RULES AND REGULATIONS

Title 25—ENVIRONMENTAL PROTECTION

COAL AND CLAY MINE SUBSIDENCE INSURANCE BOARD

[25 PA. CODE CH. 401]

Mine Subsidence Fund

The Mine Subsidence Insurance Board (Board) by this order amends 25 Pa. Code Chapter 401 (relating to mine subsidence fund). Chapter 401 addresses the administration of the Mine Subsidence Insurance (MSI) Program. The amendments clarify the regulations concerning issuance of MSI policies. There are new regulations codifying the insurance producer program, as well as, explicitly authorizing the issuance of grants and loans to foster the development of new technologies or services that will benefit the Board and the Department of Environmental Protection (Department).

This order was adopted by the Board at its meeting of July 29, 2009.

A. *Effective Date*

These amendments will go into effect upon publication in the *Pennsylvania Bulletin* as final-form rulemaking.

B. *Contact Persons*

For further information contact Lawrence Ruane, Administrator, Mine Subsidence Program, P. O. Box 8462, Rachel Carson State Office Building, Harrisburg, PA 17105-8462, (717) 783-9590; or Marc A. Roda, Assistant Counsel, Bureau of Regulatory Counsel, P. O. Box 8464, Rachel Carson State Office Building, Harrisburg, PA 17105-8464, (717) 787-7060. Persons with a disability may use the Pennsylvania AT&T Relay Service by calling (800) 654-5984 (TDD users) or (800) 654-5988 (voice users). This notice of final-from rulemaking is available electronically through the Department's web site www.depweb.state.pa.us.

C. *Statutory Authority*

The final-form rulemaking is being made under the authority of section 19 of the act of August 23, 1961 (P. L. 1068, No. 484) (52 P. S. § 3219) (act) which provides, *inter alia*, that the Board shall have the power to make rules and regulations.

The Coal and Clay Mine Subsidence Insurance Fund (Fund) was created in 1961, to provide a reliable source of compensation for damage to structures caused by underground coal and clay mine subsidence, a risk excluded from standard property and casualty insurance policies. This insurance pool of moneys for compensating owners of structures damaged by underground coal or clay mine subsidence is vital to the economic well being of this Commonwealth's coal mining regions.

D. *Background of the Amendments*

The amendments clarify the regulations concerning issuance of MSI policies by: (1) revising some of the definitions to ensure consistency with the MSI insuring agreement and insurance industry standards; (2) codifying standards for issuing MSI policies for multiple unit structures owned either conventionally, or as a condominium, or cooperative; (3) simplifying and expanding the criteria for covering multiple purpose structures at the residential rate; and (4) codifying the Board's recently adopted policy for issuing MSI policies for damaged structures. The standard for waiving the loss deductible is amended to be consistent with current practice. This final-form rulemaking also establishes new regulations: (1) codifying the submission of MSI applications by insurance producers; and (2) authorizing the issuance of grants and loans to foster the development of new technologies or services which can assist the Board and Department in administering the Fund.

The Board adopted the proposed rulemaking at its meeting of September 4, 2008. The proposed rulemaking was subsequently published at 38 Pa.B. 6931 (December 20, 2008), with a 31-day comment period that concluded on January 20, 2009. The Insurance Agents and Brokers of Pennsylvania (IA&B), the trade association representing insurance producers, submitted comments. Due to the minor and uncontroversial nature of the proposed amendments, no public meetings or hearings were held. The proposed rulemaking was provided to the Independent Regulatory Review Commission (IRRC) on December 10, 2008. IRRC provided its comments to the Board on February 19, 2009.

E. *Summary of Changes to the Proposed Rulemaking*

§ 401.1. Definitions.

The proposed definition for "commissions" and the proposed revision to the definition for "structure" are revised. The proposed definition for "commissions" is modified to be a payment to insurance producers rather than fees paid to insurance producers. This change was made for clarity. A commentator expressed the concern that using the term "fees" could be confusing because insurance producers receive fees for a number of different services. The same commentator also noted that the proposed amendment to the definition for "structure" created circularity because the term structure was being used in the revised definition. This circularity has been removed.

§ 401.11. Eligibility for insurance.

There are a number of revisions to subsection (b). First, in subparagraph (b)(1) the term "policyholder" is changed to "insured." The term "policyholder" was used to identify the person to be responsible for billing. One commentator noted that this proposed revision improved the regulation's clarity. However, the commentator suggested using the term "insured" because it better defines the insurance relationship. To ensure consistency, the term "policyholder" is changed to "insured" throughout the regulations. Also, the requirement to list all additional owners in the application is revised to clarify that the additional owners are to be listed as an additional insured. This revision is for consistency with the Board's practice of insuring all owners of a structure.

Second, subsection (b)(2) is revised to accurately state who is eligible to acquire insurance covering a structure owned as either a condominium or cooperative. When the association is insuring the structure, it must insure the entire structure, that is all common elements and units. Requiring an association to insure all the units, as well as the common elements, is the most effective method of ensuring a structure owned as a condominium or cooperative from subsidence damage. Subsidence damage primarily occurs to the structure's roof, foundation, walls and

floors. Usually, some or all of the walls, foundation, roof, and floors related to a particular unit, as well as the appurtenances, are owned by the association as common elements.

Another change is that only the association can buy insurance coverage if the structure is vertically configured with units stacked on top of each other. This change ensures consistency with subsection (f) which requires that vertically configured multiple unit structures be covered by one policy.

This subsection is further revised to clarify that where the association is not requiring insurance and the structure is not vertically configured, unit owner can only insure their units and the, common elements that are closely related to the units value and use, for example the unit's walls, floors, roof and foundation. Other common elements such as common rooms and laundry facilities are for the benefit of all the members of the association. This clarification is in response to the concerns raised by one commentator that it is highly unusual for a unit owner to insure common elements to the benefit of the whole association. The coverage is now limited to those common elements that are critical to the unit's value and use. It is recognized that it is unusual for a unit owner insurance covering common elements. However, the Board believes that, where the association does not acquire the insurance coverage, a unit owner should be able to acquire insurance coverage equivalent to a person owning a unit in a conventionally owned multiple unit structure such as a row home.

Finally, the unit owner and not the association will be the named insured when the unit owner purchases coverage. This is because it is the unit owner who is acquiring and maintaining the insurance coverage. However, the association must be listed as an additional insured in the application if the unit has related common elements. This is because the common elements are owned by the association and only a structure owner can own mine subsidence insurance. These revisions are in response to a commentator questioning making the association the insured and asking what was meant by naming the unit owner in the application. Originally, the association was to be the policyholder/insured because of concerns relating to insuring common elements. The unit owner was to be listed in the application because that is the mechanism for naming an additional owner as an additional insured. This revised approach of naming the unit owner as the insured and only listing the association as an additional insured to the extent the unit has related common elements is the better method of issuing insurance coverage to unit owners.

Subsection (d) is revised in two ways. First, the process for insuring structures with preexisting damage is clarified. The Board, based upon an inspection, will identify to the structure owner the repairs to be made or whose cost is to be estimated. As noted by a commentator, the proposed amendment was vague and did not provide any guidance as to the repairs to be made or whose cost is to be estimated. Second, structures with preexisting damage that jeopardizes the structures integrity must be repaired before insurance will be issued. Where the structure's integrity is jeopardized, either the damage will become more extensive over time or any subsequent subsidence damage will be more significant, or both.

§§ 401.15 and 401.32. Cancellation of an insurance policy; and Obligations after claim settlement.

The term "policyholder" has been changed to "insured" in these sections to be consistent with the change that was made in § 401.11 (relating to eligibility for insurance). As previously noted, the term "insured" better defines the insurance relationship. The changes are being made in response to comments and for consistency in the regulations to avoid ambiguity or confusion.

§ 401.42. Commission rates.

This section is revised by clarifying that the Board's approval of a change in commission rates will be made at a Board meeting. Also, commission rates will be posted on the Fund's web site. These changes are made in response to a commentator's concern as to how the Board establishes commission rates and how the regulated community will be notified.

§ 401.43. Payment of commissions.

This section is revised to clarify that the Board's decision to make an alternative method of payment available to insurance producers will be made at a Board meeting. Also, the availability of an alternative method of payment will be placed on the Fund's web site. These changes are made in response to a commentator's concern as to how the Board will make its determination and how the regulated community will be notified.

§ 401.44. Repayment of commissions.

This section is revised to specify that repayment of commissions for canceled policies shall occur within 60 days of the issuance of a written demand. This change is in response to one commentator's concern that the regulation should specify the amount of time an insurance producer has to submit the repayment.

§ 401.45. Confidentiality of insureds information.

This section is revised by limiting the insured's confidentiality requirement to compliance with the Insurance Department's confidentiality requirements. To require absolute confidentiality is an unnecessary burden on the insurance producer. Also, the term "policyholder" is revised to "insured." Both commentators were concerned that the proposed regulation was too broad.

F. *Summary of Other Comments to the Proposed Rulemaking*

§ 401.11(f). Eligibility for insurance.

This subsection addresses the issuance of policies for multiple unit structures. With respect to nonvertically configured multiple unit structures, one commentator asked whether there is intent to have single policy coverage for the entire structure or will individual policies for individual units be sought. Also, how will this work when applied to structures owned as condominiums or cooperatives? The Department is equally willing to sell either one policy covering the entire structure or individual policies covering individual units. When the structure is owned as a condominium or cooperative and the association will not by coverage, individual unit owners can acquire coverage for their units and any related common elements, such as the walls, floors, foundation and roof.

§ 401.51. Loans and grants.

One commentator questioned the statutory authority for this regulation. It was also recommended that the regulation should be revised to provide more detail on how the loan and grant program is to be administered,

that is, application process, review criteria and time frames. This issue was also raised by the Office of the Attorney General before it approved the proposed regulation for form and legality. In approving the proposed regulation for form and legality, the Office of the Attorney General agreed that the Board has the authority to adopt regulations authorizing the issuance of loans and grants.

The statutory authority for the Board to issue grants and loans is implied in the Board's rulemaking authority. The power and authority of an administrative agency must be conferred by the Legislature, and it must be either expressly conferred or given by necessary implication. For example, *Butler County Mushroom Farm v. DER*, 454 A.2d 1 (Pa. 1982). The Board is authorized to promulgate rules and regulations the Board deems just and expedient to fulfill the purposes of the act. The general grant of rulemaking authority extends, by necessary implication, to authorize the promulgation of regulations to allow the issuance of grants and loans. *See Section 19 of the Act (52 P. S. § 3219)*.

Regulations authorizing the issuance of grants and loans to foster the development of new technologies will assist the Board and the Department in administering the Fund. These are technologies and services such as robotic sensing devices or geographic information systems that the Department may wish to make use of, to evaluate a claim of subsidence damage, but do not want to own. A grant or loan, rather than a service purchase contract, can provide financial assistance to encourage the development of these technologies and services and provide the Department with access to these new technologies and services. The limitation on the amount of excess moneys that can be used to finance the loans or grants ensures the Fund's financial integrity will be maintained.

The Board does not believe that this regulation needs to be revised to specify additional administrative procedures, criteria or time frames. The regulatory language provides the criteria for the types of technologies and services whose development can be funded through a grant or loan. As an initial matter, the Department will follow the Commonwealth's policies for issuing grants and loans. The Department needs the flexibility to develop the appropriate administrative process, any additional criteria and time frames based on the types of services or technologies being sought.

G. *Benefits, Costs and Compliance*

Benefits

The amendment to § 401.11(c) (relating to eligibility for insurance) makes the residential rate, about 1/2 of the commercial rate, available to more structures used for both residential and commercial purposes. Section 401.43 (relating to payment of commission) benefits insurance producers because the commission is retained from the premium payment, that is, immediately paid, rather than waiting 3 months to receive a payment from the Board. Learning institutions and other entities developing technologies and services potentially valuable to the Board will benefit from the availability of grants or loans to foster those developments.

Compliance Costs

There are no costs associated with this final-form rulemaking.

Compliance Assistance Plan

The Department will notify policyholders at the time of policy renewal of the broader application of residential rates to mixed-use structures. Insurance producers registered to submit MSI applications will also be notified of changes in procedures and their obligations due to this final-form rulemaking. Finally, a link to the *Pennsylvania Bulletin* notice of the final-form rulemaking will be placed on the MSI web site (www.paMSI.org).

Paperwork Requirements

This final-form rulemaking will not impose any additional paperwork requirements on MSI policyholders or insurance producers.

H. *Pollution Prevention*

The regulations affected by this final-form rulemaking address the administration of the Commonwealth's MSI Program. They do not address pollution prevention.

I. *Sunset Review*

These regulations will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulations effectively fulfill the goals for which they were intended.

J. *Regulatory Review*

In accordance with section 5(a) and (f) of the Regulatory Review Act (71 P. S. §§ 745.5(a) and (b)), on December 10, 2008, the Department submitted a copy of the notice of proposed rulemaking, published at 38 Pa.B. 6931 (December 20, 2008), to the Legislative Reference Bureau for publication in the *Pennsylvania Bulletin* and to IRRC. In accordance with section 5(f) of the Regulatory Review Act), on February 9, 2009, the Department submitted the proposed regulations and the required material to the House Environmental Resources and Energy Committee and the Senate Environmental Resources and Energy Committee (Committees).

Under section 5(c) of the Regulatory Review Act, IRRC and the Committees were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing these final-form regulations, the Department has considered all comments from IRRC, the Committees and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on October 21, 2009, these final-form regulations were deemed approved by the Committees. Under section 5.1(e) of the Regulatory Review Act, IRRC met on October 22, 2009, and approved the final-form regulations.

K. *Findings of the Board*

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 regulations promulgated thereunder at 1 Pa. Code §§ 7.1 and 7.2 (relating to notice of proposed rulemaking required; and adoption of regulations).

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

(3) These regulations do not enlarge the purpose of the proposal published at 38 Pa.B. 6931.

(4) These regulations are necessary and appropriate for administration and enforcement of the authorizing acts identified in Section C of this order.

L. *Order of the Board*

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

(a) The regulations of the Department, 25 Pa. Code Chapter 401, are amended by amending §§ 401.1, 401.11, 401.13, 401.15, 401.22, 401.32 and by adding §§ 401.41—401.45 and 401.51 to read as set forth in Annex A.

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

(c) The Chairperson of the Board shall submit this order and Annex A to IRRC and the Committees as required by the Regulatory Review Act.

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

(e) This order shall take effect immediately.

JOHN HANGER,
Chairperson

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 39 Pa.B. 6524 (November 7, 2009).)

Fiscal Note: Fiscal Note 7-424 remains valid for the final adoption of the subject regulation.

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION

PART III. COAL AND CLAY MINE SUBSIDENCE INSURANCE BOARD

CHAPTER 401. MINE SUBSIDENCE FUND

GENERAL PROVISIONS

§ 401.1. Definitions.

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

Act—The act of August 23, 1961 (P. L. 1068, No. 484) (52. P. S. §§ 3201—3226).

Agent—Employees of the Department who work on behalf of the Board.

Association—One of the following:

(i) The unit owners' association organized under 68 Pa.C.S. § 3301 (relating to organization of unit owners' association) for condominiums.

(ii) The proprietary lessees' association organized under 68 Pa.C.S. § 4301 (relating to organization of association) for cooperatives.

Board—The Coal and Clay Mine Subsidence Insurance Board.

Commissions—Payment to insurance producers as compensation for the applications they submit to the Board.

Common elements—All portions of a condominium or cooperative other than the units.

Condominium—Real estate, portions of which are designated for separate ownership and the remainder of which is designated for common ownership solely by the owners of those portions. Real estate is not a condominium unless the undivided interests in the common elements are vested in the unit owners. Ownership of the real estate is in accordance with 68 Pa.C.S., Subpart B (relating to Uniform Condominium Act).

Cooperative—Real estate owned by an association, each of whose members is entitled, by virtue of an ownership interest in the association, to exclusive possession of a unit. Ownership of the real estate is in accordance with 68 Pa.C.S., Subpart C (relating to Real Estate Cooperative Act).

Fund—The Coal and Clay Mine Subsidence Insurance Fund established by the act.

Insurance policy—An insurance certificate, an insuring agreement, and application for mine subsidence insurance and endorsements to the insurance policy.

Insurance producer—A person that sells, solicits or negotiates contracts of insurance.

Mine subsidence—The movement of the ground's surface as a result of the collapse of underground coal or clay mine workings.

Mine workings—The roof, floor or pillars within an underground coal or clay mine.

Owner of structure—A person, corporation, organization or association holding title to a structure within the anthracite or bituminous coal or clay mine region as defined by the Board.

Structure—A complete building, which contains a roof, walls and a foundation that firmly attaches the building to the earth, and its appurtenances as defined in the insurance policy.

Units—

(i) Specific areas of a building that are separate and distinct from other areas of the building, having an individual entrance accessing either a common entry or the building's exterior.

(ii) For the purposes of the definition of "common elements" and § 401.11(b)(2) (relating to eligibility for insurance), the following apply:

(A) Units in a condominium are portions of the condominium designated for separate ownership, the boundaries of which are described in the condominium declaration.

(B) Units in a cooperative are physical portions of the cooperative designated for separate occupancy under a proprietary lease.

INSURANCE POLICIES

§ 401.11. Eligibility for insurance.

(a) Structures located within the coal and clay regions of this Commonwealth are eligible for coverage.

(b) Only an owner of a structure may be named as the insured.

(1) If there is more than one owner of a structure, the owners shall designate one owner whose name shall appear on the insurance policy for billing purposes. The other owners shall be listed in the application for insurance as additional insureds.

(2) For a structure owned as a condominium or a cooperative:

(i) The insurance must cover all the common elements and units when the association is acquiring the insurance.

(ii) Only an association can acquire insurance covering a structure comprised of vertically stacked units.

(iii) For otherwise configured structures when the association does not acquire insurance coverage, unit owner

may purchase coverage for their unit and the related common elements necessary for the owner's use of the unit. Related common elements include the unit's roof, walls, floors, foundation, as well as, a fence, retaining wall, paved or improved patio, walk, or driveway. However, the association shall be listed in the application as an additional insured. Renewals will be sent to the unit owner.

(c) Structures which are at least 50% residential are eligible for residential rates.

(d) If a structure is damaged by mine subsidence or by another cause, and the Board, based upon an inspection of the structure, determines that either:

(1) The damage jeopardizes the structure's integrity, the Board will not issue a policy until the damages identified by the inspection have been repaired as directed by the Board.

(2) The damage could not be separated or apportioned from subsequent damage and the damage does not jeopardize the structure's integrity, the Board will issue a policy if the applicant either:

(i) First repairs the damages identified by the inspection as directed by the Board.

(ii) Submits to the Board an estimate, prepared by a reputable expert, of the cost to repair the damages to the Board's satisfaction. The cost to repair, adjusted for inflation, would be excluded from any damage claim settlement. However, a policy would not be issued if the cost to repair exceeded the replacement cost of the structure or the policy limit, whichever is less, because the policy would have no value.

(e) The Board may refuse to issue a policy while the structure to be covered is being damaged by mine subsidence or by another cause, until the Fund determines that the cause of damage has ceased.

(f) Multiple unit structures are insured as follows:

(1) Structures comprised of vertically stacked units are only insurable under a single policy.

(2) Other unit configurations are insurable under a single or multiple policy at the owner's discretion.

§ 401.13. Coverage limits and premiums for insurance.

(a) The maximum amount of insurance, the term or duration of the policy, and the premium rate will be determined by the Board.

(b) An insurance policy is effective upon the date a complete application and its premium are received by the Board or its agent and provided that the applicant and structure meet the eligibility requirements in the act and in § 401.11 (relating to eligibility for insurance).

§ 401.15. Cancellation of an insurance policy.

An insurance policy cannot be canceled by the Board, or its agents, or by the insured during the term of coverage except as provided in the insurance policy or the act. When the Board, or its agents, cancels an insurance policy, it will send a written notice of the cancellation to the insured.

INSURANCE COVERAGE

§ 401.22. Loss deductible amount.

Every insurance policy must include a loss deductible amount for which the Fund is not liable. The amount will be determined by the Board and may be changed as experience may warrant, and will be included in the schedule of premium rates adopted by the Board. The loss deductible will be waived if the cost to repair the damage exceeds the amount of coverage under the policy.

CLAIMS

§ 401.32. Obligations after claim settlement.

Insureds shall contact the Board, or its agents, within 1 year of the claim settlement and permit an inspection of the insured structure to verify that the damage described in the claim settlement has been repaired. If the insured fails to contact the Board, or its agents, or refuses to permit the inspection the Board or its agents, may refuse to issue or renew an insurance policy for the insured structure.

INSURANCE PRODUCERS

§ 401.41. Submission of applications.

Insurance producers may only submit applications for mine subsidence insurance to the Board electronically from the Board's web site.

§ 401.42. Commission rates.

The Board, at an open meeting, will annually establish commission rates. The commission rate will be posted on the Fund's web site (www.pamsi.org).

§ 401.43. Payment of commissions.

The insurance producer shall retain the commission from the premium collected. The Board, at an open meeting, may authorize other forms of payment. Alternative forms of paying commissions will be posted on the Fund's web site (www.pamsi.org).

§ 401.44. Repayment of commissions.

Commissions in excess of $5 that are unearned due to the Board's rejection of a mine subsidence insurance application or the cancellation of a policy shall be repaid to the Board upon its demand. Failure by an insurance producer to repay commissions within 60 days of the Board's written request may result in exclusion from participation with the Fund. The Board's decision to exclude an insurance producer from participating with the Fund is appealable to the Environmental Hearing Board under to the Environmental Hearing Board Act (35 P. S. §§ 75.11—75.16).

§ 401.45. Confidentiality of insureds information.

Insurance producers are responsible to safeguard all applicant and insureds information in accordance with the Insurance Department's regulations found in 31 Pa. Code Chapters 146a and 146c (relating to privacy of consumer information) and standards for safeguarding information). Failure by an insurance producer to safeguard applicant and insureds information may result in exclusion from participation with the Fund. The Board's decision to exclude an insurance producer from participating with the Fund is appealable to the Environmental Hearing Board under the Environmental Hearing Board Act (35 P. S. §§ 75.11—75.16).

LOANS AND GRANTS

§ 401.51. Loans and grants.

Each year the Board may authorize up to 1% of the Fund's Unreserved Fund Balance, as declared by the Board under section 10(c) of the act (52 P. S. § 3210(c)), to be used to provide loans and grants to entities that develop technologies, perform services or engage in other activities that benefit the Fund by improving its ability to

provide mine subsidence insurance coverage or to improve the efficiency, economy and effectiveness of the Fund's operations.

[Pa.B. Doc. No. 09-2272. Filed for public inspection December 11, 2009, 9:00 a.m.]

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 611]

Home Care Agencies and Home Care Registries

The Department of Health (Department) hereby amends 28 Pa. Code by adding Subpart H, Chapter 611 (relating to home care agencies and home care registries), to govern licensure of home care agencies and home care registries. The regulations are set forth in Annex A.

Purpose of The Regulations

The final regulations set minimum standards for the operation of home care agencies and home care registries. Act 2006-69 (Act 69), signed by Governor Rendell on July 7, 2006, amended the Health Care Facilities Act (act) (35 P. S. §§ 448.101—448.904b) to require the Department to license home care agencies and home care registries. Home care agencies employ direct care workers to provide home care services to individuals in their place of residence or other independent living environment. Home care registries refer direct care workers who are independent contractors to provide home care services to individuals in their place of residence or other independent living environment. Home care services include assistance with bathing, dressing and feeding, housekeeping, shopping, meal planning and preparation and transportation, and also include companionship services, respite care and specialized care.

Section 803(1) of the act, (35 P. S. § 448.803(1)) (regarding powers of the department of health), authorizes the Department, after consultation with the Health Policy Board, to promulgate regulations necessary to carry out the purposes and provisions of the act. The Act 69 amendments also included a provision expressly authorizing the Department to promulgate regulations to implement sections 806(d.1) and 806.3 of the act (35 P. S. §§ 488.806(d.2) and 448.806c regarding licensure standards and consumer protections. Act 69 requires the Department to develop regulations in consultation with the Department of Public Welfare and other advisory groups that represent persons in the home health care industry, persons with physical disabilities and the aging community, and to take into consideration the preferences and philosophies of persons with physical disabilities who receive home and community-based services through Medicaid waiver or other publicly funded programs.

The Department distributed a set of draft regulations to the Department of Public Welfare, the Department of Aging, other designated stakeholders and interested persons in advance of stakeholder meetings in Harrisburg on December 7, 2006, in Muhlenberg on December 12, 2006, and in Pittsburgh on December 15, 2006. The Department also met on January 26, 2007, with representatives of what was, at that time, the Pennsylvania Protection and Advocacy, Inc. (PP&A), and is now the Disability Rights Network of Pennsylvania, and with other individuals representing organizations serving the disability community. Following meetings with stakeholders, and receipt of comments on the draft regulations, the Department revised the draft based on comments received and presented the proposed regulations to the Department's Health Policy Board on March 14, 2007. The Department published notice of proposed rulemaking at 37 Pa.B. 4198 (August 4, 2007). The Department provided a 30-day public comment period. After preparation of the regulations in final, the Department presented the regulations to the Department's Health Policy Board at a public meeting on July 30, 2008.

Discussion of Comments

During the public comment period, the Department received over 200 individual comments from more than 40 commentators, including members of the Legislature, the public, advocacy groups serving the disability community, and trade associations representing providers of home care services. Many of the comments were critical of some aspect of the Department's proposed regulations, although some commentators did express support for specific provisions of the proposed regulations.

While the bulk of the comments received were in response to the substantive requirements for licensure as a home care agency or home care registry (that is, hiring and training or testing of direct care workers employed or on contract, background checks, child abuse clearances, health evaluations and consumer protection), the Department also received a number of comments on the Department's proposed procedural provisions addressing the licensure process for home care agencies and registries, inspection and survey activities, and sanctions and corrective actions. The three proposed sections addressing the procedural aspects of the licensure process were intended to incorporate and expand upon the requirements in 28 Pa. Code Chapter 51 (relating to general provisions), promulgated in 1998, applicable to all health care facilities required to be licensed under the act, and to clarify procedural requirements for home care agencies and registries.

Upon further consideration, the Department has determined not to address in these regulations the Department's practices and protocols for licensure and enforcement of licensure standards as applied, specifically, to home care agencies and home care registries. The act addresses the application process, issuance of a license, inspections, notice of violations, and possible sanctions as a result of violations for all "health care facilities" required to be licensed by the Department. See 35 P. S. §§ 448.807—448.814. Moreover, the Department plans a comprehensive revision of Chapter 51 to address the licensure process for all health care facilities.

For these reasons, the Department has deleted the provisions under "Licensure," "Inspection and Survey Activities," and "Sanctions and Corrective Actions." Portions of what had been included in §§ 611.11 and 611.12 (relating to licensed required; and application for license) are now in § 611.2 (relating to license required). The remaining regulations in the "General" section have been renumbered accordingly. Section 611.2 advises of the licensure requirement generally as applied to new and to existing home care agencies and home care registries, states that the licensure requirement applies to all physical locations of home care agencies and home care registries, and informs the reader where to submit the application and the application fee of $100.

Because the Department has chosen not to adopt the bulk of the provisions under the proposed regulations labeled "Licensure," "Inspections and Survey Activities," and "Sanctions and Corrective Actions," this preamble does not include a discussion of comments received in response to those proposed provisions.

The Department received comments on each of the provisions in the proposed "Governance and Management" section, but most comments focused on the proposed § 611.55 (relating to compentency requirements) that dealt with training and on the proposed § 611.56 (relating to health screening) that dealt with health evaluations. Many commentators expressed concern that if the Department required all direct care workers to receive training or establish competency in all 16 subject areas listed in the proposed regulation, the pool of individuals willing to become a direct care worker and provide home care services would decline dramatically and the cost of home care services to the consumer would increase. Commentators explained that many potential direct care workers are individuals who have been homemakers for many years who wish to earn an income by providing some, but not all, levels of home care services. These individuals have little interest in providing the kind of hands-on care for which more intensive training is required. According to the commentators, if these individuals are required to become trained or establish competency in skills they do not intend to use, they will decline the training and the work-for-pay opportunity being offered to them.

In response to the comments received, the Department reevaluated the statute and determined that it allows for differing levels of competency; one for persons who will provide the full gamut of home care services, up to and including personal care, and another for those who will provide only companionship and assistance with tasks such as laundry, shopping, making and keeping appointments, paying bills, and engaging in social and leisure activities. Therefore, the final regulation, § 611.55, includes a list of ten mandatory subject matter areas to be included in any training program or competency examination developed by a home care agency or home care registry. If, however, the direct care worker will provide personal care, including assistance with eating, ambulating, transferring, positioning, toileting and with personal hygiene and with self-administration of medications, § 611.55 provides that the direct care worker must receive training, or establish competency through testing, in six additional subject matter areas.

The Department retained other options, per the statute, for ensuring competency, prior to assignment or referral if the agency or registry does not choose to create its own training program or competency examination; for example, a current nurse's license, the home health aide training program outlined in 42 CFR 484.36 (relating to condition of participation: Home health aide services) or the nurse aid certification and training program offered by the Department of Education. In response to a suggestion from a commentator, the Department also added, in § 611.55, as an additional method for ensuring competency, training that conforms to training standards imposed on the agency or registry by virtue of the agency's or registry's participation as a provider of home and community based services funded by a Medicaid waiver or other publicly funded program. Thus, if the direct care worker is trained to provide services funded through the Medicaid waiver or other publicly funded program, the direct care worker is competent to provide home care services.

Commentators also almost unanimously objected to the proposed health evaluation section, which would have required a screening assessment to establish that the individual had been screened, and tested as necessary, for tuberculosis, and for five other communicable diseases or conditions which were listed in the proposed regulation. There was widespread confusion regarding the meaning of the term "screening assessment" and consternation that direct care workers would need to undergo more onerous scrutiny as to their health status than other workers actually engaged in providing health care services.

In response to comments received, the Department has revised the regulation in § 611.56 (relating to health screening) to require the direct care worker and other office staff or contractors with direct consumer contact to provide documentation that the individual was screened for and is free from active tuberculosis. The individual need not be screened for other communicable diseases.

The Department's response to the comments received on the specific provisions of the proposed regulation follows:

General

§ 611.1. (legal base)

The Independent Regulatory Review Commission (IRRC) suggested that the references in this section to "subpart" should be changed to "chapter." The Department agreed and made the suggested change in this section and elsewhere within the regulation where the term "subpart" was used.

§ 611.2. (licensure required)

This section contains portions of what had been included in proposed §§ 611.11 and 611.12 (relating to license required; and application for license). This section alerts new and existing home care agencies and home care registries of the need to obtain a license for each physical location of the agency or registry, where to obtain the application, where to submit the completed application and the amount of the application fee. In accordance with a suggestion from IRRC, the Department inserted the actual fee amount for an initial license or license renewal in the final regulation. The Department also included a statement that the Department will conduct an inspection prior to issuing an initial license or a license renewal.

Several commentators suggested that the Department eliminate the requirement that each physical location of the home care agency or home care registry be separately licensed. One commentator suggested that the "central office" for the agency or registry be licensed, and that license would cover or include all physical locations of the agency or registry. IRRC has asked the Department to explain why it is necessary to separately license each physical location of an agency or registry.

The act contemplates that the Department will separately license each health care facility. See section 808 of the act (35 P. S. § 448.808). The Department, under the statute, prior to issuing a license, must determine that the entity that will provide services is a responsible person; that the entity will provide safe and efficient services which are adequate for the care, treatment and comfort of patients; and that there is substantial compliance with the rules and regulations adopted by the Department under the act. 35 P. S. § 448.808. For health care facilities that have a physical plant at which health care services are delivered, the Department also must establish that the

place to be used as a health care facility is adequately constructed, equipped, maintained and operated to safely and efficiently render the services offered.

The act also states that a separate license will not be required for different services within a single health care facility except that home health care, home care, hospice or long-term nursing care will require separate licenses. Thus, the act contemplates a license for each physical location of a health care facility, and specifically requires a separate license for home care services even though services might be offered in conjunction with services provided by, or located in, a facility also required to be licensed under the act.

The Department does allow branch offices of home health care agencies, and does not require the branch offices to be separately licensed, provided the licensure requirements specifically applicable to branch offices are met. The Department's licensure regulations for home health care agencies mirror the Federal requirements for participation in the Federal Medicare and Medicaid Programs. Both Federal certification standards and the State licensure standards permitting branch offices assume that a parent home health care agency will operate within a limited geographic area within this Commonwealth, and that the branch offices are in close physical proximity to the parent agency such that the parent agency can and does exercise administrative control and supervision, as defined in the regulations, over the branch offices. If the home health care agency has branch offices or "subunits," appropriate administrative records must be maintained for each subunit. 28 Pa. Code § 601.21(a) (relating to organization, services and administration). If the subunit, by virtue of the lack of accessibility between it and the parent agency, is not capable of sharing administration, supervision and services with the parent agency, the subunit must be separately licensed. *Id.*

The act does not give the Department authority to impose geographical limits on home care agencies or registries. The Department may permit branch offices at some point, if the Department is granted the authority to impose administrative and oversight responsibilities to a parent home care agency or registry, which would operate, along with its branch offices, within a defined geographic area within this Commonwealth.

Senator Corman suggested that a standardized fee schedule could be implemented to avoid escalating cost if a company has an agency and a registry and satellite offices of each. The act contains a fee schedule and requires a fee of $100 to accompany each application for a license to operate a home care agency or home care registry. The act does not permit an alternate fee schedule.

