

SB

87

<TARGET><BILL>SB 87</BILL><SUBJECT>SB
87</SUBJECT><COMM>SHSS28</COMM></TARGET>

CS FOR SENATE BILL NO. 87(HSS)

IN THE LEGISLATURE OF THE STATE OF ALASKA

TWENTY-EIGHTH LEGISLATURE - FIRST SESSION

BY THE SENATE HEALTH AND SOCIAL SERVICES COMMITTEE

Offered:

Referred:

Sponsor(s): SENATORS MICCICHE, McGuire

A BILL

FOR AN ACT ENTITLED

1 **"An Act requiring screening of newborns for congenital heart defects; and providing for**
2 **an effective date."**

3 **BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:**

4 *** Section 1.** AS 18.15 is amended by adding a new section to read:

5 **Sec. 18.15.205. Screening for congenital heart disease.** (a) A provider of
6 birthing services who attends a birth in the state shall ensure that, as close to 24 hours
7 after the birth as feasible, screening for congenital heart defects through pulse
8 oximetry equipment and methods appropriate for use on a newborn are performed on
9 the newborn, unless screening is refused under (d) of this section.

10 (b) A provider of birthing services who attends a birth in the state shall, as
11 soon as possible after screening conducted under (a) of this section, make a referral for
12 confirmatory testing on a newborn whose pulse oximetry results are abnormal and
13 provide advice to the parent or legal guardian regarding the need for appropriate
14 interventions.

1 (c) The provider who performs pulse oximetry screening under (a) of this
2 section shall report to the parents and attending physicians of the newborn and to the
3 department the results of screening.

4 (d) Before performing screening for congenital heart disease under (a) of this
5 section, a provider of birthing services shall provide to a parent or legal guardian of a
6 newborn information on the screening and the option to refuse the screening.

7 (e) The department shall establish procedures for submitting reports of
8 newborn screening results to the department and for summarizing reported data.

9 (f) In this section, "provider of birthing services" means a physician, midwife,
10 nurse, or other qualified professional who attends the delivery of a newborn in the
11 course of the provider's practice.

12 * **Sec. 2.** The uncodified law of the State of Alaska is amended by adding a new section to
13 read:

14 **APPLICABILITY.** AS 18.15.205, enacted by sec. 1 of this Act, does not apply to a
15 provider of birthing services who attends fewer than 20 births a year in the state until
16 January 1, 2016.

17 * **Sec. 3.** This Act takes effect January 1, 2014.

SENATE COMMITTEE REPORT First Committee of Referral

DATE: 3/27/13

FURTHER: Finance

Date of 5-Day Notice: _____
(in accordance with Uniform Rule 23)

DATE TURNED
IN TO OFFICE: 4/6/13

Health and Social Services Committee considered SENATE BILL NO. 87

SB 87-NEWBORN SCREENING FOR HEART DEFECTS

"An Act requiring screening of newborns for congenital heart defects; and providing for an effective date."

and recommends:

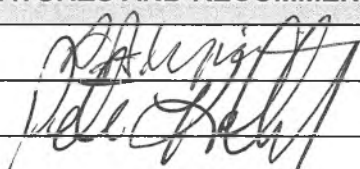
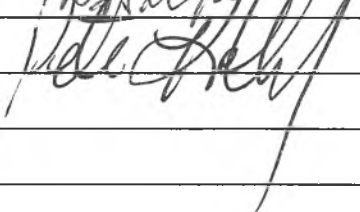

- be replaced with CS SB 87 (HSS) Same Title New Title
- adopt previous CS _____ SCS/CS- Forthcoming _____) Same Title New Title
- attached amendment(s)
- adopt _____ Letter of Intent
- further referral to _____ Committee

Dept Abbr.	
ADM	LWF
CED	LAW
COR	LEG
CRT	MVA
EED	DNR
DEC	DPS
DFG	REV
GOV	DOT
DHS	UA

NEW FISCAL NOTE(S)				
Dept.	Fiscal	Indet.	Zero	FN #
HSS			✓	

PREVIOUS FISCAL NOTE(S)				
Dept.	Fiscal	Indet.	Zero	FN #

APPROPRIATION - no fiscal note

SIGNATURES AND RECOMMENDATIONS:	PRINTED LAST NAME	Do PASS	DO NOT PASS	NO REC	AMEND
	Michelle	✓			
	Kelly	✓			
CHAIR: 	Stedman	✓			

28-LS0678\Y
Mischel
4/4/13

CS FOR SENATE BILL NO. 87()
IN THE LEGISLATURE OF THE STATE OF ALASKA
TWENTY-EIGHTH LEGISLATURE - FIRST SESSION

BY

Offered:
Referred:

Sponsor(s): SENATORS MICCICHE, McGuire

A BILL
FOR AN ACT ENTITLED

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10 nurse, or other qualified professional who attends the delivery of a newborn in the
11 course of the provider's practice.

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14 **APPLICABILITY.** AS 18.15.205, enacted by sec. 1 of this Act, does not apply to a
15 provider of birthing services who attends fewer than 20 births a year in the state until
16 January 1, 2016.

17 * **Sec. 3.** This Act takes effect January 1, 2014.

