

# PROPOSED RULEMAKING

## DEPARTMENT OF HEALTH

[ 28 PA. CODE CHS. 1101, 1103, 1105, 1107 and 1113 ]

### Supplemental Nutrition Program for Women, Infants and Children (WIC Program)

The Department of Health (Department), Bureau of Family Health, Division of WIC (WIC Program), proposes to amend 28 Pa. Code Chapters 1101, 1103, 1105, 1107 and 1113. The chapters govern the authorization and management of stores participating in the Special Supplemental Nutrition for Women, Infants and Children (WIC) Program.

Without some of these proposed revisions, the United States Department of Agriculture, Food Nutrition Services (USDA-FNS) may withhold funding to the WIC Program. If Federal funding is interrupted, the Department would likely need to suspend or eliminate the WIC Program, having a significant negative impact on the health and welfare of WIC eligible women, infants and children. Loss or even suspension of Federal funding for the WIC Program would render it inoperable, as 100% of the WIC Program's funds are Federal funds, or would place a difficult, if not impossible, financial burden on the Commonwealth, if the Commonwealth continue to operate the WIC Program with State funds. The WIC Program serves approximately 245,000 families and individuals, and is a high profile benefits program not only in this Commonwealth, but also around the country. An interruption in the funding of the WIC Program would affect the receipt of necessary food benefits for the participants of the WIC Program, the retail grocery business and the employment of personnel at 24 local WIC agencies.

Other proposed revisions to the WIC Program State regulations include the addition of language which will allow the WIC Program to more smoothly incorporate technology advancements. These advancements will ensure that the Pennsylvania WIC Program remains at the forefront of quality and efficiency and continues to provide the best experience for WIC participants and WIC authorized stores.

#### A. Summary of Amendments

##### Section 1101.2. Definitions.

The Department proposes to revise this section to add definitions for the terms "above-50-percent-store," "competitive price," "food items," "food sales," "Food Stamp Program," "full line grocery store," "peer group" and "store peer group system." These proposed terms, and their definitions, are required for the implementation of the other revisions to the regulations providing for the identification of WIC-Only stores, the term more commonly used when referring to above-50-percent stores, and for additional Federally-mandated cost containment requirements.

The Department proposes to define an "above-50-percent-store" as a store that derives more than 50% of its annual food sales revenue from WIC checks and any new store that is expected to derive more than 50% of its annual food sales revenue from WIC checks. Guidelines for determining if more than 50% of the store's food sales revenue is from WIC checks are set by the USDA in accordance with Federal laws.

The Department proposes to define "competitive price" as the price established by the Department, at or below which a store must maintain the required minimum inventory. As explained as follows, this term will replace "maximum allowable price" in some other existing provisions of the regulations, although "maximum allowable price" will remain an operative term in the regulations.

The Department proposes to define "food items" as items sold for human consumption that are eligible items under the Food Stamp Program. The Department also proposed to define "food sales" as sales of all Food Stamp Program eligible foods.

The Department proposes to define "Food Stamp Program" as the government benefits program operated under the authority of the Food Stamp Act of 1964, 7 U.S.C.A. Chapter 51, as amended, and 55 Pa. Code Part II, Subpart L (relating to Food Stamp Program). This program is administered by the USDA-FNS and the Department of Public Welfare.

The Department proposes to define "full line grocery store" as a store that, in addition to WIC authorized foods, offers for sale, food items in each of the four following food categories: 1) meat, poultry or fish; 2) bread or cereal; 3) vegetables or fruits; and, 4) dairy. A minimum of three different varieties of food items in each of the four categories must be available for sale at all times of operation and displayed in a public area of the store.

As stated previously, above-50-percent-stores are typically referred to as WIC-Only stores. WIC-Only stores generally sell only WIC foods, serve only WIC participants and charge significantly higher prices for WIC foods than typical grocery stores. In turn, these higher prices result in a higher cost for the WIC Program, which could result in a reduction in the number of WIC checks provided to WIC Program participants and ultimately a reduction in the number of participants the WIC Program can serve.

The Department proposes to define "peer group" as the classification of an authorized store under the store peer group system, as determined by the criteria selected by the Department. The term "store peer group system" is proposed to be defined as a classification of authorized stores into groups based on common characteristics or criteria that affect food prices, for the purposes of applying appropriate competitive pricing criteria to stores at authorization and reauthorization and limiting payment for foods to competitive levels. Both of these proposed terms and definitions will allow the Department to implement Federally-mandated cost containment measures.

The Department also proposes to revise the definition of "overpayment" to clarify that the maximum allowable price applicable to the store's peer group will be used for determining whether the WIC Program made payment to a store for an amount higher than what the store would be entitled to under program regulations.

##### Section 1103.1. Authorization and reauthorization process and requirements.

The Department proposes to renumber § 1103.1(b)(5) and (6) as § 1103.1(b)(6) and (7) respectively, and insert a new § 1103.1(b)(5). The Department also proposes to revise this section to renumber subsections (c)(2) and (3) as (c)(3) and (4), respectively, to insert a new subsection (c)(2).

The proposed subsections (b)(5) and (c)(2) provide that the Department may request from a store seeking authorization or reauthorization any information the Department deems necessary to determine whether the store will derive or is deriving more than 50% of its annual food items sales revenue from the sale of food items for WIC checks. This information may include, but is not limited to, official State and Federal Income Tax Filings, Official State Sales Tax records, inventory purchase records, sales records or a self-declaration, or both, from the applicant. Amendments to the Federal regulations governing the WIC Program and appropriating the funding to the WIC Program necessitate these, and other similar revisions to the Pennsylvania WIC regulations. See Child Nutrition and WIC Reauthorization Act, Pub. L. No. 108-265, § 203(e)(10), 118 Stat. 729 at 776-779 (2004) (codified at 42 U.S.C. § 1786(h)(11)); Consolidated Appropriations Act, 2005, Pub. L. No. 108-447, 118 Stat. 2809, 2833 and 2850 § 780 (2005 Appropriations Act); and, Agricultural, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2006, Pub. L. No. 109-97, 119 Stat. 2120, 2144 and 2163 § 787 (2006 Appropriations Act). The Department published a notice of its intent to implement some of these Federal mandates in the *Pennsylvania Bulletin*. See 35 Pa.B. 77 (January 1, 2005).

The Department also proposes to revise § 1103.1 to add a new subsection (d)(7). This proposed subsection will allow the Department to terminate authorization of a store if the store fails to provide the Department with the information necessary for the Department to determine whether the store will derive or is deriving more than 50% of its annual food items sales revenue from the sale of food items for WIC checks. The proposed subsection requires that the Department provide written notice to the store of the information requested and that the Department allow the store 20 calendar days to provide the information.

The proposed revisions to this section also include the addition of a new subsection (d)(8) which provides for the termination of authorization of a store as a WIC vendor in the event the Department, subsequent to authorizing the store, determines the store is deriving more than 50% of its annual food items sales revenue from the sale of food items for WIC checks.

The proposed subsection (d)(7) and (8) assists the Department in ensuring all above-50-percent-stores are properly identified to implement the Federally mandated cost containment measures. In conformity with Federal law, the proposed subsections (b)(5), (c)(2) and (d)(7) and (8) do not apply to stores that are solely owned and operated by nonprofit entities.

*Section 1103.4. Selection criteria for authorization and reauthorization.*

The Department proposes to amend paragraph (5) to require that the minimum inventory be maintained at or below the competitive price applicable to the store's peer group. The regulations currently require the minimum inventory be maintained at or below the maximum allowable price. The Department will continue to reimburse stores up to the price paid by other customers or the maximum allowable price for the food items, whichever is less.

The Department proposes to revise paragraph (8) in § 1103.4 to add language requiring the store to operate as a "full line grocery store" as defined in other revisions to these regulations.

The Department also proposes to add a new paragraph (14) which provides that one of the selection criteria for authorization is that the store does not, nor is expected to, derive more than 50% of its annual food items sales revenue from the sale of food items for WIC checks. In conformity with Federal law, this provision does not apply to stores that are solely owned and operated by nonprofit entities.

The Department also proposes to add a new paragraph (15) which would require stores to maintain certain minimum information technology requirements set by the Department and published annually in the *Pennsylvania Bulletin*. These information technology requirements, including computer, internet and telephone requirements, will allow the Department to more smoothly implement improvements in the WIC benefit and food delivery system such as automated notification of WIC transactions, updates to competitive prices and maximum allowable prices, and provide other information to stores more quickly and efficiently. Stores authorized prior to the effective date of this proposal and maintaining an uninterrupted authorized status will be exempt from the requirements of this proposed paragraph.

These proposed revisions further the Department's efforts to implement the changes in Federal law and in controlling WIC food costs. See 42 U.S.C.A. § 1786(h)(11).

*Section 1103.8. Store peer group system.*

The Department proposes to add this new section to establish the store peer group system, also defined in these proposed regulatory revisions. Proposed subsection (a) would provide that the Department will establish the peer group system and distinct pricing criteria and reimbursement levels for each peer group. Proposed subsection (b) would provide that a minimum of two criteria would be selected by the Department for creating peer groups, one of which would be geography. The Department would publish the peer group selection criteria in the *Pennsylvania Bulletin* on an annual basis. Because the Federal WIC regulations require states to maintain flexibility in the peer group criteria selection process, the Department cannot more definitively establish those criteria in these regulations.

Proposed subsection (c) would provide a means for the Department to determine which peer group a store will be classified in and how the store will receive notification of this classification. Proposed subsection (d) would require a store to adhere to competitive prices and maximum allowable prices established for the peer group in which it has been classified. Proposed subsection (e) would require stores to notify the Department of any changes which would affect its peer group classification.

*Section 1105.1. Training.*

The Department proposes to revise § 1105.1(b)(5) to make reference to the proper provision in these regulations, as proposed revisions in other portions of these regulations will be renumbered.

*Section 1105.2. Price adjustment.*

The Department proposes to revise subsection (a) to provide that the application of maximum allowable prices will be based on the store's peer group.

The Department proposes to revise subsection (e) to make reference to the proper provision in these regulations, as revisions in other portions of these regulations will be renumbered.

*Section 1105.3. Terms and conditions of participation.*

The Department proposes to revise this section by adding new subsection (a)(17) and (18).

Proposed subsection (a)(17) provides that WIC authorized vendors shall only purchase infant formula that is to be sold to WIC participants from Department-authorized infant formula manufacturers, wholesalers, distributors or retailers. The Department will maintain a list of authorized infant formula manufacturers, wholesalers, distributors and retailers, and make the list readily available to the stores. Information on where to obtain the list will be published simultaneously with the publishing of these regulatory revisions. This proposed subsection is required to conform to recent amendments in the Federal WIC statutes. See 42 U.S.C.A. § 1786(h)(8)(A)(ix) and (x).

