

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-08-35

DATE: September 5, 2008

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Drug or Alcohol Screening/Testing and Clinical Laboratory Improvement
Amendments (CLIA) Certification

Memorandum Summary

- This memorandum provides additional guidance regarding the circumstances when laboratories performing drug or alcohol screening and/or testing must be CLIA certified, and should be considered an addendum to the attached February 05, 1993 memorandum “Guidance on the Applicability of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to Substance Abuse Testing.”
- We are restating our ongoing policy that laboratories performing drug or alcohol screening and/or testing followed by individual treatment must be CLIA-certified. Facilities found to be performing such testing without CLIA certification are in violation of CLIA.

As detailed in 42 CFR 493.2, a laboratory for CLIA purposes is a facility whose examinations of human specimens are “for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings.”

Exceptions are provided to this general rule of applicability where: a “facility or component of a Facility” “*only performs testing for forensic purposes*” (emphasis added); for “research laboratories” that do not report out patient specific test results; and for “laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), in which drug testing is performed which meets SAMHSA guidelines and regulations. [42 CFR 493.3(b)1)-(3)]

The preamble to the February 28, 1992 Federal Register notice (HSQ-176FC) included an important discussion concerning this subject at 57 FR 7014, as follows:

“In the forensic testing context, laboratory results are generated purely for the purpose of detecting illegal substances or illegal amounts of certain substances in the body that may be relevant to legal proceedings. There is no concern in such testing for developing accurate and reliable data for use by health care professionals for the purpose of diagnosis or treatment, which we believe to be the focus of the CLIA legislation. However, if the entity

conducts testing for the purpose of providing information for the diagnosis, prevention or treatment of any disease, or impairment of, or the assessment of health of human beings, the entity would be subject to CLIA. The determining factor is not the test itself, but the purpose for which the test is conducted.”

It further states:

“Based on the CLIA law and its legislative history, we have determined that forensic testing is excluded under CLIA since forensic testing is conducted to determine if there has been a violation of the law and is not done for the purpose of providing remedial treatment. Urine drug testing that is conducted for non-forensic purposes is covered by this rule. [Webster’s defines treatment as “medical application of remedies so as to effect a cure: therapy.”]

Although the February 05, 1993 memorandum to the Regional Offices refers specifically to **employment** entities that perform drug and alcohol testing for the purpose of hiring or firing, when such testing serves as the basis for *treatment*, the entity is considered a laboratory subject to CLIA. This policy applies to all entities (facilities), not just those performing employment-related drug and/or alcohol testing.

Therefore, any entity or facility performing drug or alcohol testing and/or screening where the test results are used for the purpose of referring, offering, or making available to the test subjects treatment, must either obtain an appropriate CLIA certificate and meet the applicable CLIA standards or cease testing.

If you have any questions regarding this guidance, please contact Judy Yost in the Division of Laboratory Services at Judith.Yost@cms.hhs.gov or 410-786-3407.

/s/

Thomas E. Hamilton

cc: Survey and Certification Regional Office Management
Accrediting Organizations/Exempt States



Memorandum

DATE: Feb 05 1993

FROM: Director
Office of Survey and Certification, HSQB

SUBJECT: Guidance on the Applicability of the Clinical Laboratory Improvement
Amendments of 1988 (CLIA) to Substance Abuse Testing

TO: Associate Regional Administrator
Division of Health Standards and Quality
Regions I – X

The purpose of this memorandum is to share with you approved interim guidance concerning the applicability of CLIA to substance abuse testing. Please share this information with the state survey agencies in your region. This document is intended for use by you and the State agencies in answering questions from laboratories, employers and others needing clarification.

As the guidance states, the Secretary has not made a final decision about how or if substance abuse testing will be subject to CLIA requirements. Therefore, this guidance will remain in effect until a final determination is made. I am also attaching a copy of the preamble language from the January 19, 1993, Federal Register (HSQ-202FC), on which the guidance is based.

If you have any questions about this guidance, please call Wayne Smith (410) 966-6762, or Judy Yost (410) 786-3407.

Anthony J. Tirone

Attachments

GUIDANCE ON THE APPLICABILITY OF THE
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA)
TO SUBSTANCE ABUSE TESTING

In the preamble to the January 19, 1993, Federal Register notice (HSQ-202FC), which made a number of technical and substantive changes to the CLIA regulations published on February 28, 1992, the application of the CLIA requirements to employee workplace drug testing subject to CLIA would be deferred until further study of (1) the impact CLIA would have on employer participation in workplace drug testing and (2) other approaches to ensuring safety and accuracy of this type of testing that may be available.

This guidance is provided to ensure a consistent and accurate interpretation of the practical effects of this delay in implementation.

Until further notice, CLIA regulations do not apply to components or functions of any employer entity that performs substance abuse testing for any purpose other than as part of a treatment program. The CLIA rules do not apply to testing that results in disciplinary, administrative, or legal action, if the test is positive, or to testing for the presence or absence of substances of abuse involving an employee. This would include employer testing programs which might lead to disciplinary action, whether or not there is an associate referral to an employee assistance program.

The following matrix will help to clarify which aspects of substance abuse testing are subject to CLIA and which are not:

| | Forensic Testing | Employment Testing | Treatment Testing |
|---------------------|-------------------------|---------------------------|--------------------------|
| Substances of Abuse | Not Subject to CLIA | Not Subject to CLIA | Subject to CLIA |
| Alcohol | Not Subject to CLIA | Not Subject to CLIA | Subject to CLIA |

¹Employee testing for health purposes, such as cholesterol screens etc. are covered by CLIA and are not a part of this guidance. If the employer offers health screenings, but contracts for the services rather than conducting them with in house staff, the contractor must hold the CLIA certificate.

² Forensic testing was specifically excluded from CLIA in the February 28, 1992, CLIA regulation at 493.3 (b) (1), as was testing conducted in laboratories (or parts of laboratories) certified by the National Institute on Drug Abuse.

³ Positive tests that result in the employee's referral to an EAP program do not make the EAP program subject to CLIA unless the EAP program actually does testing for substances of abuse itself as a part of a substance abuse treatment program.

⁴ The Department has not yet determined how breathalyzers and other tests which do not derive a specimen from the human body will be dealt with under CLIA and, therefore, as mentioned on page 7008 of the February 28, 1992, Federal Register, these tests are currently not subject to CLIA. Thus, treatment programs which use only breathalyzers are not subject to CLIA. CLIA is applicable, however, to alcohol treatment programs which test using a specimen from the human body. Any test that involves a specimen derived from the human body, such as blood, urine and saliva that has not yet been categorized as waived, moderate or high complexity, it presumed to be high complexity until it is categorized.