ALASKA STATE LEGISLATURE

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SENATOR PETER A. MICCICHE

DISTRICT 0

Anchor Point

Clam Gulch

Cohoe

Diamond Ridge

Fox River

Fritz Creek

Funny River

Halibut Cove

Happy Valley

Homer

Kachemak City

Kachemak Selo

Kalifornsky

Kasilof

Kenai

Nikolaevsk

Ninilchik

Razdolna

Ridgeway

Seldovia

Soldotna

Voznesenka

Explanation of Changes in Committee Substitute **CS SB 87 Version "Y"-NEWBORN SCREENING FOR HEART DEFECTS**

The committee substitute makes a number of changes to the original version of the bill as follows:

- The bill is expanded to require the pulse oximetry screening not only for newborns born at birthing facilities, but all attended births (by a midwife, nurse or other qualified professional), including attended home births.
- The delayed effective date will apply to providers attending fewer than 20 births per year. The original bill calculated the delayed effective date based on the number of beds in a facility.
- The Department of Health and Social Services will be required to simply collect from each provider, the number of screenings conducted and the results of those screenings. The original bill included an elaborate reporting system with the department required to follow up on interventive treatment.
- The department will conduct the data collection and reporting within its existing structure and with no additional costs (i.e. zero fiscal note).

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SENATOR PETER A. MICCICHE

Sectional Analysis

DISTRICT 0

CS SB 87 Version "Y" -NEWBORN SCREENING FOR HEART DEFECTS

Anchor Point

Section 1 – Adds a new section to AS 18.15 Disease Control and Threats to Public Health, AS 18.15.205 is titled: Screening for congenital heart disease

Clam Gulch

Cohoe

Subsection (a) requires that a provider of birthing services (defined in subsection (f)) in Alaska conduct a pulse oximetry test on newborns as close to 24 hours after birth as reasonably feasible.

Diamond Ridge

Fox River

(b) requires the provider to conduct or order confirmatory testing in cases where the initial test was abnormal. Also requires physician, midwife or other qualified profession to advise parents of the necessity of intervention treatment.

Fritz Creek

Funny River

Halibut Cove

(c) requires the provider to report test results to the parents and to report to the Department of Health and Social Services, whether the test was performed and the results of the test.

Happy Valley

Homer

Kachemak City

(d) requires the provider to provide information on the screening to the parents and allow parents to opt out.

Kachemak Selo

Kalifornsky

(e) requires DHSS to set up a system for facilities to submit reports on the number of screenings performed and the results of those screenings.

Kasilóf

Kenai

(f) defines "provider of birthing services" as a physician, midwife, nurse or other qualified professional who attends births as part of their normal practice.

Nikolaevsk

Ninilchik

Section 2 – provides smaller hospitals, clinics, birthing centers and home delivery providers – providers who attend to less than 20 births annually, an extra two years (until January 1, 2016) to comply with the law in the event new equipment must be acquired.

Razdolna

Ridgeway

Seldovia

Section 3 – provides larger hospitals and the department at least six months to implement the testing, setting the effective date at January 1, 2014.

Soldotna

Voznesenka



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Chief Development Officer
Ginnie Gatlin

April 4, 2013

The Honorable Peter Micciche
State Senator, District O
State Capitol, Room 125
Juneau, AK 99801

RE: SB 87 (Micciche) – Support

Dear Senator Micciche:

The American Heart Association (AHA) is pleased to support SB 87. As you know, this bill will require all newborns to be screened for critical congenital heart disease (CCHD) prior to discharge from the hospital.

CCHD can range in severity from simple holes in the heart or murmurs to severe malformations, such as the complete absence of one or more chambers or valves. Some CCHD can cause severe and life-threatening symptoms that require intervention within the first days of life and directly correspond with extensive and expensive treatment.

Congenital heart defects are the leading birth defects affecting newborns in the United States, but early detection using pulse oximetry and prompt treatment can make all the difference. In fact, new research suggests wider use of pulse oximetry screening could help identify more than 90 percent of heart defects.

Pulse oximetry is a non-invasive test that measures the amount of oxygen in the baby's blood, as well as pulse rate. It is relatively quick, costs are minimal, and it has been proven to be effective in detecting CCHD. Many hospitals have begun screening every newborn. However, we need to ensure that all babies are afforded the same opportunity and that there is consistency in how the test is administered across hospitals.

The AHA supports SB 87 because requiring pulse oximetry screening for all newborn babies will save lives and will substantially reduce the long-term economic impact of CCHD. Thank you for your leadership on this issue.

Sincerely,

Jamie Morgan
Jamie Morgan

Senior Government Relations Director

Cc: Members of the State Senate

Fiscal Note

State of Alaska
2013 Legislative Session

Bill Version: SB 87
Fiscal Note Number: _____
() Publish Date: _____

Identifier: CSSB087(HSS)-WCFH-4-4-13
Title: NEWBORN SCREENING FOR HEART DEFECTS
Sponsor: MICCICHE
Requester: Senate Health & Social Services Committee

Department: Department of Health and Social Services
Appropriation: Public Health
Allocation: Women, Children and Family Health
OMB Component Number: 2788

Expenditures/Revenues

Note: Amounts do not include inflation unless otherwise noted below. (Thousands of Dollars)

	FY2014	Included in	Out-Year Cost Estimates				
	Appropriation Requested	Governor's FY2014 Request	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
OPERATING EXPENDITURES	FY 2014	FY 2014					
Personal Services							
Travel							
Services							
Commodities							
Capital Outlay							
Grants & Benefits							
Miscellaneous							
Total Operating	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Fund Source (Operating Only)

None							
Total	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Positions

Full-time							
Part-time							
Temporary							

Change in Revenues							
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Estimated SUPPLEMENTAL (FY2013) cost: 0.0

Estimated CAPITAL (FY2014) cost: 0.0

ASSOCIATED REGULATIONS

Does the bill direct, or will the bill result in, regulation changes adopted by your agency? Yes
If yes, by what date are the regulations to be adopted, amended or repealed? 06/30/14

Why this fiscal note differs from previous version:

This fiscal note reflects the most current CSSB087(HSS) version which removes most of the reporting requirements and clarifies the department's role. The result is a zero fiscal note.

