RULES AND REGULATIONS

Title 10—BANKING

DEPARTMENT OF BANKING

[10 PA. CODE CH. 7]

Corrective Amendment to 10 Pa. Code § 7.2

The Department of Banking has discovered a discrepancy between the agency text of 10 Pa. Code § 7.2 as deposited with the Legislative Reference Bureau, and the official text as published at 5 Pa. B. 72 (January 11, 1975) and published in the *Pennsylvania Code Reporter* (Master Transmittal Sheet No. 33). When the section was reprinted in the August, 1988 *Pennsylvania Code Reporter* (Master Transmittal Sheet No. 165), and as currently appears in the *Pennsylvania Code*, the definition of "performance" was codified incorrectly.

Therefore, under 45 Pa.C.S. § 901: The Department of Banking has deposited with the Legislative Reference Bureau a corrective amendment to 10 Pa. Code § 7.2. The corrective amendment to 10 Pa. Code § 7.2 is effective August 6, 1988, the date the defective official text was announced in the *Pennsylvania Bulletin*.

The correct version of 10 Pa. Code § 7.2 appears in Annex A, with ellipses referring to the existing text of the regulation.

RICHARD C. RISHEL,
Secretary

Annex A

TITLE 10. BANKING

PART I. GENERAL PROVISIONS

CHAPTER 7. RESIDENTIAL REAL ESTATE TRANSACTIONS

§ 7.2. Definitions and rules of construction.

Unless the context indicates otherwise, the following definitions and rules of construction apply:

* * * * *

Performance—The term, for purposes of sections 403 and 404 of the act (41 P. S. §§ 403 and 404), includes, but is not limited to, a conspicuous designation as to where cure shall be tendered, if the designated location is one of the following:

(i) A regular place of business of the residential mortgage lender in the county where the real property is located or in a county contiguous thereto which is open during normal business hours.

(ii) For a period of time that the required notice provides the residential mortgage debtor with knowledge of a specific sum of money, payment of which during the period will constitute satisfactory tender of cure, an address at which tender of cure may be made by mail.

(iii) If the residential mortgage lender has no place of business as set forth in subparagraph (i), any designated location in the county where the real property is located, or in a county contiguous thereto, which is open during normal business hours. The designated location may be the office of an attorney. The residential mortgage lender may require that on the day of a scheduled sheriff's sale, tender of cure be limited to the place of the sale, provided that the residential mortgage debtor is given the name of the agent of the lender authorized to accept tender of cure and the agent is present at the place of sale at least 1 1/2 hours prior to commencement of the sale.

* * * * *

[Pa.B. Doc. No. 98-1646. Filed for public inspection October 10, 1998, 9:00 a.m.]

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 6]

Drugs Which May Be Used By Certain Optometrists

The Department of Health (Department) hereby amends Chapter 6 (relating to drugs which may be used by certain optometrists), specifically § 6.1 (relating to approved drugs), to read as set forth in Annex A. By this amendment, the Secretary of Health (Secretary) is exercising the statutory authority to establish a list of drugs which qualified optometrists may use in their practices for diagnostic purposes and for the treatment of certain parts of the eye.

A. *Summary of the Regulations*

The final-form regulation contains a list of drugs which may be prescribed by optometrists who meet certain conditions, including the certification standards developed by the State Board of Optometry (Board). See 63 P. S. § 244.4a. At present, § 6.1 contains a very limited list of drugs which optometrists may use: local anesthetics, miotics (for contracting the pupil) and mydriatics or cycloplegics (for dilating the pupil or stopping the movement of the eye). The list now being adopted by the Department accommodates the change in the definition of "practice of optometry" contained in section 2 of the Optometric Practice and Licensure Act (63 P. S. § 244.2) (act), as amended by section 1 of the act of October 30, 1996 (P. L. 721, No. 130) (Act 130). That definition was amended to include the use of drugs, as prescribed by the Secretary, in the treatment of certain conditions of the human visual system under specified limitations. The final-form regulation expands the list of drugs that may be used by qualified optometrists, to reflect the authority of the optometrist to now, within the parameters of the act, treat the anterior segment of the eye, the eyelids, the lacrimal system and the conjunctiva and to remove superficial foreign bodies from the surface and adnexa. See paragraph (2) of the definition of "practice of optometry," 63 P. S. § 244.2.

B. *Discussion of Comments*

Notice of proposed rulemaking was published at 28 Pa.B. 485 (January 31, 1998). A 30-day comment period was provided. Following that publication, the Department received many comments from persons both opposed to, and supportive of, portions of the proposed amendment. Commentators included ophthalmologists, optometrists, professional organizations, institutions of higher learning and physicians with specialities other than ophthalmology. Commentators also included members of the General Assembly: the Majority and Minority Chairs of the Senate

Public Health and Welfare Committee, Senator Harold F. Mowery, Jr., and Senator Hardy Williams, respectively; Senator Jeffrey E. Piccola, who was the prime sponsor of Act 130, Senators Clarence D. Bell, Joe Conti,Vincent J. Fumo, Melissa A. Hart, Edwin G. Holl, Timothy F. Murphy and James J. Rhoades; the collective members of the House of Representatives Health and Human Services Committee by letter of its Majority Chairperson, Representative Dennis M. O'Brien; Speaker of the House Matthew J. Ryan and Representatives Mario J. Civera, Jr., Roy W. Cornell, Robert W. Godshall and David J. Steil.

The Department's responses to the comments received on specific provisions of its proposed amendment follow:

Proposed subsection (a)(4)(i). "Treatment undertaken by an optometrist pursuant to this section shall be limited to 6 weeks duration . . . ."

The Independent Regulatory Review Commission (IRRC), the Pennsylvania Academy of Ophthalmology and several members of the General Assembly made the comment that this provision would conflict with the statutory definition of "practice of optometry," which allows an optometrist to treat a patient for more than 6 weeks upon consultation with a licensed physician. The Department has revised subsection (a)(4)(i) to reflect the language of the statute.

Proposed subsection (a)(4)(ii). "Treatment undertaken by an optometrist pursuant to this section may not include . . . steroids . . . ."

Proposed subsection (a)(5). "An optometrist may not treat glaucoma."

Several commentators, all optometrists, took the position that the proposed amendment should be expanded to allow for treatment of glaucoma and the use of steroids. According to these commentators, many states permit optometrists to treatment glaucoma and to use steroids in treating the human visual system, and there are continuing education courses taken by optometrists which address these practices.

The treatment of glaucoma and the use of steroids by optometrists are specifically prohibited by statute. See paragraph (3)(iii) and (v) of the definition of "practice of optometry," 63 P. S. § 244.2. Any change in these requirements would have to be undertaken by the Legislature through statutory amendment, not by the Department through regulation.

Proposed subsection (a)(6). "An optometrist may not prescribe or administer a . . . Schedule II controlled substance."

The Lehigh Valley Pharmaceutical Association pointed out that codeine, when prescribed alone, is a Schedule II controlled substance. Permitting an optometrist to prescribe a Schedule I or II controlled substance would conflict with the statutory definition of the practice of optometry. See paragraph (3)(ii) of the definition of "practice of optometry," 63 P. S. § 244.2. As proposed subsection (b)(8)(i)(A) was written, however, it would allow an optometrist to prescribe codeine.

The Department has revised subsection (b)(8)(i)(A) to clarify its intention to permit codeine to be prescribed only in combination with aspirin or acetaminophen. Prescribed in combination with these other drugs, codeine is not being prescribed as a Schedule II controlled substance, and the act would not be violated.

Proposed subsection (b). "Allowable pharmaceutical products."

Two commentators recommended that the Secretary not limit allowable drugs in the final-form regulation to an exhaustive list, but list drugs by category. They contended that this would allow all drugs included in those approved categories to be used by optometrists as they became available for use, and so eliminate time consuming regulatory updates.

The Department did initially consider proposing a list of categories of drugs, rather than proposing an exhaustive drug list. The Department believes, however, that it would be more appropriate to list drugs specifically. This would enable the Department to consider each drug on a case-by-case basis. It is a safer course to consider the effects of each drug within a category, rather than to approve a category as a whole without being able to predict the effects of each new drug. Also, the Department's opportunity to consider public comment on the addition or deletion of drugs from the approved list should be preserved.

Proposed subsection (b)(7). "Antimicrobial agents—access to culture and sensitivity testing (as clinically indicated) is urged."

