Pathology: An Overview of Enrollment and Proficiency Testing Requirements

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This section includes information about Medi-Cal enrollment and proficiency requirements for laboratories and pathologists.

Clinical Laboratory Improvement Amendments (CLIA) Certification & Billing for Pathology

All Medi-Cal providers billing for laboratory services must have a current Clinical Laboratory Improvement Amendments (CLIA) & certificate and must be enrolled and participate in required proficiency testing to be reimbursed. With the exception of those tests that are excluded from CLIA edits as defined by the Centers for Medicare & Medicaid Services (CMS).

CLIA requires all facilities that perform even one test, including waived tests, on "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," to meet certain federal requirements. If a facility performs tests for these purposes, it is considered a laboratory under CLIA and must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed.

Medi-Cal providers with a CLIA Certificate of Waiver or Provider Performed Microscopy Certificate must obtain a Certificate of California Clinical Laboratory Registration from the California Department of Public Health (CDPH), Laboratory Field Services (LFS). Additional information and instructions may be found at the following Web site:
www.cdph.ca.gov/programs/lfs/Documents/F-Registration-Instructions.pdf

Medi-Cal providers with a CLIA Certificate of Compliance or Accreditation must obtain a California Clinical Laboratory License from the CDPH, Laboratory Field Services. Additional information and instructions may be found at the following Web site:
www.cdph.ca.gov/programs/lfs/Documents/F-Lic-Application-Instructions.pdf

All types of Certificates are effective for two years, and include:

Certificate of Waiver

- Issued to a laboratory that performs only waived tests as listed in the *Code of Federal Regulations*, Title 42, Part 493.15.
- Waived tests are those tests that have been determined to be so simple that if performed incorrectly will pose no risk of harm.
- The laboratory must comply with CLIA registration and certificate requirements and follow the manufacturer's instructions for test performance.

Certificate of Provider Performed Microscopy (PPM) Procedures

- Issued to a laboratory in which a physician, midlevel practitioner or dentist performs specific microscopy procedures during the course of a patient's visit.
- A limited list of microscopy procedures is included under this certificate type and these are categorized as moderate complexity.

Certificate of Registration

- Issued to laboratory to allow the laboratory to conduct non-waived (moderate and/or high complexity) testing until the laboratory is surveyed (inspected) to determine its compliance with the CLIA regulations.
- Only laboratories applying for a certificate of compliance or a certificate of accreditation will receive a certificate of registration.
- Laboratories must provide CMS with proof of accreditation by an approved accreditation program within 11 months of issuance of the Certificate of Registration.

Certificate of Compliance

- Issued to a laboratory once the State Department of Public Health conducts a survey (inspection) and determines that the laboratory is compliant with all applicable CLIA requirements.
- This type of certificate is issued to a laboratory that performs non-waived (moderate and/or high complexity) testing.

Note: The above information can also be found in the *Pathology: Billing and Modifiers* section of this manual.

Laboratory Proficiency Testing Requirements

CDPH requires clinical laboratories (including public health laboratories, blood bank laboratories and laboratories exempt from licensure) to provide evidence of satisfactory performance in an approved Proficiency Testing Service (PTS). Laboratories exempt from licensure are those laboratories operating in accordance with Section 1241 (b) through 1241.1 of the *California Business and Professions Code*. These may include laboratories operated by individual physicians, partnerships and medical groups, and certain organized outpatient clinics.

Proficiency testing is designed to ensure that laboratory tests performed by all laboratories, licensed or unlicensed, achieve an acceptable level of accuracy and consistency.

Enrollment Requirements For Proficiency Testing

If a provider performs any test that belongs to one of the categories of procedures designated by the Department of Health Care Services as requiring measurement of test performance, the provider must enroll with an approved PTS. Enrolled providers are sent specimens for analysis by the testing services three times a year. Analysis must be performed by the provider reporting the results and not sent to a reference or other laboratory for testing.

