

PROPOSED RULEMAKING

DEPARTMENT OF AGRICULTURE

Advance Notice of Proposed Rulemaking

The Department of Agriculture (Department) hereby gives advance notice of its intention to amend its regulations relating to animals and animal health. These regulations currently appear in 7 Pa. Code Part I (relating to Bureau of Animal Industry). The planned amendments are necessitated, in part, by 23 Pa.C.S. §§ 2301—2389 (relating to the Domestic Animal Law), which became effective on September 9, 1996, and which substantially revised, expanded and updated the Department's authority with respect to domestic animals.

Although section 2382(b) of the Domestic Animal Law allows the Department to enforce its current animal health regulations to the extent they are not inconsistent with that law, the Department seeks to accomplish the amendment of these regulations at the earliest date practicable. The Department is particularly interested in those regulatory provisions dealing with the prevention, detection, containment and elimination of transmissible disease of domestic animals.

The Department intends to accomplish this regulatory amendment by rescinding its regulations and supplanting them with entirely new regulatory provisions. The forthcoming regulations will be more logically-organized, succinct and user friendly.

Proposed Format

The Department's initial plan is to organize its regulatory authority with respect to domestic animals into five basic subparts, addressing the following general subjects:

Subpart A. General Provisions

Subpart B. Prevention of Dangerous Transmissible Diseases of Domestic Animals

Subpart C. Dangerous Transmissible Disease Elimination

Subpart D. Cooperative Domestic Animal Health Programs

In addition, the Department intends to rescind all of 7 Pa. Code Chapter 1 (relating to meat hygiene), since its underlying statutory authority, the Pennsylvania Meat and Poultry Hygiene Law of 1968 (31 P.S. §§ 483.1—483.24), has been preempted by Federal Legislation and regulations.

Public Comments and Contact Person

The Department of Agriculture encourages interested persons to participate in the preparation of the regulatory amendments described in this notice by submitting any suggested regulatory additions, deletions or changes to: Sherbyn Ostrich, Bureau of Animal Health and Diagnos-

tic Services, Department of Agriculture Building, 2301 North Cameron Street, Harrisburg, PA 17110-9408.

SAMUEL E. HAYES, Jr.,
Secretary

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[7 PA. CODE CH. 76] Food Employee Certification

The Department of Agriculture (Department), Bureau of Food Safety and Laboratory Services (Bureau), proposes to adopt Chapter 76 (relating to food employee certification).

These regulations are proposed under authority of the Food Employee Certification Act (act), 3 Pa.C.S. §§ 6503(d) and 6505 (relating to certification advisory board and programs; and rules and regulations) which, respectively: (1) require the Department to adopt food safety protection and training standards for the certification of supervisory employees who are responsible for the storage, preparation, display or serving of food to the public in establishments regulated by the Department or local health organizations; and (2) delegate to the Department the power to adopt regulations necessary for the proper enforcement and administration of the act.

In summary, the act will require most food establishments in this Commonwealth to have at least one supervisory employee who has undergone food safety training and passed a written examination evidencing food safety knowledge. The training programs will be reviewed and approved by the Department. The Department will certify persons to conduct and approve tests and certify the results of these tests to the Department. The Department will issue a certificate to persons who take the required training and pass the required test.

The act was the product of an industry-driven initiative to establish minimum food safety training requirements to be met by at least one supervisory employee in most food establishments in this Commonwealth. These requirements are specific to the category of food establishment involved. Given the industry-driven nature of the act, the Department circulated drafts of the proposed regulations to groups representing a broad cross section of the food industry, and made revisions in response to comments and suggestions from these groups. The Department intends these regulations to establish the least intrusive and least burdensome standards and procedures by which to meet the responsibilities imposed on the Department by the act.

An overview of the major provisions of the proposed regulations follows:

A food establishment need not comply with the requirements of the act until July 1, 2001. Proposed § 76.1 (relating to compliance) restates this effective date, but also emphasizes that it is to a food establishment's advantage to comply in advance of that date. It also restates the statutory provisions exempting certain food establishments from having to comply with the act.

Proposed § 76.2 (relating to definitions) contains definitions from the act and the Food and Drug Administration

Food Code. When practicable, it is the intention of the Department to define terms as they are commonly defined in the food industry and thereby help to develop or preserve a common vocabulary. Numerous terms defined in this section are required topics of instruction in approved certification programs, as described in proposed § 76.7 (relating to certification programs: food safety protection and training standards). Although some sectors of the food industry would prefer the Department not include and define such a large number of terms in the proposed regulations, the Department believes it important to be as specific as possible with respect to the required topics of instruction in a certification program.

Proposed § 76.3 (relating to requirements for food establishments) accomplishes several purposes: it delineates the industry-specific categories of food establishments required under section 6503(d) of the act. It restates the major premise of the act, that a food establishment must employ or designate at least one supervisory employe who is certified under the act with respect to the appropriate industry-specific category of the food establishment. It also sets forth the basic recordkeeping requirements for food establishments, under which the Department can monitor compliance with the act.

Although proposed § 76.4 (relating to eligibility to apply for certification) essentially restates the requirements of the act as set forth in section 6504(b) of the act (relating to certification of employees), it has been the subject of concern among several food industry representatives who were afforded the opportunity to review earlier drafts of the proposed regulation. The act does not allow for those persons who have food safety knowledge and expertise in excess of what would be required under the proposed regulation to be certified under the act without completing a Department-approved training course and passing an examination.

Proposed § 76.5 (relating to certification programs: obtaining the department's approval) sets forth the basic requirements for Departmental approval of a certification program and details the process by which an application for approval may be obtained and submitted.

Proposed § 76.7 (relating to certification programs: food safety protection and training standards) details the minimum content requirements of a certification program.

Proposed § 76.8 (relating to format of a certification examination) requires that a certification examination consist of at least 80 questions. This number corresponds with the number of questions on examinations given in connection with several of the more popular food safety courses offered by industry on a Nationwide basis. The Department believes that—given the various areas of instruction required in a certification program—it is not unreasonable to require a minimum number of questions on a certification examination.

Proposed § 76.9 (relating to reporting results of a certification examination) is intended to ensure the Department and the candidate for certification receive notice of examination scores within a reasonable time after certification examinations are administered.

Proposed § 76.10 (relating to applying for certification) describes the process by which a person may apply for certification, and requires the Department to act on an application within 20 days of receipt.

Proposed § 76.11 (relating to certificate) describes the content of a certificate, the obligation of a person having

possession of a certificate to return it to the Department upon written demand and the requirement a food establishment display the certificate of its certified supervisory employe.

The act requires a certificate be renewed at 5 year intervals, imposes a continuing education requirement on certificateholders and requires the Department approve continuing education courses. These provisions appear in section 6504(f) of the act. Proposed §§ 76.12 and 76.13 (relating to renewal of certification; and obtaining Departmental approval of a continuing education course) set forth recertification requirements and procedures and the procedure for approval of continuing education programs.

Proposed § 76.14 (relating to reciprocity with other states) essentially restates the reciprocity provisions in section 6507 of the act (relating to suspension of certification).

Proposed § 76.15 (relating to suspension or revocation of certification) describes the circumstances under which a certificate can be suspended or revoked, and describes the due process to the afforded persons facing suspension or revocation.

Proposed § 76.17 (relating to preemption and local governmental authority) clarifies that local government food employe certification programs that predate September 1, 1994, may remain in effect and that a local government unit having a program may, at its option, seek Departmental approval of any portion of its program with respect to an industry-specific category of food establishment.

Proposed § 76.19 (relating to civil penalties) repeats the penalty provisions in section 6508 of the act (relating to civil penalties), but clarifies that the Department will afford a food establishment that is assessed a penalty for not having a certified supervisory employe a period of 90 days within which to come into compliance before the Department would again penalize the food establishment for the same violation.

Fiscal Impact

Commonwealth

The proposed regulations would not impose any costs on the Commonwealth or have any fiscal impact upon the Commonwealth beyond those costs and fiscal impacts imposed by the act itself. The act requires the Department devote employe time to the review of proposed training programs, the keeping of required records and other functions. Although the Department will inspect food establishments for compliance, employes of the Department are already charged with the responsibility to inspect and license food establishments. The addition of the inspection responsibilities imposed by the act will not appreciably increase the Department's costs.

Political Subdivisions

The proposed regulations would impose no costs and have no fiscal impact upon political subdivisions.

Private Sector

The proposed regulations will not impose costs or other adverse fiscal consequences beyond those imposed by the act itself. Under the act, most food establishments in this Commonwealth will have to ensure they have at least one certified supervisory employe. Although the food establishment might impose the costs of necessary training on the supervisory employe, it is more likely the food establishment, itself, would incur these costs.

General Public

The proposed regulations would impose no costs and have no fiscal impact upon the general public. Although food establishments may incur some costs in obtaining certification for a supervisory employe, these costs are expected to be modest. In view of this expectation, and the fact that certification is valid for 5 years at a time, it is not likely any costs imposed by the act will measurably impact upon consumers.

Paperwork Requirements

The act requires that the Department issue certificates to supervisory employes who successfully complete an approved training program and pass an examination. It also requires the Department monitor compliance and enforce its provisions. This will certainly result in an increase in paperwork. The proposed regulations, however, do not impose paperwork requirements beyond those imposed by the act itself.

Regulatory Review

The Department submitted a copy of the proposed regulations to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House and Senate Standing Committees on Agriculture and Rural Affairs on June 11, 1997, in accordance with section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)). The Department also provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1982-2, "Improving Government Regulations." A copy of this material is available to the public upon request.

If IRRC has objections to any portion of the proposed regulations, it must so notify the Department within 30 days of the close of the public comment period. The notification shall specify the regulatory review criteria which have not been met by that portion. The Regulatory Review Act sets forth detailed procedures for review of these objections by the Department, the General Assembly and the Governor prior to final publication of the proposed regulations.

Contact Person

Interested persons are invited to submit written comments regarding the proposed regulations within 30 days following publication in the *Pennsylvania Bulletin*. Comments are to be submitted to the Department of Agriculture, Bureau of Food Safety and Laboratory Services, 2301 North Cameron Street, Harrisburg, PA 17110-9408, Attention: Martha M. Melton.

Effective Date

The proposed regulations will become effective upon final adoption.

SAMUEL E. HAYES, Jr.,
Secretary

Fiscal Note: 2-107. (1) General Fund; (2) Implementing Year 1996-97 is \$None; (3) 1st Succeeding Year 1997-98 is \$5,000; 2nd Succeeding Year 1998-99 is \$10,000; 3rd Succeeding Year 1999-00 is \$15,000; 4th Succeeding Year 2000-01 is \$30,000; 5th Succeeding Year 2001-02 is \$30,000; (4) Fiscal Year 1995-96 \$N/A; Fiscal Year 1994-95 \$N/A; Fiscal Year 1993-94 \$N/A; (7) General Government Operations; (8) recommends adoption.

Annex A**TITLE 7. AGRICULTURE****PART IV. BUREAU OF MARKETING****CHAPTER 76. FOOD EMPLOYE CERTIFICATION**

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§ 76.1. Compliance.

(a) *Mandatory compliance.* On or after July 1, 2001, a food establishment shall comply with the act and this chapter, unless it is exempt under subsection (d).

(b) *Interim compliance optional.* A food establishment need not comply with the act or this chapter until July 1, 2001, but is encouraged to do so in advance of that date.

(c) *Benefit of interim compliance.* If a food establishment that voluntarily complies with the act and this chapter is the subject of an action to recover fines or penalties for a violation of the Food Act, and the violation occurs prior to July 1, 2000, the voluntary compliance of the food establishment will be considered a mitigating factor in determining whether the food establishment shall be assessed more than the minimum fine or civil penalty required by law.

(d) *Exemption for certain types of food establishments.* The following food establishments are exempt from the requirements of the act and this chapter:

(1) A food establishment where only commercially pre-packaged food is handled and sold.

(2) A food establishment that does not handle potentially hazardous food.

(3) A food establishment that is a food manufacturing facility engaged in the manufacture of prepackaged foods and which does not manufacture potentially hazardous food.

§ 76.2. Definitions.

The following word and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise or unless otherwise defined in the FDA Food Code, or a subsequent amendment thereof:

Act—3 Pa.C.S. Chapter 65 (relating to Food Employee Certification Advisory Board).

Adulterated food—Food that is considered adulterated under section 8 of the Food Act (31 P. S. § 20.8).

Adulteration—An action that creates adulterated food.

Advisory Board or Board—The Food Employee Certification Advisory Board.

Air dry—The exposure of wet articles to air for the purpose of drying through evaporation.

Air gap—The vertical distance between the point where water enters a plumbing fixture—such as a sink—and the level at which the plumbing fixture would overflow.

Asymptomatic—Presenting no evidence of disease.

Backflow device—A device that prevents liquid from flowing back or moving toward the source from which the liquid was introduced.

Bacteria—Single cell microorganisms.

Bacteria growth—Multiplication of bacteria through cell division.

Bakery—A food establishment in which baked products (breads, rolls, cakes, doughnuts, biscuits, pies, macaroni, spaghetti, noodles, and the like) are manufactured for human consumption.

Bleach—Sodium hypochlorite, a chemical sanitizer.

CIP or cleaned in place—Cleaned in place by the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse and sanitizing solution onto or over equipment surfaces that require cleaning, such as the method used, in part, to clean and sanitize a frozen dessert machine. The term does not include the cleaning of equipment, such as band saws, slicers or mixers that are subjected to in-place manual cleaning without the use of a CIP system.

Certificate—A document issued by the Department to a particular person to evidence that the named individual has demonstrated adequate food protection knowledge and is certified for purposes of section 6503(d) of the act (relating to certification advisory board and programs) with respect to an industry-specific category of food establishment.

Certificate holder—A person holding a valid certificate, regardless of whether that person is a supervisory employe.

Certified supervisory employe—A supervisory employe holding a valid certificate.

Cleanability—The property of being cleanable or accessible for cleaning.

Cleaning—The process by which dirt or other foreign matter is removed from an article.