In the proposed amendment, the Department had included language to recommend that optometrists have access to culture and sensitivity testing when prescribing antimicrobial agents. The Pennsylvania Academy of Ophthalmology and several other commentators took the position that the language, "access to culture and sensitivity testing (as clinically indicated) is urged," would go beyond the scope of the act. According to these commentators, the Secretary only has the authority under the act to create a list of drugs which may be prescribed, and neither may place conditions upon, nor expand, the practice of optometry. Further, they argued that the determination that testing is clinically indicated would require professional judgment which belongs to the practice of medicine, not optometry.

Commentators also pointed out that the use of the phrase, "is urged," would be unenforceable. IRRC recommended that the phrase be deleted for this reason as well.

Because the Department agrees that urging conduct is not a regulatory standard, it has not included the language, "access to culture and sensitivity testing (as clinically indicated) is urged," in the final-form regulation. Further, the Department has been assured by the Board that optometrists who are authorized by it to prescribe drugs are familiar with culture and sensitivity testing when clinically indicated and are trained to make the appropriate clinical decisions.

Proposed subsection (b)(7)(ii) and (iv). Inclusion of oral antibacterial drugs and oral antiviral drugs in the list of drugs which may be prescribed by certain optometrists.

The proposed language which would permit the prescription of oral antibacterial drugs and oral antiviral drugs by optometrists received the second highest number of comments. There was both support and opposition to the inclusion of these drugs. The opposition fell into two categories. First, more than 30 ophthalmologists sent letters opposing the prescription of any medication by optometrists. Several of these letters argued that optometrists did not have the education or experience to prescribe medications. Several commentators expressed the opinion that there were sufficient numbers of ophthalmologists to perform these functions, so that it was unnecessary to allow optometrists to do so. One commen-

tators expressed concern that HMOs would use optometrists rather than ophthalmologists to treat patients to cut costs, and that this would severely impact the health and welfare of those patients.

The second group of opponents, approximately 20 ophthalmologists, the Pennsylvania Academy of Ophthalmology and the Pennsylvania Osteopathic Medical Association, objected specifically to language which would permit the prescription of oral antiviral and antibacterial medications. Their objections centered around a concern that the education and training of optometrists were insufficient to permit the safe prescription of these drugs. According to these commentators, allowing optometrists to prescribe these drugs independently would also result in delay in proper diagnosis and thus cause harm to the patient. Members of this group found no public health imperative requiring the Department to provide optometrists with the power to prescribe these drugs, and they believed that adoption of the proposal would be at the expense of the health and welfare of patients.

One commentator noted that if the condition of the patient was serious enough to require the use of oral antibacterial and antiviral drugs (which, in his opinion, were rarely used), the patient should be seen by a physician, not an optometrist. Another commentator expressed concern that individuals without medical training would be prescribing antibacterial and antiviral drugs when antibiotic resistance was becoming a major concern. He believed that adoption of such a regulation would lead to the over-prescription of these drugs, to the detriment of the patient and the citizens of this Commonwealth, who could then suffer from the effects of drug resistant diseases.

Commentators in opposition to this provision also stated that the language of the act did not specifically allow for the prescription of oral antibacterial and antiviral drugs. Therefore, they argued that the Secretary did not have the authority to approve those drugs as part of the proposed list.

The members of the House Health and Human Services Committee opposed the Department's proposal to include oral antiviral and antibacterial drugs in the final list if the Department had included those drugs based upon the existence of the proposed concurrence requirement. The Committee took this position because it was of the opinion that the act only allowed those drugs to be approved which could be used by an optometrist without seeking the concurrence of a physician. Because the Department's proposed amendment conditioned the prescription of oral antiviral and antibacterial drugs by a qualified optometrist on a physician's concurrence, it asserted that those drugs should be excluded to promote good medical practice.

The Department also received many comments in support of the approval of these drugs. A group of approximately 30 optometrists, as well as the Pennsylvania College of Optometry and the Pennsylvania Optometric Association, wrote to commend the Department for including oral antiviral and antibacterial medications in the proposed list. Several members of the General Assembly also expressed their support. These commentators stressed the importance of having the medications available for treatment by optometrists when needed, which would eliminate unnecessary referral of patients to physicians. The Vice President and Dean of Academic Affairs for the Pennsylvania College of Optometry pointed out that other states began to permit this prescription and usage in 1976 with low malpractice rates. Another commentator stated that currently 49 states permit their use. One commentator argued that it was absurd for him to be permitted to prescribe such drugs in his Delaware practice for his Delaware patients, but not in this Commonwealth for his Pennsylvania patients.

Further, commentators in support of the proposed inclusion of these drugs noted the existence of continuing education and examinations for optometrists on the use of the drugs. According to the Pennsylvania College of Optometry, optometrists have had extensive didactic and clinical training in using and applying skills relating to these medications, and use of these medications is an integral part of the curriculum.

Several commentators in this group stated that the language of the statute did authorize the Secretary to exercise his discretion to permit use of oral antibacterial and antiviral drugs by optometrists in treating the visual system.

In response to those commentators who argued that optometrists should not be permitted to prescribe any medication, the Department notes that the General Assembly has already determined that qualified optometrists may prescribe some drugs in the course of their practice. It has given the Secretary the authority and the discretion to approve these drugs in two definitions in the act: the definition of "practice of optometry," and the definition of "examination and diagnosis."

The argument made by some commentators that the Secretary was not given authority by the act to approve oral antiviral and antibacterial drugs is not supported by the clear language of the act. Had the General Assembly intended to limit the Secretary's authority to approve drugs under the definition of "practice of optometry" to certain categories of drugs which could only be used topically, it would have expressly done so as it did in the definition of "examination and diagnosis."

The definition of "examination and diagnosis" contained in the act provides the Secretary with the authority to approve pharmaceutical agents for diagnosis within certain categories: "miotics, mydriatics, cycloplegics, topical anesthetics and dyes when applied topically to the eye." See the definition of "examination and diagnosis," 63 P. S. § 244.2. The definition of "practice of optometry" provides the Secretary with the authority to approve drugs for treatment so long as they are "for the treatment of the anterior segment of the eye, the eyelids, the lacrimal system and the conjunctiva and the removal of superficial foreign bodies from the ocular surface and adnexa . . . ." See paragraph (2) of the definition of "practice of optometry," 63 P. S. § 244.2. Unlike in the first definition, there is no mention in the latter definition of specific categories of drugs, and no statement that the approved drugs may only be applied topically. If the General Assembly had intended to limit the Secretary's authority to approve only certain categories of drugs and to restrict them to topical applications for treatment purposes, language similar to that included in the definition of "examination and diagnosis" would have appeared in the definition of "practice of optometry." Both definitions were revised in the 1996 amendments to the act.

Also, the definition of "practice of optometry" does include a list of categories of drugs which may not be approved by the Secretary. An optometrist may not prescribe Schedule I and Schedule II controlled substances, beta blockers or steroids. See paragraph (3)(ii) and (iii) of the definition of "practice of optometry," 63 P. S. § 244.2. If the General Assembly intended to pro-

hibit optometrists from prescribing oral antibacterial drugs, oral antiviral drugs or certain analgesics, those drugs would have been specifically included in the statute's list of prohibited substances. If certain things are specifically designated in a statute, omissions from that list are to be understood as exclusions. *City Council of Hazelton v. City of Hazelton*, 134 Pa. Cmwlth. 174, 180, 578 A.2d 580, 583 (1990). Therefore, the Secretary may approve whatever drug he finds to be necessary for the treatment, both topically and orally, of those parts of the eye specifically set out in the statute, so long as the other conditions of the statute are met.

The Department is also not convinced that the inclusion of these drugs in the final-form regulation would lead to them being excessively or improperly prescribed, and, thereby, add significantly to the problem of drug-resistant diseases. The Department has consulted with the Board and is satisfied that the current educational curriculum for optometrists, and the certification requirements developed by the Board, are sufficient to make practicing optometrists aware of this problem. The Board, as the expert in this area, has developed, and both IRRC and the General Assembly have approved, certification requirements designed to ensure that optometrists using drugs specified by the Secretary are qualified to do so. See section 4.1 of the act (63 P. S. § 244.4a) (relating to certification to prescribe and administer pharmaceutical agents for therapeutic purposes). The Board has advised the Department that optometrists who meet its standards are qualified to use the listed drugs in their practice.