Prepared By: Kerre Fisher, Acting Director	Phone: (907)269-2042
Division: Public Health	Date: 04/02/2013 12:00 PM
Approved By: Sarah Woods, Deputy Director	Date: 04/04/13
Finance & Management Services	

FISCAL NOTE ANALYSIS

STATE OF ALASKA
2013 LEGISLATIVE SESSION

BILL NO. CSSB087(HSS)

Analysis

This bill amends AS 18.15 to add a new section (AS 18.15.205) to require all providers of birthing services to screen all newborns for congenital heart defects as close to 24 hours after birth as is feasible, or before discharge; order or perform confirmatory testing and intervention for all infants who have abnormal screening results; and report screening results to the parents/guardians and department. Parents or legal guardians are provided information on screening/testing by the provider and may refuse screening or testing. The department is required to establish procedures for submitting reports and summarizing data. Providers who attend fewer than 20 births a year do not have to implement the practice for two years.

The previous fiscal note (Version "C") assumed that the department would implement this bill as a comprehensive newborn screening program modeled on existing newborn hearing and metabolic screening programs in the Division of Public Health. The most current version clarifies that the department's role is limited to collecting and summarizing data. This fiscal note assumes that aggregate data will be reported annually by facility and analysis by the division is limited to counts of births and screenings. The current version applies to all providers of birthing services. The previous version applied only to licensed providers. This increases the volume of data the department will collect. Based on experience with other newborn screening programs, likely most parents/guardians will opt to have the pulse oximetry test. It is expected this volume of aggregate annual data can be handled with existing resources, if limited data is reported.

Costs for the screening test would be billed to insurance companies by providers of birthing services if the parent's insurance provides coverage. For Medicaid enrollees, costs would be included in global fees already paid for delivery services so no additional cost for benefits is anticipated.

New regulations will need to be established following national standard of care guidelines surrounding the screening, referral, and diagnosis of congenital heart defects for children with abnormal screening results and the data reporting.

Fiscal Note

State of Alaska
2013 Legislative Session

Bill Version: SB 87
Fiscal Note Number: _____
() Publish Date: _____

Identifier: SB087-DHSS-WCFH-4-1-13
Title: NEWBORN SCREENING FOR HEART DEFECTS
Sponsor: MICCICHE
Requester: Senate Health & Social Services Committee

Department: Department of Health and Social Services
Appropriation: Public Health
Allocation: Women, Children and Family Health
OMB Component Number: 2788

Expenditures/Revenues

Note: Amounts do not include inflation unless otherwise noted below. (Thousands of Dollars)

	FY2014 Appropriation Requested	Included in Governor's FY2014 Request	Out-Year Cost Estimates					
			FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
OPERATING EXPENDITURES								
Personal Services	158.8		183.8	183.8	183.8	183.8	183.8	183.8
Travel	5.0		3.5	2.0	2.0	2.0	2.0	2.0
Services	210.0		75.0	75.8	76.5	77.3	78.1	78.1
Commodities	11.0		1.0	1.0	1.0	1.0	1.0	1.0
Capital Outlay								
Grants & Benefits								
Miscellaneous								
Total Operating	384.8	0.0	263.3	262.6	263.3	264.1	264.9	264.9

Fund Source (Operating Only)

1002 Fed Rcpts	38.5		26.3	26.3	26.3	26.4	26.5
1004 Gen Fund	346.3		237.0	236.3	237.0	237.7	238.4
Total	384.8	0.0	263.3	262.6	263.3	264.1	264.9

Positions

Full-time	1.0		1.0	1.0	1.0	1.0	1.0
Part-time	1.0		1.0	1.0	1.0	1.0	1.0
Temporary							

Change in Revenues							
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Estimated SUPPLEMENTAL (FY2013) cost: 0.0

Estimated CAPITAL (FY2014) cost: 0.0

ASSOCIATED REGULATIONS

Does the bill direct, or will the bill result in, regulation changes adopted by your agency? Yes
If yes, by what date are the regulations to be adopted, amended or repealed? 06/30/14

Why this fiscal note differs from previous version:

Initial version.

Prepared By:	Kerre Fisher, Acting Director	Phone:	(907)269-2042
Division	Public Health	Date:	03/29/2013 12:00 PM
Approved By:	Sarah Woods, Deputy Director	Date:	04/01/13
	Finance & Management Services		

FISCAL NOTE ANALYSIS

STATE OF ALASKA
2013 LEGISLATIVE SESSION

BILL NO. SB087

Analysis

This bill amends AS 18.15 to add a new section (AS 18.15.205) to require all licensed birthing facilities to screen all newborns for congenital heart defects as close to 24 hours after birth as is feasible, or before discharge; provide information on screening/testing; order or perform confirmatory testing and intervention for all infants who have abnormal screening results; and report screening, testing, intervention and refusal data annually to the department and parents/guardians. Parents or legal guardians may refuse screening or testing. The department is required to collect and analyze the data. This bill does not apply to births at unlicensed birthing facilities or at home. New regulations will need to be written for statewide guidelines surrounding the screening, referral, and diagnosis of congenital heart defects for children with abnormal screening results and the data reporting process.

