

S .B. NO. 1136

JAN 24 2013

A BILL FOR AN ACT

RELATING TO NEWBORN SCREENING.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

1 SECTION 1. Traditionally, newborn screening involves blood
2 collection from a heelstick and the use of biochemical and
3 molecular testing to screen for disorders. Results of this type
4 of newborn screening are most often available only after the
5 newborn's discharge home. In the late 1990s, the first type of
6 point of care newborn hearing screening was introduced. In
7 newborn hearing screening, the newborn is screened at an
8 institution caring for the newborn infant before discharge but
9 follow-up additional screening and possible diagnostic tests are
10 scheduled after discharge. Now a more intensive type of point
11 of care screening is being introduced in which the newborn is
12 screened at an institution caring for the newborn infant before
13 discharge and if the newborn has a positive result, diagnostic
14 tests are administered before the newborn is discharged or
15 arrangements are made for transfer of the newborn to an
16 institution that can administer the diagnostic tests before the
17 newborn is discharged home.

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1 The purpose of this Act is to establish point of care
2 newborn screening and authorize administrative rulemaking for
3 its implementation.

4 SECTION 2. Chapter 321, Hawaii Revised Statutes, is
5 amended by adding a new part to be appropriately designated and
6 to read as follows:

7 **"PART . POINT OF CARE NEWBORN SCREENING**

8 **§321-A Definitions.** For the purposes of this part:

9 "Department" means the department of health.

10 "Point of care newborn screening" means newborn infant
11 screening for diseases and conditions specified by the
12 department administered at the institution caring for the
13 newborn infant, followed by diagnostic testing at the
14 institution, or at a health facility to which the infant is
15 transferred when a positive screening result is found, to
16 determine the cause of the positive screening result before the
17 newborn is discharged home.

18 "Positive screening result" means a newborn screening
19 result that is outside the normal range of screening results for
20 a newborn.

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1 **§321-B Point of care newborn screening.** (a) The
2 department shall specify diseases and conditions covered by
3 point of care newborn screening.

4 (b) The department shall specify policies and procedures
5 for administration of point of care screening to be administered
6 by institutions caring for newborn infants to best prevent
7 newborn mortality and morbidity within the State.

8 (c) The person in charge of each institution caring for
9 newborn infants and the responsible physician attending the
10 birth of a newborn or the person assisting the birth of a
11 newborn not attended by a physician, shall ensure that every
12 newborn infant in the person's care be tested for the diseases
13 and conditions for point of care screening specified by the
14 department; provided that this section shall not apply if the
15 parents, guardians, or other persons having custody or control
16 of the child object thereto on the grounds that the tests
17 conflict with their religious tenets and beliefs and written
18 objection is made a part of the newborn infant's medical record.

19 (d) The department shall adopt rules pursuant to chapter
20 91 necessary for the purposes of this section, including:

21 (1) Specifying diseases and conditions for point of care
22 newborn screening;

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- 1 (2) Establishing policies and procedures for
2 administration of point of care newborn screening
3 tests;
- 4 (3) Quality and cost control of point of care screening
5 tests;
- 6 (4) Retention of records and related data;
- 7 (5) Tracking completion and results of point of care
8 newborn screening;
- 9 (6) Guidelines for care, treatment, and follow up for
10 newborn infants with positive test results;
- 11 (7) Education for parents and healthcare providers about
12 the availability and purposes of point of care newborn
13 screening; and
- 14 (8) Maintaining the confidentiality of newborns and
15 families.
- 16 (e) The director of health shall submit an annual report
17 to the legislature twenty days prior to the convening of each
18 regular session, identifying all expenditures made from the
19 newborn metabolic screening special fund for the department's
20 point of care newborn screening activities."

21 SECTION 3. Section 321-291, Hawaii Revised Statutes, is
22 amended by amending subsection (d) to read as follows:

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Report Title:

Point of Care Newborn Screening

Description:

Authorizes the Department of Health to implement point of care newborn screening, amends section 321-291 concerning the newborn metabolic screening special fund.

