RULES AND REGULATIONS

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF PHARMACY

[49 PA. CODE CH. 27]

Supplies and Equipment

The State Board of Pharmacy (Board) amends §§ 27.14 and 27.16 (relating to supplies; and construction and equipment requirements) to read as set forth in Annex A. The final-form rulemaking deletes references to specific supplies that a pharmacy must maintain and instead allows pharmacies to maintain equipment to enable them to prepare and dispense prescriptions properly within their scope of practice. The final-form rulemaking also deletes the reference to the specific measurement of a pharmacy sink.

Notice of proposed rulemaking was published at 37 Pa.B. 1036 (March 3, 2007). Publication was followed by a 30-day public comment period. The Board received no public comments, however the Pennsylvania Pharmacists Association has indicated its support of these amendments in correspondence with the Independent Regulatory Review Commission (IRRC). The House Professional Licensure Committee (HPLC) submitted two comments to the proposed rulemaking on April 18, 2007. The Senate Consumer Protection and Professional Licensure Committee made no comments. IRRC submitted no comments to the proposed rulemaking.

Summary of Comments and Responses to Proposed Rulemaking

The HPLC noted that the proposed rulemaking deleted the requirement that the refrigerator be kept within the prescription area and asked if it was the Board's intent to remove that requirement. The Board did not intend to remove that requirement, but notes that the definition of prescription area includes the area of the pharmacy used for legend drug storage. As the refrigerator is to be used solely for drugs requiring refrigeration it would necessarily have to be kept in the prescription area. However, the Board understands that one could interpret the change in the regulation to mean that the refrigerator no longer has to be located in the prescription area. To avoid any confusion, the Board has amended § 27.14(c)(1) (relating to supplies) to require the refrigerator to be kept in the prescription area.

The HPLC next asked what criteria the Board's inspectors will use for performing inspections. In many states where the regulations are similar to these amendments, inspectors still use a checklist to guide them during a pharmacy inspection. The Bureau of Enforcement and Investigation anticipates that it will develop inspection guidelines, with input from the Board, based on different pharmacy practice settings. Inspection for supplies is only a small part of what the inspectors look for during an inspection. Inspectors also look at items such as filing of prescriptions, labels, cleanliness of the pharmacy, outdated drugs, posting of the pharmacy permit and technician protocols.

In the final-form rulemaking, the Board also reinserted the language that was added by the Board's "Technology and Automation" rulemaking in 2006. See 36 Pa.B. 2518 (May 27, 2006). This language was inadvertently omitted from the proposed rulemaking and the text was deleted from the proposed rulemaking by the Legislative Reference Bureau. The Board did not intend for this language to be deleted and has amended the final-form rulemaking package to reinsert the language as intended.

Statutory Authority

The amendments are authorized under sections 4(j) and 6(k)(1) of the Pharmacy Act (act) (63 P. S. §§ 390-(4)(j) and 390-6(k)(1)).

Fiscal Impact and Paperwork Requirements

The amendments would have not a fiscal impact on the Commonwealth, its political subdivisions, the public or the regulated community. The amendments will require the Board to revise the inspection forms. There will be no additional paperwork requirements imposed on the regulated community.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on February 21, 2007, the Board submitted a copy of the notice of proposed rulemaking, published at 37 Pa.B. 1036, to IRRC and the Chairpersons of the HPLC and the SCP/PLC for review and comment.

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

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on June 25, 2008, the final-form rulemaking was approved by the HPLC. On July 23, 2008, the final-form rulemaking was deemed approved by the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on July 24, 2008, and approved the final-form rulemaking.

Additional Information

Individuals who need information about the regulations may contact Melanie Zimmerman, R.Ph., Executive Secretary, State Board of Pharmacy, P. O. Box 2649, Harrisburg, PA 17105-2649.

