this action.

(i) If the standards of this subchapter are not met within the designated time, the nursing education program will be removed from the approved list as provided in § 21.34.

(j) A nursing education program may appeal the decision to place the program on provisional approval status in accordance with 1 Pa. Code § 35.20 (relating to appeals from actions of the staff).

§ 21.33b. Minimum rate for graduates of nursing education programs to pass the National licensure examination.

A nursing education program shall prepare its graduates to pass the National licensure examination at a rate at least equal to the minimum rate set by the Board. The minimum rate for graduates to pass the National licensure examination are as follows:

(1) A nursing education program shall achieve and maintain a minimum pass rate of 60% or more of its first-time examinees during an examination year.

(2) Beginning on October 1, _____ (*Editor's Note: The blank refers to the first October 1 that occurs after the effective date of adoption of this proposed rulemaking.*), a nursing education program shall achieve and maintain a minimum pass rate of 70% or more of its first-time examinees during an examination year.

(3) Beginning on October 1, _____ (*Editor's Note: The blank refers to a date 1 year after the date in paragraph (2).*), a nursing education program shall achieve and maintain a minimum pass rate of 80% or more of its first-time examinees during an examination year.

§ 21.34. Removal from approved list.

[The Board will give sufficient notification of intent of removal from the approved list and provide an opportunity for school officials to show cause as to why approval should not be withdrawn.]

(a) The Board may remove a nursing education program from the approved list in accordance with the following procedures if the program fails to meet and maintain minimum standards, including the minimum passing rates on the National licensure examination, as established by this subchapter.

(1) The Board will give a nursing education program notice of its intent to remove the program from the approved list.

(2) The notice of intent to remove a program from the approved list will set forth the alleged violations of the standards for nursing education programs.

(3) A program served with notice of intent to remove will be given 45 days in which to file a written answer to the notice.

(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 is 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 provide for permanent retention of student and graduate records in conformance with §§ 21.123 and 21.125 (relating to access and use of records; and custody of records).

Subchapter B. PRACTICAL NURSES
GENERAL PROVISIONS

§ 21.141. Definitions.

The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise:

* * * * *

Examination year—The period beginning on October 1st of a year through September 30th of the following year.

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APPROVAL OF PRACTICAL NURSING PROGRAMS

§ 21.162. Types of approval.

(a) The Board grants the following types of approval to nursing education programs:

(1) *Initial.* The Board may grant initial approval to a new [programs] nursing education program, with evidence that [acceptable] the standards of this subchapter are being met, for a period of time necessary to evaluate the results of the licensing examination [taken] by the [first] graduates from the program's first examination year. A program will not be placed on full approval status until it has graduated its first class and the class has achieved an acceptable rate of passing the National licensure examination, as set forth in § 21.162b (relating to minimum rate for graduates of nursing education programs to pass the National licensure examination). A program on initial approval status that fails to achieve an acceptable rate of passing the National licensure examination upon graduation of its first class will be placed on provisional approval status.

[(b)] (2) *Full.* The Board will place those nursing education programs on full approval status which attain and maintain the [acceptable] standards [and adhere to the policies and regulations of the Board considered essential for a sound program of practical nursing education] of this subchapter.

[(c)] (3) *Provisional.* The Board may place on provisional approval a nursing education program not meeting [acceptable] the standards of this subchapter. A nursing education program on full approval status will be placed on provisional approval status if the program fails to meet the provisions of § 21.162b.

[Full approval status will not be granted until acceptable standards are met. If acceptable standards are not met, the program will be removed from the approved list.]

(b) A nursing education program shall notify applicants for admission of the program's approval status and notify applicants and students whenever the program's approval status changes. The program shall provide the Board a copy of the notice sent to applicants and students. A program shall provide additional notice to applicants and students at the direction of the Board.

(c) For purposes of activities relating to the approval and status of nursing education programs, the term "Board" used in this subchapter may mean the Board's educational advisors appointed under section 2.1(j) of the act (63 P. S. § 212.1(j)). Only the Board may confer initial approval status on a proposed nursing education program and only the Board may remove a program from the approved list.

§ 21.162a. Failure to comply with standards.

(a) Whenever the Board receives information suggesting that a nursing education program has not maintained the standards of this subchapter, the Board may request information from the program or conduct a site visit and may informally resolve any deficiency. The failure of a program to cooperate will be considered a violation of this section and may result in immediate referral of the program for removal from the approved list as provided in § 21.166 (relating to removal from approved list).