Proposed subsection (a)(18) provides that as a term and condition of being an authorized WIC vendor, a store must provide the Department with all the information the Department requests for the Department to determine whether more than 50% of the store's annual food items sales revenue is derived from the sale of food items for WIC checks. This proposed provision will not apply to stores that are solely owned and operated by nonprofit entities.

The Department also proposes to revise subsection (b)(3) to provide that the application of maximum allowable prices will be based on the store's peer group.

The Department proposes to delete subsection (c)(2). This subsection provides that, with regards to WIC check processing and redemption, a WIC-authorized store can only accept a WIC check if the check is made payable to that specific store. As a result of the amendments to the Federal statutes that require states allow participants to redeem WIC checks at any authorized vendor in the state, this language must be deleted. See 42 U.S.C.A. § 1786(f)(1)(C)(i). The amendment allows WIC participants greater flexibility in the redemption of their WIC checks. To comply with Federal law, the Department has been allowing WIC participants to redeem WIC checks at any authorized store since July 1, 2006.

The Department proposes to renumber subsection (c)(3)—(18) as subsection (c)(2)—(17), respectively.

The Department proposes to add subsection (c)(18), which requires a store to transmit to the Department, records of WIC check numbers accepted by the store prior to depositing the WIC checks, through communication channels made available by the Department. This requirement will assist the Department in tracking WIC checks following state implementation of the amendments to Federal regulations that require states to allow participants to redeem WIC checks at any authorized vendor in the State, and will work in conjunction with proposed § 1103.4(15). See 42 U.S.C.A. § 1786(f)(1)(C)(i).

Stores transmit the WIC check numbers for checks accepted at the store in one of four ways by means of an electronic reporting system. First, some stores automatically transmit this data through their registers and computer systems with the addition of software provided by the Department. Second, other stores are able to install software on their computers and transmit the information with the assistance of Magnetic Ink Character Recognition (mini-MICR) readers provided by the Department. Third, stores may use a secure web site where they may log in and manually key in the WIC check numbers from WIC checks accepted by their store. Finally, those stores without computers or internet con-

nections can call a toll-free number and input the WIC check information into a touch-tone system. The toll-free touch tone phone system is available to all stores in the event the preferred methods of electronic transmission experience any technical interruptions. As WIC participants have been permitted to redeem WIC checks at any authorized store since July 1, 2006, the Department has already implemented communication channels for the transmission of this information and stores have been complying with these proposed requirements.

The Department also proposes to revise subsection (d) to allow the Department some flexibility in determining when it will deny payment for checks which were inappropriately submitted for redemption. Because of changes in the redemption process, the Department expects stores may have some initial errors in the redemption process. This proposed change will allow the Department to reimburse stores for the foods provided to participants and not punish them for mistakes which may occur as they adjust to new redemption procedures.

*Section 1105.5. Changes in availability or location of WIC authorized stores.*

The Department proposes to delete § 1105.5(e) which provides for the temporary authorization of stores to accept WIC checks redeemable at other stores. As a result of other revisions, which allow for redemption of WIC checks at any WIC-authorized store, this subsection has become inoperative and unnecessary. See 42 U.S.C.A. § 1786(f)(1)(C)(i).

*Section 1105.6. Monitoring of WIC authorized stores.*

The Department proposes to revise subsection (a) to add language providing for an annual analysis by the Department of each WIC authorized store to determine if the store is deriving more than 50% of its annual food items sales revenue from the sale of food items for WIC checks. This proposed revision furthers the Department's efforts to implement the changes to Federal law, including restrictions pertaining to WIC-Only stores, into the State WIC Program. See, 42 U.S.C.A. § 1786(h)(11); 118 Stat. 2809, 2850, § 780; and, 119 Stat. 2120, 2163, § 787. In conformity with Federal law, the proposed language does not apply to stores that are solely owned and operated by nonprofit entities.

The Department also proposes to add a new subsection (h). This proposed subsection provides for the annual determination by the Department of food items sales revenue percentages for WIC authorized stores, and includes language stating the Department may request from the store any information the Department requires to determine if more than 50% of the store's annual food items sales revenue is derived from WIC sales. This proposed subsection does not apply to stores solely owned and operated by nonprofit entities. As with other revisions to these regulations, this revision seeks to implement changes in Federal WIC laws including restrictions pertaining to WIC-Only stores. See 2005 Appropriations Act, 118 Stat. 2809, 2850, § 780; 2006 Appropriations Act, 119 Stat. 2120, 2163, § 787; and 42 U.S.C.A. § 1786(h)(11).

*Section 1107.1a. Disqualifications.*

The Department proposes to amend subsection (d)(4) to provide that a 1 year disqualification will occur if a WIC authorized store fails to make the minimum inventory of foods available at or below the current competitive price applicable to the store's peer group. The regulations currently require the minimum inventory be provided at or below the maximum allowable price.

The Department proposes to revise this section to delete subsection (d)(6). Subsection (d)(6) provides for a 1-year disqualification for a WIC authorized store in the event the Department found two or more incidences of a WIC authorized store accepting, without prior Department authorization, a WIC check made payable to another store. As a result of other proposed revisions to these regulations, this is no longer a violation of the Department's WIC regulations. See 42 U.S.C.A. § 1786(f)(1)(C)(i).

Because of this proposed deletion, the Department proposes to renumber existing subsection (d)(7)—(17) as subsection (d)(6)—(16), respectively.

#### *Section 1107.2. Civil money penalties.*

The Department proposes to revise subsection (a) to make clear that the Department will not offer a civil monetary penalty in lieu of a denial of reauthorization or disqualification for stores found to be subject to a disqualification under § 1107.1a(a). Section 1107.1a(a) provides for the permanent disqualification of a store convicted of trafficking in WIC checks or selling firearms, ammunition, explosives or controlled substances for WIC checks.

The Department also proposes to revise subsection (b)(2) to make reference to the proper provision in these regulations, as proposed in other portions of these regulations will renumber some of the subsections.

#### *Section 1113.1. Right to administrative appeal.*

The Department proposes to revise this section to add subsection (b)(4). This proposed subsection provides that the validity and appropriateness of the Department's store's peer group system and the criteria used by the Department to identify above-50-percent-stores may not be challenged by the appeal process set forth in these regulations. This language is required to conform to the recent amendments in Federal WIC regulations. See 7 CFR 246.18(a)(1)(iii)(B) (relating to administrative review of state agency actions). Because of this proposed addition, the Department proposes to renumber existing subsection (b)(4) and (5) as (b)(5) and (6) respectively.

The Department also proposes to revise subsection (c) to make reference to the proper provision in these regulations, as proposed revisions in other portions of these regulations will renumber some of the subsections.

#### *B. Fiscal Impact.*

##### *Fiscal Impact on the Department.*

The PA WIC Program is 100% Federally-funded. No State dollars are involved in the operation of the WIC Program. The proposed regulatory change to § 1105.3, allowing a WIC check to be used at any authorized store, will cause the PA WIC Program to incur a one time equipment purchase fee.

The Commonwealth is one of the few states whose regulations provide for store specific WIC checks. The customary practice in states that are nonstore specific is to require their banking contractor to capture the authorized store number from the face of each check as it is processed through the bank. This service would have added approximately \$.02 to the cost of each check processed. The Commonwealth processes approximately 8,000,000 WIC checks annually, which would result in an estimated direct cost increase of approximately \$160,000 annually if this method were implemented. Additional costs to the Department under this method would include the issuance and maintenance of WIC authorization

stamps to approximately 1,500 authorized stores. The anticipated initial cost would be \$2,800 and ongoing replacement and new applicant stamp cost of approximately \$300 annually.

The Commonwealth chose an alternate method to this check identification system, which is less costly and less labor intensive. The alternate method is through the use of direct data transfer from each WIC authorized store to the PA WIC Program. This is accomplished with the use of electronic cash registers, Magnetic Ink Character Recognition (mini-MICR) readers, a secure web site or touchtone telephones. Each WIC-authorized store is required to transfer check redemption data to the PA WIC Program prior to depositing the redeemed WIC checks. The data is then combined electronically with each WIC check number, before the bank will redeem the check. This process will incur an initial cost of \$93,823 for the cost of the mini-MICR readers that will be supplied to stores that have the appropriate communications equipment. There will be no additional banking fees incurred. Since the Department was required by Federal law to implement these changes by July 1, 2006, before regulatory revisions could be completed, some of these costs have already been absorbed by the PA WIC Program.

Although costs to the Department initially increased, the long-term costs are greatly reduced. Additionally, savings in efficiencies at the local agency level will mitigate these initial cost increases. WIC checks previously identified the authorized store at which they were to be redeemed. However, when the store did not have the products the participant wanted or ceased operating, participants had to go back to the clinics to have the WIC checks reissued to another store. This created additional workload at the clinics, which is eased with these changes. Unfortunately, the actual cost of this additional workload cannot be quantified for accurate comparison to expected increases in costs.

Other aspects of changes in these regulations may cause some additional costs to the Department. The initial and annual determination of whether a store is, or is expected to, derive more than 50% of its annual revenue from the sale of food items from WIC sales and the establishment and maintenance of the store peer group system will require additional staff time. However, it is anticipated this task can be absorbed by the existing staff.

In addition, the list of authorized infant formula manufacturers, wholesalers, distributors or retailers required to be provided to WIC authorized stores will include approximately 11,000—12,000 entities. The Department has worked with USDA and determined that such a list can be provided or made available to WIC authorized stores in an electronic format, thereby mitigating the cost of production of an 11,000—12,000 entry list to approximately 1,400 WIC authorized stores annually.

Any cost increases as a result of these proposed changes mandated by Federal law will be covered by the Federal funding provided to the WIC Program. Additional costs saving may also be realized from the cost containment measures proposed in these regulations as required by Federal law.

##### *Fiscal Impact on the Regulated Community*

The Department does not anticipate any increased costs for the regulated community as a result of these proposed amendments.

### C. Paperwork Requirements.

#### *Paperwork Requirements for the Department*

The Department's paperwork will increase in obtaining, preparing and updating the list of authorized infant formula manufacturers, wholesalers, distributors and retailers. The Department's paperwork requirements will also increase in the evaluation and documentation of the review of each store's actual or anticipated WIC sales to determine if any store is deriving more than 50% of its annual revenue from the sale of food items from WIC sales and in establishing and maintaining the store peer group system and the applicable competitive and maximum allowable prices.