Communicable disease—An infectious disease transmissible to persons or animals by direct or indirect means.

Confirmed disease outbreak—A foodborne disease outbreak in which laboratory analysis of appropriate specimens identifies a causative organism and epidemiological analysis implicates the food as the source of the illnesses.

Contamination—Soiling, staining, corrupting or infecting by contact or association.

Critical control point—A point or procedure in a specific food system where loss of control may result in an unacceptable health risk.

Critical item—An action which violates a food sanitation standard and which may contribute to food contamination, illness or environmental degradation.

Cross-contamination—The transfer of bacteria or other microorganisms from one source to another.

Department—The Department of Agriculture of the Commonwealth.

Detergent—A cleaning agent.

Easily cleanable—

(i) A characteristic of a surface that:

(A) Allows effective removal of soil by normal cleaning methods.

(B) Is dependent on the material, design, construction and installation of the surface.

(C) Varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into food based on the surface's approved placement, purpose and use.

(ii) The term includes a tiered application of the criteria that qualify the surface as easily cleanable as specified in subparagraph (i) to different situations in which varying degrees of cleanability are required such as one of the following:

(A) The appropriateness of stainless steel for a food preparation surface as opposed to the lack of need for stainless steel to be used for floors or for tables used for consumer dining.

(B) The need for a different degree of cleanability for a utilitarian attachment or accessory in the kitchen as opposed to a decorative attachment or accessory in the consumer dining area.

Escherichia coli or E. coli—Gram-negative rod-shaped bacteria normally present in the intestines of man and animals, which may be pathogenic and are indicative of fecal contamination when found in food or water.

FDA Food Code—A publication issued by the United States Food and Drug Administration which is available from the Department.

Food—A raw, cooked or processed edible substance, ice, beverage or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum.

Food Act—The Food Act (31 P. S. §§ 20.1—20.18).

Food-contact surface—One of the following:

(i) A surface of equipment or a utensil with which food normally comes into contact.

(ii) A surface of equipment or a utensil from which food may drain, drip or splash into a food, or onto a surface normally in contact with food.

Food establishment—A room, building, place or portion thereof or vehicle maintained, used or operated for the purpose of selling to the public, commercially storing, packaging, making, cooking, mixing, processing, bottling, baking, canning, freezing, packing or otherwise preparing, transporting or handling food. The term includes retail food stores and public eating and drinking licensees, except those portions of establishments operating exclusively under milk or milk products permits and those portions of establishments operating exclusively under United States Department of Agriculture inspection. The term does not include dining cars operated by a railroad company in interstate commerce or a bed and breakfast, homestead or inn as defined in the Public Eating and Drinking Place Law.

Food processor—A food establishment that manufactures foods using methods such as cutting, grinding, chipping, peeling, baking, dicing, shredding, extrusion, drying, whipping, blanching, heating, extraction, smoking, freezing, fermenting, mixing or dehydrating, or that packages, cans, jars or otherwise places food in containers.

Food service—A food establishment that prepares and serves foods to the consumer. This category of food establishment includes restaurants, hotels, auction house

stands, hot dog vendors, flea market stands, nursing home kitchens, school cafeterias, college/university cafeterias, roadside stands, hand-dipped ice cream and yogurt sellers, college snack bars, stands at fairs and carnivals, caterers, snow-cone stands, camp kitchens, church kitchens, private clubs and associations, and food vendors at stadiums, racetracks, parks and public charity events.

Foodborne disease outbreak—

(i) An incident, except as specified in subparagraph (ii), in which:

(A) Two or more persons experience a similar illness after ingestion of a common food.

(B) Epidemiological analysis implicates the food as the source of the illness.

(ii) The term includes a single case of illness such as one person ill from botulism or chemical poisoning.

*Frozen dessert manufacturer—*A food establishment that is located in this Commonwealth and that is required to be licensed under authority of the Frozen Dessert Law (31 P. S. §§ 417.1—417.14).

*Fungi—*A division of lower plant life.

*H.A.C.C.P.—Hazard Analysis Critical Control Point—*A system that identifies and monitors specific foodborne hazards (biological, chemical or physical properties) that can adversely affect the safety of the food product.

*Handwash sink—*A sink specifically designated for hand washing.

*Hazard—*A biological, chemical or physical property that may cause an unacceptable consumer health risk.

*Hepatitis A infection—*A viral foodborne illness that can be transmitted from an infected person, through food, to another person.

*Hermetically sealed container—*A container that is designed and intended to be secure against the entry of microorganisms and, in the case of low acid canned foods, to maintain the commercial sterility of its contents after processing.

*Highly susceptible population—*A group of persons who are more likely than other populations to experience foodborne disease because they are immunocompromised or older adults and in a facility that provides health care or assisted living services, such as a hospital or nursing home; or preschool age children in a facility that provides custodial care, such as a day care center.

*Infection—*A disease or condition due to the growth of microorganisms in a host.

*Intoxication—*Illness caused by ingestion of food containing a bacterial toxin.

*Lag phase—*The time period needed for bacteria to acclimate to a new environment, during which bacterial growth is limited or nonexistent.

*Lag phase—*The time period which follows the lag phase and during which bacteria undergo accelerated growth.

*Nonfood contact surface—*Exposed surfaces which do not, under normal use, come into contact with food.

*pH—*The symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution.

*ppm—*Parts per million, or milligrams per liter (mg/l).

*Parasite—*A living organism which derives its nourishment from another living organism.

*Pathogenic organism—*A disease-producing organism.

*Person—*A corporation, partnership, limited liability company, business trust, other association, government entity (other than the Commonwealth), estate, trust, foundation or natural person.

*Plan review—*The process by which plans and specifications for the construction, remodeling or alteration of a food establishment are reviewed for conformance to specified standards.

*Poisonous or deleterious substance—*A substance that would be considered poisonous or deleterious under section 11 of the Food Act (31 P. S. § 20.11).

*Potable water—*Water that is safe for human consumption.

*Potentially hazardous food—*A food which consists in whole or in part of milk or milk products, eggs, meats, poultry, fish, shellfish, edible crustaceans or other ingredients, including synthetic ingredients, and which is in a form capable of supporting rapid and progressive growth of infectious or toxicogenic microorganisms. The term does not include foods that have a pH level of 4.6 or below or a water activity of 0.85 or less under standard conditions or food products in hermetically sealed containers processed to maintain commercial sterility.

*Product protection—*Safety measures used to prevent food contamination.

*Public eating and drinking place—*A place within this Commonwealth where food or drink is served to or provided for the public, with or without charge, or a place which otherwise conforms to the definition in section 1 of the Public Eating and Drinking Place Law (35 P. S. § 655.1). The term does not include dining cars operated by a railroad company in interstate commerce or a bed and breakfast homestead or inn.

*Public Eating and Drinking Place Law—*The act of May 23, 1945 (P. L. 926, No. 369) (35 P. S. §§ 655.1—655.13).

*Quaternary ammonium compound—*A chemical sanitizer which is a derivative of ammonium hydroxide or its salts.

Ready-to-eat food—

(i) Food that is in a form that is edible without washing, cooking or additional preparation by the food establishment or the consumer and that is reasonably expected to be consumed in that form.

(ii) The term includes:

(A) Unpacked potentially hazardous food that is cooked to the temperature and time required for the specific food under the most current edition of FDA Food Code.

(B) Raw, washed, cut fruits and vegetables.

(C) Whole, raw, fruits and vegetables that are presented for consumption without the need for further washing, such as at a buffet.

(D) Other food presented for consumption for which further washing or cooking is not required and from which rinds, peels, husks or shells are removed.

Reduced oxygen packaging—

(i) The reduction of the amount of oxygen in a package by mechanically evacuating the oxygen; displacing the oxygen with another gas or combination of gases; or otherwise controlling the oxygen content in a package to a

level below that normally found in the surrounding atmosphere, which is 21% oxygen.

(ii) The term includes methods that may be referred to as altered atmosphere, modified atmosphere, controlled atmosphere, low oxygen and vacuum packaging.

Retail food store—A food establishment or a section of a food establishment where food and food products are offered to the consumer and intended for off-premises consumption.

Salmonella enteritidis—Pathogenic Salmonella bacteria found in food which, if ingested in sufficient numbers, may cause salmonellosis in humans.

Salmonellosis—Foodborne disease caused by pathogenic Salmonella strains.

Sanitization—The application of cumulative heat or chemicals on cleaned food contact surfaces that, when evaluated for efficacy, yield a reduction of 5 logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.

Secretary—The Secretary of the Department.

Slacking—The process of moderating the temperature of a food such as allowing a food to gradually increase from a temperature of -23°C (-10°F) to -4°C (25°F) in preparation for deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen food such as spinach.

Staphylococcus—Spherical bacteria which occur in grape-like clusters, certain types of which cause food poisoning by releasing toxins.

Supervisory employe—An owner or a person employed by or designated by the business owner to fulfill the requirements of the act.

Temperature danger zone—The temperature range between 45°F and 140°F , which is favorable for the growth of many types of pathogenic organisms in potentially hazardous foods.

Test strips—Indicator papers which, when immersed, assume a color that can be compared to a known color standard to measure sanitizer strength.

Time and temperature—Important factors in controlling the growth of pathogenic organisms in potentially hazardous foods.

Toxin—A poisonous substance produced by pathogenic organisms.

Transmissibility—The ability of a disease to be conveyed person-to-person, organism-to-person, food-to-person, person to food or otherwise.

Virus—An intracellular, parasitic microorganism that is smaller than a bacterium.

Warewashing—The cleaning and sanitizing of food-contact surfaces of equipment and utensils.

Water activity—A measure of the free moisture in a food. The term is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature, and is indicated by the symbol AW (aw).

§ 76.3. Requirements for food establishments.

(a) *Industry-specific categories of food establishments.* A food establishment that is not exempt from compliance under § 76.1(d) (relating to compliance) shall be classified under one or more of the following industry-specific categories:

(1) Food processor that manufactures potentially hazardous foods.

(2) Food service that prepares and serves potentially hazardous foods to the consumer.

(3) Bakery that processes potentially hazardous foods.

(4) Retail food store that offers potentially hazardous food to the consumer.

(5) Frozen dessert manufacturer.

(b) *Certified supervisory employe.* A food establishment shall employ or designate at least one certified supervisory employe who is certified with respect to the industry-specific category of the food establishment.

(c) *New food establishment.* A new food establishment shall bring itself into compliance with subsection (b) within 90 days of the date it commences operation.

(d) *Employe turnover.* If a food establishment loses its only certified supervisory employe through employe turnover or for any other reason, the food establishment shall bring itself into compliance with subsection (b) within 3 months of the date it lost its previous certified supervisory employe.

(e) *Certification records.* A food establishment shall maintain the following information at the food establishment site:

(1) The name of each certified supervisory employe in its employ.

(2) The name of each certified supervisory employe who has been in its employ in the past year.

(3) The certificate number of each certified supervisory employe referenced in paragraphs (1) and (2).

(4) The industry-specific category of food establishment with respect to which a certified supervisory employe referenced in paragraphs (1) and (2) was certified.

(5) The issuance and expiration dates of the certificate of any certified supervisory employe referenced in paragraphs (1) and (2).

(6) The date it lost any certified supervisory employe within the past year—whether through employe turnover or other change in status.

(f) *Availability of records.* Upon request by the Department, a food establishment shall make the records described in subsection (e) available for inspection by the Department during reasonable hours.

(g) *Posting of certificate.* A food establishment shall post the original certificate of its certified supervisory employe in public view at its business location.

(h) *Return of certificate.* A certificate is the property of the Department and is issued to the individual person identified on its face.

§ 76.4. Eligibility to apply for certification.

A person shall complete an approved certification program and obtain a score of 70% or higher on an approved certification examination to be eligible to apply to the Department for certification.

§ 76.5. Certification programs: obtaining the Department's approval.

(a) *Approval required.* A person shall obtain the Department's approval of a training program before the training program will be considered an approved certification program for purposes of the act and this chapter. Revisions or changes to a previously-approved certifica-

tion program shall also be approved by the Department. Approval under this section authorizes a person to develop and approve certification examinations, conduct certification examinations and certify the results of certification examinations to the Department in accordance with this chapter.

(b) *General requirements for approval.* The Department will approve a certification program if it addresses an industry-specific category of food establishment described in § 76.3(a) (relating to requirements for food establishments), meets the food safety protection and training standards described in § 76.7 (relating to certification programs: food safety protection and training standards) and has been recommended for approval by the Advisory Board.

(c) *Obtaining an application form.* The Department will provide an application form for certification program approval, or an application form for approval of revisions or changes to a previously-approved certification program, upon request. Requests for these forms shall be directed to the Department at the address in § 76.16 (relating to contacting the Department).

(d) *Contents: application for certification program approval.* The application form for certification program approval shall require the following information:

- (1) The applicant's name, address and telephone number.
- (2) A course syllabus demonstrating that the program would meet the minimum content requirements in § 76.7 (relating to certification programs: food safety protection and training standards).
- (3) The industry-specific category of food establishment, as described in § 76.3(a) (relating to requirements for food establishments), to be addressed by the certification program.
- (4) A copy of the examination to be administered at the conclusion of the certification program, together with an answer key for that examination, if these documents are available.
- (5) A copy of all teacher materials for the certification program, unless the certification program is a home-study program.
- (6) A copy of all materials to be distributed to persons taking the program.
- (7) The proposed sites and dates of the certification program, if known, unless the certification program is a home-study program.
- (8) If the certification program is a home study program, the proposed site and date the approved certification examination is to be administered.
- (9) Other information the Department might reasonably require.

(e) *Contents: application for approval of changes or revisions to a previously-approved certification program.* The application form for approval of changes or revisions to a previously-approved certification program shall require the applicant's name, address and telephone number and only information listed in subsection (d) that is relevant to the change or revision with respect to which approval is sought.

(f) *Deadline for filing the application.* An application for certification program approval or for approval of changes or revisions to a previously-approved certification program shall be delivered to the Department, at the

address in § 76.16 (relating to contacting the Department), at least 90 days in advance of the proposed date upon which the program is to be conducted.

