

March 10, 2022

Via Email: Killian@lrc.ky.gov

Representative Killian Timoney 702 Capital Avenue Annex Room 405 Frankfort, KY 40601

Re: Urgent Request for Technical Amendment -- HB 529 (Release of Patient Test Results)

Dear Representative Timoney:

On behalf of the Kentucky Society of Pathologists (KSP) and with the support of the College of American Pathologists (CAP), I am writing to urge an amendment to House Bill 529. Without this amendment, pathologists and clinical laboratory directors could face federal non-compliance legal risk.

Currently, this legislation would require a 72-hour delay in the release of certain test results to a patient. However, the language of the legislation does not clarify that the obligation to withhold the test result must be assigned to those who administer and control the patient's electronic health record. Without this explicit clarification, the state law would not establish a clear legal safe harbor to protect pathologists and clinical laboratory directors against a violation of the federal 21st Century Cures Act, Pub. L. No. 114-255, and its related federal regulations.

Please note, pathologists as laboratory directors do not administer or control the electronic health record (EHR) for patients. The EHR, which is cited in the legislation, is the portal wherein clinical laboratory test result information would reside for review by the ordering health care provider or the patient. Pathologists and other laboratory directors report finalized test results via the electronic interface of our laboratory information systems with the EHR. Accordingly, the legislation should expressly clarify that the means to delay the test result being accessed by the patient is through the EHR - not the laboratory information system (LIS).

Without this clarification, we are concerned that pathologists and clinical laboratories could face federal violations for unlawful information blocking which is not statutorily clarified or protected by House Bill 529. Accordingly, a minor, but fundamentally critical technical clarification in the verbiage of the bill is required, as follows:

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- (2) The following reports or test results and any other related results shall not be disclosed to a patient by the person or entity that administers and controls the patient's electronic health record as part of the patient's electronic health record until seventy-two (72) hours after the results are finalized, unless the health care provider directs the release of the results before the end of that seventy-two (72) hour period:
 - (a) Pathology reports or radiology reports that have a reasonable likelihood of showing a finding of malignancy; or
 - (b) Tests that could reveal genetic markers.

The red-font amendment language effectuates the intent of the bill and makes clear that those in control of the EHR are protected against any violation of the federal law, as such persons or entities are expressly safe-harbored under the amended bill language we are proposing. We regret that we were unable to offer this Amendment in the initial hearing on the bill. Nevertheless, the legislation presents an unintended legal risk for pathologists, unless the bill is amended to clarify the legal obligation and the protection from federal violation that is not provided under the current language of the legislation.

Thank you for your courtesies and consideration of this request.

Sincerely,

Amy SJGewirtz, MD

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President, Kentucky Society of Pathologists

Jeremy Hart, MD

State Issue Adviser, Kentucky Society of Pathologists

cc: Barry Ziman, Director, Legislation and Political Action, College of American Pathologists Corey Meadows, Kentucky Medical Association Cody Hunt, Kentucky Medical Association