Regulatory Analysis Form

(1) Agency	This space for use by IRRC
Department of Public Welfare	
(2) I.D. Number (Governor's Office Use) 14-508	IRRC Number: 2606.

RECEIVED
2007 APR 11 AM 11: 49
INDEPENDENT REGULATORY REVIEW COMMISSION

(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: Donald Yearsley 772-6147

(6) Type of Rule Making (Check One)	(7) Is a 120-Day Emergency Certification Attached?
_x_ Proposed Rule Making _____ 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 amendment is to amend 55 Pa.Code Chapters 1150 and 1243 to be consistent with Federal law and regulations concerning certification of laboratories.

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

The Department amends these regulations pursuant to the authority of Sections 201(2), 403 and 443.3of 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), 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 health of human beings and specify the performance requirements that apply to laboratories that are subject to CLIA regulations, and assure 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 establishes quality controls and performance standards in order to promote 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 Medical Assistance 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 proposed regulations are being amended to reflect this Federal requirement. All laboratories will be required to comply with this regulation.

(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 Federal law and regulations; therefore, there is no anticipated 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 the CLIA requirements; therefore, there is no anticipated fiscal impact.

Linda D. LeMay 5-23-06

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.

(Dollar Amounts In Thousands)

	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						
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 estimates listed above were derived.

The proposed amendments are necessary to bring the Medical Assistance regulations into compliance with the Federal Clinical Laboratory Improvement Amendments (CLIA). Since the Federal CLIA regulations have been in place since 1992, all laboratories should already be in compliance with the CLIA requirements; therefore, there is no anticipated fiscal impact.

Linda D Lucky 1-10-07

Regulatory Analysis Form

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

Program	FY 02-03	FY 03-04	FY 04-05	FY 05-06
MA-Outpatient	$516,832	$677,979	$842,991	$945,950

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

This proposed regulation will have no budget impact; however, the proposed regulation will bring State regulations in line with Federal requirements.

*Includes the total of State and other funds.

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

Nonregulatory 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.
Respond in complete sentences.

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

Regulatory Analysis Form

(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 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)

RECEIVED
2007 APR 11 AM 11: 49
INDEPENDENT REGULATORY REVIEW COMMISSION

DO NOT WRITE IN THIS SPACE 2606

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

BY: _____
(Deputy Attorney General)

APR 04 2007
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: _____

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

MAR 13 2007
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 PROPOSED 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)

Statutory Authority

The Department of Public Welfare (Department), under 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), intends to amend the regulation as set forth in Annex A to this notice.

Purpose of Regulation

These proposed amendments to 55 Pa.Code Chapter 1150 (relating to MA Program Payment Policies) and Chapter 1243 (relating to outpatient laboratory services) amend current Medical Assistance (MA) regulations in order to be consistent with Clinical Laboratory Improvement Amendments (CLIA) requirements.

Background

Under CLIA, the United States Department of Health and Human Services (HHS) was required to establish certification requirements for any laboratory performing tests on human specimens and to certify through the issuance of a certificate that those laboratories meet the requirements established by HHS (42 U.S.C.A. § 263a) (relating to certification of laboratories). Further, Federal regulations set forth the certification requirements and establish uniform certification requirements for laboratories, regardless of location, size or type of testing performed (42 CFR Part 493) (relating to

laboratory requirements). The Federal law applies to all 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 (42 U.S.C.A. § 263a).

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

The purpose of 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 CLIA and the Federal regulations require that all laboratories have a CLIA identification number and a CLIA certificate identifying those laboratory procedures the laboratory is eligible to perform (42 U.S.C.A. § 263a(b)).

A State Medicaid agency may only pay for those laboratory services performed by laboratories that have CLIA certification (42 U.S.C.A. § 1396a(a)(9)(C) (relating to state plan for medical assistance); 42 CFR § 493.1809) (relating to limitations on Medicaid payments). 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 a laboratory, and include all hospital laboratories and privately owned laboratories under the same definition, thus obsoleting the term "independent laboratory".

The Department proposes to amend the following sections of 55 Pa.Code to be consistent with the requirements of CLIA:

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

2. Section 1243.1 (relating to policy) deletes the reference to independent laboratories.

3. Section 1243.2 (relating to definitions) deletes the definition of independent laboratory and adds the definitions of CLIA and laboratory.

4. 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 all laboratories participating in the MA Program to meet CLIA certification requirements established by HHS.

Accomplishments and Benefits

The Department's adoption of the CLIA definition of a laboratory will include all 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 amendment will be consistent with federal requirements for participating laboratories.

Fiscal Impact

All 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 regulation will be effective upon publication as final rulemaking in the Pennsylvania Bulletin.

Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed rulemaking to the Department at the following address: 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, Pennsylvania 17120, within 30 calendar days after the date of 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 at 1-800-654-5984 (TDD users) or 1-800-654-5988 (voice users).

Regulatory Review Act

Under § 5(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)), on APR 11 2007 the Department submitted a copy of this proposed 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. In addition to submitting the proposed rulemaking, the Department has provided the 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.

Under § 5(g) of the Regulatory Review Act, if the IRRC has any comments, recommendations or objections to any portion of the proposed regulation, it may notify the Department and the Committees within 30 days after the close of the public comment period. Such notification shall specify the regulatory review criteria that have not been met. The Regulatory Review Act specifies detailed procedures for review by the Department, the General Assembly and the Governor, of any comments, recommendations or objections raised, prior to final publication of the regulation.

ANNEX A

TITLE 55. PUBLIC WELFARE

PART III. MEDICAL ASSISTANCE MANUAL

CHAPTER 1150. MA PROGRAM PAYMENT POLICIES

* * * * *

§ 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. 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. Definition

* * * * *

CLIA – 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.

* * * * *

(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] A [laboratories] 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.

* * * * *

§ 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

X Proposed Regulation

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

RECEIVED
2007 APR 11 AM 11: 49
INDEPENDENT REGULATORY REVIEW COMMISSION

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
X 4/11/07	Kara Sheaffer	HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
4/11/07	Jess Hunsinger	
4-11-07	Carolyn Latsha	SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
4/11	Lawrence Carter	
4/11/07	Kathy Cooper	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
4/11/07	C. Lee Brown	LEGISLATIVE REFERENCE BUREAU (for Proposed only)

April 5, 2007