(g) *Departmental and Advisory Board action on application.* The Advisory Board will consider whether to recommend Departmental approval of a certification program. If the majority of a quorum of the Advisory Board recommends Departmental approval of a certification program, the Department will grant its approval, if the other criteria in subsection (b) are met. The Department will mail the applicant its written approval of the certification program, its denial of approval or a request for additional clarification or documentation.

§ 76.6. Certification programs: audit by Department.

The Department may attend and audit an approved certification program to ascertain whether the program is conducted in accordance with the requirements of the act and in conformity to the program syllabus. A person offering or conducting an approved certification program shall allow the Department's auditors entry to the program and provide copies of course materials.

§ 76.7. Certification programs: food safety protection and training standards.

(a) *Overview of topics.* As described in detail in subsections (b)—(h), a training program shall contain instruction in the following topics:

- (1) Foodborne illness
- (2) Time and temperature
- (3) Relationship between personal hygiene and food safety
- (4) Food safety tracking system
- (5) Cleaning and sanitizing
- (6) Facilities and equipment layout
- (7) Statutory and regulatory requirements

(b) *Topic: foodborne illness.* A portion of the instruction in a training program shall pertain to the topic of foodborne illness. This instruction shall address the following:

- (1) Terms and definitions necessary to an understanding of foodborne illness. At a minimum, this shall include the following terms:
 - (i) Bacteria.
 - (ii) Communicable disease.
 - (iii) Confirmed disease outbreak.
 - (iv) Fungi.
 - (v) Potentially hazardous foods.
 - (vi) Infection.
 - (vii) Intoxication.
 - (viii) Parasite.
 - (ix) Pathogenic organism.
 - (x) Time and temperature.
 - (xi) Virus.

(2) Microorganisms that commonly cause foodborne infection or intoxication.

(3) The process by which microorganisms cause foodborne illness.

(4) The definition, characteristics and recognition of potentially hazardous foods.

(5) Factors that contribute to foodborne illness.

(6) Prevention of food contamination from employes, equipment, premises, utensils and consumers.

(7) Prevention of food contamination from chemicals.

(c) *Topic: time and temperature.* A portion of the instruction in a training program shall pertain to the topic of time and temperature. This instruction shall address the following:

(1) Terms and definitions necessary to an understanding of time and temperature requirements. At a minimum this shall include the following terms:

- (i) Bacteria growth.
- (ii) Contamination.
- (iii) Critical control point.
- (iv) Critical item.
- (v) Cross-contamination.
- (vi) Food contact surface.
- (vii) Hermetically sealed container.
- (viii) Lag phase.
- (ix) Log phase.
- (x) Ready-to-eat foods.
- (xi) Reduced oxygen packing.
- (xii) Slacking.
- (xiii) Temperature danger zones.
- (xiv) Water activity.
- (xv) Emerging pathogens.

(2) Prime factors which control the growth, survival and toxin production rate of pathogenic microorganisms in food during receiving, storing, cooking, thawing, cooling, preparation, holding/displaying, serving, freezing, transporting, reheating and storing after production.

(3) The types, uses and calibration of food thermometers.

(4) Proper food temperatures during refrigeration, freezing, cooling, hot holding, cooking, reheating, thawing and preparation.

(d) *Topic: relationship between personal hygiene and food safety.* A portion of the instruction in a training program shall pertain to the topic of the relationship between personal hygiene and food safety. This instruction shall address the following:

(1) Terms and definitions necessary to an understanding of the relationship between personal hygiene and food safety. At a minimum this shall include the following terms:

- (i) Asymptomatic.
- (ii) *Escherichia coli*.
- (iii) Hepatitis A infection.
- (iv) Highly susceptible group.
- (v) Pathogenic organism.
- (vi) *Salmonella enteritidis*.
- (vii) *Staphylococcus*.
- (viii) Transmissible.

(2) Prevention of food contamination by food establishment employe, including the following subjects:

- (i) Handwashing techniques and frequency.
- (ii) Relationship of hand contact to foodborne illness.
- (iii) Contamination by poor hygienic practices such as sneezing, coughing and scratching.
- (iv) Clothing.
- (v) Fingernails.
- (vi) Eating, drinking or using tobacco.
- (vii) Hair restraint.
- (viii) Animals in the workplace.

(3) Employe health, including the following subjects:

(i) Infections or diseases which can be transmitted by open wound, sinus infection, virus or sore throat.

(ii) Identifying employes who may transmit infection or disease.

(iii) High risk groups.

(iv) Imposition and removal of employe exclusions and restrictions.

(v) Mandatory and voluntary reporting of foodborne illness.

(4) Preventive measures such as training, written cleaning and sanitation schedules and procedures, self-inspection, integrated pest management and preventative maintenance.

(e) *Topic: food safety tracking system.* A portion of the instruction in a training program shall pertain to the topic of food safety tracking systems. This instruction shall address the following:

(1) Terms and definitions necessary to an understanding of a food safety tracking system. At a minimum this shall contain the following terms:

- (i) Adulteration.
- (ii) Contamination.
- (iii) Critical control point.
- (iv) Cross-contamination.
- (v) HACCP or Hazardous Analysis Critical Control Point.

(vi) Product protection.

(2) Receiving food, including the following subjects:

- (i) Approved sources.
- (ii) Condition of food.
- (iii) Thermometers and temperature checks.

(iv) Rejection for adulteration, temperature violations, distressed merchandise or condition of carrier.

(3) Safe storage of food, including the following subjects:

- (i) Dry storage temperature and practices.
- (ii) Refrigeration and freezing holding temperatures and product protection.
- (iii) Shelf life.
- (iv) Cross-contamination and adulteration.
- (v) Product protection in retail service/display areas and storage areas.
- (vi) Product labeling.

- (vii) Labeling of poisonous or toxic materials.
- (viii) Original containers.
- (ix) Working containers.
- (x) Food storage prohibitions, including locker rooms, toilet rooms, garbage rooms and under sewer lines.
- (4) Preparation and processing of food, including the following subjects:
 - (i) Personal hygiene.
 - (ii) Practices regarding disposable gloves.
 - (iii) Contamination by chemical or physical additives.
 - (iv) Cross-contamination.
 - (v) Equipment/utensils.
 - (vi) Hazards to humans in using equipment.
 - (vii) Machine guards, slicer blades and protective light shields.
 - (viii) Corrective actions.
 - (ix) Potentially hazardous foods.
 - (x) HACCP.
 - (xi) Critical control point.
- (f) *Topic: cleaning and sanitizing.* A portion of the instruction in a training program shall pertain to the topic of cleaning and sanitizing. This instruction shall address the following:
 - (1) Terms and definitions necessary to an understanding of cleaning and sanitizing procedures. At a minimum this shall contain the following terms:
 - (i) Adulteration.
 - (ii) Air dry.
 - (iii) Bleach.
 - (iv) CIP.
 - (v) Cleaning.
 - (vi) Contamination.
 - (vii) Cross-contamination.
 - (viii) Detergent.
 - (ix) Easily cleanable.
 - (x) Food contact surface.
 - (xi) Nonfood contact surface.
 - (xii) pH.
 - (xiii) ppm.
 - (xiv) Sanitization.
 - (xv) Test strips.
 - (xvi) Warewashing.
 - (xvii) Quaternary ammonium compound.
 - (2) MSDS Fact sheets.
 - (3) Proper use of hot water or chemicals in sanitizing.
 - (4) The difference between cleaning and sanitizing.
 - (5) Types of sanitizers, their usage and the use of test strips.
 - (6) Detergents.
 - (7) Procedures to wash-rinse-sanitize.
 - (8) The frequency with which food contact surfaces, utensils, equipment and nonfood contact surfaces should be sanitized.

- (9) Equipment.
- (10) Manual warewashing.
- (11) Mechanical warewashing.
- (12) The proper use of cleaning methods such as air drying, wiping cloths, CIP and water temperature.
- (g) *Topic: facilities and equipment layout.* A portion of the instruction in a training program shall pertain to the topic of facilities and equipment layout. This instruction shall address the following:
 - (1) Terms and definitions necessary to an understanding of the proper layout of equipment and facilities. At a minimum this shall contain the following terms:
 - (i) Air gap.
 - (ii) Backflow device.
 - (iii) Cleanability.
 - (iv) Potable water.
 - (v) Handwash sink.
 - (vi) Plan review.
 - (2) Proper equipment design and location.
 - (3) Construction of floors, walls and ceilings.
 - (4) Design of equipment such as refrigeration, hot holding, heating, ventilation, pest control, lighting and freezer equipment and design of the buildings in which the equipment is located.
 - (5) Acceptable water sources, water quality and quantity and water distribution systems.
 - (6) Plumbing design, construction, location, materials and operation.
 - (7) Management of solid and liquid waste, recyclables, refuse and returnable.
 - (8) Review of plans for equipment and building lay-out and design.

(h) *Topic: statutory and regulatory requirements.* A portion of the instruction in a training program shall pertain to the topic of statutory and regulatory requirements. This instruction shall address the following:

- (1) Terms and definitions necessary to an understanding of the requirements imposed by the act and this chapter. At a minimum this shall contain the following:
 - (i) The act.
 - (ii) The certificate.
 - (iii) The certified supervisory employee.
- (2) Statutes and regulations relevant to the industry-specific category of food establishment that is the subject of the approved certification program.

§ 76.8. Format of a certification examination.

Although it is recommended that a certification examination consist of no fewer than 100 questions, under no circumstances may a certification examination consist of fewer than 80 questions. These questions shall be multiple choice questions, true or false questions or a combination thereof that adequately test food protection knowledge with respect to an industry-specific category of food establishment described in § 76.3(a) (relating to requirements for food establishments).

§ 76.9. Reporting results of a certification examination.

A person who proctors a certification examination shall, within 20 days of proctoring the examination, mail or deliver to any person who took the examination written confirmation of that person's examination score, the date and location of the examination and the industry-specific category of food establishment addressed in the examination. The examination score shall be expressed as the percentage of correct answers. Within that same 20-day time period the proctor shall mail the same information to the Department at the address in § 76.16 (relating to contacting the Department), using a form provided by the Department upon request.

§ 76.10. Applying for certification.

(a) *Application required.* A person who has attained a score of 70% or higher on a certification examination may apply to the Department for certification. Certification is granted through issuance of the certificate described in § 76.11 (relating to certificate).

(b) *Form of application.* A person seeking certification under the act may obtain an application form from the Department at the address in § 76.16 (relating to contacting the Department). The applicant shall complete the form and return it to that same address. The application form shall require the following information:

- (1) The name and mailing address of the person seeking certification.
- (2) The location and dates of any approved certification program completed by the person seeking certification.
- (3) The location and date of the certification examination.
- (4) The industry-specific food establishment category (as described at § 76.3(a) (relating to requirement for food establishments)) with respect to which certification is sought.
- (5) Other information the Department might reasonably require.

(c) *Application fee.* A person applying for certification under this section shall pay an application fee of \$20, by check or money order made payable to the "Pa. Department of Agriculture." This payment shall accompany the application.

(d) *Department action on application.* The Department will, within 20 days of receiving an application and the application fee, mail the applicant a certificate, a disapproval notice or a request for additional clarification or documentation.

§ 76.11. Certificate.

(a) *Contents of certificate.* A certificate will bear the following information:

- (1) The name of the person to whom it is issued.
- (2) The industry-specific category of food establishment category, as described in § 76.3(a) (relating to requirement for food establishment), with respect to which the person is certified.
- (3) The date upon which the certificate was issued.
- (4) The expiration date of the certificate, which shall be 5 years from the date of issuance.
- (5) A unique identification number.
- (6) A statement that the Department has determined the person identified on the certificate to possess ad-

equated food protection knowledge and to be a certificateholder with respect to the industry-specific category of food establishment designated on the certificate.

(7) Other information the Department might reasonably include.

(b) *Ownership of certificate.* A certificate issued by the Department will remain the property of the Department. A certificateholder, certified supervisory employe, food establishment or other person having physical possession of a certificate shall, upon written notice from the Department, surrender and return the certificate to the Department.

(c) *Obligation to allow display.* A certified supervisory employe shall allow his employer to display the certificate issued by the Department, as required in § 76.3(g). Upon termination of a certified supervisory employe's employment, the employer shall surrender the certificate to the certificateholder named on the certificate.

§ 76.12. Renewal of certification.

(a) *General requirement.* A certificateholder shall obtain at least 7.5 hours of approved continuing education in the area of food safety and sanitation every 5 years, commencing with the date the certificate is issued. An approved continuing education course will not require a written examination as a condition of completion. If a certificateholder fails to obtain this approved continuing education and deliver a complete certification renewal application to the Department prior to the expiration date of the certificate, the certificate shall expire and the certificateholder shall successfully complete an approved certification program and a certification examination before certification will be granted.

(b) *Application for renewal.* A person seeking renewal of certification under this section may obtain an application form from the Department at the address in § 76.16 (relating to contacting the Department). The applicant shall complete the form and return it to that same address. The form shall require the following information:

- (1) The name and mailing address of the applicant.
- (2) Copies of course descriptions, course-completion certificates, college course transcripts and descriptions and similar documentation to evidence compliance with the requirement in subsection (a).
- (3) The industry-specific food establishment category, as described in § 76.3(a), with respect to which the applicant is certified.

(4) The identification number and expiration date of the certificate.

(5) Other information the Department might reasonably require.

(c) *Departmental action on application.* The Department will, within 30 days of receiving an application, mail the applicant a certificate (as described in § 76.11(a) (relating to certificate)), its denial of renewal of certification or a request for additional clarification or documentation.

§ 76.13. Obtaining Departmental approval of a continuing education course.

(a) *Approval required.* A person shall obtain the Department's approval of a continuing education course before the course will be considered an approved continuing education course for purposes of § 76.12 (relating to renewal of certification). Revisions or changes to a

previously-approved continuing education course shall also be approved by the Department.