Findings

The Board finds that:

(1) Public notice of intention to adopt the regulations in 49 Pa. Code Chapter 27, was given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and the regulations promulgated under those sections in 1 Pa. Code §§ 7.1 and 7.2.

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

(3) This final-form rulemaking of the Board is necessary and appropriate for the administration of the act.

(4) The amendments to this final-form rulemaking do not enlarge the original purpose of the proposed amendments published at 37 Pa.B. 1036.

Order

The Board therefore orders that:

(a) The regulations of the Board, 49 Pa. Code Chapter 27, are amended by amending §§ 27.14 and 27.16 to read as set forth in Annex A.

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

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

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

MICHAEL A. PODGURSKI, R.Ph.,
Chairperson

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 38 Pa.B. 4449 (August 9, 2008).)

Fiscal Note: Fiscal Note 16A-5415 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 27. STATE BOARD OF PHARMACY

STANDARDS

§ 27.14. Supplies.

(a) A pharmacy shall maintain a supply of drugs and devices adequate to meet the needs of the health professions and the patients it is intended to serve. The applicant for a pharmacy permit shall show proof by affidavit that the applicant has ordered or possesses and shall continue to maintain an inventory of nonproprietary drugs, devices and equipment appropriate to the practice of that pharmacy. The inventory must include at least $5,000 worth of nonproprietary drugs and devices, at cost, from a licensed wholesaler or manufacturer. The inventory may not go below this figure at any time. A central processing center is not required to maintain $5,000 worth of nonproprietary drugs and devices under § 27.203(b) (relating to centralized prescription processing).

(b) Drugs which must be removed from active stock shall be removed in accordance with the following provisions:

(1) The pharmacist manager is responsible for removing from the active stock of the pharmacy and disposing of the following:

(i) A drug whose expiration date has passed.

(ii) A drug which does not meet legal standards of strength and purity.

(iii) A drug which varies from the strength and purity indicated on the label of the commercial container.

(iv) A drug which has been improperly stored.

(v) A drug which has deteriorated.

(vi) A drug which is unfit, misbranded or adulterated under Federal or State statutes.

(2) Drugs which have been removed from active stock in accordance with this subsection may not be sold or given away. The drugs shall be returned to the wholesaler or manufacturer for disposal or disposed of by the pharmacy according to Federal or State statutes or regulations.

(3) A pharmacy desiring to or required to dispose of a controlled substance shall contact the nearest DEA office for authority and instructions to dispose of the substance.

(4) The pharmacist manager shall be responsible for keeping proper records of controlled substances which have been disposed of. These records must include the name of the substance, the number of units or the volume of the substance or the number of commercial containers and the date and manner of disposal.

(c) Except for a pharmacy operating as a central processing center, a pharmacy shall maintain at least the following equipment and supplies:

(1) A refrigerator, used solely for the storage of drugs requiring refrigeration, equipped with a thermometer or a temperature monitoring device. The refrigerator shall be kept in the prescription area.

(2) Prescription files for keeping prescriptions of nonproprietary drugs in accordance with the act and, for controlled substance prescriptions, State and Federal laws and regulations. The original prescription or image of the original prescription shall be retained for 2 years from the date of the most recent filling. A pharmacy may make use of a computerized recordkeeping system for keeping track of telephone prescriptions, refills, counseling, and the like in accordance with § 27.202 (relating to computerized recordkeeping systems).

(3) Current copies of the act and this chapter.

(4) Federal and Commonwealth statutes and regulations pertaining to the practice of pharmacy.

(5) Additional equipment and supplies necessary to enable the pharmacy to properly prepare and dispense prescriptions consistent with its scope of practice.

(6) An adequate reference library which meets the following standards:

(i) Enables a pharmacy to prepare and dispense prescriptions properly, consistent with its scope of practice.

(ii) Includes reference sources appropriate to the type of pharmacy practice at that particular location. A pharmacy shall include in the pharmacy's library current material regarding the technical, clinical and professional aspects of practice with emphasis in the area in which the pharmacy specializes.

