

RULES AND REGULATIONS

Title 22—EDUCATION

DEPARTMENT OF EDUCATION

[22 PA. CODE. CH. 335]

Community College Courses

The Secretary of the Department of Education (Department) adopts Chapter 335 (relating to community college courses) which contains standards for credit and non-credit courses at community colleges that will be eligible for reimbursement by the Commonwealth under Article XIX-A of the Public School Code of 1949 (act) (24 P. S. §§ 19-1901-A—19-1913-A). The proposed standards are set forth in Annex A and are promulgated under authority of section 1913-A(b)(1.2) of the act (24 P. S. § 19-1913-A(b)(1.2)).

Purpose

These standards are promulgated by the Secretary in order to comply with an amendment made to the Public School Code of 1949 by the act of June 7, 1993 (P. L. 49, No. 16) (Act 16). The statutory amendment requires the Secretary, in consultation with the community colleges, to promulgate standards for credit and noncredit courses that will be eligible for Commonwealth reimbursement. The statutory amendment further requires that the standards specifically exclude from eligibility for reimbursement any course or program in avocational or recreational pursuits.

The proposed standards were developed in consultation with the community colleges. The Department wrote three successive drafts of the proposed standards. Each draft was distributed among the community colleges and reviewed by a broad spectrum of community college staff, including presidents, deans, faculty, business managers and specialists in continuing education. Each draft was then revised in response to the comments and suggestions from the community college staff.

Requirements of the Standards

The proposed standards establish criteria to be met by all credit and noncredit courses in order for the courses to be eligible for reimbursement by the Commonwealth under Article XIX-A of the act. Many of the criteria, such as those relating to course approval, course structure and course outlines, were drawn from existing policies or practices at community colleges. Others were developed specifically to make a clear distinction between credit and noncredit courses.

The proposed standards also define the terms "avocational course" and "recreational course" and specify that these courses will not be reimbursed by the Commonwealth. Lastly, a schedule is set forth for implementation of the standards, and a complete description of the records necessary for the colleges to document their compliance is included.

Public Comments and Responses

The Department received comments from three community colleges and one senior citizen's center in response to publication of the proposed rulemaking at 24 Pa.B. 5421 (October 29, 1994). The Secretary considered the public comments received during the official public comment period, as well as additional comments from community college presidents after the close of the comment period.

Comments were received from the House Education Committee on February 10, 1995, from the Senate Education Committee on February 13, 1995, and from the Independent Regulatory Review Commission (IRRC) on February 22, 1995.

IRRC recommended moving the definitions for several terms from § 335.12 to § 335.1 (relating to definitions). The Secretary concurs with this recommendation, but expanded the section to include a number of definitions from both Subchapters B and C (relating to credit courses; and noncredit courses). Two community college commentators, together with the House and Senate Education Committees and IRRC, recommended several changes to the descriptive definition of "noncredit courses" in Subchapter C to eliminate extraneous terms and clarify vagueness. Several of the recommendations were adopted. The definition of "noncredit courses" was restructured and the overall organization of Subchapter C was changed to eliminate cumbersome wording and improve parallel construction.

The two community college commentators and the Education Committees questioned the language used in § 335.21 (relating to noncredit courses) to define non-credit courses, such as "not being postsecondary in nature," (having) "less depth or breadth," and (being) "less rigorous."

The Secretary notes that the descriptive terms are connected by the word "or" in order to indicate that noncredit courses differ from credit courses by at least one of the qualifying attributes, but not necessarily all of them. The term "less rigorous" was dropped, but the other two terms were retained. The term "not postsecondary in nature" was retained to ensure reimbursement for remedial, developmental and adult basic and literacy education courses that focus on content typically delivered through elementary and secondary education. This point is reinforced by the wording of §§ 335.13(a) and 335.22(4)(ii) (relating to remedial; and developmental courses). Since some noncredit courses are characterized by less depth and breadth than credit courses with similar content, this term was also retained.

The two community college commentators and the Education Committees also questioned the description of a noncredit course as not being part of a program of study that leads to a formal college award. This was retained as a point of distinction between credit and noncredit courses. The term "formal college award" was defined in § 335.1 as a "collegiate degree, collegiate certificate or collegiate diploma" in accordance with IRRC's suggestion. The Secretary believes that the new definition satisfies the commentators' concerns.

One community college, together with the Education Committees and IRRC, recommended changing the implementation dates proposed in Subchapter D to eliminate retroactivity and to allow reimbursement eligibility for noncredit courses developed between July 1, 1994, and July 1, 1996. The Secretary concurs with the commentators' recommendation to revise implementation dates. Sections 335.32 and 335.33 (relating to existing credit courses; and existing noncredit courses) were changed to provide that, for Fiscal Years 1997-98 and 1998-99, credit and noncredit courses approved by the colleges prior to July 1, 1997, will be reimbursable if they comply with Chapter 35 (relating to community colleges). Clarifying language was inserted to make existing courses reimburs-

able until Fiscal Year 1999-2000. These sections were further changed to provide that, beginning with Fiscal Year 1999-2000, and for each fiscal year thereafter, credit and noncredit courses shall meet the applicable Chapter 335 standards. The requirement for the preparation of lists of credit and noncredit courses was changed to apply to courses approved prior to July 1, 1997, to be consistent with the date change listed in this Preamble. The deadline for the submission of these lists to the Deputy Secretary of Postsecondary and Higher Education was correspondingly changed to October 1, 1997.

The Education Committees recommended adding language to clarify the years for which avocational and recreational courses are reimbursable and those years for which they are not reimbursable. The Secretary believes that this additional language is not necessary in light of the intention of section 1913-A(b)(1.2) of the act which precludes reimbursement for courses or programs in avocational or recreational pursuits beginning with Fiscal Year 1993-94.