One commentator asked how the Department will determine geographic limits for each agency. As pointed out previously, the act does not authorize the Department to, and thus the regulations do not, set geographic limits for an agency or registry. An agency or registry licensed in the State will be permitted to provide or offer home care services throughout this Commonwealth. The agency or registry will determine its geographic limits, and the business and organizational structure needed to serve the chosen geographic area.

§ 611.3. (affected home care agencies and home care registries)

IRRC suggested that the Department should move to this section that portion of the definitions of "home care agency" and "home care registry" that exceeds the statutory definitions and attempts to distinguish covered from noncovered entities. In accordance with the suggestion from IRRC, the Department incorporated within this section a listing of those entities to which this chapter does not apply. Thus, this section now states that the chapter does not apply to a home health care agency, a durable medical equipment provider, a volunteer provider, or an entity providing financial management services or supports coordination services or both. The Department added "supports coordination services" in response to a comment received that the regulations should include a specific exemption for financial management and other supports coordination services for consumer/employers who self-direct their services. The Department agreed the language was necessary to accomplish a more complete description of the kinds of services potentially offered by the noncovered entity. The definitional section also has been revised to include a definition of "supports coordination services."

One commentator suggested that the proposed definitions of "home care agency" and "home care registry" should be revised to delete the word "only" used in reference to "financial management services." Upon relocating the language referred to in this comment, the Department has accepted the suggestion, and the word "only" prior to "financial management services" has been deleted. The Department determined that use of the term is inferred. In other words, an entity that supplies services in addition to financial management services or supports coordination services, as those terms are defined, is no longer an excluded entity, and that entity will have to examine its operations to determine whether it meets the definition of home care agency or home care registry, and, therefore, needs to apply for a license.

One commentator inquired whether the licensure requirement applies only to organizations, and not to consumer employers. The licensure requirements apply to entities that meet the definition of home care agency or home care registry. The licensure requirements, per the statute, do not apply to a private contract or arrangement entered into by a consumer and caregiver, provided that the caregiver was not supplied, arranged, scheduled or referred to the consumer by a home care agency or home care registry. See 35 P. S. § 448.903a. Thus, if the consumer enters into an arrangement with a caregiver not supplied, arranged, scheduled or referred by a home care agency or home care registry, the caregiver is not subject to the requirements in this chapter. If, however, the consumer enters into an arrangement with a caregiver supplied, arranged, scheduled or referred by a home care agency or home care registry, the caregiver is, in essence, a direct care worker subject to the requirements of this chapter. Ensuring that the direct care worker meets the requirements of this chapter, however, is the responsibility of the home care agency or registry that employed or rostered the direct care worker.

Two commentators suggested that the regulations do not address the unique place of consumer-driven organizations nor the philosophies that oppose medical oppression in personal assistance services. In any set of regulations that a Commonwealth agency, such as the Department, promulgates to accomplish the objective set out by the General Assembly in the authorizing legislation, the agency must strive to address the safety and well-being of all individuals the regulations are intended to reach. Moreover, regulations promulgated must be objective in their application. Regulations must include the requirements to meet the statutory objectives. When the regulations regulate licensure, they must specify the

minimum standards that need to be met to qualify for and retain a license. Thus, these regulations address minimum requirements for licensure of entities that provide or supply direct care workers to provide home care services. Every consumer receiving home care services supplied, arranged, scheduled or referred by a home care agency or registry must receive those services from an individual who has had a background check, is competent to provide home care services, and has been screened for tuberculosis. Moreover, every consumer receiving services is entitled to certain basic consumer protections including notice of services to be provided, the cost of those services, and the identity of the individual who will provide the services. These are basic protections to which all consumers are entitled.

One commentator commented that the Department failed to meet the statutory requirement that the Department take into consideration the preferences and philosophies of persons with physical disabilities. The Department met on January 26, 2007, with representatives of what was, at that time, the Pennsylvania Protection and Advocacy, Inc. (PP&A), and is now the Disability Rights Network of Pennsylvania, and with other individuals representing organizations serving the disability community. The Department sought input from the individuals present at that meeting and engaged in an on-going dialogue in the process of drafting language to ensure the regulations were not more far-reaching than had been intended. The language exempting entities that supply financial management services or supports coordination services or both to consumers of home and community-based services through Medicaid waiver or other publicly funded programs was developed through dialogue with representatives of organizations serving the disability community. Other changes included in these regulations, such as inclusion of a training program meeting training standards for providers participating in the Medicaid waiver or other publicly funded programs as an option for satisfying competency requirements, are a direct result of input from the disability community through the public comment process.

§ 611.4. (requirements for home care agencies and home care registries)

IRRC commented that proposed subsection (b) references other Federal, State and local standards and recommended that, to clearly guide the regulated community, the Department should identify the specific standards in the final-form regulations or maintain a list of applicable standards on the Department's web site. The Department cannot list all applicable Federal, State and local standards in the final-form regulations or on the Department's web site. It is the home care agency's or registry's responsibility to be aware of all the laws that affect the agency or registry, and any changes to those standards. The Department, in its regulations for health care facilities governed by the act, routinely requires compliance with all applicable Federal, State and local standards, in accordance with section 813 of the act (35 P. S. § 448.813). This requirement is included to apprise facilities that the inspection process could encompass a requirement included in another law to which the facility is subject. For example, the Department uses this provision in order to cite facilities subject to but not in compliance with the requirements of the Older Adult Protective Services Act (OAPSA) (35 P. S. §§ 10225.101—10225.5102). The Department of Aging, assigned responsibility for implementation of OAPSA, does not have the authority to conduct inspections of facilities to confirm compliance. Compliance is confirmed by the State agency required to conduct facility licensure inspections. The Department confirms compliance with OAPSA by nursing facilities, home health care agencies and hospices. Any deficiencies in compliance are cited pursuant to the provision in the applicable licensure regulations requiring the facility to be in compliance with all applicable Federal, State and local standards.

One commentator inquired whether a home care office needs to be ADA compliant. The Department believes the reference is to the Americans With Disabilities Act, 42 U.S.C. §§ 12101—12213, which prohibits discrimination on the basis of disability in defined sectors of the economy. As noted previously, it is the responsibility of each home care agency and home care registry to be aware of all Federal, State and local standards that apply.

One commentator inquired whether a home care agency seeking to be licensed in this Commonwealth must have a physical office in this Commonwealth. Since this regulation requires inspection to determine compliance with regulatory requirements, which is confirmed through, among other means, review of required documentation, a physical office in Pennsylvania is necessary.

§ 611.5. (definitions)

IRRC commented that the terms "activities of daily living" and "instrumental activities of daily living" are defined in the act but are not found in this section and that they should be added to this section with a cross-reference to the statutory definition. One commentator also suggested that the terms should be defined in the regulation as they are defined in the act.

The term "instrumental activities of daily living" has been added to the definitional section and the definition references the act. The term "activities of daily living" has not been defined because it is not used in the regulation. The term is not used in the regulation because the statutory definition is not in accord with the industry standard. The statutory definition states that "activities of daily living" include home management activities, respite care, companionship services and personal care, including, but not limited to, assistance with self-administered medications, feeding, oral, skin and mouth care, shaving, assistance with ambulation, bathing, hair care and grooming, dressing, toileting and transfer activities. The statutory definition also states that the term "activities of daily living" includes "instrumental activities of daily living." The industry standard is that assistance with activities of daily living means assistance with self-administered medications, feeding, oral skin and mouth care, assistance with ambulation, bathing, hair care, grooming, dressing, toileting and transfer activities. The industry standard for assistance with activities of daily living does not include assistance with instrumental activities of daily living. Similarly, respite care and companionship services are separate from assistance with activities of daily living. To avoid confusion created by the statutory definition that is at odds with the industry standard, the Department has included the term "home care services" to refer to the gamut of services referenced in the statutory definition of "activities of daily living." Because the term "activities of daily living" has a particular meaning, per the statute, the Department has selected the term "personal care" to refer to those services routinely associated, per the industry, with the term "assistance with activities of daily living." The definition of the term "personal care" in this section reflects this meaning. Throughout the regulation, the term "personal care" is

used when referring to the kinds of hands-on care associated with "assistance with activities of daily living."

IRRC also commented that the definition of "direct care worker" uses the term "services." IRRC suggested that the term "services" should be defined. The Department elected to use the term "home care services" instead, and a definition of that term has been included. As stated above, the Department has defined "home care services" to include one or more of the range of services referenced in the statutory term "activities of daily living." Thus, "home care services" has been defined to include "personal care," "assistance with instrumental activities of daily living," "respite care," "companionship services," and "specialized care." Each of the terms used in the definition of "home care services" has been separately defined, as suggested by a commentator, and requested by IRRC.

As mentioned in the discussion under § 611.3 (relating to affected home care agencies and home care registries) previously, IRRC also suggested that the definitions of "home care agency" and "home care registry" should be revised to mirror the statutory definitions of the terms. IRRC suggested that the portions of the definitions seeking to distinguish covered entities from noncovered entities should be moved to § 611.2 (relating to affected home care agencies and home care registries). The Department followed IRRC's suggestion and deleted subparagraph (ii) from each definition. The information provided in proposed subparagraph (ii) is now provided in § 611.2(a). The definitions, as revised, do include language not included in the statutory definitions, however. Both definitions clarify that the home care agency or registry supplies, arranges, schedules or refers direct care workers to provide home care services as directed by the consumer or the consumer's representative. The Department added this language to acknowledge that consumers must be permitted to self-direct their home care services.

The Department also added definitions of "consumer control" and "independent living philosophy" in accordance with the suggestion of a commentator. The same commentator also suggested defining the terms "consumer direction" and "disability cultural competency." The Department has determined not to add a definition of "consumer direction" as the concept has been incorporated with the definitions of "consumer control" and "independent living philosophy." The Department also has determined not to add a definition of "disability cultural competency." The Department is aware of the considerable impact and effect of the competency requirements imposed by this regulation and has determined not to add a requirement for cultural competency, generally, or disability cultural competency, specifically, at this time. The Department will continue to monitor the need to add this competency requirement.

One commentator, voicing overall approval and support of regulation of the home care industry, has suggested that the definitions of home care agency and home care registry are overly broad to the extent that they encompass organizations that may supply, arrange, or schedule employees to provide assistance to residents or consumers who live on the same campus as the supplying entity; for example nursing homes or personal care homes.

If an entity with a personal care home license or a nursing care facility license provides health care services (including skilled nursing care) or home care services to individuals that do not reside in the personal care home or nursing care facility, the entity will need to obtain a home health care agency license or a home care agency or home care registry license, as applicable.

One commentator suggested that the Department revise the definition of "financial management services" to reference "other supports coordination services." The Department addressed this concern by adding the reference to "supports coordination services" in § 611.2, addressing affected home care agencies and home care registries. That section now indicates that, as discussed, the licensure requirements in Chapter 611 do not apply to entities that provide financial management services or supports coordination services or both to consumers of home and community-based services through Medicaid waiver or other publicly funded programs. A definition of the term "supports coordination services," based on a suggested definition included in comments received, has been incorporated in the definitional section.

The Department has deleted the definition of "qualified health professional" in accordance with revisions to § 611.56 (relating to health screening). That section has been revised to delete the requirement for a "health evaluation" by a "qualified health professional." The health care agency or registry must ensure the direct care worker is screened for tuberculosis in accordance with *CDC Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Settings*.

Finally, the Department revised the definition of "inspection" to address issues raised by IRRC in response to proposed § 611.31 (relating to inspections). In response to proposed § 611.31, IRRC recommended that the regulation make clear whether inspections would be announced or unannounced. IRRC also recommended that the Department state in the regulation that inspections would be conducted during regular business hours, in accordance with section 806.4 of the act (35 P. S. § 448.806d).

The Department, historically, in accordance with its longstanding inspection authority under section 812 of the act (35 P. S. § 448.812), has conducted unannounced and announced inspections. The act, since its inception, has required the Department to conduct inspections to determine the adequacy of the care and treatment provided or the continuing conformity of the licensees to the act and to applicable local, State and Federal regulations. The act gives the Department full and free access to the records of the facility, to persons served by the facility, and to the individuals providing services and their records. The act permits the Department to interview, inspect and examine the licensee as necessary to determine the licensee's compliance with law and regulations. The act does not address whether the entity being inspected should be apprised that the inspection will occur. The Department believes that the integrity of the inspection process is dependent, to a great extent, on its ability to conduct unannounced inspections. An entity that is aware that it will undergo an inspection is able, at least to some limited extent, to affect the outcome of the inspection. The Department must have the ability to assess compliance without the complications introduced by the knowledge of when the inspection will take place. At the same time, there are situations in which the Department must give at least minimal notice that the inspection will occur so that representatives of the business are available to provide the Department the access it requires and is entitled to, under the act, to determine compliance. Therefore, the Department will, on occasion, give the licensee 2 to 3 days notice of an impending inspection so that the Department is assured that representatives of the licensee will be available when the Department's inspectors arrive for the inspection. Also, on those occasions when the Department determines to review records only, it may ask the licensee to forward

copies of records essential to the inspection, in which case the licensee will be aware in advance of the inspection.

Accordingly, the Department has revised the definition of inspection to apprise licensees that an inspection may be scheduled or unscheduled. The Department also has added language to address the IRRC's concern that the requirement in section 806.4 of the act that inspections occur "during regular business hours" be included in the regulation. Lastly, the Department, to eliminate confusion, has eliminated language stating that the inspection may or may not be onsite. The language of the regulation as revised allows the Department to conduct an inspection by means of record review only. If the Department conducts a record review, the Department may opt to require the licensee to forward those records essential to the review to the Department. The Department will review the records and then inform the licensee of the results of its review.

§ 611.51. (hiring or rostering of direct care workers)

The act, in section 806.3(b)(7) (35 P. S. § 448.806c(b)(7)) regarding listing information to be provided to a consumer prior to commencement of services requires "documentation from the home care agency or home care registry that demonstrates personal face-to-face interviews with all employees from a home care agency or independent contractors referred by the home care registry and documentation of at least two satisfactory reference checks prior to referral to the consumer." In accordance with the act's requirements, the Department published a proposed regulation listing hiring or rostering prerequisites, including a face-to-face interview with the direct care worker and "satisfactory references." Many commentators questioned what was a "satisfactory reference." IRRC also has suggested that the Department explain what qualifies as a "satisfactory reference."

Commentators who questioned the meaning of the term also offered suggestions; sometimes, the suggestions also included questions or points for consideration. Several commentators suggested that a satisfactory reference should consist of dates of employment from a previous employer and personal references, and that home care agencies and registries should be permitted to obtain verbal, as opposed to written, references, that are then documented in the direct care worker's file. One commentator suggested that the applicant should have documentation of 2 years continuous prior employment. Another commentator suggested that because many employers have adopted policies to confirm only employment dates, requiring more could be problematic. Another commentator questioned how to proceed if there is no prior employer. One commentator suggested that references could be supervisory or personal references, but should not come from family.

In response to IRRC's suggestion, and after considering public comments, questions and suggestions, the Department has inserted in the regulation language establishing what constitutes a satisfactory reference. The reference need not be from a prior employer, in the event there is no prior employer, and can, but need not, include dates of employment. The reference, either verbal or written, and either supervisory or personal, must be from someone not related to the individual, must be verifiable, and must confirm the ability of the individual to provide home care services.

Commentators also were concerned with the way in which this requirement would impact and affect existing direct care workers, and how documentation of a face-to-face interview and satisfactory references could be included in the file for a direct care worker employed or rostered prior to the effective date of the regulations. One commentator asked how to handle documentation of direct care workers already on the roster for the registry.

Regulations have only prospective effect, unless the regulation specifically states that it applies retroactively. If the regulation applies retroactively, there must be support in the statute for the requirement. Thus, the requirement of a face-to-face interview and of documentation of at least two satisfactory references will be applied prospectively only. Files for direct care workers hired prior to the effective date of the regulations that do not contain evidence of a face-to-face interview or of two satisfactory references will not constitute a violation of the regulations. However, those files must contain documentation of completion of requirements for establishing competency, a criminal background check, and a child abuse clearance, as applicable, since the regulations (in §§ 611.55, 611.52 and 611.53, respectively) each require, per the statute, the agency or registry to meet the applicable requirements, within the time frame specified, for existing direct care workers.

One commentator was concerned with the use of "personnel" as the modifier for "file," because the term "personnel," in the commentator's view, connotes an employment relationship between the individual and the entity maintaining the file. Since registries do not employ direct care workers, the connotation, in the commentator's view, is not appropriate. *Webster's* defines "personnel" as "a body of persons usually employed (as in a factory, office, or organization)." Thus, employment is the usual, but not requisite, connection between the person and the organization. While continued use of the term "personnel" would not be wrong, it may lead to some confusion. Therefore, in this section, the Department has determined to substitute the modifier "direct care worker" for "personnel." The file required to be maintained for each caregiver being supplied, arranged, scheduled or referred by a home care agency or home care registry to provide home care services will be referred to as a "direct care worker file." The commentator recommended deletion of the term "personnel" in subsequent sections as well. The Department accepted the recommendation and has deleted the term "personnel" from subsequent sections.

A commentator has suggested that this section must require that files for direct care workers must include all documentation required under § 611.54 (relating to provisional hiring), and that the regulation must require the agency or registry to maintain in the file any other documentation required under the act or any of its implementing regulations or rules. The commentator also suggested that the Department should include a reference with this section to the proposed retention of records provision.

The Department has accepted the commentator's first suggestion and has included within subsection (b) of § 611.51 a reference to § 611.54 (relating to provisional hiring). Direct care worker files must contain documentation related to the worker's provisional hire, if applicable. The Department elected not to include language in the regulation requiring the agency to include in direct care worker files any and all other documentation that might be required under the act or any of its implementing regulations. To the extent the act or any other regulations promulgated under the act and applicable to a home care agency and home care registry require the agency or registry to maintain certain documentation, the agency or

registry will be required to comply with the regulation. The agency and registry will be required to have the documentation, and be able to produce the documentation if requested by a representative of the Department conducting an inspection, but the Department will not require the agency or registry to keep the requisite documentation in direct care worker files. If the information is pertinent to the individual, and the agency or registry chooses to maintain that information in the individual's file, it is within the agency's or registry's discretion to do so, but will not be dictated by the Department in this regulation. Finally, the Department elected not to include a reference to the proposed retention of records provision, as that provision has not been included in the final-form regulation.

Finally, one commentator suggested that the prerequisites for hiring or rostering of direct care workers should be revised to require, as an additional prerequisite, that the direct care worker hold a GED test credential or be a certified nursing assistant. The Department does not have the authority, per the statute, to impose this additional requirement. The statute does require training or testing prior to assignment or referral of a direct care worker, but no minimum level of education is dictated. Thus, the regulation lists options for training and includes mandatory content for training or testing programs developed by the agency or registry, but does not dictate a minimum education level for all direct care workers. As stated previously, these regulations contain minimum requirements that all agencies and registries must meet to be licensed. Certainly, it is within the agency's or registry's discretion to require, as a matter of policy, that any direct care worker employed or rostered by the agency or registry must meet a minimum education requirement as determined by the agency or registry.

§ 611.52. (criminal background checks)

IRRC inquired regarding the need for subsection (d) which states that an agency or registry may require an applicant to furnish proof of residency. IRRC stated that, if this provision is needed, that the circumstances when proof of residency would be required should be included in the final-form regulation.

The act requires the Department, prior to licensing a home care agency or registry, to determine that all individuals employed by an agency or referred by a registry, staff working within each entity and the owner or owners have obtained criminal history record information, in accordance with the requirements of section 503 of the OAPSA (350.5 § 10225.503) and maintain that information on file in the home care agency or registry office. Thus, the Department proposed regulations that mirror the existing background check provisions and prohibitions applicable to other health care providers under the OAPSA. OAPSA, in section 502, (35 P. S. § 10225.502), requires the following information in connection with a criminal background check: (1) a report of criminal history record information from the State Police or a statement from the State Police that their central repository contains no information relating to the individual; and (2) when the individual is not and for the 2 years immediately preceding the date of application has not been a resident of this Commonwealth, a report of Federal criminal history record information. Under the statute, the Department of Aging is the intermediary for purposes of the second method of conducting a criminal background check. See 35 P. S. § 10225.502(a)(2).

Therefore, regulations in 6 Pa. Code Chapter 15 (relating to protective services for older adults), promulgated by the Department of Aging to implement the statutory requirements under OAPSA, require the individual to submit a State Police criminal history record, unless the individual is not and, for the 2 years immediately preceding the date of application, has not been a resident of this Commonwealth, in which case the individual must submit a Federal Criminal History record. See 6 Pa. Code § 15.141 (relating to prospective facility personnel). The same section states that facilities may require the individual to furnish proof of residency by submitting one of the documents listed in the regulation.

When the Department promulgated these regulations, the requirements in OAPSA and in Department of Aging regulations were purposefully mirrored. These regulations also dictate the type of criminal history record that must be obtained based on the length of time the individual seeking to be employed or rostered has been a resident of this Commonwealth. These regulations also permit, but do not require, the agency or registry to require the individual to submit proof of residency. It is the agency or registry that will be inspected for compliance with the criminal background check requirements. Allowing the agency or registry to obtain proof of residency will allow the agency or registry to take steps to ensure compliance, if the agency or registry chooses to do so.

IRRC also inquired whether a State-issued identification would suffice to prove residency. A commentator also suggested adding a State-issued identification as another method by which residency could be established. The Department agreed with the suggestion, and has added State-issued identification as an optional method of establishing residency.

One commentator pointed out that the act requires a criminal background check not only for direct care workers, but also staff working within a home care agency or registry, and the owners. The Department agreed and, therefore, revised the regulation to include in the final form regulations a statement affirming the applicability of the criminal background check requirement to staff and the owners. Because the criminal background check requirement has wider applicability than to an "applicant for employment or referral," the Department changed the reference to "individual required to submit or obtain a criminal history report."

The commentator also suggested that the Department clarify § 611.52(2), addressing requirements for individuals currently employed or rostered, to affirm the applicability of subsection (f), addressing records maintained. The commentator suggested that the regulation, in subsection (j), should state that the criminal background check information obtained for existing employees must be included in the direct care worker's file. The Department elected not to revise subsection (j) because subsection (f) applies to all individuals employed or rostered, regardless whether they were employed or rostered before or after the effective date of the regulations.

The commentator also suggested that subsection (j) should state that a person currently employed whose State Police criminal history record reveals a prohibited conviction listed in 6 Pa. Code § 15.143 (relating to facility responsiblities), or whose Department of Aging letter of determination states that the individual is not eligible for hire or roster must be immediately terminated from the agency's employment or removed from the registry's roster. In response to this comment, the Department revised subsection (e) to state that a home care

agency or home care registry may not hire, roster or retain an individual if the State Police criminal history record reveals a prohibited conviction listed at 6 Pa. Code § 15.143.

The commentator also pointed out that OAPSA, in section 508(1) (35 P. S. § 10225.508(1)), exempts from the act's criminal background check requirement existing employees employed for one year or longer. The commentator suggested subsection (j) should be revised to exempt from the criminal background check requirement direct care workers who have been employed or rostered for 1 year or more.

The Department notes that the Legislature did not amend OAPSA to include home care agencies and home care registries as covered entities; rather, the Legislature amended the act to include home care agencies and home care registries as facilities that must be licensed by the Department and imposed a criminal background check requirement for workers, staff and owners, in accordance with section 503 of OAPSA, as one of the licensure criteria. The Legislature did not include, by reference, other sections of OAPSA. The Legislature did not incorporate by reference the section of OAPSA that limits the applicability of the criminal background check requirement and provides an exemption for existing employees employed for more than one year. Accordingly, the Department did not include an exemption for existing employees in its regulations.

A commentator inquired whether, for workers who have not been a resident of this Commonwealth for 2 years, if both the Federal criminal history record and the Department of Aging letter of determination were required, or whether the Department of Aging letter of determination "includes" the Federal criminal history record. The Department of Aging letter of determination is a letter advising the agency or registry, based on the Federal criminal history record, whether the individual for whom the report was prepared may be hired or rostered as a direct care worker. In effect, the Department of Aging letter "includes" the Federal criminal history record.

A commentator inquired how often criminal background checks must be conducted. Another commentator suggested that criminal background checks should be repeated every 2 to 3 years. Once a criminal background check is completed, the criminal background check need not be repeated. Of course, if the agency or registry has reason to know that another check should be conducted, the agency or registry is advised to conduct the check. The regulation, however, does not require routine or repeated background checks.

One commentator recommended deletion of the modifier "personnel" in the term "personnel file" for the same reasons outlined in prior paragraphs of this preamble. The Department made the recommended revision. The commentator also recommended that the Department substitute the term "direct care workers" for the phrase "individuals employed or rostered." The Department agreed with the recommendation and made the substitution where appropriate.

§ 611.53. (child abuse clearance)

Numerous commentators stated that they support the concept of a child abuse clearance for direct care workers who will provide care to a child, and even for office staff who have access to the child's personal and medical information. Commentators insisted that direct care workers who have no contact with children and staff who have no access to the child's records should not be required to obtain a child abuse clearance. Commentators also expressed concern over the expense to the agency or registry or to the individual associated with obtaining the clearance. Finally, commentators suggested that this requirement will lead agencies and registries to refuse to extend the scope of the agency's or registry's consumer base to persons under 18 years of age.

The Department has no power to vary the requirement clearly imposed by statute. The act requires that "prior to licensing a home care agency or home care registry which provides services to persons under 18 years of age, the department shall determine that all individuals employed by an agency or referred by a registry, all office staff working within each entity and the owner or owners have obtained clearance from the child abuse registry, in accordance with 23 Pa.C.S. Chapter 63 (relating to child protective services) and maintain that information on file in the home care agency or registry office."

The rules that govern promulgation of regulations do not permit the Department to promulgate a regulation with language less stringent than the language in the act on which the regulation is based.

A commentator recommended that the Department substitute the term "registrant" for "applicant" when referring to registries. Thus, the commentator would have the Department revise subsection (a) to state that an agency or registry shall "require each applicant for employment *or* registrant for referral as a direct care worker . . . to request a ChildLine verification regarding whether the applicant or member is named in the Statewide Central Register as the perpetrator of a founded or indicated report of child abuse. . . ." (Emphasis added.) The Department has not accepted this recommendation because the term "applicant" has been used elsewhere in the regulations, "applicant" does not necessarily infer "for employment," and introduction of a new term in this section would be unnecessarily confusing to the reader.

The Disability Rights Network pointed out that the requirement for a child abuse clearance applies to direct care workers, staff working within each entity, and to owners. Subsection (a) makes clear that the agency or registry must require each applicant for employment or referral as a direct care worker, and each member of the agency or registry office staff to request a ChildLine verification. Subsection (c) requires that the records maintained by the agency or registry for each individual employed or rostered include a copy of the ChildLine verification. Subsection (c) also requires the agency or registry to maintain copies of the ChildLine verification for the agency or registry owners and to make those copies available to the Department for inspection. Thus the regulation requires a child abuse clearance for direct care workers, staff, and owners.

The same commentator also recommended clarification of subsection (d) to state that the subsection applies to direct care workers, office staff, and owners. The Department accepted the recommendation and revised subsection (d) to incorporate a reference to member of the agency or registry office staff. The Department did not include a reference to owners, since subsection (c) states that a copy of the verification for the owners shall be available for inspection.

Finally, the same commentator recommended that subsection (d) must clarify that a person currently employed or rostered, including an office staff member, who is named in the Statewide Central Register as the perpetra-

tor of a founded or indicated report of child abuse must be immediately terminated by the home care agency or immediately removed from the home care registry's roster. To meet the commentator's concern, the Department revised subsection (b) to state that the home care agency or home care registry may not employ, roster, or retain an individual named in the Statewide Central Register as the perpetrator of a founded or indicated report of child abuse.

§ 611.54. (provisional hiring)

IRRC requested that the Department explain its authority for including this section in the regulation. IRRC also questioned how the Department determined that 120 days is the appropriate length of time for provisional hire. More than one commentator also questioned the length of time for provisional hire, and one commentator suggested that the provisional hiring of someone who may have a criminal history could allow such a person to move from employer to employer with no tracking or consequences for them. The commentator believed that the potential threat to consumers is too great, and that, based on the speed with which criminal background check information may be obtained, that, at a minimum, the Department should shorten the period of permitted provisional hire. Another commentator pointed out that OAPSA permits only a 30 or 90-day period of provisional hire, depending upon whether the individual being provisionally hired is and has been a resident of this Commonwealth for at least 2 years. The commentator is correct, and the Department has revised the appropriate length of time for provisional hire to mirror requirements in OAPSA and in the Child Protective Services Law, on which the Department's provisional hire provisions are based. The explanation of the Department's statutory basis for the provisional hire provision follows.

The act requires the Department to ensure for each direct care worker, a criminal background check in accordance with OAPSA and a child abuse clearance, as applicable, in accordance with 23 Pa.C.S. chapter 63 (relating to child protective services). Both statutes referenced in the act permit provisional hiring. The Department relied upon the statutes referenced in the act for statutory authority for provisional hiring.

Section 506 of OAPSA (35 P. S. § 10225.506) permits provisional hiring for a period of 30 or 90 days, depending upon whether the applicant is and has been, for at least 2 years, a resident of this Commonwealth. Thus, OAPSA expects that a resident of this Commonwealth will obtain the results of a criminal history report within 30 days, and allows an applicant who is not a resident of this Commonwealth and has not, for the 2 years preceding the date of application, been a resident of this Commonwealth, who must therefore obtain a criminal history record from the Federal Bureau of Investigation, 90 days to obtain the report. OAPSA imposes conditions upon provisional hiring; those conditions have been incorporated in the Department's regulation on provisional hiring.

The provisions of 23 Pa.C.S. § 6344(m) (relating to information relating to prospective child-care personnel) permits provisional employment for a single period not to exceed 30 days, or for out-of-State applicants, a period of 90 days, provided certain conditions are met. Those conditions have been incorporated in the Department's regulation on provisional hiring. Specifically, the Child Protective Services Law does not permit the provisionally hired individual to work alone with children; the individual must work "in the immediate vicinity of a permanent employee." Thus, the Department's regulation requires the home care agency or home care registry to supervise, or assign another direct care worker to accompany, a provisionally hired individual who will provide home care services to a consumer less than 18 years of age.

IRRC inquired, as did a number of commentators, whether the Department's conditions for provisional hire prohibit the hire of someone on a provisional basis until the individual has received the necessary training or testing. One commentator suggested revision of the regulation to make clear that the training or testing was required prior to assignment or referral, but not prior to hiring on a provisional basis. The Department agreed with the comment, and revised the condition applicable to establishing competency for a provisionally hired individual to clarify that the individual may be provisionally hired before receiving the requisite training or testing but cannot be assigned or referred to provide home care services until the individual has received the requisite training or testing to establish competency.

One commentator inquired whether the provisional hiring provision allows an agency or registry to hire someone who has not yet obtained a criminal background check and child abuse clearance, as applicable, and that the direct care worker then has the period of permitted provisional hire to obtain the necessary background check and child abuse clearance. The commentator's summary of the provision is correct.

One commentator stated that the period for provisional hire, even for an applicant who has not resided in this Commonwealth for at least 2 years, should be 30 days. The commentator believes that agency or registry should be required to submit a request for a letter of determination, for an individual who has not been a resident of this Commonwealth for at least 2 years, to the Department of Aging within 30 days of the application.

The Department agrees that the process for obtaining the criminal history report should start almost immediately after the application for employment or referral is submitted. The Department anticipates, as did the Legislature when it enacted OAPSA, that a criminal history report for a resident of this Commonwealth may be obtained from the Pennsylvania State Police within 30 days, provided there is not a significant backlog. Because, however, a criminal history report for an individual who has not been a resident of this Commonwealth for the requisite 2-year period must be obtained from the Federal Bureau of Investigation and the Department of Aging must review the report to determine whether the report contains any convictions that are prohibited convictions the Commonwealth's law, it is likely that process could very well take more than 30 days, which is the reason that both OAPSA and the Child Protective Services Law, and, as a result, the Department's regulations, permit a longer period of provisional hire for an individual who has not been a resident of this Commonwealth for the requisite 2-year period. The provisional hire provisions do impose certain conditions meant to protect the consumer, however, including supervision or oversight of the individual who has not yet obtained a criminal background check or child abuse clearance.

As the Department stated when it proposed the provisional hire provision, this provision permits, but does not require, provisional hiring. A home care agency or registry is free to assess the risks associated with provisional hiring and determine that the risks outweigh the benefits. If the agency or registry chooses to hire individuals

on a provisional basis, however, this regulation establishes the parameters for provisional hiring.

Finally, a commentator suggested the addition of the word "immediately" at the end of the second sentence in subsection (b), to mirror the wording in the first sentence. The Department agreed with the comment, and made the suggested change.

§ 611.55. (competency requirements)

The first, and most immediately obvious, change to this regulation from proposed to final is the substitution of the term "competency" for "training" in the title and in the body of the regulation. The Department made this change not because the act uses the term "competency," not "training," as was suggested by one commentator (the statutory provision does refer to training in section 806(d.1)(2) of the act, but because the Department agreed that the statutory provision is directed at requiring competency, not training, prior to assignment or referral of a direct care worker. Training, received prior to or after hire or roster, is simply one method by which competency may be established. The act also permits the agency or registry to verify, by means of a competency examination, that the individual is competent to provide services. Regardless of the method used, however, basic competency is the goal.

The Department also agreed with the commentator who suggested the Department substitute "direct care worker" for "individual," eliminate references to "personnel," and substitute "review" for "reassessment" of competency. In the commentator's view, "reassessment" implies oversight. The suggested changes have been incorporated. The same commentator suggested the Department add "consumer feedback" as a method of reviewing the direct care worker's competency to provide home care services, and the Department accepted the recommendation.