#### *Paperwork Requirements for the Regulated Community*

The proposed amendments do not increase paperwork for WIC Program participants. The WIC-authorized stores are required to submit electronic data regarding the redemption of WIC checks prior to deposit. Although this task will increase the time necessary for WIC-authorized stores to prepare WIC checks for deposit, it will be somewhat offset by the fact that cashiers will no longer need to verify that the WIC check being presented for payment is payable to the store.

### D. Effective Date/Sunset Date.

The proposed amendments will become effective upon publication in the *Pennsylvania Bulletin* as final-form rulemaking. The regulations will be monitored continuously and will be updated as required by changes in Federal laws governing the WIC Program. Therefore, no sunset date has been set.

### E. Statutory Authority.

The WIC Program was authorized through an amendment to the Federal Child Nutrition Act of 1966 (42 U.S.C.A. § 1786). Congress authorized the USDA-FNS to contract with and make funds available to states to administer the WIC Program. In this Commonwealth, the WIC Program receives 100% of its funding from the USDA-FNS. Recent amendments to the Federal WIC statutes and appropriations necessitate these regulatory revisions. See Child Nutrition and WIC Reauthorization Act, Pub. L. No. 108-265, § 203(e)(10), 118 Stat. 729 at 776-779 (2004) (codified at 42 U.S.C. § 1786(h)(11)); Consolidated Appropriations Act, 2005, Pub. L. No. 108-447, 118 Stat. 2809, 2833 and 2850 § 780; and, Agricultural, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2006, Pub. L. No. 109-97, 119 Stat. 2120, 2144 and 2163 § 787.

There are no State statutes governing the operation or administration of the WIC Program. The Women's, Infants' and Children's Nutrition Improvement Act (62 P. S. §§ 2951—2955) authorizes additional State funding for the expansion of the WIC Program. The Commonwealth, however, has not provided funding for the expansion of the program since State Fiscal Year 1996.

The State regulations governing the WIC Program were published at 29 Pa.B. 3841 (July 24, 1999), following the decision of the Commonwealth Court in *Giant Food Stores, Inc. v. Commonwealth of Pennsylvania, Department of Health*, 713 A.2d 177 (Pa. Cmwlth. 1998). The Commonwealth Court held that the Department was required to promulgate regulations governing the selection and management of grocery stores to participate in the WIC Program. The State regulations added 28 Pa. Code Part VIII (relating to supplemental nutrition program for women, infants and children (WIC program)). The regulations also rescinded 28 Pa. Code §§ 8.41—8.74,

the Department's then existing regulations pertaining to WIC Program administrative appeals.

The proposed amendments are published under section 2102(g) of The Administrative Code of 1929 (code) (71 P. S. § 532(g)), which provides the Department general power to promulgate regulations to carry out its duties. Section 2102(a) of the code gives the Department the authority and duty to protect the health of the people of this Commonwealth. (71 P. S. § 532(a))

### F. Regulatory Review.

Under section 5(a) of the Regulatory Review Act (act) (71 P. S. §§ 745.1—745.12), the Department submitted a copy of these proposed rulemaking on August 15, 2008, to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Health and Human Services and the Senate Public Health and Welfare Committees (Committees). In addition to submitting the proposed amendments, the Department has provided IRRC and the Committees with a copy of a Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

If IRRC has any objections to any portion of the proposed amendments, it will notify the Department by October 29, 2008. The notifications shall specify the regulatory review criteria which have not been met by that portion. The act specifies detailed procedures for review, prior to final publication of the regulation by the Department, the General Assembly and the Governor, of objections raised.

### G. Contact Person.

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed regulation to Greg Landis, Director, WIC Program, 2150 Herr Street, 1st Floor, Harrisburg, PA 17103, (717) 783-1289, within 30 days after publication of this notice in the *Pennsylvania Bulletin*. Persons with a disability who wish to submit comments, suggestions or objections regarding the proposed amendments may do so by using the previous number or address or for speech or hearing, or both, impaired persons by using V/TT (717) 783-6514 or the Pennsylvania AT&T Relay Service at (800) 654-5984 (TT). Persons who require an alternative format of this document may contact Greg Landis at the previous address or telephone numbers so that necessary arrangements may be made.

CALVIN B. JOHNSON, M. D., M.P.H.,  
Secretary

**Fiscal Note:** 10-180. No fiscal impact; (8) recommends adoption.

## Annex A

### TITLE 28. HEALTH AND SAFETY

#### PART VIII. SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS AND CHILDREN (WIC PROGRAM)

##### CHAPTER 1101. GENERAL PROVISIONS

#### § 1101.2. Definitions.

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

**Above-50-percent-store**—A store that derives more than 50% of its annual food sales revenue from WIC checks, and a new store applicant expected to meet this criterion under guidelines approved by USDA-FNS.

\* \* \* \* \*

**Competitive price**—The price established by the Department, at or below which a store must maintain the required minimum inventory.

\* \* \* \* \*

**Food items**—Items sold for human consumption that are eligible for purchase under the Food Stamp Program.

\* \* \* \* \*

**Food sales—**

(i) Sales of all Food Stamp Program eligible foods intended for home preparation and consumption, including meat, fish and poultry; bread and cereal products; dairy products; fruits and vegetables.

(ii) Food items such as condiments and spices, coffee, tea, cocoa and carbonated and noncarbonated drinks may be included in food sales when offered for sale along with foods in the categories identified in subparagraph (i).

(iii) The term does not include the sale of any item that cannot be purchased with food stamp benefits, such as hot foods or food that will be eaten in the store.

**Food Stamp Program**—The government benefits program operated under the authority of the Food Stamp Act of 1964 (7 U.S.C.A. Chapter 51), and 55 Pa. Code Part II, Subpart L (relating to Food Stamp Program), and administered by the USDA-FNS and the Department of Public Welfare.

**Full line grocery store**—A store that:

(i) Offers for sale, in addition to WIC-authorized foods, food items from each of the following four food categories on a continuous basis:

- (A) Meat, poultry or fish.
- (B) Bread or cereal.
- (C) Vegetables or fruits.
- (D) Dairy.

(ii) Has available for sale at all times of operation and displays in a public area of the store, a minimum of three different varieties of food items in each of the four food categories listed subparagraph (i).

\* \* \* \* \*

**Overpayment**—Payment to a WIC-authorized store of a WIC check redeemed by the store in an amount in excess of the amount to which the store was entitled based upon the maximum allowable price [of] applicable to the store's peer group for each allowable food authorized for purchase on the WIC check.

\* \* \* \* \*

**Peer group**—The classification of an authorized store pursuant to the store peer group system, as determined by the criteria selected by the Department.

\* \* \* \* \*

**Store peer group system**—A classification of authorized stores into groups based on common characteristics or criteria that affect food prices, for the purposes of applying appropriate competitive pricing criteria to stores at authorization and reauthorization and limiting payment for foods to competitive levels.

\* \* \* \* \*

**CHAPTER 1103. AUTHORIZATION OF STORES**

**§ 1103.1. Authorization and reauthorization process and requirements.**

\* \* \* \* \*

(b) *Authorization process.*

\* \* \* \* \*

(5) The Department may request from the store any information necessary for the Department to determine whether the store qualifies as an above-50-Percent-Store.

(6) The local agency shall conduct the onsite review and forward the results to the Department for a decision on the store's application.

[ (6) ] (7) The Department will deny the application if the selection criteria in § 1103.4 are not satisfied, unless the Department grants probationary authorization under § 1103.2 (relating to probationary authorization). The Department will notify the store in writing whether the store's application for authorization is granted or denied. If the Department denies the application for authorization, the store shall be eligible to reapply for authorization six months after the effective date of the denial.

(c) *Reauthorization process.*

\* \* \* \* \*

(2) The Department may request from the store any information necessary for the Department to determine whether the store qualifies as an above-50-Percent-Store.

(3) The local agency shall conduct the onsite review and forward the results to the Department for a decision on the store's application.

[ (3) ] (4) The Department will deny the application without advance warning if the selection criteria in § 1103.4 are not satisfied, unless the store requests and the Department grants temporary authorization in accordance with § 1103.3 (relating to temporary authorization) or the Department grants probationary authorization in accordance with § 1103.2. The Department will notify the store in writing whether the store's application for reauthorization is granted or denied. If the Department denies the application for reauthorization, the store shall be eligible to apply for authorization 6 months after the effective date of the denial. If the Department grants and later rescinds temporary authorization, the store shall be eligible to apply for authorization 1 year from the date of the first onsite review for reauthorization.

(d) *Termination of authorization or reauthorization.* The Department will terminate a store's authorization or reauthorization if:

\* \* \* \* \*

(7) The Department does not receive from the store, within 20 calendar days of the store's receipt of a written notice from the Department, the infor-

mation the Department has requested necessary for it to determine whether the store qualifies as an above-50-percent-store.

(8) After authorization of the store, the Department determines the store qualifies as an Above-50-Percent-Store. This paragraph does not apply to stores solely owned or operated by nonprofit entities.

§ 1103.4. Selection criteria for authorization and reauthorization.

The Department will use the following selection criteria to identify stores that meet the operational criteria to serve as a WIC-authorized store:

\* \* \* \* \*

(5) The store shall have available on the premises at all times the minimum inventory of allowable foods as established by the Department under § 1103.5 (relating to minimum inventory) at shelf prices that are equal to or less than the [maximum allowable] competitive prices applicable to the store's peer group for those foods. The Department will publish in the Pennsylvania Bulletin and mail to all WIC-authorized stores, quarterly, the competitive prices and maximum allowable prices applicable to all peer groups for allowable foods for the next quarter.

\* \* \* \* \*

(8) The store shall operate as a full line grocery store in a permanent fixed location where participants may purchase allowable foods with their WIC checks.

\* \* \* \* \*

(14) The store does not qualify or is not expected to qualify as an above-50-percent-store. This paragraph does not apply to stores solely owned or operated by nonprofit entities.

(15) The store shall meet the minimum information technology requirements set by the Department. The Department will publish in the Pennsylvania Bulletin and mail to all WIC authorized stores, by September 15 of each year, the minimum technology requirements applicable for the following calendar year. This paragraph does not apply to stores authorized prior to \_\_\_\_\_. (Editor's Note: The blank refers to the effective date of adoption of this proposed rulemaking.) and maintaining an uninterrupted authorized status.

§ 1103.8. Store peer group system.

(a) The Department will establish a store peer group system, including distinct competitive pricing criteria and allowable reimbursement levels for each peer group.

(b) The Department will create peer groups based upon at least two criteria selected by the Department, one of which will be a measure of geography, such as metropolitan or other statistical areas that form distinct labor and product markets. The Department will annually publish the peer group selection criteria in the Pennsylvania Bulletin.