IRRC recommended changing the format of § 335.42 (relating to course outlines) to simplify wording and achieve parallel construction in the description of requirements relating to the preparation and maintenance of course outlines. The Secretary concurs with this recommendation and the section was reformatted accordingly. IRRC suggested changing §§ 335.44—335.46 (relating to course evaluation and program audit; college catalog; and faculty qualifications) to include a determinate time period for the retention of course evaluations, program audits, college catalogs and faculty records. The Secretary concurs with the recommendation and the wording was changed to apply the record retention requirements of § 35.66 (relating to retention of records) to these items.

Finally, IRRC noted that since noncredit courses custom designed for employers and agencies are not available to the general public, it may be desirable to delete § 335.45(b) of the proposed rulemaking, which required that adequate descriptions of these courses be developed and maintained by the colleges. IRRC noted that descriptions of course content would, in all probability, be governed by written agreements between the colleges and contracting parties. In accordance with § 35.61(f)(2) (relating to full-time equivalent enrollment), community colleges receive the standard Commonwealth reimbursement for enrollees in these courses if aggregate gross operating costs on an average per student basis are not completely covered by the contracting party. To substantiate their control over the content and delivery of these courses, and to demonstrate their compliance with § 35.61(f)(2), the colleges must be held accountable for developing and maintaining these noncredit course descriptions. Therefore, the Secretary does not concur with the IRRC's recommendation in this regard.

Affected Parties

The regulations will affect community colleges and students at those colleges.

Cost and Paperwork Estimates

The regulations may impose some additional costs to the extent that a given community college's policy for course development, approval and review differs from what is required by the proposed standards. However, the colleges already maintain most of the documentation to support their annual reimbursement claim audits which are conducted by the Comptroller for Labor, Education and Community Services. Moreover, the burden should be

minimal since the standards provide for the use of media other than paper records for verification that courses meet the standards.

Effective Date

These regulations will be effective on July 1, 1997.

Sunset Date

The effectiveness of these regulations will be continually reviewed by the Secretary. Thus, no sunset date is necessary.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on October 19, 1994, the Secretary submitted a copy of these proposed regulations to IRRC and to the Chairpersons of the House and Senate Committees on Education. In addition to submitting the regulations, the Secretary provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form in compliance with Executive Order 1982-2, "Improving Government Regulations." A copy of this material is available to the public upon request. In compliance with section 5(b.1) of the Regulatory Review Act, the Secretary also provided IRRC and the Committees with copies of the comments received.

In preparing these final-form regulations, the Secretary considered the comments received from the Senate Education Committee on February 10, 1994, from IRRC on February 23, 1994, and from the public during the official comment period. The Secretary resubmitted the final-form regulations to the House and Senate Education Committees, and to IRRC on January 27, 1997. In addition to submitting the final-form regulations, the Department provided IRRC and the Committees with a copy of the detailed Regulatory Analysis Form prepared in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation."

These final-form regulations were submitted to IRRC and the Senate and House Education Committees on January 27, 1997. The House Education Committee met on February 5, 1997, and approved the regulations. The regulations were deemed approved by the Senate Education Committee on February 16, 1997. On February 20, 1997, IRRC disapproved the regulations barring publication in the *Pennsylvania Bulletin*. On February 26, 1997, the revised final-form regulations were submitted to IRRC and the Senate and House Education Committees. IRRC met on March 20, 1997, and approved the regulations.

Contact Person

The official responsible for information on the Department's process of promulgating these regulations is Barbara Senior, Director, Bureau of Postsecondary Services, Department of Education, 333 Market Street, Harrisburg, PA 17126-0333, (717) 787-4313. The official responsible for information on the implementation of these regulations is Michael B. Poliakoff, Deputy Secretary for Postsecondary and Higher Education, Department of Education, 333 Market Street, Harrisburg, PA 17126-0333, (717) 787-5041.

Findings

The Secretary finds that:

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

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

(3) The adoption of the standards in the manner provided by this order is necessary and appropriate for administration of the authorizing statute.

Order

The Secretary orders that:

(a) The Secretary, acting under the authorizing statute, orders that the regulations of the Department, 22 Pa. Code, are amended by adding §§ 335.1, 335.2, 335.11—335.13, 335.21—335.23, 335.31—335.33 and 335.41—335.47 to read as set forth in Annex A.

(b) The Secretary will submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for review and approval as to legality and form as required by law.

(c) The Secretary shall certify this order and Annex A and deposit them with the Legislative Reference Bureau, as required by law.

(d) This order will take effect upon publication in the *Pennsylvania Bulletin*.

EUGENE W. HICKOK,
Secretary

(Editor's Note: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 27 Pa.B. 1705 (April 5, 1997).)

Fiscal Note: Fiscal Note 6-255 remains valid for the final adoption of the subject regulations.

Annex A

**TITLE 22. EDUCATION
PART XVI. STANDARDS**

CHAPTER 335. COMMUNITY COLLEGE COURSES

Subch.

- A. GENERAL PROVISIONS**
- B. CREDIT COURSES**
- C. NONCREDIT COURSES**
- D. IMPLEMENTATION**
- E. DOCUMENTATION**

Subchapter A. GENERAL PROVISIONS

- | | |
|--------|--|
| Sec. | |
| 335.1. | Definitions. |
| 335.2. | Standards for reimbursement courses—credit and noncredit—at community college. |

§ 335.1. Definitions.

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

Act—The Public School Code of 1949 (24 P.S. §§ 1-101—27-2702).

Formal college award—A collegiate degree, collegiate certificate or collegiate diploma.

Reimbursement—Commonwealth reimbursement of a portion of a community college's operating costs for equivalent full-time students as defined in section 1913-A of the act (24 P.S. § 19-1913-A).

