February 22, 2021

Memorandum of Opposition
House Bill 995 (Destruction of Patient Specimens)

The Missouri Society of Pathologists (MSP) strongly opposes House Bill 995. There are clear medical, scientific, and legal reasons why clinical laboratories must retain patient specimens, including these points of information for the Committee to consider:

1. **REGULATORY REQUIREMENTS:** Clinical laboratories <u>are required</u> to retain patient specimens under the Federal Clinical Laboratory Improvement Amendments ("CLIA") of 1988 (42 U.S.C. § 263a). The time frame for retaining specimens under federal requirements (42CFR § 493.1105) can be as long as ten years. ***This federal law supersedes state law unless the state law is more stringent than the federal law***.
2. **PATIENT BENEFITS**: These include the potential retrospective need to test a specimen in cases where second opinions are needed, or where advances in diagnostic science require further analysis to see if patients qualify for most current cutting-edge treatments.
3. **MEDICOLEGAL ISSUES**: In legal cases of alleged medical errors, patient specimens are critical evidentiary material to document the accuracy of medical diagnosis or, conversely, a failure or omission in adherence to clinical standards of pathology diagnosis.
4. **EXISTING SAFEGUARDS**: Under both the Federal Health Insurance and Portability and Accountability Act (HIPAA) ("Privacy Rule"), and the Federal Policy for Protection of Human Subjects ("Common Rule") <u>*written consent from a patient must be obtained*</u> in order to use an identified patient diagnostic specimen for purposes of medical research. These requirements <u>apply to all</u> diagnostic clinical laboratories.

Each patient specimen constitutes an important part of the biological chronology of disease in the patient's medical record which cannot be replicated if destroyed. For example, the ability to retrieve an archived cancer specimen after initial diagnosis to determine whether a patient had a particular biomarker for which a new targeted therapy is available could change that patient's prognosis and the course of treatment.

In sum, for all these scientific, legal, and medical reasons, we strongly urge your rejection of this legislation.

Respectfully Submitted,

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