

Proposed Rescission of 105 CMR 380.000: Approval of Bacteriological and Serological Laboratories

Massachusetts Department of Public Health

April 13, 2016

Alison Mehlman, Senior Deputy General Counsel

Contents

- I. Background
- II. Proposed Rescission
- III. Next Steps/Questions



I. Background

- Chapter 111, s.184A, of the General Laws was enacted in 1939 to allow DPH to issue certificates of approval to operate a bacteriological laboratory in Massachusetts.
- Regulations to implement this law were promulgated in 1939.
- The law was amended in 1946 to add authority for DPH to also issue certificates of approval for laboratory tests for milk, foods, eating utensils, and water and sewage.
- The last substantive amendment to the regulation was in 1986.

I. Background *continued*

- More recent state and federal laws and regulations have been adopted that govern the licensing of clinical laboratories that test blood:
 - 105 CMR 180.000: *The Operation, Approval, and Licensing of Clinical Laboratories*
 - 42 CFR 493 – *Laboratory Requirements*, issued pursuant to the Clinical Laboratory Improvement Amendments (CLIA)
- The CLIA regulations are a federal program for oversight of clinical laboratory testing and establish quality standards for lab testing of human specimens, including blood, body fluid and tissue, for diagnosis, prevention, or treatment of disease or assessment of health.

I. Background *continued*

- The other provisions of these regulations that implement the 1946 statutory amendments regarding the testing of milk have been superseded by more up-to-date Food Code regulations.
- 105 CMR 541.000: *Milk and Milk Products, Grade A Condensed and Dry Milk Products, Grade A Condensed and Dry Whey, and Milk Pasteurization Plants* requires labs to have certificates of approval for testing milk and milk products.
- Dairy labs are evaluated by State Laboratory Evaluation Officers in accordance with U.S. Food and Drug Administration (FDA) guidelines and these standards will remain in place under DPH's State-Federal Cooperative Agreement with FDA.
- Note: The 105 CMR 541.000 regulations are being incorporated into the new consolidated Food Code regulations, 105 CMR 500.000: *Good Manufacturing Practices for Food*.

II. Proposed Rescission

- The provisions of these regulations requiring certificates of approval to test blood specimens and dairy products have been superseded by more recent laws and regulations.
- Since 105 CMR 380.000 is duplicative of other DPH and federal regulations and is outdated, DPH is proposing to rescind these regulations.

III. Next Steps/Questions

- Following this initial presentation, a public hearing and comment period will be held.
- Following review of any comments, DPH intends to request approval to rescind these regulations at a subsequent meeting of the Public Health Council.
- Following final approval, this regulation will be rescinded.

Questions?

