RULES AND REGULATIONS

Title 7—AGRICULTURE

DEPARTMENT OF AGRICULTURE

[7 PA. CODE CH. 110]

Noxious Weeds

The Department of Agriculture (Department) amends § 110.1 (relating to noxious weed control list) to designate *Lythrum salicaria* (purple loosestrife), *Lythrum virgatum* and their cultivars and combinations thereof as noxious weeds and to add *Galega officinalis* (Goatsrue) and *Heracleum mantegazzianum* (Giant Hogweed) to the noxious weed control list. The text of this amendment is set forth at 30 Pa.B. 636 (February 5, 2000).

Statutory Authority

Sections 3(b), 8 and 9 of the Noxious Weed Control Law (act) (3 P. S. §§ 255.3(b), 255.8 and 255.9) require the Department to establish a noxious weed control list, prescribe certain plants to be included on that list and empower the Department to adopt regulations necessary to implement the act. The regulation is advanced under authority of these statutory provisions.

Need for the Rulemaking

There is a compelling public need to protect this Commonwealth's wetland plant and animal populations from the threat posed by nonnative purple loosestrife, cultivars of the plants and cultivars that are combinations of native and nonnative purple loosestrife species.

The addition of Giant Hogweed to the noxious weed control list is necessary to provide the Department needed authority to control and eradicate this nonindigenous plant at the locations in Crawford, Erie, McKean, Venango and Warren Counties where it has appeared. The sap of this plant can cause rashes on the skin of persons with whom it comes into contact.

The addition of Goatsrue to the noxious weed control list will provide the Department needed authority to address the presence of this nonindigenous plant at the Philadelphia area location where it has been detected. This plant is toxic to livestock.

Lythrum salicaria, commonly known as purple loosestrife, is a nonnative wetland plant that thrives in the absence of the insects and diseases that controlled it in Europe and Asia. It clogs waterways, crowds-out native plant species and decreases the population of animals that are dependent upon these native plant species for survival. For this reason the Department placed *Lythrum salicaria*, commonly known as purple loosestrife on the noxious weed control list in § 110.1. This regulatory change was published at 27 Pa.B. 1704 (April 12, 1997) and became effective on that date.

Since *Lythrum salicaria* was added to the noxious weed control list, the need to add other *Lythrum* species and their cultivars and combinations has become apparent. There are many cultivars (cultivated varieties) of purple loosestrife that are listed under species names other than *Lythrum salicaria*. These other species and cultivars present as great an environmental threat as does *Lythrum salicaria*. The regulation addresses the threat posed by these plants.

Lythrum virgatum is a source of purple loosestrife cultivars. Like *Lythrum salicaria*, *Lythrum virgatum* is a European wetland plant that has been introduced into North America. These two species are very similar, differing in only several minor diagnostic characteristics. The two also cross pollinate freely. For this reason, a number of plant specialists consider *Lythrum salicaria* and *Lythrum virgatum* to be the same species. The fact that these plants intercross freely has also helped to blur scientific distinctions between cultivars of the two.

Until recently, the various ornamental purple loosestrife cultivars were thought to be sterile. As such, there would be no danger these plants could naturally cross breed with *Lythrum salicaria* and pass along genetic traits which might make purple loosestrife an even greater ecological threat than it is already. Recent research, though, has shown that no purple loosestrife cultivar is sterile.

Although most cultivars are self-sterile (that is, incapable of reproducing alone), they produce large quantities of viable seed when functioning as either male or female parents in cross breeding with other cultivars and species of loosestrife. Bees and wasps are effective pollinators of loosestrife, and provide the means for cross pollination, even between plants that are a considerable distance from each other.

It is possible a relatively benign ornamental cultivar of indigenous purple loosestrife could cross breed with *Lythrum salicaria* and produce a new cultivar of purple loosestrife that combines the native species' tolerance of this Commonwealth's temperature extremes or its ability to thrive in areas other than wetlands with the aggressive growth characteristics and the disease resistant characteristics, or both, of *Lythrum salicaria*. This is not abstract speculation. Some genetic traits of *Lythrum salicaria* have already been found in cultivars of purple loosestrife.

Galega officinalis, commonly known as Goatsrue, is a nonnative plant that is on the Federal noxious weed list and is toxic to livestock. Goatsrue is only known to exist in this Commonwealth at an arboretum in the Philadelphia area.

Heracleum mantegazzianum, commonly known as Giant Hogweed, is a nonnative plant that is on the Federal noxious weed list and causes skin rashes on many persons who come into contact with it. The plant is only known to be present in this Commonwealth in Crawford, Erie, McKean, Venango and Warren Counties.

In summary, the Department is satisfied there is a need for the final-form regulation, and that it is otherwise consistent with Executive Order 1996-1, "Regulatory Review and Promulgation."

Comments

Notice of proposed rulemaking was published at 30 Pa.B. 636 and provided for a 30-day public comment period. Neither the Legislative Committees nor the Independent Regulatory Review Commission (IRRC) offered comment with respect to that document.

The sole comment originated from the Pennsylvania Landscape and Nursery Association (PLNA). Although PLNA supports the addition of *Lythrum salicaria* (purple loosestrife), *Galega officinalis* (Goatsrue), *Heracleum mantegazzianum* (Giant Hogweed) and *Lythrum virgatum* to the noxious weed control list, it expressed concern regarding the addition of the cultivars and combinations

of *Lythrum salicaria* and *Lythrum virgatum* to that list. Rather than a broad designation of these cultivars and combinations as noxious weeds, PLNA recommended each such cultivar or combination be evaluated and considered individually for inclusion on the noxious weed control list. PLNA offered the opinion there is not "... enough evidence to support that all cultivars, both current and future, should be considered noxious weeds."

The Department gave careful consideration to PLNA's comment. On balance, the Department is satisfied that all cultivars and combinations of *Lythrum salicaria* and *Lythrum virgatum* should be included on the noxious weed control list, and that current scientific research supports this position.

Research conducted in Minnesota has shown that no purple loosestrife cultivar is sterile. All cultivars can produce viable seeds when crossed with other cultivars and species, including *Lythrum alatum* (winged loosestrife), a noninvasive native of wetlands. The cultivars pose a great risk because, unlike the parent species, they are adapted to grow in drier soils. Continued crossing between cultivars and parent species can lead to new genetic combinations that would allow loosestrife to colonize drier, more upland habitats, making it an even more troublesome weed.

The Department also believes that, even were it inclined to do so, it could not draw a workable regulatory line to exclude any particular cultivar or combination of *Lythrum salicaria* and *Lythrum virgatum* from the noxious weed control list. Distinguishing between cultivars of loosestrife is difficult at best. Like-named cultivars may look different and differently-named cultivars may appear identical. This situation would be unworkable for any plant inspector or botanist tasked with making a precise identification of a particular cultivar or combination.

The Department is mindful that certain cultivars or combinations of *Lythrum salicaria* and *Lythrum virgatum* are produced and sold commercially in this Commonwealth, and that these plants are not uncommon in ornamental flower gardens. It is satisfied, though, that there are numerous perennial plants that are suitable substitutes for these cultivars or combinations. This Commonwealth's plant nursery industry has been provided several years' advance notice that cultivars or combinations of *Lythrum salicaria* and *Lythrum virgatum* would be included on the noxious weed control list, and the Department believes the industry has prepared for this regulation by eliminating stocks of these plants or obtaining suitable substitutes for these plants. The Department views the inclusion of these plants on the noxious weed control list as the first logical step toward reducing the prevalence of these plants in this Commonwealth.

The Department is currently cooperating with the United States Department of Agriculture on a biocontrol project with respect to purple loosestrife. The project involves the release of several different species of beetles that attack loosestrife. Tests have shown these insects capable of drastically reducing loosestrife populations in natural areas, thereby allowing native plants to begin reclaiming these environments. The Department believes it would be self-defeating to allow sale of even a single cultivar or combination of loosestrife while it simultaneously pursues biological control efforts with respect to these plants.

On balance, the Department is satisfied that all cultivars and combinations of *Lythrum salicaria* and *Lythrum virgatum* should be included on the noxious weed control list, and that current scientific research supports this position.

Fiscal Impact

Commonwealth

The final-form regulation will not impose appreciable costs upon the Commonwealth.

Political Subdivisions

The final-form regulation will not impose appreciable costs upon political subdivisions.

Private Sector

The final-form regulation will not impose appreciable costs upon the private sector. Only a small percentage of this Commonwealth's plant nurseries and similar establishments ever handled purple loosestrife. Of those that did, sales of those plants comprised only a small part of their business. As a result of the nursery industry's awareness of the environmental threat posed by purple loosestrife and the fact the final-form regulation was forthcoming, it is believed the fiscal impact of this amendment upon the private sector will be insignificant.

The inclusion of Goatsrue and Giant Hogweed on the Noxious Weed Control List is not expected to result in significant costs to the private sector. These plants are present in relatively few locations in this Commonwealth, and can be eliminated without significant expense.

General Public

The final-form regulation will not impose appreciable costs upon the general public.

Paperwork Requirements

The final-form regulation will not result in an appreciable increase in the amount of paperwork handled by the Department, or increase the paperwork burden of political subdivisions, the private sector or the general public.

Contact Person

Further information is available by contacting the Department of Agriculture, Bureau of Plant Industry, 2301 North Cameron Street, Harrisburg, PA 17110-9408, Attention: Will Mountain.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on January 24, 2000, the Department submitted a copy of the notice of proposed rulemaking published at 30 Pa.B. 636 to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House and Senate Standing Committees on Agriculture and Rural Affairs for review and comment.

In compliance with section 5(c) of the Regulatory Review Act, the Department also provided IRRC and the Committees with copies of all comments received, as well as other documentation. In preparing this final-form regulation, the Department has considered the comments received from IRRC, the Committees and the public.

This final-form regulation was deemed approved by the House and Senate Committees on October 5, 2000. IRRC met on October 19, 2000. The final-form regulation was deemed approved under section 5(g) of the Regulatory Review Act.

Findings

The Department finds that:

(1) Public notice of its intention to adopt the regulation encompassed by this order has been 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 thereunder, 1 Pa. Code §§ 7.1 and 7.2.

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

(3) Any modifications that were made to this regulation in response to comments received do not enlarge the purpose of the proposed amendment published at 30 Pa.B. 636.

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

Order

The Department, acting under authority of the authorizing statute, orders that:

(a) The regulations of the Department, 7 Pa. Code Chapter 110, are amended by amending § 110.1 to read as set forth at 30 Pa.B. 636.

(b) The Secretary of Agriculture shall submit this order and 30 Pa.B. 636 to the Office of General Counsel and to the Office of the Attorney General for approval as required by law.

(c) The Secretary of the Department shall certify this order and 30 Pa.B. 636 and deposit them with the Legislative Reference Bureau as required by law.

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

SAMUEL E. HAYES, Jr.,
Secretary

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission, relating to this document, see 30 Pa.B. 5807 (November 4, 2000).)

Fiscal Note: Fiscal Note 2-117 remains valid for the final adoption of the subject regulation.

[Pa.B. Doc. No. 00-1973. Filed for public inspection November 17, 2000, 9:00 a.m.]

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF MEDICINE
STATE BOARD OF NURSING
[49 PA. CODE CHS. 18 AND 21]
CRNP Prescriptive Authority

The State Boards of Medicine and Nursing (Boards) amend their regulations governing certified registered nurse practitioners (CRNPs) in Chapters 18 and 21 (relating to State Board of Medicine; and State Board of Nursing) to read as set forth in Annex A.