In Alaska, between 1996 and 2002, cardiovascular birth defects were the most frequently reported congenital anomalies, affecting about 2% of the 11,000 deliveries per year, or 220 babies annually. Newborn screening for congenital heart defects is routinely done with pulse oximetry. Pulse oximetry screening is a quick, painless, bedside test to determine the amount of oxygen in the blood and pulse rate. Low levels of oxygen in the blood can be a sign of a critical congenital heart defect. Once identified, babies with a critical congenital heart defect can be seen by pediatric cardiologists and can receive specialized care and treatment that could prevent death or disability early in life.

Currently, there are 20 hospitals and 9 free-standing licensed birthing centers in the state offering birthing services. For the 7 hospitals with 50 or more beds, this bill takes effect January 1, 2014. For the 13 hospitals and 9 birthing centers with fewer than 50 beds, the effective date is delayed two years to 2016. While most of the free standing birthing centers are licensed, some are not and are excluded along with home deliveries. Many hospitals in Alaska have voluntarily implemented this practice or are in varying stages of implementation including: Providence Alaska Medical Center, Alaska Regional Hospital, Alaska Native Medical Center, Mat-Su Regional Hospital, Basset Army Hospital, and Fairbanks Memorial Hospital, among many others. These facilities account for about 2/3 of Alaska's deliveries. Based on experience with other newborn screening programs, 99% of parents/guardians will opt to have the pulse oximetry test.

Costs for the screening test would be billed to insurance companies by hospitals and birthing centers if the parent's insurance provides coverage. For Medicaid enrollees, costs would be included in global fees already paid for delivery services so no additional cost for benefits is anticipated. Medicaid is expected to reimburse a share of the costs to administer the program.

This program will require 2.00 FTEs to administer and support this program - 1.5 new and 0.5 existing, repurposed. To prepare for implementation as soon as regulations are adopted, starting in Year 1, a new 1.0 FTE Public Health Specialist II position would oversee the administrative and clinical implementation and maintenance of this program, write regulations, determine the data system and components to be added or purchased, and provide technical assistance to birthing facilities across the state. A new 0.5 FTE Office Assistant II would be needed for general clerical duties and to manage the paperwork, data entry, and letter generation for follow up and referral processes. Data collection and reporting would be done by an existing 0.25 FTE Health Program Associate, along with project management & quality control for the data system. Starting in Year 2, an existing 0.25 FTE Research Analyst III would analyze the data. The existing positions are currently funded by federal grants. Those funds could not be used for the purposes of this bill and therefore general funds will be needed. There would be additional costs for phones, software licenses and other contractual costs, design & printing of educational materials for providers & parents, along with \$10.0 one-time costs to set up new office spaces.

FISCAL NOTE ANALYSIS

STATE OF ALASKA
2013 LEGISLATIVE SESSION

BILL NO. SB087

Analysis Continued

Continued from p. 2

Travel will be needed for outreach and technical assistance for hospitals and birthing facilities on screening practice and data reporting. Face-to-face contact and education with the birthing facility and administrative staffs will facilitate a smoother implementation for this program. It is expected that the most travel will be needed in Year 1 for initial database training and education of providers on screening protocols and will gradually reduce and level off by Year 3.

A data system for critical congenital heart defects will be required. Currently, the Alaska Birth Defects Registry collects data on critical congenital heart defects and other cardiac anomalies from health care facilities and providers. However, the Registry is paper-based, requiring on-site chart reviews for verification. A web based data system would be the most efficient way for facilities to report data. Costs in Year 1 include \$200.0 one-time cost to procure the congenital heart defects registry required to implement this bill. Purchasing a system to encompass the entire Alaska Birth Defects Registry is outside the scope of this fiscal note. An annual hosting and maintenance fee is included in future years based on a per record (birth) price structure similar to the Newborn Hearing web based data system. Annual costs are expected to rise 1% per year as the number of births increase over time. This does not reflect any cost increases due to inflation.

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SENATOR PETER A. MICCICHE

SPONSOR STATEMENT

SB 87-NEWBORN SCREENING FOR HEART DEFECTS

DISTRICTS

Anchor Point

Clam Gulch

Cohoe

Diamond Ridge

Fox River

Fritz Creek

Funny River

Halibut Cove

Happy Valley

Homer

Kachemak City

Kachemak Selo

Kalifornsky

Kasilof

Kenai

Nikolaevsk

Ninilchik

Razdolna

Ridgeway

Seldovia

Soldotna

Voynesenka

Every week Alaska babies are discharged from hospitals with undetected heart problems. Approximately 115 Alaska babies will be born this year with congenital heart defects – the number one killer of infants with birth defects, according to the American Heart Association.

In September of 2011, the US Secretary of Health and Human Services recommended that all newborns be screened for critical congenital heart disease (CCHD) prior to being discharged from the birth hospital. That recommendation is endorsed by the American Academy of Pediatrics, March of Dimes, American Heart Association and the Newborn Coalition.

