

Senate Engrossed House Bill

FILED

MICHELE REAGAN
SECRETARY OF STATE

State of Arizona
House of Representatives
Fifty-second Legislature
First Regular Session
2015

CHAPTER 222

HOUSE BILL 2645

AN ACT

AMENDING SECTION 36-466, ARIZONA REVISED STATUTES; AMENDING TITLE 36, CHAPTER 4.1, ARTICLE 2, ARIZONA REVISED STATUTES, BY ADDING SECTION 36-468; RELATING TO CLINICAL LABORATORIES.

(TEXT OF BILL BEGINS ON NEXT PAGE)

1 Be it enacted by the Legislature of the State of Arizona:

2 Section 1. Section 36-466, Arizona Revised Statutes, is amended to
3 read:

4 36-466. Advisory committee on clinical laboratories;
5 membership; duties

6 A. The advisory committee on clinical laboratories is established
7 consisting of the following members:

8 1. Four physicians who are licensed pursuant to title 32, chapter 13
9 or 17 and who are actively engaged in the practice of medicine. The director
10 shall appoint these members.

11 2. Two physicians who are licensed pursuant to title 32, chapter 13 or
12 17 and who are employed by a clinical laboratory as pathologists. The
13 director shall appoint these members.

14 3. The director or the director's designee.

15 B. The committee shall:

16 1. Annually select a chairperson and vice-chairperson from among its
17 members.

18 ~~2. Advise the department in developing a list of direct access tests.~~
19 ~~The department shall make the list of direct access tests available to the~~
20 ~~public.~~

21 ~~3.~~ 2. Advise the department on the use and renewal of standing
22 orders.

23 ~~4.~~ 3. Conduct regular meetings at the call of the chairperson or a
24 majority of the committee members.

25 ~~C. The department's designation of a test as a direct access test does~~
26 ~~not require that the test be covered by a health insurance plan or product~~
27 ~~pursuant to title 20 or by any program administered by the Arizona health~~
28 ~~care cost containment system administration pursuant to chapter 29 of this~~
29 ~~title.~~

30 ~~D.~~ C. The department shall adopt rules based on the recommendations
31 of the advisory committee.

32 ~~E.~~ D. Committee members are not eligible to receive compensation or
33 reimbursement of expenses.

34 ~~F.~~ E. The department shall provide necessary staff services to the
35 committee.

36 ~~G.~~ F. The appointed committee members serve three-year terms.

37 ~~H. For the purposes of this section, "direct access tests" means tests~~
38 ~~that may be obtained without a physician referral including tests that have~~
39 ~~been granted waived status under the federal clinical laboratory improvement~~
40 ~~amendments of 1988 (P.L. 100-518). Direct access tests do not include tests~~
41 ~~that are required to be reported to this state for public health and safety~~
42 ~~reasons.~~

1 Sec. 2. Title 36, chapter 4.1, article 2, Arizona Revised Statutes, is
2 amended by adding section 36-468, to read:

3 36-468. Laboratory testing without health care provider's
4 order; results; report; duty of care; liability;
5 definition

6 A. A PERSON MAY OBTAIN ANY LABORATORY TEST FROM A LICENSED CLINICAL
7 LABORATORY ON A DIRECT ACCESS BASIS WITHOUT A HEALTH CARE PROVIDER'S REQUEST
8 OR WRITTEN AUTHORIZATION IF THE LABORATORY OFFERS THAT LABORATORY TEST TO THE
9 PUBLIC ON A DIRECT ACCESS BASIS WITHOUT A HEALTH CARE PROVIDER'S REQUEST OR
10 WRITTEN AUTHORIZATION.

11 B. IF A LABORATORY TEST OF A PERSON IS CONDUCTED BY OR UNDER THE
12 SUPERVISION OF A PERSON OTHER THAN A HEALTH CARE PROVIDER AND NOT AT THE
13 REQUEST OR WITH THE WRITTEN AUTHORIZATION OF A HEALTH CARE PROVIDER, ANY
14 REPORT OF THE TEST RESULTS SHALL BE PROVIDED BY THE PERSON CONDUCTING THE
15 TEST TO THE PERSON WHO WAS THE SUBJECT OF THE TEST. THE REPORT SHALL STATE
16 IN BOLD TYPE THAT IT IS THE RESPONSIBILITY OF THE PERSON WHO WAS TESTED TO
17 ARRANGE WITH THE PERSON'S HEALTH CARE PROVIDER FOR CONSULTATION AND
18 INTERPRETATION OF THE TEST RESULTS.