(b) *General requirements for approval.* The Department will approve a continuing education course if it instructs participants in current food protection practices and has been recommended for approval by the Advisory Board.

(c) *Application for approval.* A person seeking the Department's approval of a continuing education course under this section may obtain an application form from the Department at the address in § 76.16 (relating to contacting the Department). The applicant shall complete the form and return it to that same address. The form shall require the following information:

- (1) The name and mailing address of the applicant.
- (2) A course syllabus demonstrating that the course addresses regulatory or food industry changes, updates or advancements.
- (3) A copy of teaching materials for the course.
- (4) A copy of materials to be distributed to persons taking the course.
- (5) The proposed sites and dates of the course.
- (6) Other information the Department might reasonably require.

(d) *Departmental and Advisory Board action on application.* The Advisory Board will consider whether to recommend Departmental approval of the continuing education course. If the majority of a quorum of the Advisory Board recommends Departmental approval of a continuing education course, the Department will grant its approval, if the other requirements of subsection (b) are met. The Department will mail the applicant its written approval of the continuing education course, its denial of approval or a request for additional clarification or documentation.

§ 76.14. Reciprocity with other states.

The Department may accept certification issued to a person by another state if both of the following occur:

- (1) The other state has requirements for certification that are comparable to those imposed by the act.
- (2) The Department and the other state jurisdiction have entered into a reciprocal agreement to accept each state's certification program as meeting the requirements of the act.

§ 76.15. Suspension or revocation of certification.

(a) *Basis for action.* The Department may suspend or revoke the certification of a certificateholder if that person does one or more of the following:

- (1) Violates a provision of this chapter.
- (2) Violates another sanitation regulation.
- (3) Violates the Public Eating and Drinking Place Law or its attendant regulations.
- (4) Violates the Food Act or its attendant regulations.

(b) *Notice.* The Department will provide a certificateholder with written notice of its intention to suspend or revoke certification, which will afford that person notice and opportunity for an administrative hearing before the Department prior to the effective date of the suspension or revocation.

(c) *Delivery of notice.* The Department will deliver the notice described in subsection (b) to the affected certificateholder by personal service or by regular mail to

the address provided by the certificateholder on his application for certificate under § 76.10 (relating to applying for certification).

§ 76.16. Contacting the Department.

A person seeking applications or information relating to the act or this chapter shall forward his request, in writing, to the following address:

ATTN: Food Employee Certification
Department of Agriculture
Bureau of Food Safety and Laboratory Services
2301 North Cameron Street
Harrisburg, PA 17110-9408

§ 76.17. Preemption and local governmental authority.

(a) *General.* The regulation of food safety protection and training standards for employes of food establishments is preempted by the Department except that, in accordance with section 6503(f) of the act (relating to certification advisory board and programs), any food employe certification program established by a county, city, borough or incorporated town or township prior to September 1, 1994, may remain in effect.

(b) *Limitation of local certification.* If a county, city, borough, incorporated town or township elects to operate a food employe certification program that was in existence prior to September 1, 1994, the certification of persons under that local program shall be valid only within the geographic boundaries of that local government unit. This program validity may be extended to other states or local government units through reciprocal agreements among other states or local government units which operate food employe certification programs that predate September 1, 1994.

(c) *Option of certain local government units.* A county, city, borough, incorporated town or township having a food employe certification program which was in effect prior to September 1, 1994, may, at its option, apply to the Department in accordance with the procedure in § 76.5 (relating to approved certification programs: obtaining the Department's approval) to become an approved certification program with respect to one or more industry-specific categories of food establishments.

(d) *Effect of a local government unit's decision with respect to exercising option.* If a county, city, borough, incorporated town or township having a food employe certification program which was in effect prior to September 1, 1994, does not exercise the option described in subsection (c) or does not obtain Departmental approval of its certification program with respect to any particular industry-specific category of food establishment, the unit of local government shall retain exclusive responsibility for certification of the food employes who would otherwise fall into that industry-specific category.

§ 76.18. Advisory Board.

(a) *Purpose.* The Advisory Board shall review and recommend Departmental approval of industry-specific certification programs which meet the requirements of the act and this chapter.

(b) *Composition.* The Advisory Board will be appointed by the Secretary and consist of at least 21 members. The membership of the Advisory Board will be as follows:

- (1) The Secretary, or a designee, who will serve as chairperson.
- (2) The Chairperson of the Agriculture and Rural Affairs Committee of the Senate, or a designee.

(3) The Chairperson of the Agriculture and Rural Affairs Committee of the House of Representatives, or a designee.

(4) The Minority Chairperson of the Agriculture and Rural Affairs Committee of the Senate, or a designee.

(5) The Minority Chairperson of the Agriculture and Rural Affairs Committee of the House of Representatives, or a designee.

(6) A consumer representative.

(7) Two representatives of production agriculture.

(8) At least one person recommended by each of the following:

(i) Pennsylvania Association of Milk Dealers.

(ii) Pennsylvania Restaurant Association.

(iii) Pennsylvania Food Merchants Association.

(iv) Pennsylvania Convenience Store Council.

(v) Pennsylvania Bakers Association.

(vi) Pennsylvania Food Processors Association.

(vii) Pennsylvania Veterinary Medical Association.

(viii) County Commissioners Association of Pennsylvania.

(ix) Pennsylvania League of Cities and Municipalities.

(x) Pennsylvania State Association of Boroughs.

(xi) Pennsylvania State Association of Township Commissioners.

(xii) Pennsylvania State Association of Township Supervisors.

(xiii) Pennsylvania School Food Service Association.

(9) At least one of the Advisory Board members described in paragraph (8) shall have experience in the field of public health.

(c) *Terms of appointees.* Advisory Board members described in subsection (b)(1), (2), (3), (4) or (5) shall be ex officio members. The terms of the initial appointees of the Secretary under subsection (b)(6)—(8) will be 2, 3 or 4 years, as determined by the Secretary, and will be staggered so that the terms of approximately 1/3 of these initial appointees expire in each of the 2nd, 3rd and 4th years of the Advisory Board's existence. Thereafter, the term of each of these appointees shall be 3 years. The term of a person appointed to replace another member whose term has not expired shall be only the unexpired portion of that term. Persons may be appointed to successive terms.

§ 76.19. Civil penalties.

(a) *General.* The Department may assess a civil penalty of up to \$300 against any person or food establishment that violates any provision of the act or this chapter for the first offense. The Department may assess a penalty of up to \$1,000 for each subsequent offense.

(b) *Notice.* The Department will provide a person or food establishment written notice of any violation of the act or this chapter and an opportunity for an administrative hearing on the violation prior to the imposition of a civil penalty.

(c) *Time for correction of condition giving rise to civil penalty.* If the Department assesses a civil penalty against a food establishment for failing to have the required certified supervisory employe, it will allow the food establishment a period of 90 days from the violation

giving rise to the initial civil penalty before it may assess another civil penalty. During that 90-day period, the food establishment shall bring itself into compliance with the act and this chapter.

[Pa.B. Doc. No. 97-977. Filed for public inspection June 20, 1997, 9:00 a.m.]

STATE BOARD OF MEDICINE

[49 PA. CODE CH. 16]

Volunteer License

The State Board of Medicine (Board) proposes to amend § 16.11 (relating to licenses, certificates and registrations) and add § 16.18 (relating to volunteer license) to read as set forth in Annex A.

A. Effective Date

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

B. Statutory Authority

The Board is required to promulgate regulations governing the volunteer license category by section 5 of the Volunteer Health Services Act (act) (35 P. S. § 449.5) which became effective February 3, 1997. Section 5 of the act mandates regulations governing: (1) qualifications for placing an active license on volunteer status; (2) criteria under which a retired licensee who has allowed a license to become inactive may obtain a volunteer license; and (3) procedures under which a volunteer license holder may return to active status. The Board is authorized to adopt regulations necessary to the administration of its enabling statute under section 8 of the Medical Practice Act of 1985 (63 P. S. § 422.8).

C. Background and Purpose

The purpose of the proposal is to implement the act. The act is intended to increase the availability of primary health services by establishing a procedure for physicians and other health care practitioners who have retired from active practice to provide professional services as volunteers in approved clinics. Primary health services are defined in the act as including services such as regular checkups, immunizations, school physicals, health education, prenatal and obstetrical care, early periodic screening and diagnostic testing, and health education.

An approved clinic is defined in the act as an organized community-based clinic which offers services to: (1) individuals and families who cannot pay for their care; (2) Medical Assistance clients; or (3) residents of medically underserved or health professionals shortage areas. Examples of these clinics include Federal or State qualified and approved health centers or nonprofit community based clinics.

The act permits persons who have been issued a license by the State Boards of Medicine, Osteopathic Medicine, Dentistry, Podiatry, Nursing, Optometry and Chiropractic to practice a component of the healing arts to apply for volunteer status. A volunteer license will be issued to a retired individual who documents to the satisfaction of the Board that the individual will practice without remuneration in approved clinics.

The act exempts holders of a volunteer license from biennial renewal fees and, if applicable, professional liability coverage mandated by the Health Care Services Malpractice Act (40 P. S. § 1301.701) and section 6 of the Medical Practice Act (63 P. S. § 422.6). However, volunteer licenses will be subject to biennial renewal conditioned upon completion of any continuing education which the Board requires for biennial renewal generally.

D. Description of Amendments

The volunteer license category would be added to the licenses, certificates and registrations issued by the Board in § 16.11. Section 16.18 would provide the statutory references to the act, as well as the statutory basis for the volunteer license category. The Board has interpreted the act as permitting a volunteer license holder to practice exclusively in an organized community-based clinic without remuneration.

Under section 3 of the act (35 P. S. § 449.43), an active licensee must possess a current, active, unrestricted license to qualify for a volunteer license. Section 4 of the act permits a licensee to apply who retired with a license in good standing. The Board has interpreted this qualification to mean a license which at the time of the application is not subject to an outstanding disciplinary action such as revocation or suspension. The act's definition of an "approved clinic" is included in subsection (b)(3). The criteria for obtaining a volunteer license are set forth in § 16.18(b). Both active licensees and retired licensees, registrants and certificateholders with inactive licenses may receive a volunteer license in order to practice as a volunteer without remuneration in an approved clinic.

Procedures to apply for a volunteer license are set forth in § 16.18(b). Applicants would be requested to provide basic license information. In addition, the applicant would be requested to execute a verification that the applicant intends to practice exclusively within the scope of a volunteer license. Also, in order to provide proper enforcement of the limitation of the act, applicants will be required to file with the Board a letter of agreement from the clinic that the applicant will work in the clinic. Section 16.18(c) would make this notification a continuing obligation during the biennial period of the license.

Biennial renewal of the volunteer license would be provided for under § 16.18(e). A volunteer license is subject to biennial renewal. However, under the act, the applicant for biennial renewal is exempt from payment of the biennial renewal fee in § 16.13 (relating to license, certification, examination and registration fees) and professional liability insurance coverage under § 16.31 (relating to notification).

Section 16.18(f) provides for return to active, remunerative practice. A volunteer would be required to apply to the Board and meet the general reactivation requirements of § 16.15 (relating to biennial registration; inactive status and unregistered status).

Section 16.18(g) notifies the volunteer license holder that he continues to be subject to the disciplinary provisions of the Medical Practice Act of 1985 (63 P. S. §§ 422.1—422.45). In addition, § 16.18(g) proposes that a violation of the act or the regulations adopted thereunder may constitute independent grounds for discipline.

E. Compliance with Executive Order 1996-1

In accordance with the requirements of Executive Order 1996-1, in drafting and promulgating the proposed amendments the Board solicited input and suggestions

from the regulated community by providing drafts to organizations and entities which represent the professionals and to nonprofit organizations who represent qualified providers of volunteer services.

F. Fiscal Impact and Paperwork Requirements

1. *Commonwealth*—The proposed amendments will create a new license for which no fee will be charged. As such, the expenses of the program will be borne as a part of the Board's overall operating expenses which are financed through biennial renewals of active licensees. Therefore, the administration and enforcement of a new license category may have a fiscal impact on overall Board costs. The net effect, however, is estimated to be minimal owing to the relatively small number of licensee population who will seek a volunteer license compared with the number of active licensees. Additional paperwork will be incurred by the Board and the private sector to generate and file application forms.

2. *Political subdivisions*—There will be no adverse fiscal impact or paperwork requirements imposed.

3. *Private sector*—The proposed amendments will have a positive fiscal impact on individual licensees who restrict their professional activities to volunteer work since these individuals are exempt from maintaining professional liability insurance required under the Health Care Services Malpractice Act (40 P. S. §§ 1301.101—1301.1006) and the biennial renewal fee for licensure. The proposed amendments should impose no additional fiscal or paperwork requirements.

G. Sunset Date

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

H. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on June 6, 1997, the Board submitted a copy of these proposed amendments to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee. In addition to submitting the proposed amendments, the Board has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Board in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

If IRRC has objections to any portion of the proposed amendments, it will notify the Board within 30 days of the close of the public comment period. The notification shall specify the regulatory review criteria which have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the amendments, by the Board, the General Assembly and the Governor of objections raised.

I. Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed amendments to Gerald S. Smith, Board Counsel, State Board of Medicine, P. O. Box 2649, 116 Pine Street, Harrisburg, PA 17105-2649, within 30 days of publication

of this proposed rulemaking. Please reference No. 16A-494 (Volunteer License), when submitting comments.

DANIEL B. KIMBALL, Jr. M.D.,
Chairperson

Fiscal Note: 16A-494. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 16. STATE BOARD OF MEDICINE—GENERAL PROVISIONS

Subchapter B. GENERAL LICENSE, CERTIFICATION AND REGISTRATION PROVISIONS

§ 16.11. Licenses, certificates and registrations.

* * * * *

(d) The Board will issue a volunteer license to qualified licensees, certificateholders and registrants.

§ 16.18. Volunteer license.