Further, the Department notes that the areas of the eye which may be treated by optometrists with drugs from the list are narrowly circumscribed by the General Assembly. This also limits the possibilities for over-prescription of drugs.

The Department agrees that the use of oral antibacterial and antiviral drugs are important in the practice of optometry, which now includes, by definition, the treatment of specified parts of the eye. Education and certification requirements do exist. Optometrists who are qualified to prescribe these drugs must satisfy these requirements to be authorized to prescribe oral antibacterial and antiviral drugs. Therefore, the Department has included these drugs in its final-form regulation.

Proposed subsection (b)(7)(ii). "Prior to prescribing oral antibacterial agents, the optometrist shall obtain verbal or written concurrence from the patient's referring physician or usual primary care physician or from an ophthalmologist if the patient's condition so indicates. The optometrist shall record the concurrence in the patient's medical record and on the prescription form. If the patient has no continuing medical care provider, the optometrist shall refer the patient to a primary care physician or an ophthalmologist before prescribing these agents."

Proposed subsection (b)(7)(iv). "Prior to prescribing oral antiviral agents, the optometrist shall obtain verbal or written concurrence from the patient's referring physician or usual primary care physician or from an ophthalmologist if the patient's condition so indicates. The optometrist shall record the concurrence in the patient's medical record and on the prescription form. If the patient has no continuing medical care provider, the optometrist shall refer the patient to a primary care physician or an ophthalmologist before prescribing these agents."

Verbal or written concurrence.

The Department's proposed requirement that an optometrist obtain written or verbal concurrence from a physician before prescribing oral antiviral and antibacterial drugs drew more than 120 comments. All but five of these commentators, including ophthalmologists, optometrists, professional organizations and Legislators, opposed the concurrence requirement contained in proposed subsection (b)(7)(ii) and (iv). Many commentators, mostly ophthalmologists and their professional organizations, opposed the proposed concurrence requirement because they viewed it as a "comanagement" requirement. These commentators noted that the act does not specifically include language requiring concurrence before prescription of an oral antiviral or antibacterial medication. They contended that the Legislature did not intend to require such a concurrence, and that the Department's proposed concurrence requirement would be an impermissible departure from the statute. Other commentators stated that the Secretary only has authority under the act to create a list of drugs, not to circumscribe or expand the practice of optometry. Several members of the General Assembly opposed the provision because they were of the opinion that it would place impermissible restrictions on the practice of optometry under the law.

Additionally, several Legislators commented that Legislative history forbade the inclusion of a concurrence requirement. They pointed out that the concept of co-management had been considered and specifically rejected by the General Assembly in the passage of the act. They suggested that the issue of oversight of optometrists by the medical licensure boards had been a controversial one, and that the statute was crafted to avoid oversight. Many commentators argued that if the regulation imposed a concurrence requirement, the Boards of Medicine and Osteopathic Medicine would be called upon to set standards for physician concurrence, which would, in effect, contravene the Legislature's intention to prevent optometrists from being subject to oversight by those Boards. IRRC also took the view that the proposed amendment would create an impermissible co-management requirement, which would contravene the Legislative intent.

Commentators also raised concerns that the proposed concurrence requirement would harm patients. Many, including IRRC, were concerned that a physician would be requested to give concurrence to an optometrist's opinion without first seeing the patient. Others commented that for an optometrist to obtain a physician's concurrence, the patient would have to be referred to the physician. They suggested that this would require a patient to make three visits to different health care providers—first to an optometrist, then to an ophthalmologist or other physician for concurrence, and then back to the optometrist for treatment. They complained that the excessive referrals would be burdensome and add to the cost of health care. Because of limitations in managed care plans, one commentator thought the proposed concurrence requirement would be unworkable. Other commentators took the position that the proposed amendment should have required the concurrence to be obtained from an ophthalmologist only.

The Pennsylvania Medical Society (PMS) pointed out that the act requires referral to, not consultation with, a physician when systemic disease is identified, and took the position that the language of the proposed amendment would violate this requirement. The PMS took issue with the proposed concurrence language, because it believed this proposed language would require a physician to authorize up to 6 weeks of treatment without seeing or evaluating a patient. According to The PMS, a patient could be treated for 6 weeks by an optometrist under this

authorization without the physician having the opportunity to reevaluate the patient. The PMS believed this would not be in the best interest of the citizens of this Commonwealth, and would contravene the intent of the Legislature in passing Act 130.

Other concerns with the proposed language raised by commentators included issues of possible abuse by both optometrists and physicians, including the temptation to use prescription forms presigned by physicians, and physicians feeling pressured to concur with optometrists to obtain referrals. Several commentators, including the Pennsylvania Academy of Ophthalmology, expressed concern that the proposed amendment could create liability for the physician giving a concurrence without examining the patient. The Academy felt that if an optometrist were capable of prescribing the drugs in question, the optometrist should be required to assume the legal and medical responsibility for the decision. Several commentators also pointed out that as optometry is an independent profession, an optometrist should not be permitted to prescribe a drug if the optometrist would need supervision to do so.

A second large group of commentators, made up of optometrists and their professional organizations, opposed the proposed concurrence provision because they took the position that the act gives optometrists the authority to prescribe oral antibacterial and antiviral drugs, if the drugs are approved by the Secretary, without the need to obtain permission from a physician. This was also the position expressed by several State senators.

Several commentators in this group, including IRRC, expressed concern about the logistics of obtaining concurrence. IRRC questioned whether both the physician and the optometrist would be required to document the concurrence. Several commentators felt it would be difficult to locate an available physician during times when an optometrist would find it necessary to seek a concurrence. These commentators cited a probable difference in office hours as a cause of difficulty. They expressed concern that delays in locating a physician would lead to delays in the provision of treatment, or cause the optometrist to resort to less effective treatment. One commentator expressed concern that this requirement would add to already burdensome paperwork, and would create problems with managed care entities.

Some commentators were concerned that physicians would refuse to give concurrence. This would put the optometrist in the difficult ethical and legal position of either refusing treatment to a patient, or risking legal problems if treatment were to be given without meeting the proposed requirements.

Also, many commentators in this group expressed their belief that an optometrist's training and education are more than adequate to enable the optometrist to prescribe the drugs without physician concurrence. These commentators pointed to continuing education courses for optometrists and to examinations which currently exist addressing the treatment and management of ocular disease. Several commentators argued that since podiatrists and dentists are permitted to prescribe drugs without obtaining concurrence from a physician, optometrists should be permitted to do so as well. Further, they stated that other states currently allow optometrists to prescribe drugs without prior concurrence.

One commentator argued that requiring an optometrist to obtain concurrence before prescribing these drugs is what actually occurs now, so that if the proposed provision were to be included in the final-form regulation, nothing in the practice of optometry would be changed.

Another commentator expressed concern that patients would be confused as to why a concurrence was needed.

Several commentators stated that requiring prior concurrence from a physician would undermine the statute's purpose in allowing optometrists to prescribe medications. IRRC also questioned how the Department could take the position that it was reasonable to require that an optometrist obtain concurrence prior to prescribing the drugs if in fact the optometrist was prescribing oral medications and treating conditions with oral medications within the scope of the practice of optometry.

A very few commentators, some optometrists and physicians, as well as the Pennsylvania Optometric Association felt that the proposed concurrence requirement was acceptable. Some of these commentators did express concern about how the concurrence would be documented. One commentator doubted that a physician would know the correct treatment for a problem involving the eye, and believed that a concurrence requirement would be ineffective.

Two commentators recommended changing the proposed language relating to oral antibacterial and oral antiviral drugs to require that an optometrist be required to consult with a physician if a patient were to show no improvement within a specified time after treatment with the drugs had begun. One commentator suggested 72 hours as an appropriate time frame, another suggested 2 to 3 days.

One commentator suggested that the conditions for which a patient could be treated by an optometrist should be listed in the final-form regulation.

Additional issues raised relating to the proposed concurrence requirement are as follows:

Concurrence from the patient's referring physician or usual primary care physician or from an ophthalmologist if the patient's condition so indicates.

The Pennsylvania Academy of Ophthalmology commented that use of the phrase, "if the patient's condition so indicates," in the proposed amendment did not clearly state from whom the concurrence would be required. It was not clear to the Academy whether the phrase would apply to the referring physician, the primary care physician or ophthalmologist, or all three. IRRC raised this same issue.

