Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 1106
Transmittal Sheet
July 27, 2018

PATHOLOGY AND LABORATORY MEDICINE SERVICE

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive assigns responsibilities related to Department of Veterans Affairs (VA) laboratories performing testing used for the diagnosis and treatment of patients, and the requirement that such laboratories must meet the requirements of Clinical Laboratory Improvement Amendments (CLIA).

2. SUMMARY OF MAJOR CHANGES: Major changes include clarification of the requirement for issuance of a VA CLIA number for all VA testing sites, updating titles and routing symbols, and clarification on data collection activities.

3. RELATED ISSUES: VHA Handbook 1106.01, Pathology and Laboratory Medicine Service, dated April 5, 2013.

4. RESPONSIBLE OFFICE: The Office of the National Director, Pathology and Laboratory Service (10P11P) is responsible for the contents of this directive. Questions may be referred to P&LMS Program Office at 202-632-8418 or VHA CO P&LMS PMO.

5. RESCISSION: VHA Directive 1106, Pathology and Laboratory Medicine Service, dated April 5, 2013, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of July 2023. This VHA directive will continue to serve as VHA national policy until it is recertified or rescinded.

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DISTRIBUTION: Emailed to the VHA Publications Distribution List on July 31, 2018.

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

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1. PURPOSE

This Veterans Health Administration (VHA) directive assigns responsibilities related to Department of Veterans Affairs (VA) laboratories performing testing used for the diagnosis and treatment of patients, and the requirement that such laboratories must meet the requirements of Clinical Laboratory Improvement Amendments (CLIA). **AUTHORITY:** Public Law 100-578 (1988), Public Law 102-139 section 101(1991), and title 42 Code of Federal Regulations (CFR), Part 493.

2. BACKGROUND

a. In 1988, Public Law 100-578, the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), was enacted. This law amended section 353 of the Public Health Service Act (title 42 United States Code (U.S.C.), section 263a) to codify in law certain requirements for the staffing, management, procedures, and oversight of United States laboratories that perform testing used in the diagnosis and treatment of patients. The Department of Health and Human Services (HHS) promulgated regulations for CLIA-88, which are codified at 42 CFR Part 493.

b. VHA is exempted from CLIA-88 per Public Law 102-139 (1991) and is required to develop regulations, in consultation with HHS, establishing standards equal to that applicable to other medical facility laboratories in accordance with the requirements of section 353(f) of the Public Health Service Act. Under the 1991 statute, VHA laboratories must meet the requirements of CLIA-88 and VHA is responsible for enforcement and oversight of their own regulations. The Secretary of Veterans Affairs delegated authority to the Under Secretary for Health to issue regulations implementing requirements and standards for VHA laboratories. VA participates on the HHS partnership panel for Pathology and Laboratory Medicine Service with bi-directional communication regarding their respective programs.

c. Laboratory test systems, assays, and examinations are categorized as the same complexity as defined by the Food and Drug Administration in 42 CFR Part 493.

3. DEFINITIONS

a. **Ancillary Testing.** Ancillary testing is laboratory testing performed within and under the administration of the VA medical facility, health care system, or its outreach functions (clinics, etc.), but outside the physical facilities of the main clinical laboratory. This includes all laboratory testing sites, such as point of care testing, satellite or specialty laboratories, community based outpatient clinic (CBOC) testing sites, and Home-Based Health Care (HBHC) when such testing is performed by a VA employee in a patient's home. Ancillary testing includes laboratory testing sites that fall under the auspices of the main parent facility even when they may be under a separate laboratory director, CLIA registration number, or separate accreditation.

b. **High Complexity.** High complexity refers to the most complicated laboratory tests, requiring the most rigid testing requirements outlined in the CLIA regulations. Test complexity is determined by the Food and Drug Administration (FDA) per the criteria outlined in the 42 CFR 493.17. Testing sites performing highly-complex testing must obtain a highly complex CLIA certificate.