(a) *Purpose and scope.* The following subsections implement the Volunteer Health Services Act (35 P. S. §§ 449.41—449.50) and provide for the issuance of a volunteer license to a qualified Board-regulated practitioner as defined in section 2 of the act (63 P. S. § 422.2), who retires from active practice and seeks to provide professional services as a volunteer. A volunteer license authorizes the holder to practice only in an organized community-based clinic and without remuneration.

(b) *License.* A volunteer license may be issued to a Board-regulated practitioner of the Board who meets one of the following:

(1) Holds a currently renewed, active, unrestricted license, registration or certificate in this Commonwealth and retires from active practice at the time the applicant applies for a volunteer license.

(2) Retires from active practice in this Commonwealth in possession of an unrestricted license which was allowed to lapse by not renewing it. A retired licensee, registrant or certificateholder shall meet the requirements of the act or the regulations pertaining to continued education or continued competency to be eligible for renewal. As used in this section, an “unrestricted license, certification or registration” is a license which is not restricted or limited by order of the Board under its disciplinary power.

(3) Documents to the satisfaction of the Board that the applicant will practice without personal remuneration in approved clinics. As used in this section, an “approved clinic” is an organized community-based clinic offering primary health care services to individuals and families who can-

not pay for their care, to Medical Assistance clients, or to residents of medically underserved areas or health professionals shortage areas. The term may include a State health center, nonprofit community-based clinic and Federally qualified health center, as designated by Federal rulemaking or as approved by the Department of Health or the Department of Public Welfare.

(c) *Applications.* An applicant for a volunteer license shall complete an application obtained from the Board. In addition to providing information requested by the Board, the applicant shall provide:

(1) An executed verification on forms provided by the Board certifying that the applicant intends to practice exclusively as follows:

(i) Without personal remuneration for professional services.

(ii) In an organized community-based clinic offering primary health care services to one or more of the following:

(A) Individuals and families who cannot pay for their care.

(B) Medical assistance clients.

(C) Residents of medically underserved areas or health professional shortage areas.

(2) A letter signed by the director or chief operating officer of the community-based clinic that the applicant has been authorized to provide volunteer services in the named clinic by the governing body or responsible officer of the clinic.

(d) *Validity of license.* A volunteer license shall be valid for the biennial period for which it is issued, subject to biennial renewal. During each biennial renewal period, the volunteer license holder shall notify the Board of any change in clinic or volunteer status within 30 days of the date of a change, or at the time of renewal, whichever occurs first.

(e) *Renewal of license.* A volunteer license shall be renewed biennially on forms provided by the Board. The applicant shall be exempt from payment of the biennial renewal fee of § 16.13 (relating to licensure, certification, examination and registration fees), and shall be exempt from the requirements with regard to the maintenance of liability insurance coverage under section 701 of the Health Care Services Malpractice Act (40 P. S. § 1301.701) and § 16.31 (relating to notification).

(f) *Return to active practice.* A volunteer license holder who desires to return to active practice shall notify the Board and apply for biennial registration on forms provided by the Board.

(g) *Disciplinary provisions.* A volunteer license holder shall be subject to the disciplinary provisions of the act and this chapter. Failure of the licensee to comply with the Volunteer Health Services Act (35 P. S. §§ 449.41—449.50) or this section may also constitute grounds for disciplinary action.

[Pa.B. Doc. No. 97-978. Filed for public inspection June 20, 1997, 9:00 a.m.]

STATE BOARD OF NURSING

[49 PA. CODE CH. 21] Nursing Functions

The State Board of Nursing (Board) proposes to amend §§ 21.11, 21.12—21.17 and 21.145 pertaining to functions of the licensed registered nurse (RN) and functions of the licensed practical nurse (LPN) to read as set forth in Annex A.

The proposed rulemaking has two purposes. First, the proposal would require that nurses when accepting medical orders exercise responsibility to assure the correctness of the order and employ standard procedures to document the order. Second, the proposal would implement the Board's review of certain regulations in conformance with Executive Order 1996-1, which directs State agencies to eliminate unnecessary or burdensome regulations.

With respect to medical orders, the Board proposes to revise § 21.11 (relating to general functions) pertaining to registered nurses (RNs) and § 21.145 (relating to functions of the LPN) pertaining to licensed practical nurses (LPNs) to establish a single practice standard. The proposal was generated by a request from the Pennsylvania Health Care Association which suggested that the Board consider removing language in § 21.145 which prohibits an LPN from accepting an oral order except in urgent circumstances.

Although concurring in the need for regulatory relief with regard to the language of § 21.145, the Board also believes that safe nursing practice would benefit from standards and guidelines for both the RN and the LPN. The proposal would amend § 21.11 by inserting a new subsection (a)(8) governing the acceptance of orders and would revise § 21.145. The scope of practice of nursing includes the execution of medical regimens as prescribed by a licensed physician or dentist. In doing so, the nurse accepts an order from a physician in written or oral form. In accepting an order, nurses have the responsibility to question an order where circumstances indicate the order is either unclear or contraindicated for the patient. The Board proposes to add this professional standard in its regulations. Further, the Board proposes to establish uniform procedures for the acceptance of an oral order by either the RN or the LPN. A cross reference to the LPN would be made to § 21.14 (relating to administration of drugs) with regard to administration of drugs.

In proposing these changes, the Board recognizes that health care facility regulations of the Department of Health contain similar uniform regulations concerning the acceptance of oral orders. See 28 Pa. Code §§ 107.62 and 201.3. Easing the restrictions on LPNs in this regard is in accordance with the education requirements of an LPN and will improve patient care by increasing communication between the prescribing or ordering practitioner and the nurse.

The Board also proposes additional changes to § 21.11. The Board proposes to add language to subsection (a)(1), (2), (4) and (5) and to add a new subsection (a)(7) to incorporate into the functions of the RN general health care services in addition to nursing care and the RN's participation in multidisciplinary teams of professionals who collaborate to identify health care needs and plan for

the delivery of health care services. The new subsection (a)(8) governs the acceptance of oral and written orders by a registered nurse.

The Board proposes to amend subsection (b) to clarify the Board's intention to make the RN accountable for the delivery of nursing care in a safe manner. Existing subsection (b) makes the RN accountable for the quality of the care delivered. The Board deems this language ambiguous inasmuch as quality may be affected by factors beyond the nurse's control or ability to control. The Board believes that the manner of delivery of care is properly within the professional responsibility of the RN.

Existing subsection (c) was intended to cover circumstances in which the RN practices in a specialized practice. The Board determined that by revising subsection (c) the appropriate standard could be established which could apply to all areas of practice and functions. In so doing, §§ 21.12, 21.13, 21.15 and 21.16 could be deleted since the requisite criteria for performance of a function or practice, preparation skill and knowledge, remain a constant standard, embodied in § 21.11(c). By restructuring the regulations in this fashion, the Board anticipates that it will protect the public from incompetent practice while avoiding the need to increase the volume of regulations. A new subsection (d) would list functions and cross reference to subsection (c).

Technical amendments are proposed to § 21.17 pertaining to the administration of anesthesia to reflect the correct name of the National accrediting body for nurse anesthetists and to include dentists as part of the collaborating team.

Fiscal Impact and Paperwork Requirements

The proposed amendments will have no fiscal impact and will not impose additional paperwork on the private sector, the general public and the Commonwealth and its political subdivisions.

Statutory Authority

The Board has authority to promulgate these proposed amendments under section 2.1(k) of the Professional Nursing Law (63 P. S. § 212.1(k)) and section 17.6 of the Practical Nurse Law (63 P. S. § 667.6). These provisions authorize the Board to establish rules and regulations for the administration of the law.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on June 6, 1997, the Board submitted a copy of these proposed amendments to the Independent Regulatory Review Commission (IRRC) and to the Chairperson of the House Committee on Professional Licensure and to the Senate Committee on Consumer Protection and Professional Licensure. In addition to submitting the proposed amendments, the Board has provided the Committee and IRRC with a copy of a detailed Regulatory Analysis Form. A copy of this material is available to the public upon request.

If IRRC has objections to any portion of the proposed amendments, it will notify the Board within 30 days of the close of the public comment period. The notification shall specify the regulatory review criteria which have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the amendments, by the Board, the General Assembly and the Governor of objections raised.

Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed

amendments to Herbert Abramson, Board Counsel, State Board of Nursing, P. O. Box 2649, Harrisburg, PA 17105-2649, within 30 days of publication of these proposed amendments in the *Pennsylvania Bulletin*. Please refer to (16A-514) Nursing Functions, when submitting comments.

M. CHRISTINE ALICHNIE, Ph.D., R.N.
Chairperson

Fiscal Note: 16A-514. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 21. STATE BOARD OF NURSING

RESPONSIBILITIES OF THE REGISTERED NURSE

§ 21.11. General functions.

(a) The registered nurse assesses human responses and plans, implements and evaluates nursing care for individuals [or], families or groups for whom the nurse is responsible. In carrying out this responsibility, the nurse performs [all of] the following general functions:

(1) Collects complete and ongoing data to determine nursing and health care needs.

(2) Analyzes the health status of the individuals [and], families and groups and compares the data with the norm when possible in determining nursing care needs and the delivery of health care services.

* * * * *

(4) Carries out nursing care actions which promote, maintain [and], restore or support the well-being of individuals, families or groups across their life span.

(5) Involves individuals [and their], families or groups in their health promotion, maintenance [and] or restoration.

(6) Evaluates the effectiveness of [the quality of] nursing care [provided].

(7) Participates with the multidisciplinary team in identification of health care needs and coordination of health care services. A multidisciplinary team is a team composed of professionals from a variety of disciplines who are consultants in the health management of the individual, family or group for whom the nurse is responsible.

(8) Accepts oral or written orders for medical regimens as prescribed by a licensed physician or dentist.

(i) The registered nurse shall question any order which the registered nurse perceives to be unclear, unsafe or contraindicated for the patient/client. If an order appears to be unclear, unsafe or contraindicated for the patient/client, the registered nurse shall take action in accordance with standards of practice.

(ii) An oral order to execute a medical regimen accepted by the registered nurse shall be immediately transcribed in the proper place on the medical record of the patient/client. The transcription

shall include the prescriber's name, date and time of acceptance of the oral order for a medical regimen and the full signature of the registered nurse accepting the oral order for a medical regimen.

(b) The registered nurse is [fully] responsible for all actions as a licensed nurse and is accountable to patients/clients for the [quality of care delivered] delivery of safe care.

(c) The registered nurse may not engage in [areas] any area of [highly specialized] practice without [adequate knowledge of and skills in the practice areas involved] the necessary preparation, experience and knowledge to properly implement the practice.

(d) [The Board recognizes standards of practice and professional codes of behavior, as developed by appropriate nursing associations as the criteria for assuring safe and effective practice.] The registered nurse performs functions including venipuncture, intravenous fluids, resuscitation and airway maintenance, monitoring and defibrillating and immunizations in accordance with subsection (c).

(e) The Board recognizes standards of practice and professional codes of behavior, as developed by appropriate nursing associations.

§ 21.12. [Venipuncture; intravenous fluids] (Reserved).

[Performing of venipuncture and administering and withdrawing intravenous fluids are functions regulated by this section, and these functions may not be performed unless:

(1) The procedure has been ordered in writing for the patient by a licensed doctor of the healing arts.

(2) The registered nurse who performs venipuncture has had instruction and supervised practice in performing venipuncture.

(3) The registered nurse who administers parenteral fluids, drugs or blood has had instruction and supervised practice in administering parenteral fluids, blood or medications into the vein.

(4) A list of medications which may be administered by the registered nurse is established and maintained by a committee of physicians, pharmacists and nurses from the employing agency or the agency within whose jurisdiction the procedure is being performed if no employing agency is involved.

(5) The intravenous fluid or medication to be administered is the fluid or medication specified in the written order.

(6) The blood is identified as the blood ordered for the patient.

(7) An accurate record is made concerning the following:

(i) The time in the injection.

(ii) The medication or fluid injected.

(iii) The amount of medication or fluid injected.

(iv) Reactions to the fluid.]

§ 21.13. [Resuscitation and respiration] (Reserved).

[External cardiac resuscitation and artificial respiration, mouth-to-mouth, are procedures regulated by this section, and these functions may not be performed unless both of the following provisions are met:

(1) External cardiac resuscitation and artificial respiration, mouth-to-mouth, shall only be performed by a nurse on an individual when respiration or pulse, or both, cease unexpectedly.

(2) A nurse may not perform external cardiac resuscitation and artificial respiration, mouth-to-mouth, unless the nurse has had instruction and supervised practice in performing the procedures.]

§ 21.14. Administration of drugs.

(a) Administering to a patient a drug ordered for that patient by a licensed doctor of the healing arts in the dosage prescribed is a procedure regulated by this section, and the function may not be performed by a person other than a licensed registered nurse[,] and licensed practical nurse except that a licensed registered nurse, responsible for administering a drug, may supervise a nursing student in an approved program and a graduate nurse.

* * * * *

§ 21.15. [Monitoring, defibrillating and resuscitating] (Reserved).

[The use of monitoring, defibrillating or resuscitating equipment, or a combination of the three, hereinafter called "therapy," is a proper function of a registered nurse and is a function regulated by this section; the function may not be performed unless all of the following provisions are met:

(1) The employer, through written policy, has agreed that the registered nurse may administer the therapy.

(2) A committee of licensed physicians and nurses within the employing agency has established written criteria prescribing when the therapy shall be administered by a registered nurse either in the presence or absence of the attending physician.

(3) The techniques for administering the therapy have been established by a committee of licensed physicians and registered nurses within the employing agency.

(4) The registered nurse has had instruction and supervised practice in administering the therapy.

(5) The registered nurse has demonstrated competency in administering the therapy to the satisfaction of the employer.

(6) The registered nurse shall have employed the prescribed techniques in administering the therapy in accordance with the established criteria.]

§ 21.16. [Immunizations] (Reserved).

[(a) Immunization and skin testing is a proper function of a registered nurse and is a function regulated by this section, and the function may not be performed unless all of the following conditions are met:

(1) A written order has been issued by a licensed physician. The order may be a standing order applicable to individuals or groups.