IRRC also questioned what criteria would determine whether the condition "so indicates," and recommended the removal of the language, or its clarification.

Concurrence documented on the prescription form.

Approximately 35 commentators, all optometrists, commented on the inclusion of this requirement in the proposed amendment. All of them opposed the inclusion, contending that additional delay and confusion would occur by requiring such a statement on the prescription form as well as in the patient record. One State representative also stated that the language should not be included in the final-form regulation. Many commentators, including the Pennsylvania Optometric Association, noted their approval of the Department's notice published at 28 Pa.B. 1008 (February 21, 1998). That notice explained that the Department had inadvertently included the language in the proposed amendment, as it had previously communicated its intention to remove that language from an earlier draft of the proposed amendment.

Referral of patients who do not have continuing medical care providers prior to prescription.

Several commentators chose to address this specific proposal in the proposed concurrence provision separately. These commentators opposed the proposed language, arguing that there would be no reason to treat persons without continuing medical care providers any differently than those with providers. They cited delay in treatment and increase in health care costs as the most detrimental results of implementing the language. One commentator noted that there was no language in the statute supporting the proposed provision, and expressed his concern that the proposed language would remove the exercise of optometric judgment from the optometrist, and turn it over to the medical doctor. One commentator noted that many patients seen by optometrists on an emergency basis have no continuing medical provider. They contended that, if the regulation would require such an emergency patient to be referred first to a medical provider, treatment would be delayed, and the patient could be harmed.

Act 130, which amended the act to expand the definition of the "practice of optometry," was the culmination of some 15 years of discussion by persons interested in the Legislative handling of this matter. In attempting to implement the provisions relating to the prescription of drugs in a manner consistent with Act 130, the Department sought to reach a consensus among these groups prior to promulgating the proposed amendment. Unfortunately, no consensus was reached. The Department, nevertheless, felt compelled to issue proposals so that the regulatory oversight process would be engaged, and lead to a resolution of controversial issues. In promulgating the proposed amendment, the Department's intention was not to go beyond what was permitted by the act and required for the health and safety of the patient. Consultation between optometrists and ophthalmologists in the interest of the patient is required by the act in some instances. Otherwise, consultation should occur in the ordinary course of an optometrist's practice, without the Department requiring it, if necessary for the well-being of the patient. The Department now believes that it showed an excess of caution in proposing that certain conditions be met before the drugs would be considered as approved for use.

By enacting Act 130, the Legislature has proclaimed that there is a pressing need for optometrists to be able to prescribe medications enabling them to properly treat a patient who presents with one or more of the conditions of the segments of the eye listed in the act. See paragraph (2) of the definition of "practice of optometry," 63 P. S. § 244.2. The Department is not persuaded by those commentators who call into question the expertise and education of optometrists. The Board, which is the body with expertise in determining what is required of optometrists licensed in this Commonwealth, has set out in its regulation the requirements an optometrist must meet before the optometrist may prescribe drugs in the practice of optometry. See 49 Pa. Code §§ 23.1, 23.82 and 23.201 and 23.202 (relating to therapeutic drugs). The Board has assured the Department that the current educational curriculum required of persons studying to be optometrists and the certification requirements promulgated by the Board are sufficient to ensure safety for those patients treated by optometrists in accordance with the final-form regulation.

Further, the Department notes that the use of the drugs on the Secretary's approved list is limited to treatment for a very specific area of the eye. The optometrist may only use the drugs on the list to treat for conditions of the anterior segment of the eye, the eyelids, the lacrimal system and the conjunctiva and to remove superficial foreign bodies from the ocular surface and adnexa. See paragraph (2) of the definition of the "practice of optometry," 63 P. S. § 244.2. The act also prohibits an optometrist from continuing to treat a patient for longer than 6 weeks without consultation with a physician. If the patient's condition becomes one which the optometrist cannot continue to treat effectively, the optometrist, as a licensed professional, should be knowledgeable enough to refer the patient to, or to consult with, an individual with expertise in that area. Referral to a physician is required under the act when accepted practice standards so dictate. See section 7(a)(10) and (11) of the act (63 P. S. § 244.7(a)(10) and (11)).

In response to comments which suggested that the Department list the condition of the eye which may be treated, rather than the drugs which may be used to treat the eye, the Department does not have the authority to do so. Only the Legislature can provide that authority. Use of the drugs, however, must be in accordance with accepted standards of optometric practice. See section 7(a)(10) of the act.

The Department also agrees that there could be logistical problems resulting from the proposed concurrence requirement which could cause delay in needed treatment. These logistical problems could also create liability for both physicians and optometrists if physician concurrence were provided without the physician actually seeing the patient. These logistical issues, and the difficulty they could create for patients in obtaining needed treatment, outweigh whatever additional safeguards the proposed concurrence requirement would have added to an already safeguarded system of treatment.

The Department's decision not to include the proposed concurrence requirement of subsection (b)(7)(ii) and (iv) in the final-form regulation is supported by the Board's recently promulgated regulations, the current educational requirements for optometrists and the possibility of logistical problems leading to a delay in treatment and an increase in its cost.

Proposed subsection (b)(8)(i). "An optometrist shall only be permitted to prescribe the following drugs, either alone or in combination with acetaminophen or aspirin, for up to 72-hours per patient visit."

Several Legislators opposed this provision, stating that it impermissibly set limitations on the practice of optometry, which is solely for the Board to regulate. According to the House Health and Human Services Committee, as well as IRRC, optometrists have either the authority to prescribe certain drugs under the act, or they do not—if conditions beyond those set forth in the act are necessary to ensure patient safety, optometrists should not be allowed to use drugs requiring additional conditions. Further, these commentators believed that the language would violate case law principles set out in *Pennsylvania Medical Society v. Commonwealth, State Board of Medicine*, 118 Pa. Cmwlth. 635, 546 A.2d 720 (1988). PMS also opposed the proposed 72-hour prescription limitation.

Three commentators, all optometrists, as well as the Pennsylvania Optometric Association, supported the provision. The Association did recommend an additional limitation on the prescription of analgesic drugs, and suggested that the Department require that a patient be referred to a physician or ophthalmologist if these drugs are needed longer than a set period of time.

After reviewing the list of drugs in question, and the comments received, the Department has determined not to include the proposed 72-hour limitation on prescription in the final-form regulation. The Department is satisfied that the expertise exists among qualified optometrists to prescribe the drugs listed, and to make a determination of when other expertise should be called in. Therefore, the Department has not included the proposed 72-hour limitation on prescription in the final-form regulation.

General comments.

The Department received several other comments on the amendment as a whole. Those comments and the Department's responses follow:

Several commentators, including the Pittsburgh Ophthalmological Society and the Pennsylvania Academy of Ophthalmology, expressed concern that the proposed amendment would allow the expansion of the scope of the practice of optometry beyond the scope of the law. Most of these commentators were concerned about the possibility of expanding the practice of optometry to include the treatment of glaucoma. One commentator read the proposed amendment to allow treatment of glaucoma, and strongly objected to it.

The list of drugs included in the proposed amendment, as well as those set forth in the final-form regulation, are within the scope of the authority provided to the Secretary under the act. With respect to the specific comment suggesting that the proposed amendment would lead to permission for optometrists to treat glaucoma, the proposed, as well as the final amendment, expressly prohibit treatment of glaucoma by optometrists, consistent with the language of the act. See paragraph (3)(v) of the definition of "practice of optometry," 63 P. S. § 244.2.

Further, the act only gives the Secretary the authority to approve drugs which may be used by optometrists; he cannot expand the conditions for which those drugs may be used. Those conditions are set out in statute. See paragraph (3) of the definition of "practice of optometry," 63 P. S. § 244.2. Only the General Assembly may choose to allow optometrists to treat glaucoma, or to expand the scope of the practice of optometry.

IRRC requested that the Department either justify its use of trade names or revise the proposed amendment to include generic names. It was not the Department's intention to prohibit the use of generic drugs, or to require the use of trade name drugs exclusively. The Department, therefore, has added language to subsection (b) (relating to allowable pharmaceutical products) of the final-form regulation to permit the use of a generic drug when it is the A-rated generic therapeutically equivalent to the drug listed.