Testing and reporting must be within the time limits set by the PTS; late reports from the laboratory will be considered unsatisfactory. These test results are graded by the testing service and its report is forwarded to the enrolled laboratory and CDPH Laboratory Field Services. The standards for satisfactory performance by physician office laboratories operate in accordance with Section 1220(a)(2) and Section 1241 (b) through 1241.1, Division 2, Chapter 3 of the *Business and Professions Code*.

Enrollment Notification

Notification of a laboratory's enrollment in an approved proficiency testing program will be forwarded by the testing service directly to Laboratory Field Services. Laboratory Field Services will notify the Provider Enrollment Division and the laboratory's provider file will be updated to reflect those specific specialties/subspecialties for which the laboratory has been proficiency-tested.

Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in the CFR, Part 493, Subpart I and is approved by the Department of Health and Human Services (HHS). The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks clarification.

Procedures Subject to Proficiency Testing

Laboratory certification (LC) codes CLIA Specialty and Subspecialty list is as follows:

Specialty	Subspecialty	LC Code
Histocompatibility	None	010
Microbiology	Bacteriology	110
Microbiology	Mycobacteriology	115
Microbiology	Mycology	120
Microbiology	Parasitology	130
Microbiology	Virology	140
Diagnostic Immunology	Syphilis Serology	210
Diagnostic Immunology	General Immunology	220

Specialty	Subspecialty	LC Code
Chemistry	Routine Chemistry	310
Chemistry	Urinalysis	320
Chemistry	Endocrinology	330
Chemistry	Toxicology	340
Hematology	None	400
Immunohematology	ABO Group & Rh type	510
Immunohematology	Antibody Detection (transfusion)	520
Immunohematology	Antibody Detection (non-ransfusion)	530
Immunohematology	Antibody Identification	540
Immunohematology	Compatibility Testing	550
Pathology	Histopathology	610
Pathology	Oral Pathology	620
Pathology	Cytology	630
Radiobioassay	None	800
Clinical Cytogenetics	None	900

Note: The above information can also be found in the *Pathology: Billing and Modifiers* section of this manual.

List of Approved Accreditation Organizations Under CLIA

AABB
Government Relations
8101 Glenbrook Road
Bethesda, Maryland 20814-2749
(301) 907-6977

American Osteopathic Association
142 East Ontario Street
Chicago, Illinois 60611
(312) 202-8070

American Society for Histocompatibility & Immunogenetics
15000 Commerce Parkway, Suite C
Mt. Laurel, New Jersey 08054
(856) 642-4415

College of American Pathologists
325 Waukegan Road
Northfield, Illinois 60093-2750
(800) 323-4040

COLA
9881 Broken Land Parkway, Suite 200
Columbia, Maryland 21046-1195
(410) 381-6581

Joint Commission
One Renaissance Boulevard
Oakbrook Terrace, Illinois 60181
(630) 792-5000

CLIA Exempt States

New York
Clinical Laboratory Evaluation Program
State of New York Department of Health
The Nelson A. Rockefeller
Empire State Plaza
P. O. Box 509
Albany, New York 12201-0509
(518) 485-5378

Washington
Office of Laboratory Quality Assurance
Department of Health
1610 NE 150th Street
Shoreline, Washington 98155-9701
(206) 418-5418

Criteria for One Certificate for Multiple Sites

Criteria for one certificate for multiple sites is as follows:

Location

Each location where laboratory tests are performed must file a separate application, unless it meets one of the following exceptions as outlined in the CFR, Title 42, Sections 493.35(b), 493.43(b) or 493.55(b):

- Laboratories that are not at a fixed location, for example, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fair locations may be covered under the CLIA certificate and address of the designated primary site or home base.
- Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 types of moderately complex or waived tests per certificate) public health testing may file a single application.
- Laboratories within a hospital that are located at a contiguous building on the same campus and under common direction may file a single application or multiple applications for CLIA certificate(s) for the laboratory sites within the same physical location or street address.