A. Effective Date

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

B. Statutory Authority

Section 15(b) of the Medical Practice Act of 1985 (63 P. S. § 422.15(b)) authorizes the Boards to jointly promulgate regulations authorizing CRNPs to perform acts of medical diagnoses and prescription of medical, therapeutic, diagnostic or corrective measures. Section 2(1) of the Professional Nursing Law (63 P. S. § 212(1)) similarly indicates that a professional nurse may perform acts of medical diagnosis or prescription of medical therapeutic or corrective measures if the Boards promulgate regulations authorizing the acts.

C. Purpose

Under their statutory authority, the Boards have negotiated rulemaking which authorizes CRNPs to prescribe and dispense drugs within specified parameters. CRNPs are advanced practice nurses who are certified by the Boards in a particular clinical specialty area. This rulemaking will enable Pennsylvania CRNPs to make full use of their advanced education and skills and is consistent with the regulations of 41 other states which authorize CRNPs to prescribe or dispense, or both, with varying degrees of regulation or limitation. A detailed explanation of the purpose and background of the rulemaking may be found in the publication of proposed rulemaking at 29 Pa.B. 5101 (October 2, 1999).

D. Compliance with Executive Order 1996-1

In accordance with Executive Order 1996-1 (February 6, 1996), in drafting and promulgating the regulations the Boards solicited input and suggestions from the regulated community. The Boards mailed a draft on June 26, 1998, to 54 organizations, entities and individuals who had an interest in CRNP prescribing. The Boards received 373 responses to the solicitation. The Boards revised the draft as a result of the responses and submitted that revised draft as proposed rulemaking.

E. Summary of Comments and Responses to Proposed Rulemaking

Proposed rulemaking was published at 29 Pa.B. 5101 (October 2, 1999) followed by a 30-day public comment period. The Boards received reports from the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC) and public comments from more than 600 associations, entities and individuals. As a result of these reports and comments, a number of changes were made to the proposed rulemaking. These changes include specifications regarding the course work in advanced pharmacology that will be a prerequisite to prescribing and dispensing; a requirement of continuing education in pharmacology for a CRNP who prescribes or dispenses; a requirement that every category of drugs from which a CRNP might prescribe be identified in the collaborative agreement; greater precision in the listing of the categories of drugs from which a CRNP might prescribe, prescribe with limitations or not prescribe; a definition of "collaborative agreement"; identification of the contents of a collaborative agreement necessary for a CRNP who prescribes or dispenses; identification of the CRNP by nametag; and limiting a physician to collaborating with not more than four CRNPs who prescribe and dispense drugs at any one time unless the physician requests and obtains a waiver of this ratio. The Boards also combined subsections (b) and (c) of §§ 18.54 and 21.284.

The HPLC in its report of November 16, 1999, made recommendations regarding education in pharmacology, continuing education, the collaborative agreement, substitute collaborating physicians, and notice to patients when a patient is treated by a CRNP who prescribes drugs. IRRC in its report of December 2, 1999, made recommendations regarding the collaborative agreement, education in pharmacology, the categories of drugs, action to be taken if a drug is prescribed inappropriately and the clarity of draftmanship.

The Pennsylvania Coalition of Nurse Practitioners endorsed the proposed rulemaking but made recommendations for changes. The Nurse Practitioner Association of Southwestern Pennsylvania, individual physicians and nurses, and health care practices and entities supported the proposed rulemaking. The Hospital & Healthsystem Association of Pennsylvania (HAP), the Pennsylvania Academy of Pediatrics, the Pennsylvania Society of Anesthesiologists, the Pennsylvania State Nurses Association (PSNA) and Pennsylvania Academy of Family Physicians (PAFP) generally supported the proposed rulemaking, but made recommendations for changes. The Pennsylvania Medical Society (PMS) did not object to the proposed rulemaking, but also recommended changes. The American College of Emergency Physicians endorsed the recommendations of PMS and made several suggestions of their own.

Several associations and individuals generally opposed the proposed rulemaking. These associations included the Pennsylvania Podiatric Medical Association, the Pennsylvania Association of Chain Drug Stores and one chain drug store, and the Pennsylvania Osteopathic Medical Association.

The Boards received comments from consumers (individuals who did not identify themselves as physicians or nurses), physicians, and nurses. Of approximately 41 consumer comments, 40 favored the proposed rulemaking, one opposed. Consumers who favored the rulemaking stressed the quality of care received from CRNPs and said that the rulemaking would facilitate access to quality health care. Nurses almost uniformly favored the rulemaking and offered several suggestions which will be addressed in this Preamble. While a number of physicians opposed prescriptive authority for CRNPs, most physician commentators indicated that they were not opposed to the proposed rulemaking but made recommendations for changes. A large number of physician commentators supported the comments of PMS. The recommendations of physicians and their associations will also be addressed.

Equivalency of Programs in Other States—§§ 18.53(1) and 21.283(1).

The proposed rulemaking began by indicating that a CRNP might prescribe if the CRNP, among other things, completed a CRNP program approved by the Board or, if the nurse completed a CRNP education program in another state, the program was equivalent to programs approved by the Boards. IRRC asked how the Boards would determine equivalency. Section 7(b) of the Professional Nursing Law (63 P. S. § 217(b)), authorizes the State Board of Nursing to issue a certification to registered nurse practitioners who have completed a course of study in another state if the Board considers the program to be equivalent to that required in this Commonwealth. Under §§ 18.42 and 21.272 of the Boards' regulations the Boards may grant certification by endorsement to a CRNP who had been certified in another state if the credentials are equivalent to those required by the Boards. In implementing the statute and regulations, the Boards compare the courses of the non-Pennsylvania program with that of Pennsylvania program. If a comparison reveals that the programs are equivalent in course work and hours, the State Board of Nursing certifies the applicant.

Course in Advance Pharmacology—§§ 18.53(2) and 21.283(2).

The proposed rulemaking would have authorized a CRNP to prescribe and dispense if the "CRNP program include[d] a core course in advanced pharmacology." The HPLC recommended that a minimum number of hours of core education in advanced pharmacology be required for a CRNP to be permitted to prescribe and dispense drugs. IRRC, the Pennsylvania Society of Health-System Pharmacists (PSHSP), and others also suggested greater clarity in describing what would qualify as an advanced pharmacology course. PMS, which recommended that the Boards clarify the proposed rulemaking in regard to the responsibility and accountability of both the CRNP and collaborating physician, requested that the course should be at least 30 hours. The PAFP recommended a 50-hour course. Individual physicians recommended specific courses of from 30 to 50 hours.

IRRC and others noted that some programs did not have a specific course but integrated pharmacology into the overall curriculum. Some commentators suggested that boards devise a way to "grandfather" those whose education in pharmacology was not contained in a specific course. Pennsylvania Association of Nurse Anesthetists, PSNA, and numerous individual nurse commentators supported this view. The PSNA recommended that the Boards consider "grandfathering" and requiring continuing education in advanced pharmacology or requiring the CRNP to provide documentation of cumulative advanced pharmacology.

In response to these comments, the Boards have adopted a 45-hour course work requirement and further refined the education acceptable to the Boards. A course in advanced pharmacology of 45 hours has been standard in Board approved CRNP programs since 1992. A course is at a level above the pharmacology courses taught in registered nursing programs. A course in pharmacology/pharmacotherapeutics of 45 contact hours is recommended in "Curriculum Guidelines & Regulatory Criteria for Family Nurse Practitioners Seeking Prescriptive Authority to Manage Pharmacotherapeutics in Primary Care: Summary Report 1998" (Curriculum Guidelines), prepared by the Health Resources & Services Administration of the United States Department of Health and Human Services recommends.[1] Forty-five hours of course work in advanced pharmacology provides a level of education necessary for a CRNP to safely prescribe and dispense drugs. This is the standard adopted by the Boards in this rulemaking. The rulemaking has been drafted so that a CRNP who has not taken 45 hours of course work as part of the CRNP education program will be able to take additional course work from a program or programs approved by the Boards. Advanced pharmacology which has been "integrated" into other courses will be acceptable, if it can be verified through means such as a course syllabus or catalog which identifies the hours devoted to advanced pharmacology.

The Pennsylvania Association of Physician Assistants expressed the view in regard to § 18.53 that it would be a great undertaking for the Board to approve CRNP programs in this Commonwealth and elsewhere. The Boards,

[1] Of the 42 states which permit CRNPs to prescribe, 21 require that the CRNP have completed a separate pharmacology course. "Curriculum Guidelines," Table 2, page 16.

however, have a history and duty and the necessary staff to approve CRNP programs. See, §§ 18.41—18.42 and 21.271—21.272.

Continuing Education—§§ 18.53(3) and 21.283(3).

The HPLC recommended that a minimum number of hours of continuing education in advanced pharmacology be required per biennium for a CRNP to maintain prescriptive authority. PMS, PAFP, PSHSP, the Pennsylvania Psychiatric Society (PPS), and numerous physician commentators also recommended continuing education for a CRNP who prescribes drugs. The Boards believe this is a sound recommendation that would help the CRNP to stay current in pharmacological knowledge, would help insure public safety, and would be consistent with the current regulations of the Boards which require a CRNP to provide evidence of continuing competency in the area of medical diagnosis and therapeutics at the time the CRNP renews certification. See §§ 18.41(c) and 21.271(d). The Boards determined that 16 hours of continuing education biennially in pharmacology approved by the State Board of Nursing would be appropriate.

The Collaborative Agreement—§§ 18.55 and 21.285.

The HPLC, IRRC and others made recommendations concerning the collaborative agreement. The proposed rulemaking referred to, but did not define, the collaborative agreement. The HPLC recommended that the collaborative agreement be in writing, contain a list of the classes of medications that the CRNP would be authorized to prescribe, identify the collaborating physician, and provide for an identified substitute collaborating physician for up to 30 days when the collaborating physician is not available. IRRC recommended that the collaborative agreement be defined, that the collaborative agreement be signed by both the physician and CRNP before the CRNP could prescribe drugs, and that the rulemaking specify the contents of the collaborative agreement.

A number of commentators, both individual physicians and associations, recommended that the collaborative agreement be a written document that clarifies the collaborating physician/CRNP relationship. HAP recommended that the collaborative agreement be defined. The PAFP, the Pennsylvania Society of Anesthesiologists, PSHP and the Pennsylvania Association of Physician Assistants expressed the view that the proposed rulemaking did not define the collaborative agreement and that the parameters of collaborative practice should be memorialized in writing so that the parties to the agreement will have a clear understanding of their responsibilities to their patients. The PAFP recommended that the collaborative agreement be in writing, identify the parties, describe the direction each physician will provide the CRNP, the frequency with which the collaborating physician will provide chart review and consultation, identify the drugs which the CRNP may prescribe, be available to anyone seeking to confirm the scope of the CRNP's prescriptive authority, and be filed with the Board. The American Academy of Pediatrics (AAP) recommended that the collaborative agreements be spelled out publicly and in writing and kept on file with the State. The PMS recommended that the final rulemaking include a section on the collaborative agreement; that when a CRNP prescribes or dispenses drugs, the agreement should be in writing; that it be available at the practice site; that it identify the collaborating physician and any substitute collaborating physician by name; that the agreement contain the list of drugs for which the CRNP might prescribe; that it outline when a physician should see the patient and what occurrences would necessitate physician intervention; and that the collaborative agreement be filed with the State Board of Medicine if it authorized the CRNP to prescribe or dispense Schedule II controlled substances. The PMS and PPS recommended that the Boards be notified of the existence of every collaborative agreement and who is party to the agreement. PMS and PPS recommended that a physician not be permitted to include any drug in a collaborative agreement unless the physician has the expertise required to prescribe that drug so that she would be able to recognize any inappropriate prescribing or adverse reaction.