One commentator stated that the Secretary should create and amend the list through some procedure other than the regulatory process. This commentator found the regulatory process to be too cumbersome and time consuming. The Department has no discretion in determining how the list will be promulgated. Because the requirements contained in the regulation must be legally enforceable, and because the nature of the requirements and the list demand public input, the list may only be promulgated by regulation.

One commentator felt that the Cost Section of the Preamble to the proposed amendment was inappropriate and unnecessary because cost had nothing to do with the practice of optometry. State agencies are required by law to include in the Preamble information concerning the cost of proposed amendments to regulated parties and to the Commonwealth. See 71 P. S. § 745.5(a)(4). This is done to fully inform the public of the cost of the proposed amendments, and to enable them, as well as the Commonwealth, to make an informed decision about their cost effectiveness. The Department cannot voluntarily choose to eliminate a statutorily required component of the Preamble.

One commentator stated that the Board had incorrectly interpreted the criteria for certification, and inclusion of this requirement in the final-form regulation would be costly and redundant. The determination of what education and certification requirements need to be placed on optometrists to render them qualified to utilize the approved list of drugs is entrusted to the Board by statute. See section 4.1 of the act (63 P. S. § 244.4a). The Department has no authority to set these requirements. The Board has advised the Department that optometrists who meet its regulatory requirements are adequately trained and educated to employ the listed drugs in their practices.

The Lehigh Valley Pharmaceutical Association suggested that optometrists would need to obtain a DEA number to prescribe medications as permitted under the proposed amendment. According to the Association, pharmacies might be reluctant to fill prescriptions without this number. The Association pointed out that a DEA number would be needed for pharmacists to obtain reimbursement. The Department acknowedges that a DEA number is required for the prescription of some of the drugs listed. Optometrists who choose to prescribe these drugs will need to obtain a DEA number before doing so.

The Department also received a comment from the PMS stating that the Department's proposed amendment did not match an earlier draft which the PMS understood the Department would be proposing. The regulations commented on by the PMS were only proposed regulations. The Department has given consideration to every comment received by it in its development of the final-form regulation in Annex A.

C. *Cost and Paperwork Estimate*

1. *Cost*

The addition of new drugs to the approved list contained in Chapter 6 will not affect the Commonwealth, local government or the general public financially. It is possible that the expansion of the practice of optometry to include the administration and prescription of certain drugs under certain enumerated conditions may adversely affect the practice of some ophthalmologists, if individuals who would otherwise find it necessary to consult an ophthalmologist could, under the 1996 statutory amendments and this amendment, consult an optometrist and choose to do so. It is not certain that this will be the case, however, and the statute does provide for consultation with a licensed physician after treatment for a 6-week period by an optometrist.

2. *Paperwork*

No changes to reporting, recordkeeping or other paperwork are required, except to the extent that the number of drugs optometrists are permitted to administer and prescribe under certain conditions have increased, which may require optometrists to increase notations in patient records.

D. *Effective Date/Sunset Date*

This amendment will be effective immediately upon final adoption. The amendment will be continually monitored and updated as needed. Therefore, no sunset date has been set.

E. *Statutory Authority*

The Department has the authority to amend Chapter 6 under the act. Specifically, the Department's authority is contained in the definitions of "examination and diagnosis" and "practice of optometry" found in section 2 of the act (63 P. S. § 244.2), as amended by section 1 of Act 130. The Department also has general authority to promulgate regulations under section 2102(g) of The Administrative Code of 1929 (71 P. S. § 532(g)).

F. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on January 21, 1998, the Department submitted a copy of the proposed amendment to IRRC and the Chairpersons of the House Health and Human Services Committee and the Senate Public Health and Welfare Committee for review and comment. In compliance with section 5(c) of the Regulatory Review Act, the Department also provided IRRC and the Committees with copies of all comments received, as well as other documentation.

In compliance with section 5.1(a) of the Regulatory Review Act (71 P. S. § 745.5a(a)), the Department submitted a copy of the final-form regulation to IRRC and the Committees on August 10, 1998. In addition, the Department provided IRRC and the Committees with information pertaining to commentators and a copy of a detailed regulatory analysis form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

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

This final-form regulation was deemed approved by the House Health and Human Services Committee and the Senate Public Health and Welfare Committee on August 31, 1998. IRRC met on September 10, 1998, and approved the final-form regulation in accordance with section 5.1(e) of the Regulatory Review Act.

G. *Contact Person*

Persons having questions concerning the final-form regulation may contact Lori Gerhard, Director of Policy, Department of Health, P. O. Box 90, Harrisburg, PA 17108, (717) 787-4525. Persons with disabilities may submit questions in alternative formats, such as by audiotape, braille or by using TDD: (717) 783-6514. Persons with a disability who wish to obtain a copy of the final-form regulation in an alternative format (that is, large print, audio tape, braille), should contact Lori Gerhard at the telephone numbers or address listed so that the necessary arrangements may be made.

H. *Findings*

The Department finds that:

(1) Public notice of intention to adopt the final-form regulation adopted by this order has been given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202), and the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law, and all comments were considered prior to the promulgation of this final-form regulation.

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

I. *Order*

The Secretary of Health, acting under authorizing statutes, orders that:

(a) The regulations of the Department, 28 Pa. Code Chapter 6, are amended by amending § 6.1 to read as set forth in Annex A.

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

(c) The Secretary of Health shall submit this order, Annex A and a Regulatory Analysis Form to IRRC, the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare for their review and action as required by law.

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

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

DANIEL F. HOFFMANN,
Secretary

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 28 Pa.B. 4845 (September 26, 1998).)

Fiscal Note: 10-152. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 28. HEALTH AND SAFETY

PART I. GENERAL HEALTH

CHAPTER 6. DRUGS WHICH MAY BE USED BY CERTAIN OPTOMETRISTS

§ 6.1. Approved drugs.

(a) *Administration and prescription of pharmaceutical agents*. Optometrists who are certified to prescribe and administer pharmaceutical agents for therapeutic purposes under section 4.1 of the Optometric Practice and Licensure Act (35 P. S. § 244.4a), may prescribe and administer the drugs listed in subsection (b) in their practice of optometry under the following conditions:

(1) The drugs shall be approved by the Food and Drug Administration (FDA).

(2) Over-the-counter medications (per FDA listing) are fully authorized.

(3) An optometrist may not administer any drug parenterally.

(4) The treatment undertaken by an optometrist under this section:

(i) May not continue beyond 6 weeks from the initiation of treatment unless the prescribing optometrist documents consultation with a licensed physician.

(ii) May not include beta-blockers or steroids.

(iii) May not be prescribed for systemic conditions except as an adjunctive therapy and shall be limited to the anterior eye structures (and adnexa).

(5) An optometrist may not treat glaucoma.

(6) An optometrist may not prescribe or administer a Schedule I or II controlled substance.

(b) *Allowable pharmaceutical products.* Optometrists may prescribe and administer the following pharmaceutical products or the A-rated generic therapeutically equivalent drug:

(1) Topical anesthetics

(i) Proparacaine.

(ii) Benoxinate.

(iii) Tetracaine.

(2) Topical ocular lubricants.

(3) Topical opthalmic dyes and stains.

(i) Fluorescein.

(ii) Rose Bengal.

(iii) Fluorexen.

(4) Topical hyperosmotic agents.

(5) Autonomic drugs—topical only.

(i) Cholinergic agonists.

(A) Pilocarpine nitrate and pilocarpine hydrochloride—diagnostic use only.

(B) Physostigmine.

(C) DFP (diisopropylfluorophosphate).

(D) Echothiopate.

(ii) Cholinergic antagonists.

(A) Homatropine hydrobromide.

(B) Tropicamide.

(C) Atropine sulfate.

(D) Cyclopentolate hydrochloride.

(E) Scopolamine hydrobromide.

(iii) Adrenergic agonists.

(A) Hydroxyamphetamine hydrobromide.

(B) Phenylephrine hydrochloride.

(C) Tetrahydrazoline.

(D) Nefazoline.

(E) Oxymetazoline.

(iv) Adrenergic antagonists—diagnostic use only.

(A) Dapiprazole.

(B) Thymoxamine.

(6) Nonsteroidal antiinflammatory drugs—topical only.

(i) Diclofenac.

(ii) Ketorolac.

(iii) Flurbiprofen.

(iv) Suprofin.

(7) Antimicrobial agents.

(i) Antibacterial—topical use only.

(A) Cell wall inhibitors.

