State of New Jersey
DEPARTMENT OF HEALTH
PO BOX 360
TRENTON, N.J. 08625-0360
www.nj.gov/health

PHILIP D. MURPHY
Governor

TAHESHA L. WAY
Lt. Governor

KAITLAN BASTON, MD, MSC, DFASAM
Commissioner

To: All New Jersey Clinical Laboratory Owners and Directors

From: Alan Rimmer, MD
Executive Director
Clinical Laboratory Improvement Services
Public Health and Environmental Laboratories

Subject: **Revised** Guidance Memorandum Regarding Recording, Reporting and Training Requirements for Race, Ethnicity, Sexual Orientation, and Gender Identity of Patients, as required by N.J.S.A. 45:9-42.46 to -42.49

This revised guidance memorandum supersedes the guidance memorandum to clinical laboratories issued on November 16, 2022 and December 22, 2022.

The New Jersey Department of Health, Clinical Laboratory Improvement Services (CLIS) is issuing this guidance memorandum to inform clinical laboratories licensed to operate in New Jersey of statutory requirements that were enacted under the New Jersey Clinical Laboratory Improvement Act (the Act), N.J.S.A. 45:9-42.26 et seq. Specifically, N.J.S.A. 45:9-42.45 to -42.49, P.L. 2021, c. 454 as amended by P.L. 2022, c.44, require: 1) clinical laboratories to record and report certain patient demographic information, namely race, ethnicity, sexual orientation, and gender identity; 2) clinical laboratory electronic medical records systems to include demographic data entry features; and 3) clinical laboratories to implement cultural competency training programs. A copy of the law is attached to this guidance memorandum. The statutory requirements took effect on January 18, 2023, except for the recording and reporting requirements for sexual orientation and gender identity, which took effect on July 18, 2023.

The guidance is as follows:

1. **Patient Demographic Information (N.J.S.A. 45:9-42.46(a)(1)-(4))**

    a. N.J.S.A. 45:9-42.46(a)(1) requires clinical laboratories to record the race, ethnicity, sexual orientation, and gender identity of each patient who presents with a non-electronic order for testing at a clinical laboratory patient service center. In other words, when a patient presents at a clinical laboratory patient service center, as defined at N.J.A.C. 8:44-2.14(b), with a paper order for a laboratory test, the clinical laboratory must capture the patient's race, ethnicity, gender identity and sexual orientation. The statute outlines the terms/selections that clinical laboratories are to use when recording a patient's demographic information unless the Commissioner of Health modifies them as she deems appropriate or pursuant to federal requirements. Based upon a

review of these terms/selections, the Department will promulgate rules to modify the terms/selections outlined in N.J.S.A. 45:9-42.46(a)(1) to conform with federal requirements and the needs of the Department. As the Department works to promulgate rules on this matter, the Department is issuing this guidance memorandum to inform clinical laboratories how the Department's Communicable Disease Reporting and Surveillance System (CDRSS) will receive race, ethnicity, sexual orientation, and gender identity data. The Department will accept the following terms/selections as it promulgates rules on this specific topic:

i. Race: Terms/selections that comply with 45 C.F.R. 170.315(a)(5)(i)(A), which the Department has supplemented. These terms/selections are as follows:

    a. American Indian or Alaska Native;
    b. Asian;
    c. Black or African American;
    d. Native Hawaiian or Other Pacific Islander;
    e. White;
    f. Other;
    g. Unknown;
    h. Asked but unknown;
    i. Choose not to disclose.

ii. Ethnicity: Terms/selections that comply with 45 C.F.R. 170. 315(a)(5)(i)(A), which the Department has supplemented. These terms/selections are as follows:

    a. Hispanic or Latino;
    b. Non-Hispanic or Non-Latino;
    c. Other;
    d. Unknown;
    e. Asked but unknown;
    f. Choose not to disclose

iii. Sexual Orientation: Terms/selections that comply with 45 C.F.R. 170. 207(o)(1), which the Department has supplemented:

    a. Lesbian, gay, or homosexual;
    b. Straight or heterosexual
    c. Bisexual;
    d. Something else, please describe;
    e. Don't know;
    f. Choose not to disclose;
    g. Not applicable

iv. Gender Identity: Terms/selections that comply with 45 C.F.R. 170.207(o)(2), which the Department has supplemented:

a. Male;
b. Female;
c. Female-to-Male (FTM)/Transgender Male/Trans Man;
d. Male-to-Female (MTF)/Transgender Female/Trans Woman;
e. Genderqueer, neither exclusively male nor female;
f. Additional gender category or other, please specify;
g. Choose not to disclose;
h. Not applicable

b. **In the event that a patient is not present when a clinical laboratory processes a specimen, the clinical laboratory** is not responsible for recording and reporting the patient's gender identity, sexual orientation, and racial and ethnic information and **may record "not provided" in lieu of the other selections provided above**. Please note that the term/selection "not provided" is only to be used when the patient is not present, and the associated data has not been provided to the clinical laboratory with the specimen.

