THE NEW JERSEY SOCIETY OF PATHOLOGISTS

March 17, 2022

Via email: Joy.Lindo@doh.nj.gov

Ms. Joy L. Lindo
Office of Legal and Regulatory Compliance
New Jersey Department of Health
55 North Willow Street
Trenton, NJ 08618

Re: Query Related to New Jersey Public Law 454 (AB 4253) of 2021.

Dear Director Lindo:

On behalf of the New Jersey Society of Pathologists (NJSP), I am writing to request clarification regarding ambiguous and potentially conflicting provisions in New Jersey Public Law 454 (AB 4253) of 2021. To clarify clinical laboratory compliance with implementation of the law, we pose the following question:

> Question: Can a pathologist or other laboratory personnel, as an authorized user, in a clinical laboratory that receives a patient specimen without the presence of the patient, input into a laboratory information system (LIS) available, medically relevant demographic information, when other information relating to gender identity, sexual orientation, and race/ethnic information is not obtained or transmitted by the ordering physician who took the patient specimen at another location?

NJSP is concerned that the law could be misconstrued by laboratory information system vendors and information technology administrators to establish and require a software lockout feature that denies an "authorized user," including the patient's pathologist responsible for a medical diagnosis, from entering "demographic information" that is available to the laboratory (including, i.e., age, biological sex, primary language and relevant clinical medical history) **"unless a patient's gender identity, sexual orientation, and racial and ethnic information is recorded."** (Section 3)

Notwithstanding the verbiage cited above, other provisions clearly affirm that no such lockout provision is contemplated, as the statute expressly recognizes when a clinical laboratory possesses a patient specimen "without the presence of a patient" that the clinical laboratory "**shall not be responsible for recording and reporting the patient's gender identity, sexual orientation, and racial and ethnic information**." See excerpted section as follows:

> Section: 2. a. (1) A clinical laboratory shall electronically 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. **If a clinical laboratory processes a specimen without the presence of a patient the clinical laboratory shall not be responsible for recording and reporting the patient's gender identity, sexual orientation, and racial and ethnic information**.

The law also makes clear that: "Nothing in this act shall be construed to compel a patient to disclose the patient's race, ethnicity, sexual orientation, or gender identity to a clinical laboratory, health care provider, or any other entity." The law adequately provides an option for a clinical laboratory to select "**does not wish to disclose**" for race, ethnicity, sexual orientation, and gender identity to account for a patient's nondisclosure of demographic information. (Section 2 (a)(1) 2-4).

The law provides that the Commissioner of Health may "modify, by regulation, the race, ethnicity, sexual orientation, and gender identity selections provided in subsection a. of this section as appropriate or pursuant to federal requirements." (Section 4(e)).

We encourage the Department of Health to provide an additional option, such as "not available/applicable" for clinical laboratories to select in the laboratory information system when a patient's demographic data is not made available for entry or is missing per the transmittal from the ordering physician.

In response to the question, we posed in this correspondence, we seek to obtain needed clarification to ensure that pathologist medical practice is not impaired by erroneous information technology implementation of any lockout feature that would deny supervising or diagnosing pathologists, and other laboratory personnel, the ability to enter known demographic information for patients in situations where other information regarding the patient is unavailable.

We do not believe that the law was constructed with the intent to block the medically appropriate data entry of known demographic patient information, but we want to preclude, in advance, such scenarios that would be erroneously premised upon a misconstrued application of the law.

We look forward to receiving this clarification in response to our question so that we can disseminate it in advance of the law's effective date. Thank you for your courtesies and consideration of this request.

Sincerely,

Valerie A. Fitzhugh, MD

Valerie A. Fitzhugh, MD
President, New Jersey Society of Pathologists

cc: Barry R. Ziman, Director Legislation and Political Action, College of American Pathologists