

January 17, 2001

## CLINICAL LABORATORY REGISTRATION REQUIREMENTS

**1. PURPOSE:** This Veterans Health Administration (VHA) directive establishes policies and requirements for VHA laboratory registration with the Health Care Financing Administration (HCFA) and subsequent issuance of a Clinical Laboratory Improvement Amendments '88 (CLIA'88) number.

### 2. BACKGROUND

a. CLIA and its implementing regulations (Title 42 Code of Federal Regulations (CFR), Part 493) were intended to improve the quality of laboratory operations and to expand Federal oversight to virtually all laboratories in the country that are involved in testing human specimens for health assessment.

b. In 1991, Congress decided that the clinical laboratories within VHA should not be regulated by the Department of Health and Human Services (DHHS), but should have equivalent standards. These standards were established and the Secretary of DHHS stipulated to Congress that they were equivalent to those under the CLIA'88 regulations. The VHA implementing instructions (VHA Directive 1106 and VHA Handbook 1106.1) include some standards that are more stringent than those provided in CLIA'88 and cite 42 CFR Part 493 for the remaining standards.

c. In an era of declining resources, as enterprising laboratory leaders began exploring opportunities to recapture lost revenue through local community testing service agreements, some found that they were handicapped by the inability to provide a DHHS CLIA'88 number as proof of their laboratory's quality. To resolve this and other incident CLIA'88 numbering issues, an Interagency Agreement between HCFA, the agency under DHHS responsible for administration of the CLIA'88 program, and VHA was signed on April 26, 2000. In accordance with this agreement, VHA provides HCFA with certain data on VHA clinical laboratories and HCFA provides VHA with official CLIA'88 numbers for VHA laboratories. The Pathology and Laboratory Medicine Service (P&LMS) National Enforcement Office will continue to administer the VHA program and will continue monitoring VHA's clinical laboratories to ensure that they meet VHA standards.

d. Under the Interagency Agreement, VHA must submit to HCFA specific information about the organization, management, and the services provided by VHA clinical laboratories. VHA is required to update this information whenever any of the data elements are modified at a particular laboratory or that laboratory fails VHA performance standards. The P&LMS National Enforcement Office collects the required information, submits this information and all updates to HCFA, and distributes the CLIA'88 numbers.

**3. POLICY:** It is VHA policy to ensure VHA laboratories, where appropriate (see subpar. 4a), are issued CLIA'88 numbers.

**THIS VHA DIRECTIVE EXPIRES JANUARY 31, 2006**

## **VHA DIRECTIVE 2001-003**

**January 17, 2001**

### **4. ACTION**

a. All hospital-based and stand-alone clinical laboratories (independently accredited) within the VHA are required to register with the P&LMS National Enforcement Office and to be issued a CLIA'88 number. *NOTE: This policy does not apply to small Community-based Outpatient Clinics that do limited on-site testing and fall under the umbrella of the main facility laboratory accrediting organization.*

b. The P&LMS National Enforcement Office must distribute enrollment packages to all appropriate facilities. Once the completed package is received, the P&LMS National Enforcement Office enters the laboratories in the HCFA central database and issues the CLIA'88 number and certificate to the laboratory. *NOTE: The CLIA'88 numbers are valid for 10 years from the date of issue, unless withdrawn sooner by the P&LMS National Enforcement Office.*

c. Registered laboratories must provide the P&LMS National Enforcement Office with updated information on changes in the name, address, director, and type of laboratory and specialty testing performed by each laboratory within 30 days of such change.

d. Compliance with the other requirements in VHA Directive 1106; 42 CFR Part 493; and Public Law 102-139; remains in effect for all VHA laboratories.

e. All non-VHA laboratories that provide reference laboratory testing for VHA patients must be certified under HCFA and maintain a current CLIA'88 number. This includes those within Community-based Outreach Clinics staffed by non-VHA providers, and all non-VHA clinical laboratories providing reference testing for veteran patients at these clinics. P&LMS at the parent VHA facility will be provided with these CLIA'88 numbers.

f. P&LMS at the parent VHA facility is responsible for maintaining documentation of these CLIA'88 numbers.

### **5. REFERENCES**

a. Public Law 102-139, Title I, Section 101, 105 Statute 742 (1991).

b. CLIA'88.

c. Title 42 CFR Part 493.

d. VHA Directive 1106.

e. VHA Handbook 1106.1.

f. Interagency Agreement between the Department of Veterans Affairs (VA) and HCFA of April 26, 2000.

**6. FOLLOW-UP RESPONSIBILITY:** The Office of Patient Care Services, Diagnostic Services Strategic Healthcare Group (SHG) is responsible for the contents of this directive.

**7. RECESSIONS:** None. This VHA Directive expires January 31, 2006.

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Under Secretary for Health

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