Newborn screening for CCHD uses pulse oximetry – a simple, noninvasive, and effective test to measure the percent of oxygen in the blood. This screening costs less than a diaper change in the newborn nursery and is conducted in most nurseries at bedside, using existing staff and, most often, existing equipment. Pulse oximetry, *recognizable as the finger clip with a blue light affixed on adult hospital patients*, is considered the 5th vital sign by most clinicians – as simple and valuable as a blood pressure or temperature reading.

This bill will require larger hospitals, beginning in January 2014, to test newborns with pulse oximetry. Birthing centers and hospitals with fewer than 50 beds will have until January 2016 in the event they require additional time to acquire the necessary equipment. Parents will have the option of declining the testing.

In the event the tests shows abnormal results, the attending physician, direct-entry midwife or other qualified health care professional will advise the parents of the necessity for intervention treatment.

Most health insurance plans will cover the small cost under AS 21.42.351 Coverage for well-baby exams, and other state statutes. Medicaid patients will see the cost covered as well. Early diagnosis and intervention of those born with CCHD tend to lower cost of treatment.

Additionally, the bill provides a mechanism for hospitals to report newborn pulse oximetry screening results to the public health community, through the Department of Health and Social Services, a critical step in understanding and treating the detected defect.

This bill is vital to support timely and effective implementation of newborn screening for the most critical heart defects for babies born in the state's hospitals and birthing centers. This bill is a relatively simple step that will save many young Alaskans' lives.

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SENATOR PETER A. MICCICHE

Sectional Analysis

SB 87-NEWBORN SCREENING FOR HEART DEFECTS

DISTRICTS

Anchor Point

Clam Gulch

Cohoe

Diamond Ridge

Fox River

Fritz Creek

Funny River

Halibut Cove

Happy Valley

Homer

Kachemak City

Kachemak Selo

Kalifornsky

Kasilof

Kenai

Nikolaevsk

Ninilchik

Razdolna

Ridgeway

Seldovia

Soldotna

Voznesenka

Section 1 – Adds a new section to AS 18.15 Disease Control and Threats to Public Health, AS 18.15.205 is titled: Screening for congenital heart disease

Subsection (a) requires that licensed health care facilities in Alaska conduct a pulse oximetry test on newborns as close to 24 hours after birth as reasonably feasible and before the infant is discharged from the hospital or birthing center.

(b) requires a second pulse oximetry test in cases where the initial test was abnormal. Also requires physician, midwife or other qualified profession to advise parents of the necessity of intervention treatment.

(c) requires the facility to report test results and results of any intervention treatment to the parents, attending physician and the Department of Health and Social Services

(d) requires the facility to provide information on the screening to the parents and allow parents to opt out.

(e) requires DHSS to set up a system for facilities to submit testing and other information. Also requires the department to collect and analyze the data.

Section 2 – provides smaller hospitals, clinics and birthing centers – facilities with less than 50 beds, an extra two years (until January 1, 2016) to comply with the law in the event new equipment must be acquired.

Section 3 – provides larger hospitals and the department at least six months to implement the testing, setting the effective date at January 1, 2014.

Newborn Screening of Heart Defects- Pulse Oximetry Screening for Critical Congenital Heart Defects (CCHD)

Congenital heart defects are the number one killer of infants with birth defects.¹ Congenital heart defects are structural abnormalities of the heart that are present at birth. These defects range in severity from simple holes or murmurs to severe malformations, such as the complete absence of one or more chambers or valves. Some critical congenital heart defects can cause severe and life-threatening symptoms which require intervention within the first days of life.

Pulse oximetry screening is effective at determining life-threatening heart defects.⁴

Pulse oximetry screening is a non-invasive test that estimates the percentage of hemoglobin in blood that is saturated with oxygen. When performed on newborns in the delivery center it is effective at detecting life-threatening defects which otherwise can go undetected by current screening methods.

'Positive' screenings require additional follow-up.

If a baby's test results show low levels of oxygen in the blood this can be a sign of a CCHD. This does not always mean that the baby has a CCHD, it just means that more testing is needed.

Pulse oximetry screening is cost effective and offers a positive return on investment. One study calculated that the savings in healthcare costs from the prevention of one case of complications of circulatory collapse resulting from an undiagnosed CCHD may exceed the cost of screening two thousand newborns.⁵



Current, commonly used, detection methods identify less than half of all newborn cases.²

Current methods for detecting congenital heart defects generally include prenatal ultrasound screening and repeated clinical examinations can identify many affected newborns. However, these screenings alone, identify less than half of all cases, and critical heart defect cases are often missed during routine clinical exams performed prior to a newborns discharge from a birthing facility.

Secretary of Health & Human Services recommends pulse oximetry screening.³

In a September 21, 2011 letter, HHS Secretary Kathleen Sebelius recommended that pulse oximetry screening to be included as part of the Recommended Uniform Screening Panel for Newborns (RUSP). The American Heart Association stands ready to serve as a resource for those states that move forward to implement the Secretary's recommendations.

