

ADOPTIONS SECTION

HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF PUBLIC HEALTH INFRASTRUCTURE, LABORATORIES, AND

EMERGENCY PREPAREDNESS

PUBLIC HEALTH AND ENVIRONMENTAL LABORATORIES

CLINICAL LABORATORY IMPROVEMENT SERVICES

Notice of Readoption

Clinical Laboratory Services

Notice of Readoption: N.J.A.C. 8:45

Authority: N.J.S.A. 26:1A-33, 45:9-42.30, and 45:9-42.35.

Authorized By: Judith M. Persichilli, RN, BSN, MA, Commissioner, Department of Health.

Effective Date: September 29, 2021.

New Expiration Date: September 29, 2028.

Take notice that, pursuant to N.J.S.A. 52:14B-5.1, the Commissioner (Commissioner) of the Department of Health (Department) hereby readopts N.J.A.C. 8:45, Clinical Laboratory Services, which was scheduled to expire on November 20, 2020. Pursuant to Executive Order Nos. 127 (2020) and 244 (2021) and P.L. 2021, c. 103, any chapter of the New Jersey Administrative Code that would otherwise have expired during the Public Health Emergency originally declared in Executive Order No. 103 (2020) is extended through January 1, 2022. Therefore, this chapter has not yet expired and the 30-day filing date pursuant to

N.J.S.A. 52:14B-5.1.c has not yet occurred, therefore, pursuant to Executive Order No. 244 (2021), and P.L. 2021, c. 103, this notice of readoption is timely filed.

N.J.A.C. 8:45 establishes clinical laboratories licensure requirements and fees, as well as the fees for services performed by the New Jersey Department of Health, Public Health and Environmental Laboratories (PHEL). Subchapter 1, Licensure of Clinical Laboratories, establishes the licensure requirements for clinical laboratories, license renewal process, and licensing fees. Subchapter 2, Laboratory Charges, establishes the fee schedule that PHEL may charge for testing services.

The Department is developing a rulemaking to extensively revise, update, and reorganize existing N.J.A.C. 8:45, and anticipates filing this rulemaking with the Office of Administrative Law for processing in the ordinary course. However, the COVID-19 pandemic necessitated the reallocation of many Department personnel and resources to pandemic response activities, hindering the Department's efforts to finalize the anticipated rulemaking prior to chapter expiration. Therefore, the Department will not be able to finalize the anticipated rulemaking prior to the expiration of existing N.J.A.C. 8:45.

The Commissioner has reviewed N.J.A.C. 8:45 and has determined that, pending the finalization of the anticipated rulemaking described above, the existing chapter remains necessary, proper, reasonable, efficient, understandable, and responsive to the purposes for which the Department originally promulgated it, as amended and supplemented over time, and should be readopted.

Therefore, pursuant to N.J.S.A. 52:14B-5.1, N.J.A.C. 8:45 is readopted and shall continue in effect for seven years.