(c) The Department will place a store seeking authorization into an appropriate peer group based upon information gathered from the store's application as completed by the store and returned to the local agency in accordance with § 1103.1(b)(1) (relating to authorization and reauthorization process and requirements). The Department will notify a

store of its peer group classification prior to conducting an onsite review under § 1103.1(b)(5). A WIC-authorized store seeking reauthorization shall remain in the peer group previously selected for the store unless otherwise notified by the Department.

(d) A WIC-authorized store shall adhere to the competitive prices and maximum allowable prices applicable to the store's peer group.

(e) A WIC-authorized store shall inform the Department of any store changes applicable to the peer group selection criteria in effect.

CHAPTER 1105. REQUIREMENTS OF WIC AUTHORIZED STORES

§ 1105.1. Training.

\* \* \* \* \*

(b) Annual training. The Department will provide for WIC-authorized stores annual training which is designed to prevent WIC Program errors and abuses and to improve WIC Program services. The following apply to annual training:

\* \* \* \* \*

(5) Failure to have at least one representative attend training shall result in the Department imposing sanctions against the WIC-authorized store under [§ 1107.1a(d)(16)] § 1107.1a(d)(15) (relating to disqualifications).

\* \* \* \* \*

§ 1105.2. Price adjustment.

(a) Determination of overpayment. In each calendar quarter, the Department will compare the maximum amount for which a WIC-authorized store could have redeemed a WIC check based upon the maximum allowable prices applicable to the store's peer group for foods authorized for purchase on the check against the actual amount for which the WIC check was redeemed, to determine whether there was an overpayment.

\* \* \* \* \*

(e) Sanctions. The Department will impose a sanction against a WIC authorized store under [§ 1107.1a(d)(12)] § 1107.1a(d)(11) (relating to disqualifications) if the store fails to reimburse the Department for an overpayment within the time required under subsections (c) and (d).

§ 1105.3. Terms and conditions of participation.

(a) General terms and conditions. A WIC-authorized store shall adhere to this subsection. Failure to do so shall result in the imposition of sanctions under § 1107.1 (relating to imposition of sanctions). A WIC-authorized store shall:

\* \* \* \* \*

(17) Purchase infant formula for resale to WIC participants only from Department authorized infant formula manufacturers, wholesalers, distributors or retailers. Information on where to obtain the list will be published by the Department in the Pennsylvania Bulletin simultaneously with the initial publishing of this subsection. (Editor's Note: The list referred to in this paragraph will be published with this rule upon final publication.)

(18) Provide the Department, within 20-calendar days of the store's receipt of a written notice from

**the Department requesting the additional information, information the Department has requested necessary for the Department to determine whether the store qualifies as an above-50-percent-store. This paragraph does not apply to stores solely owned or operated by nonprofit entities.**

(b) *Terms and conditions of participation with regard to participants.* A WIC-authorized store shall serve participants and authorized representatives as set forth in this subsection. The Department will impose sanctions against a WIC-authorized store that fails to do so, as set forth in § 1107.1. A WIC-authorized store shall:

\* \* \* \* \*

(3) Provide an allowable food to a participant or authorized representative at or below the current price the store charges other customers, and at or below the maximum allowable price **applicable to the store's peer group.**

\* \* \* \* \*

(c) *Terms and conditions of participation with regard to WIC check processing and redemption.* A WIC-authorized store shall adhere to the requirements of this subsection with regard to WIC check processing and redemption. The Department will impose sanctions against a WIC-authorized store that fails to do so, as set forth in § 1107.1. A WIC-authorized store shall:

\* \* \* \* \*

(2) **[ Accept a WIC check only if the WIC check is made payable to that specific WIC authorized store, unless the Department has provided written authorization otherwise to the store.**

(3) **[** Accept a WIC check only if the participant or authorized representative presents the WIC check on or between the "First Day to Use" and the "Last Day to Use" designations on the WIC check.

**[ (4) ]** (3) Accept a WIC check only if a valid WIC identification card is presented at the time of the WIC transaction.

**[ (5) ]** (4) Accept a WIC check only if the signature of the participant or authorized representative is obtained on the WIC check at the time of the WIC transaction and the family identification number on the WIC check matches the family identification number on the identification card.

**[ (6) ]** (5) Accept a WIC check only if there is no visible alteration on the WIC check.

**[ (7) ]** (6) Charge the WIC Program only for the types and quantities of allowable foods specified on the WIC check and selected for purchase by the participant or authorized representative.

**[ (8) ]** (7) Record in ink, on each WIC check immediately after completion of the WIC transaction and prior to the participant or authorized representative signing the WIC check, the actual purchase amount of the transaction net of any cents-off coupons or other discounts.

**[ (9) ]** (8) Properly correct an error made in recording the "Pay Exactly" amount of a WIC check by drawing a single line through the incorrect amount and writing the correct amount above or below the error and having the participant or authorized representative initial next to the corrected amount. No other corrections are permissible.

**[ (10) ]** (9) Not alter any information on the WIC check as presented by the participant or authorized representative.

**[ (11) ]** (10) Not provide a substitute item, raincheck or cash reimbursement for an allowable food that is unavailable.

**[ (12) ]** (11) Not provide cash or credit for a WIC check.

**[ (13) ]** (12) Not provide change for a coupon tendered during the WIC transaction.

**[ (14) ]** (13) Not provide an exchange to replace an allowable food returned by a participant or authorized representative unless the exchange is to replace an identical product that was found to be damaged or otherwise unusable.

**[ (15) ]** (14) Not refund money for an allowable food purchased in a WIC transaction that is returned by a participant or authorized representative.

**[ (16) ]** (15) Not accept a WIC check as payment for an item other than an allowable food specified on the WIC check.

**[ (17) ]** (16) Not charge the WIC Program for an allowable food not received by the participant or authorized representative or for an allowable food in excess of the quantity prescribed on the WIC check.

**[ (18) ]** (17) Not charge the WIC Program for the sale of an amount of an allowable food which exceeds the store's documented inventory of that food item covering the period of time under review and in which the sale was made.

**(18) Prior to depositing WIC checks, transmit records of WIC check numbers from WIC checks accepted by the store to the Department through transmission mechanisms made available by the Department.**

\* \* \* \* \*

(d) When the Department determines, prior to payment of a check submitted for redemption, that the store has committed a violation of this section that affects the payment to the store, the Department **[ will ] may** deny payment. If payment already has been made, the Department **[ will ] may** establish a claim for reimbursement by sending the store a written notice of the overcharge or other improper charge. The store may dispute the Department's claim and shall submit the basis for its dispute in writing within 15 calendar days of the date of the Department's written notice. The Department will notify the store of the resolution of the claim dispute. The Department's resolution of a claim dispute is not an adverse action that may be appealed.

**§ 1105.5. Changes in availability or location of WIC authorized stores.**

\* \* \* \* \*

**[ (e) Temporary authorization to accept WIC checks redeemable at other stores. The Department will temporarily authorize alternate WIC authorized stores to accept WIC checks designated on the face of the check to be used at another WIC authorized store, to provide participants with access to allowable foods when a WIC authorized store has permanently or temporarily closed, the**

store's authorization has been terminated, or the store has been disqualified as a WIC authorized store. ]

§ 1105.6. Monitoring of WIC-authorized stores.

(a) Purpose and types of monitoring of WIC authorized stores.

(1) Federal, State or local representatives will conduct announced and unannounced onsite reviews of WIC authorized stores to determine compliance with applicable Federal and State regulations, and to investigate complaints regarding a store. The types of onsite reviews that may be conducted for monitoring purposes are compliance investigations, inventory audits, routine reviews and WIC transaction reviews. The monitoring process, to determine compliance with applicable Federal and State regulations, operates independently of the authorization process and may overlap more than one authorization period.

(2) The Department will conduct an annual analysis of a WIC authorized store's sales data in order to determine whether the store qualifies as an above-50-percent-store, except that stores solely owned or operated by nonprofit entities will not be subject to this annual analysis.

\* \* \* \* \*

(h) Annual determination of WIC sales percentage. The Department may request from a store any information necessary for the Department to determine whether the store qualifies as an above-50-percent-store. This subsection does not apply to stores solely owned or operated by nonprofit entities.

CHAPTER 1107. SANCTIONS

§ 1107.1a. Disqualifications.

\* \* \* \* \*

(d) One-year disqualification. The Department will disqualify a WIC-authorized store for 1 year for any of the following violations:

\* \* \* \* \*

(4) Failing to maintain on the premises at all times minimum inventory requirements of an allowable food at or below the current [ maximum allowable ] competitive price applicable to the store's peer group for that food.

\* \* \* \* \*

(6) [ Two or more incidences of accepting a WIC check made payable to another store without prior written approval from the Department.

(7) ] Failing to maintain a clean and sanitary store.

[ (8) ] (7) Failing to properly store or refrigerate an allowable food.

[ (9) ] (8) Closure of the store by a city, local or county health department.

[ (10) ] (9) Charging or demanding that a participant or authorized representative pay for an allowable food with money or with another WIC check for purchases made with a WIC check.

[ (11) ] (10) Two or more incidences of securing the signature of the participant or authorized representative prior to completing the "Pay Exactly" box on the WIC check.

[ (12) ] (11) Two or more incidences of charging the WIC Program Sales Tax.

[ (13) ] (12) Giving monetary change to the person who tenders a WIC check.

[ (14) ] (13) Failing to reimburse the Department for overpayments, overcharges or other improper charges within the specified time frame.

[ (15) ] (14) Physically altering or changing on the face of a WIC check the store name, food type or quantity, participant information, date, or printed dollar amount.

[ (16) ] (15) Failing to have at least one representative of the store attend required training.

[ (17) ] (16) Providing false information on the application for authorization or reauthorization.

\* \* \* \* \*

§ 1107.2. Civil money penalties.

(a) Option available in lieu of a disqualification or denial of reauthorization. The Department may offer to a WIC authorized store the option of paying a civil money penalty in lieu of a denial of reauthorization or a disqualification required under § 1107.1 (relating to imposition of sanctions), only if the Department finds inadequate participant access as set forth in § 1103.7 (relating to inadequate participant access). The Department will not provide this option for third or subsequent violations under § 1107.1a(b)—(d) (relating to disqualifications) or for any permanent disqualifications under § 1107.1a(a).

(b) Calculation of civil money penalty.