Final rulemaking contains a definition of the term "collaborative agreement" and requires that it be in writing.[2] See §§ 18.55(a) and 21.285(a). Sections 18.55(b) and 21.285(b) specify the contents of a collaborative agreement between a physician and a CRNP who prescribes and dispenses drugs. These subsections adopt the recommendations of the HPLC and IRRC. Additionally, under the final rulemaking the collaborative agreement of a CRNP who prescribes and dispenses drugs is required to identify the area of practice in which the CRNP is certified, contain attestation that the collaborating physician has knowledge and experience with any drug that the CRNP prescribes, specify the circumstances and how often the collaborating physician will personally see the patient, specify the conditions under which a CRNP may prescribe a Schedule II controlled substance for up to 72 hours, be kept at the primary practice location of the CRNP and a copy filed with the Bureau of Professional and Occupation Affairs, be made available for inspection to anyone seeking to confirm the scope of practice of the CRNP, be updated when it is changed substantively, and specify the amount of professional liability insurance carried by the CRNP.

Professional Liability Insurance—§§ 18.55(b)(10) and 21.285(b)(10).

The PMS, PPS, AAP, the Pennsylvania Academy of Emergency Physicians, the Pennsylvania Podiatric Medical Association, and both nurse and physician commentators recommended that a CRNP with prescriptive authority should be required to carry malpractice insurance. The PMS recommended that the Boards require a CRNP who prescribes and dispenses medications to carry $400,000 in professional liability insurance, the current level of coverage mandated for certain health care practitioners under the Health Care Services Malpractice Act (40 P. S. §§ 1301.101—1301.1004). The Boards support the principle that a CRNP should carry professional liability insurance, but lack the statutory authority to require it by regulation. The Boards, however, can require that the collaborative agreement of a CRNP with prescriptive authority identify the level of insurance that the CRNP carries. This does not require a CRNP to carry any insurance, but will assure that the collaborating physician and anyone with an interest in reviewing the agreement will be aware of the amount of professional liability insurance, if any, carried by the CRNP.

Prescribing and Dispensing Parameters—§§ 18.54 and 21.284.

IRRC and physician and nurse commentators had several recommendations regarding these sections. IRRC requested that the Boards explain the basis for restrictions and prohibitions of certain drugs in the proposed section. These sections authorize, restrict or prohibit prescribing categories or classes of drugs rather than

[2] The definition is based on the definition of the collaborative agreement between a physician and nurse midwife found at 49 Pa. Code § 18.1.

specific drugs. Sections 18.54(a) and 21.284(a) adopt the American Hospital Formulary Service Pharmacologic-Therapeutic Classification (AHFS) and either: (1) authorize a CRNP to prescribe and dispense from the formulary if the authorization is documented in the collaborative agreement (§§ 18.54(b) and 21.284(b)); or (2) authorize a CRNP to prescribe and dispense if the collaborating physician originally prescribed the drug and approved it for ongoing therapy (§§ 18.54(b)(3) and 21.284(b)(3)); or (3) authorize a CRNP to prescribe or dispense from a category while prohibiting certain subcategories (See §§ 18.54(b)(7)(i)—(ii) and 21.284(b)(7)(i)—(ii)); or (4) prohibit categories of drugs (§§ 18.54(c) and 21.284(c)); or (5) establish parameters for prescribing and dispensing controlled substances (§§ 18.54(e) and (f) and 21.284(e) and (f)). The bases for the restrictions and prohibitions include potential for harm and side effects, need for physician intervention, complexity of prescribing, categories of exceptional breadth, and potential for addiction or abuse.

IRRC suggested that the Boards delete the words "which the CRNP may prescribe and dispense subject to the parameters identified in this section" from §§ 18.54(a) and 21.284(a). The Boards have not done so to avoid suggesting that if a classification of drug were in the AHSF a CRNP would automatically be able to prescribe or dispense from it.

Under subsection (b) of the proposed rulemaking, a CRNP would have been able to prescribe and dispense any drug within the categories of the subsection "without limitation," that is, without the need to list the category of drug in the collaborative agreement. Moreover, it would have been at best implicit that a CRNP, a practitioner who is certified in a specialty area, would prescribe only in the CRNP's area of practice. Under subsection (c) of the proposed rulemaking, a CRNP would have been able to prescribe any drug if the authorization was documented in the collaborative agreement.

The PPS requested that subsections (b) and (c) be combined to clarify that all categories of drugs from which a CRNP would be authorized to prescribe shall be identified in the collaborative agreement. The PAFP also recommended that the collaborative agreement identify every category of drug from which a CRNP might prescribe. Similarly, the HAP recommended that subsection (c) be modified to authorize a CRNP to prescribe a drug in the subsection if the collaborating agreement specifically included the category. Some commentators, including the Pennsylvania Association of Nurse Anesthetists, the PSNA, and a number of nurses, requested that the Boards employ a "negative formulary," and not require the collaborative agreements to list every category of drug from which a CRNP might prescribe. The Boards have not adopted this suggestion.

On final-form rulemaking, the Boards have determined that the collaborative agreement of a CRNP who prescribes should contain a "positive formulary" which specifies every category of drug from which a CRNP might prescribe and dispense. A "positive formulary" assures that the parties to a collaborative agreement have made a conscious determination that the identified categories are appropriate for the CRNP to prescribe. Subsections (b) and (c) have been combined. Subsection (b) makes explicit that the CRNP will be permitted to prescribe and dispense drugs relevant to the CRNP's area of practice.

IRRC, PPS and several other commentators questioned the phrase "without limitation" in §§ 18.54(b) and 21.284(b). IRRC suggested that the phrase could be interpreted in a way that was inconsistent with the current regulations. The Boards have concluded that the phrase was confusing and susceptible to varying interpretations. The Boards have deleted the phrase on final rulemaking.

Several commentators pointed out that several categories of drugs in the AHFS Pharmacologic-Therapeutic Classification were omitted from the proposed rulemaking: eye, ear, nose and throat preparations, hormones and synthetic substitutes, devices, pharmaceutical aids, and unclassified therapeutic agents. These have been included in final rulemaking. Hypoglycemic agents and endocrine replacement agents, not identified as categories in the AHFS Pharmacologic-Therapeutic Classification, have been removed and are replaced with hormones and synthetic substitutes (into which categories these drugs do fall).

In regard §§ 18.54(c) and 21.284(c) of the proposed rulemaking (now subsection (b) in the final rulemaking) IRRC asked how documentation of categories of drugs would be authorized in the collaborative agreement. The parties to the collaborative agreement would simply identify the categories of drugs in the collaborative agreement.

Inappropriate Prescribing—§§ 18.54(d) and 21.284(d).

In regard to §§ 18.54(e) and 21.284(e) (now subsection (d) in final-form rulemaking), IRRC questioned the use of the word "learn" in regard to a physician's method of determining that a CRNP had prescribed incorrectly and recommended a more general course of corrective action than had been proposed. The Boards have adopted both of IRRC's suggestions. The PAFP recommended that if a physician learns that a drug has been wrongly prescribed, the physician should be required to resume direct care of the patient and make the appropriate notifications. Several nurse commentators suggested that the physician should tell the CRNP how to proceed if the physician determines that there has been incorrect prescribing. In final rulemaking, the Boards require the physician to immediately take corrective action on behalf of the patient and notify the patient of the reason for the action and advise the CRNP as soon as possible. Further, the action is required to be noted in the patient's medical record.

Controlled Substances—§§ 18.54(e) and (f) and 21.284(e) and (f).

The Boards made two editorial changes recommended by IRRC to clarify CRNP prescribing of controlled substances. In regard to §§ 18.54(f) and 21.284(f) of the proposed rulemaking (now subsection (e) in the final-form rulemaking), IRRC questioned the clarity of the phrase "immediately (within 24 hours)." The Boards agreed with IRRC's concern that the wording was unclear and replaced the phrase in question with "as soon as possible but in no event longer than 24 hours."

"Off-label" Uses—§§ 18.54(f)(2) and 21.284(f)(2). In regard to §§ 18.54(g)(2) and 21.284(g)(2) of the proposed rulemaking (now subsection (f)(2) in the final rulemaking), IRRC, PSHP and others questioned the use of the word "permitted," pointing out that the Food and Drug Administration approves drugs for clinical use for a single indication and that after a drug has been approved for a single indication a prescriber is free to use that drug for any indication that the prescriber chooses. These alternative uses are generally referred to as "unlabeled uses" or "off-label uses." The Boards replaced the word "permitted" with "approved," and will authorize a CRNP to prescribe or dispense a drug for a use not approved by the FDA if the collaborating physician approves the use.

Schedule II Controlled Substances. The PSS and PAFP recommended that CRNPs not be given the authority to prescribe Schedule II controlled substances at all. PAFP alternatively expressed the view that if CRNPs are permitted to prescribe Schedule II controlled substances, the prescription be limited to 72 hours and the types of drugs be identified in the collaborative agreement. The American Academy of Pediatrics (AAP) recommended that a CRNP be required to notify the collaborating physician promptly and obtain approval prior to dispensing or prescribing "certain" Schedule II drugs, but did not specify which drugs. PMS recommended that a CRNP be permitted to prescribe a Schedule II controlled substance for up to a 72-hour dose only if the CRNP obtains approval from the collaborating physician prior to dispensing or prescribing the medication. The Boards did not adopt these recommendations. Under the final rulemaking the CRNP will be authorized to prescribe a Schedule II controlled substance for up to 72 hours but shall inform the collaborating physician as soon as possible, but in no event longer than 24 hours. The rulemaking will, however, require the collaborative agreement to specify the conditions under which a CRNP may prescribe a Schedule II controlled substance. If a physician does not think it appropriate for a CRNP to prescribe Schedule II controlled substances, that limitation could be included in the collaborative agreement.

Identification of the CRNP—§§ 18.56 and 21.286.

The HPLC, IRRC and others recommended that a CRNP who prescribes medications provide clear and conspicuous notice to patients that he is a CRNP. Similar recommendations were made by the PMS, AAP and individual physicians. The PMS and others also recommended that a CRNP not use abbreviations that are not recognizable to the public and that a CRNP who possesses a doctorate not use only the title, "Doctor" in a clinical setting.

The final-form rulemaking requires that a patient be informed at the time of making an appointment that he or she will be seen by a CRNP, that the CRNP wear a nametag that clearly identifies himself with the title "Certified Registered Nurse Practitioner," and that a CRNP with a doctorate should take appropriate steps to inform patients that he is not a doctor of medicine or doctor of osteopathic medicine.

Physician Supervision—§§ 18.57 and 21.287.

The PMS and PPS recommended that a physician not be permitted to supervise more than four CRNPs who prescribe because it would be, in the view of the PMS, very difficult for a physician to carefully monitor more than that number. Other physician commentators noted that the regulations should require strict physician supervision and oversight. Some nurse commentators maintaind that CRNPs in "solo practice" should not need a collaborating physician. The legislative scheme, however, requires CRNPs to act in accordance with regulations authorized by section 15(a) of the Medical Practice Act (63 P. S. § 422.15(a)). Current regulations define a CRNP as a registered nurse certified in a particular clinical specialty area who performs acts of medical diagnosis or prescription of medical therapeutic or corrective measures "in collaboration with and under the direction of a physician. . . ." (See §§ 18.21 and 21.251) Final rulemaking emphasizes that a collaborating physician is required to provide meaningful direction to a CRNP who prescribes by generally limiting the number of prescribing CRNPs with whom a physican might collaborate. Sections 18.57 and 21.287 would permit a physician to collaborate with four CRNPs who prescribe and dispense drugs at any one time. Under these sections a physician could supervise a total of more than four prescribing and dispensing CRNPs, but not at the same time. Moreover, the regulation would not prohibit the physician from further collaborating with other CRNPs who do not prescribe and dispense and would permit the physician to request a waiver of the limit of four prescribing CRNPs for good cause.