As for the substantive requirements of the regulation, IRRC pointed out that Representatives Mundy and Hennessey and other commentators suggested that not all direct care workers should be required to establish competency for tasks listed in the proposed regulation in subsection (d), paragraphs (10)—(15) (for example, bathing, shaving, grooming and dressing, hair, skin and mouth care, assistance with ambulation and transferring, meal preparation and feeding, toileting, and assistance with self-administered medications). Many commentators commented that ensuring that all direct care workers are able to provide personal care is an unnecessary expense, as many direct care workers prefer not to provide personal or "hands-on" care. One commentator said that the depth and scope of the subjects listed in the proposed rulemaking is excessive for care-givers who provide only homemaker-companion care. Commentators also pointed out that the already strained workforce would shrink, as potential direct care workers will decline the work opportunity if required to participate in training or be tested for skills the direct care worker has no intention of using. Several commentators stated that the requirements as set forth in the proposed regulation would force agencies and registries to hire only individuals who had received training, or were certified, as certified nursing assistants. One commentator said that the scheme set forth in the proposed regulation would drastically reduce the number of people who will be able to provide care to clients, that it would eliminate older caregivers who might be willing to provide care for their peers but have no interest in training or competency examinations. The commentator inquired what might happen to the client who is very comfortable with her older caregiver who is not willing to take a competency examination.

As noted previously, the Department agreed with comments suggesting that not all direct care workers must be competent to provide every possible home care service and revised the regulation accordingly. As revised, the training provision allows a direct care worker to establish competency by: (1) having a valid nurse's license in this Commonwealth; (2) demonstrating competency by passing a competency examination developed by the home care agency or home care registry in accordance with regulatory requirements; or (3) successfully completing a training program developed by the agency or registry in accordance with regulatory requirements, the home health training program outlined in 42 CFR 484.36, the nurse aid certification and training program sponsored by the Department of Education, the training program meeting the training standards of the Medicaid waiver or other publicly funded program, or other program identified by the Department by subsequent publication in the *Pennsylvania Bulletin* and on the Department's web site.

Stakeholders and advocacy groups had inquired whether the competency requirements in these regulations would supersede the training requirements for providers serving clients of the Medicaid waiver programs. An advocacy group also requested that the Department list the Medicaid waiver training programs in the regulation as an approved method of establishing competency. The Department reviewed the training requirements for the Medicaid waiver programs and determined that the training meets or exceeds the Department's minimum requirements to establish competency to provide home care services. Therefore, a training program meeting the training standards of the Medicaid waiver or other publicly funded program was added as another training program option.

The Department also has included language permitting the Department to add to the list of approved training programs without having to revise the regulation. The Department will be able to identify other training programs, as they are developed, by publishing notice in the *Pennsylvania Bulletin* and on the Department's web site.

The Department did not include, in its listing of approved training programs, "a personal care worker training credentialing program." The act includes "successful completion of a personal care worker training credentialing program approved by the department" as an optional method for meeting the Act's competency requirements. 35 P. S. § 448.806(d.1)(1)(iv). The Department was not able to locate a personal care worker training credentialing program for the Department to approve or disapprove; thus, that option was not included in the regulation.

If the agency or registry establishes its own training program or competency examination, the agency must ensure the direct care worker is competent in the home care services the direct care worker will provide. The final regulation now states that a competency examination or training program developed by the agency or registry must address, at a minimum, the following subject areas: confidentiality; consumer control and the independent living philosophy; instrumental activities of daily living; recognizing changes in the consumer that need to be addressed; basic infection control; universal precautions; handling of emergencies; documentation; recognizing and reporting abuse and neglect; and dealing with difficult behaviors. These subject areas, with the exception of "instrumental activities of daily living," were listed in the

proposed regulation in subsection (d), paragraphs (1)—(9). The term "instrumental activities of daily living" was substituted for the term "home management," listed in the proposed regulation as paragraph (16). The competency examination or training program for a direct care worker who will provide personal care also must address the following subject areas pertinent to personal care: bathing, shaving, grooming and dressing; hair skin and mouth care; assistance with ambulation and transferring; meal preparation and feeding; toileting; and assistance with self-administered medications. These are the subject areas that had been listed in the proposed regulation in subsection (d), paragraphs (10)—(15).

The term "assistance with instrumental activities of daily living" was substituted for the term "home management" in response to questions from commentators regarding the meaning of the term "home management." Since the intent was to refer to some portion of the services included in "instrumental activities of daily living," the Department elected to use that term rather than create another term. "Instrumental activities of daily living" is defined in the regulation by reference to the act. The act defines the term to include meal preparation, shopping and errands, telephone use, light housework, laundry and transportation. 35 P. S. § 448.802a.

An advocacy group commented that the topics to be covered for all direct care workers should be expanded to include, in addition to "consumer control" and "independent living philosophy," "consumer direction" and "disability cultural competency." The Department has defined "consumer control" to incorporate the concepts embraced by the term "consumer direction." The Department has determined not to require cultural competency training, generally, or disability cultural competency, specifically, at this time, for the reasons given in § 611.5 (relating to definitions).

The advocacy group also asserted that "consumer control" and the "independent living philosophy" not only must be separate mandatory subject areas for purposes of establishing competency of a direct care worker, they must be incorporated into every other subject area. The advocacy group proposed that "recognizing changes in the consumer that need to be addressed" should be revised to state that any recognized change will be communicated promptly to the consumer and that consumer control will be followed. The advocacy group also proposed that, because aspects of a person's disability are often wrongly interpreted as difficult or confrontational, "dealing with difficult behaviors" should include communication skills. The advocacy group also commented that the regulation should make clear that the purpose for establishing competency in "home management" is to ensure that the consumer's instructions regarding home management can be implemented. Finally, the advocacy group stated that it anticipated that the Department may develop guidelines for ensuring competency in each of the mandated subject areas and requested to have input in the development of those guidelines.

Home care agencies and registries are required to ensure competency in consumer control and the independent living philosophy. The Department has determined, at this juncture, to leave to agencies and registries the best method for ensuring competency in both areas. Certainly, neither topic can be addressed in a vacuum. The Department fully anticipates that both topics will be addressed in the context of providing home care services, and that once competency is established, direct care workers will understand how these concepts affect the manner in which home care services are provided to consumers. Compliance will be monitored during the Department's licensure inspections. If, subsequently, the Department determines that more direction is needed, the Department may consider preparing guidelines and will seek input and advice from stakeholders at that time.

The Department believes that the final-form regulation addresses the needs and concerns of the industry, as expressed in comments the Department received. The final-form regulation accommodates the commentator who said she would like the ability to create her own training program to reduce costs and the commentator who stressed that the agency or registry should have the ability to develop its own program to ensure competency prior to assignment or referral. The regulation meets the concern of the commentator who said that his agency did not have the physical space to provide training and suggested that the Department simply require a competency examination that could be designed by the home care agency or registry. The final-form regulation also accommodates the commentator who suggested that there be the option for an examination or training geared to the individual who will provide homemaker/companion services, since getting the caregiver to the client in a timely fashion is crucial.

The final-form regulation on training makes clear that there are options available to the agency or registry. If the individual is licensed as a nurse or is a certified nursing assistant, that individual is already qualified to provide home care services. If the individual is not already trained, the agency or registry can provide training, by means of its own program or another program listed in the regulation, or the agency or registry can administer a competency examination. The training provided or competency examination administered can vary depending upon the nature of the home care services the individual will provide.

The Department was not able to address all concerns raised by commentators. Many commentators had concerns regarding the cost to the agency or registry associated with ensuring direct care workers are competent to provide the care they are assigned or referred to provide. One commentator stated that it is cost prohibitive to pay future caregivers for hours of training before the agency or registry could begin to bill for the services to be provided by the caregiver. Another commentator suggested that if extensive classroom training is required, the result will be overbearing expense to the agency or registry that will be not reimbursed by public payment sources such as the Medicaid waiver programs. Another commentator was concerned that the agency or registry would incur the expenses associated with the training of a direct care worker who, once trained, would then leave the agency or registry to go to another agency or registry. Another commentator stated that if individuals must be paid to be trained, the administrative costs for the agency will rise, which would mean an increase in costs to the consumer.

Commentators also raised other concerns that the Department was not able to address. One commentator said that hours of training will cause too long a delay from the date of hire or roster to the date when the individual can be assigned or referred in an environment in which agencies and registries struggle to find individuals to provide the care that is requested. Another commentator stated that individuals who intend to work only part-time, who might have one or more other part-time

jobs, cannot commit to long training periods. Another commentator suggested that the most valuable training is training that occurs over a period of time as the direct care worker gains experience.

The Department concurs that as a direct care worker gains on-the-job experience, the worker will become more skilled. In addition, the agency or registry may wish to offer additional training, to hone skills and teach new ones, as part of overall direct care worker retention goals for the agency or registry. The Department encourages those efforts. Ongoing training, however, is not required by the regulation. Ensuring basic competency upon hire or roster prior to assignment or referral, either through training or a competency examination, and yearly review of skills, is required. As noted, ongoing training could make the review process go more smoothly.

The regulation, under the statute, requires the agency or registry to ensure that each direct care worker, prior to being assigned or referred to provide direct care services, has the basic skills needed to provide the home care services the worker has been assigned or referred to provide. The Department acknowledges there are costs associated with ensuring basic competency. The regulation, in accordance with the statute, contains options for meeting that requirement. Different options mean different costs. Providing training will mean more time and higher costs, but may be the better way to ensure competency. Agency and registry owners will need to weigh options and associated costs and make the decision that is best for the agency or registry. Owners will need to decide whether the agency or registry will pay a direct care worker to be trained. That issue, like the issue of how to accommodate a part-time worker, will be a matter of discretion for the owner of the agency or registry, based upon the agency's or registry's own recruitment and retention goals or difficulties. The Department recognizes, as did the Legislature when it amended the act to license agencies and registries and impose certain requirements in connection with licensure, that ensuring competency of a direct care worker, through training or testing, prior to assignment or referral, may mean increased costs for industry as a whole, which may be passed onto the consumer. The ultimate goal, however, is to promote the health, safety and adequate care of the consumers of services provided by home care agencies and home care registries and to assure safe, adequate and efficient home care agencies and home care registries.

IRRC pointed out that the proposed regulation required a competency examination to be "approved by the Department." IRRC inquired how approval would be accomplished. IRRC also pointed out that Senator Corman commented that it was not clear whether there would be a Statewide test, and if so, how it would be graded or administered in a timely fashion so that new employees or contractors could begin employment. IRRC stated it agreed with Senator Corman's comment and requested that these issues should be clarified in the final-form regulation.

Other commentators made similar inquiries. One commentator inquired regarding a competency examination "approved by the Department," and asked whether there was an examination available that had been approved by the Department. Another commentator inquired whether there will be guidelines, outlines, formats and suggested subject matter made available to agencies and registries by the Department. Another commentator asked that there be a list of accepted training programs and requested that the industry be involved in reviewing programs and assembling the list of accepted training programs. Another commentator inquired whether the Department has training programs or competency examinations that are available to agencies or registries to use. One of the trade associations recommended that the Department offer at least three preapproved competency examinations to assist agencies and registries, and the trade association offered to assist in the preparation of the preapproved competency examinations.

Commentators also inquired how to submit a competency examination for approval by the Department. One commentator inquired whether the competency examination could be a written examination. Another commentator asked if a written multi-question quiz on the topics listed as required subject matter would suffice.

In the final-form regulation addressing competency requirements, the Department deleted language indicating the training program or competency examination developed by the agency or registry must be "approved by the Department." The Department seeks to eliminate the notion that the training program or competency examination must be reviewed and approved by the Department prior to use. An agency or registry planning to develop its own training program or competency examination need not submit the training program or competency examination to the Department for approval prior to use. A training program or competency examination developed by the agency or registry that meets requirements of the regulation is an approved training methodology. If an agency or registry opts to develop its own training program or competency examination, the Department will make the determination during inspection whether the training program or competency examination meets requirements of the regulation and whether direct care workers are appropriately trained prior to assignment or referral. If, upon inspection, the Department discovers that a direct care worker did not successfully complete the training or competency examination, or that the training program or competency examination does not meet the requirements of the regulation, or both, then the Department will cite the agency or registry for failure to comply with the competency regulation.

The agency or registry need not develop its own training program or competency examination. Under the statute, the Department has indicated in the regulation the existing programs which have the Department's approval, that the agency or registry may use as the agency's or registry's mechanism to ensure competency. An advocacy group has suggested that, because each training program option listed in the statute includes the language "approved by the department," the Department has the authority and must require each of those training programs to include, as part of the training program curriculum, training in consumer control and the independent living philosophy. The advocacy group also commented that the nurse aide program, per the statute, must be approved by the Department of Health, not the Department of Education, the agency referred to in the proposed regulation in connection with the nurse aide training program.

In the final-form regulation, the Department identifies the nurse aide training curriculum as one "sponsored" by the Department of Education, because it is the Department of Education that offers the curriculum. The Department of Health has no training programs appropriate for direct care workers. The nurse aide training curriculum sponsored by the Department of Education is "approved" by the Department by virtue of its inclusion in the regulation.

The other training programs are also "approved" by the Department by virtue of their inclusion in the regulation. The Department has determined that the training programs will ensure the competency of the individual to provide home care services. No further action is anticipated. The Department has no authority to dictate the curriculum content for those training programs.

The Department also has given agencies and registries the parameters for development of the agency's or registry's own training or testing mechanism which will be examined upon inspection of the agency or registry. The Department will not be developing optional competency examinations for use by agencies or registries. The Department is willing, however, to receive recommendations of competency examinations or training programs that meet the requirements of the regulation that could be made available to all home care agencies and home care registries. If, upon review of the recommendation, the Department determines that the training program or competency examination does meet the requirements of the regulation, the Department will publish notice in the *Pennsylvania Bulletin*, for the benefit of the home care industry as a whole, of the availability of the competency examination or training program. Certainly, if a trade association wishes to develop a model competency examination or training program, the Department will review the examination or program developed by the trade association, and if the Department determines that the examination or program meets the requirements of the regulation, it will publish, for the benefit of the home care industry as a whole, notice of the availability of the training program or competency examination.

A commentator asked whether new caregivers will have 2 years to take and pass a competency examination since new caregivers cannot be on the caregiver roster until they have passed a competency examination and there is no approved examination. As the Department stated, the Department will not be supplying an "approved" competency examination. If an agency or registry chooses to establish competency through administration of a competency examination, the agency or registry will need to develop or identify a competency examination that meets the regulatory criteria. This regulation takes effect upon publication. After December 12, 2009, no new direct care worker may be assigned or referred to provide home care services prior to satisfying the competency requirement. Direct care workers employed or rostered prior to the effective date have 2 years from December 12, 2009, to satisfy the competency requirement.

A commentator pointed out that the regulation does not specify the number of hours of training that must be provided. The commentator stated that her agency requires its direct care workers to have 40 hours of orientation and an additional 12 hours of training each year. The commentator is correct; the regulation does not require a specific number of hours of training that must be provided, if the agency or registry chooses to provide its own training. The Department's concern is that the required subject matter is covered. The Department will not dictate the time it should take to cover the required subject matter.

A commentator suggested that the regulation should require all direct care workers to meet the competency requirements within 30 days of the individual's hire or roster date. The Department has declined to impose a time frame within which the competency requirement must be accomplished after an individual is hired or rostered. The time frame within which the mandatory training or testing must be accomplished is within the discretion of the agency or registry.

An advocacy group has suggested that the regulation should be revised to state that the competency requirement applies to any person that has direct contact with a consumer, including specifically, an owner or member of the administrative staff for the agency or registry who, in an emergency, substitutes for the direct care worker who is unavailable. The Department has elected not to include an explicit statement in the regulation to this effect. If an office staff member is assigned or referred to provide care to a consumer, or the owner takes on the responsibility to provide care, the office staff member or owner becomes a direct care worker. Under the regulation, a direct care worker cannot provide home care services until he or she is competent to do so.

A commentator requested clarification of the provision that states that documentation of satisfactory completion of competency requirements is transferable from one home care agency or registry to another home care agency or registry. The commentator inquired how the documentation would be transferred from one agency or registry to another. The Department suggests that the direct care worker seeking to be employed or rostered by another agency or registry need simply provide a photocopy of what was included in the direct care worker's file maintained by the prior agency or registry. Another alternative is for the prior agency or registry to supply a letter either to the new agency or registry or to the direct care worker, verifying successful completion of competency requirements.

Lastly, a commentator stated that this section does not address those activities that the direct care worker is prohibited from providing; for example, eye drops, fleet enemas, suppositories, and the like. This set of regulations establishes rules for licensure of home care agencies and registries that provide home care services. Home care services are defined to include personal care, assistance with instrumental activities of daily living, companionship services, respite care, and specialized care. Each term included in the definition of home care services also is defined. Home care services do not include nursing services or skilled care. If a home care agency or home care registry seeks to provide or offer nursing or skilled care, the agency or registry would need to be licensed as a home health care agency.

§ 611.56. (health screening)

Commentators almost unanimously objected to the proposed regulation requiring a health screening prior to referral or assignment of a direct care worker. The regulation as proposed would have required a "screening assessment" to establish that the individual had been screened for tuberculosis, and for five other communicable diseases or conditions which were listed in the proposed regulation. Commentators have inquired regarding the meaning of the term "screening assessment" and expressed concern that direct care workers would need to undergo more onerous scrutiny as to their health status than other workers in the health care field.

IRRC commented that Representatives Mundy and Hennessey, Senator Corman and several other commentators question how the "screening assessment" required by the proposed regulation would be accomplished. IRRC inquired whether a laboratory test would be required or whether a physical examination by a doctor would be sufficient. Many commentators expressed concern that the Department was proposing an invasive procedure

necessitating the use of blood and stool samples to detect communicable disease. Several commentators inquired whether the screening assessment could consist of a questionnaire. IRRC recommended that the Department amend this section to clearly state how the "screening assessment" must be completed.

IRRC also pointed out that commentators asserted that the list of conditions which must be screened for, far exceed the screening required for employees of other licensed health care facilities. IRRC inquired how the Department determined that the health screenings in the proposed regulation are appropriate for use with agency or registry direct care workers.

One commentator said that prospective direct care workers do not have access to clinics that would provide the necessary health evaluation, and that home care agencies and registries do not have qualified health professionals on staff to perform the evaluation. The commentator said that lack of access to a qualified health professional would further exacerbate the growing shortage of direct care workers.

The act requires that "prior to referral to consumers, all individuals and any other office staff or contractors with direct consumer contact must obtain documentation from a physician or other appropriate health care professional that the individual is free from communicable disease, including, at a minimum, a tuberculosis screening as outlined by the screening guidelines of the department." 35 P. S. § 448.806(d.1)(5). Thus, in the draft regulations, circulated prior to publication of proposed regulations, the Department suggested that the direct care worker should be screened for tuberculosis, in accordance with guidelines issued by the Federal Centers for Disease Control and Prevention (since these are the guidelines routinely used by the Department), and tested as necessary, and screened for "other communicable diseases." Although the draft regulation did not provoke a great number of questions during the stakeholder process, the Department anticipated that once the regulations were in effect, the Department would receive questions about the kind of communicable diseases for which the individual must be screened, and the kind of communicable diseases for which the direct care worker must be screened.

In the process of revising the draft regulation dealing with health evaluations prior to publication of the regulation as proposed, the Department considered incorporating by reference a regulation included with the Department's communicable disease regulations in 28 Pa. Code Chapter 27, such as § 27.155 (relating to restrictions on health care practitioners) or § 27.71 (relating to exclusion of children, and staff having contact with children, for specified diseases and infectious conditions). The Department ultimately rejected incorporating by reference one of its communicable disease regulations. Ruling out infectious conjunctivitis, for example, listed in 28 Pa. Code § 27.71 during a physical examination conducted prior to the individual's start date would not provide any assurance regarding the individual's actual condition on the start date. Requiring a complete physical and potential testing of blood and stool samples to rule out all of the conditions listed in 28 Pa. Code § 27.155 would be cost prohibitive.

Ultimately, the Department included in the proposed regulation a list of communicable diseases for which the individual would be screened at the same time the individual was screened for tuberculosis risk factors. These diseases and conditions put the consumer at significant risk, and screening for these diseases and conditions sometime prior to the direct care worker's start date, in the Department's view, constituted a valuable and useful exercise.

As stated previously, stakeholders were consistent in their criticism of the proposed regulation, although much of the criticism stemmed from the confusion over the meaning of the term "screening assessment." The County Commissioner Association of Pennsylvania supported the Department's attempt to protect consumers from workers with communicable diseases or conditions but believed that the proposed rulemaking applicable to annual screenings was excessive, intrusive and too expensive to implement. They pointed out, as did many other commentators, that the proposed screening far exceeded the kind of screenings required in other health care facilities licensed under the act. The Association requested that the Department adopt a more broadly based regulation that would require home care agencies or home care registries to assure that employees do not have communicable disease or conditions but would not prescribe the process for doing so.

The Department also received many comments regarding the 180-day time frame in the proposed regulation. Several commented that achieving compliance was going to be challenging. Several commented that the health evaluation should be obtained in the one year prior to the start date.

As requested, the Department has revised the regulation. The final regulation has been titled "Health screening" and states that the home care agency or home care registry shall insure that each direct care worker and other office staff or contractors with direct consumer contact, prior to consumer contact, provide documentation that the individual is free from active mycobacterium tuberculosis. The regulation instructs that the determination regarding the individual's status for tuberculosis should be made using the current *CDC Guidelines for Preventing the Transmission of Mycobacteriuium Tuberculosis in Health Care Settings*. The documentation must be dated not more than 1 year prior to the individual's start date. The requirement that the direct care worker must obtain the documentation every 12 months has been deleted.

One commentator inquired whether a registered nurse could perform the health evaluation. A "health evaluation" is no longer required. The regulation now merely requires a health screening for tuberculosis. CDC guidelines do not require a physician, physician's assistant, or certified registered nurse practitioner to conduct the screening for tuberculosis. Therefore, the Department has deleted the requirement that a "qualified health professional" provide the documentation regarding the direct care worker's health status and deleted the definition of "qualified health professional" from the definitional section in § 611.5.

One commentator inquired whether the Commonwealth has a standard form that should be completed for the direct care worker. The Department will not be supplying a standard form or requiring a standard format. As long as the documentation establishes that the individual was screened for and is free from active tuberculosis, the documentation will suffice.

One commentator suggested the regulation should require agencies and registries to have a policy that workers should not present themselves for work if they have symptoms of acute illnesses such as fever, jaundice

or diarrhea. The Department considered the suggestion and determined not to impose the requirement for a policy as suggested by the commentator. The Department will not require the policy; however, the Department is in favor of such a policy and would encourage agencies and registries to put such policies in place.

One commentator said that if the agency must bear the cost of "testing," the administrative costs for the agency will increase which will raise the hourly rate to the client. Other commentators also commented on the cost to the agency or registry. The regulation does not assign the cost of the health screening to the agency or registry. The regulation merely prohibits the agency or registry from assigning or referring a direct care worker to provide services until the documentation that the screening has been conducted has been obtained. If, in the interest of having the direct care worker prepared to begin providing services in a more prompt fashion, the agency or registry wishes to arrange and pay for the health screening, that is within the discretion of the agency or registry. The agency or registry also can choose to impose the obligation on the direct care worker to obtain and supply the necessary documentation to the agency or registry, as a condition of employment or roster.

Several commentators inquired whether the regulation will address the agency's or registry's obligations with regard to existing employees. After December 12, 2009, the home care agency or home care registry cannot assign or refer a direct care worker to provide home care services unless documentation of the health screening meeting the requirements of the regulation is part of the individual's file. In accordance with the recommendation of one or more commentators, the regulation gives the agency or registry 180 days to obtain the necessary documentation for direct care workers employed or rostered as of December 12, 2009.

A commentator requested the Department delete references to "personnel." The Department made the changes as requested. The commentator also suggested that the Department replace "180 days" with "one year" prior to the individual's start date. The time frame, if not the exact wording, has been inserted in the final regulation. The commentator suggested the Department delete the five communicable diseases, in addition to tuberculosis, listed in the proposed regulation. The Department accepted this recommendation. The commentator suggested that the Department replace the reference in subsection (c) to "individual employed or rostered by the agency or registry" with "direct care worker." The Department accepted this recommendation.

§ 611.57. (consumer protections)

IRRC pointed out that commentators stated that there are situations when there is not time to get an information packet to the consumer or the consumer's family member prior to the start of services, when, for example, the consumer is being discharged from the hospital and is in immediate need of services and the family member requesting the services lives out of town. IRRC inquired whether the family member could give verbal permission for services to begin without having first received the required information, and asked that this be clarified in the final form regulation.

The act requires that "each consumer or the consumer's legal representative or responsible family member shall receive an information packet from the home care agency or home care registry prior to the commencement of services. . . " 35 P. S. § 448.806c(b). The information packet is to include a listing of available services that will be provided to the consumer, the hours when the services will be provided, fees and costs for the services on an hourly or weekly basis, Department contact information for agency and registry licensure requirements and for compliance information, information regarding the Department's 24-hour hotline and the local ombudsman program, and information about the direct care worker who will be providing home care services, including information about the hiring process and training or testing to ensure competency. The information packet, per the statute, also must include a disclosure whether the direct care worker is an employee or an independent contractor and information regarding the respective employment and tax obligations of the consumer and the agency or registry.

The Department has no authority to alter the statutory requirement for written notice of the requisite items prior to the commencement of services.

One commentator suggested that the language in subsection (c)(6) of the proposed regulation requiring an agency or registry to provide, in advance of services, information regarding hiring and competency requirements applicable to direct care workers, a description of the manner and frequency of periodic reassessment of direct care worker competency, and information regarding documentation maintained by the home care agency or home care registry to confirm compliance with hiring and training requirements was not likely to be helpful to the consumer. The commentator suggested that the regulation should require the agency or registry to provide information specific to the skills and abilities of the direct care worker and to list the services the direct care worker can and cannot provide.

Another commentator also commented on the awkward language in proposed subsection (c)(6), and suggested that the Department merely require the agency or registry to confirm for the consumer, prior to commencement of services, that all direct care workers referred have: (1) successfully completed a competency examination approved by the Department of Health; (2) acceptable reference checks; (3) a face-to-face interview; (4) a health screen completed by a licensed health care professional; and (5) a criminal background review conducted by the Pennsylvania State Police or the Federal Bureau of Investigation.

The Department agreed with the comments and has revised the proposed regulation to require general information regarding hiring and competency requirements applicable to direct care workers, and information about the specific services the direct care worker assigned to the consumer will provide. While the Department did not add language to the regulation requiring the agency or registry to include information about services the direct care worker will not provide, it is certainly with the discretion of the agency or registry to include this information in the packet to be given to the consumer or the consumer's family member or legal representative.

The same commentator also suggested that the Department clarify subsection (c)(2) which requires the agency or registry to provide information, in advance of the service start date, regarding the hours when direct care services would be provided. The commentator suggested that the Department add the following language to the subsection: "Such hours that are requested by and agreed to by the consumer."

The final-form regulation now requires the agency or registry to provide the consumer or the consumer's family member or legal representative a listing of the actual home care services to be provided to the consumer and the hours during which the services will be provided. The hours identified when services will be provided are those mutually agreed upon by the consumer and the agency or registry. The notice will serve as confirmation for the consumer.

One commentator suggested that the home care agency or registry, prior to commencement of services, must provide a full disclosure statement acknowledging the responsibilities of the agency or registry. The commentator went on to list the items the commentator believed should be included in the disclosure statement: the employment status of the direct care worker, specifically, an explanation of which party is responsible for payment the wages or salary of the direct care worker, paying Federal social security taxes and state and Federal unemployment taxes for the direct care worker, and procuring worker's compensation or liability insurance covering injury to the direct care worker. The commentator also suggested that the disclosure statement should identify which party is responsible for supervising the direct care worker, assigning duties to the direct care worker, and for hiring, firing and discipline of the direct care worker. The commentator stated that the disclosure statement should identify the party responsible and liable if a direct care worker is hurt on the job.

The commentator stated that it is critical that the disclosure form include a place for the consumer's signature and that the regulation require the consumer's signature on the disclosure form as a mechanism for acknowledging receipt and understanding of the information on the disclosure statement. The commentator stated that the home care agency or registry should be required to keep a copy of the signed disclosure statement in agency or registry files. Another commentator suggested that the regulation should require documentation of when consumer information was provided as well as dates informational packets were mailed.

The regulation states that information provided to the consumer must include a disclosure addressing the employee or independent contractor status of the direct care worker providing services to the consumer, and the resultant respective tax and insurance obligations and other responsibilities of the consumer and the home care agency and home care registry. The regulation states that the disclosure must be in the format as published by the Department in the *Pennsylvania Bulletin* by February 10, 2010. As indicated by the outline of information required to be included in the disclosure statement, the Department fully intends that the disclosure statement will address the points listed by the commentator.

As for the suggestion that the Department should require the agency or registry to obtain the consumer's signature on the disclosure form, the Department will take into consideration the suggestion when drafting the disclosure form to be published in the *Pennsylvania Bulletin* following publication of the final-form regulations. As for the suggestion that the regulation should require the agency or registry to maintain documentation to establish compliance with the requirements applicable to consumer protections, the Department has added a subsection (e) to the regulation to require the agency or registry to maintain documentation on file at the agency or registry for verification by the Department of compliance with the requirements in the regulation.

One commentator requested that disclosure form to be drafted by the Department should be made available for public comment prior to publication in the *Pennsylvania Bulletin*. The Department will make every effort to obtain stakeholder input on the disclosure form prior to publication. The comment process will be brief, however, in light of the Department's obligation, per the language of the regulation, to publish the form by February 10, 2010. The regulations are effective December 12, 2009.

One commentator inquired whether the requirement that consumers be informed of tax obligations and employment responsibilities was pertinent only to registries and consumer employers. The responsibility to provide information listed above applies to home care agencies and registries. If a home care agency will assume all employment responsibilities and tax obligations associated with employment, this is information that should be provided to the consumer. The regulations do not apply to "consumer employers." "Consumer employer" is a term used in the Medicaid waiver and other publicly funded programs to refer to the individual receiving services who has elected to serve as employer of the individual providing the services to the consumer. A "consumer employer," most likely, does not meet the definition of a "home care agency" or "home care registry" as set forth in the act and in the definitional section in these regulations. Only those entities who meet the definition, and are not excluded under the terms of the act or these regulations (see § 611.3, need to obtain a license and comply with the requirements set forth in the act and these regulations.

Another commentator inquired whether the requirement that information be provided to consumers concerning the services to be provided, the hours when services will be provided, and fees and costs for services applies only to private pay clients and not to clients whose services are paid by the Medicaid waiver or other publicly funded program. The requirement applies to all home care agencies and registries, regardless of the payment source for the services. For those clients or consumers whose services are paid by a Medicaid waiver or other publicly funded program, the information about specific fees and costs for the specific services to be provided to the client or consumer should reference the Medicaid waiver or other publicly funded program.

The Disability Rights Network commented that when a publicly funded program, such as the Medicaid Home and Community Based Waiver or the Act 150 Attendant Care Program, is involved, the home care agency or home care registry already is required to provide certain types of information and notices prior to the commencement of services. The commentator suggested that the regulation, therefore, also should require the home care agency or home care registry receiving public funds to comply with all information and notice requirements of the publicly-funded program.

The Disability Rights Network also commented that the Medicaid waiver and other publicly funded programs include due process requirements for reduction or termination of services. The commentator suggested that, to avoid confusion, the Department should revise the regulation to require agencies and registries providing services to the publicly funded program recipients to follow the publicly funded program's due process requirements for termination of services. The commentator suggested that the requirements applicable to termination of services in

the proposed regulation should apply only to agencies and registries with private-pay clients.

The Department cannot impose through regulations, having the force and effect of law, the requirements imposed by the Medicaid waiver or other publicly funded program through contract with the provider. Further, the Department can only promulgate regulations authorized by the statute. The Legislature has determined that all recipients of services provided by a licensed home care agency or home care registry are entitled to at least 10 days notice of termination of services, unless lack of payment or an immediate threat to the health or safety of the consumer or provider warrants less notice. If the home care agency or home care registry provides services to individuals who are beneficiaries of a publicly funded program, there may be additional or other requirements connected with termination or reduction of services to these individuals. A publicly funded program, subject to laws requiring due process in the event of termination or reduction of a public benefit, may require a participating provider to offer certain due process to the client or consumer as a condition of the provider's participation in the program. The Department has no authority to impose those requirements. Thus, an entity meeting the definition of a "home care agency" or "home care registry" that provides services to individuals and receives payment through the Medicaid waiver or other publicly funded program will need to be aware of and comply with licensure requirements in the act and in these regulations, *and* they will need to be aware of and comply with any requirements imposed by the Medicaid waiver or other publicly funded program as a condition of participation as a provider in the program.

Fiscal Impact

State Government.

The licensure program for home care agencies and home care registries will cost approximately $1,060,000 for the first full year of the program. This projection is based on the approximate cost to survey a home care agency or registry and the projected number of home care agencies and home care registries (650).

The Department also will incur certain start-up costs associated with hiring and training of surveyors or inspectors and updating the Department's electronic Survey Agency Information System (SAIS) through which the Department coordinates and manages its licensure functions. Through SAIS, the Department schedules and tracks surveys or inspections of all facilities, tracks surveyor time and efforts, and tracks complaints about facilities. The SAIS system also includes a function through which a statement of deficiencies, in the event of regulatory violations identified during an inspection, can be generated. The system also allows the facilities to submit its plan of correction electronically. The SAIS system will need to be revised to include the home care agency and home care registry licensing function.

