Frequently Asked Questions (FAQs):
Recording, Reporting, and Training Requirements for Race, Ethnicity, Sexual Orientation, and Gender Identity Information (SOGI) of Patients, as required by N.J.S.A. 45:9-42.46 through 42.49, and N.J.S.A 26:2H-5.36

Section A.   General Compliance:

Q1.   Question: We are a clinical lab that receives specimens via courier for processing only. We do not collect specimens. We do not see any patients. What do we need to do to comply with this law?

Answer: When a clinical laboratory processes a specimen without the presence of a patient and the patient's race, ethnicity, and SOGI information are not provided with the specimen, the laboratory may record "not provided" for those demographic fields in their system. If you do receive the race, ethnicity, and/or SOGI data with the specimen, you must record that data in your system. If you are required to report to the New Jersey Department of Health's Communicable Disease Reporting and Surveillance System (CDRSS), you must report the race, ethnicity, and SOGI information for the patient, or report "not provided" if you do not receive the demographic information, when making that report using a system that is compatible with CDRSS. If your lab supplies non-electronic specimen collection and analysis requisition forms, then the forms must be updated to include a section to manually enter the patient's race, ethnicity, and SOGI information.

Q2.   Question: If our lab does not do any testing that is potentially reportable to CDRSS, does this law even apply to us?

Answer: Yes. Reporting data to CDRSS is only one aspect of the law. The law also requires clinical laboratories to record the race, ethnicity, and SOGI data of their patients. Additionally, the law requires changes to clinical laboratories' and acute care hospitals' (ACH) electronic medical records or laboratory information management systems (LIMS) by configuring the systems in a manner that prevents an authorized user from saving or storing a patient's demographic information unless a selection for race, ethnicity, and SOGI have been selected. Additionally, the law requires any non-electronic specimen collection and analysis requisition forms that that a laboratory circulates to be updated/revised in order for the requisition form to collect race, ethnicity, and SOGI data. Furthermore, the law also requires clinical laboratories and ACHs to train their staff that interacts with patients on how to collect the demographic information in a culturally competent and sensitive manner.

Q3.   Question: We are a clinical lab located out of state. We have employees and/or contractors who collect specimens in New Jersey. We process the specimens, which are sent to us by courier. Does the law apply to us?

Answer: The law applies to all clinical laboratories that are licensed by the Department, Clinical Laboratory Improvement Services (CLIS), pursuant to the New Jersey Clinical Laboratory Improvement Act, N.J.S.A. 45:9-42.26 to -42.49.

Q4. **Question:** We are a collection station in the state. What are our obligations under this law?

Answer: Collection stations are considered clinical laboratories pursuant to N.J.S.A. 45:9-42.27 and N.J.S.A. 45:9-42.28 and are licensed by CLIS as such. Accordingly, the law's requirements for clinical laboratories equally apply to collection stations.

Section B.   Compliance with Recording Requirements:

Q1. **Question:** What are the specific race, ethnicity, and SOGI selections that are required to be recorded under this new law?

Answer: The race, ethnicity, and SOGI terms/selections that the CDRSS system accepts are listed in the CLIS Guidance Memo issued to all New Jersey licensed clinical laboratories on December 20, 2022, which describes in more detail the recording, reporting, and training requirements as required by N.J.S.A. 45:9-42.46 to 42.49 (the "CLIS Guidance Memo"). A link to the CLIS Guidance Memo can be found below.

Q2. **Question:** Do we have to collect the SOGI information from infants, patients under 18 years of age, patients who have dementia, or in other circumstances that make it difficult to collect the additional demographic information required by this law?

Answer: The Department recognizes the concerns and challenges faced by clinical laboratories with collecting SOGI information from certain patient populations. However, the law does not contain any patient exclusions or age limitations for collecting the information. Accordingly, clinical laboratories must collect the SOGI information for all patients, regardless of age or condition, to the best of their abilities. Please note that the law also requires clinical labs and ACHs to train their staff to collect the demographic information in a culturally competent and sensitive manner, which will assist staff with collecting the information from a diverse patient population.

Q3. **Question:** How often do we have to ask patients for their race, ethnicity, and SOGI information? For instance, are clinical labs/ACHs required to record the information at every patient encounter or only once for each patient?

Answer: Clinical labs and ACHs must collect the race, ethnicity, and SOGI information at each patient encounter. ACHs should follow their own policies and procedures when determining whether a new patient encounter exists in certain circumstances (e.g., a patient presents to the Emergency Department for treatment and is then admitted to the hospital).

Section C.   Compliance with Reporting Requirements:

Q1. **Questions:** Are clinical labs required to send SOGI data to CLIS?

Answer: No. The law requires that race, ethnicity, and SOGI data is reported to CDRSS. This law does not require the demographic information to be reported to CLIS.

Q2.   Question: When clinical labs are reporting SOGI data to CDRSS, what HL7 values should be utilized?