Further Comments.

The Pennsylvania College of Emergency Physicians recommended that the Boards include specific regulatory requirements pertaining to CRNPs prescribing in emergency departments. The Boards decline to do this but point out that the contents of a collaborative agreement could reflect the particular needs of any type of practice, including emergency departments.

The PAFP and several commentators, most of whom were physicians, recommended that CRNPs be required to pass a standard examination for certification. While a board examination is not required for certification under the Medical Practice Act of 1985 (63 P. S. §§ 422.1—422.45) and the Professional Nursing Law (63 P. S. §§ 211—225.5), §§ 18.41 and 21.271 of the regulations of the State Board of Medicine and Nursing establish educational criteria for certification of nurse practitioners. Moreover the Boards carefully review CRNP education programs and approve only those which offer rigorous course work and assessment of the nurse practitioner students.

The PAFP observed that the Boards did not specify that a CRNP must comply with § 16.95 of the regulations of the State Board of Medicine (relating to medical records). While these regulations are not specifically cited, every professional nurse is required to document and maintain accurate records under § 21.18(a)(5) of the regulations of the State Board of Nursing. Further, § 18.111 of the regulations of the State Board of Medicine and § 21.351 of the regulations of the State Board of Nursing authorize the Boards to suspend or revoke the certification of a CRNP who violates any provision of the Medical Practice Act of 1985, the Professional Nursing Law, or the regulations adopted under those acts.

The Pennsylvania Podiatric Medical Association and a number of physician commentators in their opposition to the proposed rulemaking stated that the proposal did not require a collaborative agreement, that a CRNP lacked the knowledge to medically treat a patient, that the State Board of Nursing could amend future regulations without input from the State Board of Medicine, and that the CRNP was wrongly permitted to practice independently and was now the "captain of the ship." While the proposed rulemaking did not adequately address the collaborative agreement, final rulemaking both requires a written agreement and outlines the contents of the agreement. The General Assembly has given the Boards the power to jointly promulgate regulations authorizing CRNPs to perform acts of medical diagnoses and prescription of medical, therapeutic, diagnostic or corrective measures. *See* Part B of this Preamble, Statutory Authority. The current regulations of both Boards provide that a CRNP while functioning in the expanded role as a professional nurse, performs acts of medical diagnosis or corrective measures "in collaboration with and under the direction of a physician. . . ." §§ 18.21 and 21.251. Section 15(b) of the Medical Practice Act of 1985 requires the

joint action of both Boards to promulgate regulations regarding medical acts that might be performed by a CRNP.

The Pennsylvania Association of Chain Drug Stores, Inc. and one chain drug store opposed the proposed rulemaking. PACDS and the chain suggested that while the Boards have the statutory authority to implement regulations authorizing a CRNP to prescribe drugs, statutory authority to authorize a CRNP to dispense a drug is lacking. The Boards have the authority to jointly promulgate regulations authorizing CRNPs to perform acts of medical diagnoses and prescription of medical, therapeutic, diagnostic or corrective measures. *See* Part B of this Preamble, Statutory Authority. Prescribing drugs is the prescription of a medical measure. Section 8(2) of the Pharmacy Act (63 P. S. § 390-8(2)) makes clear that while it is unlawful for someone who is not licensed as a pharmacist to dispense drugs, that prohibition does not extend to "a duly licensed medical practitioner." Section 2(9) of the Pharmacy Act (63 P. S. § 390-2(9)) defines the phrase medical practitioner as "a physician, dentist, veterinarian or other individual duly authorized and licensed by law to prescribe drugs." Authorization to prescribe drugs includes authorization to dispense drugs.

Finally, the Pennsylvania Osteopathic Medical Association expressed the view that CRNPs should be "under the jurisdiction of a physician" and was concerned that "CRNPs are not adequately trained to practice independently with prescriptive authority." A CRNP performs in an expanded role as a professional nurse and performs acts of medical diagnosis or prescription of medical therapeutic or corrective measures in collaboration with and under the direction of a physician licensed to practice medicine in this Commonwealth. See §§ 18.51 and 21.251. This rulemaking does not curtail the responsibility of the collaborating physician to provide collaboration and direction.

F. Fiscal Impact and Paperwork Requirements

There will be an increase in costs to the Commonwealth. Board staff will have to receive and file copies of the collaborative agreements of those CRNPs who prescribe and dispense drugs. Board staff will also have to slightly modify the CRNP renewal application to include a provision which will enable a CRNP with prescriptive authority to certify that the CRNP has completed the 16 hours of required continuing education courses. Board staff will have to review renewal applications to ascertain that prescribing CRNPs have fulfilled continuing education requirements. The Nurse Board and its staff will have to review programs wishing to offer either courses in advanced pharmacology or continuing education, or both. The amount of these costs have not been ascertained because there is no history of these costs. Costs to the regulated community will be increased in that collaborating physicians and CRNPs who wish to prescribe will have to modify their collaborative agreements to include the required content of §§ 18.55 and 21.285 (relating to the collaborative agreement). A CRNP who wishes to prescribe but who has not already taken 45 hours of advanced pharmacology will have to bear the costs of taking a course or courses in advanced pharmacology. Prescribing CRNPs will also have to bear the costs of continuing education courses. CRNPs who prescribe and their collaborating physicians will bear the costs of forwarding a copy of the collaborative agreement to the Bureau of Professional and Occupational Affairs. The costs of this rulemaking may be passed on to consumers of CRNP services. It is unlikely that these costs will result in significantly increased prices. The costs may be offset by the greater availability of medical services and the increased efficiency engendered by having CRNPs who can prescribe without the prior intervention of a physician. Citizens of this Commonwealth will benefit from having more ready access to cost-effective, quality health care. Revising collaborative agreements and forwarding a copy to the Bureau represent the largest increase in paperwork in regard to this rulemaking.

G. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), the Boards submitted a copy of the notice of proposed rulemaking, published at 29 Pa.B. 5101, to IRRC and to 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(c) of the Regulatory Review Act, the Boards also provided IRRC and the Committees with copies of the comments received as well as other documentation.

In preparing these final-form regulations, the Boards have considered the comments received from IRRC and the public.

These final-form regulations were disapproved by IRRC at its meeting of July 13, 2000. IRRC's order of disapproval was received by the Boards on September 11, 2000. On that date the Boards, under section 7(a) of the Regulatory Review Act (71 P. S. § 745.7(a)), submitted written notice of their intention to modify the final-form rulemaking in accordance with section 7(c) of the Regulatory Review Act, to the Governor, IRRC and the House and Senate Committees.

On October 2, 2000, the Boards delivered final revised rulemaking and the section 7(c) report to the Governor, IRRC and the House and Senate Committees.

The final-form regulations were approved by the House Committee on October 3, 2000, deemed approved by the Senate Committee on October 12, 2000, and approved by IRRC on October 19, 2000.

H. Sunset Date

The Board continuously monitors its final-form regulations. Therefore, no sunset date has been assigned.

I. Contact Person

Further information may be obtained by contacting Ann Steffanic, Board Administrator, State Board of Nursing or Cindy Warner, Board Administrator, State Board of Medicine, P. O. Box 2649, Harrisburg, PA 17105-2649, (717) 783-7142 and 783-1400, respectively.

J. Findings

The Boards find 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 in 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 29 Pa.B. 5101.

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

K. Order

The Boards, acting under their authorizing statutes, order that:

(a) The regulations of the Boards, 49 Pa. Code Chapters 18 and 21, are amended by adding §§ 18.53—18.57 and 21.283—21.287 to read as set forth in Annex A.

(b) The Boards 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 Boards 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*.

CHARLES D. HUMMER, Jr., MD,
STEPHEN K. ANDERSON, RN, CRNA,
Chairpersons

Fiscal Note: Fiscal Note 16A-499 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 18. STATE BOARD OF MEDICINE

Subchapter C. CERTIFIED REGISTERED NURSE PRACTITIONERS

CRNP PRACTICE

§ 18.53. Prescribing and dispensing drugs.

A CRNP may prescribe and dispense drugs if the following requirements are met:

(1) The CRNP has completed a CRNP program which is approved by the Boards or, if completed in another state, is equivalent to programs approved by the Boards.

(2) The CRNP has successfully completed at least 45 hours of course work specific to advanced pharmacology in accordance with the following:

(i) The course work in advanced pharmacology may be either part of the CRNP education program or, if completed outside of the CRNP education program, an additional course or courses taken from an educational program or programs approved by the Boards.

(ii) The course work in advanced pharmacology must be at an advanced level above a pharmacology course required by a professional nursing (RN) education program.

(3) A CRNP who has prescriptive authority shall complete at least 16 hours of State Board of Nursing approved continuing education in pharmacology in the 2 years prior to the biennial renewal date of his or her CRNP certification. The CRNP shall show proof that she completed the continuing education when submitting a biennial renewal.

(4) In prescribing and dispensing drugs, a CRNP shall comply with standards of the State Board of Medicine in §§ 16.92—16.94 (relating to prescribing, administering and dispensing controlled substances; packaging; and labeling of dispensed drugs) and the Department of Health in 28 Pa. Code §§ 25.51—25.58, 25.61—25.81 and 25.91—25.95.

§ 18.54. Prescribing and dispensing parameters.

(a) The Board adopts the American Hospital Formulary Service Pharmacologic-Therapeutic Classification to identify drugs which the CRNP may prescribe and dispense subject to the parameters identified in this section.

(b) A CRNP may prescribe and dispense a drug relevant to the area of practice of the CRNP from the following categories if that authorization is documented in the collaborative agreement (unless the drug is limited or excluded under this or another subsection):

(1) Antihistamines.

(2) Anti-infective agents.

(3) Antineoplastic agents, unclassified therapeutic agents, devices and pharmaceutical aids if originally prescribed by the collaborating physician and approved by the collaborating physician for ongoing therapy.

(4) Autonomic drugs.

(5) Blood formation, coagulation and anticoagulation drugs, and thrombolytic and antithrombolytic agents.

(6) Cardiovascular drugs.

(7) Central nervous system agents, except that the following drugs are excluded from this category:

(i) General anesthetics.

(ii) Monoamine oxidase inhibitors.

(8) Contraceptives including foams and devices.

(9) Diagnostic agents.

(10) Disinfectants for agents used on objects other than skin.

(11) Electrolytic, caloric and water balance.

(12) Enzymes.

(13) Antitussive, expectorants and mucolytic agents.

(14) Gastrointestinal drugs.

(15) Local anesthetics.

(16) Eye, ear, nose and throat preparations.

(17) Serums, toxoids and vaccines.

(18) Skin and mucous membrane agents.

(19) Smooth muscle relaxants.

(20) Vitamins.

(21) Hormones and synthetic substitutes.

(c) A CRNP may not prescribe or dispense a drug from the following categories:

(1) Gold compounds.

(2) Heavy metal antagonists.

(3) Radioactive agents.

(4) Oxytocics

(d) If a collaborating physician determines that the CRNP is prescribing or dispensing a drug inappropriately, the collaborating physician shall immediately take corrective action on behalf of the patient and notify the patient of the reason for the action and advise the CRNP as soon as possible. This action shall be noted by the CRNP or the collaborating physician, or both, in the patient's medical record.

(e) Restrictions on CRNP prescribing and dispensing practices are as follows:

(1) A CRNP may write a prescription for a Schedule II controlled substance for up to a 72 hour dose. The CRNP shall notify the collaborating physician as soon as possible but in no event longer than 24 hours.

(2) A CRNP may prescribe a Schedule III or IV controlled substance for up to 30 days. The prescription is not subject to refills unless the collaborating physician authorizes refills for that prescription.

(f) A CRNP may not:

(1) Prescribe or dispense a Schedule I controlled substance as defined in section 4 of the Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § 780-14).