References

1. Xu J, Kochanek KD, Murphy SL, Tejada-Vera B. Deaths: Final data for 2007. *National Vital Statistics Reports*. 2010;58(19). Hyattsville, MD: National Center for Health Statistics. [[Read article ↗](#)]
2. Knapp, AA, Metterville, DR, Kemper, AR, Prosser, L, Perrin, JM. Evidence review: Critical congenital cyanotic heart disease, Final Draft, September 3, 2010. Prepared for the Maternal and Child Health Bureau, Health Resources and Services Administration
<http://archpedi.ama-assn.org/cgi/content/full/162/10/969>
3. <http://www.hrsa.gov/advisorycommittees/mchbadvisorv/heritabledisorders/recommendations/correspondence/cvanoticheartsecre09212011.pdf>
4. http://www.cdc.gov/ncbddd/pediatricgenetics/documents/CCHD_one_pager.pdf
5. de-Wahl Granelli A, Wennergren M, Sandberg K, Mellander M, Bejlum C, et al. Impact of pulse-oximetry screening on the detection of duct-dependent congenital heart disease: a Swedish prospective screening study in 39,821 newborns. *BMJ*. 2009;338:a3037

About Congenital Heart Defects

Congenital Heart Defects (CHDs) are both the most common and the most lethal birth defects, accounting for 24% of all infant deaths due to birth defects and affecting more than 650 newborn infants and their families each year in Minnesota. Approximately 25% of heart defects are referred to as Critical Congenital Heart Defects (CCHD), requiring intervention in the first days, weeks or months of life. A major cause of infant mortality as a result of CCHD is that a significant number of children appear healthy at first and are not detected as having heart disease in the newborn nursery.

Two babies are born each day in Minnesota with a heart defect. Only one of them will be diagnosed prenatally. The other baby has a 30-40% risk of being discharged from the hospital with an undiagnosed heart defect.

Early diagnosis can reduce rates of death or disability and the costs associated with delayed diagnosis - including surgical compromise, neurological impairment, developmental delay, organ failure, and long-term feeding issues. Rural and underserved populations are particularly vulnerable to missed or delayed diagnosis - and have significantly lower rates of prenatal detection.

About Newborn Screening for CCHD using Pulse Oximetry

Referred to by clinicians as the "5th vital sign", pulse oximetry is a simple, non-invasive, bedside where sensors are placed on the baby's hand and foot to determine their pulse rate and the amount of oxygen in their blood. Pulse oximetry takes just minutes, is about the cost of a diaper change, and is as simple as taking a baby's temperature or blood pressure.

Pulse oximetry is effective at detecting critical, life-threatening CCHD when performed at approximately 24 hours of age and used along with physical examination. These heart defects would otherwise go undetected by current screening methods. Newborns with abnormal pulse oximetry results require immediate confirmatory testing, intervention, and specialized care to help prevent disability and death early in life.

Universal Support

CCHD screening of newborns has been recently adopted by the Secretary of Health and Human Services for inclusion in the Uniform Screening Panel (RUSP), and has also been endorsed by the American Academy of Pediatrics, the American Heart Association and the American College of Cardiology.

This simple, non-blood-spot screening has now been implemented for all newborns in 3 states, required in 6 states, and an additional 12 states have legislation introduced. <http://www.cchdscreeningmap.com/>.

Pulse oximetry is simple, non-invasive, and painless, requiring no blood draw or specimen collection.



"It's a rare day when you know a piece of legislation you signed saved a life,"

Baby Dylan's life-threatening heart defect was detected with pulse ox screening on the very first day of implementation in New Jersey.



"My baby went 4 and a half weeks undiagnosed despite our complaints of poor eating, and breathing strangely! He saw 4 different pediatricians, after the two he saw in the hospital and no one bothered with a pulse ox because I was a first time, very tired mother. He nearly died in our arms 3 days after his one-month check up! Inexcusable!!! What is the extra expense of babies like Gunner who then was so critical that he required a life flight and weeks of life support? Had the defect been caught initially, our entire family could have endured less trauma. Thank God we still have him and he is healthy, that is ONLY because of God's grace. I know there are too many others who are not so lucky."

Minnesota Model

cchdscreeningmap.com



Physicians, hospitals, and advocates clearly understand the importance of early detection of newborn diseases and disorders in saving lives and reducing healthcare cost burdens associated with late diagnosis. Minnesota can build on its successful **Newborn Heart Screening Pilot Program** by requiring each licensed hospital or birthing facility to provide that all newborns are, prior to discharge, but as much as is feasible, at 24 hours of age or later, screened for congenital heart disease as a standard of care.

Within less than two years, Minnesota's evidence-based protocol and implementation toolkit was developed, resulting in nearly 20% of Minnesota newborns being screened for heart defects before discharge. This program has garnered national attention, and was critical to the recent federal recommendation from the U.S. Department of Health and Human Services that all newborns be screened for CCHD.

- Newborn heart screening would not require testing to be done in the health department laboratory, eliminating the need to purchase additional equipment or provide staff for this screening.
- It is assumed that the immediate follow up of patients with failed screens will occur within the provider setting, with limited resources required by the Department of Health.
- Pulse oximetry testing is currently a covered benefit when determined medically necessary by most public and private payers.

