



News Release

PO Box 360, Trenton, N.J. 08625-0360

Fred M. Jacobs, M.D., J.D.
Commissioner

For Release:
May 21, 2007

For Further Information, Contact

(609) 984-7160

Department of Health and Senior Services Proposes to Amend N.J.A.C. 8:44-2.5 Governing Clinical Laboratory Proficiency Testing Providers

The Clinical Laboratory Improvement Service of the Division of Public Health and Environmental Laboratories of the Public Health Services Branch of the Department of Health and Senior Services (Department) proposes to amend N.J.A.C. 8:44, Clinical Laboratory Improvement Services, at N.J.A.C. 8:44-2.5. The notice of proposal appears in the May 21, 2007 issue of the New Jersey Register.

N.J.A.C. 8:44, also known as Chapter IV of the State Sanitary Code, establishes requirements for the operation of clinical laboratories. N.J.A.C. 8:44-2 establishes standards for the operation of clinical laboratories. N.J.A.C. 8:44-2.5 establishes standards for tests clinical laboratories can perform within the scope of the specialties and subspecialties for which it and its staff hold licensure and establishes requirements for proficiency testing. N.J.A.C. 8:44-2.5(b) requires clinical laboratories to enroll and successfully participate in proficiency testing the Department of Health and Senior Services (Department) offers or in specifically designated surveys that two specified proficiency testing providers offer.

The Department proposes to amend N.J.A.C. 8:44-2.5(b) to authorize clinical laboratories to use the proficiency testing services of entities that the Centers for Medicare and Medicaid Services of the United States Department of Health and Human Services (CMS) have approved to provide proficiency testing programs pursuant to 42 C.F.R. Part 493, the Federal regulations that implement the Clinical Laboratory Improvement Amendments of 1988. The proposed amendment would ensure that clinical laboratories participate in proficiency testing offered by entities that CMS has determined to be qualified. The proposed amendment would ensure that, in accordance with N.J.S.A. 45:9-42.34, the State's rules governing clinical laboratory oversight are consistent with Federal standards.

The Department will convene a public hearing on the proposed amendment at 1:00 p.m. on Monday, June 11, 2007 at the New Jersey Department of Health and Senior Services, First Floor Auditorium, Health and Agriculture Building, 369 South Warren Street (at Market Street), Trenton, NJ 08608. Persons wishing to testify at the public hearing who wish to be placed on the list of speakers are requested to telephone Mr. McDonough at (609) 984-7923 by Tuesday, June 5, 2007, and to bring an extra written copy of their remarks for submission to the public record.

The public has until July 20, 2007 to comment on the proposal. Persons wishing to comment on the proposal must submit their comments in writing to Dennis P. McDonough, M.P.H., Director, Clinical Laboratory Improvement Service, Division of Public Health and Environmental Laboratories, Public Health Protection and Emergency Preparedness Branch, Department of Health and Senior Services, P O Box 361, Trenton, NJ 08625-0361. Written comments must be postmarked on or before July 20, 2007, which is the close of the 60-day public comment period.

###