(iii) Enables the pharmacist to compound medications in a safe and effective manner consistent with accepted standards of pharmacy practice.

(iv) Lists the possible drug interactions and possible adverse effects of medications dispensed by the pharmacy.

(v) Lists the therapeutic equivalents for medications.

(vi) Lists the therapeutic usage and dosages of medications dispensed by the pharmacy.

(vii) Provides guidelines for the counseling of patients.

(viii) A pharmacy that specializes in nuclear or parenteral prescriptions may limit the library it maintains under subparagraph (ii) relating to the pharmacy's own specialization.

(ix) Maintains the latest editions including current supplements of each of its reference sources.

(d) A pharmacy operating as a central processing center shall maintain equipment, supplies and access to a reference library recognized by the pharmacy community in this Commonwealth as meeting minimum standards of practice as a central processing center.

§ 27.16. Construction and equipment requirements.

(a) *Approval of plans.* The following requirements are applicable to approval of plans:

(1) *New pharmacy or change-of-location.* Plans for construction of a new pharmacy or new location for an existing pharmacy may be submitted to the Board for approval prior to proceeding with construction. Within 90 days of receiving the plans, the Board will notify the applicant of its approval of the planned pharmacy or of its disapproval and the reasons for disapproval. The plans, including dimensions, must demonstrate compliance with applicable regulations and show the layout and fixtures for the prescription area and the immediately adjacent area.

(2) *Alterations.* The practice of pharmacy shall cease while substantial alterations in the layout or fixtures of an approved pharmacy are being made unless:

(i) The pharmacy makes the alterations and takes adequate precautions so that the health and safety of professionals, employees and the public is protected during the continuing operation of the pharmacy.

(ii) The plans for the alterations and a description of the precautions are submitted to the Board at least 30 days before the beginning of alteration work. If the Board raises no objection during that time, the pharmacy is authorized to proceed with the alterations as planned.

(b) *Building standards.* The following apply to building standards:

(1) *Minimum size.*

(i) The minimum size of the prescription area must be at least 250 square feet, and must be large enough, considering the level of activity, to carry on the practice of pharmacy in a manner that protects the health and safety of professionals, employees and the public. Within the prescription area, there must be a prescription working counter of at least 10 linear feet in length and 2 linear feet in width. If more than two pharmacists are on duty simultaneously, the minimum counter length shall be increased by 5 linear feet for an additional pharmacist. Institutions with special considerations may apply to the Board for a waiver.

(ii) A pharmacy operating as a central processing center need not conform to the minimum space requirements in subparagraph (i).

(2) *Pharmacies in retail establishments.* Pharmacies located within retail establishments whose business hours differ shall adhere to the following standards:

(i) The pharmacy can be securely sealed off from the remainder of the retail establishment.

(ii) The barrier devices which seal off the pharmacy must be capable of providing security for the pharmacy. The barrier devices must reach from floor to ceiling, shall be impenetrable by hand or the use of a reach extender, and be securely locked whenever a licensed pharmacist is not present and on duty.

(iii) The pharmacy shall be closed whenever a licensed pharmacist is not present and on duty.

(iv) Safes, electrical equipment or other facilities of the retail establishment may not be located in or approached through the pharmacy unless a pharmacist is on duty whenever staff from the retail establishment need access to these facilities.

(v) The hours of the pharmacy shall be posted at all points of public access.

(vi) Protocols for access to the pharmacy when it is closed by nonpharmacist staff for bona fide emergencies, such as fires, natural disasters or police matters, must include notification to the pharmacist manager.

(3) *Locked compartment.* Space shall be provided in the prescription area for a substantially constructed cabinet or safe to contain controlled substances unless the pharmacy disperses controlled substances throughout the stock of noncontrolled substances in a manner that obstructs the theft of controlled substances. If the pharmacy stocks Schedule I controlled substances, these substances shall be stored in a securely locked, substantially constructed cabinet or safe.

