

SB 808 A STAFF MEASURE SUMMARY

Senate Committee On Health Care

Action Date: 04/18/17

Action: Do pass with amendments and requesting referral to Ways and Means. (Printed A-Engrossed.)

Vote: 4-0-1-0

Yeas: 4 - Beyer, Kruse, Monnes Anderson, Steiner Hayward

Exc: 1 - Knopp

Fiscal: Fiscal impact issued

Revenue: No revenue impact

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WHAT THE MEASURE DOES:

Requires Oregon Health Authority (OHA) to adopt rules specifying that a health testing service may conduct a newborn screening test when the federal Food and Drug Administration (FDA) approves of a new methodology after a health condition is added to the most recent edition of the Recommended Uniform Screening Panel (RUSP). Requires screening laboratories in Oregon that provide testing of newborns to implement, to the extent practicable, FDA-approved tests no later than three years after a condition is added to national guidelines (i.e. RUSP). Establishes the Review Committee on Health Screen Testing for Newborns. Tasks the Review Committee to study and propose recommendations for health screen testing of newborns in Oregon. Sunsets Review Committee on December 31, 2018. Takes effect 91st after day sine die.

ISSUES DISCUSSED:

- National Recommended Uniform Screening Panel (RUSP)
- Treatment effectiveness for a health disorder and validity of new technology for testing newborns
- Ability for local laboratories to implement new laboratory screening technologies as health conditions are added to national guidelines (i.e. RUSP)

EFFECT OF AMENDMENT:

Requires the Oregon Health Authority (OHA) to adopt rules specifying a newborn screening test when the federal Food and Drug Administration (FDA) approves of a new methodology. Requires screening laboratories that provide testing of newborns to implement FDA-approved tests no later than three years after a condition is added to national guidelines, to the extent practicable.

BACKGROUND:

A well-established practice of state public health programs is universal screening of newborns before leaving the hospital. Screening helps to detect serious medical conditions that can result in early death or lifelong disability even when a newborn appears healthy. Early detection and intervention can prevent mortality and improve the quality of life for newborns with a metabolic disorder. Advances in screening technologies have enabled health care providers to detect an increased number of metabolic disorders.

The federal Department of Health and Human Services (DHHS) publishes a recommended set of disorders for newborn screening programs, the Recommended Uniform Screening Panel. The most recent recommendations include 32 core disorders and 26 secondary disorders (2016). Based on the federal recommendations, each year, approximately four million babies in the U.S. are screened for disorders. As a result, the Centers for Disease Control (CDC) reports that newborn screening detects 3,000 new cases of metabolic disorders each year.

Oregon law requires hospitals and midwives to collect a blood sample from every baby born as part of the newborn screening program (ORS 432.285). Newborns are often screened twice, once at the hospital and then again at the

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child's first medical appointment. As of 2014, the Northwest Regional Newborn Screening Program screens newborns for more than 40 metabolic disorders approved by OHA (OAR 333-024-0210). The Oregon State Public Health Laboratory tests blood samples from newborns and shares the results with health care providers. The testing results help health care professionals know when a newborn needs immediate medical attention.

Senate Bill 808-A requires OHA to adopt rules for newborn health screening tests as new health conditions are added to national guidelines. The bill also creates a statewide committee to make and submit recommendations on Oregon's newborn screening program to Legislative Assembly no later than September 15, 2018.