\* \* \* \* \*

(2) For a civil money penalty in lieu of disqualification under [ § 1107.1a(d)(3)—(16) ] § 1107.1a(d)(3)—(15), the Department will calculate the civil money penalty for each violation identified by multiplying 5% of the average monthly total value of WIC checks redeemed for the most recent 6-month period by the number of months the store would be disqualified under § 1107.1. For a store to which the Department may deny reauthorization and for which this option is available, the Department will multiply 5% of the average monthly total value of WIC checks for the most recent 6-month period by 6 months to determine the civil money penalty to be paid. If 6 months of information relating to the monthly value of WIC checks redeemed is not available, the Department will calculate the monthly average based upon the number of months for which information is available.

\* \* \* \* \*

CHAPTER 1113. STORE APPEALS.

§ 1113.1. Right to administrative appeal.

\* \* \* \* \*

(b) A store may not appeal the following:

\* \* \* \* \*

(4) **The validity or appropriateness of the Department's store peer group system criteria and the criteria used by the Department to identify stores that qualify as an above-50-percent-store or that are comparable to an above-50-percent-stores.**

**[(4)] (5)** Disqualification from the WIC Program as a result of disqualification from the Food Stamp Program.

**[(5)] (6)** The resolution of an overpayment dispute under § 1105.2(d) (relating to price adjustment) or the resolution of an overcharge dispute under § 1105.3(d) (relating to terms and conditions of participation).

(c) A denial of authorization under **[§ 1103.1(b)(6)] § 1103.1(b)(7)** and a disqualification imposed under § 1107.1a(a) (relating to disqualifications) shall be effective on the date of the store's receipt of notice of the adverse action. All other adverse actions shall be effective on the date set forth in the written notice.

[Pa.B. Doc. No. 08-1588. Filed for public inspection August 29, 2008, 9:00 a.m.]

## ENVIRONMENTAL QUALITY BOARD

### Acceptance of Rulemaking Petition for Study

On August 19, 2008, the Environmental Quality Board (Board) accepted a rulemaking petition for study under 25 Pa. Code Chapter 23 (relating to Environmental Quality Board policy for processing petitions—statement of policy). The petition, submitted by Foundation Mining, LP, requests the Board amend 25 Pa. Code § 93.9v (relating to drainage list V) to redesignate tributaries to South Fork of Tenmile Creek, including House, Hoge and McCourtney Runs in Greene County, from High Quality-Warm Water Fishes (HQ-WWF) to Warm Water Fishes (WWF) designation.

Under 25 Pa. Code, § 93.4d(a) (relating to processing of petitions, evaluations and assessments to change a designated use), the Department of Environmental Protection (Department) is required to publish a notice of intent to assess candidate waters. The Department's assessment notice for South Fork of Tenmile Creek will appear in a future issue of the *Pennsylvania Bulletin*.

The previously-referenced petition submitted by Foundation Mining, LP is available to the public by contacting the Environmental Quality Board, P. O. Box 8477, Harrisburg, PA 17105-8477, (717) 787-4526 and is also accessible on the Department's web site at [www.depweb.state.pa.us](http://www.depweb.state.pa.us) (DEP Keywords: EQB ("EQB Meeting/Agendas/Handouts/Minutes").

JOHN HANGER,  
*Acting Chairperson*

[Pa.B. Doc. No. 08-1589. Filed for public inspection August 29, 2008, 9:00 a.m.]

[ 25 PA. CODE CH. 85 ]

### Bluff Recession and Setback

[ Correction ]

A typographical error occurred in the fiscal note notation for the proposed rulemaking which appeared at 38 Pa.B. 4617, 4619 (August 23, 2008). The correct fiscal note number is 7-404.

[Pa.B. Doc. No. 08-1523. Filed for public inspection August 22, 2008, 9:00 a.m.]

## FISH AND BOAT COMMISSION

[ 58 PA. CODE CH. 63 ]

### Fishing

The Fish and Boat Commission (Commission) proposes to amend Chapter 63 (relating to general fishing regulations). The Commission is publishing this proposed rulemaking under the authority of 30 Pa.C.S. (relating to the Fish and Boat Code) (code).

#### A. Effective Date

The proposed rulemaking, if approved on final-form rulemaking, will go into effect on January 1, 2009.

#### B. Contact Person

For further information on the proposed rulemaking, contact Laurie E. Shepler, Esq., P. O. Box 67000, Harrisburg, PA 17106-7000, (717) 705-7810. This proposed rulemaking is available on the Commission's web site at [www.fish.state.pa.us](http://www.fish.state.pa.us).

#### C. Statutory Authority

The proposed addition of § 63.53 (relating to egg collection) is published under the statutory authority of section 2102(a) of the code (relating to rules and regulations).

#### D. Purpose and Background

The proposed rulemaking is designed to improve, enhance and update the Commission's fishing regulations. The specific purpose of the proposed regulation is described in more detail under the summary of proposal.

#### E. Summary of Proposal

The Commission's waterways conservation officers during the past year encountered anglers catching large female brown trout and removing the eggs contained within the fish. The fish were released back into the waters from which they were taken. The anglers indicated that they used these eggs as bait to fish for trout in other water areas. The continued removal of eggs from large female trout may have a detrimental effect on the numbers of young of the year fish in a wild trout population and likely cause undue harm to a fish that is released. Currently, the regulations require that fish must be released immediately unharmed from most specially regulated trout waters. Officers successfully charged two individuals for a violation of this regulation and, in doing so, had to prove that the fish were harmed by the removal of the eggs. To clearly prohibit this activity, the Commission proposes that a new regulation be added to read as set forth in Annex A.

By notice published at 38 Pa.B. 3875 (July 12, 2008), the Executive Director, acting under the authority of § 65.25 (relating to temporary changes to fishing regulations), took immediate action to make it unlawful to take eggs from a fish taken from waters of this Commonwealth outside the Lake Erie watershed or to possess these eggs or use them as bait. Eggs taken from lawfully harvested fish from the Lake Erie watershed may be possessed and used as bait in the Lake Erie watershed only. This temporary modification went into effect immediately and will remain in effect until January 1, 2009, unless the Commission, by appropriate action, adopts the new regulation.

F. *Paperwork*

The proposed rulemaking will not increase paperwork and will not create new paperwork requirements.

G. *Fiscal Impact*

The proposed rulemaking will have no adverse fiscal impact on the Commonwealth or its political subdivisions. The proposed rulemaking will impose no new costs on the private sector or the general public.

H. *Public Comments*

Interested persons are invited to submit written comments, objections or suggestions about the proposed rulemaking to the Executive Director, Fish and Boat Commission, P. O. Box 67000, Harrisburg, PA 17106-7000, within 30 days after publication of this notice in the *Pennsylvania Bulletin*. Comments submitted by facsimile will not be accepted.

Comments also may be submitted electronically by completing the form at [www.fishandboat.com/regcomments](http://www.fishandboat.com/regcomments). If an acknowledgment of electronic comments is not received by the sender within 2 working days, the comments should be retransmitted to ensure receipt. Electronic comments submitted in any other manner will not be accepted.

DOUGLAS J. AUSTEN, Ph.D.,  
*Executive Director*

**Fiscal Note:** 48A-205. No fiscal impact; (8) recommends adoption.

**Annex A**

**TITLE 58. RECREATION**

**PART II. FISH AND BOAT COMMISSION**

**Subpart B. FISHING**

**CHAPTER 63. GENERAL FISHING REGULATIONS**

**§ 63.53. Egg collection.**

It is unlawful to take eggs from a fish taken from waters of this Commonwealth outside the Lake Erie watershed or to possess these eggs or use them as bait. Eggs taken from lawfully harvested fish from the Lake Erie watershed may be possessed and used as bait in the Lake Erie watershed only. This section does not prohibit the possession of eggs contained within a lawfully harvested fish that is possessed for the purpose of human consumption.

[Pa.B. Doc. No. 08-1590. Filed for public inspection August 29, 2008, 9:00 a.m.]

**STATE BOARD OF DENTISTRY**

[ 49 PA. CODE CH. 33 ]

**Dental Hygiene Scope of Practice; Local Anesthesia**

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

*Effective Date*

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

*Statutory Authority*

Under section 3(d), (j.2) and (o) of the Dental Law (law) (63 P. S. § 122(d), (j.2) and (o)), the Board has authority to adopt, promulgate and enforce regulations for the general supervision, scope of practice and continuing education of dental hygienists. The law requires amendments to the regulations to implement a new class of certificate for "public health dental hygiene practitioners."

*Background and Purpose*

The Board has been considering expanding the scope of practice of dental hygienists to include the administration of local anesthesia since 2002, when the Pennsylvania Dental Hygienists' Association provided testimony on the subject at the January 18, 2002, Board meeting. At that time, 27 states permitted dental hygienists to administer local anesthesia. Today, 39 states and the District of Columbia permit the administration of local anesthesia by dental hygienists. Since 2002, an ongoing dialog has continued within the dental community in this Commonwealth regarding this proposal. In 2005, a draft of this proposed rulemaking was sent out to over 150 organizations, schools and individuals to solicit input from the regulated community and other interested parties. The proposal received overwhelming support from the dental hygiene community. In addition, the dental community was generally supportive of the proposal provided that dental hygienists receive adequate education and are properly supervised. The proposal was revised based on the comments received by the Board.

Some parties to this dialog objected to permitting dental hygienists to administer local anesthesia through both block and infiltration techniques. Essentially, when a nerve is anesthetized along the nerve trunk before it branches, block anesthesia occurs. A block is used to anesthetize the entire area of the nerve's innervation. When a branch of a nerve is anesthetized by depositing the anesthetic solution in the area of the nerve branch so that the solution filters through the underlying bone to reach the nerve, infiltration anesthesia occurs. Initially, the Board considered restricting dental hygienists to infiltration injections only. The Board reviewed the regulations of the 39 states that permit dental hygienists to administer local anesthesia. Of these, 37 states permit both infiltration and block techniques and have not reported significant problems relating to dental hygienists administering local anesthesia. Ultimately, the Board determined that dental hygienists who meet the educa-

tion requirements being proposed and are properly supervised could safely perform infiltration injections and intraoral nerve blocks limited to the second (maxillary) and third (mandibular) divisions of the trigeminal nerve. Under this proposal, a dental hygienist must meet the educational requirements to obtain a local anesthesia permit. In addition, a dental hygienist who holds a local anesthesia permit may administer local anesthesia only under the direct on-premises supervision of a licensed dentist. Direct supervision requires the dentist to examine the patient, authorize the procedure to be performed, be physically present in the dental facility and available during performance of the procedure and examine and take full responsibility for the completed procedure. This proposal would permit a dental hygienist to administer local anesthesia only as authorized by the supervising dentist. A supervising dentist exercising the dentist's professional judgment may choose not to authorize it, authorize it by infiltration only, or authorize it by both infiltration and nerve block techniques.