(4) *Telephone.* At least one telephone shall be accessible in the prescription area, and the telephone number must be the telephone number printed on the prescription label.

(5) *Sanitary facilities.* Except for pharmacies operating as central processing centers, pharmacies shall be equipped with a sink within the prescription area to be used solely for pharmaceutical purposes. The sink must be connected properly to supply hot and cold water. Restroom facilities for employees of the pharmacy shall be provided reasonably close to, but outside of the prescription area.

(6) *Lighting and ventilation.* The pharmacy must be well lighted and ventilated.

(7) *Television set.* A television set may not be placed within the prescription area or so situated in the pharmacy that its viewing screen may be seen when looking at it from within the prescription area.

(8) *Physical arrangement.* The prescription area must be arranged so that prescription drugs and devices are inaccessible to an unlicensed or unauthorized person. The prescription area may not be used for storage of merchandise or other items other than those used in the preparation, dispensing or delivery of drugs. Animals may not be allowed in a prescription area except for security reasons.

(9) *Existing pharmacies.* Existing pharmacies licensed by the Board prior to the effective date of this chapter may continue if they reasonably conform, or are made to reasonably conform, to the intent of this chapter. The Board will determine what constitutes reasonable conformity consonant with the public interest, health, safety and welfare.

[Pa.B. Doc. No. 08-1623. Filed for public inspection September 5, 2008, 9:00 a.m.]

Title 55—PUBLIC WELFARE

DEPARTMENT OF PUBLIC WELFARE

[55 PA. CODE CHS. 1150 AND 1243]

Clinical Laboratory Improvement Amendments

The Department of Public Welfare (Department), by this order, adopts the amendments set forth at 37 Pa.B. 1865 (April 21, 2007) under the authority of sections 201(2), 403 and 443.3 of the Public Welfare Code (62 P. S. §§ 201(2), 403 and 443.3).

Purpose of the Final-Form Rulemaking

The purpose of this final-form rulemaking is to amend current Medical Assistance (MA) regulations set forth in Chapters 1150 and 1243 (relating to MA program payment policies; and outpatient laboratory services) to be consistent with the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

Background

Under the CLIA, specifically 42 U.S.C.A. § 263a, regarding certification of laboratories, the United States Department of Health and Human Services (HHS) was required to establish certification requirements for laboratories performing tests on human specimens and to certify through the issuance of a certificate that those laboratories meet the requirements established by the HHS. Further, 42 CFR Part 493 (relating to laboratory requirements) sets forth the certification requirements and establishes uniform certification requirements for laboratories, regardless of location, size or type of testing performed. The provisions of 42 U.S.C.A. § 263a apply to laboratories that examine human specimens for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of human beings.

The provisions in 42 U.S.C.A. § 263a(f) also specify performance requirements, based on test complexity and risk factors related to erroneous test results. This section also provides requirements that ensure the quality of laboratory services and support the best interest of public health.

The purpose of the CLIA and the Federal regulations is to ensure that appropriate standards are established to ensure quality laboratory testing to improve the diagnosis of disease, management of care for treatment and assessment of the health of patients and to avoid or eliminate test errors that might result in patient harm. In addition, both 42 U.S.C.A. § 263a(b) and the Federal regulations require that laboratories have a CLIA identification number and a CLIA certificate identifying those laboratory procedures the laboratory is eligible to perform.

A State Medicaid agency may only pay for laboratory services performed by laboratories that have CLIA certification. See 42 U.S.C.A. § 1396a(a)(9)(C), regarding state plan for medical assistance, and 42 CFR 493.1809 (relating to limitation on Medicaid payment). The Department is now amending its regulations to reflect this Federal requirement.

Summary

A complete description of the amendment was published at 37 Pa.B. 1865 (April 21, 2007).

Affected Individuals and Organizations

The final-form rulemaking requires laboratories participating in the MA Program to meet CLIA certification requirements established by the HHS.

