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Department of Public Health
Helping People Lead Healthy Lives In Healthy Communities

The Operation, Approval, and Licensing of Clinical Laboratories
Draft Regulations

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Public Health Council
January 13, 2016

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Outline

Today we will:

- Provide a brief introduction to the requirements for operation, approval, and licensing of clinical laboratories
- Describe current regulations, 105 CMR 180.000;
- Outline the proposed changes to clinical laboratory regulations.

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State and Federal Requirements

- 105 CMR 180.000 implements the requirements of chapter 111D of the General Laws, governing Massachusetts clinical laboratories by:
  - setting forth licensure and approval processes; and
  - establishing minimum standards for clinical laboratories, including those operating within DPH-licensed clinics or hospitals.
- Chapter 111D was enacted in 1975; the DPH regulations were initially promulgated in 1981.
- The statute and regulations predate the Clinical Laboratory Improvement Act of 1988 (CLIA), the federal requirements governing clinical laboratory testing.

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Need for Revision of State Regulations

- Since CLIA was implemented, Massachusetts clinical laboratories have been responsible for complying with both federal and state requirements.
- The Department has identified some issues:
  - State regulations have not kept pace with advances made in laboratory science, equipment and technology;
  - Regulated parties and other stakeholders confront significant differences between state and federal regulatory requirements.
- Although the Department made minor changes to the state regulation in 1989 and 1999, the Department has not conducted a substantive revision of 105 CMR 180 in over 30 years.

Process for Regulatory Review

- DPH sought the advice and assistance of the Clinical Laboratory Advisory Committee (the CLAC) (established under M.G.L. c. 111D, § 4) in the regulatory review and revision process.
- Beginning in 2010 through June 2014, the CLAC conducted a comprehensive review and analysis of state and national standards and recommended the **complete** revision of 105 CMR 180.000.

Slide 5

Proposed Revision

The proposed revision will achieve the following:

- Streamline state licensure types;
- Align state regulations with applicable federal regulations (except where state statutory requirements differ);
- Update terminology and requirements to conform to laboratory advances;
- Create standards for laboratories performing genetic testing; and
- Incorporate new legal amendments regarding consistent ownership definitions.

Slide 6

Proposed Revision Highlights-- Test Classification

Current regulations:

- Categorizes and defines laboratory tests as "simple laboratory test" or "complex laboratory test."
- The regulatory definitions of "simple" and "complex" laboratory testing are similar to the definitions used in chapter 111D.

Proposed revision:

- Updates terminology; and
- Defines tests using the nationally recognized CLIA classifications:
  - waived tests,
  - moderate complexity testing, and
  - high complexity testing.

Slide 7

Proposed Revision Highlights: Licensure Categories

Current regulations:

- Provides two types of laboratory licenses: full and limited.
- The determination as to which license applies depends on whether the laboratory performs "simple laboratory tests" or "limited laboratory examinations tests approved by the Department."

Proposed revision:

- Combines the licensure types and deletes references to outdated test categories.

Slide 8

Proposed Revision Highlights: Personnel Requirements

Current Regulation:

- Contains minimum qualifications/responsibilities for laboratory personnel, such as technical supervisor, general supervisors, technologists, cytotechnologists, technicians.

Proposed Revision:

- Reduces confusion between federal and state standards by deferring largely to CLIA except where state laboratory regulations differ.
  - Revised regulation retains minimum qualifications/responsibilities for Laboratory Director to conform to statute (Ch. 111D, section 7) but,
  - defers to CLIA for qualifications/responsibilities of other laboratory personnel.

Slide 9

Proposed Revision Highlights: Quality Control

Current Regulation:

- Requires laboratories to perform specific quality control (QC) both generally and by specialty areas.
- Many of the QC provisions use outdated terminology and do not conform to current industry practices.

Proposed Revision:

- Requires laboratories to follow CLIA requirements except for Immunohematology, Genetic Testing, and Health Promotion Screening.

Slide 10

Proposed Revision Highlights: Genetic Testing

Current Regulation:

- There are no specific state regulations and limited federal regulatory provisions for performing genetic testing.

Proposed Revision:

- The CLAC recommended including a new laboratory specialty area of Genetics with the following requirements:
  - Deemed-by-accreditation process whereby an accreditation organization would assess the laboratory's compliance with standards;
  - Specialized training or experience for the laboratory director and technical supervisor;
  - Test performance, analytic requirements (e.g. Quality Control and Proficiency Testing), reporting and Quality Assurance.

Slide 11

Proposed Revision Highlights Other Updates

Additional proposed revisions include the following:

- changing the regulatory definitions of "ownership interest" and "person" to conform to the 2014 statutory amendments pertaining to the prohibition against self-referrals;
- including regulatory provisions governing determinations of suitability for licensure;
- including a provision requiring every laboratory to have a disaster plan;
- updating the licensing fee provisions to conform to the current fees ($300.00) as authorized in 2004; and
- identifying a process for handling complaints related to laboratory performance.

Slide 12

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Next Steps

Next Steps:

- The Department intends to conduct a public hearing to solicit comments on the proposed revision.
- Following the public comment period, the Department will return to the Public Health Council to report on testimony and any recommended changes to this revision, and seek final promulgation.

Slide 13

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Contact Information

- Thank you for the opportunity to present this information today.
- For more information on clinical laboratories please find the relevant statutory language and the full current regulation here:
  https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter111D
  http://www.mass.gov/eohhs/docs/dph/regs/105cmr180.pdf

Please direct any questions to:
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Slide 14