Local Government.

There would be no cost to local government.

Public.

There may be a cost to the public in the form of higher charges for care because the home care agency or home care registry would need to recoup start-up and ongoing costs of compliance with licensure criteria.

Regulated Entity.

Home care agencies and home care registries would incur costs as a result of these regulations. To the extent an agency or registry currently does not have hiring policies and procedures in place equal to or more stringent than the hiring prerequisites contained in the proposed rulemaking, the agency or registry would incur the one-time cost of establishing systems and procedures that comply with the proposed regulation and the ongoing cost of doing business in the manner dictated by the regulation. The proposed rulemaking would permit choices, however, and the choice made by an agency or registry would have an impact on overall costs. Establishing competency of a direct care worker through a competency examination, for example, might cost less than establishing competency through a training program. The agency or registry also would be required to pay the annual licensing fee of $100.

Paperwork Requirements

State Government.

The Department will have additional paperwork responsibilities connected with its role as the licensing agency. Much of the licensing paperwork is handled electronically through the Department's SAIS system. The Department will issue a hard copy license to the agency or registry. The Department also will issue a hard copy statement of deficiencies.

Local Government.

There would be no additional paperwork requirements for local government.

Public.

Consumers of home care services will receive paperwork as a result of these regulations. Consumers will receive written notice of termination of services. Consumers also will receive written notice of services to be provided, the hours when those services will be provided, fees and costs associated with the services, and who to contact with complaints. Consumers also will receive a written description of the hiring and training requirements applicable to direct care workers and a written disclosure of the worker's status as an employee or independent contractor and the resultant respective tax and insurance obligations of the consumer and the agency or registry.

Regulated Entity.

Home care agencies and home care registries will be required to submit paperwork to receive or renew a license. Home care agencies and home care registries would need to respond to any identified regulatory deficiencies in the form of a plan of correction. They will need to create and maintain files for direct care workers containing documentation of a face-to-face interview, references, a criminal history report and ChildLine verification, if necessary, and documentation of satisfactory completion of the competency prerequisites and the annual competency review. The files also will be required to contain documentation of a health evaluation obtained prior to employment or roster.

Home care agencies and home care registries will be required to provide written notice to the consumer of the intent to terminate services. Finally, home care agencies and home care registries will be required to provide written documentation to the consumer listing services to be provided, the hours when those services would be provided, fees and costs associated with the services, and who to contact with complaints. The written documentation also must describe the hiring and training requirements applicable to the direct care worker being sent to the consumer's home or other independent living environ-

ment and disclose the worker's status as an employee or independent contractor and the resultant respective tax and insurance obligations of the consumer and the agency or registry.

Effective Date

These regulations will take effect immediately upon publication as final-form rulemaking.

Sunset Date

These regulations will be continually monitored for their effectiveness and updated as needed. Therefore, no sunset date has been established.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a), the Department submitted a copy of a notice of proposed rulemaking, published at 37 Pa.B. 4431 to IRRC and to the House Committee on Health and Human Services, the Senate Committee on Public Health and Welfare, the House Older Adult Services Committee, and the Senate Aging and Youth Committee (Committees). 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 during the formal comment period, as well as other documentation.

In compliance with section 5.1(a) of the Regulatory Review Act (71 P. S. § 745.5a(a)), the Department provided IRRC and the Committees with a copy of a Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

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

This final-form regulations were deemed approved by the Committees on September 30, 2009. IRRC met on October 1, 2009, and approved the regulations in accordance with section 5.1(e) of the Regulatory Review Act.

Contact Person

Questions regarding these regulations should be submitted to Janice Staloski, Director, Bureau of Community Program Licensure and Certification, 132 Kline Plaza, Suite A, Harrisburg, PA 17104-1579, (717) 783-8665. Persons with a disability may submit questions in alternative format such as by audio tape, Braille, or by using V/TT (717) 783-6514, or the Pennsylvania AT&T Relay Service at (800) 654-5984 [TT]. Persons who require an alternative format of this document may contact Janice Staloski at the previous address or telephone number so that necessary arrangements may be made.

Findings

The Department, after consultation with the Health Policy Board, finds that:

(1) Public notice of intention to adopt the regulations 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 (relating to notice of proposed rulemaking required; and adoption of regulations).

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

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

Order

The Department, after consultation with the Health Policy Board, acting under the authorizing statute, orders that:

(1) The regulations of the Department, 28 Pa. Code, are amended by adding §§ 611.1—611.5 and 611.51—611.57 to read as set forth in Annex A.

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

(3) The Secretary of Health shall submit this order, Annex A and a Regulatory Analysis Form to IRRC, the Committees for their review and action as required by law.

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

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

(*Editor's Note*: The proposal to add §§ 611.11—611.21, included in the proposed rulemaking at 37 Pa.B. 4198 (August 4, 2007) has been withdrawn. For a notice relating to this rulemaking, see 39 Pa.B. 7064 (December 12, 2009).)

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 39 Pa.B. 6204 (October 17, 2009).)

Fiscal Note: 10-184. (1) General Fund; (2) Implementing Year 2008-09 is $1.060 M; (3) 1st Succeeding Year 2009-10 is $1.114 M; 2nd Succeeding Year 2010-11 is $1.171 M; 3rd Succeeding Year 2011-12 is $1.232 M; 4th Succeeding Year 2012-13 is $1.297 M; 5th Succeeding Year 2013-14 is $1.366 M; (4) 2007-08 Program—$17.308 M; 2006-07 Program—$15.557 M; 2005-06 Program—$16.057 M; (7) Quality Assurance; (8) recommends adoption. Funds have been included in the budget to cover this increase.

Annex A

TITLE 28. HEALTH AND SAFETY

PART IV. HEALTH FACILITIES

Subpart H. HOME CARE AGENCIES AND HOME CARE REGISTRIES

CHAPTER 611. HOME CARE AGENCIES AND HOME CARE REGISTRIES

GENERAL

§ 611.1. Legal base.

(a) This chapter is promulgated by the Department under the powers granted and the duties mandated under sections 803 and 809.1 of the act (35 P. S. §§ 448.803 and 448.804a).

(b) The Department has the power and its duty is to promulgate the regulations necessary to implement the provisions of Chapter 8 of the act (35 P. S. §§ 448.801a—448.820) and to assure that its regulations and the act are enforced.

(c) The purpose of this chapter is to protect and promote the public health and welfare through the establishment and enforcement of regulations setting minimum standards for the operation of home care agencies and home care registries. The standards are intended by the Department to assure safe, adequate and efficient home care agencies and home care registries, and to

promote the health, safety and adequate care of the consumers of services provided by home care agencies and home care registries.

§ 611.2. License required.

(a) Except as set forth in subsection (c), no entity or organization may operate, maintain, or hold itself out as operating or maintaining a home care agency or home care registry without first having obtained a license from the Department in accordance with this chapter. Each physical location of the home care agency or home care registry must be separately licensed. The Department will conduct an inspection prior to issuing an initial license or a license renewal.

(b) The license will specify whether the entity is licensed as a home care agency, a home care registry, or both, the term of the license, and any conditions or limitations imposed on the license.

(c) An entity operating a home care agency or home care registry, or both, as of December 12, 2009, may continue to operate after December 12, 2009, provided it submits an application for a license to the Department in accordance with instructions published in the *Pennsylvania Bulletin* and posted on the Department's web site by February 10, 2010. An entity that has submitted an application for licensure in accordance with the requirements of this subsection may continue to operate the home care agency or home care registry until a date that the Department may refuse the application for licensure. If the Department grants the application for licensure, the home care agency or home care registry may continue operation of the agency or registry in accordance with this chapter.

(d) The applicant shall obtain the application for a license to operate a home care agency or home care registry from the Department of Health, Division of Home Health.

(e) The applicant shall submit an application or renewal form to the Department with the fee of $100. The applicant shall submit a renewal form at least 60 days prior to the expiration date on the license. There will be no rebate, refund, or prorating of the application fee. The applicant shall complete a separate application and pay a separate application fee for each separately licensed home care agency or home care registry that it intends to operate.

(f) The applicant shall specify on its application the type of facility for which it is seeking a license.

§ 611.3. Affected home care agencies and home care registries.

(a) This chapter applies to home care agencies, home care registries and to entities that meet both definitions, profit or nonprofit, operated in this Commonwealth, as defined in this chapter. This chapter does not apply to a home health care agency, a durable medical equipment provider, a volunteer provider, or an organization or business entity designated under section 3504 of the Internal Revenue Code (26 U.S.C.A. § 3504) regarding acts to be performed by agents and either IRS revenue procedure 70-6 or IRS revenue procedure 80-4, that provides financial management services or supports coordination services, or both, to consumers of home and community-based services through Medicaid Waiver or other publicly funded programs.

(b) Existing home care agencies and home care registries which were home care agencies or home care registries prior to December 12, 2009, shall be required to meet the same standards as home care agencies and home care registries created after December 12, 2009.

§ 611.4. Requirements for home care agencies and home care registries.

(a) A current copy of this chapter shall be maintained at the home care agency or home care registry.

(b) Chapter 51 (relating to general information), applicable to all entities licensed as health care facitilies under the act, applies to home care agencies and home care registries licensed under this chapter.

(c) Home care agencies and home care registries licensed under this chapter shall comply with applicable environmental, health, sanitation and professional licensure standards which are required by Federal, State and local authorities.

(d) If there is a difference in applicable State or local standards, the standards established under State statutes apply for the purpose of compliance with this chapter.

§ 611.5. Definitions.

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

Act—The Health Care Facilities Act (35 P. S. §§ 448.101—448.904b).

ChildLine—An organizational unit of the Department of Public Welfare which operates a State-wide toll-free system for receiving reports of suspected child abuse established under 23 Pa.C.S. 6332 (relating to establishment of Statewide toll-free telephone number), refers the reports for investigation and maintains the reports in the appropriate file.

ChildLine verification—Confirmation regarding whether an applicant for employment or referral by a home care agency or home care registry is named in the Department of Public Welfare's Statewide Central Register as the perpetrator of a founded or indicated report of child abuse (as defined in 55 Pa. Code § 3490.4 (relating to definitions)).

Companionship services—Socialization, support and assistance with instrumental activities of daily living.

Consumer—An individual to whom services are provided.

Consumer control—Control and direction by the consumer in identifying, exercising choice of, and managing home care services in accordance with the consumer's needs and personal preferences.

Criminal history report—A State Police criminal history record or a Department of Aging letter of determination of eligibility for hire or roster based on a review of a Federal criminal history record.

Department—The Department of Health of the Commonwealth.

Department of Aging letter of determination—A written decision supplied by the Department of Aging regarding whether, based on the criminal history report from the Federal Bureau of Investigation, the applicant for employment by a home care agency or referral by a home care registry may be employed or rostered.

Direct care worker—The individual employed by a home care agency or referred by a home care registry to provide home care services to a consumer.

Direct consumer contact—Face-to-face interaction with the consumer in the consumer's place of residence or other independent living environment.

Financial management services—One or more of the following services:

(i) Managing payroll including Federal, State and local employment taxes for direct care workers recruited and retained by the consumer.

(ii) Processing the payment of workers' compensation, health and other insurance benefits for the direct care worker.

(iii) Assisting consumers in calculating and managing individual budgets for Medicaid Waiver and other publicly funded home and community based services.

(iv) Monitoring the consumer's spending of public funds and any underage or overage in accordance with the consumer's approved budget.

(v) Collecting, processing and maintaining time sheets for direct care workers.

(vi) Providing training to consumers related to employer-related tasks (for example, recruiting, hiring, training, managing and discharging direct care workers and managing payroll and bill paying).

Home care agency—An organization that supplies, arranges or schedules employees to provide home care services, as directed by the consumer or the consumer's representative, in the consumer's place of residence or other independent living environment for which the organization receives a fee, consideration or compensation of any kind.

Home care registry—An organization or business entity or part of an organization or business entity that supplies, arranges or refers independent contractors to provide home care services, as directed by the consumer or the consumer's representative, in the consumer's place of residence or other independent living environment for which the registry receives a fee, consideration or compensation of any kind.

Home care services—The term encompasses the following activities:

(i) Personal care.

(ii) Assistance with instrumental activities of daily living.

(iii) Companionship services.

(iv) Respite care.

(v) Specialized care.

Independent living philosophy—A system of beliefs, concepts and attitudes that emphasize self-direction, control, peer support and community integration for individuals with disabilities.

Inspection—A scheduled or unscheduled examination or assessment of a home care agency or home care registry during regular business hours, to determine compliance with requirements for licensure using one or more of the following means: inspection of records, interviews with office staff, consumers and direct care workers, and observation of the provision of services to consumers who have consented in advance to observation.

Instrumental activities of daily living—As defined in section 802.1 of the act (35 P. S. § 448.802a).

Nurse—A registered nurse or a licensed practical nurse.

Personal care—The term includes, but is not limited to, assistance with self-administered medications, feeding, oral, skin and mouth care, shaving, assistance with ambulation, bathing, hair care and grooming, dressing, toileting and transfer activities.

Respite care—Personal care and assistance with instrumental activities of daily living provided on a short term basis because of the absence or need for relief for those persons normally providing the services.

Roster—To place an individual on a list of individuals eligible to be referred by a home care registry to provide home care services to an individual in the individual's place of residence or other independent living environment; or the list of individuals eligible to be referred by a home care registry to provide home care services to an individual in the individual's place of residence or other independent living environment.

Specialized care—Nonskilled services unique to the consumer's care needs that facilitate the consumer's health, safety and welfare, and ability to live independently.

Statewide central register—A register of child abuse established in the Department of Public Welfare, which consists of founded and indicated reports of child abuse.

Supports coordination services—Services to consumers of home and community-based services through Medicaid Waiver or other publicly funded programs including intake services, needs assessment, and advocacy to ensure coordination of medical, social, educational and other services and maximum consumer independence.

GOVERNANCE AND MANAGEMENT

§ 611.51. Hiring or rostering of direct care workers.

(a) *Hiring or rostering prerequisites*. Prior to hiring or rostering a direct care worker, the home care agency or home care registry shall:

(1) Conduct a face-to-face interview with the individual.

(2) Obtain at least two satisfactory references for the individual. A satisfactory reference is a positive, verifiable reference, either verbal or written, from a former employer or other person not related to the individual that affirms the ability of the individual to provide home care services.

(3) Require the individual to submit a criminal history report, in accordance with § 611.52 (relating to criminal background checks), and a ChildLine verification, if applicable, in accordance with the requirements of § 611.53 (relating to child abuse clearance).

(b) *Direct care worker files*. Files for direct care workers employed or rostered must include documentation of the date of the face-to-face interview with the individual and of references obtained. Direct care worker files must also include other information as required under § 611.52, § 611.53, and if applicable, §§ 611.54, 611.55 and 611.56 (relating to provisional hiring; competency requirements; and health screening).

§ 611.52. Criminal background checks.

(a) *General rule*. The home care agency or home care registry shall require each applicant for employment or referral as a direct care worker to submit a criminal history report obtained at the time of application or within 1 year immediately preceding the date of applica-

tion. An applicant for employment as a member of the office staff for the home care agency or home care registry and the owner or owners of the home care agency or home care registry also are required to obtain a criminal history report in accordance with requirements contained in this section.

(b) *State Police criminal history record*. If the individual required to submit or obtain a criminal history report has been a resident of this Commonwealth for 2 years preceding the date of the request for a criminal history report, the individual shall request a State Police criminal history record.

(c) *Federal criminal history record*. If the individual required to submit or obtain a criminal history report has not been a resident of this Commonwealth for the 2 years immediately preceding the date of the the request for a criminal history report, the individual shall obtain a Federal criminal history record and a letter of determination from the Department of Aging, based on the individual's Federal criminal history record, in accordance with 6 Pa. Code § 15.144(b) (relating to procedure).

(d) *Proof of residency*. The home care agency or home care registry may request an individual required to submit or obtain a criminal history record to furnish proof of residency through submission of any one of the following documents:

(1) Motor vehicle records, such as a valid driver's license or a State-issued identification.

(2) Housing records, such as mortgage records or rent receipts.

(3) Public utility records and receipts, such as electric bills.

(4) Local tax records.

(5) A completed and signed, Federal, State or local income tax return with the applicant's name and address preprinted on it.

(6) Employment records, including records of unemployment compensation.

(e) *Prohibition*. The home care agency or home care registry may not hire, roster or retain an individual if the State Police criminal history record reveals a prohibited conviction listed in 6 Pa. Code § 15.143 (relating to facility responsibilities), or if the Department of Aging letter of determination states that the individual is not eligible for hire or roster.

(f) *Records maintained*. The home care agency or home care registry shall maintain files for direct care workers and members of the office staff which include copies of State Police criminal history records or Department of Aging letters of determination regarding Federal criminal history records. The files shall be available for Department inspection. The agency or registry shall maintain copies of the criminal history report for the agency or registry owners, which shall be available for Department inspection.

(g) *Confidentiality*. The home care agency or home care registry shall keep the information obtained from State Police criminal history records and Department of Aging letters of determination regarding Federal criminal history records confidential and use it solely to determine an applicant's eligibility to be hired, rostered or retained.

(h) *Opportunity to appeal*. If the decision not to hire, roster or retain an individual is based in whole or in part on State Police criminal history records, Department of Aging letters of determination regarding Federal criminal history records, or both, the home care agency or home care registry shall provide an affected individual with information on how to appeal to the sources of criminal history records if the individual believes the records are in error.

(i) *Exceptions*. A direct care worker who has complied with this section and who transfers to another agency or registry owned and operated by same entity is not required to obtain another criminal history report. A direct care worker employed or rostered by an entity that undergoes a change of ownership is not required to obtain another criminal history report to submit to the new owner.

(j) *Individuals currently employed or rostered*. A direct care worker and each member of the agency or registry office staff who is employed by or rostered by a home care agency or home care registry as of December 12, 2009, shall obtain and submit a State Police criminal history record or Department of Aging letter of determination, as applicable, to the home care agency or home care registry by April 12, 2010. This subsection does not apply if the home care agency or home care registry obtained a criminal history report meeting the requirements of this subsection when the direct care worker or office staff member was hired or rostered and a copy of the report is included in the individual's file.

§ 611.53. Child abuse clearance.

(a) *General rule*. A home care agency or home care registry that serves persons under 18 years of age shall require each applicant for employment or referral as a direct care worker, each applicant for employment as a member of the agency or registry office staff to request a ChildLine verification regarding whether the applicant is named in the Statewide Central Register as the perpetrator of a founded or indicated report of child abuse as defined in 55 Pa. Code § 3490.4 (relating to definitions).

(b) *Prohibition*. A home care agency or home care registry may not employ, roster or retain an individual where ChildLine has verified that the individual is named in the Statewide Central Register as the perpetrator of a founded or indicated report of child abuse.

(c) *Records maintained*. The files maintained by the home care agency or home care registry for each individual employed or rostered and for each member of the office staff must include copies of the ChildLine verification. The agency or registry shall maintain copies of the ChildLine verification for the agency or registry owners, which shall be available for Department inspection.

(d) *Individuals currently employed or rostered*. A person who is employed by or rostered by the home care agency or home care registry, including each member of the agency or registry office staff, as of December 12, 2009, shall obtain and submit a ChildLine verification to the home care agency or home care registry by April 12, 2010. This subsection does not apply if the home care agency or home care registry obtained a ChildLine verification when the individual was hired or rostered and a copy of the verification is included in the individual's file.

§ 611.54. Provisional hiring.

(a) *General rule*. The home care agency or home care registry may hire an applicant for employment or referral on a provisional basis, pending receipt of a criminal history report or a ChildLine verification, as applicable, if the following conditions are met:

(1) The applicant shall have applied for a criminal history report and ChildLine verification, as applicable, and provided the home care agency or home care registry with a copy of the completed request forms.

(2) The home care agency or home care registry shall have no knowledge about the applicant that would disqualify the applicant under 18 Pa.C.S. § 4911 (relating to tampering with public record information).

(3) The applicant shall swear or affirm in writing that the applicant is not disqualified from employment or referral under this chapter.

(4) The home care agency or home care registry may not assign or refer the provisionally hired applicant until that person has met the requirements of § 611.55 (relating to competency requirements).

(5) The home care agency or home care registry shall monitor the provisionally hired applicant awaiting a criminal background check through random, direct observation and consumer feedback. The results of monitoring shall be documented in the individual's file.

(6) The home care agency or home care registry shall directly supervise, or assign another direct care worker to accompany, a provisionally hired applicant awaiting a child abuse clearance who will provide home care services to a consumer less than 18 years of age.

(7) The period of provisional hire of an individual who is and has been, for a period of 2 years or more, a resident of this Commonwealth, may not exceed 30 days. The period of provisional hire of an individual who has not been a resident of this Commonwealth for 2 years or more may not exceed 90 days.

(b) *Termination*. If the information obtained from the criminal history report or ChildLine verification, or both, reveals that the individual is disqualified from employment or referral under § 611.52 (relating to criminal background checks) or under § 611.53 (relating to child abuse clearance), the individual shall be terminated by the home care agency or removed from the home care registry's roster immediately. If the individual fails to provide the ChildLine verification or criminal history report, or both, within the time period permitted for provisional hire, the individual shall be terminated by the home care agency or removed from the home care registry's roster immediately.

§ 611.55. Competency requirements.

(a) Prior to assigning or referring a direct care worker to provide services to a consumer, the home care agency or home care registry shall ensure that the direct care worker has done one of the following:

(1) Obtained a valid nurse's license in this Commonwealth.

(2) Demonstrated competency by passing a competency examination developed by the home care agency or home care registry which meets the requirements of subsections (b) and (c).

(3) Successfully completed one of the following:

(i) A training program developed by a home care agency, home care registry, or other entity which meets the requirements of subsections (b) and (c).

(ii) A home health aide training program meeting the requirements of 42 CFR 484.36 (relating to the conditions of participation; home health aide services).

(iii) The nurse aid certification and training program sponsored by the Department of Education and located at www.pde.state.pa.us.

(iv) A training program meeting the training standards imposed on the agency or registry by virtue of the agency's or registry's participation as a provider in a Medicaid Waiver or other publicly funded program providing home and community based services to qualifying consumers.

(v) Another program identified by the Department by subsequent publication in the *Pennsylvania Bulletin* or on the Department's web site.

(b) A competency examination or training program developed by an agency or registry for a direct care worker must address, at a minimum, the following subject areas:

(1) Confidentiality.

(2) Consumer control and the independent living philosophy.

(3) Instrumental activities of daily living.

(4) Recognizing changes in the consumer that need to be addressed.

(5) Basic infection control.

(6) Universal precautions.

(7) Handling of emergencies.

(8) Documentation.

(9) Recognizing and reporting abuse or neglect.

(10) Dealing with difficult behaviors.

(c) A competency examination or training program developed by an agency or registry for a direct care worker who will provide personal care must address the following additional subject areas:

(1) Bathing, shaving, grooming and dressing.

(2) Hair, skin and mouth care.

(3) Assistance with ambulation and transferring.

(4) Meal preparation and feeding.

(5) Toileting.

(6) Assistance with self-administered medications.

(d) The home care agency or home care registry shall include documentation of the direct care worker's satisfactory completion of competency requirements in the direct care worker's file. If the direct care worker has a nurse's license or other licensure or certification as a health professional, the individual's file shall include a copy of the current license or certification. Documentation of satisfactory completion of competency requirements is transferable from one home care agency or registry to another home care agency or registry, provided the break in the individual's employment or roster status does not exceed 12 months.

(e) The home care agency or home care registry also shall include documentation in the direct care worker's file that the agency or registry has reviewed the individual's competency to perform assigned duties through direct observation, testing, training, consumer feedback or other method approved by the Department or through a combination of methods. The competency review must occur at least once per year after initial competency is established, and more frequently when discipline or other sanction, including, for example, a verbal warning or suspension, is imposed because of a quality of care infraction.

(f) A direct care worker employed by a home care agency or rostered by the home care registry on December

12, 2009, shall achieve compliance with the competency requirements imposed by this chapter by December 12, 2011.

§ 611.56. Health screening.

(a) A home care agency or home care registry shall insure that each direct care worker and other office staff or contractors with direct consumer contact, prior to consumer contact, provide documentation that the individual has been screened for and is free from active mycobacterium tuberculosis. The screening shall be conducted in accordance with CDC guidelines for preventing the transmission of mycobacterium tuberculosis in health care settings. The documentation must indicate the date of the screening which may not be more than 1 year prior to the individual's start date.

(b) A home care agency or home care registry shall require each direct care worker, and other office staff or contractors with direct consumer contact, to update the documentation required under subsection (a) at least every 12 months and provide the documentation to the agency or registry. The 12 months must run from the date of the last evaluation. The documentation required under subsection (a) shall be included in the individual's file.

(c) A direct care worker employed by a home care agency or rostered by the home care registry on December 12, 2009, shall achieve compliance with the health evaluation requirements imposed by this chapter by June 10, 2010.

§ 611.57. Consumer protections.

(a) *Consumer rights*. The consumer of home care services provided by a home care agency or through a home care registry shall have the following rights:

(1) To be involved in the service planning process and to receive services with reasonable accommodation of individual needs and preferences, except where the health and safety of the direct care worker is at risk.

(2) To receive at least 10 calendar days advance written notice of the intent of the home care agency or home care registry to terminate services. Less than 10 days advance written notice may be provided in the event the consumer has failed to pay for services, despite notice, and the consumer is more than 14 days in arrears, or if the health and welfare of the direct care worker is at risk.

(b) *Prohibitions*. No individual as a result of the individual's affiliation with a home care agency or home care registry may assume power of attorney or guardianship over a consumer utilizing the services of that home care agency or home care registry. The home care agency or home care registry may not require a consumer to endorse checks over to the home care agency or home care registry.

(c) *Information to be provided*. Prior to the commencement of services, the home care agency or home care registry shall provide to the consumer, the consumer's legal representative or responsible family member an information packet containing the following information in a form that is easily read and understood:

(1) A listing of the available home care services that will be provided to the consumer by the direct care worker and the identity of the direct care worker who will provide the services.

(2) The hours when those services will be provided.

(3) Fees and total costs for those services on an hourly or weekly basis.

(4) Who to contact at the Department for information about licensure requirements for a home care agency or home care registry and for compliance information about a particular home care agency or home care registry.

(5) The Department's complaint Hot Line (1-866-826-3644) and the telephone number of the Ombudsman Program located with the local Area Agency on Aging (AAA).

(6) The hiring and competency requirements applicable to direct care workers employed by the home care agency or referred by the home care registry.

(7) A disclosure, in a format to be published by the Department in the *Pennsylvania Bulletin* by February 10, 2010, addressing the employee or independent contractor status of the direct care worker providing services to the consumer, and the resultant respective tax and insurance obligations and other responsibilities of the consumer and the home care agency or home care registry.

(d) *Documentation*. The home care agency or home care registry shall maintain documentation on file at the agency or registry of compliance with the requirements of this section which shall be available for Department inspection.

[Pa.B. Doc. No. 09-2273. Filed for public inspection December 11, 2009, 9:00 a.m.]

Title 37—LAW

Office of Victims' Services
[37 PA. CODE CH. 411]
Crime Victims Compensation

The Office of Victims' Services (OVS) of the Pennsylvania Commission on Crime and Delinquency (PCCD) amends §§ 411.2, 411.17 and 411.42 to read as set forth at 39 Pa.B. 2591 (May 23, 2009) and amends § 411.1 to read as set forth in Annex A. This final-form rulemaking has been submitted with no revisions to the proposed rulemaking.

Statutory Authority

This final-form rulemaking is authorized under section 312(3) of the Crime Victims Act (act) (18 P. S. § 11.312(3)).

Purpose of Chapter

Chapter 411 sets forth regulations governing the processing of crime victim compensation claims, providing for reimbursement to crime victims of crime related expenses when no other resources are available.

Purpose of the Final-Form Rulemaking

The purpose of the final-form rulemaking is to increase reimbursement to crime victims in accordance with rising costs, expand eligibility for reimbursement and simplify claims processing procedures, while reducing the percentage that OVS may reimburse hospitals and other licensed health care providers to conform to the practice of other third party payors.

Summary of Amendments

Section 411.1 (relating to scope) has been amended to establish the effective date for the amendments.

Section 411.2 (relating to definitions) has been amended to increase the number of days a victim has to relocate under the definition of "immediate need" from 30 days to 120 days.

Section 411.17 (relating to emergency awards) has been amended to increase the maximum compensation allowed for an emergency award from $1,500 to $5,000 per claim.

Section 411.42 (relating to out-of-pocket loss) has been amended as follows:

Subsection (b) has been amended to reduce the percentage of the usual and customary charge for services rendered that OVS may reimburse to providers from 70% to 65% and to set the effective date for this percentage change. This reduction conforms to the practice of other third-party payors. This section has also been amended to allow reimbursement to a victim who has been billed in error for a forensic rape exam. The reimbursement for a forensic rape exam billed in error will be subject to the $1,000 monetary limit.

Subsection (c) has been amended to increase the total award for funeral expenses from $5,000 to $6,500 and eliminate caps on individual expenses. The elimination of individual caps will allow the claimant flexibility in submitting expenses and increase the reimbursement to claimant on individual expenses within the $6,500 maximum award. This section is also amended to add the cost of an "urn" as an eligible funeral expense.

Subsection (f) has been amended to increase the total reimbursement amount from $1,000 per crime incident per household to $1,000 for each direct victim within the household, when immediate relocation is necessary as a result of the crime. Since there may be more than one direct victim of a crime, this amendment allows each direct victim to receive compensation up to $1,000 per household.

Subsection (g) has been amended to include travel reimbursement associated with attendance or participation in court proceedings and other circumstances if good cause is shown and for attendance of funeral services. The addition of "good cause" allows OVS discretion if a travel expense is not specifically listed in the regulation, but the travel was necessary as a result of the crime.

Subsection (h) has been amended to include food, paint or other materials used to deface property as eligible for crime scene cleanup reimbursement.

Comments and Responses

Notice of the proposed rulemaking was published at 39 Pa.B. 2591 (May 23, 2009) with a 30-day comment period. During the 30-day comment period, comments were received from Alice Paul House in Indiana County and the Network of Victim Assistance in Bucks County.

Comment

Alice Paul House expressed that the $100 minimum out of pocket loss requirement for filing a claim for compensation should be eliminated.

Response

The $100 minimum out of pocket loss requirement is a statutory requirement and cannot be addressed through regulations. Alice Paul House commented in support of the proposed amendments.

The Network of Victim Assistance commented in support of the proposed amendments.

The House and Senate Judiciary Committees (Committees) had no objections, comments or recommendations on these amendments.

The Independent Regulatory Review Commission (IRRC) had no objections, comments or recommendations on these amendments.

Persons and Entities Affected

Victims of crimes, as defined in the act, will benefit from the increase in reimbursement for funeral expenses in keeping with current costs for services and allowing flexibility for reimbursement within the $6,500 maximum award. The number of days, as defined in immediate need, expands the relocation time frame, allowing victims sufficient time to relocate to become or remain safe.

Medical providers will be adversely affected because they will receive less reimbursement with the 65% rate. However, the 65% reimbursement rate conforms to the practice of other third-party payors.

Fiscal Impact

It is estimated that the recommended changes will aid 1,149 victims by increasing benefits that are available through victim's compensation. The fiscal impact to PCCD will consist of an estimated annual net savings of $143,739. This calculation takes into account the estimated costs to PCCD from increased benefits of $151,261 and savings to PCCD resulting from reducing the awards to medical providers from a 70% reimbursement rate to 65% on behalf of the victim ($295,000).

Summary of Costs, Savings and Federal Reimbursements

Year One (2009-2010)—It is estimated that implementation of this schedule will take place by December 1, 2009, therefore statistics are included for that part of State Fiscal Year 2009-2010. As the average time from the date of a crime incident until the date a claim is filed is 92 days, or 3 months, the costs have been projected for 4 months (March 1, 2010 to June 30, 2010). The savings from the reduction in the reimbursement rate for medical providers affects benefits for claims relating to services rendered on or immediately after the effective date of the regulation; therefore, the savings have been projected for the entire 7 months (December 1, 2009 to June 30, 2010). Costs are estimated at $126,051; savings are projected at $172,083; or an overall savings of $46,033.

Year Two (2010-2011)—First full year of implementation. For this period, costs are projected at $378,152 with savings estimated at $295,000, or an overall cost of $83,152.

Year Three (2011-2012)—For this period, costs are projected at $397,060 with savings estimated at $309,750, or an overall cost of $87,310.

Victims of Crime Act (VOCA) Reimbursement—State victims compensation programs enjoy a 60% reimbursement that is eventually returned by the United States Department of Justice (DOJ) under VOCA funding stream for allowable benefits paid under the program. As all of the rates set by the Office under the act are for benefits allowable under VOCA, the cost figures would need to be adjusted downward to reflect the 60% reimbursement that will be paid to PCCD by DOJ. Costs paid in 2009-2010 will be reimbursed by VOCA in 2011-2012; costs paid in 2010-2011 will be reimbursed in 2012-2013, and the like.

For year one (2009-2010), the VOCA reimbursement will be $75,630 resulting in an overall savings of $121,663 ($126,051 at 60% = $75,630 reimbursement) which will be paid by the DOJ in 2011-2012. Therefore, the real cost of the increased benefits will actually be a savings of $121,663 ($46,033 + DOJ VOCA reimbursement of $75,630 = $121,663).

