Florida Medical Association

How the new DNA privacy law could affect your practice

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On June 29, 2021, Gov. Ron DeSantis signed into law HB 833, the "Protecting DNA Privacy Act." The stated purpose of the legislation is to protect a person's DNA from being collected or analyzed without his or her consent. To prevent the unauthorized use of a person's DNA information, the legislation establishes new criminal offenses applicable to persons who willfully, and without express consent:

- Collect or retain another person's DNA sample with the intent to analyze such sample
- Submit another person's DNA sample for analysis or conduct or procure the conducting of such analysis
- Disclose another person's DNA analysis to a third party, unless such results were previously voluntarily disclosed by the person whose DNA was analyzed
- Sell or otherwise transfer another person's DNA sample or analysis results to a third party

HB 833 will have the biggest impact on physicians who employ DNA testing in their practices. Physicians who collect or submit a patient's DNA sample for DNA analysis will have to first obtain the patient's express consent to do so.

"Express consent" is defined as "authorization by the person whose DNA is to be extracted or analyzed, or such person's legal guardian or authorized representative, evidenced by an affirmative action demonstrating an intentional decision, after the person receives a clear and prominent disclosure regarding the manner of collection, use, retention, maintenance, or disclosure of a DNA sample or results of a DNA analysis for specified purposes."

This means that physicians who wish to have a patient's DNA analyzed for a specified purpose need to explain to the patient how the DNA sample will be collected, used, retained, and maintained, and how the results of the DNA analysis will be used. This information ideally will be set forth in a document that the patient signs clearly stating that it is the patient's express intent to allow the DNA sample to be collected and a DNA analysis to be performed for the purposes specified, and in the manner set forth in the consent form. The legislation allows physicians to obtain a single express consent for every instance of a specified purpose or use.

Unfortunately, one provision in HB 833 will potentially affect all physicians, not just those who utilize DNA testing in their practices. Subsection (5) of the newly created section 817.5655 provides that "it is unlawful for a person to willfully, and without express consent, sell or otherwise transfer another person's DNA sample or the results of another person's DNA analysis to a third party, regardless of whether the DNA sample was originally collected, retained, or analyzed with express consent." This

provision is problematic due to the use of the term "DNA sample," which HB 833 defines as "any human biological specimen from which DNA can be extracted or the DNA extracted from such specimen."

Thus, HB 833 makes it a crime to transfer any human biological specimen from which DNA can be extracted to a third party without the express consent of the patient. This would apparently include having medical waste, which could include blood, hair, or skin cells, picked up for disposal by a third party, or sending laundry soiled with blood or urine to an outside service for cleaning.

While absolutely not the intent of this legislation, as evidenced by statements made on the floor of the Florida House requested by the FMA, the new statute does not provide any exceptions for the transfer of DNA samples or material containing DNA samples for disposal or cleaning. The exceptions that were included provide that the provisions of the new law do not apply when the DNA sample/analysis is used for the purposes of:

- Criminal investigation or prosecution
- Complying with a subpoena, summons or other lawful court order
- Complying with federal law
- Medical diagnosis, conducting quality assessments, improvement activities, and treatment of a patient when either (1) express consent for clinical laboratory analysis was obtained by the health care practitioner who obtained the DNA sample, or (2) performed by a clinical laboratory certified by the Centers for Medicare and Medicaid Services
- The newborn screening program
- Determining paternity
- Performing any activity authorized under s. 943.325 (statute governing the statewide DNA database)
- Conducting research, and designing and preparing such research, subject to the requirements of, and in compliance with certain federal regulations; or utilizing information that is deidentified consistent with federal regulations and that is originally collected and maintained for research

While the FMA does not expect that law enforcement will begin arresting healthcare providers for failing to obtain express consent from patients prior to properly disposing of medical waste containing blood or bodily fluids, given that the violation of the new law constitutes a second-degree felony, we recommend that physicians incorporate the sample consent form into their practices. The FMA will work to clarify the law and remove this inadvertent requirement during the next legislative session.

Fortunately, the FMA and the Florida Society of Pathologists were able to amend HB 833 to include the certified clinical laboratory exception. With this change, physicians will not have to go through the hassle of obtaining express consent when submitting blood, urine, tissue, or any other type of human biological specimen to a CMS-certified clinical laboratory for analysis not involving the patient's DNA.

If you are an FMA member who has questions regarding HB 833 and how it affects your practice, please contact our General Counsel's office at (850) 224-6496 or legal@flmedical.org.