Remedial or developmental course—A course designed for students who are deficient in the general competencies necessary for a regular postsecondary curriculum and educational setting.

Stipend reimbursement—Commonwealth reimbursement on account of a community college's operating costs for equivalent full-time students enrolled in designated

categories of 2-year or less than 2-year occupational or technical programs as defined in section 1913-A(b)(1.4)(iii) of the act.

§ 335.2. Standards for reimbursable courses—credit and noncredit—at community colleges.

To be eligible for reimbursement by the Commonwealth, each credit and each noncredit course that is offered by a community college shall meet the following criteria:

(1) The course has stated learning goals and consists of a planned sequence of topics or learning activities designed to help students achieve the stated learning goals.

(2) The course is summarized in an outline which includes at least the following elements:

(i) The course title and description.

(ii) The learning goals.

(iii) A planned sequence of topics or learning activities designed to help students achieve the learning outcomes.

(iv) A list of reference, resource or learning materials to be used by the students.

(3) The course is consistent with the college's mission, and is or was developed, approved and offered in accordance with the policies, standards, guidelines and procedures established by the college for the approval of new courses or programs.

(4) An accurate description of the course is published in the college's catalog or other official publication pertaining to the academic semesters, terms or years in which the course is offered. This criterion does not apply to noncredit courses which are custom designed to meet the needs of a particular employer or agency and, therefore, which are not available to the general public.

Subchapter B. CREDIT COURSES

- | | |
|---------|--|
| Sec. | |
| 335.11. | Credit courses. |
| 335.12. | Standards for reimbursable credit courses at community colleges. |
| 335.13. | Remedial and developmental courses. |

§ 335.11. Credit courses.

Credit courses are planned, postsecondary activities designed to enable students to achieve stated learning goals.

§ 335.12. Standards for reimbursable credit courses at community colleges.

To be eligible for reimbursement by the Commonwealth, each credit course offered by a community college shall meet the criteria in § 335.2 (relating to standards for reimbursable courses—credit and noncredit—at community colleges) and the following criteria:

(1) The course is assigned units of credit based on Nationally or regionally accepted practices or guidelines which are consistent with Chapter 35 (relating to community colleges).

(2) The course is delivered, or directly supervised, by an instructor whose qualifications meet the college's requirements for instructors of credit courses.

(3) The course's stated learning outcomes are necessary to enable students to attain the essential knowledge and skills embodied in the program's educational objectives, if the course is a requirement of a degree, certificate or diploma program. The college reevaluates the necessity for the course's learning goals when conducting the academic audit required by § 35.21(b) (relating to non-credit courses).

(4) The course is comparable to similar courses which are generally accepted for transfer of credit to accredited 4-year colleges and universities, if designed for transfer.

(5) The course is articulated with other courses so that it is an elective or a requirement of at least one of the college's programs of study which lead to a formal college award.

(6) The course is an elective or a requirement of a program which does not require the student to have more than 30 credit hours of postsecondary study prior to enrolling in the program unless the program is an upper-division program that was approved in accordance with § 42.21 (relating to approval).

(7) The course is evaluated at least once every 5 years in accordance with § 35.21(b) (relating to curricula) using a method determined by the college.

§ 335.13. Remedial and developmental courses.

(a) Remedial and developmental courses are eligible for reimbursement as credit courses, if they meet the criteria in §§ 335.2 and 335.12(1)–(4) (relating to standards for reimbursable courses—credit and noncredit—at community colleges; and standards for reimbursable credit courses at community colleges). Each college decides for itself whether the courses are approved for credit toward a formal college award.

(b) Remedial and developmental courses are not eligible for stipend reimbursement by the Commonwealth.

Subchapter C. NONCREDIT COURSES

Sec.

335.21. Noncredit courses.

335.22. Standards for reimbursable noncredit courses at community colleges.

335.23. Courses or programs in avocational and recreational pursuits.

§ 335.21. Noncredit courses.

Noncredit courses are planned educational activities designed to enable students to achieve stated learning goals. They differ from credit courses by offering less depth or breadth in subject matter; or by being custom designed to meet the workforce training needs of local employers and other community organizations; or by being designed to provide advanced training for professionals or training or retraining for occupational workers; or by not being postsecondary in nature. They also differ from credit courses by not being part of a program of study which leads to a formal college award.

§ 335.22. Standards for reimbursable noncredit courses at community colleges.

To be eligible for reimbursement by the Commonwealth, each noncredit course shall meet the criteria in § 335.2 (relating to standards for reimbursable courses—credit and noncredit—at community colleges) and the following criteria:

(1) A noncredit course whose topic is the same as, or similar to, that of one of the college's credit courses will differ from the credit course in terms of learning goals or will offer less depth or breadth of subject matter.

(2) The course outline includes the number of hours of instruction—lecture and laboratory—which comprise the course.

(3) The course is delivered or directly supervised by an instructor who leads the learning process and assists the students in their learning. The college is responsible for selecting, supervising, and, whenever appropriate, dismissing the instructor.

(4) The course is designed exclusively for education or training in one of the following areas of study:

(i) *Public safety.* Training in firefighting, the handling of hazardous materials, emergency medical services, police work, or, with the approval of the Department of Education, training mandated by a National or State agency to ensure the public safety.

(ii) *Adult basic education or adult literacy.* Training in basic academic skills and life skills.

(iii) *Occupational skills.* Training or retraining in vocational skills and in continuing education for professions such as nursing, accounting and engineering.

(iv) *Academics.* Studies in the arts, sciences, humanities and mathematics.

(5) The quality of the course's content and its learning process is evaluated at least once every 5 years using a method determined by the college.

(6) The course is not a course in recreational or avocational pursuits.

§ 335.23. Courses or programs in avocational and recreational pursuits.