(2) The policies and procedures under which the registered nurse may administer immunizing agents and do skin testing have been established by a committee representing the nurses, the physicians, and the administration of the agency or institution. These written policies and procedures shall be available to the nurse. The committee shall also perform the following functions:

(i) Identify the immunizing and skin testing agents which the nurse may administer.

(ii) Determine contraindications for the administration of specific immunizing and skin testing agents.

(iii) Outline medical principles governing the treatment of possible anaphylactic reactions.

(iv) Establish instruction and supervised practice required to insure competency in administering immunizing and skin testing agents.

(b) Following skin testing, the size of the induration or its absence may be observed and recorded by the properly instructed registered nurse.]

§ 21.17. Anesthesia.

The administration of anesthesia is a proper function of a registered nurse and is a function regulated by this section; this function may not be performed unless:

(1) The registered nurse has successfully completed the education program of a school for nurse anesthetists accredited by the Council on Accreditation of [Education Programs of] Nurse Anesthesia Educational Program of the American Association of Nurse Anesthetists.

* * * * *

(b) For purposes of this section, "cooperation" means a process in which the nurse anesthetist and the surgeon or dentist work together with each contributing an area of expertise, at their individual and respective levels of education and training.

FUNCTIONS OF THE LICENSED PRACTICAL NURSE

§ 21.145. Functions of the LPN.

* * * * *

(b) The LPN administers medication and carries out the therapeutic treatment prescribed or ordered for the patient/client. The LPN [shall] may accept [only] oral or written prescriptions or orders [from the responsible practitioner] as directed by the licensed physician or dentist for medication and therapeutic treatment [unless the urgency of the medical circumstances requires immediate medication or therapeutic treatment]. The LPN shall question any order which is not clear, perceived as unsafe or contraindicated for the patient/client. If an order appears to be unclear, unsafe or contraindicated for the patient/client, the LPN shall take action in accordance with standards of practice. The LPN may not accept an oral prescription or order [under this subsection] which is not within the scope of functions permitted by this [subsection] section or which the

LPN does not understand. An oral prescription or order accepted by the LPN [**under this subsection**] shall be immediately transcribed by the LPN in the proper place on the medical record of the patient/client. The transcription shall include the [**name of the physician giving the order,**] the **prescriber's name,** date and time of **acceptance** of the oral prescription or order and the full signature of the LPN accepting the oral prescription or order. [**The countersignature of the physician shall be obtained in accordance with applicable regulations of the Department of Health governing the licensed facility.**]

* * * * *

[Pa.B. Doc. No. 97-979. Filed for public inspection June 20, 1997, 9:00 a.m.]

**[49 PA. CODE CH. 21]
Volunteer License**

The State Board of Nursing (Board) proposes to add Chapter 21, Subchapter F (relating to volunteer licenses) to read as set forth in Annex A.

A. Effective Date

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

B. Statutory Authority

The Board is required to promulgate regulations governing the volunteer license category by section 5 of the Volunteer Health Services Act (act) (35 P.S. § 449.5) which became effective February 3, 1997. Section 5 of the act mandates regulations governing: (1) qualifications for placing an active license on volunteer status; (2) criteria under which a retired licensee who has allowed a license to become inactive may obtain a volunteer license; and (3) procedures under which a volunteer license holder may return to active status. The Board is authorized to adopt regulations necessary to the administration of its enabling statute under section 2.1(k) of the Professional Nursing Law (63 P.S. § 212.1(k)) and section 17.6 of the Practical Nurse Law (63 P.S. § 667.6).

C. Background and Purpose

The purpose of the proposal is to implement the act. The act is intended to increase the availability of primary health services by establishing a procedure for retired nurses and other health care practitioners to provide professional services as volunteers in approved clinics. Primary health services are defined in the act as including services such as regular checkups, immunizations, school physicals, health education, prenatal and obstetrical care, early periodic screening and diagnostic testing, and health education.

An approved clinic is defined in the act as an organized community-based clinic which offers services to: (1) individuals and families who cannot pay for their care; (2) Medical Assistance clients; or (3) residents of medically underserved or health professionals shortage areas. Examples of these clinics include Federal or State qualified and approved health centers or nonprofit community-based clinics.

The act permits persons who have been issued a license by the State Boards of Medicine, Osteopathic Medicine,

Dentistry, Podiatry, Nursing, Optometry and Chiropractic to practice a component of the healing arts to apply for volunteer status. A volunteer license will be issued to a retired individual who documents to the satisfaction of the Board that the individual will practice without remuneration in approved clinics.

The act exempts holders of a volunteer license from biennial renewal fees.

D. Description of the Regulations

The volunteer license category would be added as Subchapter F. Section 21.601 (relating to purpose and scope) would provide the statutory references to the act, as well as the statutory basis for the volunteer license category. The Board has interpreted the act as permitting a volunteer license holder to practice exclusively in an organized community-based clinic without remuneration.

The criteria for obtaining a volunteer license are set forth in § 21.602 (relating to volunteer license). Under section 3 of the act (35 P.S. § 449.3), an active licensee must possess a current, active, unrestricted license to qualify for a volunteer license. Section 4 of the act permits a licensee to apply who retired with a license in good standing. The Board has interpreted this qualification to mean a license which at the time of the application is not subject to an outstanding disciplinary action such as revocation or suspension. Both active licensees and retired licensees with inactive licenses may receive a volunteer license in order to practice as a volunteer without remuneration in an approved clinic. Currently licensed nurses qualify for a volunteer license so long as their license is unrestricted, that is, not subject to or limited by a disciplinary order of the Board. Retired nurses must have retired with an unrestricted license. In addition, a nurse returning to active practice as a volunteer whose license has been inactive for 5 or more years must satisfy the Board's regulations regarding continued competency in § 21.30a and § 21.156a (relating to continued competency). The act's definition of an "approved" clinic is included in subsection (c).

Procedures to apply for a volunteer license are set forth in § 21.603 (relating to application). Applicants would be requested to provide basic license information. In addition, the applicant would be requested to execute a verification that the applicant intends to practice exclusively within the scope of a volunteer license. Also, in order to provide proper enforcement of the limitation of the act, applicants will be required to file with the Board a letter of agreement from the clinic that the applicant will work in the clinic. Section 21.604 (relating to validity of license) would make this notification a continuing obligation during the biennial period of the license.

Biennial renewal of the volunteer license would be provided for under § 21.605 (relating to biennial renewal). Under the act, volunteer licenses may be renewed without paying the biennial renewal fee; therefore, § 21.605 cross references §§ 21.5, 21.147 and 21.253 (relating to fees).

Section 21.606 (relating to return to active practice) provides for return to active, remunerative practice by a volunteer by applying to the Board.

Section 21.607 (relating to disciplinary provisions) notifies the volunteer license holder that he continues to be subject to the disciplinary provisions of the Professional Nursing Law (63 P.S. §§ 211—225) and the Practical Nurse Law (63 P.S. §§ 651—667). In addition, § 21.607

proposes that a violation of the act or the regulations adopted thereunder may constitute independent grounds for discipline.

E. Compliance with Executive Order 1996-1

In accordance with the requirements of Executive Order 1996-1, in drafting and promulgating the proposed regulations the Board solicited input and suggestions from the regulated community by providing drafts to organizations and entities which represent the professionals and to nonprofit organizations who represent qualified providers of volunteer services.

F. Fiscal Impact and Paperwork Requirements

1. *Commonwealth*—The proposed regulations will create a new license for which no fee will be charged. As such, the expenses of the program will be borne as a part of the Board's overall operating expenses which are financed through biennial renewals of active licensees. Therefore, the administration and enforcement of a new license category may have a fiscal impact on overall Board costs. The net effect, however, is estimated to be minimal owing to the relatively small number of licensee population who will seek a volunteer license compared with the number of active licensees. Additional paperwork will be incurred by the Board and the private sector to generate and file application forms.

2. *Political subdivisions*—There will be no adverse fiscal impact or paperwork requirements imposed.

3. *Private sector*—The proposed regulations will have a positive fiscal impact on individual licensees who restrict their professional activities to volunteer work since these individuals are exempt from maintaining professional liability insurance required under the Health Care Services Malpractice Act (40 P. S. §§ 1301.101—1301.1006) and the biennial renewal fee for licensure. The proposed regulations should impose no additional fiscal or paperwork requirements.

G. Sunset Date

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

H. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on June 6, 1997, the Board submitted a copy of these proposed regulations to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee. In addition to submitting the proposed regulations, the Board has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Board in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

If IRRC has objections to any portion of the proposed regulations, it will notify the Board within 30 days of the close of the public comment period. The notification shall specify the regulatory review criteria which have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the regulations, by the Board, the General Assembly and the Governor of objections raised.

I. Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed regulations to Herbert Abramson, Board Counsel, State

Board of Nursing, P. O. Box 2649, 116 Pine Street, Harrisburg, PA 17105-2649, within 30 days of publication of this proposed rulemaking. Please reference No. 16A-517 (Volunteer License), when submitting comments.

CHRISTINE ALICHNIE, Ph.D., R.N.
Chairperson

Fiscal Note: 16A-517. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 21. STATE BOARD OF NURSING

Subchapter F. VOLUNTEER LICENSES

Sec.	
21.601.	Purpose and scope.
21.602.	Volunteer license.
21.603.	Applications.
21.604.	Validity of license.
21.605.	Biennial renewal.
21.606.	Return to active practice.
21.607.	Disciplinary provisions.

§ 21.601. Purpose and scope.

This subchapter implements the Volunteer Health Services Act (35 P. S. §§ 449.41—449.50) and provides for the issuance of a volunteer license to a qualified registered nurse, a certified registered nurse practitioner and a licensed practical nurse who retires from active practice and seeks to provide professional services as a volunteer. A volunteer license authorizes the holder to practice only in an organized community-based clinic and without remuneration.

§ 21.602. Volunteer license.

A volunteer license may be issued to a licensee of the Board who meets one of the following conditions:

(1) Holds a currently renewed, active, unrestricted license as a registered nurse, a certified registered nurse practitioner or a licensed practical nurse in this Commonwealth and retires from active practice at the time the applicant applies for a volunteer license.

(2) Retires from the active practice of nursing in this Commonwealth in possession of an unrestricted license which was allowed to lapse by not renewing it. A registered nurse whose license had lapsed or had been placed on inactive status shall comply with § 21.30a or § 21.156a (relating to continued competency). As used in this section, an "unrestricted license" is a license which is not restricted or limited by order of the Board under its disciplinary power.

(3) Documents to the satisfaction of the Board that the applicant will practice without personal remuneration in approved clinics. As used in this section, an "approved clinic" is an organized community-based clinic offering primary health care services to individuals and families who cannot pay for their care, to Medical Assistance clients, or to residents of medically underserved areas or health professionals shortage areas. The term may include a State health center, nonprofit community-based clinic and Federally qualified health center, as designated by Federal rulemaking or as approved by the Department of Health or the Department of Public Welfare.

§ 21.603. Applications.

An applicant for a volunteer license shall complete an application obtained from the Board. In addition to providing information requested by the Board, the applicant shall provide:

(1) An executed verification on forms provided by the Board certifying that the applicant intends to practice nursing exclusively:

(i) Without personal remuneration for professional services.

(ii) In an organized community-based clinic offering primary health care services to one or more of the following:

(A) Individuals and families who cannot pay for their care.

(B) Medical Assistance clients.

(C) Residents of medically underserved areas or health professional shortage areas.

(2) A letter signed by the director or chief operating officer of the community-based clinic that the applicant has been authorized to provide volunteer services in the named clinic by the governing body or responsible officer of the clinic.

§ 21.604. Validity of license.

A volunteer license shall be valid for the biennial period for which it is issued, subject to biennial renewal. During each biennial renewal period, the licensee shall notify the Board of any change in clinic or volunteer status within 30 days of the date of a change, or at the time of renewal, whichever occurs first.

§ 21.605. Biennial renewal.

A volunteer license shall be renewed biennially on forms provided by the Board. The applicant shall be exempt from payment of the biennial renewal fee of § 21.5, § 21.147 or § 21.253 (relating to fees), as applicable.

§ 21.606. Return to active practice.

A volunteer license holder who desires to return to active practice shall notify the Board and apply for biennial registration on forms provided by the Board.

§ 21.607. Disciplinary provisions.

A volunteer license holder shall be subject to the disciplinary provisions of the act and this chapter. Failure of the licensee to comply with the Volunteer Health Services Act (35 P. S. §§ 449.41—449.50) or this subchapter may also constitute grounds for disciplinary action.

[Pa.B. Doc. No. 97-980. Filed for public inspection June 20, 1997, 9:00 a.m.]

**STATE BOARD OF
OPTOMETRY**

[49 PA. CODE CH. 23]
Volunteer License

The State Board of Optometry (Board) proposes to add § 23.26 (relating to volunteer license) to read as set forth in Annex A.

A. Effective Date

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

B. Statutory Authority

The Board is required to promulgate regulations governing the volunteer license category by section 5 of the Volunteer Health Services Act (act) (35 P. S. § 449.5) which became effective February 3, 1997. Section 5 of the act mandates regulations governing: (1) qualifications for placing an active license on volunteer status; (2) criteria under which a retired licensee who has allowed a license to become inactive may obtain a volunteer license; and (3) procedures under which a volunteer license holder may return to active status. The Board is authorized to adopt regulations necessary to the administration of its enabling statute under section 3(b)(14) of the Optometric Practice and Licensure Act (63 P. S. § 244.3(b)(14)).

C. Background and Purpose

The purpose of the proposal is to implement the act. The act is intended to increase the availability of primary health services by establishing a procedure for retired physicians and other health care practitioners to provide professional services as volunteers in approved clinics. Primary health services are defined in the act as including services such as regular checkups, immunizations, school physicals, health education, prenatal and obstetrical care, early periodic screening and diagnostic testing, and health education.

An approved clinic is defined in the act as an organized community-based clinic which offers services to: (1) individuals and families who cannot pay for their care; (2) Medical Assistance clients; or (3) residents of medically underserved or health professionals shortage areas. Examples of these clinics include Federal or State qualified and approved health centers or nonprofit community based clinics.

