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To: All New Jersey Clinical Laboratory Owners and Directors

SUBJECT: Guidance Memorandum Regarding Certain Revisions of the New Jersey Clinical Laboratory Improvement Act, N.J.S.A. 45:9-42.26 et seq.

On January 9, 2017, Governor Christie signed into law amendments to the New Jersey Clinical Laboratory Improvement Act (Act), N.J.S.A. 45:9-42.26 et seq. See New P.L.2016, Chapter 86, Senate, No. 976. The amendments to the Act took effect immediately upon enactment.

In response to this legislation, the New Jersey Department of Health's Clinical Laboratory Improvement Services (CLIS) is issuing this guidance memorandum to explain the amendments to the Act and how CLIS is implementing the amendments pending official changes to the rules at N.J.A.C. 8:44-2.1 et seq. The guidance is as follows:

I. The amendments to the Act exempt from CLIS licensure those facilities that perform only point-of-care laboratory testing. Facilities that perform only point-of-care laboratory testing must meet **all four criteria** listed below in order to be exempt from licensure.

   1. The instrument or kit must be used in close proximity to the patient for whom the test or examination is being conducted;

   2. The instrument or kit must be used to perform testing outside the physical facilities of a non-waived laboratory;

   3. The testing instrument, kit or test:

      i. is used to perform waived tests or moderate complexity clinical laboratory tests or examinations classified under the federal "Clinical Laboratory Improvement Amendments of 1988," Pub.L.100-578 (42 U.S.C. s.263a) and any regulations adopted pursuant thereto;

      ii. is used to perform tests or examinations on biological specimens that require no preparation after collection; and

      iii. is used to perform tests or examinations without the necessity for testing personnel to perform calibration or maintenance, except resetting pursuant to the manufacturer's instructions or basic cleaning or disinfecting; **and**

4. For moderate complexity testing, the testing instrument, kit, or test is used in accordance with the patient test management system, the quality control program, and the comprehensive quality assurance program established and maintained by the laboratory pursuant to the standards established under the "Clinical Laboratory Improvement Amendments of 1988," Pub.L.100-578 (42 U.S.C. s.263a), any regulations adopted pursuant thereto, and any other procedures currently or subsequently approved by the federal Centers for Medicare & Medicaid Services and specified in Appendix C of the State Operations Manual.

II. The amendments to the Act also provide that quality control program standards for clinical laboratories shall not exceed the standards set forth in the federal regulations promulgated pursuant to the "Clinical Laboratory Improvement Amendments of 1988," Pub.L.100-578 (42 U.S.C.s.263a), effective as of January 1, 2016, or as subsequently amended, including the following alternative quality control testing procedures approved by the federal Centers for Medicare and Medicaid Services:

1. Two levels of quality control materials run every day of patient testing; or

2. Individualized Quality Control Plans (IQCP), as specified in Appendix C of the State Operations Manual, as amended and supplemented; and

3. any other quality control procedures subsequently approved by the Centers for Medicare and Medicaid Services and specified in Appendix C of the State Operations Manual.

Thus, any quality control program standards currently set forth in N.J.A.C. 8:44 that exceed the above federal requirements will not be enforced by CLIS in order to be in compliance with the Act's amendments.

III. Under the amendments to the Act, CLIS is required to recognize all waived tests under the "Clinical Laboratory Improvement Amendments of 1988" (Public Law 100-578) 42 U.S.C. 263a and all regulations adopted pursuant thereto (42 C.F.R. Part 493). The amendments further require the standards for the use of waived tests by clinical laboratories to not exceed the standards set forth in the federal rules and regulations promulgated pursuant to the "Clinical Laboratory Improvement Amendments of 1988," Pub.L.100-578 (42 U.S.C.s.263a), effective as of January 1, 2016, or as subsequently amended, unless expressly required under this Act or determined by the Department to be necessary to protect the public health and are promulgated through the rule-making process. Accordingly, any current rules pertaining to CLIA Waived testing within N.J.A.C. 8:44 that conflict with the federal requirements will not be enforced by CLIS.

IV. New Jersey Schools that collect patient specimens and refer the specimens to a reference laboratory for testing must continue to retain a collection station license.

V. Collection stations must maintain CLIS licensure. Obtaining a CLIA Certificate of Waiver does not exempt a collection station from state licensure.

VI. For laboratory complaints or concerns, CLIS maintains authority to investigate all clinical laboratories, including collection stations, requiring licensure by CLIS under the Act.

VII. Pursuant to the amendments of the Act, anatomic pathology, such as histopathology, is now within the scope of practice of a clinical laboratory, thereby requiring licensure by CLIS. CLIS will provide additional guidance on the licensure process for facilities performing anatomic pathology in the near future.

Please note:

All applications with payments from now-exempt facilities received on or after January 9, 2017 will be returned.

CLIS has initiated the rule-making process to further improve all rules to safeguard the health and safety of New Jersey residents.

CLIS strongly encourages those facilities that only perform point-of-care laboratory testing to maintain good laboratory practices, which include but are not limited to: the training of testing personnel, competency evaluation, proficiency testing participation, and performance of quality control (if applicable).

Please review the P.L.2016, Chapter 86, Senate No. 976 carefully to ensure your laboratory's compliance. http://www.njleg.state.nj.us/2016/Bills/PL16/86_.PDF

If you have any questions or comments, please e-mail joan.mikita@doh.nj.gov.

Sincerely,

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References:
P.L.2016, Chapter 86 Senate, No. 976
N.J.S.A. 45:9-42.26 et seq.
N.J.A.C. 8:44-2.1 et seq.
CMS (42 CFR 493)