While these discussions continued, the Board's Regulations Review Committee (Committee) proposed other changes relating to the scope of practice of dental hygienists, specifically with regard to the supervision and continuing education requirements. The Committee suggested that the requirement that routine dental hygiene services (for example, scaling, root planing and polishing) be provided under direct supervision in all cases except for ASA class I patients was unduly restrictive. ASA class I patients are currently defined in § 33.1 (relating to definitions) as those that are without systemic disease. The Committee proposed expanding this exception to provide for general supervision with regard to ASA Class I and II patients. ASA Class II patients are defined as those with mild systemic disease. The Committee also proposed an expansion in the definition of general supervision to permit a dental hygienist to provide dental hygiene services, as authorized by a licensed dentist, within 1 year of an examination by the dentist. Currently the regulations provide a standard of 90 days. Finally, the Committee proposed a change in the continuing education requirements for dental hygienists to permit dental hygienists to complete up to 3 of the required 20 hours of continuing education in the area of communication skills. The Committee made this proposal in recognition of the fact that the education of the patient with regard to oral hygiene care is an important function of a dental hygienist and that effective communication skills are essential to that function.

A draft of the Committee's proposal was also circulated within the regulated community and other interested parties in 2005. Input provided from the dental and dental hygiene communities was, again, generally supportive of the proposal. Some concerns were raised by the dental community regarding the expansion of general supervision to extend to dental hygiene services to be performed within 1 year of a dental examination. The Board, however, believes that this proposal establishes a minimum standard and that each individual dentist is responsible for exercising the dentist's professional judgment in authorizing dental hygiene services to be provided to patients based on each patient's condition and treatment plan. Patients with chronic conditions may need more frequent exams, while patients who are generally healthy and who have good oral hygiene may need less frequent exams. Other commentators agreed that communication skills are essential for dental hygienists, however they objected to any reduction in the number of clinical continuing education hours required and sug-

gested that the Board require 3 additional hours of continuing education be completed in the area of communication skills. The Board, however, does not have the statutory authority to increase the total number of hours of continuing education required beyond the statutorily mandated 20 hours. This proposal would permit, but not require, a dental hygienist to complete up to 3 hours of continuing education in communication skills.

As a result, the Board prepared a prior version of this proposed rulemaking to implement these changes to the scope of practice of dental hygienists. However, before the Board was able to publish the proposed rulemaking, Act 51 was enacted on July 20, 2007. Act 51 made three major amendments to the law which affected this proposal. First, Act 51 created a new classification of certificate for "public health dental hygiene practitioners." Second, Act 51 created a "hierarchy" relating to the provision of radiological procedures in a dental office, with public health dental hygiene practitioners able to take X-rays without supervision, dental hygienists able to take X-rays under general supervision, and other auxiliary staff able to take X-rays only under direct supervision. Finally, section 5 of Act 51 abrogated the Board's regulations relating to the supervision of dental hygienists in § 33.205(d)(1) (relating to practice as a dental hygienist), requiring that section to be completely re-drafted.

#### *Description of Proposed Amendments*

The definition of "general supervision" in § 33.1 would be amended to extend general supervision to dental hygiene services to be performed within 1 year of an examination by a dentist, instead of the current standard of 90 days. Section 33.1 would also be amended to define the term "local anesthesia" as "the elimination of sensations, especially pain, in one part of the body by regional injection of an anesthetic agent." As regards dental hygienists administration of local anesthesia under a permit issued by the Board, the term would include local infiltration anesthesia and intraoral nerve block anesthesia limited to the second (maxillary) and third (mandibular) divisions of the trigeminal nerve. Finally, a definition of "public health dental hygiene practitioner" would be added to comport to Act 51.

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

Section 33.102 (relating to professional education) would be amended to comport with changes made by Act 51.

Section 33.115 would be added to set forth the requirement for a dental hygienist to secure a permit prior to administering local anesthesia. This section also sets forth the qualifications required by the Board for a dental hygienist to both secure and maintain a local anesthesia permit. First, a dental hygienist must hold a current license in good standing to practice as a dental hygienist in this Commonwealth. Second, a dental hygienist must maintain certification in basic life support (BLS). Finally, a dental hygienist must take one of three alternate educational paths prior to applying for a local anesthesia permit. The first is graduation, within the 5 years immediately preceding the filing of the application for a local anesthesia permit, from a dental hygiene school accredited by the American Dental Association's Commission on Dental Accreditation (CODA) which included the successful completion of a didactic and clinical course in

the administration of local anesthesia. The second option is the successful completion, within the 5 years immediately preceding the filing of the application for local anesthesia permit, of a course consisting of a minimum of 30 hours of didactic and clinical instruction in the administration of local anesthesia sponsored by a dental or dental hygiene education program accredited by CODA. The third avenue is for dental hygienists who are licensed in other jurisdictions that permit dental hygienists to administer local anesthesia. The Board will issue permits to these dental hygienists provided that the other jurisdiction required completion of a course in the administration of local anesthesia accredited by CODA or by the Commission on Dental Accreditation of Canada (CDAC) prior to obtaining the authority to administer local anesthesia; the dental hygienist actively engaged in the administration of local anesthesia under a current license or permit within the 5 years immediately preceding the filing of the application for a local anesthesia permit; and the dental hygienist certifies that he at all times administered local anesthesia in accordance with all applicable rules and regulations of the other jurisdiction and provides a letter or certificate of good standing indicating that there has been no disciplinary action taken against the dental hygienist relating to the administration of local anesthesia.

The Board is also proposing a requirement for biennial renewal of the local anesthesia permit. To maintain the local anesthesia permit, a dental hygienist shall submit a renewal application and renewal fee and maintain certification in BLS.

Section 33.116 would be added to implement the provisions of Act 51. Subsection (a) would require a dental hygienist who desires to obtain a certification as a public health dental hygiene practitioner to submit an application and fee to the Board. Subsection (b) sets forth the qualifications for a public health dental hygiene practitioner certificate to include a current license in good standing to practice as a dental hygienist in this Commonwealth; 3,600 hours of practice as a licensed dental hygienist under the supervision of a license dentist; and professional liability insurance. The Board determined the minimum amount of \$1 million per occurrence and \$3 million per annual aggregate in consultation with the Pennsylvania Dental Hygienists' Association as well as by surveying a number of insurance providers licensed to issue this coverage in this Commonwealth.

Subsection (c) provides for the expiration and biennial renewal of the public health dental hygiene practitioner's certificate.

Section 33.205 would be amended to make some minor changes to the description of certain dental hygiene services. Subsection (a)(1) would be amended to replace the more specific "placement of antimicrobial cord," with a more general alternative "placement of subgingival agents." The Board makes this proposal because the existing description is outdated. Therapeutic and technological advances in the delivery of oral health care occur rapidly, while the regulatory process can take years. Dental hygienists are qualified to place a variety of subgingival agents, including antimicrobials, antibiotics, antiseptics or anesthetics, and they may be delivered by a variety of methods, including pastes, ointments, gels, fibers, strips, spheres, discs or chips.

In addition, subsection (a)(2) provides that a dental hygienist may engage in "periodontal probing, scaling, root planing, polishing or another procedure required to remove calculus deposits, accretions, excess or flash re-

storative materials and stains from the exposed surfaces of the teeth and beneath the free margin of the gingiva to the base of the junctional epithelium." The Board proposes to replace the histological reference "beneath the free margin of the gingiva to the base of the junctional epithelium" with "beneath the gingiva." The gingiva is the tissue (covered by mucous membranes) that surrounds the bases of the teeth, commonly referred to as the gums. The "junctional epithelium" is defined as "a circular arrangement of epithelial cells occurring at the base of the gingival sulcus and attached to both the tooth and the subepithelial connective tissue." In layman's terms, the junctional epithelium is a grouping of cells that attach the gums to the teeth. Realistically, the only way to determine "the base of the junctional epithelium" is with a microscope. The fact is that a dental hygienist provides the listed services both above and below the gum line. In fact, root planing, by definition, must be done beneath the gingiva (gums). The current description is overly technical and serves no practical regulatory purpose.

Subsection (a)(7) is added to include the administration of local anesthesia by regional injection within the scope of practice of a dental hygienist in accordance with § 33.115.

Subsection (d)(1) pertaining to supervision requirements for dental hygienists in dental offices would be amended in its entirety as a result of Act 51, which abrogated the existing language. In its place, the text provides that the placement of subgingival agents, some of which require a prescription by a dentist, would be permitted only under direct supervision, unless the dentist has reviewed the patient's dental records and medical history and has written a prescription or given an order for the placement of subgingival agents by the dental hygienist, in which case general supervision is required. Scaling, root planing, polishing, and the like, may be provided under general supervision if the patient is relatively free of systemic disease or suffers only mild systemic disease, as determined by the dentist. Otherwise, if the patient suffers from systemic disease that is severe, incapacitating or life threatening, these services may only be provided under direct supervision. The provision of local anesthesia services may only be provided under direct supervision under a permit issued by the Board. All other dental hygiene services may be provided under general supervision.

Section 33.205(d)(2), pertaining to supervision requirements for dental hygienists (who are not public health dental hygiene practitioners) in public and private institutions and institutions under the jurisdiction of Federal, State or local health agencies, would be amended to provide similar supervision requirements relating to the placement of subgingival agents and local anesthesia by regional injection. All other dental hygiene services would be provided under general supervision.

The Board also proposes to add § 33.205b to set forth the standards for public health dental hygiene practitioners in accordance with Act 51. Subsection (a) addresses the scope of practice of public health dental hygiene practitioners. A public health dental hygiene practitioner would be permitted to perform the dental hygiene services set forth in § 33.205(a)(2)—(6) without supervision of a dentist. However, placement of subgingival agents (antimicrobials, antibiotics, anesthetics, and the like) would require a prescription or order of a dentist, and administration of local anesthesia would require direct supervision pursuant to a permit issued by the Board. Although Act 51 provides for a public health dental

hygiene practitioner to practice generally "without the authorization, assignment or examination by a dentist," the General Assembly could not have anticipated the expansion of the scope of practice to include the placement of all subgingival agents and the administration of local anesthesia because these provisions had not yet been proposed by the Board.

Subsection (b) would incorporate the requirement of referral set forth in Act 51. Subsection (c) would establish the practice settings in which a public health dental hygiene practitioner would be authorized to practice without supervision. In subsection (d), the Board proposes minimum standards for recordkeeping by public health dental hygiene practitioners. The Board's existing recordkeeping regulation in § 33.209 (relating to preparing, maintaining and retaining patient records) places the onus on the dentist to assure that dental records are properly maintained. Public health dental hygiene practitioners are authorized to practice in public health settings without supervision, so the onus must fall on them to maintain proper records.