For year two (2010-2011), the VOCA reimbursement will be $226,891 resulting in an overall cost savings of

$143,739 ($378,152 at 60% = $226,891 reimbursement) which will be paid by VOCA in 2012-2013. Therefore, the real cost of the increased benefits will actually be a savings of $143,739 ($83,152 + DOJ VOCA reimbursement of $226,891 = $143,739).

For year three (2011-2012), the VOCA reimbursement will be $238,236 resulting in an overall cost savings of $150,926 ($397,060 at 60% = $238,236 reimbursement) which will be paid by VOCA in 2013-2014. Therefore, the real cost of the increased benefits will actually be a savings of $150,926 ($87,310 + DOJ VOCA reimbursement of $238,236 = $150,926).

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)) on May 13, 2009, OVS submitted a copy of these proposed amendments, published at 39 Pa.B. 2591 (May 23, 2009), to IRRC and to the Committees. In addition to submitting the proposed amendments, OVS has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form.

In compliance with section 5(c) of the Regulatory Review Act, IRRC and the Committees were provided with copies of the comments received during the public comment period. The public comments were supportive of the amendments. IRRC had no comments or objections to the amendments. The Committees provided no comments.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2), the final-form rulemaking was deemed approved by the Committees effective October 21, 2009. Under section 5(g) of the Regulatory Review Act, the final-form rulemaking was deemed approved by IRRC effective October 21, 2009. The Attorney General approved the final-form rulemaking on November 23, 2009.

Effective Date

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

Sunset Date

No sunset date has been assigned. These regulations will be reviewed annually.

Contact Person

The contact person for additional information regarding this final-form rulemaking is Lynn Shiner, Deputy Director, Office of Victims' Services at (717) 265-8736.

Findings

(1) Public notice of the intention to adopt amendments to the regulations 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 promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2 (relating to notice of proposed rulemaking required; and adoption of regulations).

(2) A public comment period was provided as required by law and all comments were considered and forwarded to IRRC and the Committees.

(3) No modifications to these regulations in response to comments received were necessary or made and therefore there is no enlargement of the purpose of the proposed regulation published at 39 Pa.B. 2591.

(4) The adoption of this final-form rulemaking in the manner provided by this order is necessary and appropriate for administration and enforcement of the authorizing statute.

Order

The Commission, acting under the authorizing statutes, orders that:

(a) The Crime Victims Compensation regulations, 37 Pa. Code Chapter 411, are amended by amending §§ 411.2, 411.17 and 411.42 to read as set forth at 39 Pa.B. 2591 and by amending § 411.1 to read as set forth in Annex A.

(b) The Commission shall submit this order, 39 Pa.B. 2591, and Annex A to the Office of General Counsel and the Office of Attorney General for approval as required by law.

(c) The Commission shall submit this order, 39 Pa.B. 2591, Annex A and a Regulatory Analysis Form to IRRC and the Committees for their review and action as required by law.

(d) The Commission shall certify this order, 39 Pa.B. 2591, and Annex A and deposit them with the Legislative Reference Bureau as required by law.

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

MICHAEL J. KANE,
Executive Director

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 39 Pa.B. 6524 (November 7, 2009).)

Fiscal Note: Fiscal Note 35-31 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 37. LAW

PART VI. COMMISSON ON CRIME AND DELINQUENCY

CHAPTER 411. CRIME VICTIMS COMPENSATION

GENERAL PROVISIONS

§ 411.1 Scope.

Except as otherwise provided, this chapter applies to claims for compensation relating to crime injuries occurring on or after December 12, 2009.

[Pa.B. Doc. No. 09-2274. Filed for public inspection December 11, 2009, 9:00 a.m.]

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF DENTISTRY

[49 PA. CODE CH. 33]

Dental Hygiene Scope of Practice; Local Anesthesia

The State Board of Dentistry (Board) hereby amends §§ 33.1, 33.3, 33.102, 33.205, 33.301, 33.302 and 33.402, and adds §§ 33.115, 33.116 and 33.205b (relating to local anesthesia permit; certification of public health dental hygiene practitioners; and practice as a public health dental hygiene practitioner) to read as set forth in Annex A.

Effective Date

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

Statutory Authority

Under section 3(d), (j.2) and (o) of the Dental Law (law) (63 P. S. § 122(d), (j.2) and (o)), the Board has authority to adopt, promulgate and enforce regulations for the general supervision, scope of practice and continuing education of dental hygienists. The act of July 20, 2007 (P. L. 376, No. 51) (Act 51) requires amendments to the regulations to implement a new class of certificate for "public health dental hygiene practitioners."

Background and Purpose

The final-form rulemaking accomplishes three goals: to implement a new classification of Board-regulated practitioner created by Act 51—the public health dental hygiene practitioner; to make revisions to the scope of practice of dental hygienists, including the addition of the administration of local anesthesia; and to revise the supervision requirements for dental hygienists.

Summary of Comments and the Board's Response

Notice of proposed rulemaking was published at 38 Pa.B. 4777 (August 30, 2008), followed by 30 days of public comment. During the public comment period, the Board received numerous public comments. In addition, as part of their review under the Regulatory Review Act, the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC) submitted comments. The following represents a summary of the comments received and the Board's response.

Comments from the House Professional Licensure Committee

The only comment received from the HPLC requested that the Board clarify whether a newly graduated dental hygienist can apply for an initial license and a local anesthesia permit simultaneously. If an applicant meets the qualifications for licensure and for a local anesthesia permit, the applicant can apply for both credentials simultaneously. The Board will consider the application for a dental hygiene license first, and once that license is issued, will then consider the application for local anesthesia permit. The Board must review the applications sequentially because one of the requirements for issuance of a local anesthesia permit is that the applicant hold a current license in good standing to practice as a dental hygienist in this Commonwealth.

Comments from the Independent Regulatory Review Commission

IRRC first asked the Board to generally address the Board's statutory authority for allowing dental hygienists to administer local anesthesia, and how allowing them to do so protects the public health, safety and welfare. Answering this question requires an overview of the legislative and regulatory scheme in the practice of dentistry. The definition of the practice of dentistry in section 2 of the law (63 P. S. § 121) is a very broad definition—it includes treating any disease, pain or injury, or regulating any deformity or physical condition of the human teeth, jaws or associated structures. It also includes the administration of ionizing radiation. Every procedure performed in a dental office is "the practice of dentistry." Some of the procedures require the professional competence and skill of a dentist. Those dental procedures that do not require the professional competence and skill of a dentist may be delegated to others. Dental hygiene encompasses a subset of dental procedures that do not require the professional competence and skill of a dentist. Specifically, there are certain "intraoral" procedures that licensed dental hygienists are educated to perform. There is another subset of dental procedures that may only be performed by expanded function dental assistants. It is all "the practice of dentistry." Some of it is reserved for dentists, some of it may be done by dental hygienists, some of it may be done by EFDAs, and some of it may be delegated to any competent person under section 11.8 of the law (63 P. S. § 130i).

The law also provides the authority to the Board to determine by regulation which dental procedures may be performed by dental hygienists, including the necessary education and level of supervision required. IRRC noted that the definition of the practice of dentistry includes administering anesthetic agents, a broad term which encompasses a wide range of agents from topical anesthetics (such as a gel one might use on a teething baby or to dull the pain of a toothache) through general anesthesia. IRRC also pointed out that the law further limits the administration of general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia to licensed dentists. It is significant to note that there is no statutory limitation placed on the administration of local anesthesia or topical anesthetics. The Board is of the opinion that, if the General Assembly had meant to limit local anesthesia to be performed only by dentists, it would have done so when section 11.2 of the law (63 P. S. § 130c), pertaining to anesthesia, was amended in 2002. Therefore, it is left to the Board to determine whether local anesthesia falls within the range of procedures that may be performed by a dental hygienist.

Clearly, the Board may only permit dental hygienists to perform those procedures they are educated to perform. At the time of this writing, 41 states and the District of Columbia permit dental hygienists to administer local anesthesia. Therefore, many dental hygienists currently practicing have been educated to perform this procedure. However, because dental hygienists in this Commonwealth have not been permitted to perform the procedure for a number of years, most dental hygiene programs located in this Commonwealth do not include the administration of local anesthesia in the dental hygiene curriculum. For these reasons, the Board determined that the administration of local anesthesia could only be delegated to those dental hygienists who meet the educational criteria in § 33.115 or have been administering local anesthesia lawfully under the laws and regulations of another jurisdiction. In addition, the administration of local anesthesia may only be performed by a dental hygienist under the direct supervision of a licensed dentist who has examined the patient, has authorized the procedure to be performed and takes full professional responsibility for it. Therefore, if a dentist does not believe the dental hygienist can safely perform the procedure, the dentist should not authorize it. Finally, the Board has placed additional safeguards in the regulation by limiting dental hygienists to using local infiltration anesthesia and intraoral nerve block anesthesia limited to the 2nd (maxillary) and 3rd (mandibular) divisions of the trigeminal nerve. The Board believes these limitations, along with the education and supervision requirements, properly safeguard the public health, safety and welfare.

Additionally, as noted by many of the commentators, the Board believes this change will in many instances increase access to and enhance the quality of dental care

in this Commonwealth. As an example, the removal of subgingival calculus is often painful for the patient. If a patient needs to have local anesthesia to tolerate the procedure, currently a dentist must administer it. This means that if the dentist is not available to administer the local anesthesia because the dentist is involved in the treatment of another patient, the choices are to either terminate the treatment and reschedule, or to continue with the treatment in spite of the pain to the patient. In either event, the patient may not return to complete the treatment. Even if the dentist were able to administer the local anesthesia, it would require the dentist to interrupt the treatment of another patient, causing delays and inefficiencies in offering dental services to all patients. Therefore, the Board believes this change to the scope of practice for hygienists, as appropriately limited in these regulations, does not pose a significant risk to the public health, safety and welfare, and in the long run, will increase access to and enhance the quality of oral health care being delivered by dentists and dental hygienists.

With regard to § 33.1 (relating to definitions), IRRC asked the Board to add the term "public health dental hygiene practitioner" to the existing definition of "board-regulated practitioner." After receiving this comment, the Board's final-form rulemaking pertaining to "sexual misconduct" was published at 38 Pa.B. 6279 (November 15, 2008), which included the requested amendment. IRRC also asked that the second sentence of the definition of "local anesthesia" be moved to § 33.115 because it applies only to that section. The Board has made the requested change.

IRRC noted that § 33.115(c)(3) requires a dental hygienist seeking a local anesthesia permit to provide "acceptable documentation" to the Board, and recommended that the final-form regulation specify the type of documentation that would be acceptable to the Board. IRRC also noted that this section also requires dental hygienists to certify certain information to the Board and recommended that the final-form regulation specify how that information can be "certified." The Board has amended § 33.115 to specify what type of documentation must be submitted for each of the three avenues to obtaining a local anesthesia permit and to clarify the certification process. Specifically, a dental hygienist seeking a local anesthesia permit based on having graduated from a CODA-accredited dental hygiene program which included the successful completion of a course in the administration of local anesthesia would need to provide a "certificate of education" completed by the dental hygiene program on a form provided by the Board. Similarly, if the dental hygienist was seeking the permit based on completion of a 30-hour course sponsored by a dental or dental hygiene program, a "certificate of education" would be required from the dental or dental hygiene program. Finally, if the dental hygienist is seeking the local anesthesia permit based on similar authority issued by the proper licensing authority of another state, territory or district of the United States, or of a province or territory of Canada, the dental hygienist would have to submit a certificate or letter of good standing from that jurisdiction verifying that the jurisdiction required completion of a course in the administration of local anesthesia as a prerequisite and that there had been no disciplinary action against the dental hygienist related to the administration of local anesthesia. The Board also clarified that the dental hygienist is required to sign a "certification statement" on the application for local anesthesia permit verifying that the dental hygienist actively engaged in the administration of local anesthesia under a current license or permit within the 5 years immediately preceding the filing of the application for local anesthesia permit, and that the dental hygienist at all times administered local anesthesia in accordance with all applicable laws and regulations of that jurisdiction.

IRRC raised four concerns regarding the requirement in § 33.116(b)(3) which requires professional liability insurance. First, IRRC asks what is the Board's statutory authority for requiring public health dental hygiene practitioners to obtain professional liability insurance. Section 4 of Act 51 amended the law by adding section 11.9, which sets forth the requirements for public health dental hygiene practitioners. See 63 P. S. § 130; Section 11.9(a)(3) establishes the statutory requirement that a public health dental hygiene practitioner "purchase a malpractice policy in an amount determined to be adequate by the board." IRRC noted that no other practitioner regulated by the Board is required by statute or regulation to obtain professional liability insurance and asked why public health dental hygiene practitioners are required to do so. In response, the Board notes that it is a statutory requirement provided by Act 51, and that the only discretion the Board had was in the "amount determined to be adequate by the board." However, the Board believes the policy behind the requirement was one of public protection because public health dental hygiene practitioners are authorized to practice on the public without the "authorization, assignment or examination of a dentist" who would normally "take full professional responsibility" for the acts of those dental hygienists under the dentist's supervision. Additionally, although the law does not require dentists to obtain professional liability insurance, all prudent dentists would have such coverage.

IRRC also noted that some employers of public health dental hygiene practitioners provide liability coverage for their employees and asked if the Board would consider the coverage provided by the employer acceptable. In response, the Board amended the rulemaking to require applicants for certification as a public health dental hygiene practitioner to provide documentation demonstrating that the dental hygienist has obtained professional liability insurance or is a named insured covered by a group policy. IRRC also asked what would be considered acceptable proof of coverage. The Board has clarified in the final-form rulemaking that this documentation may include a certificate of insurance issued by the insurer, or a copy of the declarations page of the professional liability insurance policy. Finally, IRRC asked if coverage provided by an employer is less than the minimum amount specified in the regulation, would supplemental coverage for the difference be required. A dental hygienist must demonstrate coverage in the minimum amount of $1,000,000 per occurrence and $3,000,000 per annual aggregate. The Board has surveyed a number of insurance providers and determined that the average annual premium for such a policy for dental hygienists in this Commonwealth is currently approximately $100—$125. Even if coverage by the employer is less than the minimum amount required, the Board does not believe that the cost of obtaining a conforming policy is prohibitive. Otherwise, the Board would have no objection to a dental hygienist meeting this requirement by combining two or more professional liability policies.

With regard to § 33.205 (relating to practice as a dental hygienist), IRRC asked the Board to define "subgingival agents." As noted in the preamble to the proposed rulemaking, dental hygienists are qualified to administer a wide range of antimicrobial, antibiotic,

antiseptic or anesthetic agents below the gum line. These agents may be delivered by a variety of methods, including injectable systems for pastes, ointments and gels, as well as degradable and non-degradable fibers, films, strips, spheres, discs or chips. In response to IRRC's comment, the Board has added a definition of the term to § 33.1.

IRRC also raised three concerns with proposed § 33.205b. First, IRRC asked the Board to define what it means by schools, correctional facilities, and Federally-qualified health centers. In response the Board has clarified those terms in the final-form rulemaking. IRRC also asked the Board to ensure that the final-form rulemaking is consistent with existing statutory and regulatory provisions that apply to dental hygienists that practice in school districts. The Board believes that, with regard to permitting public health dental hygiene practitioners to practice in "schools," the intent was to cover any public or private educational institution that provides elementary or secondary instruction to school aged children, which are required under Article XIV of the Public School Code of 1949 to provide dental and dental hygiene services to their students (see 24 P. S. §§ 14-401 and 14-403). Additionally, in response to IRRC and the various school dental hygienists who commented, the Board does not believe the intent was to relieve anyone of their responsibilities under the Public School Code or the regulations of the State Board of Education to be certified as an educational specialist. In addition, under the regulations of the Department of Health in 28 Pa. Code § 23.35 (relating to dental hygienists), a dental hygienist providing dental hygiene services in schools must be licensed by the Board and certified by the Department of Education. This has not changed. The only change is that if a dental hygienist wants to work in the schools without the supervision of a dentist, the dental hygienist must also be certified as a public health dental hygiene practitioner. Otherwise, the dental hygienist must be under the general supervision of a dentist as set forth in § 33.205(d)(2).

The Board has also provided a definition of correctional facilities, which the Board intends to cover all Federal, State, regional, county and local prisons, jails, detention facilities and correctional institutions located within this Commonwealth. Finally, the Board provided a cross reference to the definition of "federally qualified health center" in section 1905(l)(2)(B) of the Social Security Act (42 U.S.C. § 1369d(l)(2)(B)). In addition, in response to a number of comments, the Board clarified that this term includes Federally-qualified health center look-alikes, which qualify for, but do not receive, grants under section 330 of the Public Health Service Act (42 U.S.C.A. § 254b).

Thirdly, IRRC noted that under § 33.205b(d), public health dental hygiene practitioners are required to maintain dental records for 5 years, but that the regulation does not specify whether the records are required to be maintained in written form, or if electronic records are acceptable. The Board would also point out that the Board's regulations in § 33.209 (relating to preparing, maintaining and retaining patient records), which require dentists to maintain dental records for 5 years also does not dictate the format of those records. To date, the Board has not determined it necessary to distinguish between formats in which the records may be maintained, so long as they are accurate, legible and complete. However, due to the increase in the utilization of electronic records in medical and dental practice, the Board is considering the possibility of future regulations relating to standards for electronic recordkeeping, which would apply to dentists and public health dental hygiene practitioners.

With regard to § 33.302 (relating to requirements for personnel performing radiologic procedures), IRRC asked what the Board's statutory authority is for allowing public health dental hygiene practitioners to perform radiologic procedures without the supervision of a dentist and whether the health and safety of the public is adequately protected if a public health dental hygiene practitioner is allowed to perform these procedures. Section 3 of Act 51 amended Section 11.4 of the law (63 P. S. § 130c) pertaining to radiologic procedures by adding subsection (e), which specifically states that, "[n]otwithstanding the supervision requirements of this act, a public health dental hygiene practitioner may perform radiological procedures in any setting without supervision of a dentist on or after the effective date of this subsection." Additionally, in response to a related comment by the Pennsylvania Academy of General Dentistry (PAGD), to protect patients from unnecessary exposure to ionizing radiation and to enhance the public health and safety, the Board has added a provision that requires a public health dental hygiene practitioner to provide to the patient a copy of any radiograph taken, along with a referral to a dentist.

Finally, IRRC pointed out an error in § 33.116(c), which inadvertently referred to biennial renewal of the local anesthesia permit, rather than the public health dental hygiene practitioner certificate. This has been corrected in the final-form rulemaking.

Comments from the Pennsylvania Dental Hygienists' Association

The Pennsylvania Dental Hygienists' Association (PDHA) was generally supportive of the proposed amendments, but asked the Board to consider certain amendments in the final-form rulemaking. PDHA recommended that the Board insert the words "and the dental hygienist" into § 33.205(d)(1)(ii) and (iii) to include dental hygienists in the decision making process regarding the level of supervision required. In response, the Board elected to leave the final decision with the dentist, "with input from the dental hygienist" and has made that amendment to the final-form rulemaking. PDHA also asked the Board to consider an alternate definition of "direct supervision" for the administration of local anesthesia by dental hygienists, which would not include the requirement that the dentist re-examine the patient after the completed injection procedure. After extensive discussion, the Board agreed with the PDHA that their intent was not to require the dentist to "directly supervise" the individual injection procedure, but rather to "directly supervise" the dental hygienist's overall provision of dental hygiene services, including the administration of local anesthesia. Therefore, the Board revised the definition of direct supervision for purposes of the administration of local anesthesia to mean supervision by a dentist who has examined the patient and authorized the procedure to be performed, is physically present in the dental facility and available during the performance of the procedure, and takes full professional responsibility for the completed procedure.

PDHA was among the numerous commentators that asked the Board to include "federally qualified health center look-alikes" as sites where public health dental hygiene practitioners may practice without the supervision of a dentist. As noted previously, the Board has made this change. In addition, PDHA asked the Board to consider adding free and reduced-fee nonprofit clinics.

The Board considered this request and agreed to add it to the rulemaking in § 33.205b(c)(10).

PDHA also asked the Board to consider a change in the heading of Subchapter D and of § 33.302 by deleting the references to "auxiliary personnel" in that public health dental hygiene practitioners who work without the supervision of a dentist do not fit the definition of "auxiliary personnel." The Board has made these amendments. PDHA also suggested that the Board consider amending the proposed rulemaking in § 33.402(c) (relating to continuing education subject areas) to permit both dental hygienists and dentists to complete at least three of the required continuing education credit hours in communications. The Board considered, but rejected, this suggestion. Generally, the regulations require that continuing education credit hours must be completed in subjects that contribute to the Board-regulated practitioner's clinical competence and specifically excludes courses in nonclinical subjects such as communication skills. The proposed amendment to subsection (c) provided an exception for dental hygienists, who are permitted to complete up to 3 hours in communications. This exception was based on the very definition of "dental hygienist" included in the law, which provides that a dental hygienist is licensed to perform "educational, preventive, and therapeutic services and procedures." The essence of an educator is the ability to communicate information to one's patients. Therefore, the exception for dental hygienists, which permits, but does not require, courses in communications is directly related to the professional services being provided by dental hygienists. While the Board agrees with PDHA that the dentist-patient relationship could benefit from courses in communications, the Board has elected to continue to require that all 30 hours of required continuing education must be in areas that contribute to the dentist's clinical competence. However, the Board notes that the required 30 hours is a minimum requirement and joins PDHA in encouraging dentists to acquire additional continuing education in the area of communications.

Comments from the Pennsylvania Academy of General Dentistry

The PAGD expressed concerns about public health dental hygiene practitioners treating patients with severe or life-threatening systemic disease (ASA Class III—ASA Class V) without supervision. Historically, the Board determined the level of supervision required for dental hygienists based on the American Society of Anesthesiologists (ASA) classification of the health status of the patient. However, when the General Assembly adopted Act 51, it required the Board to reconsider the supervision requirements in their entirety. (See section 5 of Act 51, which abrogated the Board's supervision regulations.) By definition, a public health dental hygiene practitioner provides dental hygiene services in certain public health settings without the authorization, assignment or examination of a dentist. The legislature did not provide any exceptions based on the health status of the patient.

The PAGD also expressed concern about public health dental hygiene practitioners performing radiologic procedures without the supervision of a dentist. As noted previously, Act 51 provides specifically that "[n]otwithstanding the supervision requirements of this act, a public health dental hygiene practitioner may perform radiologic procedures in any setting without supervision of a dentist." The Board has no statutory authority to require any supervision with regard to public health dental hygiene practitioners when they are providing services in the enumerated public health settings set forth in section 11.9 of the law. However, the PAGD suggested that the Board include a requirement that any radiograph taken by a public health dental hygiene practitioner be reviewed by a dentist within 1 week to determine the absence or presence of any diagnosable conditions. Inasmuch as all dental hygienists, including public health dental hygiene practitioners, are specifically prohibited from diagnosis or treatment planning, and considering the fact that it is considered unprofessional conduct for a dentist or dental hygienist to unnecessarily expose a patient to ionizing radiation under the Board's existing regulations in § 33.211(a)(6) and (b)(5) (relating to unprofessional conduct), the Board found this suggestion reasonable. However, after extensive discussion and public comment at its March 20, 2009, Board meeting, the Board determined that the 1 week time frame suggested by the PAGD was unduly restrictive and elected to require radiographs taken by public health dental hygiene practitioners to be reviewed by a dentist within 1 month. Subsequently, the Board received correspondence dated June 11, 2009, from the Pennsylvania Dental Association (PDA) suggesting alternative language to that suggested by the PAGD. Rather than simply require the radiograph to be reviewed by a dentist within 30 days, PDA suggested that the public health dental hygiene practitioner provide to the patient a copy of the radiograph and a referral to a dentist with instructions to consult the dentist. Thereafter, upon presentation of the patient, the dentist would be required to examine the patient, review the radiograph and report any findings to the patient and the public health dental hygiene practitioner. The PDHA sent a letter to the Board on July 26, 2009, indicating that while they did not object to the content of the recommendation of the PDA, they felt that it was not necessary to amend the final rulemaking because standard dental hygiene protocols would require a public health dental hygiene practitioner to refer a patient to a dentist with a copy of any radiograph taken if the public health dental hygiene practitioner observed a need for further evaluation and treatment. The Board considered PDA's proposal at its meeting on July 31, 2009, and based on the input received at that meeting from representatives of the PDA, PAGD and PDHA, voted to incorporate PDA's proposal into the final rulemaking. The language requiring referral has been added to § 33.302(a).

Finally, the PAGD suggested that the Board consider a requirement for all dental hygienists administering local anesthesia to complete at least 3 hours of continuing education in pharmacology or other related courses, instead of courses relating to communication skills. The Board considered this comment and has amended § 33.402 to add subsection (f) which requires a dental hygienist who holds a local anesthesia permit to complete at least 3 hours of continuing education in courses relating to the administration of local anesthesia, including pharmacology. However, because the 3 credit hours in communications skills are permitted, but not required, the Board did not make a change in that aspect of the proposed rulemaking.

Comments from other public commentators

Dr. Dino Angelici, Chief of Dentistry for the Department of Corrections (DOC), raised a concern about the need for public health dental hygiene practitioners who work in correctional facilities to maintain professional liability insurance. He indicated that employees of the DOC are already covered by the DOC for their dental practice within the Commonwealth's correctional system.

He also suggested that many insurance companies will not provide coverage for dentists and dental hygienists for correctional practice due to the fact that inmates can be extremely litigious, even though most claims are determined to be frivolous and are subsequently dismissed. Unfortunately, the Board does not believe it has the statutory authority to waive the requirement for malpractice insurance. The Board would, however, support an amendment to the act if the DOC determines one is warranted.

A number of certified school dental hygienists commented in opposition to the proposed rulemaking because they believed that the Board intended to permit public health dental hygiene practitioners to work in public schools without meeting the requirements of the Department of Health and the Department of Education, which require school dental hygienists to hold both a license issued by the Board and a certificate issued by the Department of Education. The Board believes the amendments to § 33.205b(c)(1) described previously clarify that a public health dental hygiene practitioner may only practice in schools in accordance with the applicable laws and regulations of the Department of Health and the Department of Education.

Dr. Charles M. Ludwig, a former member of the Board, commented in opposition to the proposed amendments. He suggested that because in 1993, the Board unsuccessfully tried to add the administration of local anesthesia and nitrous oxide/oxygen conscious sedation to the scope of practice for dental hygienists, the Board may not again propose to add the administration of local anesthesia at this point in time. The Board would point out that, in amending the act in 2002, the General Assembly specifically addressed the administration of anesthesia. The 2002 amendments to section 11.4 of the law reserve the administration of general anesthesia, deep sedation, conscious sedation and nitrous oxide/oxygen analgesia to dentists. The General Assembly did not at that time restrict the administration of local anesthesia. The Board believes that had the General Assembly intended to restrict the administration of local anesthesia to dentists, it would have done so at that time. Because it did not, it is within the authority of the Board to determine whether the administration of local anesthesia is a procedure that may be safely delegated to dental hygienists.

Dr. Ludwig also suggested that Act 51 is unconstitutional because it creates conflicting provisions in the law. Specifically, he suggested that a public health dental hygiene practitioner is prohibited from diagnosis and treatment planning, yet they would need to do a certain amount of diagnosis and treatment planning to determine what dental hygiene services to provide to a patient. The Board is without the authority to rule on the constitutionality of a statute passed by the General Assembly and signed by the Governor. The Board's role is to implement the provisions of Act 51. These regulations are intended to implement the law in accordance with the legislative mandate. Dr. Ludwig also opposed the amendment to § 33.102 (relating to professional education) to license dental hygienists who have graduated from a dental hygiene program accredited by an approved United States Department of Education-recognized regional accrediting agency. However, this amendment was made by Act 51, and the Board is simply amending its regulations to conform to the amendment to the act. Dr. Ludwig further objects to the Board's proposed amendment to the definition of "general supervision." The Board believes that Dr. Ludwig misapprehends the amendment's intent. This provision does not give the hygienist up to 1 year to schedule a procedure assigned by the dentist as the hygienist sees fit, as Dr. Ludwig would suggest. It is not a "wait period" added for the convenience of the hygienist. It is not intended to delay treatment for up to 1 year. It essentially gives the dentist the authority to assign up to 1 year's worth of dental hygiene procedures to a dental hygienist, which could then be completed by the dental hygienist even if the dentist is not physically present in the facility at the time the procedures are performed. The dentist is still responsible for examining the patient, developing the treatment plan, authorizing the dental hygienist to perform the procedures, and taking full professional responsibility for the completed procedures. The Board believes this change, allowing the dentist the flexibility to authorize dental hygiene services up to 1 year in advance, rather than 90 days, will provide more efficiency in the delivery of dental hygiene services and increase access to care for this Commonwealth's citizens.

Finally, Dr. Ludwig objects to the creation of two standards of dental hygiene care—one for patients in private dental offices, and one for patients in public health settings. The Board disagrees with Dr. Ludwig's assessment. The standard of care for the delivery of dental hygiene services is the same regardless of the setting in which it is performed. A dental hygienist shall always conform to the standards of acceptable and prevailing dental hygiene practice in this Commonwealth. The only difference is how closely the hygienist is supervised by a dentist in the provision of those services.

On the other hand, some licensed dentists commented in favor of the proposed rulemaking. One dentist commented that the proposed amendments are needed because dental hygienists are well-educated and clinically competent dental professionals and an integral part of the dental health team. For the most part, those dentists who supported the proposed rulemaking felt that local anesthesia should be included in the scope of practice of a dental hygienist. They also noted that the changes would enable dental hygienists to improve the oral health of the citizens of this Commonwealth by providing necessary preventive oral health care.

A large number of commentators from the dental hygiene community, including educators, practicing dental hygienists and students currently enrolled in dental hygiene programs throughout this Commonwealth, wrote in support of the proposed amendments. They believe that the proposed amendments will expand public access to early and essential preventative dental heath services and ultimately lead to the reduction in more complex and costly dental care. They also believe that the changes will keep this Commonwealth from losing the best and the brightest hygienists due to lack of career choices and autonomy. Many of those who work in the public health field urged the Board to consider adding Federally-qualified health center look-alikes and free and reduced-fee nonprofit dental clinics to the practice sites for public health dental hygiene practitioners. The Board has responded by making these changes. Many of the dental hygienists who commented joined the PDHA in recommending input from the dental hygienist into the decision of the level of supervision required. As noted previously, the Board has responded by making amendments to the final-form rulemaking.

Description of Amendments

The definition of "general supervision" in § 33.1 is amended to extend general supervision to dental hygiene services to be performed within 1 year of an examination by a dentist, instead of the current standard of 90 days. Section 33.1 is also amended to define the terms "local anesthesia," "public health dental hygiene practitioner" and "subgingival agents."

Section 33.3 (relating to fees) is amended to include the fees necessary for processing applications for and biennial renewal of local anesthesia permits and public health dental hygiene practitioner certificates.

Section 33.102 is amended to comport with changes made by Act 51.

Section 33.115 is added to set forth the requirement for a dental hygienist to secure a permit prior to administering local anesthesia. This section also sets forth the qualifications required by the Board for a dental hygienist to both secure and maintain a local anesthesia permit. This section has been amended in the final-form rulemaking to include the substantive language that had been included in the definition of "local anesthesia" in the proposed rulemaking and to clarify the types of documentation necessary to support an application for a local anesthesia permit.

Section 33.116 is added to implement the provisions of Act 51. This section has also been amended in the final-form rulemaking to clarify the types of documentation necessary to demonstrate the qualifications for a public health dental hygiene practitioner certificate and to correct a typographical error in the proposed rulemaking.

Section 33.205 is amended to make some minor changes to the description of certain dental hygiene services and to include the administration of local anesthesia by regional injection within the scope of practice of a dental hygienist in accordance with § 33.115. In addition, subsection (d)(1) pertaining to supervision requirements for dental hygienists in dental offices is amended in its entirety as a result of Act 51 which abrogated the prior language. In the final-form rulemaking, this section has been amended to include input from the dental hygienist into the decision regarding the level of supervision required, and to define "direct supervision" with regard to the administration of local anesthesia.

The Board adds § 33.205b to set forth the standards for public health dental hygiene practitioners in accordance with Act 51. Subsection (a) addresses the scope of practice of public health dental hygiene practitioners. Subsection (b) incorporates the requirement of referral set forth in Act 51. Subsection (c) establishes the practice settings in which a public health dental hygiene practitioner would be authorized to practice without supervision. This subsection has been amended in the final-form rulemaking to further define "schools," "correctional facilities" and "federally qualified health centers" and to add Federally-qualified health center look-alikes, and free and reduced-fee health clinics to the list of practice sites for public health dental hygiene practitioners. It has also been amended to clarify that public health dental hygiene practitioners who wish to work in public schools must continue to comply with the regulations of the Department of Health and Department of Education, that is, they must hold a license from the Board and a certification from the Department of Education. In subsection (d), the Board establishes minimum standards for recordkeeping by public health dental hygiene practitioners.

The Board also is amending its regulations relating to the performance of radiologic procedures in Subchapter D. Section 33.301 is amended to establish the Radiation Health and Safety examination administered by the Dental Assisting National Board (DANB) as the required examination for auxiliary personnel who wish to administer ionizing radiation in a dental office. Section 33.302 is amended to comport with changes made by Act 51. In the final-form rulemaking, this section and the title of subchapter D have been renamed to reflect the fact that public health dental hygiene practitioners are not "auxiliary personnel" as that term is defined in § 33.1. In addition, at the suggestion of the PAGD and PDA, this section has been amended to include a requirement that public health dental hygiene practitioners provide to the patient a copy of the radiograph and a referral to a dentist for further evaluation and possible treatment. The amendment would also require dentists to review the radiograph, examine the patient and report any findings to the patient and the public health dental hygiene practitioner.