Sources: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, Newborn Coalition, 1in100



"CHD is the most common birth defect leading frequently to death or severe morbidity. Studies suggest that early recognition of critical congenital heart disease (CCHD) is a significant and potentially modifiable risk factor, but tragically, the diagnosis of a CCHD is often missed. Newborn screening with pulse oximetry is a promising tool to narrow the diagnostic gap. We continue to make progress in our region, implementing pulse oximetry screening one hospital at a time. This piecemeal approach leaves too many newborns and their parents vulnerable. Leadership is needed to ensure all newborns, regardless of which hospital they are born in, are screened for critical congenital heart disease." ~ Lazaros Kochilas, MD, U of M Pediatric Cardiology, MN Newborn Heart Screening Pilot Program

Eve's Story

Eve Isley Saarinen was diagnosed at two days old with critical congenital heart disease (CCHD) and associated Wolff-Parkinson-White Syndrome. Eve spent her first 5 months in 4 different hospitals and underwent two heart surgeries, 6 transfusions, and more than 120 episodes of SupraVentricular Tachycardia. Because of early intervention and excellent medical care, Eve is expected to lead a full and normal life. Although she may still have to undergo more cardiac care or surgeries, she has proven to be a very resilient and happy child. Following her surgeries, Eve's family established the CHD community 1in100, and collaborated with Minnesota physicians, advocates, and the state Department of Health in establishing a landmark pilot program to screen newborns for heart defects using pulse oximetry. Eve's mother, Annamarie Saarinen, went on to spearhead a federal recommendation from the Department of Health and Human Services which has resulted in the recommendation that all newborns in the United States should be screened for CCHD. That recommendation has also been formally endorsed by the American Academy of Pediatrics, the American Heart Association, and the American College of Cardiology.

Answers to Frequently Asked Questions

Q: How much does the screening cost for the parents of a newborn?

The screening costs about \$2.00 if a reusable probe is used. It costs about \$8.00 if a disposable, single-use probe is utilized.

Q: How reliable are the screenings?

Newborn screening with pulse oximetry helps detect more than 75 percent of critical heart lesions, with a sensitivity rate of more than 99% and a false positive rate of less than .03 percent.

Q: Who manufactures the equipment for pulse oximetry testing?

To date, only Masimo corporation has been certified by the FDA as having proper testing equipment. This is because the equipment must meet a number of criteria, including that it be motion-tolerant, be able to report function oxygen saturation and have been validated in low-blood oxygen conditions.

Q: In the long run, does screening for CCHDs save money?

Yes. If an abnormal screening is detected it can lead to faster medical intervention preventing disability or death later on. The cost of screening is minimal compared to the cost of caring for a disabled child later. Not to mention the individual benefits for the child and the family.

Q: Does the Department of Health and Social Services currently have the regulatory authority to require this test?

No.

Q: Will this screening be covered by health insurers in Alaska?

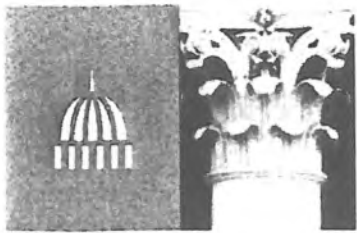
Yes. See AS 21.42.345(b) and AS 21.42.351.

Q: How many other diseases are newborns screened for in Alaska?

Currently, the Department of Health and Social Services requires that 46 tests be performed on newborn infants. The vast majority of these tests are performed through the use of blood spot testing. Blood spot testing involves drawing a small amount of blood from the newborn and then sending that sample to a lab in Oregon for evaluation.

Q: How many infants will this impact?

It is estimated that 1 in 100 children will be born with a congenital heart defect. Heart disease kills more children in their first year of life than any other birth defect.



National Conference of State Legislatures

LEGISBRIEF

BRIEFING PAPERS ON THE IMPORTANT ISSUES OF THE DAY

DECEMBER 2012

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Newborn Health Screenings

By Austin Rueschhoff

Every year, thousands of infants are born with serious genetic disorders that can be identified by testing just a few drops of blood. State newborn screening programs test about 4 million infants annually for genetic disorders and other health problems that are not apparent at birth. Early detection of many disorders can not only prevent disabilities, additional health problems or death, they may also save states and families money by avoiding high medical costs and using other state services.

Newborn screening also detects conditions such as hearing, hormonal and blood disorders. By the time symptoms for these conditions appear, they often are irreversible and can lead to severe health problems, developmental disabilities, mental retardation or even death. To identify most of these problems soon after birth, blood samples are collected from newborns through a small heel-prick—typically before the baby leaves the hospital. According to a 2003 study by the Government Accountability Office, states spend an average of \$30 per infant on screening. Early detection and treatment of newborn conditions, however, often can prevent future state costs for medical, educational and support services.

Although states determine newborn screening requirements, they often rely on national recommendations. In 2006, the U.S. Department of Health and Human Services (HHS) developed the Uniform Newborn Screening Panel, a list of tests based on recommendations by the American College of Medical Genetics and supported by the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children. Today, the recommended panel consists of 31 core and 26 secondary conditions. Guidelines for selecting core conditions consider the tests' ability to detect the condition soon after birth, the availability of an effective test, and the benefits of early detection and treatment. Secondary conditions are disorders that may be detected through further examination of core condition screening results.

State Action

Each state determines the disorders required for screening, appropriates funding sources for the programs and designs initiatives to educate parents. Currently, all states require screens for at least 26 of the federally recommended core conditions; state testing requirements for secondary conditions range from none to all 26.

Because the federal advisory committee has added recommendations, some states have included these conditions in their requirements. In 2010 and 2011, for example, the committee added screenings for critical congenital heart disease (CCHD) and severe combined immunodeficiency disorder (SCID) to the Uniform Newborn Screening panel. Since 2011, Connecticut, Indiana, Maryland, New Hampshire, New Jersey, Tennessee and West Virginia

Did You Know?

- Newborn screening first started when a screen was developed for phenylketonuria (PKU) in the 1960s. Today, screening is available for more than 60 conditions.
- Each year, about 12,500 infants are diagnosed with a core condition on the Uniform Newborn Screening Panel.
- Early detection of genetic disorders can save money for states and families.