The Board also proposes to amend its regulations relating to the performance of radiologic procedures in Subchapter D. Section 33.301 (relating to definitions) would be amended to establish the Radiation Health and Safety examination administered by the Dental Assisting National Board (DANB) as the required examination for auxiliary personnel who wish to administer ionizing radiation in a dental office. Section 33.302 (relating to auxiliary personnel performing radiologic procedures) would also be amended to comport with changes made by Act 51. The result is that public health dental hygiene practitioners may perform radiologic procedures without the supervision of a dentist; dental hygienists may do so under general supervision, as defined in Act 51, and all other auxiliary personnel who have passed the examination may do so under direct supervision.

Finally, the Board proposes an amendment to § 33.402 (relating to continuing education subject areas) to permit dental hygienists to complete no more than 3 of the required 20 hours of continuing education in courses relating to communication skills; to require public health dental hygiene practitioners to complete 5 of the required 20 hours in public health-related courses; and to permit public health dental hygiene practitioners who are also certified educational specialists by the Department of Education to submit evidence of compliance with section 1205.2 of the Public School Code (24 P.S. § 12-1205.2) meet the 20-hour continuing education requirement.

#### *Fiscal Impact and Paperwork Requirements*

The proposed rulemaking should have no fiscal impact on the Commonwealth or its political subdivisions because the costs associated with processing the local anesthesia permits and public health dental hygiene practitioner certificates will be borne by applicants. Dental hygienists who apply for local anesthesia permits will incur some costs associated with the permit application and renewal fees and possibly the costs of completing a local anesthesia course. Dental hygienists who wish to obtain certification as public health dental hygiene practitioners will incur costs associated with the permit application and biennial renewal fees. There are currently approximately 7,904 licensed dental hygienists in this Commonwealth. The Board has no way of knowing how many dental hygienists will apply for the local anesthesia permit or the public health dental hygiene practitioner certificate.

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

#### *Sunset Date*

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

#### *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on August 18, 2008, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review of comments, recommendations and objections by the Board, the Governor and the General Assembly, prior to final publication of the rulemaking.

#### *Public Comment*

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed amendments to Christopher P. Grovich, Counsel, State Board of Dentistry, P. O. Box 2649, Harrisburg, PA 17105-2649, within 30 days following publication of this proposed rulemaking.

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

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

##### **Subchapter A. GENERAL PROVISIONS**

##### **§ 33.1. Definitions.**

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

\* \* \* \* \*

*General supervision*—In a dental facility, supervision by a dentist who examines the patient, develops a treatment plan, authorizes the performance of dental hygiene services to be performed within [ 90 days ] 1 year of the examination, and takes full professional responsibility for the performance of the dental hygienist. In facilities

identified in § 33.205(c)(2) and (3) (relating to practice as a dental hygienist), general supervision is defined in § 33.205(d)(2).

\* \* \* \* \*

**Local anesthesia**—The elimination of sensations, especially pain, in one part of the body by regional injection of an anesthetic agent. For the purposes of § 33.115 (relating to local anesthesia permit), the term includes local infiltration anesthesia and intraoral nerve block anesthesia limited to the 2nd (maxillary) and 3rd (mandibular) divisions of the trigeminal nerve.

\* \* \* \* \*

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

\* \* \* \* \*

§ 33.3. Fees.

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

\* \* \* \* \*

Application fee—certificate of public health dental hygiene practitioner..... \$20

Application fee—local anesthesia permit..... \$20

\* \* \* \* \*

Biennial renewal fee—certificate of public health dental hygiene practitioner..... \$40

Biennial renewal fee—local anesthesia permit \$40

\* \* \* \* \*

Subchapter B. LICENSURE OF DENTISTS AND DENTAL HYGIENISTS

§ 33.102. Professional education.

\* \* \* \* \*

(b) *Dental hygienists.*

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

\* \* \* \* \*

§ 33.115. Local anesthesia permit.

(a) **Permit required.** A dental hygienist shall possess a current permit issued by the Board under this section before administering local anesthesia to a patient in a dental office.

(b) **Application.** A dental hygienist who desires to obtain a permit to administer local anesthesia shall submit an application on a form provided by the

Board, pay the permit fee prescribed in § 33.3 (relating to fees) and meet the qualifications for the permit as prescribed in this section.

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

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

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

(3) Provide to the Board acceptable documentation evidencing one of the following:

(i) Graduation, within the 5 years immediately preceding the filing of the application for local anesthesia permit, from a dental hygiene program that meets the following criteria:

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

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

(ii) Successful completion, within the 5 years immediately preceding the filing of the application for local anesthesia permit, of a course consisting of a minimum of 30 hours of didactic and clinical instruction in the administration of local anesthesia sponsored by a dental or dental hygiene education program accredited by CODA.

(iii) Possession of a current license or permit issued by the proper licensing authority of another state, territory or district, or by Canada, where the dental hygienist is authorized under the laws of that jurisdiction to administer local anesthesia, provided that the following conditions are met:

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

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

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

(D) The jurisdiction where the dental hygienist is so licensed or permitted provides a letter or certificate of good standing indicating that there has been no disciplinary action taken against the dental hygienist relating to the administration of local anesthesia.

(d) **Expiration and biennial renewal.** A local anesthesia permit issued by the Board under this section will expire at the same time as the permit holder's dental hygiene license but may be renewed biennially at the same time the dental

hygiene license is renewed. A dental hygienist who desires to renew a local anesthesia permit shall submit the following:

- (1) A renewal application on a form provided by the Board.
- (2) The permit renewal fee set forth in § 33.3.
- (3) Proof of current certification in BLS.

§ 33.116. Certification of public health dental hygiene practitioners.

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

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

- (1) Hold a current license in good standing to practice as a dental hygienist in this Commonwealth.
- (2) Provide to the Board acceptable documentation demonstrating that the dental hygienist has completed 3,600 hours of practice as a licensed dental hygienist under the supervision of a licensed dentist.

(3) Provide to the Board acceptable documentation demonstrating that the dental hygienist has obtained professional liability insurance in the minimum amount of \$1,000,000 per occurrence and \$3 million per annual aggregate.

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

- (1) A renewal application on a form provided by the Board.
- (2) The permit renewal fee set forth in § 33.3.

Subchapter C. MINIMUM STANDARDS OF CONDUCT AND PRACTICE

§ 33.205. Practice as a dental hygienist.

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

- (1) Placement of [ antimicrobial cord ] subgingival agents.
- (2) Periodontal probing, scaling, root planing, polishing or another procedure required to remove calculus deposits, accretions, excess or flash restorative materials and stains from the exposed surfaces of the teeth and beneath the [ free margin of the ] gingiva [ to the base of the junctional epithelium ].

\* \* \* \* \*

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

\* \* \* \* \*

(d) *Supervision.*

(1) [ In subsection (c)(1) practice sites, the following apply:

(i) A dental hygienist may provide the professional services identified in subsection (a)(1) to patients in any ASA Class under the direct supervision of a dentist.

(ii) A dental hygienist may provide the professional services identified in subsection (a)(2) to ASA Class I patients under the general supervision of a dentist.

(iii) A dental hygienist may provide the professional services identified in subsection (a)(2) to ASA Class II—ASA Class V patients under the direct supervision of a dentist.

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

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

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

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

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

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

(v) A dental hygienist may provide the professional services identified in subsection (a)(7) only under the direct supervision of a dentist.

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

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

(ii) A dental hygienist may provide the professional services identified in subsection (a)(2)—(6)

under the general supervision of a dentist. For the purposes of this paragraph, general supervision is defined as supervision by a dentist who authorizes and takes full professional responsibility for the provision of the services. A single authorization may, when appropriate, apply to one or more classes or categories of students/patients.

(iii) A dental hygienist may provide the professional service identified in subsection (a)(7) only under the direct supervision of a dentist.

(3) For professional services not identified in subsection (a)(1)—[ (6) ] (7) or § 33.302 (relating to auxiliary personnel performing radiologic procedures), the dentist shall compare the listed services and the supervision required with the unlisted service and utilize the appropriate supervision. Supervision for noncomparable services shall be determined by the Board on a modality basis.

\* \* \* \* \*

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

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

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

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

- (1) Schools.
- (2) Correctional facilities.
- (3) Health care facilities, as defined in section 802.1 of the Health Care Facilities Act (35 P. S. § 448.802a).
- (4) Personal care homes, as defined in section 1001 of the Public Welfare Code (62 P. S. § 1001).
- (5) Domiciliary care facilities, as defined in section 2202-A of The Administrative Code of 1929 (71 P. S. § 581-2).
- (6) Older adult daily living centers, as defined in section 2 of the Older Adult Daily Living Centers Licensing Act (62 P. S. § 1511.2).
- (7) Continuing-care provider facilities, as defined in section 3 of the Continuing-Care Provider Registration and Disclosure Act (40 P. S. § 3203).
- (8) Federally qualified health centers.
- (9) Public or private institutions under the jurisdiction of a Federal, State or local agency.

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

- (1) The name and address of the patient and, if the patient is a minor, the name of the patient's parents or legal guardian.
- (2) The date dental hygiene services are provided.
- (3) A description of the treatment or services rendered at each visit.
- (4) The date and type of radiographs taken, if any, and documentation demonstrating the necessity or justification for taking radiographs, as well as the radiographs themselves.
- (5) Documentation of the annual referral to a dentist.

**Subchapter D. PERFORMANCE OF RADIOLOGIC PROCEDURES BY AUXILIARY PERSONNEL**

**§ 33.301. Definitions.**

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

\* \* \* \* \*

*Radiologic procedure examination*—[ An examination adopted by the Board for auxiliary personnel performing radiologic procedures in the office of a licensed dentist in this Commonwealth ] The Radiation Health and Safety examination administered by The Dental Assisting National Board, Inc. (DANB).

**§ 33.302. Auxiliary personnel performing radiologic procedures.**

[ The following auxiliary personnel may perform radiologic procedures on the premises of a dentist under the direct supervision of the dentist. These procedures include applying ionizing radiation on the maxilla, mandible and adjacent structures of human beings for diagnostic purposes. The dentist shall be on the premises when a radiologic procedure is being performed. The dentist is not required to personally observe performance of the procedure.

- (1) Dental hygienists currently licensed in this Commonwealth.
- (2) Auxiliary personnel who have passed the radiologic procedure examination adopted by the Board. ]

(a) Public health dental hygiene practitioners may perform radiologic procedures in those settings set forth in § 33.205b(c) (relating to practice as a public health dental hygiene practitioner) without the supervision of a dentist.