(2) Prescribe or dispense a drug for a use not approved by the United States Food and Drug Administration without approval of the collaborating physician.

(3) Delegate prescriptive authority specifically assigned to the CRNP by the collaborating physician to another health care provider.

(g) A prescription blank shall bear the certification number of the CRNP, name of the CRNP in printed format at the top of the blank and a space for the entry of the DEA registration number, if appropriate. The collaborating physician shall also be identified as required in § 16.91 (relating to identifying information on prescriptions and orders for equipment and service).

(h) The CRNP shall document in the patient's medical record the name, amount and dose of the drug prescribed, the number of refills, the date of the prescription and the CRNP's name.

§ 18.55. Collaborative agreement.

(a) A collaborative agreement is the signed written agreement between a CRNP and a collaborating physician in which they agree to the details of the collaborative arrangement between them with respect to the care of CRNP patients.

(b) The collaborative agreement between a physician and a CRNP who will prescribe drugs shall satisfy the following requirements. The agreement shall:

(1) Identify the parties, including the collaborating physician, the CRNP and a substitute physician who will provide collaboration and direction for up to 30 days if the collaborating physician is unavailable.

(2) Identify the area of practice in which the CRNP is certified.

(3) Identify the categories of drugs from which the CRNP may prescribe or dispense in accordance with § 18.54.

(4) Contain attestation by the collaborating physician that the CRNP has knowledge and experience with any drug that the CRNP will prescribe.

(5) Specify the circumstances and how often the collaborating physician will personally see the patient, based on the type of practice, sites of service and condition of the patient, whether the treatment is for an ongoing or new condition, and whether the patient is new or continuing.

(6) Specify the conditions under which the CRNP may prescribe a Schedule II controlled substance for up to 72 hours.

(7) Be kept at the primary practice location of the CRNP and a copy filed with the Bureau of Professional and Occupational Affairs.

(8) Be made available for inspection to anyone seeking to confirm the scope of practice of the CRNP.

(9) Be updated by the collaborating physician and the CRNP whenever it is changed substantively.

(10) Specify the amount of professional liability insurance carried by the CRNP.

(c) The CRNP shall notify the Bureau whenever a collaborative agreement of a CRNP who prescribes and dispenses drugs is updated or terminated.

§ 18.56. Identification of the CRNP.

(a) A patient shall be informed at the time of making an appointment that the patient will be seen by a CRNP.

(b) A CRNP shall wear a name tag that clearly identifies the CRNP with the title "Certified Registered Nurse Practitioner."

(c) A CRNP who holds a doctorate should take appropriate steps to inform patients that the CRNP is not a doctor of medicine or doctor of osteopathic medicine.

§ 18.57. Physician supervision.

(a) At any time a physician may not supervise more than four CRNPs who prescribe and dispense drugs. This subsection does not limit the number of collaborative agreements that a physician may have with prescribing CRNPs. By way of example, a physician may supervise four prescribing CRNPs who work in the morning and four other prescribing CRNPs who work in the afternoon as long as the physician has a collaborative agreement with each CRNP.

(b) A physician may apply for a waiver of the supervision requirements expressed in subsection (a) for good cause, as determined by the Boards.

(c) The limit of the general rule of not more than four prescribing CRNPs to one physician does not apply to CRNPs who do not prescribe or dispense drugs. By way of example, a physician may supervise at the same time four CRNPs who prescribe and dispense drugs and one or more CRNPs who do not prescribe and dispense drugs.

CHAPTER 21. STATE BOARD OF NURSING

Subchapter C. CERTIFIED REGISTERED NURSE PRACTITIONERS

CRNP PRACTICE

§ 21.283. Prescribing and dispensing drugs.

A CRNP may prescribe and dispense drugs if the following requirements are met:

(1) The CRNP has completed a CRNP program which is approved by the Boards or, if completed in another state, is equivalent to programs approved by the Boards.

(2) The CRNP has successfully completed at least 45 hours of course work specific to advanced pharmacology in accordance with the following:

(i) The course work in advanced pharmacology may be either part of the CRNP education program or, if completed outside of the CRNP education program, an additional course or courses taken from an educational program or programs approved by the Boards.

(ii) The course work shall be at an advanced level above a pharmacology course required by a professional nursing (RN) education program.

(3) A CRNP who has prescriptive authority shall complete at least 16 hours of State Board of Nursing approved continuing education in pharmacology in the 2

years prior to the biennial renewal date of the CRNP certification. The CRNP shall show proof that the CRNP completed the continuing education when submitting a biennial renewal.

(4) In prescribing and dispensing drugs, a CRNP shall comply with standards of the State Board of Medicine in §§ 16.92—16.94 (relating to prescribing, administering and dispensing controlled substances; packaging; and labeling of dispensed drugs) and the Department of Health in 28 Pa. Code §§ 25.51—25.58, 25.61—25.81 and 25.91—25.95.

§ 21.284. Prescribing and dispensing parameters.

(a) The Board adopts the American Hospital Formulary Service Pharmacologic-Therapeutic Classification to identify drugs which the CRNP may prescribe and dispense subject to the parameters identified in this section.

(b) A CRNP may prescribe and dispense a drug relevant to the area of practice of the CRNP from the following categories if that authorization is documented in the collaborative agreement (unless the drug is limited or excluded under this or another subsection):

(1) Antihistamines.

(2) Anti-infective agents.

(3) Antineoplastic agents, unclassified therapeutic agents, devices and pharmaceutical aids if originally prescribed by the collaborating physician and approved by the collaborating physician for ongoing therapy.

(4) Autonomic drugs.

(5) Blood formation, coagulation and anticoagulation drugs, and thrombolytic and antithrombolytic agents.

(6) Cardiovascular drugs.

(7) Central nervous system agents, except that the following drugs are excluded from this category:

(i) General anesthetics.

(ii) Monoamine oxidase inhibitors.

(8) Contraceptives including foams and devices.

(9) Diagnostic agents.

(10) Disinfectants for agents used on objects other than skin.

(11) Electrolytic, caloric and water balance.

(12) Enzymes.

(13) Antitussive, expectorants and mucolytic agents.

(14) Gastrointestinal drugs.

(15) Local anesthetics.

(16) Eye, ear, nose and throat preparations.

(17) Serums, toxoids and vaccines.

(18) Skin and mucous membrane agents.

(19) Smooth muscle relaxants.

(20) Vitamins.

(21) Hormones and synthetic substitutes.

(c) A CRNP may not prescribe or dispense a drug from the following categories:

(1) Gold compounds.

(2) Heavy metal antagonists.

(3) Radioactive agents.

(4) Oxytocics.

(d) If a collaborating physician determines that the CRNP is prescribing or dispensing a drug inappropriately, the collaborating physician shall immediately take corrective action on behalf of the patient and notify the patient of the reason for the action and advise the CRNP as soon as possible. This action shall be noted by the CRNP or the collaborating physician, or both, in the patient's medical record.

(e) Restrictions on CRNP prescribing and dispensing practices are as follows:

(1) A CRNP may write a prescription for a Schedule II controlled substance for up to a 72 hour dose. The CRNP shall notify the collaborating physician as soon as possible but in no event longer than 24 hours.

(2) A CRNP may prescribe a Schedule III or IV controlled substance for up to 30 days. The prescription is not subject to refills unless the collaborating physician authorizes refills for that prescription.

(f) A CRNP may not:

(1) Prescribe or dispense a Schedule I controlled substance as defined in section 4 of the Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § 780-14).

(2) Prescribe or dispense a drug for a use not approved by the United States Food and Drug Administration without approval of the collaborating physician.

(3) Delegate prescriptive authority specifically assigned to the CRNP by the collaborating physician to another health care provider.

(g) A prescription blank shall bear the certification number of the CRNP, name of the CRNP in printed format at the top of the blank and a space for the entry of the DEA registration number, if appropriate. The collaborating physician shall also be identified as required in § 16.91 (relating to identifying information on prescriptions and orders for equipment and service).

(h) The CRNP shall document in the patient's medical record the name, amount and dose of the drug prescribed, the number of refills, the date of the prescription and the CRNP's name.

§ 21.285. Collaborative agreement.

(a) A collaborative agreement is the signed written agreement between a CRNP and a collaborating physician in which they agree to the details of the collaborative arrangement between them with respect to the care of CRNP patients.

(b) The collaborative agreement between a physician and a CRNP who will prescribe drugs shall satisfy the following requirements. The agreement shall:

(1) Identify the parties, including the collaborating physician, the CRNP, and a substitute physician who will provide collaboration and direction for up to 30 days if the collaborating physician is unavailable.

(2) Identify the area of practice in which the CRNP is certified.

(3) Identify the categories of drugs from which the CRNP may prescribe or dispense in accordance with § 21.284 (relating to prescribing and dispensing parameters).

(4) Contain attestation by the collaborating physician that the CRNP has knowledge and experience with any drug that the CRNP will prescribe.

(5) Specify the circumstances and how often the collaborating physician will personally see the patient, based

on the type of practice, sites of service and condition of the patient, whether the treatment is for an ongoing or new condition, and whether the patient is new or continuing.

(6) Specify the conditions under which the CRNP may prescribe a Schedule II controlled substance for up to 72 hours.

(7) Be kept at the primary practice location of the CRNP and a copy filed with the Bureau of Professional and Occupational Affairs.

(8) Be made available for inspection to anyone seeking to confirm the scope of practice of the CRNP.

(9) Be updated by the collaborating physician and the CRNP whenever it is changed substantively.

(10) Specify the amount of professional liability insurance carried by the CRNP.

(c) The CRNP shall notify the Bureau whenever a collaborative agreement of a CRNP who prescribes and dispenses drugs is updated or terminated.

§ 21.286. Identification of the CRNP.

(a) A patient shall be informed at the time of making an appointment that the patient will be seen by a CRNP.

(b) A CRNP shall wear a name tag that clearly identifies the CRNP with the title "certified registered nurse practitioner."

(c) A CRNP who holds a doctorate should take appropriate steps to inform patients that the CRNP is not a doctor of medicine or doctor of osteopathic medicine.

§ 21.287. Physician supervision.

(a) At any time a physician may not supervise more than four CRNPs who prescribe and dispense drugs. This section, however, does not limit the number of collaborative agreements that a physician may have with prescribing CRNPs. By way of example, a physician may supervise four prescribing CRNPs who work in the morning and four other prescribing CRNPs who work in the afternoon as long as the physician has a collaborative agreement with each CRNP.

(b) A physician may apply for a waiver of the supervision requirements expressed in subsection (a) for good cause, as determined by the Boards.

(c) The limit of the general rule of not more than four prescribing CRNPs to one physician does not apply to CRNPs who do not prescribe or dispense drugs. By way of example, a physician may supervise at the same time four CRNPs who prescribe and dispense drugs and one or more CRNPs who do not prescribe and dispense drugs.

[Pa.B. Doc. No. 00-1974. Filed for public inspection November 17, 2000, 9:00 a.m.]

STATE BOARD OF NURSING
[49 PA. CODE CH. 21]
Biennial Renewal Fees

The State Board of Nursing (Board) amends §§ 21.5, 21.147 and 21.253 (relating to fees) by revising biennial renewal fees. The amendments increase renewal fees for registered nurses from $21 to $45, for licensed practical nurses from $16 to $40 and for certified registered nurse practitioners (CRNPs) from $26 to $50.

A. Effective Date

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

B. Statutory Authority

Section 11.2(a), (b) and (d) of the Professional Nursing Law (63 P. S. § 221.2(a), (b) and (d)) and section 17.5(a) and (b) of the Practical Nurse Law (63 P. S. § 667.5(a) and (b)), require the Board to set fees required for renewal of licenses and certificates by regulation. The same provisions require the Board to increase fees by regulation to meet or exceed projected expenditures if the current revenues raised by fees, fines and civil penalties are not sufficient to meet projected expenditures and to increase fees in an amount that insures adequate revenues are raised to meet the required enforcement efforts.

