



ARIZONA STATE SENATE
Fifty-Second Legislature, First Regular Session

FACT SHEET FOR H.B. 2645

laboratory testing without physician order
(NOW: laboratory testing; without order)

Purpose

Allows a person to obtain any laboratory test from a licensed clinical laboratory on a direct access basis without a health care provider's request or written authorization.

Background

The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing, with the exception of research, performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). In total, CLIA covers approximately 244,000 laboratory entities with the objective of ensuring quality laboratory testing (cms.gov). CLIA is regulated by the federal government through the Department of Health Services' (DHS) Clinical Laboratory Program (Program). The Program is charged with certifying and regulating laboratories that perform clinical laboratory tests for the diagnosis, prognosis, treatment of disease and health screening services of all certified clinical laboratories in this state. Additionally, the Program investigates complaints and ensures compliance with state and federal laws to assure that high quality standards are maintained.

The Advisory Committee on Clinical Laboratories (Committee) was established to advise DHS in developing a list of direct access tests (tests that may be obtained without a physician referral including tests that have been granted waived status under CLIA), and statute requires DHS to make the list available to the public. Additionally, the Committee is required to advise DHS on the use and renewal of standing orders (A.R.S. § 36-466).

There is no anticipated fiscal impact to the state General Fund associated with this legislation.

Provisions

1. Allows a person to obtain any laboratory test from a licensed clinical laboratory on a direct access basis without a health care provider's request or written authorization if the laboratory offers that laboratory test to the public on a direct access basis without a health care provider's request or written authorization.
2. Requires, if the laboratory test is conducted by or under the supervision of a person other than a health care provider and not at the request or with the written authorization of a health care provider, the report of the test results to:

FACT SHEET

H.B. 2645

Page 2

- a) be provided by the person conducting the test to the person who was subject of the test; and
 - b) state in bold type that it is the responsibility of the person who was tested to arrange with the person's health care provider for consultation and interpretation of the test results.
3. States, if the health care provider did not request or authorize the laboratory test, the following apply:
 - a) the health care provider's duty of care to a patient does not include any responsibility to review or act on the laboratory test result; and
 - b) the health care provider is not subject to the liability or disciplinary actions for the failure to review or act on the results of the laboratory test.
 4. States that a laboratory test is not required to be covered by a health insurance plan or by any plan administered by the Arizona Health Care Cost Containment System.
 5. Exempts DHS from rulemaking requirements for one year to amend or adopt rules to address changes in direct access laboratory testing.
 6. Removes the requirement that the Committee advise DHS in developing a list of direct access tests, and removes the requirement of DHS to make the list of direct access tests available to the public.
 7. Defines *health care provider*.
 8. Removes the definition of *direct access tests*.
 9. Makes conforming changes.
 10. Becomes effective on the general effective date.

House Action

HEALTH	2/17/15	DPA	6-0-0-0
3 rd Read	2/19/15		57-0-3

Prepared by Senate Research

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