Accomplishments and Benefits

The Department's adoption of the CLIA definition of "laboratory" will include hospital and privately owned laboratories under the same definition. This final-form rulemaking will help ensure consistency across the MA Program, both for laboratory providers and for laboratory services provided to MA recipients. In addition, the final-form rulemaking will be consistent with Federal requirements for participating laboratories.

Fiscal Impact

Laboratories should already be in compliance with Federal law and regulations; therefore, there is no anticipated fiscal impact.

Paperwork Requirements

There are no additional reports, paperwork or new forms needed to comply with the final-form rulemaking.

Public Comment

Written comments, suggestions and objections regarding the proposed rulemaking were requested within a 30-day period following publication of the proposed rulemaking. No public comments were received within the 30-day time frame. The Independent Regulatory Review Commission (IRRC) did not comment on the proposed amendments.

Regulatory Review Act

Under section 5.1(a) of the Regulatory Review Act (71 P. S. § 745.5a(a)), on June 20, 2008, the Department submitted a copy of this final-form rulemaking to IRRC and to the Chairpersons of the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare (Committees). No comments were received on the proposed amendments.

In accordance with section 5.1(j.1) and (j.2) of the Regulatory Review Act, this final-form rulemaking was deemed approved by the Committees on July 22, 2008.

Under section 5(g) of the Regulatory Review Act, the final-form rulemaking was deemed approved effective July 23, 2008.

In addition to submitting the final-form rulemaking, the Department provided IRRC and the Committees with a copy of a Regulatory Analysis Form prepared by the Department. A copy of this form is available to the public upon request.

Order

The Department finds that:

(1) Public notice of intention to amend 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 promulgated there under, 1 Pa. Code §§ 7.1 and 7.2.

(2) The adoption of this final-form rulemaking in the manner provided by this order is necessary and appropriate for the administration and enforcement of the Public Welfare Code (62 P. S. §§ 101—1412).

The Department acting under sections 201(2), 403 and 443.3 of the Public Welfare Code, orders that:

(a) The regulations of the Department, 55 Pa. Code Chapters 1150 and 1243, are amended by amending §§ 1150.57, 1243.1, 1243.2, 1243.41, 1243.42, 1243.52 and 1243.54 to read as set forth in Annex A.

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

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

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

ESTELLE B. RICHMAN,
Secretary

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 38 Pa.B. 4449 (August 9, 2008).)

Fiscal Note: Fiscal Note 14-508 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 55. PUBLIC WELFARE

PART III. MEDICAL ASSISTANCE MANUAL

CHAPTER 1150. MA PROGRAM PAYMENT POLICIES

PAYMENT FOR SERVICES

§ 1150.57. Diagnostic services and radiation therapy.

(a) The fees for diagnostic radiology, nuclear medicine, radiation therapy, pathology and medical diagnostic procedures are comprised of a total fee, which is divided into a professional component fee and a technical component fee.

(b) The technical component of any diagnostic services provided on an inpatient basis will be included in the hospitals' payment for inpatient services. No other payment will be made for the total component or technical component for inpatient services.

(c) Physicians may bill for a visit in addition to the professional component if an appropriate medical care visit is provided. However, a visit to a practitioner's office or the outpatient department of a hospital solely for the purpose of receiving a diagnostic service or radiation therapy does not qualify for payment for a visit and the diagnostic service or radiation therapy. In this kind of situation, payment is made only for the diagnostic service or radiation therapy.

(d) A practitioner may bill for laboratory services performed in the office only if the practitioner is licensed by the Department of Health and enrolled in the MA Program as a laboratory.

(e) A practitioner may bill for medical diagnostic, surgical diagnostic, diagnostic radiology, nuclear medicine and radiation therapy in addition to:

(1) A surgical procedure.

(2) A medical care visit if the situation described in subsection (c) does not occur.

