PROPOSED RULEMAKING

DEPARTMENT OF PUBLIC WELFARE

[55 PA. CODE CHS. 1150 AND 1243]

Clinical Laboratory Improvement Amendments

The Department of Public Welfare (Department), 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), proposes to amend Chapters 1150 and 1243 (relating to MA Program payment policies; and outpatient laboratory services) to read as set forth in Annex A.

Purpose of Proposed Rulemaking

The proposed amendments to Chapters 1150 and 1243 amend current Medical Assistance (MA) regulations 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 establish uniform certification requirements for laboratories, regardless of location, size or type of testing performed. Section 263a of the U.S.C.A. applies 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 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.

Requirements

Under existing MA regulation, the Department limited MA payment to hospital and independent laboratories enrolled in the MA Program. The Department will adopt the CLIA definition of "laboratory" and include hospital laboratories and privately owned laboratories under the same definition, thus the term "independent laboratory" is obsolete.

The Department proposes to amend the following sections to be consistent with the CLIA:

Section 1150.57(d) (relating to diagnostic services and radiation therapy) by deleting the reference to an independent laboratory.

Section 1243.1 (relating to policy) by deleting the reference to independent laboratories.

Section 1243.2 (relating to definitions) by deleting the definition of "independent laboratory" and by adding the definitions of "CLIA" and "laboratory."

Sections 1243.41(1), (3) and (4), 1243.42(1) and (3), 1243.52(a) and 1243.54(3) are amended to incorporate CLIA requirements and definitions.

Individuals and Organizations

The proposed 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 amendment will help ensure consistency across the MA Program, both for laboratory providers and for laboratory services provided to MA recipients. In addition, the amendments 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 proposed rulemaking.

Effective Date

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

Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed rulemaking to the Department of Public Welfare, Office of Medical Assistance Programs, Attention: Regulations Coordinator, c/o Deputy Secretary's Office, Room 515, Health and Welfare Building, Harrisburg, PA 17120 within 30 calendar days after publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Reference Regulation No. 14-508 when submitting comments.

Persons with a disability who require an auxiliary aid or service may submit comments by using the AT&T Relay Service, (800) 654-5984 (TDD users) or (800) 654-5988 (voice users).

Regulatory Review Act

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on April 11, 2007, the Department submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairper-

sons of the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare. A copy of this material is available to the public upon request.

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

ESTELLE B. RICHMAN,
Secretary

Fiscal Note: 14-508. No fiscal impact; (8) recommends adoption.

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.

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(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 **[an independent] a** laboratory.

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CHAPTER 1243. OUTPATIENT LABORATORY SERVICES

§ 1243.1. Policy.

The MA Program provides payment for specific outpatient laboratory services rendered to eligible recipients by **[hospital and independent]** laboratories enrolled as providers under the **[program] 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).**

[*Independent laboratory*—A laboratory that is licensed by the Department of Health and which is not affiliated with the medical practitioners it serves.]

***Laboratory*—A facility for the biological, microbiological, serological, chemical, immunohematological, 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.**

* * * * *

PROVIDER PARTICIPATION

§ 1243.41. Participation requirements.

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

* * * * *

(1) **[Hospital and independent laboratories whether in or out-of-State shall, at the time of enrollment, submit to the Bureau of Provider Relations, a list of the diagnostic procedures that are Medicare approved to perform and the fee currently charged to the general public for each of the procedures. Each procedure shall be identified in accordance with the Uniform Procedure Terminology (UPT) Code used by Medicare and Pennsylvania Blue Shield.] 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.

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(3) **[Independent laboratories] A laboratory** shall be currently licensed by the Department of Health, **[Division] Bureau** of Laboratories and be Medicare certified under Title XVIII, or certified as meeting standards comparable to those of Medicare.

(4) Out-of-State **[hospital and independent]** laboratories shall meet the applicable requirements established in paragraphs (1) and (2) and shall sign the **[outpatient]** 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 **[changes in laboratory fees or procedures and the dates the changes became effective to the Bureau of Provider Relations] 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.**

* * * * *

(3) **[Independent laboratories] 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 **[Bureau of Provider Relations] Department** as specified in § 1243.41(1) (relating to participation requirements).

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§ 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:

* * * * *

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

[Pa.B. Doc. No. 07-683. Filed for public inspection April 20, 2007, 9:00 a.m.]