C. Background and Purpose

The Board's licensure laws require that the Board fund enforcement and operating expenses through biennial renewal fees, fines and penalties. The biennial renewal fees fund nearly all of the Board's costs.

In accordance with the laws, the Board, in conjunction with the Department's Budget and Financial Management Office and its Revenue Office, has reviewed the actual expenditures and revenue history of the Board against its projected expenses and revenue. The review of the actual expenditures and revenue determined that the last recorded positive revenue balance was on June 30, 1998, and that the biennial renewal fees were not adequate to meet current and projected expenditures. The amendments update the biennial renewal fees to meet or exceed expenditures. A detailed explanation of the background of these fees as well as a description of the fees was published at 30 Pa.B. 2265 (May 6, 2000).

D. Summary of Comments and Responses on Proposed Rulemaking

Notice of proposed rulemaking was published at 30 Pa.B. 2265. Publication was followed by a 30-day public comment period. The Board received comments from three public commentators, the Hospital and Healthsystem Association of Pennsylvania (HAP), Johanna B. Mattiola, RN (Mattiola) and Paula D. Earliwine, RN (Earliwine). In accordance with the Regulatory Review Act (71 P. S. §§ 745.1—745.15), the proposal was reviewed by the Independent Regulatory Review Commission (IRRC), the House Professional Licensure Committee (HPLC) and the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC). No objections, suggestions or comments were made. The following is the Board's response to the public comments.

HAP suggested that the Board use the biennial renewal process to collect and disseminate comprehensive data about licensed nurses in this Commonwealth. The comprehensive data HAP suggested that the Board collect and disseminate includes demographic information, professional characteristics, employment characteristics and educational characteristics. HAP also recommended that the cost of data collection should be built into the biennial renewal fees.

The Board notes that it does not have the statutory authority to collect the comprehensive data that HAP has suggested. Further, the purpose of the biennial renewal fee regulation is to fund the Board's costs for general operations, enforcement, and confirming continued eligibility for licensure, all of which have specific statutory and regulatory requirements. Comprehensive data collec-

tion is not the purpose of the biennial renewal fee regulation. Thus, the addition of comprehensive data collection would impermissibly exceed the scope of the Board's statutory authority and impermissibly exceed the purpose of proposed rulemaking. The Board also notes that the biennial renewal fees are calculated based upon actual and projected expenditures and do not include the costs of comprehensive data collection. Comprehensive data collection would result in increased fees to licensees for activities that are beyond the authority of the Board and beyond the purpose of proposed rulemaking. Therefore, the Board has determined that comprehensive data collection should not be included in final-form rulemaking.

Mattiola and Earliwine expressed concern that the increase in fees was excessive and suggested that legal costs should be offset by collecting fees from those who are disciplined by the Board. The Board notes that the costs of monitoring licensees in monitoring programs are borne by the monitored licensees, and that the revenue received from civil penalties and fines has already been factored into the calculations used to increase the biennial renewal fees. The Board further notes that the biennial renewal fees fund nearly all the Board's costs; that the biennial renewal fees were last updated in 1992; and that the Board last recorded a positive revenue/expenditure balance on June 30, 1998. The Board is required by law to increase fees to meet or exceed expenditures. Additionally, the Commonwealth's biennial renewal fees remain significantly lower than the biennial renewal fees in several neighboring states. Details of the Board's analysis are in the Regulatory Review Form, which is available upon request.

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 community under the directives of Executive Order 1996-1 (February 6, 1996), Regulatory Review and Promulgation. The final-form regulations address a compelling public interest as described in this Preamble and otherwise comply with Executive Order 1996-1.

F. Fiscal Impact

These final-form regulations will have no adverse fiscal impact on the Commonwealth or its political subdivisions. The fees will have a modest fiscal impact on licensees who renew their license biennially. Licensed practical nurses, registered nurses and certified registered nurse practitioners will pay an additional $24 for biennial renewal.

G. Paperwork Requirements

The final-form regulations will require the Board to alter some of its forms to reflect the new biennial renewal fees; however, the regulations should not create additional paperwork for the private sector.

H. Sunset Date

The Professional Nursing Law (63 P. S. §§ 651—667.8) and the Practical Nurse Law (63 P. S. §§ 211—225.5) require that the Board monitor its revenue and cost on a fiscal year and biennial basis. Therefore, no sunset date has been assigned.

I. Regulatory Review

Under to section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), the Board submitted a copy of notice of proposed rulemaking, published at 30 Pa.B. 2265, to IRRC, and to the Chairpersons of the HPLC and SCP/PLC for review and comment.

In accordance with section 5(c) of the Regulatory Review Act, the Board also provided IRRC and the Committees with copies of comments received, as well as other documentation. In preparing these final-form regulations, the Board has considered the comments received.

These final-form regulations were approved by the HPLC on October 11, 2000, and deemed approved by the SCP/PLC on October 15, 2000. IRRC met on October 19, 2000. The final-form regulations were deemed approved in accordance with section 5.1(g) of the Regulatory Review Act (71 P. S. § 745.5a(g)).

I. Contact Person

Further information may be obtained by contacting Ann Steffanic, Administrative Assistant, State Board of Nursing, P. O. Box 2649, Harrisburg, PA 17105-2649, (717) 783-7200.

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, 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 30 Pa.B. 2265.

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

K. Order

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

(1) The regulations of the Board, 49 Pa. Code Chapter 21, are amended by amending §§ 21.5, 21.147 and 21.253 to read as set forth at 30 Pa.B. 2265.

(2) The Board shall submit this order and 30 Pa.B. 2265 to the Office of General Counsel and to the Office of Attorney General as required by law.

(3) The Board shall certify this order and 30 Pa.B. 2265 and deposit them with the Legislative Reference Bureau as required by law.

(4) This order shall take effect on publication in the *Pennsylvania Bulletin*.

K. STEPHEN ANDERSON, CRNP,
Chairperson

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission, relating to this document, see 30 Pa.B. 5807 (November 4, 2000).)

Fiscal Note: Fiscal Note 16A-5113 remains valid for the final adoption of the subject regulations.

[Pa.B. Doc. No. 00-1975. Filed for public inspection November 17, 2000, 9:00 a.m.]

STATE BOARD OF VETERINARY MEDICINE
[49 PA. CODE CH. 31]
Biennial Renewal Fees

The State Board of Veterinary Medicine (Board) adopts an amendment to § 31.41 (relating to fees).

Notice of proposed rulemaking was published at 30 Pa.B. 2378 (May 13, 2000). Publication was followed by a 30-day public comment period during which the Board received no comments from the general public. Neither the House Professional Licensure Committee nor the Senate Consumer Protection and Professional Licensure Committee made comments on the proposed amendment. On July 13, 2000, the Independent Regulatory Review Commission (IRRC) sent a letter to the Board, stating it had no objections, comments or suggestions to offer on the amendment.

The amendment will increase the biennial license renewal fee for veterinarians from $105 to $225 and for animal health technicians from $30 to $60, as required to support the operations of the Board. A detailed description of the amendment may be found in the notice of proposed rulemaking.

Statutory Authority

The amendment is authorized under section 13(a) and (b) of the Veterinary Medicine Practice Act (act) (63 P. S. § 485.13(a) and (b)). Section 13(a) of the act requires the Board to fix the fees required for renewal of licenses and certificates by regulation. In addition, section 13(b) of the act requires the Board to increase fees to meet or exceed projected expenditures if the revenues raised by fees, fines and civil penalties are not sufficient to meet expenditures.

Fiscal Impact

The amendment will increase the biennial renewal fee for veterinarians and animal health technicians. A veterinarian will pay an additional $120 for biennial renewal. An animal health technician will pay an additional $30 for biennial renewal. The amendment should have no other fiscal impact on the private sector, the general public or political subdivisions.

Paperwork Requirements

The amendment will require the Board to alter some of its forms to reflect the new biennial renewal fees; however, the amendment should not create additional paperwork for the private sector.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), the Board submitted a copy of the notice of proposed rulemaking, published at 30 Pa.B. 2378 to IRRC and to the Chairpersons of the House Committee on Professional Licensure and the Senate Committee on Consumer Protection and Professional Licensure.

Publication of the notice of proposed rulemaking was followed by a 30-day public comment period during which the Board received no written comment from the public. Subsequent to the close of the public comment period, the Board received no comments from the House or Senate Committee. The Board received and considered comments from IRRC.

This final-form regulation was approved by the House Professional Licensure Committee on October 3, 2000, and was deemed approved by the Senate Consumer Protection and Professional Licensure Committee on October 9, 2000. The final-form regulation was deemed approved by IRRC under section 5(g) of the Regulatory Review Act, effective October 11, 2000.

Further Information

Individuals who need information about the final-form regulation may contact Robert Kline, Administrative Assistant, State Board of Veterinary Medicine, P. O. Box 2649, Harrisburg, PA 17105-2649, (717) 783-4848.

Findings

The Board finds that:

(1) Public notice of intention to adopt an amendment to Chapter 31 was given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (5 P. S. §§ 1201 and 1202) and the regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) The amendment is necessary and appropriate for the administration of the act.

Order

The Board orders that:

(a) The regulations of the Board, 49 Pa. Code Chapter 31, are amended by amending § 31.41 to read as set forth at 30 Pa.B. 2378.

(b) The Board shall submit a copy of this order and 30 Pa.B. 2378 to the Office of the Attorney General and the Office of General Counsel for approval as required by law.

(c) The Board shall certify this order and 30 Pa.B. 2378 and shall deposit them with the Legislative Reference Bureau as required by law.

(d) The amendment shall take effect immediately upon publication in the *Pennsylvania Bulletin*.

BRIAN V. HARPSTER, V.M.D.,
Chairperson

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission, relating to this document, see 30 Pa.B. 5807 (November 4, 2000).)

Fiscal Note: Fiscal Note 16A-579 remains valid for the final adoption of the subject regulation.

[Pa.B. Doc. No. 00-1976. Filed for public inspection November 17, 2000, 9:00 a.m.]

STATE REAL ESTATE COMMISSION
[49 PA. CODE CH. 35]
General Revisions

The State Real Estate Commission (Commission) amends Chapter 35 (relating to State Real Estate Commission) to read as set forth in Annex A.

Summary

This rulemaking updates the Commission's existing regulations to address issues of current importance to the

real estate industry and to better serve and protect the interest of consumers who use the services of a licensee in a real estate transaction.

In the final-form rulemaking, the Commission made changes to §§ 35.271, 35.304, 35.305 and 35.308. Editorial changes are also made to §§ 35.201, 35.281 and 35.287. As to proposed changes to §§ 35.222, 35.223, 35.245, 35.322 and 35.327, the Commission has withdrawn the proposed rulemaking.

Response to Comments

Notice of proposed rulemaking was published at 29 Pa.B. 565 (January 30, 1999). Publication was followed by a 30-day public comment period during which the Board received comments from the Pennsylvania Association of Realtors (PAR). Following the close of the public comment period, the Board also received comments from the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC). The final-form rulemaking is in response to the comments and suggestions received by the commentators and the regulatory review bodies.

For ease of reference, the Commission will address the comments in the order in which the amendments appear.

1. *§ 35.222(b). Licensure as broker.*
§ 35.223(b). Licensure as salesperson.