Finally, the Board is amending § 33.402 to permit dental hygienists to complete no more than three of the required 20 hours of continuing education in courses relating to communication skills; to require public health dental hygiene practitioners to complete five of the required 20 hours in public health-related courses; to permit public health dental hygiene practitioners who are also certified educational specialists by the Department of Education to submit evidence of compliance with section 1205.2 of the Public School Code (24 P. S. § 12-1205.2) to meet the 20-hour continuing education requirement; and to require dental hygienists who hold anesthesia permits to complete three of the required 20 hours in courses related to the administration of local anesthesia, including pharmacology or related courses.

Fiscal Impact and Paperwork Requirements

The amendments should have no fiscal impact on the Commonwealth or its political subdivisions because the costs associated with processing the local anesthesia permits and public health dental hygiene practitioner certificates will be borne by applicants. Dental hygienists who apply for local anesthesia permits will incur some costs associated with the permit application and renewal fees and possibly the costs of completing a local anesthesia course. Dental hygienists who wish to obtain certification as public health dental hygiene practitioners will incur costs associated with the permit application and biennial renewal fees. There are currently approximately 8,163 licensed dental hygienists in this Commonwealth. The Board has no way of knowing how many dental hygienists will apply for the local anesthesia permit or the public health dental hygiene practitioner certificate.

The amendments will require the Board to develop applications for the local anesthesia permit, public health dental hygiene practitioner certificate, and biennial renewal forms for each of these credentials, but should not result in any additional legal, accounting or reporting requirements for the Commonwealth or the regulated community.

Sunset Date

The Board continuously monitors the cost effectiveness of its regulations. Therefore, no sunset date has been assigned.

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 38 Pa.B. 4777, to IRRC, the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) and the HPLC for review and comment.

In compliance with section 5(c) of the Regulatory Review Act, the Board also provided IRRC, the SCP/PLC and the HPLC with copies of comments received as well as other documents when requested. In preparing the final-form regulations, the Board has considered the comments received from IRRC, the HPLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), these final-form regulations were approved by the HPLC on October 7, 2009, and deemed approved by the SCP/PLC on November 4, 2009. Under section 5.1(e) of the Regulatory Review Act, IRRC met on November 5, 2009, and approved the final-form regulation.

Contact Person

Further information may be obtained by contacting Cynthia Montgomery, Regulatory Counsel, State Board of Dentistry, P. O. Box 2649, Harrisburg, PA 17105-2649.

Findings

The State Board of Dentistry 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 (relating to notice of proposed rulemaking required; and adoption of regulations).

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

(3) The amendments to the final form rulemaking do not enlarge the purpose of proposed rulemaking published at 38 Pa.B. 4777.

(4) This final-form rulemaking is necessary and appropriate for administering and enforcing the authorizing act identified in this preamble.

Order

The State Board of Dentistry, acting under its authorizing statutes, orders that:

(a) The regulations of the Board, 49 Pa. Code Chapter 33, are amended by amending §§ 33.1, 33.3, 33.102, 33.205, 33.301, 33.302 and 33.402, and by adding §§ 33.115, 33.116 and 33.205b 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 the Office of Attorney General as required by law.

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

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

JOHN V. REITZ, D.D.S.,
Chairperson

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 39 Pa.B. 6705 (November 21, 2009).)

Fiscal Note: Fiscal Note 16A-4617 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 33. STATE BOARD OF DENTISTRY

Subchapter A. GENERAL PROVISIONS

§ 33.1. Definitions.

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

* * * * *

General supervision—In a dental facility, supervision by a dentist who examines the patient, develops a treatment plan, authorizes the performance of dental hygiene services to be performed within 1 year of the examination, and takes full professional responsibility for the performance of the dental hygienist. In facilities identified in § 33.205(c)(2) and (3) (relating to practice as a dental hygientist), general supervision is defined in § 33.205(d)(2).

* * * * *

Local anesthesia—The elimination of sensations, especially pain, in one part of the body by regional injection of an anesthetic agent.

* * * * *

Public health dental hygiene practitioner—A licensed dental hygienist who is certified by the Board as having met the requirements of section 11.9 of the act (63 P. S. § 130j), and who is authorized to perform dental hygiene services in accordance with § 33.205b (relating to practice as a public health dental hygiene practitioner) without the authorization, assignment or examination of a dentist.

* * * * *

Subgingival agents—Therapeutic agents, including antimicrobials, antibiotics, antiseptics or anesthetics, placed below the free margin of the gingiva by a local delivery system or device, including injectable systems for ointments, gels or pastes, and degradable or nondegradable devices, such as fibers, films, strips, slabs, spheres, discs or chips.

§ 33.3. Fees.

(a) Following is the schedule of fees charged by the Board:

Application fee—dentists, dental hygienists and expanded function dental assistants	$20
Application fee—certificate of public health dental hygiene practitioner	$20
Application fee—local anesthesia permit	$20
Criteria approval application fee—dentists, dental hygienists and expanded function dental assistants	$35
Fictitious name registration fee	$35
Verification of license, permit or registration fee—dentists, dental hygienists and expanded function dental assistants	$15
Certification of scores, permit or registration fee—dentists, dental hygienists and expanded function dental assistants	$25
Biennial renewal fee—dentists (for the renewal period beginning April 1, 2005, and thereafter)	$250
Biennial renewal fee—dental hygienists	$40
Biennial renewal fee—expanded function dental assistants	$25
Biennial renewal fee—certificate of public health dental hygiene practitioner	$40
Biennial renewal fee—local anesthesia permit	$40
Temporary permit—expanded dental assistants	$15
Application fee—dental radiology authorization	$20
Notification application—postgraduate training or faculty member	$25

(b) For fees related to anesthesia permits, refer to § 33.339 (relating to fees for issuance of permits).

Subchapter B. LICENSURE OF DENTISTS AND DENTAL HYGIENISTS

§ 33.102. Professional education.

(a) *Dentists.*

(1) Candidates for licensure as dentists shall show compliance with section 3(c) of the act (63 P. S. § 122(c)) which requires a diploma from an "approved institution or college," by submitting certification of graduation from a dental school accredited or provisionally accredited by the Commission on Accreditation of the American Dental Association.

(2) Candidates for licensure who received their professional education outside the United States in a nonaccredited school may satisfy the education requirement by submitting their credentials to an accredited or provisionally accredited school and obtaining additional preclinical and clinical training that will lead to the awarding of the D.M.D. or D.D.S. degree by that school.

(b) *Dental hygienists.*

(1) Candidates for licensure as dental hygienists shall show compliance with section 3(d) of the act by submitting certification of graduation from a dental hygiene school accredited or provisionally accredited by an approved United States Department of Education-recognized regional accrediting agency or the Commission on Dental Accreditation (CODA) of the American Dental Association, if the school's dental hygiene course of study comprises a minimum of 2 years of at least 32 weeks of at least 30 hours each week or its equivalent.

(2) Candidates for licensure who received their professional education outside the United States in a nonaccredited school may satisy the education requirement by submitting their credentials to an accredited or provisionally accredited school and obtaining additional training that will lead to the awarding of a degree in dental hygiene by that school.

(c) *Expanded function dental assistants.*

(1) Candidates for certification as expanded function dental assistants shall show compliance with section 3(d.1) of the act by submitting verification of one of the following:

(i) Graduation from an expanded function dental assisting program at a 2-year college or other institution accredited or provisionally accredited by an accrediting agency approved by the United States Department of Education Council on Postsecondary Accreditation which offers an Associate Degree.

(ii) Graduation from a dental hygiene school which required the successful completion of at least 75 hours of clinical and didactic instruction in restorative functions accredited or provisionally accredited by the Commission on Accreditation of the American Dental Association.

(iii) Completion of a certification program in expanded function dental assisting of at least 200 hours of clinical and didactic instruction from a dental assisting program accredited by one of the following:

(A) The Commission on Dental Accreditation of the American Dental Association.

(B) An accrediting agency approved by the United States Department of Education Council on Postsecondary Accreditation whose expanded function educational standards are approved by the Board.

(2) Candidates for certification who receive their professional education outside the United States or from a nonaccredited program may satisfy the education requirement by submitting their credentials to a program listed in paragraph (1) and obtaining additional training that will lead to the awarding of a degree by that school.

(3) This subsection does not apply to persons who are not required to meet the educational requirements under section (3)(d.1)(2) of the act.

§ 33.115. Local anesthesia permit.

(a) *Permit required.* A dental hygienist shall possess a current permit issued by the Board under this section before administering local anesthesia to a patient in a dental office. For purposes of this section, the term "local anesthesia" includes local infiltration anesthesia and intraoral nerve block anesthesia limited to the 2nd (maxillary) and 3rd (mandibular) divisions of the trigeminal nerve.

(b) *Application.* A dental hygienist who desires to obtain a permit to administer local anesthesia shall submit an application on a form provided by the Board, pay the permit fee prescribed in § 33.3 (relating to fees) and meet the qualifications for the permit as prescribed in this section.

(c) *Qualifications.* To obtain a local anesthesia permit, a dental hygienist shall:

(1) Hold a current license in good standing to practice as a dental hygienist in this Commonwealth.

(2) Hold current certification in Basic Life Support (BLS).

(3) Provide to the Board one of the following:

(i) Certification of education by the dental hygiene program on a form provided by the Board verifying that the dental hygienist graduated, within the 5 years immediately preceding the filing of the application for local anesthesia permit, from a dental hygiene program that meets the following criteria:

(A) The dental hygiene program is accredited by the American Dental Association's Commission on Dental Accreditation (CODA).

(B) The dental hygiene program included the successful completion of a didactic and clinical course in the administration of local anesthesia.

(ii) Certification of education by the dental or dental hygiene program on a form provided by the board verifying that the dental hygienist successfully completed, within the 5 years immediately preceding the filing of the application for local anesthesia permit, a course consisting of a minimum of 30 hours of didactic and clinical instruction in the administration of local anesthesia sponsored by a dental or dental hygiene education program accredited by CODA.

(iii) A certificate or letter of good standing from the proper licensing authority of another state, territory or district of the United States, or of a province or territory of Canada, verifying that the dental hygienist possesses a current license or permit issued by the proper licensing authority of another state, territory or district of the United States, or by the proper licensing authority of a province or territory of Canada, where the dental hygienist is authorized under the laws of that jurisdiction to administer local anesthesia, provided that the following additional conditions are met:

(A) The jurisdiction where the dental hygienist is so licensed or permitted requires completion of a course in the administration of local anesthesia accredited by CODA or by the Commission on Dental Accreditation of Canada (CDAC) prior to obtaining certification, endorsement or other such authority.

(B) The dental hygienist signs a certification statement on the application for a local anesthesia permit verifying that the dental hygienist actively engaged in the administration of local anesthesia under a current license or permit within the 5 years immediately preceding the filing of the application for a local anesthesia permit.

(C) The dental hygienist signs a certification statement on the application for a local anesthesia permit verifying that, at all times prior to filing the application for local anesthesia permit, the dental hygienist administered local anesthesia in accordance with all applicable laws and regulations of the jurisdiction where the dental hygienist is so licensed or permitted.

(D) The jurisdiction where the dental hygienist is so licensed or permitted verifies that there has been no disciplinary action taken against the dental hygienist relating to the administration of local anesthesia.

(d) *Expiration and biennial renewal.* A local anesthesia permit issued by the Board under this section will expire at the same time as the permitholder's dental hygiene license but may be renewed biennially at the same time the dental hygiene license is renewed. A dental hygienist who desires to renew a local anesthesia permit shall submit the following:

(1) A renewal application on a form provided by the Board.

(2) The permit renewal fee set forth in § 33.3.

(3) Proof of current certification in BLS.

§ 33.116. Certification of public health dental hygiene practitioners.

(a) *Application.* A licensed dental hygienist who desires to obtain certification as a public health dental hygiene practitioner shall submit an application on a form provided by the Board, pay the application fee prescribed in § 33.3 (relating to fees) and meet the qualifications for certification as prescribed in this section.

(b) *Qualifications.* To qualify for certification as a public health dental hygiene practitioner, a dental hygienist shall:

(1) Hold a current license in good standing to practice as a dental hygienist in this Commonwealth.

(2) Provide to the Board a certification statement signed by a licensed dentist verifying that the dental hygienist has completed 3,600 hours of practice as a licensed dental hygienist under the supervision of the licensed dentist.

(3) Provide to the Board documentation demonstrating that the dental hygienist has obtained professional liability insurance or is a named insured covered by a group policy in the minimum amount of $1,000,000 per occurrence and $3,000,000 per annual aggregate. This documentation may include a certificate of insurance issued by the insurer, or a copy of the declarations page of the professional liability insurance policy.

(c) *Expiration and biennial renewal.* A certificate issued by the Board under this section will expire at the same time as the certificateholder's dental hygiene license but may be renewed biennially at the same time the dental hygiene license is renewed. A dental hygienist who desires to renew a public health dental hygiene practitioner certificate shall submit the following:

(1) A renewal application on a form provided by the Board.

(2) The permit renewal fee set forth in § 33.3.

Subchapter C. MINIMUM STANDARDS OF CONDUCT AND PRACTICE

§ 33.205. Practice as a dental hygienist.

(a) *Scope of professional practice.* A dental hygienist may offer to perform or perform services that involve:

(1) Placement of subgingival agents.

(2) Periodontal probing, scaling, root planning, polishing or another procedure required to remove calculus deposits, accretions, excess or flash restorative materials and stains from the exposed surfaces of the teeth and beneath the gingiva.

(3) Evaluation of the patient to collect data to identify dental hygiene care needs.

(4) The application of fluorides and other recognized topical agents for the prevention of oral diseases.

(5) Conditioning of teeth for and application of sealants.

(6) Taking of impressions of the teeth for athletic appliances.

(7) Administration of local anesthesia by regional injection in accordance with § 33.115 (relating to local anesthesia permit).

(b) *Prohibition against independent practice.* A dental hygienist is prohibited from establishing or maintaining an office or other workplace for the provision of dental hygiene services separate or independent from the office or other workplace in which the supervision of a dentist is provided.

(c) *Practice sites.* A dental hygienist may engage in professional practice at the following sites under the supervision of a dentist as required in subsection (d):

(1) In dental facilities.

(2) In public or private institutions such as schools, hospitals, public health care agencies, nursing homes, mobile health units and homes for juveniles, the elderly and the handicapped.

(3) In institutions under the jurisdiction of Federal, State or local health agencies.

(d) *Supervision.*

(1) In subsection (c)(1) practice sites (dental facilities), a dental hygienist shall provide professional services as follows:

(i) A dental hygienist may provide the professional services identified in subsection (a)(1) under the direct supervision of a dentist, except that these services may be provided under general supervision if the dentist has reviewed the patient's dental records and medical history and has written a prescription or given an order for the placement of subgingival agents by the dental hygienist.

(ii) A dental hygienist may provide the professional services identified in subsection (a)(2) under the general supervision of a dentist when the patient is free of systemic disease or suffers from mild systemic disease, as determined by the dentist with input from the dental hygienist and upon review of the patient's medical history.

(iii) A dental hygienist may provide the professional services identified in subsection (a)(2) under the direct supervision of a dentist when the patient is suffering from systemic disease which is severe, incapacitating, or life threatening, as determined by the dentist with input from the dental hygienist and upon review of the patient's medical history.

(iv) A dental hygienist may provide the professional services identified in subsection (a)(3)—(6) under the general supervision of a dentist.

(v) A dental hygienist may provide the professional services identified in subsection (a)(7) only under the direct supervision of a dentist. For purposes of this subparagraph, direct supervision means supervision by a dentist who has examined the patient and authorized the procedure to be performed, is physically present in the dental facility and available during the performance of the procedure, and takes full professional responsibility for the completed procedure.

(2) In subsection (c)(2) and (3) practice sites (public and private institutions and institutions under the jurisdiction of Federal, State or local health agencies), a dental hygienist shall provide professional services as follows:

(i) A dental hygienist may provide the professioinal services identified in subsection (a)(1) under the direct supervision of a dentist, except that these services may be provided under general supervision if a dentist has reviewed the patient's dental records and medical history and has written a prescription or given an order for the placement of subgingival agents by the dental hygienist.

(ii) A dental hygienist may provide the professional services identified in subsection (a)(3)—(6) under the general supervision of a dentist. For the purposes of this paragraph, general supervision is defined as supervision by a dentist who authorizes and takes full professional responsibility for the provision of the services. A single authorization may, when appropriate, apply to one or more classes or categories of students/patients.

(iii) A dental hygienist may provide the professional service identified in subsection (a)(7) only under the direct supervision of a dentist. For purposes of this subparagraph, direct supervision means supervision by a dentist who has examined the patient and authorized the procedure to be performed, is physically present and available during the performance of the procedure, and takes full professional responsibility for the completed procedure.

(3) For professional services not identified in subsection (a)(1)—(7) or § 33.302 (relating to auxiliary personnel performing radiologic procedures), the dentist shall compare the listed services and the supervision required with the unlisted service and utilize the appropriate supervision. Supervision for noncomparable services will be determined by the Board on a modality basis.

(4) Notwithstanding the supervision requirements in this subsection, a dental hygienist may provide oral health education and perform preliminary dental screenings in any setting without the supervision of a dentist.

§ 33.205b. Practice as a public health dental hygiene practitioner.

(a) *Scope of professional practice.* A public health dental hygiene practioner may perform the dental hygiene services set forth in § 33.205(a)(2)—(6) (relating to practice as a dental hygienist) in the practice settings identified in subsection (c) without the authorization, assignment or examination by a dentist. A public health dental hygiene practitioner may perform the dental hygiene services set forth § 33.205(a)(1) and (7) in accordance with § 33.205(d).

(b) *Requirement of referral.* A public health dental hygiene practitioner shall refer each patient to a licensed dentist on an annual basic. Documentation of the referral must be maintained in the patient's dental record. The failure of the patient to see a dentist as referred will not prevent the public health dental hygiene practitioner from continuing to provide dental hygiene services to the patient within the scope of professional practice set forth in subsection (a).

(c) *Practice settings.* A public health dental hygiene practitioner may perform dental hygiene services without the supervision of a dentist in the following practice settings:

(1) Public and private educational institutions that provide elementary and secondary instruction to school aged children under the jurisdiction of the State Board of Education, and in accordance with all applicable provisions of the Public School Code of 1949 (24 P. S. §§ 1-101—27-2702.), the regulations relating to the certification of professional personnel in 22 Pa. Code Chapter 49 (relating to certification of professional personnel), and the regulations of the Department of Health in 28 Pa. Code § 23.35 (relating to dental hygienists).

(2) Correctional facilities. For purposes of this section, correctional facilities include Federal prisons and other institutions under the jurisdiction of the United States Department of Justice, Bureau of Prisons which are located within this Commonwealth; institutions, motivational boot camps and community corrections centers operated or contracted by the Department of Corrections; and jails, prisons, detention facilities or correctional institutions operated or contracted by local, county or regional prison authorities within this Commonwealth.

(3) Health care facilities, as defined in section 802.1 of the Health Care Facilities Act (35 P. S. § 802a).

(4) Personal care homes, as defined in section 1001 Public Welfare Code (62 P. S. § 1001).

(5) Domiciliary care facilities, as defined in section 2202-A of The Administrative Code of 1929 (71 P. S. § 581-2).

(6) Older adult daily living centers, as defined in section 2 of the Older Adult Daily Living Centers Licensing Act (62 P. S. § 10225.102).

(7) Continuing-care provider facilities, as defined in section 3 of the Continuing-Care Provider Registration and Disclosure Act (40 P. S. § 3203).

(8) *Federally-qualified health centers*, as defined in section 1905(1)(2)(B) of the Social Security Act (42 U.S.C.A. § 1369(1)(2)(B)). For purposes of this section, the term includes Federally-qualified health center lookalikes that do not receiver grant funds under section 330 of the Public Health Service Act (42 U.S.C.A. § 254b).

(9) Public or private institutions under the jurisdiction of a Federal, State or local agency.

(10) Free and reduced-fee nonprofit health clinics.

(d) *Recordkeeping.* A public health dental hygiene practitioner shall maintain a dental record which accurately, legibly and completely reflects the dental hygiene services provided to the patient. The dental record must be retained for at least 5 years from the date of the last treatment entry. The dental record must include, at a minimum, the following:

(1) The name and address of the patient and, if the patient is a minor, the name of the patient's parents or legal guardian.

(2) The date dental hygiene services are provided.

(3) A description of the treatment or services rendered at each visit.

(4) The date and type of radiographs taken, if any, and documentation demonstrating the necessity or justification for taking radiographs, as well as the radiographs themselves.

(5) Documentation of the annual referral to a dentist.

Subchapter D. PERFORMANCE OF RADIOLOGIC PROCEDURES

§ 33.301. Definitions.

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

Ionizing radiation—

(i) Gamma rays and X-rays; alpha and beta particles, high-speed electrons, neutrons, protons and other nuclear particles.

(ii) The term does not include ultrasound, sound or radio waves or visible, infrared or ultraviolet light.

Premises of the dentist—A location at which a dentist practices dentistry, other than a health care facility regulated by the Department of Health, Department of Public Welfare or the Federal government.

Radiologic procedure—A dental diagnostic procedure that utilizes ionizing radiaiton.

Radiologic procedure examination—The Radiation Health and Safety examination administered by The Dental Assisting National Board, Inc. (DANB).

§ 33.302. Requirements for personnel performing radiologic procedures.

(a) Public health dental hygiene practitioners may perform radiologic procedures in those settings set forth in § 33.205b(c) (relating to practice as a public health dental hygiene practitioner) without the supervision of a dentist. Public health dental hygiene practitioners shall take radiographs under this section in accordance with the following:

(1) Within 30 days of taking a radiograph, the public health dental hygiene practitioner shall provide to the patient a copy of the radiograph and a referral to a dentist indicating the reason the radiograph was taken and any observations noted by the public health dental hygiene pracitioner.

(2) The public health dental hygiene practitioner shall instruct the patient to consult with the dentist as indicated on the referral form.

(3) Upon presentation by the patient, the dentist shall perform an examiniation of the patient, review the radiograph and report any diagnosis to the public health dental hygiene practitioner and the patient.

(b) Dental hygienists may perform radiologic procedures in any setting under the general supervision of a licensed dentist. For the purpose of this subsection, "general supervision" means supervision by a dentist who examines the patient, develops a dental treatment plan, authorizes the performance of the radiologic services to be performed within 1 year of the examination, and takes full professional responsibility for performance of the dental hygienist.

(c) Auxiliary personnel who have passed the radiologic procedure examination adopted by the Board may perform radiologic procedures on the permises of a dentist under the direct supervision of a dentist. The dentist shall be on the premises when a radiologic procedure is performed, but is not required to personally observe performance of the procedure.

Subchapter F. CONTINUING DENTAL EDUCATION

§ 33.402. Continuing education subject areas.

(a) Except as provided in subections (c)—(e), the required credit hours shall be completed in subjects which contribute directly to the maintenance of clinical competence of a dentist, dental hygienist, public health dental hygiene practitioner or expanded function dental assistant. Examples of acceptable subjects include:

(1) Diagnosis and treatment of oral pathosis.

(2) Clinical and technological subjects.

(3) Emergency procedures excluding hours required for cardiopulmonary resuscitation (CPR) certification.

(4) Infection control.

(5) Abuse and neglect.

(6) Medical and scientific subjects.

(7) Laws and regulations pertaining to dentists, dental hygienists and expanded function dental assistants.

(b) Credit hours will not be awarded in nonclinical subjects, including:

(1) Billing.

(2) Office management.

(3) Practice building.

(4) Insurance reimbursement.

(5) Communication skills, except as provided in subsection (c).

(c) A dental hygienist may complete no more than three of the required 20 hours of continuing education in courses relating to communication skills.

(d) A public health dental hygiene practitioner shall complete five of the required 20 hours of continuing education in public health-related courses.

(e) A school dental hygienist who is certified as a public health dental hygiene practitioner and who, as a certified educational specialist is required to obtain continuing professional education under the act and under section 1205.2 of the act Public School Code of 1949 (24 P. S. § 12-1205.2) may submit evidence of the completion of education courses approved for certification by the school district to meet the 20-hour continuing education requirement.

(F) A dental hygienist who holds a local anesthesia permit shall complete three of the required 20 hours of continuing education in courses related to the administration of local anesthesia, including pharmacology or other related courses.

[Pa.B. Doc. No. 09-2275. Filed for public inspection December 11, 2009, 9:00 a.m.]

STATE BOARD OF NURSING

[49 PA. CODE CH. 21]

Certified Registered Nurse Practitioners; General Revisions

The State Board of Nursing (Board) amends Chapter 21, Subchapter C (relating to certified registered nurse practitioners), to read as set forth in Annex A.

Effective Date

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

Statutory Authority

The amendments are authorized under sections 2.1(k) and (l) and 8.1—8.3 of The Professional Nursing Law (act) (63 P. S. §§ 212.1(k) and (l) and 218.1—218.3).

Background and Purpose

The Board and the State Board of Medicine jointly promulgated regulations regarding certified registered nurse practitioner (CRNP) practice at 30 Pa.B. 5943 (November 18, 2000), under statutory provisions that provided for joint regulation of CRNPs by the Board and the State Board of Medicine. The act of December 9, 2002 (P. L. 1567, No. 206) (Act 206), amended the act to give the Board exclusive jurisdiction over the regulation of CRNPs. The act was further amended by the act of July 20, 2007 (P. L. 318, No. 48) (Act 48). The Board's proposed rulemaking implementing the 2002 and 2007 amendments to the act was published at 38 Pa.B. 6161 (November 8, 2008).

During the 30-day public comment period, the Board received 218 letters from the general public and 471 letters from nurses supporting the proposed amendments. The Board received about 20 letters from nursing and hospital groups supporting the proposed rulemaking and about 53 letters from physicians and pharmacists supporting the proposed rulemaking. The Board also received about 23 letters from physicians and pharmacists opposed to the proposed rulemaking and letters from five physician groups opposed to the proposed rulemaking. In addition to considering all of the comments received from the public, the Board met with representatives from the Pennsylvania Coalition of Nurse Practitioners and the Pennsylvania Medical Society regarding amendments to the final-form rulemaking.

The existing regulations prevented the effective use of CRNPs to the full extent of their education, skills and abilities, thereby depriving the citizens of this Commonwealth necessary, high quality care. More than half of states' laws permit CRNPs to practice with fewer restrictions on their ability to order diagnostic tests, treat illnesses and prescribe medications to patients. *The Pearson Report*, The American Journal for Nurse Practitioners, vol. 13, no. 2, February 2009. To the Board's knowledge, every study completed has concluded that CRNPs provide safe and effective care, even when practicing independently from physicians. *Cochrane Database of Systematic Reviews* 2004, Issue 4, Art. NO.: CD00127. DOI: 10.1002/14651858.CD00127.pub2. There is no evidence that expanded CRNP prescribing endangers the public. The Board's final-form rulemaking increases access to care while protecting the public.

Response to Comments

Following the close of the public comment period, the Board received comments from the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC). The Senate Consumer Protection and Professional Licensure Committee did not comment. The following is a summary of the comments and the Board's response.

Approximately 53 physicians and pharmacists wrote letters in support of the proposed rulemaking. Of this number, 49 noted that the proposed amendments would benefit patients and that the current regulations, specifically the limitations on CRNPs' prescription of controlled substances, create a financial hardship to patients and are unnecessary for patient safety. Thirteen physicians specifically noted that removing the physician—CRNP ratio will improve healthcare and allow more CRNPs to serve some of the neediest patients. Sixteen of the group noted that the education and training of CRNPs prepares CRNPs to complete medical examinations and to effectively diagnose and treat patients. These physicians practice successfully with CRNPs.

About 20 nursing and health care organizations and facility groups wrote in support of the proposed rulemaking. The Hospital and Healthsystem Association of Pennsylvania (HAP) noted that the Board had substantially improved the existing regulations by reiterating that a CRNP can issue written and oral orders for medical, diagnostic and therapeutic measures. HAP also supported the deletion of the provisions related to CRNP identification and the Board's proposed revision on the restrictions on CRNPs prescribing controlled substances and dispensing professional drug samples.

Several health systems wrote in support of the proposed rulemaking. The College of Health Professions at Temple University applauded the Board's deletion of the ratio of nurse practitioners to physicians, stating: "Please eliminate false ratios that restrict the number of nurse practitioners that any one physician can collaborate with—these health teams must be unhindered in their work." The Safe Harbor Behavioral Health organization applauded the Board's elimination of the CRNP-physician ratio and the elimination of the 72-hour restriction on prescribing Schedule II controlled substances and 30-day restriction on Schedule III—IV controlled substances. This organization stated that the current restrictions on CRNPs negatively impacts children with ADHD who are prescribed Schedule II medications and patients with chronic anxiety disorders that are prescribed schedule IV medications.

The Rothman Institute in Philadelphia wrote in support of the 30-day prescriptive privileges for Schedule II controlled substances, noting that CRNPs determine post-surgical discharge pain medications for patients based on the CRNPs frequent evaluation and adjustment of the medication during the hospital stay. Rothman Institute wrote that the current restriction on Schedule III and IV controlled substances are "barriers [that] create an unnecessary burden on the patients." These views were echoed consistently throughout the comments received from members of the public.

The Pennsylvania Medical Society (PMS) submitted comprehensive comments. The Board met with representatives from PMS twice to discuss their concerns and specific language in the regulation. Most of the issues raised by PMS were resolved through these meetings and amendments to the proposed rulemaking reflect these resolutions. PMS expressed to the Board its continuing concern with the provision related to the length of treatment with Schedule II controlled substances and the deletion of the ratio limiting the number of CRNPs with which a physician may collaborate. The Board's rationale in maintaining the rulemaking as proposed on these issues is discussed fully below.

The comments submitted by the HPLC and IRRC reflect and summarize many of the comments made by physician groups in opposition to some provisions of the proposed rulemaking. The HPLC first commented that eliminating the regulatory restriction that requires that all collaborative agreements be in writing "does not provide any consumer protection, cannot be proven if called into question, does not protect the physician or the CRNP, and could cause problems with discipline by the board." IRRC noted that while it did not question the Board's authority to allow oral collaborative agreements, it questioned the reasonableness of permitting oral collaborative agreements. The Board believes that the act requires a written collaborative agreement only for CRNPs who have prescriptive authority. Nevertheless, in light of the comments by the HPLC and IRRC, the Board has amended its proposed rulemaking to require that all collaborative agreements be in writing.

The HPLC next urged the Board "to continue to specify the minimum requirements for what needs to be contained within the non-prescriptive authority collaborative agreement" by including the definition of "collaborative agreement" or specifying the terms in a separate section. The Board has repeated the statutory definition for "collaboration" and has added a definition for "collaborative agreement," which references the minimum requirements of collaboration. IRRC suggested that the details found in section 8.3(a)(2)(i)—(iii) of the act (63 P. S. § 218.3(a)(2)(i)—(iii)) addressing minimum requirements for a prescriptive authority collaborative agreement, be repeated in the Board's regulations. The Board does not believe it is necessary to repeat these statutory provisions because CRNPs are required to submit their prescriptive authority collaborative agreements on a form provided by the Board and the form includes the three provisions found in section 8.3(a)(2)(i)—(iii) of the act, as well as additional information that must be submitted to the Board.

The HPLC noted that § 21.261(c) (relating to use of title; authorization to practice) should refer to "individuals" rather than "persons". The Board amended its proposal to refer to an individual.

Regarding § 21.282a (relating to CRNP practice), the HPLC suggested that the section be amended to specify that a CRNP may only perform the listed tasks if the CRNP is acting within the scope of the CRNP's specialty and collaborative agreement. Because section 8.2(a) and (b) of the act (63 P. S. § 218.2(a) and (b)) provide that CRNPs may only act in the expanded role in their specialties and in accordance with their collaborative agreements, the Board had thought it redundant to repeat these statutory provisions. Given the concerns raised by the commentators, the Board has amended § 21.282a(b) to repeat the statutory limitations, and apply the limitations to all of the enumerated functions of a CRNP.

In addition, it was strongly suggested that the Board should repeat, in its regulation, the list of tasks that a CRNP may perform enumerated by the Legislature in section 8.2(c.1) of the act. Based on this urging, the Board reproduced the list from section 8.2(c.1) in § 21.282a(b)(8)—(15). After the Board added the list, the Department of Public Welfare suggested that the Board should mention in this preamble that Federal Medicaid or Medicare, or both, law currently only allows providers of home health and hospice care to receive reimbursement for patients whose initial order and recertification order was written by a physician. CRNPs and their collaborating physicians should consider whether these providers can obtain Federal reimbursement when writing these initial or recertification orders.

Regarding § 21.284(e) (relating to prescribing and dispensing parameters), the HPLC asked if the changes in the length of time for which a CRNP may prescribe controlled substances is a change that must be submitted to the Drug Review Committee (DRC). IRRC asked why the changes proposed by the Board are not additions or deletions to the categories of drugs. Section 8.4 of the act (63 P. S. § 218.4), requires the Board to submit "any proposed change to the categories of drugs that CRNPs were authorized to prescribe under the board regulations in effect on the effective date of this section. The board shall not change, by addition or deletion, the categories of authorized drugs without prior approval of the Drug Review Committee." The categories of drugs were identified in § 21.284(a) of the jointly promulgated regulations—the categories identified in the American Hospital Formulary Service Pharmacologic-Therapeutic Classification.