Answer: If clinical labs are reporting to CDRSS electronically, CDRSS cannot currently accept SOGI data elements because Health Level Seven International (HL7) has not yet communicated the HL7 standards/mapping for those two data elements. CDRSS is waiting for the HL7 standards concerning SOGI data to be finalized. Once HL7 communicates the standards and mapping for SOGI data, CDRSS will begin incorporating the new SOGI standards and mapping in order for CDRSS to accept SOGI data elements. CDRSS anticipates that it will not be able to accept SOGI data values electronically via HL7 standards by the law's effective date of July 18, 2023. CDRSS will communicate with stakeholders when CDRSS is able to accept SOGI values electronically via HL7 standards. Please note, HL7 values for race and ethnicity are currently available and accepted by CDRSS.

As for manual reporting, CDRSS anticipates that it will be able to accept the SOGI data selections outlined in the CLIS Guidance Memo beginning July 18, 2023, which is the effective date of the new law. A link to the CLIS Guidance Memo can be found below. Please note that the law requires the reporting of race and ethnicity of a patient by January 18, 2023, but SOGI data reporting does not begin until July 18, 2023.

Q3.   Question: Do ACHs have to report SOGI data to the NJ Hospital Discharge Data Collection System (NJDDCS) through Uniform Bill (UB) information?

Answer: No. The reporting requirements of the law do not apply to UB information within NJDDCS. The reporting requirements only apply to health care related data (inclusive of race, ethnicity, and SOGI) required to be reported by a clinical laboratory to the appropriate disease reporting surveillance system, which is CDRSS.

Section D.   Compliance with N.J.S.A. 45:9-42.47:

Q1.   Question: If we submitted a Corrective Action Attestation Form, is there going to be an additional grace period concerning the requirements for electronic medical records (EMR) or laboratory information management systems (LIMS) to be configured in a manner that prevents an authorized user from saving/storing a patient's demographic information unless a selection for race, ethnicity, and SOGI have been included??

Answer: Consistent with N.J.S.A. 45:9-42.47, the Department accepted Corrective Action Attestation Forms from clinical labs and ACHs if they were submitted to the Department by January 18, 2023. The Corrective Action Attestation Forms completed by clinical labs and ACHs outlined whether the organization was in compliance with N.J.S.A. 45:9-42.47 (i.e., configuring its EMR or LIMS by requiring users to select race, ethnicity, and SOGI before saving/storing a patient's information) and, if not, the organization's corrective action plan to achieve compliance. If your clinical lab or ACH submitted a Corrective Action Attestation Form to the Department by January 18, 2023, your clinical lab or ACH was provided with an additional 120 days to comply with the requirements of N.J.S.A. 45:9-42.47. In other words, if your clinical lab or ACH submitted a Corrective Action Attestation Form to the Department, you were provided with a grace period to comply with N.J.S.A. 45:9-42.47 until May 18, 2023. Thus, full compliance will be expected by May 18th for the clinical labs and ACHs that submitted Corrective Action Attestation Forms.

If your clinical lab or ACH did not submit an Attestation Form to the Department by January 18, 2023, then you were required to comply with the requirements of N.J.S.A. 45:9-42.47 by January 18, 2023. There is no grace period for clinical labs or ACHs that did not submit an Attestation Form. Full compliance with N.J.S.A. 45:9-42.47 was expected by the law's effective date, January 18, 2023.

Section E.   Compliance with Training Requirement:

Q1.   Question: Can CLIS or the Department provide us with cultural competency training or recommend a company that provides cultural competency training?

Answer: No. The Department does not provide training. For additional resources regarding cultural competency, please see the below links from the U.S. Department of Health and Human Services (HHS), the National Institute of Health (NIH), and the Centers for Medicare and Medicaid Services (CMS):

- https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=1&lvlid=6#:~:text=OMH%20developed%20the%20National%20Standards,services%2C%20and%20help%20eliminate%20disparities.
- https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/clear-communication/cultural-respect
- https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/CLAS-Toolkit-12-7-16.pdf

Please note that the law requires that the training include the following information: how to collect patient demographic information in a culturally competent and sensitive manner. The law states that the training *may* also include related topics which are listed in the ACH Guidance Memo and CLIS Guidance Memo. A link to the ACH Guidance Memo and CLIS Guidance Memo can be found below.

If you have any questions about this law or your obligations, ACHs should email DOH-Financial.Reports@doh.nj.gov and clinical labs should email CLIS@doh.nj.gov. For clinical laboratories, please provide your CLIS license # and relevant information about the lab's operations.

CLIS Guidance Memo:
- https://www.nj.gov/health/phel/documents/CLIS_Doc/Final%20SOGI%20Lab%20Guidance%20Memo%20REVISED%2012.16.22.pdf

ACH Guidance Memo:
- https://nj.gov/health/hcf/documents/Hospital_Guidance_Memo_Revised_2-10-23.pdf