(I) Bacitracin.

(II) Cephalosporins.

(III) Penicillins.

(IV) Vancomycin.

(B) Protein synthesis inhibitors.

(I) Aminogylcosides.

(II) Tetracycline.

(III) Erythromycin.

(IV) Chloramphenicol.

(C) Intermediary metabolism inhibitors.

(I) Sodium sulfacetamide and sulfisoxazole.

(II) Trimethoprim.

(D) DNA synthesis inhibitors.

(I) Ciprofloxacin.

(II) Norfloxacin.

(III) Ofloxacin.

(E) Cell membrane permeability.

(I) Polymyxin B.

(II) Gramicidin.

(ii) Antibacterial—oral.

(A) Cell wall inhibitors.

(I) Penicillins—including in combination with clavulanic acid.

(II) Cephalosporins.

(1) First generation—cephalexin and cefadroxil.

(2) Second generation—cefaclor and cefuroxime.

(B) Protein synthesis inhibitors.

(I) Tetracycline.

(II) Doxycycline.

(III) Erythromycin.

(IV) Azithromycin.

(iii) Antivirals—topical only.

(A) Idoxurine.

(B) Vidarabine.

(C) Trifluridine.

(iv) Antivirals—oral.

(A) Acyclovir.

(B) Valacyclovir.

(C) Famciclovir.

(v) Antifungal and antiparasitic—topical only.

(A) Amphotericin B, nystatin, natamycin.

(B) Miconazole, ketoconazole, clotrimazole.

(C) Thiabendazole.

(D) Neomycin and polymyxin B.

(E) Paromycin.

(8) Analgesic drugs—oral and topical.

(i) Analgesic drugs—oral.

(A) Codeine in combination with acetaminophen or aspirin.

(B) Hydrocodone.

(C) Pentazocine.

(D) Propoxyphene.

(ii) Antihistamines and mast cell stabilizers—topical only.

(A) Pheniramine.

(B) Pyrilamine.

(C) Antazoline.

(D) Levocarbastine.

(E) Cromolyn.

(F) Nedocromil.

(G) Lodoxamide.

(H) Olopatadine.

[Pa.B. Doc. No. 98-1647. Filed for public inspection October 9, 1998, 9:00 a.m.]

Title 40—LIQUOR

LIQUOR CONTROL BOARD

[40 PA CODE CH. 11]

Wine in Kegs; Sale by Limited Winery Licensees

The Liquor Control Board (Board) under the authority of section 207(i) of the Liquor Code (47 P. S. § 2-207(i)), adopts amendments to §§ 11.104 and 11.111 (relating to wine in kegs; and sale by limited winery licensees).

The Board regulations amended by this order will permit the sale of sparkling grape wines, as defined in 27 CFR 4.21(b)(1)—(3) (relating to standards of identity), in glass containers larger than 5 liters by the Board's liquor stores and by Pennsylvania limited wineries for sale within this Commonwealth.

Comments

Notice of proposed rulemaking was published at 28 Pa.B. 2591 (June 6, 1998), with a 30 day written public comment period.

The Board received no comments either in support of or in opposition to the proposed amendments during the public comment period.

Fiscal Impact

These final-form regulations will not impose additional costs on the regulated community, the State or local governments.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on May 11, 1998, the Board submitted a copy of the notice of proposed rulemaking to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House Committee on Liquor Control and the Senate Committee on Law and Justice for review and comment. These final-form regulations were submitted to the Chairpersons of the Senate Committee on Law and Justice and the House Committee on Liquor Control and the IRRC on August 20, 1998.

Under 5.1(d) of the Regulatory Review Act (71 P. S. § 745.5a(d)), these final-form regulations were deemed approved by the House and Senate Committees on September 9, 1998, and were deemed approved by IRRC on September 10, 1998, in accordance with section 5.1(e) of the Regulatory Review Act.

Contact Person

Persons requiring an explanation of the final-form regulations, or information related thereto should contact Jerry Danyluk, Liquor Control Board, Room 401, Northwest Office Building, Harrisburg, PA 17124-0001.

Findings

The Board finds that:

(1) Public notice of intention to adopt amendments to the administrative regulations by this order has been given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) The adoption of the final-form regulations set forth in this order is necessary and appropriate for the administration and enforcement of the authorizing statute.

Order

The Board, acting under the enabling statute, orders that:

(a) The regulations of the Board, 40 Pa. Code Chapter 11, are amended by amending §§ 11.104 and 11.111 to read as set forth at 28 Pa.B. 2591.

(b) The Board shall submit this order and 28 Pa.B. 2591 to the Office of the Attorney General for approval as to form and legality as required by law.

(c) The Board shall certify this order and 28 Pa.B. 2591 and deposit them with the Legislative Reference Bureau as required by law.

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

JOHN E. JONES III,
Chairperson

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 28 Pa.B. 4845 (September 26, 1998).)

Fiscal Note: Fiscal Note 54-54 remains valid for the final adoption of the subject regulations.

[Pa.B. Doc. No. 98-1648. Filed for public inspection October 9, 1998, 9:00 a.m.]

Title 58—RECREATION

FISH AND BOAT COMMISSION

[58 PA. CODE CH. 61]

Fishing

The Fish and Boat Commission (Commission) by this order amends §§ 61.1 and 61.2 (relating to Commonwealth inland waters; and Delaware River and River Estuary). The Commission is publishing these amendments under the authority of 30 Pa.C.S. (relating to the Fish and Boat Code) (code). The amendments relate to fishing.

A. *Effective Date*

These amendments will go into effect on January 1, 1999.

B. *Contact Person*

For further information on the amendments, contact Laurie E. Shepler, Assistant Counsel, (717) 657-4546, P. O. Box 67000, Harrisburg, PA 17106-7000. This final rulemaking is available electronically through the Commission's Web site at http://www.fish.state.pa.us.

C. *Statutory Authority*

These amendments are published under the statutory authority of section 2102 of the code (relating to rules and regulations).

D. *Purpose and Background*

The amendments are designed to update, modify and improve Commission regulations pertaining to fishing. The specific purpose of the various amendments is described in more detail under the summary of changes.

E. *Summary of Changes*

Sections 61.1 and 61.2. Management of American shad, hickory shad, gizzard shad and river herring (alewife and blueback herring) stocks are a real challenge to today's fisheries managers. Restoration efforts to one extent or the other for one or more of these species are occurring in the Susquehanna River basin and the Delaware River drainage, specifically the Lehigh River and to a lesser extent the Schuylkill River.

Recently, the Commission amended its prohibition of harvest of American shad in the Susquehanna River to include hickory shad and river herring (alewife and blueback herring) and increased the coverage to include all tributaries. Hickory shad are listed as a Candidate Species in § 75.3 (relating to candidate species) and, as such, could achieve endangered or threatened status in the future. The Commission is concerned that existing regulations, particularly as applied to the Delaware River, Estuary and tributaries, are not in harmony with the Candidate Species listing or the intent of restoration efforts.

Also, river specific and Statewide regulations are not clear as to the harvest of gizzard shad, particularly those longer than 8 inches (those 8 inches or less are considered baitfish) taken by means of hook and line either for personal consumption or use as bait for larger gamefish, such as muskellunge or striped bass. Gizzard shad occur in various waters across this Commonwealth with many "landlocked" populations maintained through natural reproduction, while others are of a migratory nature congregating in large concentrations downstream of dams. Harvest of this species should pose no threat to the stock but needs to be regulated from the standpoint of natural resource conservation ethics. Therefore, the Commission has amended § 61.1 by adding "no open season" for hickory shad, by adding gizzard shad with an open year-round season with a 50 fish possession limit, and by adding a 50 fish daily possession limit for herring. The Commission also has amended § 61.2 by adding hickory shad with a "no open season."

F. *Paperwork*

The amendments will not increase paperwork and will create no new paperwork requirements.

G. *Fiscal Impact*

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

H. *Public Involvement*

A notice of proposed rulemaking containing the proposed amendments were published at 28 Pa.B. 1840 (April 18, 1998). The Commission received one comment from the Water Quality Subcommittee of the Pennsylvania Electric Association that opposes the proposal. A copy of this public comment was provided to all Commissioners.

Findings

The Commission finds that:

(1) Public notice of intention to adopt the amendments adopted by this order has been given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and the regulations promulgated thereunder 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided and that all comments received were considered.