In proposed form, the Commission rewrote the requirements for nonresident brokers and salespersons seeking to obtain licensure by recognition of a license in another state. The HPLC questioned the rationale of the Commission's requirement that a broker be licensed in another state for 5 years prior to submitting an application for licensure. IRRC suggested that the term "active" replace "current" since a current license may be inactive. The Commission has determined that it wishes to study the issue of license by endorsement of another state's license. As such, the Commission has withdrawn the proposed revision. Therefore no changes to §§ 35.322(b) and 35.323(b) are made in final-form rulemaking.

2. *§ 35.245. Display of licenses in office.*

Proposed § 35.245 required licensees to display their licenses in their broker's office and display a photocopy in the office where they work. The HPLC questioned the Commission's authority to require that a photocopy and not the original be displayed. Owing to HPLC's concern, the Commission has withdrawn the revision and has determined to make no change to § 35.245 in the final-form rulemaking.

3. *§ 35.271(b)(2). Examination for broker's license.*

Proposed § 35.271(b)(2) would be amended to require mandatory education courses for brokers in office management and real estate law. The HPLC suggested that these courses would be more appropriate for continuing education for all licensees and not just newly licensed brokers. Although these courses may be of some educational value to licensees generally, it is the Commission experience that many broker violations involve escrow accounts and failure to supervise salespersons. These activities are, in the view of the Commission, core practices, knowledge of which should form the basis of broker education. In an attempt to reduce the number of violations, the Commission believes that applicants for a license should be required to complete an intensive course specifically designed to address the additional responsibilities imposed upon brokers. Finally, the Commission notes that salespersons and licensed brokers may take either the office management or law courses as part of their continuing education requirement.

4. *§ 35.271(b)(3)(iv). Examination for broker's license.*

The proposed amendment to § 35.271(b)(3)(iv) would permit education courses offered by real estate organizations in another jurisdiction, provided they are approved by the licensing authority in that state to be counted toward the education requirement to sit for the examination.

The HPLC questioned whether permitting out-of-State courses to be counted toward the educational requirement would raise or lower standards for licensure. Under the current regulations, only courses offered in this Commonwealth are eligible for credit. Unfortunately, not all National courses, especially those in specialized areas such as commercial and property management, are taught in this Commonwealth. Therefore the Commission believes that permitting applicants to receive credit for a real estate course taught in another jurisdiction may raise educational standards and will benefit the licensees and consumers of real estate services in this Commonwealth.

5. *§ 35.305. Business name on advertisements.*

Proposed § 35.305 eliminates the current requirement that the brokers name and telephone number be given greater prominence in advertisements. As proposed, the section requires that the broker's name and number be the same size as the advertising licensee. The HPLC questioned the necessity of the amendment.

The HPLC commented that the current regulation accomplishes the Commission's objective of "ensuring that a consumer will know the name and telephone number of the broker who is legally responsible for the activities of the employe." The HPLC requested a cost analysis of the cost differential under the current regulation and the proposed amendment.

The existing regulation imposes a cost on salespersons not justified by a larger typeface. Since advertising fees vary by media and market area it is not possible to quantify the costs throughout this Commonwealth. Nonetheless, the Commission believes most licensees experience a substantial cost savings annually by eliminating the greater prominence requirement because advertisements are paid by the inch. The public will be able to identify the broker's name and number, equally as well as those of the salesperson. For these reasons, no change has been made in final rulemaking.

6. *§ 35.308. Relationship with educational institution.*

Proposed § 35.308 requires real estate companies, franchises and networks to disclose ownership interests in advertisements, promotions and endorsements.

The HPLC requested an explanation why the Commission reversed its position taken when this provision was originally promulgated, that this regulation was needed "to prevent real estate firms from steering prospective students to real estate providers with which the firms have business of financial relationships."

The Commission understands that some real estate companies have an ownership interest in real estate schools. The Commission believes that it is in the best interest of students and consumers to know of this ownership interest and make choices accordingly. Despite this notice ability, § 35.354(a)(8) prohibits schools from recruiting or soliciting students.

7. *§ 35.322. Transfer of escrow funds.*

Proposed § 35.322 would have permitted buyers and sellers to change how the escrow moneys are being held after the agreement is signed. The Commission is aware there are circumstances when the parties desire to have escrow funds released prior to the consummation of the agreement. For example, after the agreement is signed, the seller may agree to extend the settlement date for the buyer if the buyer agrees to release the escrow funds. To accomplish this under the current regulations, the agreement must be terminated and a new agreement executed.

The HPLC commented that section 604(5)(I) of the Real Estate Licensing and Registration Act (63 P. S. §§ 455.604 (5)(l)) (act) prohibits a broker from transferring funds prior to the consummation or termination of the real estate transaction. It opined that "the Commission lacks the legislative authority to promulgate the provisions related to the transfer of escrow funds." Echoing PAR's comment, IRRC suggested that the term "separate" be deleted.

In response to the comments of the HPLC, the Commission has removed the language added on proposed.

8. *§ 35.327. Procedure when entitlement to money held in escrow is disputed.*

Under the current regulations, when parties to disputed escrow funds are unwilling to sign a release, it is left to the broker to file an interpleader action in the courts of common pleas. The costs associated with this interpleader action include the filing fee and the attorney's fees to draft the pleading. The amendment to subsection (a) would have permitted the broker to recoup the costs of filing the interpleader.

Also, during the Commission's public meetings and in many inquiries by consumers and licensees, the Commission has been asked what a broker is to do when the broker either goes out of business or retires and there is money in the disputed escrow fund. Under the current regulations, the accounts must remain open. In an attempt to deal with this issue, the Commission would have amended subsection (b).

Both the HPLC and IRRC commented that the Commission does not have the statutory authority under section 604(a)(5)(iv) of the act to permit the broker to deduct costs from the escrow account or dispose of moneys when the parties have not consented or a civil action filed. The HPLC further suggested that subsection (b) "improperly places the broker in the position of being the final arbiter of fact and law" and "unnecessarily exposes the broker to claims of liability from the aggrieved party." Both recommend deleting all amendments. Additionally, PAR and IRRC recommended that the term "release" be replaced with "agreement regarding its disposition."

Owing to the statutory concerns raised by the HPLC and IRRC the Commission has withdrawn the amendatory language in final rulemaking.

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 interest as described in this Preamble and otherwise comply with Executive Order 1996-1.

Fiscal Impact and Paperwork Requirements

The amendments will have no fiscal impact on the Commonwealth, its political subdivisions, the public and the regulated community. Likewise, the amendments will not necessitate any legal, accounting, reporting or other paperwork requirements on the regulated community.

Statutory Authority

The amendments are authorized by sections 404 and 602 of the act (63 P. S. §§ 455.404 and 455.602).

Sunset Date

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

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on January 30, 1999, the Commission submitted a copy of the notice of proposed rulemaking, published at 29 Pa.B. 565, to IRRC and the Chairpersons of the HPLC and the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) for review and comment.

In compliance with section 5(c) of the Regulatory Review Act, the Commission also provided IRRC and the Committees with copies of the comments received, as well as other documentation. In preparing these final-form regulations, the Commission has considered the comments received from IRRC and the public.

These final-form regulations were approved by the HPLC on October 11, 2000, and deemed approved by the SCP/PLC. IRRC met on October 19, 2000, and approved the final-form regulations in accordance with section 5.1(e) of the Regulatory Review Act (71 P. S. § 745.5(e)).

Contact Person

Further information may be obtained by contacting Deborah A. Sopko, Administrative Assistant, State Real Estate Commission, at P. O. Box 2649, Harrisburg, PA 17105-2649 (717) 783-7155.

Findings

(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 the proposed rulemaking published at 29 Pa.B. 565.

(4) These amendments are necessary and appropriate for administration and enforcement of the Board's authorizing statute.

Order

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

(a) The regulations of the Board, 49 Pa. Code Chapter 35, are amended by amending §§ 35.201, 35.271, 35.281, 35.287, 35.304, 35.305, 35.308 and 35.321 to read as set forth in Annex A, with ellipses referring to the existing text of the regulations.

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

JOSEPH TARANTINO, Jr.,
Chairperson

(*Editor's Note*: The proposal to amend §§ 35.222, 35.223, 35.245, 35.322 and 35.327, included in the proposed rulemaking published at 29 Pa.B. 565, has been withdrawn by the Commission.

For the text of the order of the Independent Regulatory Review Commission, relating to this document, see 30 Pa.B. 5807 (November 4, 2000).)

Fiscal Note: Fiscal Note 16A-560 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 35. STATE REAL ESTATE COMMISSION

Subchapter B. GENERAL PROVISIONS

§ 35.201. Definitions.

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

* * * * *

Broker—An individual or entity that, for another and for a fee, commission or other valuable consideration, does one or more of the following:

(i) Negotiates with or aids a person in locating or obtaining for purchase, lease or acquisition of interest in real estate.

(ii) Negotiates the listing, sale, purchase, exchange, lease, time share and similarly designated interests, financing or option for real estate.

(iii) Manages real estate.

(iv) Represents himself or itself as a real estate consultant, counsellor or house finder.

(v) Undertakes to promote the sale, exchange, purchase or rental of real estate. This subparagraph does not apply to an individual or entity whose main business is that of advertising, promotion or public relations.

(vi) Attempts to perform one of the actions listed in subparagraphs (i)—(v).

* * * * *

Salesperson—An individual who is employed by a broker to do one or more of the following:

(i) Sell or offer to sell real estate, or list real estate for sale.

(ii) Buy or offer to buy real estate.

(iii) Negotiate the purchase, sale or exchange of real estate.

(iv) Negotiate a loan on real estate.

(v) Lease or rent real estate, or offer to lease or rent real estate or to place real estate for rent.

(vi) Collect rent for the use of real estate, or offer or attempt to collect rent for the use of real estate.

(vii) Assist a broker in managing property.

* * * * *

Subchapter C. LICENSURE

LICENSURE REQUIREMENTS

§ 35.271. Examination for broker's license.

(a) An individual who wants to take the broker's examination for a Pennsylvania broker's license shall:

(1) Be 21 years of age or older.

(2) Be a high school graduate or have passed a high school general education equivalency examination.

(3) Have worked at least 3 years as a licensed salesperson, with experience qualifications that the Commission considers adequate for practice as a broker, or possess at least 3 years of other experience, education, or both, that the Commission considers the equivalent of 3 years' experience as a licensed salesperson.

(4) Have acquired 16 credits, or 240 hours of instruction, in professional real estate education as determined by the Commission under subsection (b).

(5) Submit a completed examination application to the Commission or its designee with:

(i) Official transcripts evidencing the acquisition of course credits

(ii) A detailed resume of real estate activities performed by the candidate while working as a salesperson and a sworn statement from the candidate's employing broker confirming that these activities were performed if the candidate is a licensed salesperson.

(iii) A complete description of work experience and education that the candidate considers relevant to the requirements of paragraph (3) if the candidate is not a licensed salesperson.

(iv) A certification from the real estate licensing authority of the jurisdiction in which the candidate is licensed stating that the candidate had an active license for each year that credits are claimed if the candidate is applying brokerage experience to satisfy the professional education requirement.

(v) The fees for review of the candidate's qualifications to take the examination and for administration of the examination prescribed in § 35.203 (relating to fees).

(b) The Commission will apply the following standards in determining whether an examination candidate has met the education requirement of subsection (a)(4):

(1) A candidate who has obtained one of the following degrees will be deemed to have met the education requirement and will not be required to show completion of coursework in specific areas of study:

(i) A bachelor's degree with a major in real estate from an accredited college, university or institute of higher learning.

(ii) A bachelor's degree from an accredited college, university or institute of higher learning, having completed coursework equivalent to a major in real estate.

(iii) A juris doctor degree from an accredited law school.