19 C. A HEALTH CARE PROVIDER'S DUTY OF CARE TO A PATIENT DOES NOT INCLUDE
20 ANY RESPONSIBILITY TO REVIEW OR ACT ON THE LABORATORY TEST RESULTS OF A
21 PATIENT IF THE HEALTH CARE PROVIDER DID NOT REQUEST OR AUTHORIZE THE
22 LABORATORY TEST. A HEALTH CARE PROVIDER IS NOT SUBJECT TO LIABILITY OR
23 DISCIPLINARY ACTIONS FOR THE FAILURE TO REVIEW OR ACT ON THE RESULTS OF A
24 LABORATORY TEST OF ANY PATIENT IF THE HEALTH CARE PROVIDER DID NOT REQUEST OR
25 AUTHORIZE THE LABORATORY TEST.

26 D. A CLINICAL LABORATORY MAY NOT SUBMIT A CLAIM FOR REIMBURSEMENT FROM
27 A THIRD-PARTY PAYOR FOR ANY LABORATORY TEST CONDUCTED WITHOUT A HEALTH CARE
28 PROVIDER'S REQUEST OR WRITTEN AUTHORIZATION.

29 E. THIS SECTION DOES NOT REQUIRE THAT A LABORATORY TEST BE COVERED BY
30 A HEALTH INSURANCE PLAN OR PRODUCT PURSUANT TO TITLE 20 OR BY ANY PROGRAM
31 ADMINISTERED BY THE ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM
32 ADMINISTRATION PURSUANT TO CHAPTER 29 OF THIS TITLE.

33 F. FOR THE PURPOSES OF THIS SECTION, "HEALTH CARE PROVIDER" MEANS A
34 PERSON WHO IS LICENSED PURSUANT TO TITLE 32 AND WHO IS AUTHORIZED TO ORDER
35 LABORATORY TESTING.

36 Sec. 3. Rulemaking; exemption

37 The department of health services shall amend or adopt rules to address
38 the changes in direct access laboratory testing as enacted by this act. For
39 this purpose, the department is exempt from the rulemaking requirements of
40 title 41, chapter 6, Arizona Revised Statutes, for one year after the
41 effective date of this act.

~~APPROVED BY THE GOVERNOR APRIL 6, 2015.~~

~~FILED IN THE OFFICE OF THE SECRETARY OF STATE APRIL 7, 2015.~~

Passed the House February 19, 20 15

by the following vote: 57 Ayes,

0 Nays, 3 Not Voting

[Signature]
Speaker of the House

[Signature]
Chief Clerk of the House

Passed the Senate March 24, 20 15

by the following vote: 24 Ayes,

2 Nays, 2 Not Voting

[Signature]
President of the Senate

[Signature]
Secretary of the Senate

EXECUTIVE DEPARTMENT OF ARIZONA
OFFICE OF GOVERNOR

This Bill received by the Governor this

_____ day of _____, 20____

at _____ o'clock _____ M.

Secretary to the Governor

Approved this _____ day of

at _____ o'clock _____ M.

Governor of Arizona

EXECUTIVE DEPARTMENT OF ARIZONA
OFFICE OF SECRETARY OF STATE

This Bill received by the Secretary of State

this _____ day of _____, 20____

at _____ o'clock _____ M.

Secretary of State

H.B. 2645

HOUSE CONCURS IN SENATE
AMENDMENTS AND FINAL PASSAGE

March 30, 2015,

by the following vote: 60 Ayes,

0 Nays, 0 Not Voting

[Signature]
Speaker of the House

[Signature]
Chief Clerk of the House

EXECUTIVE DEPARTMENT OF ARIZONA
OFFICE OF GOVERNOR

This Bill was received by the Governor this
30th day of March, 2015,

at 4:07 o'clock P. M.

[Signature]
Secretary to the Governor

Approved this 6th day of

April, 2015,

at 9:52 o'clock A M.

[Signature]
Governor of Arizona

H.B. 2645

EXECUTIVE DEPARTMENT OF ARIZONA
OFFICE OF SECRETARY OF STATE

This Bill was received by the Secretary of State
this 7th day of April, 2015,

at 8:30 o'clock A M.

[Signature]
Secretary of State