(a) Courses or programs in avocational pursuits are designed to provide enrollees with skills or knowledge to be used in an activity which is subordinate to their current or their planned future customary employment.

(b) Courses or programs in recreational pursuits are designed to provide enrollees with diversion or distraction from workaday routines.

(c) Course topics in avocational and recreational pursuits include:

(i) Leisure activities.

(ii) Hobbies.

(iii) Crafts.

(iv) Sports.

(v) Personal, physical or mental development, fulfillment or fitness.

(vi) Management of personal matters.

(vii) Cultural events.

(viii) Travelogues and tours.

(d) Courses in avocational and recreational pursuits are not reimbursable in accordance with section 1913-A(b)(1.2) of the act (24 P. S. § 19-1913-A(b)(1.2)).

(e) Courses in avocational and recreational pursuits will not be deemed reimbursable by virtue of the possible vocational interests of some or all of the students enrolled therein.

Subchapter D. IMPLEMENTATION SCHEDULE

Sec.

335.31. New credit and noncredit courses.

335.32. Existing credit courses.

335.33. Existing noncredit courses.

§ 335.31. New credit and noncredit courses.

Beginning July 1, 1997, to be eligible for reimbursement by the Commonwealth, each new credit course for Fiscal Year 1997-98 and for each fiscal year thereafter, shall meet the standards in Subchapters A and B (relating to general provisions; and credit courses), and each new noncredit course shall meet the standards in Subchapter A and Subchapter C (relating to noncredit courses).

§ 335.32. Existing credit courses.

(a) Until the beginning of Fiscal Year 1999-2000, credit courses approved by the college prior to July 1, 1997, will be eligible for reimbursement, if they comply with Chapter 35 (relating to community colleges). Beginning with Fiscal Year 1999-2000 and for each fiscal year thereafter, each credit course claimed for Commonwealth reimbursement shall meet the standards in Subchapters A and B (relating to general provisions; and credit courses).

(b) To verify that existing courses are eligible for reimbursement in Fiscal Years 1997-98 and 1998-99, the college shall prepare a list of all its credit courses approved by the college prior to July 1, 1997. The list shall be prepared and submitted to the Deputy Secretary for Postsecondary and Higher Education by October 1, 1997. The list shall also be retained by the college until its State audits for those years are finalized. The list will be used by the State's auditors to verify each course's eligibility for reimbursement.

§ 335.33. Existing noncredit courses.

(a) Until the beginning of Fiscal Year 1999-2000, noncredit courses, excluding avocational and recreational courses, approved by the college prior to July 1, 1997, will be eligible for reimbursement, if they comply with Chapter 35 (relating to community colleges). Beginning with Fiscal Year 1999-2000 and for each fiscal year thereafter, each noncredit course claimed for Commonwealth reimbursement shall meet the standards in Subchapters A and C (relating to general provisions; and noncredit courses).

(b) To verify that existing courses are eligible for reimbursement in Fiscal Years 1997-98 and 1998-99, the college shall prepare a list of its noncredit courses approved by the college prior to July 1, 1997. The list shall be prepared and submitted to the Deputy Secretary for Postsecondary and Higher Education by October 1, 1997. The list shall also be retained by the college until its State audits for those years are finalized. The list will be used by the State's auditors to verify each course's eligibility for reimbursement.

Subchapter E. DOCUMENTATION

Sec.

335.41.	Verification of eligibility for reimbursement.
335.42.	Course outlines.
335.43.	Program approval policy and records.
335.44.	Course evaluation and program audit.
335.45.	College catalog.
335.46.	Faculty qualifications.
335.47.	Source of documentation.

§ 335.41. Verification of eligibility for reimbursement.

Each community college shall maintain and make available for review by the Department of Education or the Department's auditors the documentation provided for in this part to support claims for reimbursement of courses.

§ 335.42. Course outlines.

(a) Each community college shall prepare and maintain an outline for each course. Outlines shall:

(1) Bear the date on which the course was approved by the college.

(2) Bear an authorizing signature to indicate that the course was approved by the college and is in compliance with § 335.2(2) (relating to standards for reimbursable courses—credit and noncredit—at community colleges). The signature on the outline shall be that of the incumbent in the position specified in the college's policy on program approval as responsible for approving course outlines.

(b) Each community college shall establish an onsite depository for course outlines where they will be available for review.

§ 335.43. Program approval policy and records.

(a) Each community college shall establish and implement a written policy on program approval. The policy shall, at a minimum:

(1) Include provisions for ensuring that proposed programs, and the courses which comprise them, are consistent with the college's mission.

(2) Provide guidance on assigning units of credit to courses to ensure that the assignment complies with Chapter 35 (relating to community colleges) and reflects Nationally or regionally accepted practices.

(3) Specify the position of the person responsible for approving programs.

(4) Specify the position of the person responsible for approving course outlines.

(b) Each community college shall also maintain, in accordance with § 35.66 (relating to retention of records), a record of each approved program bearing the signature of the incumbent in the position specified in the college's policy on program approval as responsible for approving programs.

§ 335.44. Course evaluation and program audit.

(a) Each community college shall conduct course evaluations, which for credit courses shall be part of the academic audit specified in § 35.21(b) (relating to curricula). The college shall develop a written program audit and course evaluation policy that specifies the position of the person responsible for program audits. The policy shall also include provisions which require a review of the program's courses to ensure that:

(1) Course materials and content reflect current knowledge in the program's field of study.

(2) Course content is appropriate for both the objectives of the course and the goals of the program.

(3) The catalog description of the course is accurate.

(4) Each required course's stated learning goals are necessary to enable students to attain the essential knowledge and skills embodied in the program's educational objectives.

(5) The content of each course designed for transfer is similar to courses which are generally accepted for transfer of credit to accredited 4-year colleges and universities.