The act permits persons who have been issued a license by the State Boards of Medicine, Osteopathic Medicine, Dentistry, Podiatry, Nursing, Optometry and Chiropractic to practice a component of the healing arts to apply for volunteer status. A volunteer license will be issued to a retired individual who documents to the satisfaction of the Board that he will practice without remuneration in approved clinics.

The act exempts holders of a volunteer license from biennial renewal fees. However, volunteer licenses will be subject to biennial renewal conditioned upon completion of any continuing education which the Board requires for biennial renewal generally.

D. Description of Amendments

The volunteer license category would be added to § 23.26. Section 23.26(a) would provide the statutory references to the act, as well as the statutory basis for the volunteer license category. The Board has interpreted the act as permitting a volunteer license holder to practice exclusively in an organized community-based clinic without remuneration.

The criteria for obtaining a volunteer license are set forth in § 23.26(b). Both active licensees and retired optometrists with inactive licenses may receive a volunteer license in order to practice as a volunteer without remuneration in an approved clinic. The act's definition of an "approved clinic" is included in subsection (b)(3). In addition to the criteria, under section 3 of the act (35 P. S.

§ 449.3), an active licensee must possess a current, active, unrestricted license in order to qualify for a volunteer license. Section 4 of the act (35 P. S. § 449.4) permits a licensee to apply who retired with a license in good standing. The Board has interpreted this qualification to mean a license which at the time of the application is not subject to an outstanding disciplinary action such as revocation or suspension.

Procedures to apply for a volunteer license are set forth in § 23.26(c). Applicants would be requested to provide basic license information. In addition, the applicant would be requested to execute a verification that the applicant intends to practice exclusively within the scope of a volunteer license. Also, in order to provide proper enforcement of the limitation of the act, applicants will be required to file with the Board a letter of agreement from the clinic that the applicant will work in the clinic. Section 23.26(d) would make this notification a continuing obligation during the biennial period of the license.

Biennial renewal of the volunteer license would be provided for under § 23.26(e). Subsection (e) references continuing education requirements which must be met and § 23.91 (relating to fees) pertaining to the renewal fee from which a volunteer license is exempt under the act.

Section 23.26(f) provides for return to active, remunerative practice by a volunteer by applying to the Board and meeting the general reactivation requirements.

Section 23.26(g) notifies the volunteer license holder that he continues to be subject to the disciplinary provisions of the Optometric Practice and Licensure Act (63 P. S. §§ 244.1—244.12). In addition, § 23.26(g) proposes that a violation of the act or the regulations adopted thereunder may constitute independent grounds for discipline.

E. Compliance with Executive Order 1996-1

In accordance with the requirements of Executive Order 1996-1, in drafting and promulgating the proposed regulation the Board solicited input and suggestions from the regulated community by providing drafts to organizations and entities which represent the professionals and to nonprofit organizations who represent qualified providers of volunteer services.

F. Fiscal Impact and Paperwork Requirements

1. *Commonwealth*—The proposed regulation will create a new license for which no fee will be charged. As such, the expenses of the program will be borne as a part of the Board's overall operating expenses which are financed through biennial renewals of active licensees and may have a fiscal impact on overall Board costs. The net effect, however, is estimated to be minimal owing to the relatively small number of licensee population who will seek a volunteer license. Additional paperwork will be incurred by the Board and the private sector to generate and file application forms.

2. *Political subdivisions*—There will be no adverse fiscal impact or paperwork requirements imposed.

3. *Private sector*—The proposed regulation will have a positive fiscal impact on individual licensees who restrict their professional activities to volunteer work since these individuals are exempt from maintaining professional liability insurance required under the Health Care Services Malpractice Act (40 P. S. §§ 1301.101—1301.1006) and the biennial renewal fee for licensure. The proposed regulation should impose no additional fiscal or paperwork requirements.

G. Sunset Date

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

H. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on June 6, 1997, the Board submitted a copy of this proposed regulation to the Independent Regulatory Review Commission (IRRC) and the Chairperson of the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee. In addition to submitting the proposed regulation, the Board has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the agency in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

If IRRC has objections to any portion of the proposed regulation, it will notify the Board within 30 days of the close of the public comment period. The notification shall specify the regulatory review criteria which have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the regulation, by the Board, the General Assembly and the Governor of objections raised.

I. Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed regulation to April L. McClaine, Board Counsel, State Board of Optometry, P. O. Box 2649, 116 Pine Street, Harrisburg, PA 17105-2649, within 30 days of publication of this proposed rulemaking. Please reference No. 16A-526 (Volunteer License), when submitting comments.

ROBERT A. GINSBURG, O.D.,
Chairperson

Fiscal Note: 16A-526. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 23. STATE BOARD OF OPTOMETRY

§ 23.26. Volunteer license.

(a) *Purpose and scope.* The following subsections implement the Volunteer Health Services Act (35 P. S. §§ 449.41—449.50) and provide for the issuance of a volunteer license to a qualified individual who retires from active practice and seeks to provide professional services as a volunteer. A volunteer license authorizes the holder to practice only in an organized community-based clinic and without remuneration.

(b) *License.* A volunteer license may be issued to a licensee of the Board who meets one of the following conditions:

(1) Holds a currently renewed, active, unrestricted license as an optometrist in this Commonwealth and retires from active practice at the time the applicant applies for a volunteer license.

(2) Retires from the active practice of optometry in this Commonwealth in possession of an unrestricted license which was allowed to lapse by not renewing it. A retired

licensee shall meet the requirements of the act or the regulations pertaining to continued education or continued competency to be eligible for renewal. As used in this section, an "unrestricted license" is a license which is not restricted or limited by order of the Board under its disciplinary power.

(3) Documents to the satisfaction of the Board that the applicant will practice without personal remuneration in approved clinics. As used in this section, an "approved clinic" is an organized community-based clinic offering primary health care services to individuals and families who cannot pay for their care, to Medical Assistance clients or to residents of medically underserved areas or health professionals shortage areas. The term may include a State health center, nonprofit community-based clinic and Federally qualified health center, as designated by Federal rulemaking or as approved by the Department of Health or the Department of Public Welfare.

(c) *Applications.* An applicant for a volunteer license shall complete an application obtained from the Board. In addition to providing information requested by the Board, the applicant shall provide:

(1) An executed verification on forms provided by the Board certifying that the applicant intends to practice optometry exclusively:

(i) Without personal remuneration for professional services.

(ii) In an organized community-based clinic offering primary health care services to one or more of the following:

(A) Individuals and families who cannot pay for their care.

(B) Medical Assistance clients.

(C) Residents of medically underserved areas or health professional shortage areas.

(2) A letter signed by the director or chief operating officer of the community-based clinic that the applicant has been authorized to provide volunteer services in the named clinic by the governing body or responsible officer of the clinic.

(d) *Validity of license.* A volunteer license shall be valid for the biennial period for which it is issued, subject to biennial renewal. During each biennial renewal period, the licensee shall notify the Board of any change in clinic or volunteer status within 30 days of the date of a change, or at the time of renewal, whichever occurs first.

(e) *Biennial renewal.* A volunteer license shall be renewed biennially on forms provided by the Board.

(1) As a condition of biennial renewal, the applicant shall satisfy the same continuing education requirements as the holder of an active, unrestricted license.

(2) The applicant shall be exempt from payment of the biennial renewal fee of \$ 23.91 (relating to fees).

(f) *Return to active practice.* A volunteer license holder who desires to return to active practice shall notify the Board and apply for biennial registration on forms provided by the Board.

(g) *Disciplinary provisions.* A volunteer license holder shall be subject to the disciplinary provisions of the act and this chapter. Failure of the licensee to comply with the Volunteer Health Services Act (35 P. S. §§ 449.41—449.50) or this section may also constitute grounds for disciplinary action.

[Pa.B. Doc. No. 97-981. Filed for public inspection June 20, 1997, 9:00 a.m.]

STATE BOARD OF OSTEOPATHIC MEDICINE

[49 PA. CODE CH. 25]

Volunteer License

The State Board of Osteopathic Medicine (Board) proposes to amend Chapter 25, by adding Subchapter L (relating to volunteer license) to read as set forth in Annex A.

A. *Effective Date*

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

B. *Statutory Authority*

The Board is required to promulgate regulations governing the volunteer license category under section 5 of the Volunteer Health Services Act (act) (35 P. S. § 449.5) which became effective February 3, 1997. Section 5 of the act mandates regulations governing: (1) qualifications for placing an active license on volunteer status; (2) criteria under which a retired licensee who has allowed a license to become inactive may obtain a volunteer license; and (3) procedures under which a volunteer license holder may return to active status. The Board is authorized to adopt regulations necessary to the administration of its enabling statute under section 16 of the Osteopathic Medical Practice Act (63 P. S. § 271.16).

C. *Background and Purpose*

The purpose of the proposal is to implement the act. The act is intended to increase the availability of primary health services by establishing a procedure for physicians and other health care practitioners who have retired from active practice to provide professional services as volunteers in approved clinics. Primary health services are defined in the act as including services such as regular checkups, immunizations, school physicals, health education, prenatal and obstetrical care, early periodic screening and diagnostic testing, and health education.

An approved clinic is defined in the act as an organized community-based clinic which offers services to: (1) individuals and families who cannot pay for their care; (2) Medical Assistance clients; or (3) residents of medically underserved or health professionals shortage areas. Examples of these clinics include Federal or State qualified and approved health centers or nonprofit community based clinics.

The act permits persons who have been issued a license by the State Board of Medicine, Osteopathic Medicine, Dentistry, Podiatry, Nursing, Optometry and Chiropractic to practice a component of the healing arts to apply for volunteer status. A volunteer license will be issued to a

retired individual who documents to the satisfaction of the Board that the individual will practice without remuneration in approved clinics.

The act exempts holders of a volunteer license from biennial renewal fees and professional liability coverage mandated by the Health Care Services Malpractice Act (40 P. S. § 1301.701). However, volunteer licenses will be subject to biennial renewal conditioned upon completion of any continuing education which the Board requires for biennial renewal generally.

D. Description of the Proposed Regulations

The volunteer license category would be added in § 25.601 (relating to purpose and scope). Section 25.601 would provide the statutory references to the act, as well as the statutory basis for the volunteer license category. The Board has interpreted the act as permitting a volunteer license holder to practice exclusively in an organized community-based clinic without remuneration.

Under section 3 of the act (35 P. S. § 449.43), an active licensee must possess a current, active, unrestricted license to qualify for a volunteer license. Section 4 of the act (35 P. S. § 449.44) permits a licensee to apply who retired with a license in good standing. The Board has interpreted this qualification to mean a license which at the time of the application is not subject to an outstanding disciplinary action such as revocation or suspension. Accordingly, the Board uses the term unrestricted license as a qualification for the issuance of a volunteer license in subsection (d). The criteria for obtaining a volunteer license are set forth in § 25.602. Both active licensees and retired licensees with inactive licenses may receive a volunteer license in order to practice as a volunteer without remuneration in an approved clinic. The act's definition of an "approved" clinic is included in subsection (c).

Procedures to apply for a volunteer license are set forth in proposed § 25.603 (relating to applications). Applicants would be requested to provide basic license information. In addition, the applicant would be requested to execute a verification that the applicant intends to practice exclusively within the scope of a volunteer license. Also, in order to provide proper enforcement of the limitation of the act, applicants will be required to file with the Board a letter of agreement from the clinic that the applicant will work in the clinic. Section 25.604 (relating to validity of license) would make this notification a continuing obligation during the biennial period of the license.

Biennial renewal of the volunteer license would be provided for under § 25.605 (relating to biennial renewal). Subsections (a) and (b) would cross reference § 25.271 (relating to requirements for renewal) pertaining to continuing education requirements which must be met and § 25.231 (relating to schedule of fees) pertaining to the renewal fee from which a volunteer license is exempt under the act.

Section 25.606 (relating to return to active practice act) provides for return to active, remunerative practice by a volunteer by applying to the Board and meeting the general reactivation requirements.

Section 25.607 (relating to disciplinary provisions) notifies the volunteer license holder that he continues to be subject to the disciplinary provisions of the Osteopathic

Medical Practice Act (63 P. S. §§ 271.1—271.18). In addition, § 25.607 proposes that a violation of the act or the regulations adopted thereunder may constitute independent grounds for discipline.

E. Compliance with Executive Order 1996-1

In accordance with the requirements of Executive Order 1996-1, in drafting and promulgating the proposed regulations the Board solicited input and suggestions from the regulated community by providing drafts to organizations and entities which represent the professionals and to nonprofit organizations who represent qualified providers of volunteer services.

F. Fiscal Impact and Paperwork Requirements

1. *Commonwealth*—The proposed regulations will create a new license for which no fee will be charged. As such, the expenses of the program will be borne as a part of the Board's overall operating expenses which are financed through biennial renewals of active licensees. Therefore, the administration and enforcement of a new license category may have a fiscal impact on overall Board costs. The net effect, however, is estimated to be minimal owing to the relatively small number of licensee population who will seek a volunteer license compared with the number of active licensees. Additional paperwork will be incurred by the Board and the private sector to generate and file application forms.

2. *Political subdivisions*—There will be no adverse fiscal impact or paperwork requirements imposed.

3. *Private sector*—The proposed regulations will have a positive fiscal impact on individual licensees who restrict their professional activities to volunteer work since these individuals are exempt from maintaining professional liability insurance required under the Health Care Services Malpractice Act (40 P. S. §§ 1301.101—1301.1006) and the biennial renewal fee for licensure. The proposed regulations should impose no additional fiscal or paperwork requirements.

G. Sunset Date

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

H. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on June 6, 1997, the Board submitted a copy of these proposed regulations to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee. In addition to submitting the proposed regulations, the Board has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Board in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

If IRRC has objections to any portion of the proposed regulation, it will notify the Board within 30 days of the close of the public comment period. The notification shall specify the regulatory review criteria which have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the regulations, by the Board, the General Assembly and the Governor of objections raised.

I. Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed

regulations to Herbert Abramson, Board Counsel, State Board of Osteopathic Medicine, P. O. Box 2649, 116 Pine Street, Harrisburg, PA 17105-2649, within 30 days of publication of this proposed rulemaking. Please reference No. 16A-537 (Volunteer License), when submitting comments.

SILVIA M. FERRETTI, D.O.,
Chairperson

Fiscal Note: 16A-537. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 25. STATE BOARD OF OSTEOPATHIC MEDICINE

Subchapter L. VOLUNTEER LICENSE

Sec.	
25.601.	Purpose and scope.
25.602.	Volunteer license.
25.603.	Applications.
25.604.	Validity of license.
25.605.	Biennial renewal.
25.606.	Return to active practice.
25.607.	Disciplinary provisions.

§ 25.601. Purpose and scope.

This subchapter implements the Volunteer Health Services Act (35 P. S. §§ 449.41—449.50) and provides for the issuance of a volunteer license to a qualified Board-regulated practitioner as defined in section 2 of the act (63 P. S. § 271.2), who retires from active practice and seeks to provide professional services as a volunteer. A volunteer license authorizes the holder to practice only in an organized community-based clinic and without remuneration.

§ 25.602. Volunteer license.

A volunteer license may be issued to a Board-regulated practitioner who meets one of the following conditions:

(1) Holds a currently renewed, active, unrestricted license, registration or certificate in this Commonwealth and retires from active practice at the time the applicant applies for a volunteer license.

(2) Retires from the active practice in this Commonwealth in possession of an unrestricted license which was allowed to lapse by not renewing it. A retired licensee, registrant or certificateholder shall meet any requirements of the act or the regulations pertaining to continued education or continued competency to be eligible for renewal. As used in this section, an “unrestricted license, certification or registration” is a license which is not restricted or limited by order of the Board under its disciplinary power.

(3) Documents to the satisfaction of the Board that the applicant will practice without personal remuneration in approved clinics. As used in this section, an “approved clinic” is an organized community-based clinic offering primary health care services to individuals and families who cannot pay for their care, to Medical Assistance

clients, or to residents of medically underserved areas or health professionals shortage areas. The term may include a State health center, nonprofit community-based clinic and Federally qualified health center, as designated by Federal rulemaking or as approved by the Department of Health or the Department of Public Welfare.

§ 25.603. Applications.

An applicant for a volunteer license shall complete an application obtained from the Board. In addition to providing information requested by the Board, the applicant shall provide:

(1) An executed verification on forms provided by the Board certifying that the applicant intends to practice exclusively:

(i) Without personal remuneration for professional services.

(ii) In an organized community-based clinic offering primary health care services to one or more of the following:

(A) Individuals and families who cannot pay for their care

(B) Medical assistance clients

(C) Residents of medically underserved areas or health professional shortage areas.

(2) A letter signed by the director or chief operating officer of the community-based clinic that the applicant has been authorized to provide volunteer services in the named clinic by the governing body or responsible officer of the clinic.

§ 25.604. Validity of license.

A volunteer license shall be valid for the biennial period for which it is issued, subject to biennial renewal. During each biennial renewal period, the volunteer license holder shall notify the Board of any change in clinic or volunteer status within 30 days of the date of a change, or at the time of renewal, whichever occurs first.

§ 25.605. Biennial renewal.

A volunteer license shall be renewed biennially on forms provided by the Board.

(1) As a condition of biennial renewal, the applicant shall satisfy the same continuing education requirements as the holder of an active, unrestricted license under § 25.271 (relating to requirements for renewal).

(2) The applicant shall be exempt from § 25.231 (relating to schedule of fees) pertaining to the biennial renewal fee and shall be exempt from § 25.283 (relating to biennial renewal of license) with regard to the maintenance of liability insurance coverage under section 701 of the Health Care Services Malpractice Act (40 P. S. § 1301-701).

§ 25.606. Return to active practice.

A volunteer license holder who desires to return to active practice shall notify the Board and apply for biennial registration on forms provided by the Board.

§ 25.607. Disciplinary provisions.

A volunteer license holder shall be subject to the disciplinary provisions of the act and this chapter. Failure of the licensee to comply with the Volunteer Health

Services Act (35 P. S. §§ 449.41—449.50) or this subchapter may also constitute grounds for disciplinary action.

[Pa.B. Doc. No. 97-982. Filed for public inspection June 20, 1997, 9:00 a.m.]

STATE BOARD OF PODIATRY

[49 PA. CODE CH. 29] Volunteer License

The State Board of Podiatry (Board) proposes to add § 29.55 (relating to volunteer license) to read as set forth in Annex A.

A. Effective Date

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

B. Statutory Authority

The Board is required to promulgate regulations governing the volunteer license category by section 5 of the Volunteer Health Services Act (act) (35 P. S. § 449.5) which became effective February 3, 1997. Section 5 of the act mandates regulations governing: (1) qualifications for placing an active license on volunteer status; (2) criteria under which a retired licensee who has allowed a license to become inactive may obtain a volunteer license; and (3) procedures under which a volunteer license holder may return to active status. The Board is authorized to adopt regulations necessary to the administration of its enabling statute under section 15 of the Podiatry Practice Act (63 P. S. § 42.15).

C. Background and Purpose

The purpose of the proposal is to implement the act. The act is intended to increase the availability of primary health services by establishing a procedure for podiatrists and other health care practitioners who have retired from active practice to provide professional services as volunteers in approved clinics. Primary health services are defined in the act as including services such as regular checkups, immunizations, school physicals, health education, prenatal and obstetrical care, early periodic screening and diagnostic testing, and health education.

An approved clinic is defined in the act as an organized community-based clinic which offers services to: (1) individuals and families who cannot pay for their care; (2) Medical Assistance clients; or (3) residents of medically underserved or health professionals shortage areas. Examples of these clinics include Federal or State qualified and approved health centers or nonprofit community based clinics.

The act permits persons who have been issued a license by the State Boards of Medicine, Osteopathic Medicine, Dentistry, Podiatry, Nursing, Optometry and Chiropractic to practice a component of the healing arts to apply for volunteer status. A volunteer license will be issued to a retired individual who documents to the satisfaction of the Board that the individual will practice without remuneration in approved clinics.

The act exempts holders of a volunteer license from biennial renewal fees and professional liability coverage mandated by section 701 of the Health Care Services Malpractice Act (40 P. S. § 1301.701). However, volunteer licenses will be subject to biennial renewal conditioned upon completion of any continuing education which the Board requires for biennial renewal generally.

D. Description of Amendments

The volunteer license category would be added to § 29.55. Section 29.55 would provide the statutory references to the act, as well as the statutory basis for the volunteer license category. The Board has interpreted the act as permitting a volunteer license holder to practice exclusively in an organized community based clinic without remuneration.

Under section 3 of the act (35 P. S. § 449.3), an active licensee must possess a current, active, unrestricted license to qualify for a volunteer license. Section 4 of the act permits a licensee to apply who retired with a license in good standing. The Board has interpreted this qualification to mean a license which at the time of the application is not subject to an outstanding disciplinary action such as revocation or suspension. Accordingly, the Board uses the term "unrestricted license" as a qualification for the issuance of a volunteer license in subsection (b). The criteria for obtaining a license are set forth in new § 29.55(b)(1). Both active licensees and retired podiatrists with inactive licenses may receive a volunteer license in order to practice as a volunteer without remuneration in an approved clinic. The act definition of an "approved clinic" is included in subsection (b)(3).

Procedures to apply for a volunteer license are set forth at proposed § 29.55(c). Applicants would be requested to provide basic license information. In addition, the applicant would be requested to execute a verification that the applicant intends to practice exclusively within the scope of a volunteer license. Also, to provide proper enforcement of the limitation of the act, applicants will be required to file with the Board a letter of agreement from the clinic that the applicant will work in the clinic. Section 29.55(d) would make this notification a continuing obligation during the biennial period of the license.

Biennial renewal of the volunteer license would be provided for in § 29.55(e). This subsection cross references § 29.13 (relating to fees) pertaining to the renewal fee from which a volunteer license is exempt under the act.

Section 29.55(f) provides for return to active, remunerative practice by a volunteer by applying to the Board and meeting the general reactivation requirements.

Section 29.55(g) notifies the volunteer license holder that he continues to be subject to the disciplinary provisions of the Podiatry Practice Act of 1956 (63 P. S. §§ 42.1—42.21a). In addition, § 29.55(g) proposes that a violation of the act or the regulations adopted thereunder may constitute independent grounds for discipline.

E. Compliance with Executive Order 1996-1

In accordance with the requirements of Executive Order 1996-1, in drafting and promulgating the regulation the Board solicited input and suggestions from the regulated community by providing drafts to organizations and entities which represent the professionals and to nonprofit organizations who represent qualified providers of volunteer services.

F. Fiscal Impact and Paperwork Requirements

1. *Commonwealth*—The proposed regulation will create a new license for which no fee will be charged. As such, the expenses of the program will be borne as a part of the Board's overall operating expenses which are financed through biennial renewals of active licensees. Therefore, the administration and enforcement of a new license category may have a fiscal impact on overall Board costs. The net effect, however, is estimated to be minimal owing to the relatively small number of licensee population who will seek a volunteer license compared with the number of active licensees. Additional paperwork will be incurred by the Board and the private sector to complete and file application forms.

2. *Political subdivisions*—There will be no adverse fiscal impact or paperwork requirements imposed.

3. *Private sector*—The proposed regulation will have a positive fiscal impact on individual licensees who restrict their professional activities to volunteer work since these individuals are exempt from maintaining professional liability insurance required under the Health Care Services Malpractice Act (40 P. S. §§ 1301.101—1301.1006) and the biennial renewal fee for licensure. The regulation should impose no additional fiscal or paperwork requirements.

G. Sunset Date

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

H. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on June 6, 1997, the Board submitted a copy of this proposed regulation to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee. In addition to submitting the proposed regulation, the Board has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Board in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

If IRRC has objections to any portion of the proposed regulation, it will notify the Board within 30 days of the close of the public comment period. The notification shall specify the regulatory review criteria which have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the regulation, by the Board, the General Assembly and the Governor of objections raised.

I. Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed regulation to Beth Sender Michlovitz, Board Counsel, State Board of Podiatry, P. O. Box 2649, 116 Pine Street, Harrisburg, PA 17105-2649, within 30 days of publication of this proposed rulemaking. Please reference No. 16A-443 (Volunteer License), when submitting comments.

STANLEY E. BOC, D.P.M.,
Chairperson

Fiscal Note: 16A-443. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 29. STATE BOARD OF PODIATRY LICENSURE APPLICATIONS

§ 29.55. Volunteer license.

(a) *Purpose and scope.* The following subsections implement the Volunteer Health Services Act (35 P. S. §§ 449.41—449.50) and provide for the issuance of a volunteer license to a qualified individual who retires from active practice and seeks to provide professional services as a volunteer. A volunteer license authorizes the holder to practice only in an organized community-based clinic and without remuneration.

(b) *Issuance of license.* A volunteer license may be issued to a licensee of the Board who meets one of the following conditions:

(1) Holds a currently renewed, active, unrestricted license as a podiatrist in this Commonwealth and retires from active practice at the time the applicant applies for a volunteer license.

(2) Retires from active practice in this Commonwealth in possession of an unrestricted license which was allowed to lapse by not renewing it. A retired licensee shall meet any requirements of the act or the regulations pertaining to continued education or continued competency to be eligible for renewal. As used in this section, an "unrestricted license" is a license which is not restricted or limited by order of the Board under its disciplinary power.

(3) Documents to the satisfaction of the Board that the applicant will practice without personal remuneration in approved clinics. As used in this section, an "approved clinic" is an organized community-based clinic offering primary health care services to individuals and families who cannot pay for their care, to Medical Assistance clients or to residents of medically underserved areas or health professionals shortage areas. The term may include a State health center, nonprofit community-based clinic and Federally qualified health center, as designated by Federal rulemaking or as approved by the Department of Health or the Department of Public Welfare.

(c) *Applications.* An applicant for a volunteer license shall complete an application obtained from the Board. In addition to providing information requested by the Board, the applicant shall provide:

(1) An executed verification on forms provided by the Board certifying that the applicant intends to practice nursing exclusively as follows:

(i) Without personal remuneration for professional services.

(ii) In an organized community-based clinic offering primary health care services to one or more of the following:

(A) Individuals and families who cannot pay for their care.

(B) Medical Assistance clients.

(C) Residents of medically underserved areas or health professional shortage areas.

(2) A letter signed by the director or chief operating officer of the community-based clinic that the applicant has been authorized to provide volunteer services in the named clinic by the governing body or responsible officer of the clinic.

(d) *Validity of a license.* A volunteer license shall be valid for the biennial period for which it is issued, subject to biennial renewal. During each biennial renewal period, the volunteer license holder shall notify the Board of any change in clinic or volunteer status within 30 days of the date of a change, or at the time of renewal, whichever occurs first.

(e) *Renewal of license.* A volunteer license shall be renewed biennially on forms provided by the Board.

(1) As a condition of biennial renewal, the applicant shall satisfy the same continuing education requirements as the holder of an active, unrestricted license.

(2) The applicant shall be exempt from § 29.13 (relating to fees) pertaining to the biennial renewal fee and

shall be exempt from the requirements with regard to maintenance of liability insurance coverage under section 701 of the Health Care Services Malpractice Act (40 P. S. § 1301-701) and §§ 29.51—29.54.

(f) *Return to active practice.* A volunteer license holder who desires to return to active practice shall notify the Board and apply for biennial registration on forms provided by the Board in accordance with §§ 29.51 and 29.52 (relating to applicants; and requirements for applicants).

(g) *Disciplinary provisions.* A volunteer license holder shall be subject to the disciplinary provisions of the act and this chapter. Failure of the licensee to comply with the Volunteer Health Services Act (35 P. S. §§ 449.41—449.50) or this chapter may also constitute grounds for disciplinary action.

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