(b) If the Board determines that a nursing education program should be placed on provisional approval status, the Board will notify the program, in writing, that the program has been placed on provisional approval status.

(c) If the Board places a nursing education program on provisional approval status, the Board will notify the program, in writing, of the deficiencies and the amount of time that will be allowed for correction of the deficiencies that resulted in the program's placement on provisional approval status. The Board may extend the time period for correction of deficiencies at its discretion if the program is making demonstrable progress toward the correction of deficiencies. If additional deficiencies are identified, the existing provisional period may be extended at the discretion of the Board.

(d) The Board may place restrictions on a nursing education program on provisional approval status as deemed necessary by the Board to bring the program into compliance with this subchapter. The failure of a program to adhere to the restrictions mandated by the Board will be considered a violation of this section and may result in immediate referral of the program for removal from the approved list as provided in § 21.166.

(e) The Board may require that a nursing education program on provisional approval status prepare and submit additional reports. The failure of a program to timely provide reports required by the Board will be considered a violation of this section and may result in immediate referral of the program for removal from the approved list as provided in § 21.166.

(f) The Board may make announced or unannounced site visits to a nursing education program on provisional approval status.

(g) Two years will be the maximum time allowed for the correction of deficiencies resulting in provisional approval status.

(h) If the standards of this subchapter are met within the designated time, the nursing education program will be removed from provisional approval status and returned to the approved list. The Board will notify the program in writing of this action.

(i) If the standards of this subchapter are not met within the designated time, the nursing education program will be removed from the approved list as provided in § 21.166.

(j) A nursing education program may appeal the decision to place the program on provisional approval status in accordance with 1 Pa. Code § 35.20 (relating to appeals).

§ 21.162b. Minimum rate for graduates of nursing education programs to pass the National licensure examination.

A nursing education program shall prepare its graduates to pass the National licensure examination at a rate at least equal to the minimum rate set by the Board. The minimum rate for graduates to pass the National licensure examination are as follows:

(1) A nursing education program shall achieve and maintain a minimum pass rate of 60% or more of its first-time examinees during an examination year.

(2) Beginning on October 1, _____ (*Editor's Note: The blank refers to the first October 1 after the effective date of adoption of this proposed rulemaking.*), a nursing education program shall achieve and maintain a minimum pass rate of 70% or more of its first-time examinees during an examination year.

(3) Beginning on October 1, _____ (*Editor's Note: The blank refers to a date 1 year after the date of the adoption of this proposed rulemaking.*), a nursing education program shall achieve and maintain a minimum pass rate of 80% or more of its first-time examinees during an examination year.

§ 21.166. Removal from approved list.

(a) The Board may remove a nursing education program from the approved list in accordance with the following procedures if the program fails to meet and maintain minimum standards, including the minimum passing rates on the National licensure examination, as established by this subchapter.

(1) The Board will give a nursing education program notice of its intent to remove the program from the approved list.

(2) The notice of intent to remove a program from the approved list will set forth the alleged violations of the standards for nursing education programs.

(3) A program served with notice of intent to remove will be given 45 days in which to file a written answer to the notice.

(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 § 27.32 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 accredited 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-

cist to take a 30-minute break, but still be available for emergencies or counseling if needed.

Effective Date

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

Statutory Authority

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

Background and Need for Amendment

Currently, the Board does not have regulations pertaining to when and how a sole pharmacist on duty may take a break while the pharmacy remains open. The Board's regulations only state that a pharmacy may not be open without a licensed pharmacist present and on duty. This has created a disparity among different types of pharmacies. In traditional "drug stores" the entire building is licensed as a pharmacy, therefore a pharmacist may take a break anywhere in the store and still be in the pharmacy. However, in large retail establishments only the area containing the pharmacy is licensed. Retail establishments include large wholesale stores, grocery stores and retail stores. Because the regulation mandates that the pharmacy must be closed when the pharmacist is not present in the pharmacy, the pharmacy must close if the pharmacist leaves the pharmacy to take a break in another area of the retail store. This has put retail establishments at a disparity with the more traditional drug stores.