(b) Each community college shall establish an onsite depository of reports on the results of each program audit and course evaluation. The reports shall, at a minimum, demonstrate that the program audit addressed each of the provisions in subsection (a) and shall be signed by the incumbent in the position responsible for program audits to indicate that the program audit was performed and accepted by the college's administration. Each college shall maintain the results of each program audit and course evaluation in accordance with § 35.66 (relating to retention of records).

§ 335.45. College catalog.

(a) Each community college shall publish and maintain a catalog or other official publication of its credit and

noncredit courses. The catalog or other publication shall contain accurate descriptions of courses and shall specify their prerequisites, if any. Two catalogs or other publications may be used: one for credit courses and another for noncredit courses. The latter may be an informal publication such as a tabloid or brochure.

(b) Noncredit courses which are custom designed to meet the needs of a particular employer or agency and which are not available to the general public may be omitted from the college's catalog. However, an accurate description of these courses shall be developed and maintained by the college.

(c) Catalogs and other official publications of the college's credit and noncredit programs shall be maintained as official records in accordance with § 35.66 (relating to retention of records).

§ 335.46. Faculty qualifications.

(a) Each community college shall establish and maintain a written policy on the qualifications required for faculty who teach credit courses.

(b) Each college shall also maintain a list of the instructors for its credit and noncredit courses. The list shall be maintained in accordance with § 35.66 (relating to retention of records), and shall include:

- (1) The name of each instructor.
- (2) The course taught by the instructor.
- (3) The academic year and semester or term in which the instructor taught the course.

§ 335.47. Source of documentation.

With the approval of the Department of Education, the college may provide and make available for review the documentation required under § 335.41 (relating to verification of eligibility for reimbursement) by means of media other than paper records.

[Pa.B. Doc. No. 97-973. Filed for public inspection June 20, 1997, 9:00 a.m.]

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF PHARMACY [49 PA. CODE CH. 27] Facsimile Machines

The State Board of Pharmacy (Board) by this order adopts amendments to Chapter 27 (relating to State Board of Pharmacy) to read as set forth in Annex A.

A. Effective Date

The amendments are effective upon publication in the *Pennsylvania Bulletin*.

B. Statutory Authority

The amendments are adopted under the authority of 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)).

C. Background

On May 19, 1994, the Federal Drug Enforcement Administration (DEA) amended its regulations to allow for the transmission of controlled substance prescriptions between the prescriber and the dispenser by facsimile machine. See, 59 F.R. 26109 et seq. The Board has determined to adopt the DEA standards in this Commonwealth. Likewise, the Board has received numerous questions from its licensees regarding the legality of filling a prescription which was received in a pharmacy by means of facsimile equipment.

Section 27.18(o) (relating to standards of practice) already authorizes a pharmacist to dispense a drug on the basis of a prescription or order which is an original or direct copy of the original issued by a prescriber who may be using electronic or computerized equipment. Even before the promulgation of the DEA regulations in 1994 the Board had interpreted this section to mean that it was lawful for a pharmacist to fill a prescription received on a facsimile machine for a drug other than a controlled substance. The Board, by this order, clarifies this lawful practice and adds rules pertaining to filling a prescription for a controlled substance received on a facsimile machine to track the DEA regulations.

The Board believes that the use of a facsimile machine to transmit a prescription from prescriber to pharmacist may result in fewer errors than telephone transmission of prescriptions. When a prescription is transmitted by means of telephone, it is possible for the pharmacist or for the person who makes the call to make an error. There may well be less possibility for error in both transmission and reception of a prescription transmitted by facsimile machine for the pharmacist will read an exact copy of the prescription. For this reason, the Board believes that the public health and safety will be as well if not better protected than under the current methods of prescription transmission. Moreover, all consumers of health care requiring pharmaceutical treatment will benefit from the cost and time savings inherent in quicker transmission of drug prescriptions, reduced errors and freed up pharmacist time to devote to counseling patients on appropriate drug use.

D. Summary of Comments and Responses on Proposed Rulemaking

Notice of proposed rulemaking was published at 26 Pa.B. 1030 (March 9, 1996). The Board received comments from several public commentators, the House Professional Licensure Committee and the Independent Regulatory Review Commission (IRRC). Responses to these comments follow.

Most institutional commentators, including IRRC, questioned the propriety of requiring the prescriber's signature on a prescription which is faxed for dispensing by an institutional pharmacy prior to actual dispensing of the drug. The commentators noted that drug orders affecting patients/residents in an institution often involve the treatment of severe pain requiring immediate dispensing of the drug for administration to the patient. The commentators noted that institutions have established protocols which are consistent with regulations affecting the individual institutions to obtain the prescriber's signature within 24 or 48 hours for drug orders placed on the patient's medical chart in the institution.

The commentators believed that the proposed rulemaking in § 27.20(b) (relating to facsimile machines) requiring an institutional pharmacist to view the actual prescriber's signature prior to dispensing any

nonproprietary drug, including a Schedule II, III, IV or V controlled substance, prior to dispensing the drug, would create undue delays in necessary patient care. IRRC suggested that proposed § 27.20(b), relating to institutional pharmacies, be eliminated to resolve this concern. The remaining institutional commentators, including the Pennsylvania Society of Health-System Pharmacists, suggested that the section be amended to permit at least a 24 to 48 hour period of time within which to obtain a signature on the patient chart related to the prescription or drug order.

The Board has considered these comments and determined that the elimination of proposed § 27.20(b) would best serve the public interest and the Board's interest in protecting patient health while preserving an efficient method for drug dispensing in an institutional setting. To this end, in final rulemaking, the Board has eliminated proposed § 27.20(b), relating to institutional pharmacies, and has added a new paragraph (4) to subsection (c), relating to general issues surrounding facsimile transmission of prescriptions. The new subsection reads:

For purposes of this section, a prescription may not include an order for medication which is dispensed for immediate administration to a patient in an institution.