CHAPTER 1243. OUTPATIENT LABORATORY SERVICES

§ 1243.1. Policy.

The MA Program provides payment for specific outpatient laboratory services rendered to eligible recipients by laboratories enrolled as providers under the Program. Payment for outpatient laboratory services is subject to this chapter and Chapters 1101 and 1150 (relating to general provisions; and MA Program payment policies) and the MA Program fee schedule.

§ 1243.2. Definitions.

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

CLIA—The Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C.A. § 263a).

Laboratory—A facility for the biological, microbiological, serological, chemical, immunohema-tological, hematological, biophysical, cytological, pathological or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens, or both, or only serving as a mailing service and not performing testing are not considered laboratories.

Panel test—A series of diagnostically related laboratory tests ordered by a practitioner to confirm a presumptive diagnosis.

PROVIDER PARTICIPATION

§ 1243.41. Participation requirements.

In addition to the participation requirements established in Chapter 1101 (relating to general provisions) laboratories shall meet the following requirements:

(1) Each laboratory, whether in or out-of-State, shall submit the following to the Department:

(i) A copy of its CLIA certificate.

(ii) A copy of its CLIA identification number.

(iii) A list of diagnostic procedures that the laboratory is CLIA-certified to perform with the corresponding Healthcare Common Procedure Coding System (HCPCS) codes.

(iv) The fee currently charged to the general public for each of the procedures.

(2) For hospital laboratories, the hospital shall be currently Medicare certified or currently certified by the Department of Health as meeting standards comparable to those of Medicare.

(3) A laboratory shall be currently licensed by the Department of Health, Bureau of Laboratories and be Medicare certified under Title XVIII (42 U.S.C.A. §§ 1395—1395hhh), or certified as meeting standards comparable to those of Medicare.

(4) Out-of-State laboratories shall meet the applicable requirements established in paragraphs (1) and (2) and shall sign the provider agreement designated by the Department.

§ 1243.42. Ongoing responsibilities of providers.

In addition to the ongoing responsibilities established in § 1101.51(a)—(e) (relating to ongoing responsibilities of providers), laboratories shall, as a condition of participation, comply with the following requirements:

(1) Promptly report to the Department changes in the laboratory's CLIA certification, including changes in the type of CLIA certificate, changes in laboratory fees or procedures and the effective date of these changes.

(2) Permit authorized State and Federal officials or their authorized agents to conduct onsite reviews for the purpose of verification of information furnished as a basis for payment under the MA Program. During the course of the review, the reviewers shall be allowed access to the laboratory area. The provider shall also allow reviewers access to laboratory procedure manuals and any records or documents necessary to determine whether payment for services that have or are being provided comply with Federal and State laws and regulations. The reviewers shall be allowed to photograph, photocopy or duplicate the manuals, records, and documents. Onsite reviews shall be conducted during the normal hours of operation or at another time mutually agreeable to the officials and the provider.

(3) Laboratories shall avoid locked-in referral arrangements between themselves and a prescriber.

PAYMENT FOR OUTPATIENT LABORATORY SERVICES

§ 1243.52. Payment conditions for various services.

(a) If a laboratory refers work to another laboratory, payment will be made to either the referring laboratory or the laboratory actually performing the test. Payment will be made only if the laboratory billing the Department is currently participating in the MA Program and has listed the diagnostic procedure being billed with the Department as specified in § 1243.41(1) (relating to participation requirements).

(b) Laboratory procedures billed to the Department will be based on a written request of the practitioner. The written request must include the following:

(1) The name of the practitioner, the Medical Assistance Identification (M.A.I.D.) number of the practitioner or the DEA number of the practitioner.

(2) The name of the recipient.

(3) The case number of the recipient.

(4) The date of the request.

(5) The handwritten signature of the practitioner or the designee of the practitioner.

(c) Preadmission laboratory tests performed by a hospital laboratory shall be included in the inpatient billing of the hospital. If the recipient is not admitted for some reason, the preadmission laboratory tests shall be billed as an outpatient claim.