Note: The above information can also be found in the *Pathology: Billing and Modifiers* section of this manual

Home Health Agencies

A parent Home Health Agency (HHA) with multiple branches may apply for one CLIA certificate as long as these sites are under one National Provider Identifier (NPI), for example, parent branch. Subunits by definition operate independently and have a unique provider number; therefore, each subunit must apply for a separate CLIA certificate.

Note: The parent or provider location must perform laboratory testing. Since branches cannot operate independently, the parent defines the services provided in the branches and is responsible for the day-to-day operation, supervision, and administration of laboratory testing, including the employment of qualified personnel. (For consistency, the Medicare designated terms parent and branches are used for this policy.)

Hospices

The guidance for HHAs applies to hospices. The Medicare designated term for the hospice multiple sites is multiple locations instead of branches.

See CMS Update: *www.cms.hhs.gov/Survey/CertificationGenInfo*

Note: The above information can also be found in the *Pathology: Billing and Modifiers* section of this manual.

CLIA: Billing for Pathology

A pathologist/pathology group that wishes to bill Medi-Cal for the professional component of a laboratory test or examination he or she performs, supervises or directs for a hospital laboratory provider on hospital patients must provide the California Department of Public Health (CDPH) a copy of the written agreement between the hospital and the pathologist/pathology group, or the pathologist's/pathologist group's partnership or professional corporation, authorizing the pathologist/pathology group, partnership or professional corporation to use the hospital laboratory's CLIA Certificate and state license.

The Medi-Cal application must be accompanied by a current copy of the hospital laboratory's CLIA Certificate, a copy of the current Laboratory Certification (LC) specialty and subspecialty codes approved for the hospital laboratory under its CLIA Certificate, state license, and NPI.

The agreement between the hospital and the pathologist/pathology group must be signed by the pathologist (or the person authorized to bind the partnership or professional corporation to which he or she belongs) and an authorized representative who may bind the hospital and its laboratory to the agreement. The agreement must include the following:

- All laboratory work billed by the pathologist/pathology group, partnership or professional corporation with the Pathology NPI is performed on hospital patients under the federal and state certificates, licenses and registrations issued to the hospital laboratory performing the work.
- The hospital laboratory will not bill separately for the same component of a laboratory service.
- The hospital and the pathologist/pathology group, partnership or professional corporation will not include the same laboratory work within any laboratory work that is reimbursed by the Medi-Cal, Medicaid or Medicare programs on a per diem or capitated basis (for example, reimbursed other than on a fee-for-service basis).
- The hospital laboratory, as the provider of service, agrees to be responsible for any overpayments owed to the Medi-Cal, Medicaid or Medicare programs based upon the provision of laboratory services to its patients.

Note: The above discussion deals with the performance of laboratory tests for hospital patients. A pathologist/pathology group wishing to bill the Medi-Cal program for the technical and/or professional component of a clinical laboratory test or examination that the pathologist/pathology group performs, supervises or directs at the hospital laboratory for a non-hospital patient must have their own CLIA and state license or registration and laboratory NPI or have a Pathology NPI.

Provider Enrollment

All clinical laboratories, including reference laboratories and out-of-state providers seeking reimbursement for clinical laboratory tests or examinations, must be enrolled in the Medi-Cal program and possess a Clinical Laboratory Improvement Amendments (CLIA) certificate. If the reference laboratory is not Medi-Cal-enrolled and CLIA-certified, the claim will be denied. Providers using the services of unaffiliated reference laboratories should contact the laboratory to verify enrollment and CLIA level of certification. Laboratories that are not enrolled in Medi-Cal may contact the DHCS Provider Enrollment Division at (916) 323-1945.

Billing for Reference Laboratories With Modifier 90

Please see additional information in the *Pathology: Billing and Modifiers* section in this manual.