c. To capture the demographic information, the statutory requirements require clinical laboratories to modify their non- electronic specimen collection and analysis requisition forms that they distribute to include a section for the manual entry of a patient's racial, ethnic, sexual orientation, and gender identity information.

d. As stated above, these statutory requirements took effect on January 18, 2023, except for the recording and reporting requirements for sexual orientation and gender identity, which took effect on July 18, 2023. The Department is currently updating CDRSS to accept the sexual orientation and gender identity data. Clinical laboratories should not electronically report sexual orientation or gender identity data unless CLIS or the Department's Communicable Disease Service advises that CDRSS is able to receive said data.

2. Electronic Medical Records/Data (N.J.S.A. 45:9-42.47)

a. N.J.S.A. 45:9-42.47 states that any electronic medical records or laboratory information management systems used by a clinical laboratory in this State or sold by a vendor of such system in this State for use by a clinical laboratory shall be configured in a manner that prevents an authorized user from saving or storing a patient's demographic information unless a selection of a patient's gender identity, sexual orientation, and racial and ethnic information is recorded. The statute further requires laboratory orders that are generated by an electronic medical record system to include a patient's race, ethnicity, gender identity and sexual orientation information. However, clinical laboratories are not prohibited from receiving, processing, or saving data that is related to specimens that are ordered or received from outside of New Jersey.

If a clinical laboratory has more than one electronic medical record or laboratory information management system where demographics are captured (for instance, a registration system and a practice management system), the clinical laboratory is required to configure at least one system in a manner that prevents an authorized user from saving or storing a patient's demographic information unless a selection for gender identity, sexual orientation, and racial and ethnic information is recorded. Although the clinical laboratory is required to configure only one system, the gender identity, sexual orientation, and racial and ethnic information must be recorded in all electronic medical record or laboratory information management systems that the clinical laboratory utilizes.

3. <u>Cultural Competency Training</u>

a. N.J.S.A. 45:9-42.49 requires each clinical laboratory to implement an evidence-based cultural competency training program for all staff members employed by or working under the supervision of the clinical laboratory who have direct contact with patients and are responsible for collecting race and ethnicity, sexual orientation, or gender identity information from patients.

b. Each cultural competency training program implemented by clinical laboratories must include training on how to collect patient demographic information in a culturally competent and sensitive manner and may include the following topics/components:

   i. common terminology for race, ethnicity, sexual orientation and gender identity data;
   ii. information on when each designation may be appropriate, including when it is appropriate to collect sexual orientation and gender identity data versus when it is appropriate to choose "not applicable;"
   iii.
   iv. information on the relationship between patient health and collecting race, ethnicity, sexual orientation and gender identity data;
   v. information on how race, ethnicity, sexual orientation and gender identity data will be used;
   vi. information on how to navigate discomfort in patients and staff when asking patients for their race, ethnicity, sexual orientation and gender identity information; and
   vii. information on how to create an inclusive and affirming environment for all patients.

c. Clinical laboratories are also responsible for ensuring that each staff member who is employed by or working under the supervision of the clinical laboratory, has direct contact with patients, and is responsible for collecting race, ethnicity, and sexual orientation information from patients, completes the cultural competency training program at such times and intervals as the laboratory shall

require, and completes a cultural competency refresher course at least once biennially if completion of the course is deemed necessary by the laboratory.

d. The Department recommends that clinical laboratories develop internal policies and procedures to assist their staff with collecting patient demographic information in a way that is culturally competent and clinically appropriate, including procedures for recording the information for patients for whom sexual orientation and gender identity information is not applicable.

Please review N.J.S.A. 45:9-42.46 to -42.49. carefully to ensure your laboratory's compliance. If you have any questions or comments, please email CLIS@doh.nj.gov

References: N.J.S.A. 45:9-42.46 et seq.