



State of New Jersey

DEPARTMENT OF HEALTH AND SENIOR SERVICES

PO BOX 361
TRENTON, N.J. 08625-0361

JON S. CORZINE
Governor

www.nj.gov/health

HEATHER HOWARD
Commissioner

November 12, 2008

Dear Substance Abuse Treatment Provider:

Questions have been raised to the New Jersey Department of Health and Senior Services concerning the applicability of Federal CLIA regulations and New Jersey's statute and rules governing clinical laboratories to drug and alcohol treatment facilities performing testing for drugs of abuse such as opiates, cocaine, amphetamines etc.

This is to advise you that any person or facility performing any testing of bodily specimens for the purpose of yielding information to be used in the prevention, diagnosis and treatment of disease or the assessment of medical conditions must hold both a CLIA certificate from the Centers for Medicaid and Medicare Services and a clinical laboratory license from the Department's Clinical Laboratory Improvement Service (CLIS). The requirements for certification and licensure can be found in 42 CFR Part 493, N.J.S.A. 45:9 – 42.26 et seq and N.J.A.C. 8:44. In accordance with N.J.S.A. 45:9-42.43, persons in violation of the statute or rules may be subject to penalties of up to \$1,000 per violation. Please note that a treatment program performing only urinalysis for screening purposes to detect the presence of alcohol or illegal substances may be exempt from New Jersey Clinical Laboratory licensing requirements if the follow conditions are met:

- Testing is performed exclusively for persons under the jurisdiction of the Department of Corrections, county jails and county probation departments or for persons in a program of supervisory treatment pursuant to N.J.S. 2C:43-13; and
- Testing is performed using procedures, methods and devices approved by the Attorney General.

If your facility does not meet the above criteria to be exempt from state licensure requirements and you are currently performing testing for drugs of abuse, HIV or other tests without both a CLIA certificate and a New Jersey clinical laboratory license, please cease testing and submit an application for CLIA certification and/or state licensure as applicable. Information and applications can be found on the Department's CLIS website at <http://nj.gov/health/phel/instruct116.shtml> (for CLIA application) and <http://nj.gov/health/forms/d-3.pdf> (for clinical laboratory license application).

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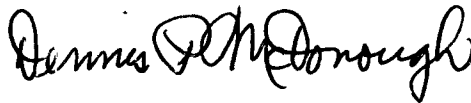
Page 2

Please be advised that Federal CLIA requirements for laboratory director, supervisors and testing personnel and other provisions of CLIA regulations are less stringent than New Jersey's rules for the operation of clinical laboratories at N.J.A.C. 8:44, a copy of which may be accessed on the Department's website at www.state.nj.us/health/pheh/clis.shtml. The Laboratory Director must hold a Bioanalytical Laboratory Director's license from the New Jersey Board of Medical Examiners. In addition, the Laboratory Director or a qualified Technical or General Supervisor must be onsite at all times when testing is performed and testing personnel must meet education and experience requirements working under qualified supervision. See N.J.A.C. 8:44-2.3, 2.4, 2.5 and 2.6.

Upon receipt of completed CLIA and state licensure applications, an inspection will be scheduled of your laboratory to determine eligibility for licensure.

If you have any questions concerning this information, please contact Joan Mikita, Supervisor of the Clinical Laboratory Licensure program at (609) 984-7923.

Sincerely,



Dennis P. McDonough, M.P.H.
Director
Clinical Laboratory Improvement Service

C: K. Morrow, DMAHS
M. Greene, DHS/DAS