By this language, the Board clarifies that facsimile transmissions within a particular institution of drug orders reduced to writing on the patient's medical chart, subsequently signed by the prescriber within 24 to 48 hours as required by regulations affecting the particular institution, would not be subject to the requirements related to facsimile transmissions of prescriptions generally.

The Board notes, however, that prescriptions received by a facsimile machine to an institutional pharmacy for dispensing of drugs to persons outside of the particular institution, that is, for a patient discharged to another institution or to home or hospice, even if within a larger health system, must adhere to the requirements established in § 27.20. The Board notes that, with these changes, the section exactly tracks the DEA regulations.

Moreover, the Board notes that it has not, as IRRC had suggested, deferred control of institutional pharmacies to the Department of Public Welfare and the Department of Health. On the contrary, § 27.18(o) outlines the Board's requirements for drug orders in institutions. Neither does the Board relinquish control of institutional pharmacies by the changes which it has made to § 27.20.

Proposed § 27.20(a) outlined two exceptions to the requirements that a pharmacist review the original of a prescription received on a fax machine before dispensing a Schedule II controlled substance. Those exceptions are:

(i) A prescription for a Schedule II controlled narcotic substance which will be administered to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion in the patient's home or hospice.

(ii) A prescription for a Schedule II controlled substance for a resident of a long-term care facility.

IRRC suggested that long-term care facilities should be included under the first exception, citing a DEA distinction between Schedule II narcotic substances and Schedule II substances, and the fact that there are potentially urgent needs of patients in long-term care facilities to receive Schedule II narcotic substances for the relief of pain. A Schedule II narcotic controlled substance is a subset of a Schedule II controlled substance already covered by the second exception involving long-term care

facilities. The Board therefore declines to create a redundancy by adding long-term care facilities to the first exception.

IRRC also recommended that the Board add provisions in final rulemaking related to emergency situations. The Board notes, as has DEA, that the exceptions related to Schedule II prescriptions in § 27.20(a)(2)(i) and (ii) eliminate the need for redundant language related to emergency prescriptions. The Board adopts DEA's interpretation of the language. The Board further notes that pharmacists dispensing scheduled controlled substances always do so subject to DEA requirements, including requirements related to emergency prescriptions.

In response to one commentator who asked the Board to clarify what is meant by the term "narcotic," the Board notes that Pennsylvania law under the Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. §§ 780-101—780-144) defines a "narcotic" in section 2 thereof (35 P. S. § 780-102). This definition tracks that of the Federal Controlled Substances Act and has been incorporated in the Board's standards of practice regulation in § 27.18(u).

Several commentators believed that the Board intended under proposed § 27.20(c) to require pharmacies to maintain fax transmissions in addition to original prescriptions and drug orders. It was never the Board's intention to require duplicate recordkeeping. On the contrary, the Board intends only that if the facsimile copy will be maintained as the original pharmacy record under section 4(a)(3) of the act, then the paper on which the transmission is made must last for at least that long. To avoid any misconceptions about the provision, the Board has revised § 27.20(c)(2) to make this clarification.

Likewise, IRRC and the House Committee suggested a revision to § 27.20(c)(3) which characterizes as unlawful conduct a contribution of a pharmacist or pharmacy to the installation of a facsimile machine in an institution or medical office. The Board's proposal was initially justified by its reference to section 5(a)(9) of the act (63 P. S. § 390-5(a)(9)), which declares kickbacks between pharmacists and medical practitioners to be grossly unprofessional conduct subjecting a pharmacist's license to discipline. IRRC and the House Committee distinguished this characterization from the term "unlawful", which implicates criminal penalties. IRRC therefore suggested that the Board reference this statutory provision in the language of § 27.20(c)(3).

In redrafting § 27.20(c)(3) to accommodate the concerns expressed by IRRC and the House Committee (with which the Board agrees), the Board finds instructive the decision of the Pennsylvania Supreme Court in *Pennsylvania State Board of Pharmacy v. Cohen*, 448 Pa. 189, 292 A.2d 277 (1972). The court there said:

... sections 390-5(a)(6) and (b)(2) both provide for suspension or revocation of licenses and permits respectively upon proof of violation of any properly adopted rules or regulations promulgated by the Board. It is only by means of these statutorily granted rulemaking powers that the Legislature has empowered the Board to provide additional grounds for sanctions.

448 Pa. 197-98, 292 A.2d 281-82.

Section 5(a)(6) and (b)(2) of the act (63 P. S. § 390-5(a)(6) and (b)(2)) provides for disciplinary action against pharmacist licenses and pharmacy permits, respectively, for violations of the act or regulations of the Board. Accordingly, the Board has revised § 27.20(c)(3) to read:

A pharmacist or pharmacy may not contribute in any way to the installation of a facsimile machine in the office of a medical practitioner or in an institution.

A pharmacist or pharmacy who engages in this prohibited conduct could be disciplined under section 5(a)(6) or (b)(2) of the act, respectively.

Finally, several commentators suggested that the amendments should be broadened to include all forms of electronic prescription transmission, together with regulating adequate security measures for the same. The Board notes that, because the proposed regulation was limited to facsimile machine transmission of drug prescriptions, it would be both improper and inconsistent with the law to expand the scope of the regulation on final rulemaking to include transmission of prescriptions through other electronic means.

The Board has also incorporated several technical revisions suggested by IRRC in final rulemaking.

E. Compliance with Executive Order 1996-1, Regulatory Review and Promulgation

The Board reviewed this rulemaking and considered its purpose and likely impact upon the public and the regulated population under the directives of Executive Order 1996-1, Regulatory Review and Promulgation. The final form regulations address a compelling public health interest in assuring that drug dispensing is accurate, efficient and cost-effective as described in this Preamble, and it otherwise complies with Executive Order 1996-1.

