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December 20, 2022

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.

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 new 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, were recently enacted, which 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 new law is attached to this guidance memorandum. The new statutory requirements take effect on January 18, 2023, except for the recording and reporting requirements for sexual orientation and gender identity, which take 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), as amended and supplemented. The current version of 45 in C.F.R. 170.207(o)(1) provides the following terms/selections:

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.

iv. Gender Identity: Terms/selections that comply with 45 C.F.R. 170.207(o)(2) as amended and supplemented. The current version of 45 C.F.R. 170.207(o)(2) provides the following terms/selections:

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.

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 new 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 take effect on January 18, 2023, except for the recording and reporting requirements for sexual orientation and gender identity, which take effect on July 18, 2023. In other words, clinical laboratories shall record and report race and ethnicity data

in accordance with N.J.S.A. 45:9-42.46 beginning on January 18, 2023. However, the reporting requirement for sexual orientation and gender identity data does not take effect until July 18, 2023. The Department is currently updating CDRSS to accept the sexual orientation and gender identity data, in accordance with 45 C.F.R. 170.207(o), so that clinical laboratories may begin reporting this data on the effective date of the statute. However, clinical laboratories should not begin reporting sexual orientation or gender identity data to CDRSS on July 18, 2023, 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.

b. In the event that a clinical laboratory's electronic medical record or laboratory management system is not configured by January 18, 2023 to prevent 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 Department may impose necessary

corrective action. The Department will provide clinical laboratories with an additional 120-days from the January 18, 2023 effective date to comply with N.J.S.A. 45:9-42.47, if the clinical laboratory submits the *Corrective Action Attestation Form* (enclosed) to the Department by January 18, 2023. The Attestation requires a clinical laboratory to describe the specific steps that will be taken by the laboratory to achieve compliance within 120 days following the January 18, 2023 effective date; acknowledge legal obligations and penalties; and provide relevant vendor information. Completed *Corrective Action Attestation Forms* shall be submitted to CLIS via email at CLIS@doh.nj.gov or via U.S. Mail at either of the following addresses:

Regular Mail:
New Jersey Department of Health
Clinical Laboratory Improvement Services
Attn: Clinical Laboratory Licensing
P.O. Box 361, Trenton, NJ 08625-0361

Overnight Delivery:
New Jersey Department of Health
Clinical Laboratory Improvement Services
Attn: Clinical Laboratory Licensing
3 Schwarzkopf Drive, Ewing, NJ 08628

Upon receipt of a clinical laboratory's executed Corrective Action Attestation Form, CLIS will review and determine whether additional corrective action steps are needed.

3. Cultural Competency Training

   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 the relationship between patient health and collecting race, ethnicity, sexual orientation and gender identity data;
iii. information on how race, ethnicity, sexual orientation and gender identity data will be used;
iv. information on how to navigate discomfort in patients and staff when asking patients for their race, ethnicity, sexual orientation and gender identity information; and
v. 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.

For additional information concerning clinical laboratories, CLIS has attached its 2017 guidance memorandum regarding previous revisions to the Act.

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.
2017 guidance memorandum
Corrective Action Attestation Form

NEW JERSEY DEPARTMENT OF HEALTH
CORRECTIVE ACTION ATTESTATION FORM
PURSUANT TO N.J.S.A. 45:9-42.47

SECTION I. Instructions & Background Information

This Corrective Action Attestation Form (Form) is intended for use by **[name of clinical laboratory]** to report compliance status with N.J.S.A. 45:9-42.47, which will become effective on January 18, 2023. Please ensure that you have fully read the Form prior to signing the attestation at the bottom and return the Form to the New Jersey Department of Health (Department), Clinical Laboratory Improvement Services (CLIS) via email at CLIS@doh.nj.gov or via U.S. Mail at either of the following address:

Regular Mail
New Jersey Department of Health
Clinical Laboratory Improvement Services
Attn: Clinical Laboratory Licensing
P.O. Box 361, Trenton, NJ 08625-0361

Overnight Delivery:
New Jersey Department of Health
Clinical Laboratory Improvement Services
Attn: Clinical Laboratory Licensing
3 Schwarzkopf Drive, Ewing, NJ 08628

SECTION II. Compliance Statement

By submitting this Form to the Department, **[name of clinical laboratory]** confirms (please review and check all that apply):

☐ [**name of clinical laboratory] <u>is not currently</u>** in compliance with N.J.S.A. 45:9-42.47, and **<u>does not</u>** expect to be able to achieve compliance by January 18, 2023.

☐ [**name of clinical laboratory**] has a corrective action plan with specific steps that will ensure full compliance with all components of N.J.S.A. 45:9-42.47, no later than May 18, 2023 (which is 120 days following the effective date of January 18, 2023).

SECTION III. Corrective Action

To achieve compliance by May 18, 2023, **[name of clinical laboratory]** has identified specific steps and actions, which it has already begun or will begin soon, which include the following (please provide additional details as requested):

☐ Taken (or plans to take) all of the following specific steps and implemented (or will implement) necessary safeguards to ensure that the technology/system is configured in a manner that prevents an authorized user from saving or storing a patient's demographic information into the electronic medical records management technology/system, unless a selection for patient's racial, ethnic, sexual orientation, and gender identity information is recorded.

Specific steps include the following (please describe each step separately and in detail and note whether the step is completed, ongoing, or not initiated yet):
Click or tap here to enter text.

SECTION IV: Acknowledgement of Legal Obligations & Penalties

☐ By checking this box and submitting this Form to the Department, **[name of clinical laboratory]** confirms that it understands its legal obligations pursuant to the requirements outlined in N.J.S.A. 45:9-42.47, as well as the associated corrective action that may be taken and civil penalties imposed by the Department.

SECTION V: Vendor Information

Relative to the electronic medical record technology/system requirements in N.J.S.A. 45:9-42.47, **[name of clinical laboratory]** (select the one that applies):

☐ Manages and oversees an in-house electronic medical records technology/system, and does not utilize a third-party vendor. Corrective action will be taken by **[name of clinical laboratory]** as described in Section III above.

☐ Contracts with a third-party vendor for use of an electronic medical record technology/system. Corrective action will be taken by **[name of clinical laboratory]** as described in Section III above, in partnership with its contracted vendor. The contracted vendor's contact information is as follows:

- Vendor Name: Click or tap here to enter text.
- Vendor Address:Click or tap here to enter text.
- Vendor Website:Click or tap here to enter text.
- Primary Point of Contact (POC) Name:Click or tap here to enter text.
- Primary POC Email Address:Click or tap here to enter text.
- Primary POC Phone Number:Click or tap here to enter text.

SECTION VI: Attestation & Signature:

By signing this Form, **[name of clinical laboratory]** attests that it will be in compliance with N.J.S.A. 45:9-42.47 by **May 18, 2023** as outlined in Section III above. **[name of clinical laboratory]** agrees to provide the Department with regular updates on progress towards compliance, and understands that the Department is committed to actively working with your clinical laboratory to monitor progress with respect to this Form.

Name of Chief Executive Officer (CEO) or Designee	Date
Signature of CEO or Designee	Email Address
Title of CEO or Designee	Phone Number