Description of Proposed Amendments

The Board proposes to amend § 27.11(c) to state that the prescription area of a pharmacy may not be open without a licensed pharmacist on duty at all times. This is to clarify that the retail area in a traditional drug store where the whole building is licensed as a pharmacy may still be open when the prescription area is closed. The prescription area is already defined in § 27.1 (relating to definitions) as the area of the pharmacy used for compounding, legend drug storage and other activities necessary to the practice of pharmacy. The term prescription area does not include waiting counters or display space attached to the waiting counters. The Board also proposes to amend § 27.11(c) to allow a sole pharmacist on duty in a pharmacy to take up to a 30-minute break. The proposed amendment does not affect multiple pharmacists on duty taking staggered breaks. If only one pharmacist is on duty, the pharmacist shall remain in the building containing the pharmacy during the break. For pharmacies where the entire building is licensed this does not change current practice. However for pharmacies located in large retail establishments and institutions, the pharmacist shall remain in the immediate building. The immediate building is defined as the physical structure that contains the pharmacy. For example in a large retail, wholesale or grocery store, the pharmacist shall remain in that store. In an institution, the pharmacist shall remain in the building containing the pharmacy, so that in institutions on a campus with multiple buildings, the pharmacist could not go to another building during a break. Pharmacies located in malls are not included in the class of pharmacies that only have a portion of the store licensed, as those pharmacies are typically the traditional retail pharmacy where the entire store is licensed. If a large retail establishment with a pharmacy inside is attached to a mall, the restriction that the pharmacist shall remain in the retail establishment ap-

plies. The pharmacist should not leave the store to go into the mall while the pharmacy remains open.

The Board proposes to add § 27.11(c)(2) to allow a pharmacy to remain open during a sole pharmacist's break to receive new written prescriptions, prepare prescriptions for final verification by the pharmacist and to deliver prescription medications that have already been verified by the pharmacist.

Finally, the Board proposes to amend § 27.16(b)(2)(iii) to cross reference § 27.11(c)(1) and add and define the term "immediate building."

With the implementation of these standards, the Board intends to allow pharmacists to take breaks as needed while still being available for counseling or other emergencies. The public is protected because while the pharmacist is away from the pharmacy, no prescriptions could be delivered to a patient that were not first verified by the pharmacist; however new written prescriptions could be accepted and pharmacy technicians and pharmacy interns may prepare prescriptions for final verification.

Fiscal Impact

The proposed amendments will have no fiscal impact on the Board or the regulated community.

Paperwork Requirements

The proposed amendments will impose no paperwork requirements on the Board or the regulated community.

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 these proposed amendments 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 amendments 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 amendments in the *Pennsylvania Bulletin*.

EDWARD J. BECHTEL, R.Ph.,
Chairperson

Fiscal Note: 16A-5420. 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

§ 27.11. Pharmacy permit and pharmacist manager.

* * * * *

(c) [A] The prescription area of a pharmacy may not be open without a licensed pharmacist on duty at all times. A sole pharmacist on duty may take up to a 30-minute break while working in a pharmacy consistent with the following:

(1) The pharmacist shall remain in the pharmacy or, in the case of a pharmacy located within a retail establishment or institution, in the immediate building containing the pharmacy, and shall be accessible for emergencies or for counseling, if requested. For purposes of this paragraph, the term "immediate building" means the physical structure that contains the pharmacy. A pharmacy located at a complex consisting of multiple retail and other business establishments, such as a mall, is not considered to be "located within a retail establishment." In that case, the entire store containing the pharmacy is licensed, and the pharmacist shall remain in the store during a break.

(2) The pharmacy may remain open during the pharmacist's break for patient-related services, including:

(i) The receipt of new written prescriptions.

(ii) The preparation of prescriptions for final verification by the pharmacist.

(iii) The delivery of prescription medications that have been verified by the pharmacist.

* * * * *

§ 27.16. Construction and equipment requirements.

* * * * *

(b) Building standards. The following apply to building standards:

* * * * *

(2) Pharmacies in retail establishments. Pharmacies located within retail establishments whose business hours differ shall adhere to the following standards:

* * * * *

(iii) The pharmacy shall be closed whenever a licensed pharmacist is not present in the immediate building and on duty. For purposes of this section, the term "immediate building" has the same meaning given to it in § 27.11(c)(1) (relating to pharmacy permit and pharmacist manager).

* * * * *

[Pa.B. Doc. No. 08-93. Filed for public inspection January 18, 2008, 9:00 a.m.]