STATE BOARD OF FUNERAL DIRECTORS

[49 PA. CODE CH. 13]

Forms Review

The State Board of Funeral Directors (Board) proposes to amend §§ 13.204 and 13.224 (relating to written agreement; and funding and reporting of prepaid burial contracts) to read as set forth in Annex A.

Effective Date

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

Statutory Authority

The proposed rulemaking is authorized under section 16(a) of the Funeral Director Law (act) (63 P. S. § 479.16(a)).

Background, Need and Description of the Proposed Amendment

Currently, §§ 13.204 and 13.224 set forth requirements for contracts typically used by licensees in providing, or agreeing to provide, funeral goods and services. Under § 13.204(a), a licensee shall use a form agreement or statement of funeral goods and services that has been reviewed and approved by the Board. Likewise, § 13.224(f) requires a licensee to use a form prepaid burial contract or preneed contract form that has been reviewed and approved by the Board. However, the existing provisions do not state the basis upon which the Board may disapprove a form submitted to it.

In implementing the existing sections, the Board has refused to approve form contracts or agreements that include a term prohibited by the act or Board regulations, or form contracts or agreements that do not include a term required by the act or Board regulations. However, in the absence of express language in its regulations, the Board has not disapproved a form that includes a contractual provision the enforcement of which would lead to a violation of a provision of the act or Board regulations.

Under the proposed amendments to §§ 13.204 and 13.224, the Board would have authority to refuse to approve a form that does not comply with the act or the regulations or if the enforcement of any terms of the form would result in a violation of the act or Board regulations.

The Board solicited input from and provided an exposure draft of this proposed rulemaking to funeral directors and organizations. In addition, the Board considered the impact the proposed amendments would have on the regulated community and on public health, safety and welfare. The Board finds that the proposed amendments address a compelling public interest as described in this preamble.

Fiscal Impact and Paperwork Requirements

The proposed rulemaking will have no adverse fiscal impact on the Commonwealth or its political subdivisions. The proposed rulemaking will impose no additional paperwork requirement upon the Commonwealth, political subdivisions or the private sector.

Sunset Date

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

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on April 11, 2007, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee. A copy of this material is available to the public upon request.

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

Public Comment

Interested persons are invited to submit written comments, recommendations or objections regarding this proposed rulemaking to Michelle T. Smey, Administrator, State Board of Funeral Directors, P. O. Box 2649, Harrisburg, PA 17105-2649 within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Reference No. 16A-4813 (Forms Review) when submitting comments.

ANTHONY SCARANTINO,
Chairperson

Fiscal Note: 16A-4813. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 13. STATE BOARD OF FUNERAL DIRECTORS

STANDARDS OF PRACTICE AND CONDUCT

§ 13.204. Written agreement.

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(h) The Board will not approve a form statement of funeral goods and services that does not comply with the act or this chapter, or the enforcement of any term of which would result in the violation of the act or this chapter.

PREPAID BURIAL CONTRACTS

§ 13.224. Funding and reporting of prepaid burial contracts.

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(f) **[Prepaid] Form prepaid** burial contracts or **form** preneed contracts to be used by a funeral director shall be reviewed and approved by the Board and should reflect whether or not an additional service fee or arrangement fee is charged. **[Prepaid] Form prepared** burial contracts or **form** preneed contracts used by a funeral director may not incorporate a contract for funeral merchandise entered into by a person or entity other than a funeral director. **The Board will not approve a form prepaid burial contract or preneed contract that does not comply with the act or this chapter, or the enforcement of any term of which would result in the violation of the act or this chapter**.

[Pa.B. Doc. No. 07-684. Filed for public inspection April 20, 2007, 9:00 a.m.]

[49 PA. CODE CH. 13]

Renewal Fee

The State Board of Funeral Directors (Board) proposes to amend § 13.12 (relating to fees) to read as set forth in Annex A. The proposed rulemaking will raise the biennial renewal fee for licensed funeral directors and funeral establishments from $185 to $325.

Effective Date

The proposed rulemaking will be effective upon final-form publication in the *Pennsylvania Bulletin*. The increase in the biennial renewal fee will go into effect beginning with renewal for the February 1, 2008, through January 31, 2010, biennial renewal period.

Statutory Authority

This proposed rulemaking is authorized by section 18.1 of the Funeral Director Law (act) (63 P. S. § 479.18.1).

