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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, sexual orientation and/or gender identity (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 when provided. Additionally, the law requires changes to clinical laboratories' 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 a laboratory circulates to be updated/revised in order for the requisition form to collect race, ethnicity, and SOGI data. A selection for "not applicable" for SOGI data can be offered or provided when necessary. Furthermore, the law also requires clinical laboratories to train their staff that interacts with patients on how to collect the demographic information in a culturally competent

and sensitive manner. This includes knowing when the collection of SOGI data is clinically relevant and/or when to choose “not applicable.”

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 of Health, Clinical Laboratory Improvement Services, 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 March 25, 2025, 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 newborns, 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. The law requires that SOGI data be collected in a culturally competent way and that staff be trained in how to collect SOGI data in a culturally competent and clinically appropriate manner. To ensure that staff collect SOGI data in a way that is culturally competent and clinically appropriate, the Department recommends that clinical laboratories and acute care hospitals develop internal policies and procedures to assist their staff with collecting the data from their patients, including procedures for recording the information for patients for whom SOGI information is not clinically appropriate, such as newborns and infants.

To account for circumstances when the collection of SOGI data is not clinically appropriate or unable to be identified, clinical laboratories and acute care hospitals should develop SOGI data recording procedures using prompts that make clear that a response is not required, such as “not applicable,” or prompts that make clear that a response is otherwise is “unknown” or was “not provided.” This can be applied to any age or population for which SOGI data is not clinically or medically able to be known as it is not clinically applicable unless the individual patient is physically, cognitively, and emotionally able to express it. The policies and procedures should be based upon trusted and

evidence-based sources, such as the 2018 policy statement by the American Academy of Pediatrics (AAP) entitled “Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents.” The recommended policies and procedures would be in addition to, and not in replace of, the statutorily required training that clinical laboratories must provide to their staff on the manner in which to collect the demographic information in a culturally competent, sensitive and clinically appropriate manner.

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 laboratories must record the race, ethnicity, and SOGI information at each patient encounter.

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 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 accepts the SOGI data selections outlined in the CLIS Guidance Memo. A link to the CLIS Guidance Memo can be found below.

Q3. Question: Do acute care hospitals 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 Training Requirement:

Q1. Question: Can CLIS or NJDOH 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 American Academy of Pediatrics, The American Academy of Family Physicians, and Harvard University. :

- <https://www.aap.org/en/patient-care/lgbtq-health-and-wellness/a-pediatricians-guide-to-an-lgbtq-friendly-practice/>
- <https://www.aafp.org/pubs/afp/issues/2018/1201/p645.html>

- <https://dicp.hms.harvard.edu/sites/default/files/202210/SOGI%20Data%20Collection.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 CLIS Guidance Memo. A link to the 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.

The 2018 policy statement by the American Academy of Pediatrics (AAP) entitled "Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents":

<https://publications.aap.org/pediatrics/article/142/4/e20182162/37381/Ensuring-Comprehensive-Care-and-Support-for?autologincheck=redirected>

CLIS Guidance Memo:

<http://www.nj.gov/health/phel/clinical-lab-imp-services/>

Hospital Guidance Memo:

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