Clinical laboratory providers who use reference laboratories must follow the guidelines below to receive reimbursement for these services:

- Use modifier 90 to bill reference laboratory services
- Ensure that the reference laboratories used are licensed as clinical laboratories and enrolled as Medi-Cal laboratory providers
- Enter only the rendering provider's provider number in the *Operating* field (Box 77)/*Additional Claim Information* field (Box 19) of the claim
- Do not enter the billing provider number in the *Operating* field (Box 77)/*Additional Claim Information* field (Box 19) of the claim. Medi-Cal defines "Rendering Provider" as the party actually performing the service(s)
- Enter the name and address of the laboratory at the bottom of the claim in the designated area

CLIA Approved Proficiency Testing Programs

To enroll in a Federal and State approved proficiency testing program, one of the following organizations should be contacted:

- Accutest (DigitalPt) 800-665-2575 *www.digitalpt.com*
- American Academy of Family Physicians 800-274-7911 *www.aafp.org/pt/ptcentral*
- American Association of Bioanalysts 800-234-5315 *www.aab-pts.org*
- American Proficiency Institute 800-333-0958 *www.api-pt.com*
- American Society for Clinical Pathology 800-267-2727 *www.ascp.org*
- California Thoracic Society 415-536-0287 *calthoracic.org*
- College of American Pathologists 800-323-4040 *www.cap.org*
- Medical Laboratory Evaluation 800-338-2746 *www.acponline.org/mle*
- Wisconsin State Laboratory of Hygiene (WSLH) 800-462-5261 *www.wslhpt.org*

The CMS Web site provides a complete list of testing programs at:
www.cms.hhs.gov/CLIA/14_Proficiency_Testing_Providers.asp#TopOfPage

Additional Information

Questions about the testing programs offered should be directed to the testing services listed on a previous page. Questions concerning the State and/or Federal requirements for proficiency testing should be directed to:

California Department of Public Health

Laboratory Field Services

850 Marina Bay Parkway, Bldg. P, 1st Floor

Richmond, CA 94804-6403

(510) 620-3800

Laboratories will be notified by Laboratory Field Services of any new regulatory requirements concerning proficiency testing.

Laboratories should also regularly monitor the CMS website for new CLIA regulatory requirements: *www.cms.hhs.gov/home/regsguidance.asp*

Laboratory Services Reservation System

Laboratory services are subject to frequency limits. These limits are set per recipient, per service, per month via the Laboratory Services Reservation System (LSRS). Laboratory providers may use the LSRS to make reservations or verify if a frequency limit has been reached for a specific recipient for a specific laboratory service, prior to performing the procedure. When a reservation is made, the claim must be billed with the provider number used to make the reservation.

Frequency limits may be overridden on a case-by-case basis when the provider submits medical justification to support the frequency of the laboratory service for a recipient. Justification will be reviewed by medical review staff for final approval. Providers are reminded that laboratory service claims that are denied due to frequency limitations may be appealed with submission of medical justification. Failure to make a laboratory service reservation prior to performing the laboratory service may result in denial of the claim.

The following entities are excluded from frequency limitations when the laboratory service is rendered onsite: End Stage Renal Disease (Dialysis) Clinics, county public health clinics, Skilled Nursing Facilities Level B (NF-B), inpatient hospitals and emergency rooms.

Note: When billing laboratory services for Medi-Cal recipients residing in an NF-B, providers must include both the facility's name in Box 17 and the facility's National Provider Identifier (NPI) in Box 17b of the *CMS-1500* form.

The following programs are excluded from frequency limitations: California Children's Services (CCS) and Genetically Handicapped Persons Program (GHPP).

Note: Providers are reminded that independent clinical laboratories that provide services to recipients in NFs and dialysis clinics must adhere to the same requirements to supply their claims with further documentation in support of medical justification for rendering laboratory services to these recipients

‹‹Legend››

‹‹Symbols used in the document above are explained in the following table.››

Symbol	Description
‹‹	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
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