In the fall of 2007, the Board proposed to the DRC to amend the regulations to provide for a negative formulary rather than a positive formulary, and to increase the treatment time periods for controlled substances. The proposal was deemed approved. The Board then decided to maintain the positive formulary and submitted the

version published as proposed to the Department of Health (Department). Upon review by the Department, the Board was advised that the DRC approval was not required. The Office of Attorney General (OAG) was fully apprised of this matter by both the Board and the Department during its review of the proposed rulemaking, and the OAG approved the legality of the proposal.

The HPLC asked about the current acceptable standards for prescribing controlled substances and the justifications the Board used to suggest the changes proposed in the proposed rulemaking. CRNPs possess the knowledge and skills to safely prescribe controlled substances for up to these longer time frames. Board research has found that every academic study that has been conducted has concluded that CRNPs prescribe safely. CRNPs have been prescribing for these longer periods without issue in many other states for years. The current restrictions are unnecessary and cause significant and unnecessary delays in treatment and expenses to the public.

The HPLC next questioned the deletion of § 21.286(a) and (c) (relating to identification of the CRNP), and the changes to § 21.286(b). Section 21.286(a) provided that a patient must be informed at the time the patient makes an appointment that the patient will be seen by a CRNP. The Board is deleting this subsection. Clerical staff makes patient appointments; therefore, it would be unfair to discipline a CRNP for an inadvertent omission by a staff member employed by a facility or office. Similarly, the State Board of Medicine's regulations do not provide for disciplining a physician assistant for a misstatement by clerical staff.

Section 21.286(b) provided that a CRNP wear a name tag with the title "certified registered nurse practitioner." The title for a CRNP is "CRNP." CRNPs working in pediatrics are unable to wear name tags because pediatric patients try to pull them off and can be injured by a name tag or its pin. In consultation with the PMS, the Board proposes to delete this provision and provide instead that CRNPs comply with State, Federal and facility regulations regarding identification of personnel to provide up-to-date provisions applicable to all personnel.

Section 21.286(c) regarding identification of CRNPs who hold doctoral degrees. CRNPs are already required, under subsection (b) to be appropriately identified. The Board finds it unnecessary to have a second provision regarding the identification of CRNPs. The Board's proposed amendment is consistent with regulations of other healthcare practitioners, such as optometrists and podiatrists, which require the practitioners to use their title in addition to "Dr."

The HPLC next commented on the Board's rescission of § 21.287 (relating to physician supervision). This section was promulgated under the old statutory scheme, wherein physicians supervised CRNPs. Section 21.287 provided that a physician could not supervise more than four CRNPs who prescribe and dispense drugs at any one time. In its December 2002 amendments to the act, the General Assembly deleted the physician supervision provisions. Under the new statutory scheme, CRNPs practice in the expanded role of an advanced practice nurse in collaboration with physicians. Section 21.287 is outdated and contrary to the statutory scheme enacted in December 2002.

The HPLC stated that it "believes [the § 21.287] restriction is necessary for patient safety and to ensure the quality of care." The HPLC did not explain the basis of this belief. Many nurses, physicians, group practices and organizations submitted comments to the contrary, and provided examples of ways that the § 21.287 restriction created a situation where patients were unable to receive the care that they needed and increased the risk of harm to patients. The Board is not aware of any research that has demonstrated that a limitation on the number of CRNPs collaborating with one physician increases patient safety or quality of care. No group or individual who submitted comments objecting to the proposed amendment cited evidence in any research that suggests that deleting this provision would compromise patient safety or quality of care. CRNPs practice in many other states without this arbitrary restriction, and there is no evidence that patients in these states receive a lower quality of care than patients in this Commonwealth. The Board respectfully rejects the HPLC's recommendation.

The HPLC next addressed § 21.288 (relating to CRNP standards of conduct), and suggested that the section should specify that practice by a CRNP must be within the specifications of the CRNP's collaborative agreement. The Board has adopted the recommendation.

The HPLC next questioned the rescission of §§ 21.291—21.294. These provisions purported to place requirements on health care facilities. Health care facilities are regulated by the Department of Health. The Board does not have any regulatory authority over health care facilities. The HPLC commented that "[s]ince the statutory requirement on which these sections are based continues to apply, the Committee suggests retaining these sections." By Act 48 of 2007, the General Assembly provided that section 8.2(c.2) of the act could not be construed to "[s]upersede the authority of the Department of Health and the Department of Public Welfare to regulate the types of health care professionals who are eligible for medical staff membership or clinical privileges" or to "[r]estrict the authority of a health care facility to determine the scope of practice and supervision or other oversight requirements for health care professionals practicing within the facility." (63 P. S. § 218.2(c.2)). The Board does not believe that these provisions give the Board the authority to direct the formation, composition, meeting dates or duties of committees that may operate within a health care facility to make determinations about staff within the facility. Finally, the Hospital and Healthsystem Association of Pennsylvania supports the deletion of these provisions. The Board respectfully declines the HPLC's suggestion.

The HPLC noted that the Board used, in § 21.351(1) (relating to penalties for violation), both the abbreviation CRNP and the words certified registered nurse practitioner, and suggested that the Board be consistent. Although the Board submitted the proposed rulemaking to the HPLC using both the abbreviation and the words, the Legislative Reference Bureau corrected this error and only the abbreviation was used in the published version of the proposed rulemaking. The HPLC next noted that § 21.351 did not require CRNP practice to be consistent with the collaborative agreement. The Board has added a provision explaining that a CRNP may be subject to discipline if the Board finds that the CRNP practiced in violation of the collaborative agreement.

Finally, the HPLC suggested that the Board require a CRNP to only form collaborative agreements with a physician who holds an unrestricted license. The Board

understands the Committee's concern, and has added to § 21.282a(a) a provision that a CRNP may only collaborate with physicians who hold a current license. Physicians who hold a current license are authorized by the State Board of Medicine or State Board of Osteopathic Medicine to practice in this Commonwealth. At the meeting held by the Board on April 2, 2009, the PMS recommended that the Board prohibit CRNPs from collaborating with certain types of medical and osteopathic medical license holders, such as physicians participating in residency programs. The Board believes that the State Boards of Medicine and Osteopathic Medicine are in a better position to determine which of their licensee classes may enter into collaborative agreements with CRNPs.

In addition to voicing some of the same concerns as the HPLC, IRRC asked why the definition of "direction" was being deleted from the Board's regulations. Act 206 amended the act by deleting the definition of "direction" and replacing that definition with the definition of "collaboration." The amendment to the Board's regulations conforms the regulations to the statute.

IRRC suggested that the Board specify in § 21.273(a) (relating to application for certification) the kinds of documents that a CRNP may submit to the Board with the application for certification as a CRNP to verify compliance with the statutory provision mandating liability insurance. CRNPs, like physicians, will not be required to submit any documents. When Act 48 of 2007 became effective, the Board added a verification statement to its application that was modeled after the verification statement used on the application for physicians.

IRRC suggested that the Board list the eight activities set forth in section 8.2(c.1) of the act that a CRNP may perform in its list of permissible activities in § 21.282a(b). The Board has added the statutory provisions to its regulation. IRRC noted that it found the term "other laws and regulations" and "pharmaceutical treatments" vague terms. The Board has replaced the reference to other laws and regulations with a reference to the collaborative agreement. The Board has determined that it need not amend the term pharmaceutical treatments, that is, treatments utilizing pharmaceutical agents or drugs, because the term is not vague to health care practitioners.

Regarding § 21.283, IRRC asked what was meant by the term "oral orders" and recommended that the term be defined. The term "oral order" is already defined in § 21.141 (relating to definitions) as a "spoken order issued by a practitioner authorized by law and by facility policy to issue orders for medical and therapeutic measures." The definition was added to the regulations related to Licensed Practical Nurses (LPNs) when those regulations were amended at 33 Pa.B 6219 (December 20, 2008) because LPNs had not previously been permitted to take oral orders. Because professional nurses (RNs) have always been permitted to take oral orders, the term is not new to CRNPs and a definition is not required.

IRRC recommended that the Board add a definition for the term "categories of drugs" to avoid further confusion if this section is amended in the future. Section 21.284(a) provides that the categories are those identified in the American Hospital Formulary Service Pharmacologic-Therapeutic Classification.

IRRC next recommended that the Board retain the language in existing § 21.284(d), which mandates certain conduct by physicians. The Board does not believe that it has the statutory authority to mandate conduct by physicians. The Board's regulations already mandate that CRNPs act to safeguard patients. This mandate would, of course, require a CRNP to take action to safeguard a patient for whom a prescription was erroneously issued, regardless of whether the prescription was erroneously issued by the CRNP, another CRNP or a physician.

Regarding the new time periods for which a CRNP is permitted to write a prescription for controlled substances, IRRC asked the Board to further explain why it was deleting the requirement that a CRNP notify the collaborating physician of the prescription and address why it believes CRNPs have the appropriate education and training to administer these provisions without the oversight of a physician.

In considering the comments to § 21.284(d), specifically the notification provision, the Board held two meetings with representatives from PMS. After the first meeting, at which the representatives raised their concerns about the deletion of the provision, the Board agreed to include a provision requiring that CRNPs notify their collaborating physician within 24 hours when a CRNP prescribes a Schedule II drug for a 30-day period or a Schedule III—IV drug for a 90-day period. The PMS representatives then advised the Board that they objected to the notification provision because it might increase physician liability. At the second meeting held with the PMS representatives, the representatives and the Board agreed that the period of time for which a CRNP may prescribe controlled substances, subject to the 30-day and 90-day limitations, is a matter that could be addressed individually between CRNPs and physicians. Therefore, the Board added language to the revised subsection (d) to provide that the CRNP may prescribe controlled substances "as identified in the collaborative agreement." When the regulation becomes final, the Board will amend the prescriptive authority collaborative agreement form consistent with this provision.

IRRC asked what education was required for CRNPs. CRNPs must complete a minimum of a master's degree or post-master's degree certificate in nursing that prepared the nurse to practice as a CRNP. In addition, CRNPs must obtain and maintain National certification in their specialty by an organization that requires passing an examination. To maintain National certification requires significant continuing education in the specialty. CRNPs have expertise as clinicians and have an excellent record of providing effective and safe care to patients.

In response to IRRC's inquiry whether CRNPs can safely administer these provisions "without the oversight of a physician," the Board points out that CRNPs practice safely and effectively in most other states without the level of physician involvement as is in this Commonwealth. The qualifications met by CRNPs in this Commonwealth are similar to the qualifications to practice as a prescribing CRNP in the other 50 states, all of which, plus the District of Columbia and the United States Virgin Islands, have prescriptive authorization for CRNPs. The prescriptive authority granted to CRNPs varies from state to state. Seven states and this Commonwealth restrict CRNP prescribing to a formulary, 12 states authorize CRNPs to prescribe consistent with protocols, 27 states authorize CRNPs to prescribe consistent with their collaborative agreements, 16 states authorize CRNPs to prescribe independently within their specialty, and seven states authorize CRNPs to prescribe independently both within and outside their specialty.

CRNPs were authorized to prescribe in 48 states prior to obtaining prescriptive authority authorization in this Commonwealth.

A comprehensive study of disciplinary actions imposed on CRNPs, conducted over a 2-year period from data from 38 boards of nursing that license or certify 86,940 CRNPs, found that 0.12% of CRNPs were disciplined for exceeding their scope of practice. Hudspeth, R., (2007). *Advanced Practice Registered Nurse Discipline 2003-2004*. Institute of Regulatory Excellence, National Council of State Boards of Nursing. In this Commonwealth, CRNPs have held prescriptive authority since 2000. There are approximately 4,150 CRNPs with prescriptive authority in this Commonwealth. From 2000 to date, three CRNPs have been charged with improper prescribing and found guilty by the Board. Each case involved a single instance of improper prescribing as an accommodation to a relative or friend.

The extremely low rate of improper prescribing cases brought in this Commonwealth echoes the findings of numerous research studies—that CRNPs practice—including prescribing—safely, and with virtually identical patient outcomes. According to a study published in the *Journal of the American Medical Association in 2000*, the data "strongly supported the hypothesis that, using the traditional medical model of primary care, patient outcomes for nurse practitioner and physician delivery of primary care do not differ." *Primary care outcomes in patients treated by nurse practitioners or physicians*. JAMA 2000; 283(1):59-68. Other studies have reached a similar conclusion in particular fields. (*For example, Prescribing patterns for gerontological nurse practitioners in the United States*; Journal of the American Academy of Nurse Practitioners 20 (2008) 28-34; *Quality of HIV care provided by nurse practitioners, physician assistants, and physicians;* Annals of Internal Medicine 2005; 143(10):729-735; *Improving the effectiveness of screening for colorectal cancer by involving nurse clinicians*. Medical Care 1991; 29(1):1-5; and *Pediatric trauma nurse practitioners provide excellent care with superior patient satisfaction for injured children*; Journal of Pediatric Surgery (2006) 41, 277-281). A comprehensive survey of 4,253 articles related to nurse practitioner care, including nurse practitioner prescribing, concluded that "appropriately trained nurses can produce as high quality care as primary doctors and achieve as good health outcomes for patients." Substitution of doctors by nurses in primary care. *Cochrane Database of Systematic Reviews* 2004, Issue 4, Art. NO.: CD00127. DOI: 10.1002/14651858.CD00127.pub2.

IRRC asked the Board to consider alternative language offered by some of the commentators to this subsection, specifically the suggestion by PMS that CRNPs be permitted to write a prescription for a 7-day dosage, with proper notification to the physician and for 30-day dosage for ongoing therapy as approved by the collaborating physician. The Board considered the suggestions. In the face of the many comments from physicians, nurses and patients applauding the Board's proposal as necessary to ensure adequate access to safe and effective healthcare for this Commonwealth's citizens, the Board determined that it should not amend its proposal.

IRRC noted that the preamble and proposed Annex were inconsistent regarding whether the prescription blanks of CRNPs must identify the collaborating physician. IRRC asked what was the Board's intention for § 21.284a(b)(1) and suggested that the name of the collaborating physician should be on the prescription as finally written. Section 21.284a(b)(1) requires prescriptions to bear the name, title and Pennsylvania CRNP certification number of the CRNP. Because CRNPs often collaborate with multiple physicians, it would be both impractical and confusing to patients and pharmacists for CRNPs to have multiple prescription pads. The Board has made available, on its public verification web site, information on the certification of CRNPs, including, where applicable, the identity of a CRNP's collaborating physician.

IRRC next addressed § 21.285 (relating to prescriptive authority collaborative agreements) and expressed concern that the Board proposed to delete subsections (a)(4) and (6). IRRC asked the Board to further explain why it is in the public interest to delete these two sections. Section 21.285(a)(4) required physicians to attest to the physician's knowledge and experience with drugs that a CRNP may prescribe. The Board does not believe it is the appropriate body to require physicians to attest to their knowledge of drugs. Section 21.285(a)(6) provided that the collaborative agreement specify the conditions under which a CRNP could prescribe Schedule II controlled substances. A similar provision has been added to § 21.284(d).

IRRC also noted that subsection (a)(6) is being amended to limit access to a prescriptive authority collaborative agreement to any license pharmacist or pharmacy and asked why the Board would not maintain the existing regulatory language to allow patients access to information they may need. The Board's proposed rulemaking required CRNPs to make the collaborative agreement available for inspection, including to patients. In addition, the Board's proposed rulemaking required CRNPs to provide a copy of the collaborative agreement to pharmacists and pharmacies at no charge. The Board has added additional language to clarify its original intent.

The Board approved the final version of the rulemaking for promulgation at its meeting on May 5, 2009. On May 6, 2009, the Board received communication from the Pennsylvania Society of Anesthesiology (Society), expressing concern that § 21.17 (relating to anesthesia), which prohibits all nurses except Certified Registered Nurse Anesthetists (CRNAs) and certain nurse anesthesia students and graduates from administering anesthesia, might not be considered applicable to CRNPs in light of the deletion from § 21.284(b)(7) of the prior prohibition on CRNPs' prescribing general anesthetic drugs. Through discussions between representatives of the Board and representatives of the Society, it was determined that the Board and the Society agreed on the interaction of these sections of the regulations. It was also agreed that the preamble to this final-form rulemaking should further explain the role of CRNPs in the administration of general anesthetic drugs, but that the final rulemaking should not be amended. The Pennsylvania Coalition of Nurse Practitioners also provided input on this matter. The Board approved this addition to the preamble at its June 4, 2009, meeting.

In accordance with sections 8.2(a), (b) and (c.2)(1) and (2), and 8.3(a)(2) of the act, CRNPs practice within their specialty, consistent with their collaborative agreements, subject to other statutes and regulations, and in accordance with the policies of health care facilities in which they practice. The amendment to § 21.284(b)(7) does not alter the § 21.17 provisions that limit the administration of anesthesia by licensed nurses to CRNAs. The amendment to § 21.284(b)(7) also does not affect the provisions

of § 21.413(d) (relating to interpretations regarding the administration of drugs—statement of policy), which set forth the scope of practice of the professional nurse related to administering intravenous conscious sedation medications during minor therapeutic and diagnostic procedures.

CRNPs may administer central nervous system agents classified as general anesthetics to intubated patients in a health care facility and, when credentialed by their employer, may administer central nervous system agents classified as general anesthetics for sedation in connection with procedures being performed in a health care facility in collaboration with a physician trained in airway management or with the immediate availability of a CRNA or anesthesiologist.

Fiscal Impact and Paperwork Requirements

The amendments will have no adverse fiscal impact on the Commonwealth or its political subdivisions, because the costs of the Board's activities are supported by fees charged to licensees and others who benefit from specific activities of the Board. The amendments will impose no additional paperwork requirements upon the Commonwealth or political subdivisions.

Sunset Date

The Board continuously monitors the effectiveness of its regulations. Therefore, no sunset date has been assigned.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), the Board submitted a copy of this proposed rulemaking, published at 38 Pa.B. 6161, to IRRC and the House Professional Licensure Committee (HPLC) and the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC, the HPLC and the SCP/PLC were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Board has considered all comments from IRRC, the HPLC, the SCP/PLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on November 4, 2009, the final-form rulemaking was deemed approved by the HPLC and SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on November 5, 2009, and approved the final-form rulemaking.

Additional Information

Additional information may be obtained by writing to Ann Steffanic, Board Administrator, State Board of Nursing, P. O. Box 2649, Harrisburg, PA 17105-2649.

Findings

The Board finds that:

(1) Public notice of intention to adopt the administrative amendments adopted by this order 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 (relating to notice of proposed rulemaking required; and adoption of regulations).

(2) A public comment period was provided as required by law and all comments were considered in drafting this final-form rulemaking.

(3) The amendments made to the final-form rulemaking do not enlarge the original purpose of the proposed rulemaking as published at 38 Pa.B. 6161.

(4) These amendments to the regulations of the Board are necessary and appropriate for the regulation of the practice of CRNPs in this Commonwealth.

Order

The Board therefore orders that:

(a) The regulations of the Board, 49 Pa. Code Chapter 21, are amended by amending §§ 21.251, 21.261, 21.271, 21.283—21.286, 21.331, 21.332, 21.332a, 21.333, 21.334 and 21.351; by adding §§ 21.273, 21.282a, 21.284b and 21.288; and by deleting §§ 21.252, 21.272, 21.281, 21.282, 21.287, 21.291—21.294, 21.311 and 21.321 to read as set forth in Annex A.

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

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

ANN L. O'SULLIVAN, PhD, FAAN, CRNP,
Chairperson

(Editor's Note: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 39 Pa.B. 6705 (November 21, 2009).)

Fiscal Note: Fiscal Note 16A-5124 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 21. STATE BOARD OF NURSING

Subchapter C. CERTIFIED REGISTERED NURSE PRACTITIONERS

GENERAL PROVISIONS

§ 21.251. Definitions.

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

Act—The Professional Nursing Law (63 P. S. §§ 211—225.5).

Board—The State Board of Nursing of the Commonwealth.

CRNP—Certified Registered Nurse Practitioner—A professional nurse licensed in this Commonwealth who is certified by the Board in a specialty and who, while functioning in the expanded role as a professional nurse, performs acts of medical diagnosis or prescription of medical therapeutic or corrective measures in collaboration with a physician licensed to practice in this Commonwealth and in accordance with the act and this subchapter. Nothing in this subchapter is to be deemed to limit or prohibit a professional nurse from engaging in those activities which constitute the practice of professional nursing as defined in section 2 of the act (63 P. S. § 212).

Certification—The authorization granted by the Board to a professional nurse who has demonstrated the qualifications for recognition as a CRNP.

Collaboration—A process in which a CRNP works with one or more physicians to deliver health care services within the scope of the CRNP's expertise. The process includes the following:

(i) Immediate availability of a licensed physician to a CRNP through direct communications or by radio, telephone or telecommunications.

(ii) A predetermined plan for emergency services.

(iii) A physician available to a CRNP on a regularly scheduled basis for referrals, review of the standards of medical practice incorporating consultation and chart review, drug and other medical protocols within the practice setting, periodic updating in medical diagnosis and therapeutics and cosigning records when necessary to document accountability by both parties.

Collaborative agreement—The written and signed agreement between a CRNP and a collaborating physician in which they agree to the details of their collaboration including the elements in the definition of collaboration.

Initial certification—The first certification or licensure as a nurse practitioner that an individual receives in any jurisdiction.

National certification—Certification by a Board-recognized National certification organization which required passing a nurse practitioner National certifying examination in a specialty.

Prescriptive authority collaborative agreement—The written and signed agreement between a CRNP with prescriptive authority and a collaborating physician in which they agree to the details of their collaboration.

Specialty—The area of practice or population in which a CRNP is certified by the Board.

§ 21.252. (Reserved).

LEGAL RECOGNITION

§ 21.261. Use of title; authorization to practice.

(a) A professional nurse who has satisfactorily met the requirements set forth in the act and this subchapter and holds current certification as a CRNP or whose certification is maintained on inactive status may use the designation CRNP.

(b) The Board will identify the specialty in which a CRNP is certified on the certification issued to the CRNP.

(c) Only an individual who holds current active certification may practice or offer to practice as a CRNP in this Commonwealth.

(d) A professional nurse may not practice or offer to practice as a CRNP in a specialty in this Commonwealth during the time the professional nurse's certification in that specialty or the professional nurse's RN license is inactive, lapsed or expired. A professional nurse may not practice or offer to practice as a CRNP in this Commonwealth if the professional nurse's certification or RN license is revoked or suspended.

CERTIFICATION REQUIREMENTS

§ 21.271. Certification requirements.

(a) *Initial certification.* An applicant for initial certification shall meet the following requirements:

(1) *Registered nurse license.* An applicant for certification shall hold a current, unrestricted license as a professional nurse in this Commonwealth.

(2) *Education.* An applicant for certification shall have completed an accredited, Board-approved master's or postmaster's nurse practitioner program or other Board-approved program that awarded an advanced degree or a course of study considered by the Board to be equivalent to that required for certification in this Commonwealth at the time the course was completed.

(3) *National certification.* An applicant for initial certification after February 7, 2005, shall hold current National certification in the specialty in which the professional nurse is seeking certification.

(b) *Certification by endorsement.* An applicant for certification who holds a current, unrestricted license or certificate as a nurse practitioner from another state, territory or possession of the United States or a foreign country, shall meet the certification requirements that were effective at the time the applicant was licensed or certified as a nurse practitioner by the other jurisdiction. Applicants who were initially licensed or certified by another state, territory or possession of the United States or a foreign country after February 7, 2005, shall hold current National certification in the specialty in which the nurse is seeking certification. Nurse practitioners applying for certification from a jurisdiction that does not designate the nurse practitioner's specialty will be required to present evidence satisfactory to the Board to demonstrate the nurse practitioner's specialty.

(c) *Addition of a specialty.* A CRNP who holds an unrestricted certification to practice may apply for certification in an additional specialty. To be granted certification in an additional specialty, the CRNP shall meet the educational and National certification requirements for the specialty in which the CRNP is applying for certification.

§ 21.272. (Reserved).

§ 21.273. Application for certification.

(a) Applicants for certification shall pay a fee set forth in § 21.253 (relating to fees), and submit an application form provided by the Board to the Board for its review and approval. Applicants shall verify compliance with section 8.7 of the act (63 P. S. § 218.7) regarding professional liability coverage.

(b) An applicant for initial certification shall include documentation satisfactory to the Board of the following:

(1) Proof of completion of a Board-approved education program or proof of completion and official transcript from another course of study that meets the requirements of § 21.271(a)(2) (relating to certification requirements).

(2) Proof of current National certification as set forth in § 21.271(a)(3).

(c) An applicant for certification by endorsement shall include documentation satisfactory to the Board of the following:

(1) Verification of current, unrestricted licensure or certification as a nurse practitioner issued by the proper licensing authority of another state, territory or possession of the United States or a foreign country.

(2) Copy of the licensure or certification requirements at the time the applicant was initially licensed or certified by another jurisdiction and a copy of the criteria under

which the applicant was initially licensed or certified, obtained from the jurisdiction's board of nursing or licensing authority.

(3) Official transcript from the applicant's nurse practitioner program, including degree awarded.

(4) Proof of current National certification in the specialty in which the nurse is seeking certification by the Board, if the applicant obtained initial certification or licensure after February 7, 2005.

(5) Proof of specialty designation. for a nurse practitioner who obtained initial certification in a specialty before February 7, 2005, and who does not hold current National certification, the specialty designation shall be demonstrated by certification from the nurse practitioner's original state of certification. For a nurse practitioner whose certification is from a state that does not designate a specialty, the specialty designation shall be demonstrated by the nurse practitioner's educational program.

(d) An applicant who holds certification who is applying for certification in another specialty shall submit documentation of the following:

(1) Official transcript from the applicant's nurse practitioner program and any additional educational programs, including degree awarded, demonstrating a concentration in the specialty in which the applicant is seeking certification.

(2) Proof of current National certification in the specialty in which the nurse is seeking certification by the Board.

(e) Applicants shall remit the fee set forth in § 21.253.

(f) Applicants shall submit additional information as identified on the application or as requested by the Board. Applications will remain on file for 12 months.

(g) All forms are available on the Board's web site or by contacting the Board.

§ 21.281. (Reserved).

§ 21.282. (Reserved).

CRNP PRACTICE

§ 21.282a. CRNP Practice.

(a) A CRNP may collaborate only with physicians who hold a current license to practice in this Commonwealth.

(b) When acting in collaboration with a physician as set forth in a collaborative agreement and within the CRNP's specialty, a CRNP may:

(1) Perform comprehensive assessments of patients and establish medical diagnoses.

(2) Order, perform and supervise diagnostic tests for patients and, to the extent the interpretation of diagnostic tests is within the scope of the CRNP's specialty and consistent with the collaborative agreement, may interpret diagnostic tests.

(3) Initiate referrals to and consultations with other licensed professional health care providers, and consult with other licensed professional health care providers at their request.

(4) Develop and implement treatment plans, including issuing orders to implement treatment plans. However, only a CRNP with current prescriptive authority approval may develop and implement treatment plans for pharmaceutical treatments.

(5) Complete admission and discharge summaries.

(6) Order blood and blood components for patients.

(7) Order dietary plans for patients.

(8) Order home health and hospice care.

(9) Order durable medical equipment.

(10) Issue oral orders to the extent permitted by the health care facilities' by-laws, rules, regulations or administrative policies and guidelines.

(11) Make physical therapy and dietitian referrals.

(12) Make respiratory and occupational therapy referrals.

(13) Perform disability assessments for the program providing temporary assistance to needy families (TANF).

(14) Issue homebound schooling certifications.

(15) Perform and sign the initial assessment of methadone treatment evaluations, provided that any order for methadone treatment shall be made only by a physician.

(c) The provisions of this section are subject to limitation as set forth in section 8.2(c.2) of the act (63 P. S. § 218.2(c.2)), regarding the authority of state agencies and health care facilities.

§ 21.283. Authority and qualifications for prescribing, dispensing and ordering drugs.

(a) A CRNP with prescriptive authority approval may, when acting in collaboration with a physician as set forth in a prescriptive authority collaborative agreement and within the CRNP's specialty, prescribe and dispense drugs and give written or oral orders for drugs and other medical therapeutic or corrective measures. These orders may include:

(1) Orders for drugs, total parenteral nutrition and lipids, in accordance with §§ 21.284 and 21.285 (relating to prescribing and dispensing parameters; and prescriptive authority collaborative agreements).

(2) Disposables and devices adjunctive to a treatment plan.

(b) To obtain prescriptive authority approval, a CRNP shall:

(1) Successfully complete 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 Board.

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

(iii) The course work shall have been completed within 5 years immediately preceding the date the applicant applies for initial prescriptive authority approval.

(2) Submit an application for prescriptive authority approval to the Board.

(3) Pay the fee set forth in § 21.253 (relating to fees).

(c) A CRNP who has prescriptive authority shall complete at least 16 hours of Board-approved continuing education in pharmacology in the 2 years prior to the

biennial renewal date of the certification. The CRNP shall verify completion of the continuing education when submitting a biennial renewal.

§ 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 with current prescriptive authority approval from the Board may prescribe, dispense and administer drugs and therapeutic or corrective measures consistent with the prescriptive authority collaborative agreement and relevant to the CRNP's specialty from the following categories:

(1) Antihistamines.

(2) Anti-infective agents.

(3) Antineoplastic agents, unclassified therapeutic agents, devices and pharmaceutical aids.

(4) Autonomic drugs.

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

(6) Cardiovascular drugs.

(7) Central nervous system agents.

(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.

(5) Schedule I controlled substances as defined by section 4 of The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § 780-104).

(d) 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 30-day supply as identified in the collaborative agreement.

(2) A CRNP may prescribe a Schedule III or IV controlled substance for up to a 90 day supply as identified in the collaborative agreement.

(e) A CRNP may not delegate prescriptive authority.

§ 21.284a. Prescribing and dispensing drugs.

(a) *Professional samples.* A CRNP who holds current prescriptive authority approval may request, receive and sign for professional samples and may dispense professional samples to patients.

(b) *Prescriptions.*

(1) Prescriptions must bear the name, title and Pennsylvania CRNP certification number of the CRNP.

(2) When appropriate, the CRNP's National Provider Identifier (NPI) number must appear on the prescription.

(3) Prescriptions may not be presigned.

(c) *Documentation requirements.* When prescribing or dispensing a drug, the CRNP shall document in the patient's medical record the name, amount and dosage of the drug, instructions for taking the drug, the number of refills, the date and the CRNP's name.

(d) *Packaging.* Prescription drugs shall be dispensed in accordance with Federal regulations pertaining to packaging. (See 16 CFR Part 1700 (relating to poison prevention packaging).)

(e) *Labeling of dispensed drugs.*

(1) The label on a dispensed drug container must include the name of the drug, using abbreviations if necessary; the quantity; and the name of the manufacturer if the drug is a generic drug. If a CRNP specifically indicates that the name of the drug may not appear on the label, the recognized National drug code number shall be placed on the label if the number is available for the product. The label shall also bear the name and address of the CRNP, the date dispensed, the name of the patient and the directions for use of the drug by the patient.

(2) Drugs that, at the time of their dispensing, have full potency for less than 1 year, as determined by the expiration date placed on the original label by the manufacturer, may only be dispensed with a label that indicates the expiration date. The label must include the statement, "Do not use after manufacturer's expiration date," or similar wording.

(f) *Compliance with regulations relating to prescribing, administering, dispensing, packaging and labeling of drugs.* A CRNP shall comply with this section, § 21.284b (relating to prescribing, administering and dispensing controlled substances) and regulations of the Department of Health in 28 Pa. Code §§ 25.51—25.58, 25.61—25.63, 25.72, 25.81 and 25.91—25.95.

§ 21.284b. Prescribing, administering and dispensing controlled substances.

(a) A CRNP authorized to prescribe or dispense, or both, controlled substances shall register with the Drug Enforcement Administration.

(b) A CRNP shall carry out the following minimum standards when prescribing, administering or dispensing controlled substances:

(1) *Initial evaluation.* In a health care facility regulated by the Department of Health, the Department of Public Welfare or the Federal government, an initial medical history shall be taken and an initial physical examination shall be conducted to the extent required by the Department of Health in 28 Pa. Code (relating to health and safety) or Department of Public Welfare in 55 Pa. Code (relating to public welfare) or the Federal government in appropriate Federal regulations, whichever is applicable, and bylaws of the health care facility and its medical staff. In other practice settings, before commencing treat-

ment that involves prescribing, administering or dispensing a controlled substance, an initial medical history shall be taken and an initial physical examination shall be conducted unless emergency circumstances justify otherwise. Alternatively, medical history and physical examination information recorded by another health care provider may be considered if the medical history was taken and the physical examination was conducted within the immediately preceding 30 days. The physical examination must include an evaluation of the heart, lungs, vital signs, pain level, and body functions that relate to the patient's specific complaint.

(2) *Reevaluations.* Among the factors to be considered in determining the number and frequency of follow-up evaluations that should be recommended to the patient are the condition diagnosed, the controlled substance involved, expected results and possible side effects. For chronic conditions, periodic follow-up evaluations shall be recommended to monitor the effectiveness of the controlled substance in achieving the intended results.

(3) *Patient counseling.* Appropriate counseling shall be given to the patient regarding the condition diagnosed and the controlled substance prescribed, administered or dispensed. Unless the patient is in an inpatient care setting, the patient shall be specifically counseled about dosage levels, instructions for use, frequency and duration of use and possible side effects.