c. **Laboratory Test.** A laboratory test is an examination, diagnostic, or monitoring procedure on a human specimen removed from the body to determine specific information for diagnosis, treatment, or prevention of disease, and to detect the impairment of health status, or to assess the health of human beings.

d. **Minimal Complexity.** VA recognizes the complexity level for laboratory procedures as listed in 42 CFR Part 493, but requires minimal standards be met for waived testing performed by VA laboratories. Minimally complex CLIA certificates are issued to VA Waived testing sites and waived testing sites are held to the VA minimal standards.

e. **Moderate Complexity Testing.** Moderate complexity testing is the rating given by the FDA to commercially marketed in vitro diagnostic tests based on their risks to public health level. The complexity is determined based on the scoring criteria outlined in 42 CFR 493.17. Testing sites performing moderate complexity testing must obtain a moderately-complex CLIA certificate.

f. **Point of Care Testing.** Point of care testing refers to tests designed to be used at or near the site where the patient is located, and that are performed outside the physical facilities of the clinical laboratory.

g. **Proficiency Testing.** Proficiency testing is a program in which samples are periodically sent to a laboratory for analysis in which each laboratory's results are compared with peer laboratories and reported to the participating laboratory and the VA CLIA program.

h. **Provider Performed Microscopy Testing.** Provider performed microscopy (PPM) testing refers to a subset of specific moderate complexity light microscopy procedures outlined in the CLIA regulations, which a physician, midlevel practitioner, or dentist performs on a specimen obtained from the provider's own patient.

i. **Testing Site.** A location that performs laboratory testing (waived or non-waived) used in the diagnosis, treatment or assessment of patients within the VA health care organization and outreach functions. This includes testing that may occur outside the physical facilities of the main laboratory.

j. **Waived Testing.** A category of tests defined as simple laboratory examinations. Testing sites performing waived tests must obtain a VA CLIA certificate for minimal complexity.

4. POLICY

All VHA laboratories performing testing used for the diagnosis and treatment of patients must meet the requirements of CLIA, VHA Handbook 1106.01, Pathology and Laboratory Medicine Service, dated April 5, 2013, and applicable VA requirements.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Deputy Under Secretary for Health for Operations and Management.** The deputy Under Secretary for Health for Operations and Management is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISN);

(2) Ensuring that each VISN Director has the sufficient resources to fulfill the terms of this directive in all the VA medical facilities within that VISN; and

(3) Providing oversight of VISNs to assure compliance with this directive, relevant standards, and applicable regulations.

c. **National Director, Pathology and Laboratory Service (P&LMS).** The National Director, P&LMS, in concert with the P&LMS National Enforcement Officer, is responsible for providing oversight and enforcement of the policies defined in this directive and its related handbooks.

d. **P&LMS National Enforcement Officer.**

(1) Directs the VA CLIA Program and ensures that all VA testing sites are registered with the P&LMS National Enforcement Program and are issued a VA CLIA number.

(2) Responsible for regulatory compliance and enforcement for VA laboratory testing sites for requirements as defined in 42 CFR Part 493, VA Directives and related Handbooks.

e. **P&LMS Regional Commissioner.**

(1) Appointed by the National Director, P&LMS.

(2) Works under the direction of the National Enforcement Officer to ensure that all VA testing sites are in compliance with the inspection and accreditation requirements.

(3) Advises the P&LMS National Enforcement Officer of problems and concerns relating to the quality of the work in P&LMS and laboratory-related services.

f. **Veterans Integrated Service Network (VISN) Director.** Each VISN Director is responsible for ensuring all laboratories or individuals, within the VISN, performing testing used for the diagnosis and treatment of patients are compliant with the policies in 42 CFR Part 493, this directive, and the related handbooks.

g. **Medical Facility Director.** The VA medical facility Director is responsible for ensuring:

(1) The applicable requirements of 42 CFR Part 493 and appropriate accrediting agencies are met when any laboratory patient care services are offered by facility laboratories, regardless of the physical location of the laboratory, or the service or administrative structure assigned to direct the personnel or technical aspects of the test site.