The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.

JUSTIFICATION SHEET

DEPARTMENT: Health

TITLE: A BILL FOR AN ACT RELATING TO NEWBORN SCREENING.

PURPOSE: Clarify the roles and responsibilities of the Department of Health, birthing facilities and providers for point of care newborn screening.

MEANS: Add new part of Chapter 321.

JUSTIFICATION: Traditionally, newborn screening (NBS) is done by collecting blood from a heelstick onto a collection filter paper kit to screen for disorders using biochemical and molecular testing. Early screening, diagnosis, and treatment of the disorders detected by NBS prevent death and clinical crises in newborns. Hawaii mandated NBS in 1986. The statute was amended in 1996 to institute a user fee (currently \$55 per newborn) and a special fund to be used for the collection kits, laboratory screening tests, follow-up, education, tracking of screening, quality assurance, payment for indigent families, and the Department of Health NBS staff. The screening fee is prepaid to the Department of Health by the birthing facilities to get the collection kits. The birthing facility recoups the cost of the NBS from the third party payers who all cover NBS. Currently, Hawaii screens for 32 disorders and hearing loss.

Since NBS has been a state based activity, screening practice and types of disorders screened have differed across the country. In 2004, Congress enacted a bill to form the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC). SACHDNC was charged to review disorders and make recommendations to the Secretary of Health and Human Services

regarding which disorders should be included in the NBS panel. This list of disorders is called the "Recommended Uniform Screening Panel" (RUSP). Due to the federal actions, adding the disorders on the RUSP to state programs has now become unfunded federal mandates.

In the late 1990s, the first type of Point of Care (PoC) screening was introduced, newborn hearing screening. In newborn hearing screening the newborn is screened for hearing loss before discharge but follow-up additional screening and possible diagnostic tests are scheduled for after discharge.

Now a more intensive type of PoC screening is being introduced where the newborns are screened and diagnosed before discharge. If the newborn has positive screening result, diagnostic tests are done before discharge if the facility has the capacity to do them or the newborn is transferred to a facility that can do the diagnostic testing. The first such PoC screening recommended by the Secretary of Health and Human Services to the RUSP is the use of pulse oximetry to screen for Critical Congenital Heart Defects (CCHD). Newborns who are found to have a low oxygen saturation on the pulse oximetry screening need to have an echocardiogram to rule out one of the CCHDs.

The new bill will:

- Clarify Responsibilities
The responsibilities of the state, birthing facilities, and providers for PoC NBS will be set out. We are using PoC NBS and not specifically referencing CCHD screening since there may be other PoC NBS disorders added to the RUSP in the future.
- Leadership

The bill will allow the state to propagate administrative rules to ensure that the newborns in the state receive quality PoC NBS services.

- Risk Management
Since PoC NBS disorders like CCHD are on the RUSP, this has made doing this type of NBS like a federal mandate. The state needs to have screening for CCHD on its state NBS panel to meet the federal performance measures. Also, parents will expect that the state provide as much guidance and oversight for the PoC NBS as we do for the metabolic disorders and hearing loss, especially since the Affordable Care Act requires that all third party payers cover the cost of NBS for all disorders on the RUSP.

Impact on the public: Assures statewide screening and assures the public that point of care newborn screening will be done in a responsible manner with state oversight.

Impact on the department and other agencies: Assists the department to clarify roles and responsibilities for this new type of newborn screening.

GENERAL FUND: None.

OTHER FUNDS: Any additional costs for adding point of care newborn screening activities will become part of the newborn metabolic screening user fee and available through the newborn metabolic screening special fund.

PPBS PROGRAM DESIGNATION: HTH-560.

OTHER AFFECTED AGENCIES: None.

EFFECTIVE DATE: January 1, 2014.