Regulatory Analysis Form

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(1) Agency	This space for use by IRRC
Department of Public Welfare	2008 JUN 20 PM 2: 24 INDEPENDENT REGULATORY REVIEW COMMISSION
(2) I.D. Number (Governor's Office Use) 14-508	IRRC Number: #2606

(3) Short Title

Clinical Laboratory Improvement Amendments (CLIA)

(4) PA Code Cite	(5) Agency Contacts & Telephone Numbers
55 Pa.Code Chapters 1150 and 1243	Primary Contact: Dawn Poppenwimer 772-6341 Secondary Contact: Leesa Allen 772-6341

(6) Type of Rule Making (Check One)	(7) Is a 120-Day Emergency Certification Attached?
___ Proposed Rule Making _X_ Final Order Adopting Regulation ____ Final Order, Proposed Rule Making Omitted	_x_ No ____ Yes: By the Attorney General ____ Yes: By the Governor

8) Briefly explain the regulation in clear and nontechnical language.

The purpose of this final-form rulemaking is to amend 55 Pa.Code Chapters 1150 and 1243 to be consistent with the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

The Department of Public Welfare (Department) amends these regulations pursuant to the authority of Sections 201(2) 403 and 443.3 of the Public Welfare Code, act of June 13, 1967 (P.L. 31. No. 21) (62 P.S. §§ 201(2), 403 and 443.3).

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

Yes. Under the Social Security Act 42 U.S.C.A. § 1396a(a)(9)(C) (relating to the state plan for medical assistance), the Department may only make Medical Assistance (MA) payments to laboratories with certification as required by the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C.A. § 263a (relating to certification of laboratories).

Regulatory Analysis Form

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

Federal law on laboratory certification 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 and specifies the performance requirements that apply to laboratories that are subject to CLIA regulations, and assures uniform access to and standards for laboratories. Federal law also prohibits Medicaid payments to those laboratories that do not have CLIA certification. In order to be consistent with Federal requirements and to ensure that MA recipients receive services from laboratories that are certified as meeting quality and performance standards established under CLIA, the Department is amending its regulations relating to laboratory services.

(12) State the public health, safety, environmental or general welfare risks associated with non-regulation.

Federal law and regulations establish quality controls and performance standards in order to ensure the reliability of laboratory test results. Since those results are relied upon by physicians in the diagnosis, prevention or treatment of disease in their patients, unreliable results could result in inaccurate and ineffective treatment of patients. The Department is amending its regulations in order to comply with these Federal requirements and to ensure laboratories providing services to MA recipients meet the standards set forth by the Federal government.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

All providers of health care services will benefit, as will their patients, by being assured of high quality, accurate laboratory testing.

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

No one will be adversely affected by these regulations.

Regulatory Analysis Form

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

Federal law requires all laboratories to have a CLIA certificate; therefore the regulations are being amended to reflect this Federal requirement. All laboratories will be required to comply with these regulations.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

These regulations were submitted to the Medical Assistance Advisory Committee for review. No comments on the regulations were received.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.

All laboratories should already be in compliance with the Federal law and regulations; therefore, there is no fiscal impact.

Regulatory Analysis Form

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

There is no cost or savings to local governments associated with CLIA compliance.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required.

All laboratories should already be in compliance with CLIA requirements; therefore there is no fiscal impact.

Linda D Lee Henry 2-28-08

Regulatory Analysis Form

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:						
Regulated Community						
Local Government						
State Government	$0	$0	$0	$0	$0	$0
Total Savings	$0	$0	$0	$0	$0	$0
COSTS:						
Regulated Community						
Local Government						
State Government	$0	$0	$0	$0	$0	$0
Total Costs	$0	$0	$0	$0	$0	$0
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses	$0	$0	$0	$0	$0	$0

(20a) Explain how the cost estimates listed above were derived.

The amendments are necessary to bring the Medical Assistance regulations into compliance with CLIA. Since all laboratories should already be in compliance with Federal law and regulations, there is no anticipated fiscal impact.