F. Fiscal Impact and Paperwork Requirements

The regulatory amendments will not have a negative fiscal impact on the Commonwealth, political subdivisions or the private sector. In fact, cost savings in time and money can be anticipated through increased efficiency in drug dispensing.

The amendments will not affect paperwork requirements for the Commonwealth or political subdivisions. Paperwork in the public sector relative to drug dispensing and recordkeeping will be reduced.

G. Sunset Date

The Board continually monitors the effectiveness of its regulations through communications with the regulated population; accordingly, no sunset date has been set.

H. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on March 9, 1996, the Board submitted a copy of the notice of proposed rulemaking, published at 26 Pa.B. 1030 (March 9, 1996), to IRRC and the Chairpersons of the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee for review and comment. In compliance with section 5(b.1) of the Regulatory Review Act, the Board also provided IRRC and the Committees with copies of the comments received, as well as other documentation.

In preparing these final-form regulations the Board has considered the comments received from IRRC, the Committees and the public.

These final-form regulations were approved by the House Committee on May 14, 1997, and approved by the Senate Committee on May 13, 1997. IRRC met on May 22, 1997, and approved the final-form regulations in accordance with section 5(c) of the Regulatory Review Act.

I. Contact Person

Further information may be obtained by contacting W. Richard Marshman, Executive Secretary, State Board of Pharmacy, at P. O. Box 2649, Harrisburg, PA 17105-2649 (717) 783-7157.

J. 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) (45 P. S. §§ 1201 and 1202) and the regulations promulgated thereunder at 1 Pa. Code §§ 7.1 and 7.2.

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

(3) These amendments do not enlarge the purpose of proposed rulemaking published at 26 Pa.B. 1030.

(4) These amendments are necessary and appropriate for administration and enforcement of the authorizing act identified in Part B of this Preamble.

K. 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 by adding § 27.20 to read as set forth in Annex A.

(b) The Board shall submit this order and Annex A to the Office of General Counsel and to the Office of Attorney General 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) This order shall take effect on publication in the *Pennsylvania Bulletin*.

PAULA L. CASTOR, R.Ph.,
Chairperson

(Editor's Note: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 27 Pa.B. 2790 (June 7, 1997).)

Fiscal Note: Fiscal Note 16A-543 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 American Council of Pharmaceutical Education.

Act—The Pharmacy Act (63 P. S. §§ 390-1—390-13).

BNDD—The Federal Bureau of Narcotics and Dangerous Drugs.

Board—The State Board of Pharmacy.

Caution legend drug or device—Controlled substances and other drugs or devices which by statute or regulation may be dispensed to a patient by a pharmacist only upon the prescription of a medical practitioner.

CEU—Continuing Education Units—The unit of measuring contact hours of continuing education provided by ACPE accredited providers. Ten contact hours are equivalent to 1.0 CEU.

Commissioner—The Commissioner of Professional and Occupational Affairs in the Department.

Contact hours—Continuing education units of measure equivalent to 50 to 60 minutes of participation in an approved organized learning experience, including home study with approved educational materials.

Continuing education—Professional education obtained to maintain, improve or expand current skills or knowledge, or to develop new skills or knowledge.

Department—The Department of State of the Commonwealth.

Institutions—Extended care facilities, nursing homes, nursing care facilities, convalescent homes, resident care facilities, hospitals or another place which offers medical treatment to patients who require food, board and overnight sleeping facilities and care.

Long term care facility—A nursing home, retirement care, mental care or other institution that provides extended health care to resident patients.

Pharmacist manager—The pharmacist in charge of a pharmacy who is responsible for operations involving the practice of pharmacy under section 4 of the act (63 P. S. § 390-4).

Pharmacy—The store or other place licensed by the Board where the practice of pharmacy is conducted.

Practice of pharmacy—The practice of that profession concerned with the art and science of preparing, compounding and dispensing of drugs and devices, whether dispensed on the prescription of a medical practitioner or legally dispensed or sold directly to the ultimate consumer. The term includes the proper and safe storage and distribution of drugs, the maintenance of proper records therefor and the responsibility of relating information as required concerning the drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease.

Prescription area—That area of the pharmacy used for compounding, legend drug storage and other activities necessary to the practice of pharmacy. The term does not include waiting counters or display space attached to the waiting counters.

STANDARDS

§ 27.20. Facsimile machines.

(a) *Schedule II controlled substances.*

(1) A pharmacist may fill a prescription for a Schedule II controlled substance which was received on a facsimile machine if the original prescription signed by the medical practitioner is presented to the pharmacist for review prior to the actual dispensing of the controlled substance. The original prescription shall be maintained as the original pharmacy record.

(2) There are two exceptions to the requirement that the pharmacist review the original of the prescription received on a facsimile machine before dispensing a

Schedule II controlled substance. A pharmacist may fill and dispense a prescription for a Schedule II controlled substance which was received on a facsimile machine and may use the facsimile as the original pharmacy record of the following:

(i) A prescription for a Schedule II controlled narcotic substance which will be administered to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion in the patient's home or hospice.

(ii) A prescription for a Schedule II controlled substance for a resident of a long term care facility.

(b) *Schedule III, IV and V controlled substances and other nonproprietary drugs.* A pharmacist may fill and dispense a prescription signed by a medical practitioner for a Schedule III, IV or V controlled substance or other nonproprietary drug which was received on a facsimile machine. The pharmacist may use the facsimile as the original pharmacy record.

(c) *General.*

(1) A pharmacist shall exercise professional judgment regarding the accuracy and authenticity of the facsimile copy of a prescription.