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

Order

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

(a) The regulations of the Commission, 58 Pa. Code Chapter 61, are amended by amending §§ 61.1 and 61.2 to read as set forth at 28 Pa.B. 1840.

(b) The Executive Director will submit this order and 28 Pa.B. 1840 to the Office of Attorney General for approval as to legality as required by law.

(c) The Executive Director shall certify this order and 28 Pa.B. 1840 and deposit them with the Legislative Reference Bureau as required by law.

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

PETER A. COLANGELO,
Executive Director

Fiscal Note: Fiscal Note 48A-80 remains valid for the final adoption of the subject regulations.

[Pa.B. Doc. No. 98-1649. Filed for public inspection October 9, 1998, 9:00 a.m.]

Title 61—REVENUE

DEPARTMENT OF REVENUE

[61 PA. CODE CH. 103]

Personal Income Tax; Net Gains or Income from Disposition of Property

The Department of Revenue (Department), under the authority contained in section 354 of the Tax Reform Code of 1971 (TRC) (72 P. S. § 7354) and section 20 of the act of April 23, 1998 (P. L. 239, No. 45) (Act 45), by this notice of proposed rulemaking omitted, adopts amendments to § 103.13 (relating to net gains or income from disposition of property) to read as set forth in Annex A.

Purpose of Amendment

The amendment of § 103.13 is the result of statutory changes set forth in Act 45. Act 45 repeals the current rules for determining whether gain from the sale or other disposition of a principal residence is subject to the personal income tax. The statutory change is effective for taxable years beginning after December 31, 1997.

Explanation of Regulatory Requirements

The heading of subsection (g) of § 103.13 has been amended to address the exclusion of gain from sale of a principal residence before January 1, 1998. Prior to Janu-

ary 1, 1998, and subject to the limitations of § 103.13(g)(2), and except as provided in § 103.13(g)(1)(iii), (3) or (5), a taxpayer could elect to exclude the taxpayer's portion of the aggregate gain realized on the sale of a residence only under the following conditions:

- The taxpayer is at least 55 years of age on the date of sale.
- The taxpayer used the residence as his principal residence for periods aggregating 3 years or more, during the 5-year period ending on the date of sale.
- The taxpayer owned the residence for periods aggregating 3 years or more, during the 5-year period ending on the date of sale.
- The date of sale of the residence is after June 30, 1987.
- The taxpayer has not previously made an election under § 103.13(g)(1)(i) for Pennsylvania tax purposes or has revoked previous elections.

A new subsection (h) has been added to § 103.13 to address the exclusion of all gain from disposition of a principal residence after December 31, 1997. Paragraph (1) provides that an individual may exclude from tax gain realized on the sale or other disposition of a principal residence if the conditions in subparagraphs (i)—(iv) are met.

Section 103.13(h)(2) provides that for purposes of paragraph (1)(iv), it shall be immaterial that a prior disposition was delayed due to market exigencies or other reason. Section 103.13(h)(3)(i) explains how situations where a taxpayer holds title to a residence with a spouse or other person as joint tenants, tenants in common or tenants by the entireties are handled; subparagraph (ii) explains how Act 45 applies when a joint return of income is made with respect to the sale of a married couple's jointly owned residence. Subparagraphs (iii)—(v) under subsection (h)(3) explain how Act 45 applies regarding unmarried widow or widower, tenant-stockholders in cooperative housing corporations and when an estate is the taxpayer.

Section 103.13(h)(3) explains in subparagraph (vi) what is a principal residence and the use and ownership requirements. For purposes of the new § 103.13(h), subparagraph (vii) under paragraph (3) defines the word "disposition" and explains what is meant by the phrase "date of disposition." Subparagraph (viii) explains the rules that apply when the property consists of farms, duplexes and other mixed use property. Subparagraph (ix) addresses the rules pertaining to depreciable property and subparagraph (x) explains how split interests are addressed.

The existing subsections (h), (i) and (j) under § 103.13 are relettered as (i), (j) and (k) accordingly. No other revisions are being made to these subsections.

Fiscal Impact

The Department has determined that the amendment will have no significant fiscal impact on the Commonwealth.

Paperwork

The amendment will not generate additional paperwork for the public or the Commonwealth.

Effectiveness/Sunset Date

The amendment will become effective upon final publication in the *Pennsylvania Bulletin*. The amendment is scheduled for review within 5 years of final publication. No sunset date has been assigned.

Contact Person

The contact person for an explanation of the amendment is Anita M. Doucette, Office of Chief Counsel, PA Department of Revenue, Dept. 281061, Harrisburg, PA 17128-1061.

Statutory Authority

The amendment is promulgated under section 354 of the TRC and section 20 of Act 45.

Regulatory Review

In accordance with section 20 of Act 45, the Department was directed to promulgate regulations which are final-form regulation, under the Regulatory Review Act, and omit notice of proposed rulemaking under section 201 of the act of July 31, 1968 (P. L. 769, No. 240), referred to as the Commonwealth Documents Law. Section 20 of Act 45-1998 also requires the regulation to be submitted to the Legislative Reference Bureau by November 24, 1998, for publication in the *Pennsylvania Bulletin*.

Under section 5.1(c) of the Regulatory Review Act (71 P. S. § 745.5a(c)), on August 25, 1998, the Department submitted a copy of the final-form regulation with proposed rulemaking omitted to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Committee on Finance and the Senate Committee on Finance. On the same date, the final-form regulation was submitted to the Office of Attorney General for review and approval under the Commonwealth Attorneys Act (71 P. S. §§ 732-101—732-506). In accordance with section 5.1(d) of the Regulatory Review Act, the final-form regulation was deemed approved by the House and Senate Committees on September 14, 1998. IRRC met on September 24, 1998, and approved the final-form regulation.

Findings

The Department finds that the amendment is necessary and appropriate for the administration and enforcement of the authorizing statute. In accordance with section 20 of Act 45, the Department was directed to promulgate regulations which are final-form regulations, under the Regulatory Review Act, and omit notice of proposed rulemaking under section 201 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. § 1201).

Order

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

(a) The regulations of the Department, 61 Pa. Code Chapter 103, are amended by amending § 103.13 to read as set forth in Annex A, with elipses referring to the existing text of the regulation.

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

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

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

ROBERT A. JUDGE, Sr.
Secretary

Fiscal Note: 15-405. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 61. REVENUE

PART I. DEPARTMENT OF REVENUE

Subpart B. GENERAL FUND REVENUES

ARTICLE V. PERSONAL INCOME TAX

CHAPTER 103. IMPOSITION AND DETERMINATION OF TAX

§ 103.13. Net gains or income from disposition of property.

* * * * *

(g) *Exclusion of gain from sale of principal residence before January 1, 1998.*

(1) *Eligible individuals.* In determining whether an individual is eligible to claim the exclusion of gain from the sale of a principal residence, the individual shall comply with the following:

(i) Subject to the limitations of paragraph (2), and except as provided in subparagraph (iii), paragraph (3) or paragraph (5), a taxpayer may elect to exclude the taxpayer's portion of the aggregate gain realized on the sale of a residence only under the following conditions:

(A) The taxpayer is at least 55 years of age on the date of sale.

(B) The taxpayer used the residence as his principal residence for periods aggregating 3 years or more, during the 5-year period ending on the date of sale.

(C) The taxpayer owned the residence for periods aggregating 3 years or more, during the 5-year period ending on the date of sale.

(D) The date of sale of the residence is after June 30, 1987, and before January 1, 1998.

(E) The taxpayer has not previously made an election under this subparagraph for Pennsylvania tax purposes or has revoked previous elections.

* * * * *

(h) Exclusion of all gain from disposition of principal residence after December 31, 1997.

(1) *Eligible individuals.* An individual may exclude from tax gain realized on the sale or other disposition of the taxpayer's principal residence of the following conditions are met:

(i) The date of disposition of the residence is after December 31, 1997.

(ii) The taxpayer used the residence as his principal residence for periods aggregating 2 years or more during the 5-year period ending on the date of its disposition.

(iii) The taxpayer owned the residence for periods aggregating 2 years or more during the 5-year period ending on the date of its disposition.

(iv) One of the following applies:

(A) During the 2-year period ending on the date of disposition of the taxpayer's principal residence, there was no prior disposition by the taxpayer of a principal residence.

