



**ARIZONA STATE SENATE**  
*Fifty-Seventh Legislature, First Regular Session*

**FACT SHEET FOR S.B. 1344**

newborn screening program

Purpose

Adds an exemption to 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 (RUSP) if laboratory testing is required but there is not yet a commercially available test approved by the U.S. Food and Drug Administration (FDA).

Background

The newborn screening program was established in the Department of Health Services to ensure that testing for congenital disorders and reporting of hearing test results for newborns is conducted in an effective and efficient manner. The Arizona State Public Health Laboratory screens every newborn in Arizona twice, once at 24-36 hours of age and again at 5-10 days old, for 35 different conditions, including but not limited to, sickle cell anemia, cystic fibrosis, hearing differences and congenital heart defects ([DHS](#)).

Statute requires the newborn screening panel to include all congenital disorders that are included on the RUSP adopted by the Secretary of the U.S. Department of Health and Human Services for both core and secondary conditions. Disorders that are added to the core and secondary conditions list of the RUSP must be added to Arizona's newborn screening panel within two years ([A.R.S. § 36-694](#)).

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

Provisions

1. Waives the requirement that new congenital disorders be added to the newborn screening panel within two years of being added to the RUSP if:
  - a) there is no commercially available test approved by the FDA; and
  - b) a laboratory-developed test is used to identify the disorder but the test still requires FDA premarket review and approval.
2. Makes technical and conforming changes.
3. Becomes effective on the general effective date.

Prepared by Senate Research  
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MM/AO/slp