



810 West Bethany Home Road
Phoenix, AZ 85013

Hon. Heather Carter
Chair, House Health Committee, Arizona House

January 22, 2018

Re: HB 2450 Amendments Needed to Ensure Patients Access to Personalized Medicine for Diagnosis and Treatment

Dear Chairwoman Carter:

On behalf of the Arizona Society of Pathologists (ASP), I am writing to you and your committee to request amendment of the Arizona genetic testing law that is the subject of amendment under HB 2450. The ASP is a statewide medical specialty society, comprised of many pathologists in the state who actively practice in academic medical centers, hospitals, and independent laboratories.

In 2016, Arizona enacted a modified law (A.R.S. 20-448.02) that mistakenly encompassed in a faulty definition for "genetic testing" as those tests that are fundamental to patient diagnosis and treatment for medical conditions such as cancer. This definition, if enforced, would be a substantial impediment to the routine practice of pathology medicine in the state and would hinder patient care.

Specifically, existing AZ Law 20-448.02 prohibits the ordering (Chapter 37 Laws of 2016) of a genetic test on a patient specimen by a pathologist without "the specific written informed consent of the subject." The definition of "genetic test" for such informed consent is as follows:

"Genetic test" means an analysis of an individual's DNA, gene products or chromosomes that indicates a propensity for or susceptibility to illness, disease, impairment or other disorders, whether physical or mental, or that demonstrates genetic or chromosomal damage due to environmental factors, or carrier status for a disease or disorder

Because the definition used in multiple places in this statute is overly broad, a pathologist (who has no direct patient contact and thus very limited ability to secure a timely, supplemental patient informed consent in writing) is legally impeded from ordering or requiring the performance of a genetic test to diagnosis a patient, or in order to determine an optimal therapeutic treatment that may be targeted to a somatic mutation in the patient's cancer. In some cases, the need for genetic testing may be imperative and time sensitive, depending on the patient specimen.

For example, most cancer diagnoses now involve some form of molecular/genetic testing for biomarkers to aid treatment decisions. **In many of these cases, pathologists order these tests, and some of these orders are made based upon an initial pathologist examination of the specimen.** In addition, many tests that are normally not considered genetic tests but rather detect proteins (gene products) are encompassed by this definition. **The standard of care in other states allows pathologists to order these tests as medically necessary without legal impediment or legal encumbrance** (i.e. without Informed consent in addition to the informed consent obtained by the treating physician who obtained the specimen).

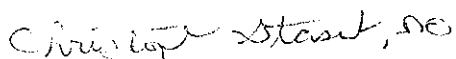
The need to exclude **diagnostic testing** from the informed consent requirement for predictive genetic testing for inherited conditions is widely accepted in public policy and codified in other state laws that govern this area. (See other state laws: M.G.L.A 111 70(G) (A) (5) excludes from informed consent any “test for the purpose of diagnosing or detecting an existing disease, illness, impairment or disorder.” N.M. Stat Ann § 24-21-3 (c)(11) exempts any “laboratory conducting an analysis or test of a specified individual pursuant to a written order to the laboratory from a health care practitioner or the health care practitioner’s agent, including by electronic transmission.” Iowa Code § 729.6 (e) “ ‘Genetic testing’ does not mean routine physical measurement, a routine chemical, blood, or urine analysis, a biopsy, an autopsy, or clinical specimen obtained solely for the purpose of conducting an immediate clinical or diagnostic test to detect an existing disease, illness, impairment, or disorder, or a test for drugs or for human immunodeficiency virus infections.”)

Moreover, recent advances in targeted therapies and diagnostic assays all incorporate genetic/molecular testing as a standard of care. Quite simply, Arizona with this overly broad definition is inadvertently impeding access to the most current diagnostic and therapeutic practices that are now routinely used around the nation and saving patients’ lives. The most direct way to remedy the statute is to amend the definition that appears in multiple places in the statute. The amendment to the definition we suggest is underscored below:

"Genetic test" means an analysis of an individual's DNA, gene products or chromosomes that indicates a propensity for or susceptibility to illness, disease, impairment or other disorders, whether physical or mental, or that demonstrates genetic or chromosomal damage due to environmental factors, or carrier status for a disease or disorder, except for a test ordered for diagnosis or treatment of the individual if performed in a clinical laboratory that has received a specimen referral from the individual's treating physician who has obtained the specimen or another clinical laboratory.

House Bill 2450 gives the Arizona Legislature an opportunity to refine the existing definition in statute so as to remove improperly conceived impediments to high quality pathology diagnostic services that are counter to the interests of patients. Thank you for your courtesies and consideration of our requested amendment.

Sincerely,



Christopher J Stasik, DO, FCAP
President, Arizona Society of Pathologists

cc; Pele Fischer, Vice President, Arizona Medical Association, pele@azmed.org