Background and Need for the Amendment

Section 18.1(a) of the act requires the Board to fix the fees for renewal of licenses by regulation and if the revenue generated by fees, fines and civil penalties is not sufficient to match expenditures over a 2-year period, the Board is required to increase those fees by regulation. Section 18.1(b) of the act requires the Board to increase fees when revenue raised by fees, fines and civil penalties are not sufficient to meet expenditures.

The Board's current biennial license renewal fee was established by regulation and took effect for the 2004-2006 biennial renewal period, the only increase since 1992. The Board raises virtually all its revenue through fees. The biennial license renewal fee is the most substantial revenue-generating fee of the fees charged by the Board.

At the Board's meeting on June 7, 2006, the Department of State's Revenue and Budget Offices presented a summary of the Board's actual revenues and expenses for Fiscal Year (FY) 2004-05 and projected revenues and expenses for FY 2005-06 through FY 2016-17. At the end of FY 2004-05, the Board had a deficit of $99,582. The Budget Office projects that, without an increase in the renewal fee, deficits will continue to grow, with an anticipated deficit of $684,119 at the end of FY 2008-09, an anticipated deficit of $1,212,119 at the end of FY 2010-11 and an anticipated deficit of $4,037,119 by the end of FY 2016-17.

For the Board's consideration, the Budget Office presented summaries for various increases in the renewal fee beginning with the 2008-10 renewal period. If the renewal fee were increased to $230, an increase of approximately 25%, the Budget Office projected continued deficits. Specifically, the Board would experience a deficit of $374,009 at the end of FY 2008-09, a deficit of $591,899 at the end of FY 2010-11 and a deficit of $1,002,789 at the end of FY 2012-13. The deficits would continue to grow to $2,486,569 at the end of FY 2016-17. Similarly, if the renewal fee were increased to $280, an increase of approximately 50%, the Budget Office projected a deficit of $46,159 at the end of FY 2008-09, a surplus of $63,801 at the end of FY 2010-11 and a deficit of $19,239 at the end of FY 2012-13. The deficits would continue to grow to $847,319 at the end of FY 2016-17.

If, however, the renewal fee were increased to $325, an increase of approximately 75%, the Budget Office projected a surplus of $249,906 at the end of FY 2008-09, a surplus of $653,931 at the end of FY 2010-11 and a surplus of $865,956 at the end of FY 2012-13. The surplus would then continually decrease to $628,006 at the end of FY 2016-17. If the renewal fee were increased to $370, an increase of approximately 100%, the Budget Office projected a surplus of $543,971 at the end of FY 2008-09 and a surplus of $1,244,061 at the end of FY 2010-11. The surplus would then continually increase to $2,103,331 at the end of FY 2016-17. After considering each of these options, the Board elected to increase the biennial renewal fee to $325, as the least restrictive means of eliminating the projected deficits and restoring the Board's fiscal integrity as required by section 18.1 of the act.

Description of the Proposed Amendments

Section 13.12 (relating to fees) will be amended to increase the biennial renewal fee from $185 to $325.

Fiscal Impact and Paperwork Requirements

The proposed rulemaking will increase the biennial renewal fee for funeral directors and funeral establishments in this Commonwealth, but, otherwise, should have no adverse fiscal impact on the Commonwealth, its political subdivisions or the private sector. The proposed

rulemaking will impose no additional paperwork requirements upon the Commonwealth, its political subdivisions or the private sector.

Sunset Date

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

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on April 11, 2007, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee. A copy of this material is available to the public upon request.

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

Public Comment

Interested persons are invited to submit written comments, recommendations or objections regarding this proposed rulemaking to Michelle T. Smey, Board Administrator, State Board of Funeral Directors, P. O. Box 2649, Harrisburg, PA 17105-2649 within 30 days of publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Reference No. 16A-4817 (Renewal Fee) when submitting comments.

ANTHONY SCARANTINO,
Chairperson

Fiscal Note: 16A-4817. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 13. STATE BOARD OF FUNERAL DIRECTORS

LICENSURE

§ 13.12. Fees.

Following is the schedule of fees charged by the Board:

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Biennial renewal ..... $**[185] 325**

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[Pa.B. Doc. No. 07-685. Filed for public inspection April 20, 2007, 9:00 a.m.]