(b) Dental hygienists may perform radiologic procedures in any setting under the general supervision of a licensed dentist. For the purposes of this subsection, "general supervision" means supervision by a dentist who examines the patient, devel-

ops a dental treatment plan, authorizes the performance of the radiologic services to be performed within 1 year of the examination, and takes full professional responsibility for performance of the dental hygienist.

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

**Subchapter F. CONTINUING DENTAL EDUCATION**  
**§ 33.402. Continuing education subject areas.**

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

\* \* \* \* \*

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

\* \* \* \* \*

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

(c) A dental hygienist may complete no more than 3 of the required 20 hours of continuing education in courses relating to communication skills.

(d) A public health dental hygiene practitioner shall complete 5 of the required 20 hours of continuing education in public health-related courses.

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

[Pa.B. Doc. No. 08-1591. Filed for public inspection August 29, 2008, 9:00 a.m.]

**STATE BOARD  
 OF PHARMACY**

[ 49 PA. CODE CH. 27 ]

**Fees**

The State Board of Pharmacy (Board) proposes to amend § 27.91 (relating to schedule of fees) to read as set forth in Annex A. The proposed amendment would increase the application fees for the pharmacy intern certificate, pharmacist license, new pharmacy permit,

reinspections, pharmacy permit changes and the biennial renewal fees for pharmacist licenses and pharmacy permits.

*Effective Date*

The amendment will be effective upon final-form publication in the *Pennsylvania Bulletin*. The increased biennial renewal fees will take effect beginning with the pharmacy permit biennial renewal period commencing on September 1, 2009, and the pharmacist license biennial renewal period commencing on October 1, 2010. The other fee increases will take effect upon final-form publication.

*Statutory Authority*

The proposed amendment is authorized under section 8.2(a) of the Pharmacy Act (act) (63 P. S. § 390-8.2(a)). In addition, section 8.2(b) requires the Board to increase fees by regulation in an amount adequate to meet the minimum enforcement efforts required by the act.

*Background and Need for Amendment*

The Board is required by law to support its operations from revenue it generates from fees, fines and civil penalties. In accordance with section 8.2 of the act, if the Board anticipates that its revenue will not meet its expenditures, the Board must increase its revenue. The Board raises virtually all of its operating revenue through fees. The biennial license renewal fees are the most substantial revenue generating fees of all the fees charged by the Board.

With the exception of the biennial renewal fees, the Board has not revised its fees since the 1990s. The application fees are now being revised to reflect the current cost of processing an application. The inspection fees are being revised to reflect the current cost to the Board of the inspectors performing the required inspection. The biennial renewal fees were last raised in 2006. Initially, the Board conservatively raised those fees in attempt to not place a hardship on its licensees with a large increase. The Board reviews its revenues on an annual basis and subsequent reviews have shown that another increase is necessary to support its operations. The Board is again being conservative in raising fees so as not to place a hardship on its licensees. Given that a deficit is still projected, the Board will evaluate another fee increase in the future. However, if pending legislation is passed, increased revenue from the registration of pharmacy technicians and imposing investigative costs for disciplinary actions could negate the necessity to further raise renewal fees.

At its April 17, 2007, Board meeting and again at its June 19, 2007, and March 18, 2008, Board meetings, the Bureau of Finance and Operations (BFO) presented a summary of the Board's revenues and expenses for Fiscal Years (FY) 2004-2005, 2005-2006 and 2006-2007, and projected revenues and expenses for FYs 2007-2008—2013-2014. The summary, presented in the following table, demonstrated that the Board must raise fees to maintain a positive balance after the pharmacist renewal takes place in the even-numbered years.

2004-2005 beginning balance	324,955.04
FY 04-05 revenue	2,304,562.44
FY 04-05 expenses	1,655,000.00
Remaining balance	974,517.48
2005-2006 beginning balance	974,517.48
FY 05-06 revenue	529,381.83
FY 05-06 expenses	1,850,000.00
Remaining balance	(346,100.69)

2006-2007 beginning balance	(346,100.69)
FY 06-07 revenue	3,035,093.83
Prior year returned funds	122,155.06
Adjust for prior year expenses	243,901.49
FY 06-07 projected expenses	1,788,000.00
Remaining balance	779,206.71
2007-2008 beginning balance	779,206.71
FY 07-08 projected revenue	500,000.00
Prior year returned funds	576,709.95
FY 07-08 projected expenses	1,842,000.00
Remaining balance	(24,665.09)
2008-2009 beginning balance	(24,665.09)
FY 08-09 projected revenue	3,000,000.00
FY 08-09 projected expenses	1,934,000.00
Remaining balance	1,041,334.91
2009-2010 beginning balance	1,041,334.91
FY 09-10 projected revenue	502,000.00
FY 09-10 projected expenses	2,031,000.00
Remaining balance	(726,925.77)
2010-2011 beginning balance	(726,925.77)
FY 10-11 projected revenue	3,866,000.00
FY 10-11 projected expenses	2,133,000.00
Remaining balance	1,325,334.91
2011-2012 beginning balance	1,325,334.91
FY 11-12 projected revenue	582,000.00
FY 11-12 projected expenses	2,240,000.00
Remaining balance	(332,665.09)
2012-2013 beginning balance	(332,665.09)
FY 12-13 projected revenue	3,866,000.00
FY 12-13 projected expenses	2,352,000.00
Remaining balance	1,181,334.91
2013-2014 beginning balance	1,181,334.91
FY 13-14 projected revenue	582,000.00
FY 13-14 projected expenses	2,470,000.00
Remaining balance	(706,655.09)

As the table indicates, at the close of FY 2005-2006, the Board's expenses exceeded its revenues by \$346,100.69. While the pharmacist renewal brought the Board's account back to a positive balance in FY 2006-2007, in FY 2007-2008, the Board will run at a deficit again and in the off-renewal years the Board will continue to have a deficit. BFO anticipates that the proposed new fees will enable the Board to recapture the deficits every other year.

The increases in the Board's biennial expenses occurred primarily in administrative costs and law enforcement costs. Administrative costs increased from approximately \$343,682 in FY 2005-2006 to approximately \$513,063 in FY 2006-2007. Law enforcement (the Bureau of Enforcement and Investigation) expenditures increased from approximately \$551,194 in FY 2005-2006 to approximately \$630,080 in FY 2006-2007. Legal office costs remained about the same, however the number of complaints filed continued to rise from previous years. Administrative costs likely increased because the Board began receiving applications for the authority to administer injectable medications, immunizations and biologicals. Additionally, vacant pharmacy inspector positions were filled which led to the increase in law enforcement costs both due to the salaries and the increased inspections the additional inspectors performed.

The Board carefully reviewed several options in fee increases to ensure the lowest fee increase possible while keeping the Board out of a long run deficit. Before the Board dramatically raises its renewal fees it prefers to wait until two pieces of legislation that would bring significantly more revenue to the Board complete their journey through the legislative process. If either of these pieces of legislation fails to be enacted during this legislative session, the Board will reevaluate. In addition to increasing fees, the Board is looking at ways to streamline procedures to cut costs; however, the fee increases are still necessary to maintain a positive balance in the Board account in the long run. Finally, in developing the proposal, the Board reviewed fees of other states. It found that the proposed fees are comparable to the renewal fees charged in surrounding states and should cause no competitive disadvantage to the Commonwealth.

#### *Description of Proposed Amendment*

Based upon the previous expense and revenue estimates provided to the Board, the Board proposes to amend § 27.91 to increase the fee for biennial renewal of licenses for pharmacists from \$150 to \$190 and increase the biennial renewal fee for pharmacy permits from \$100 to \$125. The Board is also proposing to increase the application fee for a pharmacy intern certificate from \$30 to \$35, the application fee for a pharmacist license from \$40 to \$45, the application fee for a new pharmacy permit from \$100 to \$125, the fee for reinspection of a new pharmacy after failure at first inspection from \$90 to \$115, the application fee for a pharmacy permit change without inspection from \$30 to \$45 and the application fee for a pharmacy permit change when inspection required from \$95 to \$125.

#### *Fiscal Impact*

The proposed amendment will increase the biennial renewal fees for pharmacists and pharmacies as well as several other fees the Board charges for its services to applicants. The proposed amendment should have no other fiscal impact on the private sector, the general public or political subdivisions.

#### *Paperwork Requirements*

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

#### *Sunset Date*

The act requires that the Board monitor its revenue and expenses on a FY and biennial basis. Therefore, no sunset date has been assigned.

#### *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), the Board submitted a copy of this proposed rulemaking on August 18, 2008, to the Independent Regulatory Review Commission (IRRC), the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee (Committees). In addition to submitting the proposed amendment, the Board has provided IRRC and the committees with a copy of a detailed Regulatory Analysis Form prepared by the Board. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, if IRRC has comments, recommendations or objections regarding any portion of the proposed rulemaking, it will

notify the Board within 30 days after the close of the public comment period. The notification must specify the regulatory review criteria that have not been met. The Regulatory Review Act specifies detailed procedures for review of comments, recommendations and objections by the Board, the General Assembly and the Governor prior to publication of the amendment.

*Public Comment*

Interested persons are invited to submit written comments, recommendations or objections regarding this proposed rulemaking to Melanie Zimmerman, Executive Secretary, State Board of Pharmacy, P. O. Box 2649, Harrisburg, PA 17105-2649, within 30 days following publication of this proposed amendment in the *Pennsylvania Bulletin*.

MICHAEL A. PODGURSKI, R. Ph.,  
*Chairperson*

**Fiscal Note:** 16A-5422. No fiscal impact; (8) recommends adoption.

**Annex A**

**TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS**

**PART I. DEPARTMENT OF STATE**

**Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS**

**CHAPTER 27. STATE BOARD OF PHARMACY FEES**

**§ 27.91. Schedule of fees.**

An applicant for a license, certificate, permit or service shall pay the following fees at the time of application:

Application for pharmacy intern certificate .....	[ \$30 ]	\$35
Application for pharmacist license .....	[ \$40 ]	\$45
* * * * *		
Registered pharmacist biennial renewal .....	[ \$150 ]	\$190
* * * * *		
New pharmacy permit application .....	[ \$100 ]	\$125
Reinspection of new pharmacy after failure at first inspection .....	[ \$90 ]	\$115
Pharmacy permit change without inspection .....	[ \$30 ]	\$45
Pharmacy permit change when inspection required .....	[ \$95 ]	\$125
* * * * *		
Biennial renewal of pharmacy permit ...	[ \$100 ]	\$125
* * * * *		

[Pa.B. Doc. No. 08-1592. Filed for public inspection August 29, 2008, 9:00 a.m.]