§ 1243.54. Noncompensable services.

Payment will not be made to a laboratory for the following services regardless of where or to whom they are provided:

(1) Procedures not listed in the fee schedule in the MA Program fees schedule.

(2) Travel to a recipient's place of residence to collect a specimen. The provider will be reimbursed for performing the procedure if it is compensable; however, no extra payment will be made for mileage.

(3) Procedures that the laboratory is not CLIA-certified to perform.

[Pa.B. Doc. No. 08-1624. Filed for public inspection September 5, 2008, 9:00 a.m.]

Title 58—RECREATION

FISH AND BOAT COMMISSION

[58 PA. CODE CH. 63]

Fishing

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

A. *Effective Date*

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

B. *Contact Person*

For further information on the final-form rulemaking, contact Jason E. Oyler, Esq., P. O. Box 67000, Harrisburg, PA 17106-7000, (717) 705-7810. This final-form rulemaking is available on the Commission's web site at www.fish.state.pa.us.

C. *Statutory Authority*

The amendment of § 63.8 (relating to long bows, crossbows, spears and gigs) was published under the statutory authority of section 2102(b) of the code (relating to rules and regulations).

D. *Purpose and Background*

The final-form rulemaking is designed to improve, enhance and update the Commission's fishing regulations. The specific purpose of the amendment is described in more detail under the summary of changes.

E. *Summary of Changes*

Currently, § 63.8(a) allows the use of long bows and arrows, including compound bows, crossbows, spears and gigs to take carp and suckers in Commonwealth waters and waters bounding and adjacent thereto. Under § 63.8(b), catfish may also be harvested by these gear in the Delaware River. A number of anglers recently have expressed to Commission staff a desire to be permitted to harvest catfish with these gear in all Commonwealth waters. This method of angling is not anticipated to result in any significant population level impacts to catfish, as the angler use levels are likely to be relatively low throughout this Commonwealth.

Currently, under § 63.8(b)(1), the harvest of herring is permitted in the Delaware River. Considering the current declines in river herring populations along the entire Atlantic coast, the Commission proposed that the harvest of these species by longbows, crossbows, spears and gigs be no longer be permitted. Finally, § 63.8(b)(2) restricts the use of use long bows and arrows, including compound bows, crossbows, spears or gigs to take fish within 275 yards of an eel weir. This is an archaic regulation that the Commission proposed be removed.

The Commission adopted the amendments as set forth in the notice of proposed rulemaking.

F. *Paperwork*

The final-form rulemaking will not increase paperwork and will not create new paperwork requirements.

G. *Fiscal Impact*

The final-form rulemaking will have no adverse fiscal impact on the Commonwealth or its political subdivisions.

The final-form rulemaking will impose no new costs on the private sector or the general public.

H. *Public Involvement*

A notice of proposed rulemaking was published at 38 Pa.B. 3241 (June 14, 2008). Prior to the official comment period, the Commission received nine public comments concerning this proposal. All nine supported it. During the formal public comment period, the Commission received 12 public comments. Eleven supported the proposal and one opposed allowing the use of weapons like bows and arrows for the taking of catfish except where they occur in nuisance numbers. Copies of all public comments were provided to the Commissioners.

Findings

The Commission finds that:

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

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

(3) The adoption of the amendment 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 63, are amended by amending § 63.8 to read as set forth in 38 Pa.B. 3241.

(b) The Executive Director will submit this order and 38 Pa.B. 3241 to the Office of Attorney General for approval as to legality as required by law.

(c) The Executive Director shall certify this order and 38 Pa.B. 3241 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*.

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

Fiscal Note: Fiscal Note 48A-203 remains valid for the final adoption of the subject regulation.

[Pa.B. Doc. No. 08-1625. Filed for public inspection September 5, 2008, 9:00 a.m.]