Regulatory Analysis Form

(20b) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY-0405	FY-0506	FY-0607	FY-0708
MA-Outpatient	$842,991	$945,950	$671,472	$593,992

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

These amended regulations will have no budget impact; however, the amended regulations will bring State regulations in line with Federal requirements.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

Non-regulatory alternatives were not considered. The requirement for compliance with CLIA is mandated by Federal law and regulations.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

No alternative regulatory schemes were considered because compliance with Federal law is mandatory.

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(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

No, there are no provisions that are more stringent than the Federal standards.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

Federal law and regulations apply to all states, except those with already existing laboratory requirements which equal or exceed the CLIA requirements. Therefore, Pennsylvania is not at a competitive disadvantage.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

No, the regulation will not affect existing or proposed regulations.

Regulatory Analysis Form

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

No public hearings are planned.

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

No, there are no additional reports, paperwork or new forms.

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

Not applicable.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The regulation will be effective upon publication as final rulemaking.

(31) Provide the schedule for continual review of the regulation.

The Department will evaluate the effectiveness of this regulation on an ongoing basis.

CDL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

#2606

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INDEPENDENT REGULATORY
REVIEW COMMISSION

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General

BY: _____
(Deputy Attorney General)

_____
Date of Approval

☐ Check if applicable
Copy not approved.
Objections Attached.

Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:

Department of Public Welfare
(Agency)

LEGAL COUNSEL: Gillei Cohen

DOCUMENT/FISCAL NOTE NO. 14-508

DATE OF ADOPTION: _____

BY: Estelle B. Richman

TITLE: Secretary of Public Welfare
(Executive Officer, Chairman or Secretary)

Copy below is hereby approved as to form and legality. Executive or Independent Agencies.

BY: _____
Andrew C. Clark

JUN 10 2008
Date of Approval

(Deputy General Counsel)
(~~Chief Counsel, Independent Agency~~)
(Strike inapplicable title)

☐ Check if applicable. No Attorney General approval or objection within 30 days after submission.

NOTICE OF FINAL-FORM RULEMAKING

DEPARTMENT OF PUBLIC WELFARE

OFFICE OF MEDICAL ASSISTANCE PROGRAMS

[55 Pa.Code Chapter 1150 MA Program Payment Policies]
[55 Pa.Code Chapter 1243 Outpatient Laboratory Services]

Clinical Laboratory Improvement Amendments (CLIA)

The Department of Public Welfare (Department), by this order, adopts the amendment 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).

Notice of proposed rulemaking was published at 37 Pa.B. 1865.

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 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. 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 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 in the Pennsylvania Bulletin on 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 timeframe. IRRC did not comment on the proposed regulation.

Regulatory Review Act

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

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 _____. The IRRC met on _____and approved the final-form rulemaking.

In addition to submitting the final-form rulemaking, the Department provided the IRRC and 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:

(a) Public notice of intention to amend the administrative regulation by this order has been given pursuant to 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.

(b) 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 pursuant to sections 201(2), 403 and 443.3 of the Public Welfare Code orders that:

(a) The regulation of the Department, 55 Pa.Code Chapters 1150 and 1243 are amended to read as set forth at 37 Pa.B. 1865 (April 21, 2007).

(b) The Secretary of the Department shall submit this Order and 37 Pa.B. 1865 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 37 Pa.B. 1865 with the Legislative Reference Bureau as required by law.

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

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.

* * * * *

(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.

* * * * *

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, 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.

* * * * *

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.

* * * * *

(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).

* * * * *

§ 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.

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	14-508
SUBJECT:	CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)
AGENCY:	DEPARTMENT OF PUBLIC WELFARE

TYPE OF REGULATION

Proposed Regulation

X Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

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FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
X 6/20/08		HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
6/20/08		MAJORITY CHAIRMAN Hon Frank L Oliver
X 6/20/08		SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
X 6/20/08		MAJORITY CHAIRMAN Hon Edwin B. Erickson
6/20/08		INDEPENDENT REGULATORY REVIEW COMMISSION
		~~ATTORNEY GENERAL (for Final Omitted only)~~
		~~LEGISLATIVE REFERENCE BUREAU (for Proposed only)~~

June 11, 2008