(2) Except as provided in paragraph (6), *2* of the required 16 credits shall be in a Commission-developed or approved real estate office management course and 2 of

the required 16 credits shall be in a Commission-developed or approved law course. At least 6 of the remaining 12 credits shall be in 3 or more of the Commission-developed courses listed in this paragraph. The remaining 6 credits shall be in real estate courses but not necessarily those listed in this paragraph. A candidate may not apply credits used to qualify for the salesperson's examination toward fulfillment of the broker education requirement.

(i) Real Estate Law.

(ii) Real Estate Finance.

(iii) Real Estate Investment.

(iv) Residential Property Management.

(v) Nonresidential Property Management.

(vi) Real Estate Sales.

(vii) Residential Construction.

(viii) Valuation of Residential Property.

(ix) Valuation of Income-Producing Property.

(3) To be counted toward the education requirement, a real estate course shall have been offered by:

(i) An accredited college, university or institute of higher learning, whether in this Commonwealth or outside this Commonwealth.

(iii) A real estate school outside this Commonwealth that has been approved by the real estate licensing authority of the jurisdiction where the school is located. The course transcript or certificate of completion shall state that the course is approved by the licensing authority of the jurisdiction where the school is located.

(iv) A real estate industry organization outside this Commonwealth, if the course is approved by the licensing jurisdiction of another state. The course transcript or certificate of completion shall state that the course is approved by the licensing jurisdiction which has approved it.

(4) A maximum of four credits will be allowed for each real estate course. A maximum of four credits will be allowed for each area of real estate study listed in paragraph (2).

(5) Courses shall have been completed within 10 years prior to the date of successful completion of the licensing examination.

(6) Two credits will be allowed for each year of active practice the candidate has had a licensed broker in another jurisdiction during the 10-year period immediately preceding the submission of the examination application.

GENERAL ETHICAL RESPONSIBILITIES

§ 35.281. Putting contracts, commitments and agreements in writing.

(a) A licensee who acts in a representative capacity shall ensure that sale or lease contracts, commitments and agreements in connection with a real estate transaction that he has knowledge of, or that he reasonably should be expected to have knowledge of, are in writing.

(b) A licensee who enters into an open listing agreement shall provide the seller or lessor with a written memorandum stating the terms of the agreement.

(c) A rental listing referral agent shall ensure that the agreement between himself and a prospective tenant is in writing.

§ 35.287. Supervised property management assistance by salespersons.

A salesperson may assist in the management of real estate if the salesperson's work is directly supervised and controlled by the employing broker. The salesperson may not independently negotiate the terms of a lease nor execute a lease on behalf of the lessor.

ADVERTISING AND SOLICITATION

§ 35.304. Disclosure of licensure when advertising own real estate.

A licensee who sells or leases his own real estate shall disclose that he is a real estate *licensee* in advertisements for the property. This requirement does not apply if the property is listed with a real estate company.

§ 35.305. Business name on advertisements.

(a) Brokerage companies, including sole proprietorships, cemetery companies and rental listing referral agencies shall advertise or otherwise hold *themselves* out to the public only under the business name designated on *their* license.

(b) Individual brokers of record, associate brokers, salespersons, cemetery associate brokers, cemetery salespersons and rental listing referral agents who wish to use and advertise nicknames (for example, Jack v. John or Margaret v. Peggy) shall include the names on their licensure applications or biennial renewal applications.

(c) An advertisement by an associate broker, salesperson, cemetery associate broker or cemetery salesperson shall contain the business name and telephone number of the employing broker. The names and telephone numbers shall be of equal size.

§ 35.308. Relationship with educational institution.

A real estate company, franchise or network may promote, endorse, or advertise its association, affiliation or connection with a real estate school or with a college, university or institute of higher learning regarding its offering of real estate instruction. An association, affiliation or connection which includes an ownership interest shall be disclosed in all promotions, endorsements or advertisements. For purposes of this section, an ownership interest will be considered by the Commission to include proprietary or beneficial interests through which the real estate company, franchise or network earns or has the potential to earn income, or which produces a direct or indirect economic benefit.

ESCROW REQUIREMENTS

§ 35.321. Duty to deposit money belonging to another into escrow account.

(a) Except as provided in subsection (b), a broker shall deposit money that the broker receives belonging to another into an escrow account in a Federally or State-insured bank or depository to be held pending consummation of the transaction or a prior termination thereof that does not involve a dispute between the parties to the transaction, at which time the broker shall pay over the full amount to the party entitled to receive it. If a broker is a partnership, association or corporation, its broker of record shall be responsible for ensuring that the escrow duty is performed.

(b) A broker is not required to hold in escrow rents that he receives as a property manager for a lessor. A broker shall deposit rents received into a rental management account that is separate from the broker's escrow and general business accounts.

(c) If a broker receives money belonging to another under an installment land purchase agreement, the transaction shall be considered consummated, for purposes of subsection (a), when the buyer has been afforded the opportunity, by means of the seller's written acknowledgement on or affixed to the agreement, to record the agreement, unless the agreement specifies otherwise.

(d) If a broker receives money belonging to another under an agreement of sale involving cemetary property, the transaction shall be considered consummated, for purposes of subsection (a), when the buyer receives a copy of the agreement of sale.

(e) If a broker receives a security deposit belonging to another under a lease agreement, the broker's duty to pay over the deposit for purposes of subsection (a), shall arise when the tenancy ends. If a sale of the leased premises or a change in a property management contract occurs during the term of the tenancy, the broker may transfer the security deposit from the broker's escrow account to the escrow account of the lessor or the lessor's broker upon notification in writing to each tenant from whom the broker received a deposit of the name and address of the banking institution in which the deposits will be held, and the amount of the deposits.

[Pa.B. Doc. No. 00-1977. Filed for public inspection November 17, 2000, 9:00 a.m.]

Title 58—RECREATION

GAME COMMISSION

[58 PA. CODE CH. 141]

Flintlock Muzzleloading Season

To effectively manage the wildlife resources of this Commonwealth, the Game Commission (Commission), at its October 12, 2000, meeting, adopted the following change:

Amend § 141.43 (relating to deer) to expand the types of ammunition lawful for use in the flintlock muzzleloader season.

This amendment is adopted under the authority of 34 Pa.C.S. (relating to the Game and Wildlife Code) (code).

Introduction

To more effectively manage the wildlife resources of this Commonwealth, the Commission at its June 21, 2000, meeting proposed, and at its October 12, 2000, meeting finally adopted an amendment to § 141.43 to allow the use of single projectile ammunition during the muzzleloading deer season. This change was made under section 2102(d) of the code (relating to regulations).

Purpose and Authority

The Commission is mandated by section 2102(d) of the code to promulgate regulations "... stipulating ... the type of firearms and ammunition, which may be used." The change was adopted under this authority.

There has been a great deal of confusion with regard to what ammunition may be used during the muzzleloading deer season. The change will simplify what ammunition can be used.

Regulatory Requirements

The change will expand the types of ammunition that can be lawfully used and relax regulatory requirements. The requirements of section 2322(a)(4) of code (relating to prohibited devices and methods) will still govern composition if any ammunition used.

Persons Affected

Those wishing to hunt deer during the special muzzleloading seasons will be affected by the change.

Comment and Response Summary

No written comments were received with regard to the adopted change.

Cost and Paperwork Requirements

The amendment will not result in any additional cost or paperwork.

Effective Date

The amendment will be effective on final publication in the *Pennsylvania Bulletin* and will remain in effect until changed by the Commission.

Contact Person

For further information on the amendment, contact David E. Overcash, Acting Director, Bureau of Law Enforcement, 2001 Elmerton Avenue, Harrisburg, PA 17110-9797, (717) 783-6526.

Findings

The Commission finds that:

(1) Public notice of intention to adopt the administrative amendment adopted by this order has been 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 thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) The adoption of the amendment of the Commission in the manner provided in this order is necessary and appropriate for the administration and enforcement of the authorizing statute.

Order

The Commission, acting under authorizing statute, orders that:

(a) The regulations of the Commission, 58 Pa. Code Chapter 141, are amended by amending § 141.43, to read as set forth at 30 Pa.B. 4622 (September 2, 2000).

(b) The Executive Director of the Commission shall certify this order and 30 Pa.B. 4622 and deposit them with the Legislative Reference Bureau as required by law.

(c) This order amending § 141.43, shall become effective upon final publication in the *Pennsylvania Bulletin*.

VERNON R. ROSS,
Executive Director

Fiscal Note: 48-124. No fiscal impact; (8) recommends adoption.

[Pa.B. Doc. No. 00-1978. Filed for public inspection November 17, 2000, 9:00 a.m.]

GAME COMMISSION

[58 PA. CODE CH. 141]

Uses of Muzzleloading Firearms in Southeast and Southwest Special Regulations Areas

To effectively manage the wildlife resources of this Commonwealth, the Game Commission (Commission), at its October 12, 2000, meeting, adopted the following change:

Amend § 141.1 (relating to special regulations areas) to allow the use of muzzleloading pistols in the Southeast and Southwest Special Regulations Areas to remain consistent with the Commission's intent to expand hunting opportunities.

This amendment is hereby adopted under the authority of 34 Pa.C.S. (relating to the Game and Wildlife Code) (code).

Introduction

To more effectively manage the wildlife resources of this Commonwealth, the Commission at its meeting held on June 21, 2000, proposed, and at its meeting held on October 12, 2000, finally adopted amendments to § 141.1 to allow the use of any muzzleloading firearm with single projectile ammunition for deer hunting in special regulations areas. This will allow more flexibility for muzzleloaders in special regulations areas and create more hunting opportunities. The change was adopted under the authority contained in section 2102 of the code (relating to regulations).

Purpose and Authority

Because of excessive deer populations within the established special regulations areas, the Commission has decided to encourage deer hunting as much as possible. One way in which this can be done is by allowing the use of muzzleloading pistols with appropriate ammunition during the applicable season. The change will allow this.

Section 2102(a) of the code directs the Commission to "... promulgate such regulations as it deems necessary and appropriate concerning ... the ways, manner, methods, and means of hunting or furtaking ..." section 2102(d) of the code also directs the Commission to promulgate regulations stipulating "... the type of firearms and ammunition and other devices which may be used ..." The change was adopted under this authority.

Regulatory Requirements

The amendment will relax current requirements.

Persons Affected

Individuals wishing to hunt deer in special regulations areas with muzzleloading firearms using single projectile ammunition will be affected by the change.

Comment and Response Summary

No written comments were received with regard to the adopted change.

Cost and Paperwork Requirements

The change will not result in any additional cost or paperwork.

Effective Date

The change will be effective on final publication in the *Pennsylvania Bulletin* and will remain in effect until changed by the Commission.

Contact Person

For further information on the change, contact David E. Overcash, Acting Director, Bureau of Law Enforcement, 2001 Elmerton Avenue, Harrisburg, PA 17110-9797, (717) 783-6526.

Findings

The Commission finds that:

(1) Public notice of intention to adopt the administrative amendments adopted by this order has been 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 thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) The adoption of the amendments of the Commission in the manner provided in this order is necessary and appropriate for the administration and enforcement of the authorizing statute.

Order

The Commission, acting under authorizing statute, orders that:

(a) The regulations of the Commission, 58 Pa. Code Chapter 141, are amended by amending § 141.1 to read as set forth at 30 Pa.B. 1262 (March 4, 2000).

(b) The Executive Director of the Commission shall certify this order and 30 Pa.B. 1262 and deposit them with the Legislative Reference Bureau as required by law.

(c) This order amending § 141.1, shall become effective upon final publication in the *Pennsylvania Bulletin*.

VERNON R. ROSS,
Executive Director

Fiscal Note: Fiscal Note 48-123 remains valid for the final adoption of the subject regulation.

[Pa.B. Doc. No. 00-1979. Filed for public inspection November 17, 2000, 9:00 a.m.]