(2) VA laboratories and testing sites, including CBOCs performing waived testing and/or provider-performed microscopy (PPM) testing sites, register with the P&LMS National Enforcement Program in VA Central Office, and are assigned a VA CLIA number.

(3) The main clinical laboratory in each VHA health care network and each VA medical facility are under the oversight of a VHA Chief or Director, P&LMS who is a licensed pathologist, board certified in pathology by The American Board of Pathology.

(4) The facility laboratory meets the requirements of the accrediting organization in those cases where a laboratory accrediting organization requires that certain tests be treated as if they are more complex than is listed in 42 CFR Part 493.

(5) Testing sites that perform laboratory tests categorized as moderately or highly complex are inspected and accredited by a Center for Medicare and Medicaid Services (CMS) approved accrediting organization.

(6) Sites performing VHA-recognized waived testing and PPM procedures are inspected and accredited as part of the main laboratory accreditation or in conjunction with the main facility accreditation process.

(7) Testing, regardless of complexity level or the physical location, is under the oversight of the facility Chief or Director, P&LMS.

(8) Ancillary testing sites (ATS) are under the quality oversight and technical direction of the facility Chief or Director P&LMS.

(9) Individuals performing testing meet the personnel requirements defined in 42 CFR Part 493 for the identified testing complexity.

(10) P&LMS and all ATS successfully participate in a CMS approved proficiency testing program.

(a) The laboratory proficiency testing program must meet the requirements of CLIA, the accrediting agency, and VA, for all analytes for which proficiency testing is available, including waived and unregulated analytes.

(b) For analytes where no proficiency testing is available, an alternate method must be in place.

(c) All testing sites must perform proficiency testing at all sites and on every instrument used for patient testing, including backup instruments.

(11) P&LMS providing Anatomic Pathology, Histopathology, and/or Cytopathology Services must participate in an approved proficiency testing program.

(12) The facility participates in the VHA workload collection program designated by the National Director, P&LMS, such as the College of American Pathologists Customized Laboratory Management Index Program.

h. **Facility Chief or Director, P&LMS.** Each facility Chief or Director, P&LMS must:

(1) Direct and coordinate the patient care, administration, education, and research functions of P&LMS.

(2) Develop and implement the quality improvement plan.

(3) Ensure that there are sufficient qualified personnel with adequately documented training and experience to meet the needs of the laboratory.

(4) Plan and set goals for the development and allocation of resources for P&LMS appropriate to the medical environment.

(5) Provide effective and efficient administration of the pathology service to include budget planning and control.

(6) Develop selection criteria for reference laboratories and monitor for quality of service in accordance with federal regulations and accreditation requirements.

(7) Act as a consultant whenever a non-VA provider is contracted to perform laboratory testing for Veterans; this includes providing documentation to ensure the contracted laboratory is CLIA certified and all test results are entered into the laboratory section of the Veterans Health Information System.

(8) Establish a laboratory management data collection system and participate in informational queries or surveys initiated by the National Director, P&LMS, or any other management information program designated as a VA national laboratory program.

6. TRAINING REQUIREMENTS

There are no formal training requirements associated with this directive.

7. RECORDS MANAGEMENT

All records regardless of format (paper, electronic, electronic systems) created by this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. If you have any questions regarding any aspect of records management contact your facility Records Manager or your Records Liaison.

8. REFERENCES

a. Public Laws 100-578 and 102-139.

b. The Public Health Service Act Section 353 (codified at 42 U.S.C. 263a).

c. 42 CFR Part 493.

d. VHA Handbook 1106.01, dated January 29, 2016.

e. Clinical Laboratory Improvement Amendments.