(4) *Medical records.* In a health care facility regulated by the Department of Health, the Department of Public Welfare or the Federal government, information pertaining to the prescription, administration or dispensation of a controlled substance shall be entered in the medical records of the patient and the health care facility under 28 Pa. Code or 55 Pa. Code or appropriate Federal regulations, whichever is applicable, and bylaws of the health care facility and its medical staff. In other practice settings, certain information shall be recorded in the patient's medical record on each occasion when a controlled substance is prescribed, administered or dispensed. This information must include the name of the controlled substance, its strength, the quantity and the date it was prescribed, administered or dispensed. On the initial occasion when a controlled substance is prescribed, administered or dispensed to a patient, the medical record must also include a specification of the symptoms observed and reported, the diagnosis of the condition for which the controlled substance is being given and the directions given to the patient for the use of the controlled substance. If the same controlled substance continues to be prescribed, administered or dispensed, the medical record must reflect changes in the symptoms observed and reported, in the diagnosis of the condition for which the controlled substance is being given and in the directions given to the patient.

(5) *Emergency prescriptions.* In the case of an emergency contact by a known patient, a prudent, short-term prescription for a controlled substance may be issued. Neither a refill nor a consecutive issuance of this emergency prescription may be given unless a physical examination and evaluation of the patient are first conducted. The results of this examination and evaluation must be set forth in the patient's medical record together with the diagnosis of the condition for which the controlled substance is being prescribed. An emergency oral prescription for a Schedule II controlled substance shall be covered by a written prescription delivered to the pharmacist within 72 hours. In certain health care facilities regulated by the Department of Health, the Department of Public Welfare and the Federal government, an order for the immediate, direct administration of a Schedule II controlled substance to a patient is not considered a prescription and is, therefore, not subject to the requirements in this paragraph. Further information regarding this exclusion can be found in The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. §§ 780-101—780-144) and 28 Pa. Code Chapter 25 (relating to controlled substances, drugs, devices, and cosmetics).

(c) This section establishes minimum standards for the prescription, administration and dispensation of controlled substances by a CRNP. This section does not restrict or limit the application of The Controlled Substance, Drug, Device and Cosmetic Act or of another statute or regulation, and does not relieve a CRNP from complying with more stringent standards that may be imposed by another statute or regulation, or policy of the CRNP's employer or facility in which the CRNP is employed.

(d) Compliance with this section will not be treated as compliance with the standards of acceptable and prevailing practice as a CRNP when medical circumstances require that the CRNP exceed the requirements of this section.

§ 21.285. Prescriptive authority collaborative agreements.

(a) The prescriptive authority collaborative agreement between a physician and a CRNP who will prescribe and dispense drugs and other medical therapeutic or corrective measures, as set forth in § 21.283(a) (relating to authority and qualifications for prescribing, dispensing and ordering drugs) must satisfy the following requirements. The agreement must:

(1) Be in writing, identify the parties, including the collaborating physician, the CRNP, and at least one substitute physician who will provide collaboration if the collaborating physician is unavailable, include the signature of the CRNP and the collaborating physician, and contain the date that the agreement is signed and the date that the agreement is effective.

(2) Identify the specialty in which the CRNP is certified.

(3) Identify the categories of drugs from which the CRNP may prescribe or dispense in accordance with section 8.3 (a)(2)(ii) of the act (63 P. S. § 218.3(a)(2)(ii)).

(4) Specify the circumstances and how often the collaborating physician will personally see the patient.

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

(6) Be made available for inspection to anyone who requests it and be provided, without charge, to any licensed pharmacist or pharmacy upon request.

(7) Be reviewed and updated by the parties at least once every 2 years or whenever the agreement is changed.

(8) Specify the amount of professional liability insurance that covers the CRNP.

(b) The CRNP shall notify the Board, in writing, whenever a prescriptive authority collaborative agreement is updated or terminated, and, when appropriate, shall file the "Change Of Prescriptive Authority Collaborative Agreement" form and the amended prescriptive authority collaborative agreement with the Board and pay the fee set forth in § 21.253 (relating to fees).

§ 21.286. Identification of the CRNP.

(a) A CRNP shall comply with State, Federal and facility regulations regarding identification of personnel.

(b) The listing of a CRNP in an advertisement or publicly displayed sign shall identify CRNPs who use the designation "Dr." as CRNPs by using the title CRNP following the individual's name.

§ 21.287. (Reserved).

§ 21.288. CRNP standards of conduct.

A CRNP shall undertake a specific practice or procedure only if the CRNP has the necessary knowledge, preparation, experience and competency to properly execute the practice or procedure and the practice is within the scope of the CRNP's specialty and consistent with the CRNP's collaborative agreement. A CRNP shall comply with § 21.18 (relating to standards of nursing conduct).

§ 21.291. (Reserved).

§ 21.292. (Reserved).

§ 21.293. (Reserved).

§ 21.294. (Reserved).

§ 21.311. (Reserved).

§ 21.321. (Reserved).

MAINTENANCE OF CERTIFICATION

§ 21.331. Biennial renewal of certification.

(a) The certification, and prescriptive authority approval, if applicable, of a CRNP will expire at the same time as the CRNP's registered nurse license as provided in § 21.29 (relating to expiration and renewal of license).

(b) Notice of application for renewal will be forwarded biennially to each active CRNP at the CRNP's address of record with the Board prior to the expiration date of the current biennial period.

(c) As a condition of biennial renewal, a CRNP shall:

(1) Renew the CRNP's registered nurse license.

(2) Verify completion of a minimum of 30 hours of Board-approved continuing education in the 2 years prior to renewal. As a condition of biennial renewal of prescriptive authority approval, a CRNP shall complete a minimum of 16 of the 30 hours of Board-approved continuing education in pharmacology in the 2 years prior to renewal.

(3) Demonstrate current National certification, if the CRNP was certified by the Board after February 7, 2005

(4) Pay the required biennial renewal fee set forth in § 21.253 (relating to fees).

(5) Verify compliance with section 8.7 of the act (63 P. S. § 218.7) regarding liability coverage.

(d) Any written communication with the Board must be typed or printed and include the CRNP's full name, including former names, the current address and certification number.

§ 21.332. Requirement of continuing education.

(a) A CRNP shall comply with this section and §§ 21.332a—21.337.

(b) Continuing education requirements shall be completed each biennial renewal cycle.

(1) A CRNP who does not meet the continuing education requirements for a biennial period will be subject to formal disciplinary action under section 14(a)(3) of the act (63 P. S. 244(a)(3)).

(2) The Board may waive the requirements of continuing education in cases of illness or undue hardship. It is the duty of each CRNP who seeks a waiver to notify the Board in writing and request the waiver at least 90 days prior to the end of the renewal period. The Board will grant, deny or grant in part the request for waiver.

(3) A CRNP who requests a waiver may not prescribe or dispense drugs after the expiration of his current prescriptive authority until the Board grants the waiver request or the prescriptive authority approval has been renewed.

§ 21.332a. Inactive status and reactivation.

(a) A CRNP who places his certification on inactive status is not required to meet the continuing education requirements in section 8.1(c) of the act (63 P. S. § 218.1(c)) during the period the certification is on inactive status. Upon application for reactivation of certification, the CRNP shall show proof of meeting the continuing education requirements for the biennial period immediately preceding the request for reactivation, and, if the certification has been lapsed or on inactive status for 5 years or longer, the CRNP must have a current, active professional nurse license, reactivated in accordance with the continued competency requirements in § 21.30a (related to continued competency), and at least one of the following:

(1) Proof of current National certification in the specialty in which the nurse is seeking reactivation, if the CRNP is subject to section 8.1(b) of the act.

(2) Evidence that the applicant has practiced as a nurse practitioner in another jurisdiction at some period of time within the last 5 years under a current license or certification during that time.

(b) A CRNP who places his prescriptive authority approval on inactive status for less than 3 years is not required to meet the continuing education requirements in § 21.332(b)(2) (relating to requirement of continuing education) during the period the prescriptive authority approval is on inactive status. Upon application for reactivation of prescriptive authority approval, the CRNP shall show proof of meeting the continuing education requirements for the biennial period immediately preceding the request for reactivation.

(c) A CRNP who places his prescriptive authority approval on inactive status for 3 years or longer or whose prescriptive authority approval is lapsed for 3 years or longer, may reactivate the prescriptive authority approval by meeting one of the following conditions:

(1) Complete the requirement in § 21.283(b)(1) (relating to authority and qualifications for prescribing, dispensing and ordering drugs) by taking at least 45 hours of course work in advanced pharmacology.

(2) Provide evidence to the Board that:

(i) The CRNP has practiced, for at least 1 of the last 3 years, as a CRNP with prescriptive authority in another jurisdiction.

(ii) The scope of the prescriptive authority in the other jurisdiction is equivalent to prescriptive authority in this Commonwealth.

(iii) The CRNP was required, as a condition for continued practice in the other jurisdiction, to complete continu-

ing education that is substantially equivalent to the requirements of § 21.283(b)(1).

(iv) The CRNP met the continuing education requirements of the other jurisdiction within 1 year of the request for reactivation of prescriptive authority.

(d) A CRNP whose certification has been suspended for 5 years or longer shall meet the requirements in § 21.332(b), and any other requirements set forth by Board order. A CRNP whose prescriptive authority approval has been suspended for 3 years or longer shall, in addition to meeting the requirements to renew the CRNP certification, meet the requirements in subsection (c), and any other requirements set forth by Board order.

(e) A CRNP whose certification has been revoked shall meet all of the requirements for certification in § 21.271(a) (relating to certification requirements), the requirements in § 21.332(b), and any other requirements set forth by Board order. A CRNP whose prescriptive authority approval has been revoked shall, in addition to meeting the requirements to reinstate the CRNP certification, meet the requirements in subsection (c), and any other requirements by Board order.

§ 21.333. Continuing education content.

(a) Continuing education activities must address the CRNP's specialty.

(b) Pharmacology continuing education activities must provide the knowledge and skills to understand the pharmacokinetics and pharmacodynamics of broad categories of drugs or drugs used in the CRNP's specialty and to analyze the relationship between pharmacologic agents and physiologic/pathologic responses.

§ 21.334. Sources of continuing education.

(a) The following providers of continuing education and credentialing organizations have currently met the standards for approval for continuing education. Therefore, all activities offered by these providers are approved for continuing education hours required for biennial license renewal.

(1) Board-approved CRNP educational programs and CRNP educational programs approved by other state boards of nursing or that hold current accreditation issued by a National nursing accreditation organization.

(2) National and international nursing organizations and their state and local affiliates.

(3) National and international medical and osteopathic organizations and their state and local affiliates.

(4) National pharmaceutical organizations and their state and local affiliates.

(5) National nursing specialty organizations.

(6) Continuing education programs approved by other state boards of nursing for advanced practice nurses or nurse practitioners.

(b) CRNPs may obtain hours for continuing education activities offered by providers not indicated in subsection (a)(1)—(6) if the provider receives approval of the activity under § 21.336 (relating to continuing education course approval) prior to its implementation.

(c) CRNPs may obtain credit for continuing education hours on an individual basis if the CRNP, prior to attendance at the course, obtains Board approval by submitting a request for course approval and supporting documentation listed in § 21.336(b).

(d) CRNPs may obtain credit for correspondence courses, taped study courses and other independent study courses if the course is Board approved.

(e) Up to 4 hours will be credited for service as a teacher, preceptor, lecturer or speaker and for publication in a refereed journal or other scholarly publication relating to pharmacology or the CRNP's area of practice. Application shall be made prior to the service or within 90 days of the publication to assure that the Board will approve the service or publication and to allow the Board to determine the number of contact hours that will be granted.

(f) An hour for purposes of nurse practitioner continuing education is 50 minutes.

PENALTIES FOR VIOLATION

§ 21.351. Penalties for violation.

Certification as a CRNP may be suspended, revoked or otherwise restricted or subjected to remedial measures when, after notice and opportunity to be heard, the Board finds that:

(1) The CRNP has engaged in the performance of medical functions and tasks beyond the scope of practice permitted for a CRNP, beyond the scope of the CRNP's specialty, or in violation of the CRNP's collaborative agreement, as provided in the act and this subchapter.

(2) The CRNP has performed a medical task or function which the CRNP does not have the necessary knowledge, preparation, experience and competency to perform properly or is not qualified under the act and this subchapter to perform.

(3) The CRNP has violated the act or this subchapter, or engaged in any conduct prohibited for professional nurses.

[Pa.B. Doc. No. 09-2276. Filed for public inspection December 11, 2009, 9:00 a.m.]

STATE BOARD OF PHARMACY
[49 PA. CODE CH. 27]
Pharmacist Breaks

The State Board of Pharmacy (Board) amends §§ 27.11 and 27.16 (relating to pharmacy permit and pharmacist manager; and construction and equipment requirements) to read as set forth in Annex A.

Description and Need for the Rulemaking

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

another area of the retail store. This has put retail establishments at a disparity with the more traditional drug stores.

The Board proposed to amend § 27.11(c) to state that the prescription area of a pharmacy may not be open without a licensed pharmacist on duty at all times. This would clarify that the retail area in a traditional drug store where the whole building is licensed as a pharmacy may still be open when the prescription area is closed. The prescription area is already defined in § 27.1 (relating to definitions) as the area of the pharmacy used for compounding, legend drug storage and other activities necessary to the practice of pharmacy. The term "prescription area" does not include waiting counters or display space attached to the waiting counters.

The Board also proposed to amend § 27.11(c) to allow a sole pharmacist on duty in a pharmacy to take up to a 30-minute break. The proposed amendment would not affect multiple pharmacists on duty taking staggered breaks. If only one pharmacist is on duty the pharmacist must remain in the building containing the pharmacy during the break. For pharmacies where the entire building is licensed this would not change current practice. However for pharmacies located in large retail establishments and institutions, the pharmacist shall remain in the immediate building. The term "immediate building" is defined as the physical structure that contains the pharmacy. For example in a large retail, wholesale or grocery store, the pharmacist shall remain in that store. In an institution, the pharmacist shall remain in the building containing the pharmacy, so that in institutions on a campus with multiple buildings, the pharmacist could not go to another building during his break. Pharmacies located in malls are not included in the class of pharmacies that only have a portion of the store licensed, as those pharmacies are typically the traditional retail pharmacy where the entire store is licensed. If a large retail establishment with a pharmacy inside is attached to a mall then the restriction that the pharmacist shall remain in the retail establishment applies. The pharmacist should not leave the store to go into the mall while the pharmacy remains open.

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

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

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

Summary of Comments and Responses to Proposed Rulemaking

The Board published notice of proposed rulemaking at 38 Pa.B. 351 (January 19, 2008) with a 30-day public comment period. The Board received comments from the Pennsylvania Pharmacists Association (PPA), but from no other members of the public. The Board received comments from the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC) as part of their review of proposed rulemaking under the Regulatory Review Act (71 P. S. §§ 745.1—745.12). The Board did not receive any comments from the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC).

The PPA supported the proposed rulemaking.

The HPLC first questioned whether a break of 30 minutes is consistent with labor law and policies of the large pharmacies. The HPLC, joined by IRRC, also questioned whether the break was a single break or multiple breaks totaling up to 30 minutes throughout the entire shift. This rulemaking does not set standards for how often or for how long a pharmacy may or must permit a pharmacist to go on break; rather it provides the opportunity for a pharmacy to remain open when the sole pharmacist on duty is on a break of 30 minutes or less. Therefore, the amendment will not conflict with labor laws or policies.

The HPLC also questioned what protocol should be followed for requested counseling during a pharmacist's break. Would a customer seeking counseling from a pharmacist be expected to wait until the pharmacist returned from break, or would the pharmacist have to cut the break short. Proposed § 27.11(c)(1) provides that the pharmacist "shall be accessible for emergencies or for counseling, if requested." The implication of this provision is that the pharmacist would return to the prescription area as needed during this period.

The Board has not found a need to revise its rulemaking in response to the comments. However, in the course of reviewing these comments, the Board noticed that the phrase "while working in a pharmacy" in § 27.11(c) was not consistent with the language of the general rule of that section. Accordingly, the Board has replaced this phrase with "while the pharmacy is open."

Fiscal Impact and Paperwork Requirements

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

Effective Date

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

Statutory Authority

The final-form rulemaking is authorized under sections 4(2) and 6(k)(1) and (9) of the Pharmacy Act (act) (63 P. S. §§ 390-4(j), 390-6(k)(1) and (9)).

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on January 9, 2008, the Board submitted a copy of the notice of proposed rulemaking, published at 38 Pa.B. 351, to IRRC and the HPLC and the SCP/PLC for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC, the HPLC and the SCP/PLC were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Board has considered all comments received from IRRC, the HPLC, the SCP/PLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on October 7, 2009, the final-form rulemaking was approved by the HPLC. On November 4, 2009, the final-form rulemaking was deemed approved by the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on November 5, 2009, and approved the final-form rulemaking.

Additional Information

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

Findings

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) and regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2 (relating to notice of proposed rulemaking required; and adoption of regulations).

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

(3) The amendments to this final-form rulemaking do not enlarge the scope of proposed rulemaking published at 38 Pa.B. 351.

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

Order

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

(a) The regulations of the Board, 49 Pa. Code Chapter 27, are amended, by amending §§ 27.11 and 27.16 to read as set forth in Annex A.

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

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

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

MICHAEL A. PODGURSKI, R.Ph.,
Chairperson

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 39 Pa.B. 6705 (November 21, 2009).)

Fiscal Note: Fiscal Note 16A-5420 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 27. STATE BOARD OF PHARMACY

STANDARDS

§ 27.11. Pharmacy permit and pharmacist manager.

(a) A permit to conduct a pharmacy issued under section 4 of the act (63 P. S. § 390-4) shall show the name and address of the pharmacy, the name of the current owner and the name of the current pharmacist manager.

(b) A pharmacy may not display, advertise or use any name other than the name in which it is registered.

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

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

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

(i) The receipt of new written prescriptions.

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

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

(d) A change in name or ownership or controlling interest of the pharmacy shall require a new permit. Applications for new permits shall be filed within 30 days of the change in name, ownership or controlling interest.

(e) A person or entity holding a certificate, license, permit or registration as a licensed pharmacist or pharmacy may not post or display in public view a current certificate, license, permit, registration or renewal of a person not lawfully employed by the licensee.

(f) A pharmacy which closes or otherwise ceases operation shall immediately return to the Board its current permit and shall immediately inform the Board of the disposition of the prescription files and nonproprietary drugs. After 30 days, neither prescription files nor nonproprietary drugs may be sold, transferred or disposed of without prior permission from the Board. When a pharmacy closes or ceases operation, signs, symbols or other indications of a pharmacy shall immediately be removed from both the interior and exterior of the premises.

(g) If the pharmacist manager ceases to hold that position, the pharmacy permit holder shall inform the Board in writing of this fact and of the new pharmacist manager not more than 15 days later. If the Board does not object within 30 days of notification, the new pharmacist manager may be deemed approved. If the permit holder is unable to replace the pharmacist manager within those 15 days, the permit holder may request in writing an extension of up to 30 additional days to obtain a replacement. A pharmacy may not operate without a pharmacist manager for more than 15 days unless the pharmacy first obtains from the Board an extension of time for obtaining a replacement.

(h) A pharmacist may not serve as the pharmacist manager of more than one pharmacy at any given time. The holder of a permit to operate a pharmacy which has

lost the services of a pharmacist manager and cannot obtain a suitable replacement may apply in writing to the Board for a temporary waiver of this subsection. The Board may grant a waiver which would authorize a pharmacist manager to serve as pharmacist manager of more than one pharmacy for up to 60 days after the initial 15 days permitted under subsection (g).

(i) Each pharmacy in this Commonwealth will require a separate permit regardless of ownership unless the pharmacy is a satellite pharmacy as defined in § 27.1 (relating to definitions).

§ 27.16. Construction and equipment requirements.

(a) *Approval of plans*. The following requirements are applicable to approval of plans:

(1) *New pharmacy or change-of-location*. Plans for construction of a new pharmacy or new location for an existing pharmacy may be submitted to the Board for approval prior to proceeding with construction. Within 90 days of receiving the plans, the Board will notify the applicant of its approval of the planned pharmacy or of its disapproval and the reasons for disapproval. The plans, including dimensions, must demonstrate compliance with applicable regulations and show the layout and fixtures for the prescription area and the immediately adjacent area.

(2) *Alterations*. The practice of pharmacy shall cease while substantial alterations in the layout or fixtures of an approved pharmacy are being made unless:

(i) The pharmacy makes the alterations and takes adequate precautions so that the health and safety of professionals, employees and the public is protected during the continuing operation of the pharmacy.

(ii) The plans for the alterations and a description of the precautions are submitted to the Board at least 30 days before the beginning of alteration work. If the Board raises no objection during that time, the pharmacy is authorized to proceed with the alterations as planned.

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

(1) *Minimum size*.

(i) The minimum size of the prescription area must be at least 250 square feet, and must be large enough, considering the level of activity, to carry on the practice of pharmacy in a manner that protects the health and safety of professionals, employees and the public. Within the prescription area, there must be a prescription working counter of at least 10 linear feet in length and 2 linear feet in width. If more than two pharmacists are on duty simultaneously, the minimum counter length shall be increased by 5 linear feet for an additional pharmacist. Institutions with special considerations may apply to the Board for a waiver.

(ii) A pharmacy operating as a central processing center need not conform to the minimum space requirements in subparagraph (i).

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

(i) The pharmacy can be securely sealed off from the remainder of the retail establishment.

(ii) The barrier devices which seal off the pharmacy must be capable of providing security for the pharmacy. The barrier devices must reach from floor to ceiling, shall be impenetrable by hand or the use of a reach extender, and be securely locked whenever a licensed pharmacist is not present and on duty.

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

(iv) Safes, electrical equipment or other facilities of the retail establishment may not be located in or approached through the pharmacy unless a pharmacist is on duty whenever staff from the retail establishment need access to these facilities.

(v) The hours of the pharmacy shall be posted at all points of public access.

(vi) Protocols for access to the pharmacy when it is closed by nonpharmacist staff for bona fide emergencies, such as fires, natural disasters or police matters, must include notification to the pharmacist manager.

(3) *Locked compartment*. Space shall be provided in the prescription area for a substantially constructed cabinet or safe to contain controlled substances unless the pharmacy disperses controlled substances throughout the stock of noncontrolled substances in a manner that obstructs the theft of controlled substances. If the pharmacy stocks Schedule I controlled substances, these substances shall be stored in a securely locked, substantially constructed cabinet or safe.

(4) *Telephone*. At least one telephone shall be accessible in the prescription area, and the telephone number must be the telephone number printed on the prescription label.

(5) *Sanitary facilities*. Except for pharmacies operating as central processing centers, pharmacies shall be equipped with a sink within the prescription area to be used solely for pharmaceutical purposes. The sink must be connected properly to supply hot and cold water. Restroom facilities for employees of the pharmacy shall be provided reasonably close to, but outside of the prescription area.

(6) *Lighting and ventilation*. The pharmacy must be well lighted and ventilated.

(7) *Television set*. A television set may not be placed within the prescription area or so situated in the pharmacy that its viewing screen may be seen when looking at it from within the prescription area.

(8) *Physical arrangement*. The prescription area must be arranged so that prescription drugs and devices are inaccessible to an unlicensed or unauthorized person. The prescription area may not be used for storage of merchandise or other items other than those used in the preparation, dispensing or delivery of drugs. Animals may not be allowed in a prescription area except for security reasons.

(9) *Existing pharmacies*. Existing pharmacies licensed by the Board prior to the effective date of this chapter may continue if they reasonably conform, or are made to reasonably conform, to the intent of this chapter. The Board will determine what constitutes reasonable conformity consonant with the public interest, health, safety and welfare.

[Pa.B. Doc. No. 09-2277. Filed for public inspection December 11, 2009, 9:00 a.m.]

Title 58—RECREATION

FISH AND BOAT COMMISSION

[58 PA. CODE CH. 69]

Fishing in Lake Erie and Boundary Lakes

Corrective Amendment to 58 Pa. Code § 69.12(f)

The Fish and Boat Commission has discovered a discrepancy between the agency text of 58 Pa. Code § 69.12(f) (relating to seasons, sizes and creel limits—Lake Erie and Lake Erie tributaries), as deposited with the Legislative Reference Bureau, and the official text published at 39 Pa.B. 1860, 1865 and 1866 (April 11, 2009) and codified in the June 2009 *Pennsylvania Code Reporter* (Master Transmittal Sheet No. 415) and as currently appearing in the *Pennsylvania Code*. The table in § 69.12(f) was printed incorrectly.

Therefore, under 45 Pa.C.S. § 901: The Fish and Boat Commission has deposited with the Legislative Reference Bureau a corrective amendment to 58 Pa. Code § 69.12(f). The corrective amendment to 58 Pa. Code § 69.12(f) is effective as of April 11, 2009, the date the defective text in § 69.12(f) was printed in the *Pennsylvania Bulletin*.

The correct version of 58 Pa. Code § 69.12(f) appears in Annex A, with ellipses referring to the existing text of § 69.12.

Annex A

TITLE 58. RECREATION

PART II. FISH AND BOAT COMMISSION

Subpart B. FISHING

CHAPTER 69. FISHING IN LAKE ERIE AND BOUNDARY LAKES

Subchapter B. SPORT FISHING AND ANGLING

§ 69.12. Seasons, sizes and creel limits—Lake Erie and Lake Erie tributaries.

* * * * *

(f) Subject to the provisions of subsections (d) and (e), the following seasons, sizes and creel limits apply to Lake Erie, Lake Erie tributaries and Presque Isle Bay, including peninsula waters:

SPECIES	*SEASONS*	*MINIMUM SIZE*	*DAILY LIMIT*
MUSKELLUNGE and MUSKELLUNGE HYBRIDS	Inland seasons apply. See § 61.1 (relating to Commonwealth inland waters).	40 inches	1
PIKE Northern	Inland seasons apply. See § 61.1 (relating to Commonwealth inland waters).	24 inches	2
WALLEYE	January 1 to midnight March 15 and 12:01 a.m. the first Saturday in May to December 31.	15 inches	6
BASS Largemouth Smallmouth	January 1 to first Saturday after April 11 and first Saturday after June 11 until December 31.	15 inches	4 (combined species)
	First Saturday after April 11 until first Saturday after June 11.*	20 inches	1
TROUT and SALMON	First Saturday after April 11 until midnight Labor Day.	9 inches	5 (combined species only 2 of which may be lake trout).
	12:01 a.m. the day after Labor Day until midnight on the Friday before the first Saturday after April 11.	15 inches	3 (combined species only 2 of which may be lake trout).
STURGEON	No open season	ENDANGERED SPECIES	
YELLOW PERCH	From December 1 through March 31	7 inches	30

SPECIES	*SEASONS*	*MINIMUM SIZE*	*DAILY LIMIT*
	From April 1 through November 30	None	30
SUNFISH, CRAPPIES, CATFISH, ROCK BASS, SUCKERS, EELS, CARP, WHITE BASS	Open year-round	None	50 (combined species)
BURBOT (when taken by hook and line)	Open year-round	None	5
BURBOT (when taken by scuba divers by use of nonmechanical spears or gigs at a depth of at least 60 feet)	June 1 to September 30	None	5
SMELT (when taken by hook and line)	Open year-round	None	None
BAIT FISH FISH BAIT	Open year-round	None	50 (combined species)
ALL OTHER SPECIES	Inland Regulations apply. (See § 61.1.)		

* It is unlawful to conduct or participate in a fishing tournament (as defined in § 63.40 (relating to seasons for fishing tournaments)) for bass on Lake Erie, Lake Erie tributaries or Presque Isle Bay during the period from the first Saturday after April 11 until the first Saturday after June 11.

[Pa.B. Doc. No. 09-2278. Filed for public inspection December 11, 2009, 9:00 a.m.]

PENNSYLVANIA GAMING CONTROL BOARD

[58 PA. CODE CHS. 401a, 435a AND 441a]

Employee Revisions and Pennsylvania Race Horse Development Fund

The Pennsylvania Gaming Control Board (Board), under the general authority in 4 Pa.C.S. § 1202(b)(30) (relating to general and specific powers) and specific authority in 4 Pa.C.S. §§ 1311, 1311.1, 1311.2, 1321 and 1406, amends Chapters 401a, 435a and 441a to read as set forth at 39 Pa.B. 3459 (July 11, 2009).

Purpose of the Final-Form Rulemaking

The final-form rulemaking makes minor revisions to provisions related to employees to improve the clarity and effectiveness of the Board's regulations. It also revises the time frame within which distributions of funds received by Category 1 slot machine licensees from the Pennsylvania Race Horse Development Fund must be made.

Explanation of Amendments to Chapters 401a, 435a and 441a

In § 401a.3 (relating to definitions), the definition of "gaming employee" has been amended to include employees of certified vendors whose duties require the employee to be on the gaming floor or in a restricted area. This makes the definition consistent with the existing requirement pertaining to these employees in § 437a.7(b) (relating to registered and certified vendor responsibilities).

In § 435a.1 (relating to general provisions), a new subsection (n) has been added which requires licensees and certified vendors to contact the Bureau of Licensing to verify that the license, permit or registration of an individual who currently holds a license, permit or registration is still valid before the individual is allowed to work in a licensed facility. Licenses, permits and registrations are not licensed facility specific. This allows the individuals to seek employment at other licensed facilities without having to obtain a new license, permit or registration. Requiring licensees and certified vendors to contact the Bureau of Licensing will insure that an individual's license, permit or registration is in good standing.

In § 441a.18 (relating to employee status report), subsection (b) has been amended to require that the monthly status report prepared by a slot machine licensee also include the expiration date of the license or permit held by employees who hold a license or a permit. This is being done so that the slot machine licensees can more easily track when renewal applications should be filed by these employees.

Section 441a.19 (relating to notice of employee misconduct and offenses and employee resignations) has been amended to simplify the process for reporting terminations of slot machine licensee's employees. Currently, slot machine licensees must report individual terminations within 5 days. This has resulted in slot machine licensees having to file multiple reports throughout any given week. By changing to weekly reporting, slot machine licensees will have to make fewer filings and will be less likely to inadvertently fail to report a termination.

In § 441a.22 (relating to Category 1 slot machine licensees), subsection (b)(3)(i) and (ii) has been amended. Currently, these subparagraphs require the transfer of funds received for purses or health and pension benefits to occur within 36 hours of receipt. However, if the funds are received late in the day prior to a weekend or holiday, slot machine licensees have sometimes not been able to comply with the 36-hour requirement. To remedy this problem, the language in both of these subparagraphs has been changed to require that the transfer of funds be completed by the close of the next business day.

Comment and Response Summary

Notice of proposed rulemaking was published at 39 Pa.B. 3459.

During the public comment period, the Board did not receive any public comments. By letter dated September

9, 2009, the Independent Regulatory Review Commission (IRRC) notified the Board that it had no comments, recommendations or objections to the proposed rulemaking.

The Board has made no changes to the proposed amendments in the final-form version of this rulemaking.

Affected Parties

This final-form rulemaking will affect slot machine licensees, manufacturers, manufacturer designees, suppliers and certified vendors.

Fiscal Impact

Commonwealth

Under this final-form rulemaking, the Bureau of Licensing will have to respond to additional inquiries from licensees and certified vendors seeking to confirm the status of individuals who were employed by another licensee or certified vendor. The Bureau of Licensing will also receive fewer employee termination reports. Neither of these changes is anticipated to have any significant fiscal impact on the Board.

Political Subdivisions

This final-form rulemaking will have no fiscal impact on political subdivisions of this Commonwealth.

Private Sector

Slot machine licensees, manufacturers, manufacturer designees, suppliers and certified vendors will have to verify the status of new employees that already hold a license, permit or registration. However, the Board intends to allow the verification to be done by telephone or email, so the costs associated with completing these verifications should be minimal.

The change in the timing for slot machine licensees to transfer funds received for purses or health and pension benefits will eliminate the potential for any sanctions related to noncompliance with the existing requirement.

General Public

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

Paperwork Requirements

This final-form rulemaking will result in a reduction in the number of termination reports that will have to be filed by slot machine licensees and reviewed by the Bureau of Licensing.

Effective Date

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

Contact Person

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

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on June 29, 2009, the Board submitted a copy of this proposed rulemaking, published at 39 Pa.B. 3459 and a copy of the Regulatory Analysis Form to IRRC and to the House Gaming Oversight Committee and the Senate Community, Economic and Recreational Development Committee (Committees).

Under section 5(c) of the Regulatory Review Act, IRRC and the Committees were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Board has considered all comments received from IRRC, the Committees and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), the final-form rulemaking was deemed approved by the Committees on November 4, 2009. Under section 5(g) of the Regulatory Review Act (71 P. S. § 745.5a(e)) the final-form rulemaking was deemed approved by IRRC, effective November 4, 2009.

Findings

The Board finds that:

(1) Public notice of intention to adopt these amendments 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 thereunder, 1 Pa. Code §§ 7.1 and 7.2 (relating to notice of proposed rulemaking required; and adoption of regulations).

(2) The final-form rulemaking is necessary and appropriate for the administration and enforcement of 4 Pa.C.S. Part II (relating to gaming).

Order

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

(a) The regulations of the Board, 58 Pa. Code Chapters 401a, 435a and 441a, are amended by amending §§ 401a.3, 435a.1, 441a.18, 441a.19 and 441a.22 to read as set forth at 39 Pa.B. 3459.

(b) The Chairperson of the Board shall certify this order and 39 Pa.B. 3459 and deposit them with the Legislative Reference Bureau as required by law.

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

GREGORY C. FAJT,
Chairperson

Fiscal Note: Fiscal Note 125-104 remains valid for the final adoption of the subject regulations.

[Pa.B. Doc. No. 09-2279. Filed for public inspection December 11, 2009, 9:00 a.m.]