(B) The disposition of the taxpayer's principal residence is by reason of an unforeseen change in employment or health or severe financial hardship to the taxpayer resulting from a sudden and unexpected accident, loss of property due to casualty or other similar extraordinary and unforeseeable circumstance arising as a result of events beyond the control of the taxpayer.

(2) *Market exigencies.* For purposes of paragraph (1)(iv), it shall be immaterial that a prior disposition was delayed due to market exigencies or other reason.

(3) *Ownership and use conditons.* For purposes of paragraph (1):

(i) *Exception.* Except as provided in subparagraph (ii), when a taxpayer holds title to a residence with a spouse or other person as joint tenants, tenants in common or tenants by the entireties, the ownership and use conditions in paragraph (1) apply separately to each coowner and only the coowner who meets the conditions of paragraph (1) may claim the exclusion.

(ii) *Joint return.* When a joint return of income is made with respect to the disposition of a married couple's jointly owned residence, it is not necessary that both spouses satisfy the ownership and use conditions of paragraph (1). If one spouse satisfies the conditions, both spouses shall be considered to satisfy the conditions. If separate returns of income are made, the general rule that the ownership and use conditions apply separately to each spouse is applicable and only the spouse who meets ownership and use conditions may make an election.

(iii) *Unmarried widow or widower.* If a decedent, during the 5-year period ending on the date of disposition, satisfied both ownership and use conditions with respect to the property sold, the surviving spouse is also treated as satisfying the ownership and use conditions if not remarried.

(iv) *Tenant-stockholders in cooperative housing corporations.* An individual who holds stock as a tenant-stockholder in a cooperative housing corporation may qualify for exclusion with respect to the disposition of the stock. To determine whether a taxpayer meets requirements, the usual ownership conditions are applied to the holding of the stock and the usual use conditions are applied to the house or apartment which the taxpayer is entitled to occupy because of the taxpayer's stock ownership.

(v) *Estate as taxpayer.* A disposition made by an estate will not qualify for the exclusion, unless the disposition is under an executory contract made prior to death by an individual meeting the ownership and use conditions.

(vi) *Principal residence; use and ownership conditions.*

(A) A residence is a house, lodging or place of habitation, including a trailer or condominium, which:

(I) Has independent or self-contained cooking, sleeping and sanitation facilities.

(II) Is physically occupied and used for residential purposes by the taxpayer.

(B) The ownership and use conditions need not be met simultaneously. Both tests shall be met during the 5-year period preceding the date of the disposition. For example, a lessee could rent a residence for 1 year, then purchase the residence and again live in it for only 1 of the 4 following years and could still qualify for the election.

(C) The residence which the taxpayer physically occupies the most within a time period shall be his principal residence for the period. When a taxpayer alternates between homes, the home that he personally occupies the most shall be considered his principal residence. The test of physical occupancy is not satisfied by merely moving

furniture or other personal belongings into a residence without actually living there or by the taxpayer's family's physical occupancy.

(D) In determining whether a residence has been occupied and used for residential purposes, a taxpayer need not consider temporary absences from the principal residence if the residence was not rented during the taxpayer's absence. A temporary absence is an absence of less than 90 consecutive days or an absence of any length when the taxpayer is convalescing in a hospital, nursing home or a personal care facility.

(vii) *Disposition and date of disposition.*

(A) For purposes of this subsection, the word "disposition" means a sale, exchange, taking by eminent domain, destruction or other conversion of property into cash or other property giving rise to taxable gain. The date of disposition by sale of a principal residence is the date on which the deed is accepted by the buyer and title passes—ordinarily, the date of settlement—or, if delivery of the deed is postponed, the date on which possession and the burdens and benefits of beneficial ownership pass from the seller to the buyer under the contract of sale.

(B) The date a taxpayer received condemnation proceeds giving rise to taxable gain will be considered the date of disposition in the case of a condemnation. In the case of the destruction of a residence, the date the taxpayer receives casualty insurance proceeds or damages giving rise to taxable gain will be considered the date of disposition.

(viii) *Farms, duplexes and other mixed use property.* If the property sold includes business or rental property or the land surrounding the residence is in excess of that which is reasonably necessary for the use of the dwelling as a home, special rules apply:

(A) Where the land surrounding the residence is in excess of that which is reasonably necessary for the use of the dwelling as a home, only the portion of the gain on the disposition of the property allocable to the portion used as a residence is subject to the exclusion. Real estate used for commercial farming or for another commercial purpose is not reasonably necessary for the use of the dwelling as a home.

(B) If a residence includes business or rental premises, only that portion of gain on the disposition of the property allocable to the portion used as a residence is subject to the exclusion. Examples include a sole proprietor's residence above the sole proprietor's store, an office in home and a duplex where one unit is rented.

(ix) *Depreciable property.* If, at any time during the taxpayer's holding period, any portion of the principal residence sold was ever subject to the allowance for depreciation, only that part of gain on the disposition of the principal residence that is allocable to the portion of the principal residence which has never been subject to the allowance is subject to the exclusion.

(x) *Split interests.* A taxpayer's disposition of an immediate possessory interest, remainder interest or other interest in his principal residence shall qualify for exclusion, if the taxpayer would have qualified had he disposed of the entire interest in the property.

(i) *Accounting methods.*

(1) *Immediately recognized gain*. If gain on disposition of property does not qualify for installment or cost recovery treatment or if the transaction does qualify but the seller chooses not to use the installment method of accounting, the excess of the face amount of the evidence of indebtedness given the exchange for the property sold or otherwise disposed of together with the value of other consideration received by the seller over the seller's adjusted basis shall be recognized as gain in the year of the sale or disposition.

(2) *Installment sales method*. When a seller who is a cash basis taxpayer enters into an agreement for the sale of tangible personal property or real property under which agreement at least one payment is to be received in a taxable year following the year of sale, the seller may irrevocably elect to allocate the gain upon the transaction in equal proportion to each payment to be received under the following conditions:

(i) The sale was made on or after January 1, 1984.

(ii) The object of the transaction is not the lending of money or the rendition of services.

(iii) The taxpayer has not elected to exclude gains under subsection (g).

(3) *Cost recovery method*. When a seller who is a cash basis taxpayer enters into an agreement for the sale of intangible personal property under which agreement at least one payment is to be received in a taxable year following the year of sale, the seller shall use the cost recovery method of accounting if the note, contractual promise or other evidence of that obligation is not assignable.

(4) *Repossessed property*. When property is sold pursuant to a deferred payment contract, and the seller repossesses the property upon default of the buyer in a subsequent tax year, the seller shall account for the gain or loss by adjusting his basis in the property repossessed by the amount of gain previously reported on that sale.

(j) *Determination of net gain or income.* For purpose of determining net gains or income from the disposition of property, gain or loss shall be recognized on the sale, exchange or other disposition of obligations issued by the Commonwealth, a public authority, commission, board or other agency created by the Commonwealth, a political subdivision of this Commonwealth or a public authority created by the political subdivision or exempt from State taxation under the laws of the United States only with respect to obligations issued on or after February 1, 1994. Regardless of the obligation's date of issuance, gain or loss shall be recognized on the sale, exchange or other disposition of obligations issued by this Commonwealth, a publc authority, commission, board or other agency created by the Commonwealth, a political subdivision of the Commonwealth or a public authority created by the political subdivision or exempt from State taxation under the laws of the United States for one or more of the following purposes:

(1) Computing earnings and profits.

(2) Adjusting basis.

(3) Determining an individual's poverty income.

(k) *Adjustments to basis.*

(1) For taxable years beginning on or after January 1, 1993, the basis of a debt instrument in the hands of the holder shall be adjusted upward by the amount of unstated or imputed interest includible in the income of the holder and shall be adjusted downward, but not below zero, by the amount of any payment under the debt instrument other than a payment of stated interest.

(2) The basis of an obligation issued by the Commonwealth, a public authority, commission, board or other agency created by the Commonwealth, a political subdivision of this Commonwealth or a public authority created by the political subdivision or an obligation exempt from tax under the laws of the United States in the hands of the holder shall be adjusted upward by the amount of unstated or imputed interest that would have been includible in income but for its statutory exemption and shall be adjusted downward, but not below zero, by the amount of any payment under the debt instrument other than a payment of stated interest.

[Pa.B. Doc. No. 98-1650. Filed for public inspection October 9, 1998, 9:00 a.m.]