

HEALTH AND SENIOR SERVICES
PUBLIC HEALTH SERVICES BRANCH
DIVISION OF PUBLIC HEALTH AND ENVIRONMENTAL
LABORATORIES

CLINICAL LABORATORY IMPROVEMENT SERVICES

Chapter IV of the State Sanitary Code

Operation of Clinical Laboratories

Tests Performed

Proposed Amendment: N.J.A.C. 8:44-2.5

Authorized By: Fred M. Jacobs, M.D., J.D., Commissioner,

Department of Health and Senior Services, in consultation with the
Public Health Council, Herbert Yardley, M.A., Chair.

Authority: N.J.S.A. 26:1A-7 and 45:9-42.34 and 42.35; and Reorganization
Plan No. 003-2005 (June 27, 2005), 37 N.J.R. 2735(a) (August 1,
2005).

Calendar Reference: See Summary below for explanation of exception to
calendar requirement.

Proposal Number: PRN 2007-15B .

A public hearing on the proposed amendment will be held at

1:00 P.M. on Monday, June 11, 2007 at the following location:

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 comment on the proposal 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 June 5, 2007, and to bring an extra written copy of their remarks for submission to the public record.

Submit written comments by July 20, 2007 to:

Dennis P. McDonough, M.P.H., Director

Clinical Laboratory Improvement Services

Division of Public Health and Environmental Laboratories

Public Health Services Branch

Department of Health and Senior Services

PO Box 361

Trenton, NJ 08625-0361

The agency proposal follows:

Summary

N.J.A.C. 8:44, 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) provides or in specifically designated surveys that two specified proficiency testing providers provide.

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 perform proficiency testing pursuant to 42 CFR Part 493, the Federal regulations that implement the Clinical Laboratory Improvement Amendments of 1988.

As the Department has provided a 60-day comment period for this notice of proposal, this notice is excepted from the rulemaking calendar requirement, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The proposed amendment would ensure that proficiency testing of clinical laboratories is performed 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 proposed amendment would increase the number of eligible proficiency testing providers available to provide services to clinical laboratories that must

participate in proficiency testing, while ensuring that eligible providers are subject to uniform quality standards. As described in the Economic Impact, this may increase competition and enhance cost savings to clinical laboratories. Clinical laboratories in turn may pass on cost savings they may realize to consumers of clinical laboratory services, thereby reducing public healthcare costs generally.

Economic Impact

The proposed amendment would have an economic impact on CMS-approved proficiency testing providers by making those that are not eligible to provide required proficiency testing services under existing N.J.A.C. 8:44-2.5(b) eligible to perform those services and to generate revenues from the provision thereof. The proposed amendment would presumably have a negative impact on the two providers eligible to provide proficiency testing services under existing N.J.A.C. 8:44-2.5(b) by reducing the exclusivity of their provision of services to the clinical laboratory market in New Jersey. The proposed amendment would increase competition among CMS-approved proficiency testing providers, which may result in savings to clinical laboratories required to retain the services of proficiency testing providers.

Federal Standards Statement

The proposed amendment at N.J.A.C. 8:44-2.5(b) would be consistent with and would not exceed the 1988 Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. §263a, and the regulations CMS promulgates pursuant thereto at 42 CFR Part 493. Therefore, a Federal standards analysis is not required.

Jobs Impact

The Department does not anticipate that the proposed amendment would result in the generation or loss of jobs in the State.

Agriculture Industry Impact

The Department does not anticipate that the proposed amendment would have an impact on the agriculture industry of the State.

Regulatory Flexibility Statement

The proposed amendment would impose no requirements on small businesses as defined in the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. The existing rules require clinical laboratories to participate in proficiency testing. The proposed amendment expand the class of entities eligible to provide required proficiency testing services.

Full text of the proposed amendment follows (additions indicated in boldface **thus**; deletions in brackets [thus]):

8:44-2.5 Tests performed

(a) (No change.)

(b) All clinical laboratories shall enroll and successfully participate in [either the Department of Health] a proficiency testing [(PT)] program provided by either the Department of Health and Senior Services, or [specifically designated surveys in the College of American Pathologists' CAP Surveys Program or the American Association of Bioanalysts (AAB) PT Program] by a proficiency testing provider that the Centers for Medicare and Medicaid Services (CMS) has approved to perform proficiency testing pursuant to the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a, and the regulations CMS promulgates pursuant thereto at 42 CFR Part 493.

1. A list of CMS-approved proficiency testing providers is available at <http://www.cms.hhs.gov/CLIA/downloads/ptlist.pdf>, as amended and supplemented, or upon request to the Department.

2. Enrollment in [the CAP Surveys or AAB PT Programs must cover] a proficiency testing program with a provider other than the Department pursuant to (b) above shall encompass all clinical laboratory specialties, analytes and/or subspecialties for which a given laboratory is approved to perform tests [which have been designated by] that the Department has designated as requiring proficiency testing.

3. Laboratories shall: [enroll]

i. Enroll and participate in proficiency testing surveys appropriate to their level of service; [receive]

ii. Receive and examine and/or analyze specimens delivered by mail or messenger, at such times as designated by the proficiency testing provider; and [maintain]

iii. Maintain records of all proficiency testing results in surveys in which they participate and make such records, including results, interpretations and cumulative performance data routinely available to the Department of Health and Senior Services.

4. The Department of Health and Senior Services shall reserve authority to regrade data from [the CAP Surveys Program or the AAB PT Program] proficiency testing providers other than the Department (that is, survey scores and cumulative performance interpretations) through the Clinical Laboratory Improvement Service according to its own licensing standards.

5. Any report issued by [the CAP Surveys Program or the AAB PT Program] proficiency testing providers other than the Department by itself shall not be construed as determinative of compliance with the New Jersey licensing standards.

6. An exception to the enrollment requirements of this subsection may be made, provided the Department of Health and

Senior Services determines that an appropriate proficiency testing survey is not readily available.

(c) (No change.)