



February 16, 2015

(Via email [hcarter@azleg.gov](mailto:hcarter@azleg.gov) / first class mail)

Representative Heather Carter  
Chair, House Health Committee  
Arizona House of Representatives  
1700 W. Washington, Room 303  
Phoenix, Arizona 85007

*Re: Request for Amendment to House Bill 2645 – Direct Access Laboratory Tests*

Dear Chairperson Carter:

On behalf of the Arizona Society of Pathologists (ASP) and the College of American Pathologists (CAP), I am requesting an amendment to House Bill 2645 (Direct Access Laboratory Tests). The ASP is a state medical specialty society representing many practicing pathologists in Arizona. The CAP is a national medical specialty society representing nearly 18,000 physicians who practice clinical and anatomic pathology in community hospitals, independent clinical laboratories, academic medical centers and federal and state health facilities.

Both ASP and CAP have no objection to providing patients with clinical laboratory tests, provided: (i) that the decision to provide such tests is a decision of the laboratory provider and is not compelled under law; and (ii) that any test being provided to a patient be reliable as evidenced by the laboratory's participation for that test in a federally approved proficiency testing program, when available for the particular test.

**Rationale for Proposed Amendments (underscored)**

Proposed Amendment 1 – 36-468 A. A person may obtain any laboratory test without a physician's request or written authorization; provided, however that the provision of such testing is a decision of the laboratory provider.

It is the position of CAP and ASP that each individual laboratory should make its own determination, based upon the interest of the patient, legal exposure of the laboratory, medical staff bylaws, and other relevant medical or financial considerations, whether to accept requests for diagnostic laboratory services directly from patients. Simply stated, laboratories should not be compelled to accept these requests which entail medical judgment and which can have substantial impact on individuals, their families and their health care.

In addition, laboratories will need to condition the provision of tests on certain financial criteria to ensure advance payment by the individual or prospective ability to pay for testing, since such testing is not covered by third party payers. Moreover, given the ability of consumers to access laboratory tests through willing participation of certain laboratory providers, we do not believe that the discretion to provide laboratory tests will impede the ability of consumers to access laboratory testing.

Proposed Amendment 2 – 36-468 New Section (E). Any laboratory test ordered under this section, regardless of test complexity, as defined under the clinical laboratory improvement amendments of 1988, must be provided by a laboratory that routinely participates in proficiency testing for such test in a program approved by the Centers for Medicare and Medicaid Services. This provision shall not be construed to mandate proficiency testing for a laboratory test if it is not available from any approved program.

It is the position of CAP and ASP that all clinical laboratory testing used for the diagnosis, prevention, treatment and assessment of human disease should be subject to quality control and proficiency testing. It is the CAP's belief that no test is so simple and straightforward to perform that erroneous results cannot occur and that no incorrect test result is "risk free" or inconsequential with regard to potential harm.

Laboratory participation in proficiency testing, where available, is in the best interests of patients directly ordering these tests. Such participation should not adversely affect patient direct access to laboratory testing. Moreover, we believe that given the absence of physician participation in the ordering and review of clinical laboratory tests, when directly ordered and availed by patients, there is an imperative and heightened public safety need to ensure a more rigorous state requirement for the testing. Thus, the proposed requirement for proficiency testing by a federally approved program reduces the potential for erroneous tests results, especially with respect to waived tests that are not otherwise subject to this requirement under federal law.

Please feel free to contact Barry Ziman, Director of Legislation and Political Action, College of American Pathologists, at 202-354-7116 if you have questions regarding these amendments. Thank you for your courtesies and consideration of these amendment requests.

Sincerely,



Richard Trepeta, MD

President, Arizona Society of Pathologists

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