(2) Unless the original prescription will be maintained as the original pharmacy record, the quality of paper on which a facsimile copy of a prescription is printed shall be of a type that the facsimile copy can be maintained as a record for at least 2 years, as required under section 4(a)(3) of the act (63 P. S. § 390-4(a)(3)).

(3) A pharmacist or pharmacy may not contribute in any way to the installation of a facsimile machine in the office of a medical practitioner or in an institution.

(4) For purposes of this section, a prescription may not include an order for medication which is dispensed for immediate administration to a patient in an institution.

[Pa.B. Doc. No. 97-974. Filed for public inspection June 20, 1997, 9:00 a.m.]

BUREAU OF CHARITABLE ORGANIZATIONS

[49 PA. CODE CHS. 51, 53 AND 55]

Charitable Organizations

The Department of State (Department) deletes Chapters 51, 53 and 55.

These chapters are being deleted because they were promulgated under the authority and reflect the provisions of the Solicitation of Charitable Funds Act (Act 1963) (10 P. S. §§ 160-1—160-17) which was repealed by the Charitable Organizations Reform Act (Act 1986) (10 P. S. §§ 161.1—161.19). Act 1986 was, in turn, repealed by the current Solicitation of Funds for Charitable Purposes Act (Act 1990) (10 P. S. §§ 162.1—162.24). These chapters are deleted in anticipation of the promulgation of regulations under the Act 1990.

Public notice of intention to delete the regulations under the procedures in sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) (CDL) has been omitted as authorized under section 204(3) of the CDL (45 P. S. § 1204(3)) because the Department finds that these procedures are, under the circumstances, unnecessary. Public comment is unnecessary and under the circumstances impractical because this rulemaking is intended to merely delete outdated

regulations which were promulgated under a prior statute which has been repealed. Furthermore, all registrants affected by the deletion have been given actual notice that the regulations at Chapters 51, 53 and 55 have no bearing on filings made under the Act 1990 and are concomitantly advised that filings made under the Act 1990 should not be made utilizing these out of date regulations. Accordingly, no substantive rights of any person will be affected by this order.

Compliance with Executive Order 1996-1

The Department reviewed this rulemaking and considered its purpose and likely impact upon the public and the regulated population under the directives of Executive Order 1996-1, Regulatory Review and Promulgation. The final/proposed omitted regulations address a compelling public interest as described in this preamble and otherwise comply with Executive Order 1996-1.

Statutory Authority

The Department's Bureau of Charitable Organizations general authority to delete these regulations is set forth in section 506 of The Administrative Code of 1929 (71 P. S. § 186). Authority is also specifically granted the Secretary of the Commonwealth in section 4 of the act (10 P. S. § 162.4(3)) which provides that the Secretary of the Commonwealth has the power to promulgate, adopt and enforce regulations necessary to carry out the act.

Fiscal Impact and Paperwork Requirements

This rulemaking will have no negative fiscal impact on the Commonwealth or its political subdivisions. The Department's Bureau of Charitable Organizations will no longer need to expend resources in rejecting filings based upon the out of date regulations and explaining to the public that the regulations have no applicability to registrations made under Act 1990. The public will realize a positive fiscal impact from not being confused by trying to comply with out of date regulations.

Regulatory Review

Under section 5(f) of the Regulatory Review Act (71 P. S. § 745.5(f)), on April 22, 1997, the Department submitted a copy of this rulemaking with proposed rulemaking omitted to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the Senate and House Committees on State Government. On the same date, this rulemaking was submitted to the Office of Attorney General for review and approval under the Commonwealth Attorneys Act (71 P. S. §§ 732-101—732-506).

Under section 5(c) of the Regulatory Review Act, the rulemaking was deemed approved by the House and Senate Committees on June 11, 1997, and approved by IRRC on May 22, 1997.

Additional Information

Individuals who desire information regarding this rulemaking are invited to submit inquiries to John T. Henderson, Jr., Deputy Chief Counsel, Department of State, Room 302 North Office Building, Harrisburg, PA 17120 (717) 787-6802.

Findings

The Department finds that:

(1) Public notice of intention to delete the regulations as adopted by this order under the procedure specified in sections 201 and 202 of the CDL has been omitted under the authority contained in section 204(3) of the CDL because the Department has, for good cause, found that the procedure specified in sections 201 and 202 of the CDL is in this circumstance, unnecessary, because the regulations are based upon a repealed statute.

(2) Persons affected by the deletion of these regulations as adopted by this order have been given actual notice of the Department's intention to delete the regulations under section 204(2) of the CDL.

(3) The deletion of the regulations in the manner provided in this order is necessary and appropriate for the administration of the act.

Order

The Department, acting under its statutory authority, orders that:

(a) The regulations of the Department's Bureau of Charitable Organizations, 49 Pa. Code Chapters 51, 53 and 55, are amended by deleting §§ 51.1, 51.2, 53.1—53.4 and 55.1—55.7 to read as set forth in Annex A.

(b) The Department shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for approval as to legality as required by law.

(c) The Department shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(d) This order shall become effective immediately upon publication in the *Pennsylvania Bulletin*.

YVETTE KANE,
Secretary of the Commonwealth

(Editor's Note: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 27 Pa.B. 2790 (June 7, 1997).)

Fiscal Note: 16-14. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART II. DEPARTMENT OF STATE

Subpart B. [Reserved]

CHAPTER 51. [Reserved]

§§ 51.1 and 51.2. [Reserved]

CHAPTER 53. [Reserved]

§§ 53.1—53.4. [Reserved]

CHAPTER 55. [Reserved]

§§ 55.1—55.7. [Reserved]

[Pa.B. Doc. No. 97-975. Filed for public inspection June 20, 1997, 9:00 a.m.]