FACT SHEET FOR H.B. 2491

newborn screening program

Purpose

Requires the Department of Health Services (DHS) Director (Director) to adopt rules requiring critical congenital heart defect screening using pulse oximetry to be ordered as a part of the Newborn Screening Program (NSP), adds hearing disorders to the panel of newborn tests and permits the Director to designate laboratories, other than the state laboratory, to test as outlined. Establishes an advisory committee within DHS to study and report on the financing and availability of vaccines as outlined by December 15, 2014.

Background

Pursuant to law, DHS established a newborn screening program to ensure that the testing for congenital heart disorders and the reporting of hearing test results that are required to be ordered by a physician attending a birth or a person required to make a report of a birth, are conducted in an effective and efficient manner. DHS specifies in rule the disorders to be tested, the process for collecting specimens and reporting requirements for test results. The U.S. Department of Health and Human Services recommends a panel of 31 screened disorders. Currently, Arizona has adopted 29 of the 31 recommended disorders to screen. Current statute requires the Director to designate the state laboratory as the only testing facility for the NSP (A.R.S. § 36-694).

According to the Centers for Disease Control and Prevention (CDC), using pulse oximetry to screen newborns can detect critical congenital heart defects in some infants, which accounts for about 25 percent of all congenital heart defects (cdc.gov). Pulse oximetry is the use of a device that measures the oxygen saturation of arterial blood by using a sensor attached typically to a person’s finger, toe or ear to determine the percentage of oxyhemoglobin in blood pulsating through a network of capillaries (Merriam-Webster.com).

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

Provisions

1. Requires, by July 1, 2015, DHS to adopt rules adding critical congenital heart defect screening using pulse oximetry to the panel of tests required to be ordered for every newborn delivered.
2. Adds hearing disorders to the panel of tests required to be ordered on each birth by the attending physician or person required to report on the birth.

3. Allows DHS to designate laboratory testing facilities, other than the state laboratory, for conditions or tests added to the NSP on or after the effective date of this act and requires the facility to follow all of the privacy and sample destruction timeframes required of the state laboratory.

4. Allows DHS to adopt rules adding severe combined immunodeficiency testing and Krabbe disease testing to the tests contained within the NSP and requires DHS to perform and consider a cost benefit analysis and seek stakeholder input from health care providers in the development of these rules.

Vaccine Study Committee

5. Establishes an advisory committee (committee) within DHS to study the financing and availability of vaccines for newborns, children and adolescents.

6. Requires the DHS Director to serve as the chairperson of the committee and appoint the following members:
   a) two representatives of different health care insurers that offer products that include coverage for newborn, childhood and adolescent vaccines;
   b) three licensed health professionals whose current practice includes administering newborn or childhood and adolescent vaccines as follows:
      i) a licensed physician specializing in pediatrics;
      ii) a licensed physician specializing in family medicine; and
      iii) a licensed and certified nurse practitioner;
   c) two directors of local health departments, one of whom must be from a county having a population of at least three million persons;
   d) one representative of an Arizona nonprofit statewide coalition whose mission is to foster a comprehensive, sustained community program for the immunization of Arizonans against vaccine-preventable diseases;
   e) one representative of a vaccine manufacturer or a national association of vaccine manufacturers and who has experience in vaccine policy;
   f) one representative of a statewide association of pharmacists; and
   g) one representative of an Arizona company that is not a health care insurer or a self-insured employer and that offers its employees a health insurance product in the commercial market that includes coverage for newborn, childhood and adolescent vaccines.

7. Requires the Directors of the Arizona Health Care Cost Containment System Administration and the Department of Insurance, or their designees, to serve as nonvoting members of the committee.

8. Prohibits committee members from receiving compensation or reimbursement of expenses.
9. Requires the committee to develop recommendations regarding the following and report findings to the Governor and Legislature by December 15, 2014:
   a) the existing system of the financing, storage, distribution and availability of newborn, childhood and adolescent vaccine products and the potential impacts on the health care system, taxpayers and the community at large;
   b) the costs associated with, and the adequacy of reimbursement levels for newborn, childhood and adolescent vaccines administered by private and public providers in all counties in all Arizona counties; and
   c) the vaccine financing, storage, distribution and reimbursement models utilized in other states.

10. Requires the committee, to the extent possible, to include and consider any estimated costs or cost savings to the state and local governments associated with the committee’s recommendations.

11. Allows the committee to:
   a) request information, data and reports from any state agency, political subdivision or other persons or businesses involved in the public or private financing or administration of newborn, childhood or adolescent vaccines; and
   b) hold hearings and take testimony from affected persons, including members of the public.

12. Requires the committee to maintain documents in a manner that preserves the confidentiality of confidential business information that may be disclosed to the committee during the course of its business.

13. Repeals the committee from and after December 31, 2015.

Miscellaneous

14. Exempts DHS from rulemaking through July 1, 2015, for the implementation of this act.

15. Becomes effective on the general effective date.

Amendments Adopted by Committee

- Stipulates that if the Director designates a laboratory testing facility, other than the state laboratory, the facility must follow all of the privacy and sample destruction timeframes that are required of the state laboratory.

Amendments Adopted by Committee of the Whole

1) Establishes an advisory committee within the Department of Health Services to study the financing and availability of vaccines for newborns, children and adolescents.

2) Requires the committee to develop recommendations as outlined and report findings to the Governor and Legislature by December 15, 2014.
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Prepared by Senate Research
April 21, 2014
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