



**Bill Number: S.B. 1344**

**Shope Floor Amendment**

**Reference to: printed bill**

**Amendment drafted by: Michael Madden**

## **FLOOR AMENDMENT EXPLANATION**

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- **Waives the requirement that new congenital disorders be added to the Arizona newborn screening panel within two years of being added to the federal Recommended Uniform Screening Panel if a laboratory-developed test is used to identify the disorder but the test still requires premarket review and authorization by the U.S. Food and Drug Administration.**

SHOPE FLOOR AMENDMENT  
SENATE AMENDMENTS TO S.B. 1344  
(Reference to printed bill)

Amendment instruction key:

[GREEN UNDERLINING IN BRACKETS] indicates text added to statute or previously enacted session law.

[Green underlining in brackets] indicates text added to new session law or text restoring existing law.

[~~GREEN STRIKEOUT IN BRACKETS~~] indicates new text removed from statute or previously enacted session law.

[~~Green strikeout in brackets~~] indicates text removed from existing statute, previously enacted session law or new session law.

<<Green carets>> indicate a section added to the bill.

<<~~Green strikeout in carets~~>> indicates a section removed from the bill.

1 The bill as proposed to be amended is reprinted as follows:

2 Section 1. Section 36-694, Arizona Revised Statutes, is amended to  
3 read:

4 36-694. Report of blood tests; newborn screening program;  
5 committee; fee; definitions

6 A. When a birth or stillbirth is reported, the attending physician  
7 or other person required to report the birth shall state on the  
8 certificate whether a blood test for syphilis was made on a specimen of  
9 blood taken from the woman who bore the child or from the umbilical cord  
10 at delivery, as required by section 36-693, and the approximate date when  
11 the specimen was taken.

12 B. When a birth is reported, the attending physician or person who  
13 is required to report the birth shall order or cause to be ordered tests  
14 for certain congenital disorders, including hearing disorders. The  
15 results of tests for these disorders must be reported to the department of  
16 health services. The department of health services shall specify in rule  
17 the disorders, the process for collecting and submitting specimens and the  
18 reporting requirements for test results.

19 C. When a hearing test is performed on a newborn, the initial  
20 hearing test results and any subsequent hearing test results must be  
21 reported to the department of health services as prescribed by department  
22 rules.

23 D. The director of the department of health services shall  
24 establish a newborn screening program within the department to ensure that  
25 the testing for congenital disorders and the reporting of hearing test  
26 results required by this section are conducted in an effective and  
27 efficient manner. The newborn screening program shall include all  
28 congenital disorders that are included on the recommended uniform

1 screening panel adopted by the secretary of the United States department  
2 of health and human services for both core and secondary conditions.  
3 ~~Beginning January 1, 2022~~ EXCEPT AS OTHERWISE PROVIDED IN SUBSECTION E OF  
4 THIS SECTION, disorders that are added to the core and secondary  
5 conditions list of the recommended uniform screening panel shall be added  
6 to this state's newborn screening panel within two years after their  
7 addition to the recommended uniform screening panel. The newborn  
8 screening program shall include an education program for the general  
9 public, the medical community, parents and professional groups. The  
10 director shall designate the state laboratory as the only testing facility  
11 for the program, except that the director may designate other laboratory  
12 testing facilities for conditions or tests added to the newborn screening  
13 program on or after July 24, 2014. If the director designates another  
14 laboratory testing facility for any condition or test, the director shall  
15 require the facility to follow all of the privacy and sample destruction  
16 time frames that are required of the state laboratory.

17 E. THE TWO-YEAR TIME FRAME TO ADD DISORDERS TO THIS STATE'S NEWBORN  
18 SCREENING PANEL DOES NOT APPLY IF BOTH:

19 1. THERE IS NO COMMERCIALY AVAILABLE TEST METHOD APPROVED BY THE  
20 UNITED STATES FOOD AND DRUG ADMINISTRATION.

21 2. A LABORATORY-DEVELOPED TEST METHOD IS USED TO IDENTIFY THE  
22 DISORDER AND THE LABORATORY-DEVELOPED TEST METHOD REQUIRES UNITED STATES  
23 FOOD AND DRUG ADMINISTRATION PREMARKET REVIEW AND APPROVAL [OR  
24 AUTHORIZATION].

25 ~~F.~~ F. The newborn screening program shall establish and maintain a  
26 central database of newborns and infants who are tested for hearing loss  
27 and congenital disorders that includes information required in rule. Test  
28 results are confidential subject to the disclosure provisions of sections  
29 12-2801 and 12-2802.

30 ~~F.~~ G. If tests conducted pursuant to this section indicate that a  
31 newborn or infant may have a hearing loss or a congenital disorder, the  
32 screening program shall provide follow-up services to encourage the  
33 child's family to access evaluation services, specialty care and early  
34 intervention services.

35 ~~G.~~ H. The director shall establish a committee to provide  
36 recommendations and advice to the department on at least an annual basis  
37 regarding newborn screening best practices and emerging trends.

38 ~~H.~~ I. The director may establish by rule a fee that the department  
39 may collect for operating the newborn screening program, including  
40 contracting for the testing pursuant to this section. The director shall  
41 present any change to the fee for the newborn screening program to the  
42 joint legislative budget committee for review.

43 ~~I.~~ J. Not later than sixty days after the department adjusts the  
44 newborn screening program fee established pursuant to subsection ~~H~~ I of  
45 this section:

46 1. Each health insurer that is subject to title 20 shall update its  
47 hospital rates that include newborn screening to reflect the increase.

1           2. For the Arizona health care cost containment system and  
2 contractors acting pursuant to chapter 29, article 1 of this title that  
3 are not subject to title 20, the Arizona health care cost containment  
4 system shall update its hospital rates that include newborn screening to  
5 reflect the increase.

6           ~~J.~~ K. For the purposes of this section:

7           1. "Infant" means a child who is twenty-nine days of age to two  
8 years of age.

9           2. "Newborn" means a child who is not more than twenty-eight days  
10 of age.

11 Enroll and engross to conform

12 Amend title to conform

THOMAS "T.J." SHOPE

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