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have passed laws requiring newborn screening for CCHD, while a California law requires that the test be offered. During the 2011-2012 legislative session, California, Illinois and Missouri enacted legislation to include screening for SCID. Some other states have required the screens through state agency regulations or other means; a few states are studying or considering the issue.

After testing is complete, some states retain blood samples for research, data collection and birth defect registries to help identify birth defect causes and prevalence. To protect patient privacy, many state laws require that genetic material remain private unless parents give informed consent for the sample to be used for purposes other than screening their child. Some states also regulate how long the samples should be stored—some for only a few weeks, and some indefinitely—and proper disposal methods to ensure genetic information remains private. Finally, laws in many states allow parents to opt out of newborn screening programs entirely if it is against their religious or philosophical beliefs.

Policymakers play important roles in follow-up activities—ensuring additional diagnostic tests or specialty care, providing access to needed treatment and informing parents about services available to children with special health care needs. For example, many states require insurance companies to provide coverage for infant formula specifically designed for metabolic disorders, at an average annual cost of \$7,100.

Federal Action

Medicaid covers newborn screening as one of the many services required by the Early Periodic Screening, Diagnosis and Treatment benefit. Under the benefit, states have some flexibility. They are not required to cover all the recommended tests in the Uniform Screening Panel. The benefit requires Medicaid to cover further testing services and medically necessary care for treatable abnormal screening results.

The Patient Protection and Affordable Care Act also expands access to newborn screening by requiring insurance coverage of specified preventive services for children without cost sharing (such as copayments and co-insurance, for example). Under this provision, most private health insurance plans now must cover all newborn screens on the Uniform Screening Panel without cost sharing, even in states that do not require screens for all listed conditions.

NCSL Contacts and Resources

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Insurance Coverage of Medically Necessary
Foods and Formula to Treat Disorders
Identified Through Newborn Screening

Newborn Genetic and Metabolic Screening State Laws

Newborn Hearing Screening State Laws


Other Resources

Centers for Disease Control and Prevention:
Newborn Screening

National Newborn Screening and Genetics
Resource Center

Baby's First Test

Screening Newborns for Heart Defects



Newborns across the country are routinely screened for all sorts of health problems. Eight state legislatures have recently added a test for congenital heart defects to the list, and others are considering doing so.

Problems with the walls, valves, arteries or veins of the heart are some of the most common types of birth defects, affecting up to nine of every 1,000 births. Of the approximately 4 million babies born in the United States each year, more than 4,800 have a critical heart defect, putting them at higher risk for disabilities and early death. Early treatment is crucial, but often these babies appear healthy and go home before problems are detected. Critical heart disease is responsible for more deaths in the first year of life than any other birth defect.

All states screen for some genetic disorders and hearing problems. The U.S. Department of Health and Human Services' advisory committee on heritable disorders recommends screenings for 31 core disorders and 26 secondary disorders. The committee added a recommendation for congenital heart disease screening—known as pulse oximetry—in September 2011, which was endorsed by the American Academy of Pediatrics, the American College of Cardiology Foundation and the American Heart Association.

The pulse oximetry test measures the oxygen saturation in the blood; a low level can indicate additional testing is needed to look for heart problems. The screening detects about 77 percent of all congenital heart defects and is more effective than a basic clinical exam and prenatal tests.

Diagnosing heart problems early may eliminate future health care costs, such as emergency room visits, and may reduce the risk of medical malpractice suits against providers for failing to detect heart problems at birth. Supporters point out that many hospitals already have pulse oximeter machines, and that the test costs only \$5 to \$10 and takes about three minutes.

There are downsides, however. Smaller hospitals may not have the proper equipment or specialists to conduct follow-up tests, and false positives may require additional costly tests and cause unnecessary stress on parents. A recent study in the United Kingdom, however, found that false positive rates are low, occurring approximately one in 1,000 times.

Connecticut, Indiana, Maryland, New Hampshire, New Jersey, Tennessee and West Virginia passed laws requiring—and California requires offering—pulse oximetry screening of newborns. Another nine states have considered legislation, and two had bills pending at press time. And some states, even without legislation, require the test and are studying the issue. In Minnesota, a group of medical professionals, state officials and administrators developed a pilot program to conduct screenings. The Colorado General Assembly adopted a resolution requesting that the Department of Public Health and Environment develop a screening system, while an Alabama resolution commends the health department for requiring screening. In addition, six states have adopted resolutions to raise awareness about congenital heart defects.

—Jennifer B. Saunders

21-33B-10
NJ

CHAPTER 74

AN ACT concerning newborn screening and supplementing Title 26 of the Revised Statutes.

BE IT ENACTED by the Senate and General Assembly of the State of New Jersey:

C.26:2-111.3 Findings, declarations relative to newborn screening for congenital heart defects.

1. The Legislature finds and declares that:

a. Congenital heart defects (CHDs) are structural abnormalities of the heart that are present at birth; CHDs range in severity from simple problems such as holes between chambers of the heart, to severe malformations, such as the complete absence of one or more chambers or valves; some critical CHDs can cause severe and life-threatening symptoms which require intervention within the first days of life;

b. According to the United States Secretary of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children, congenital heart disease affects approximately seven to nine of every 1,000 live births in the United States and Europe; the federal Centers for Disease Control and Prevention states that CHD is the leading cause of infant death due to birth defects;

c. Current methods for detecting CHDs generally include prenatal ultrasound screening and repeated clinical examinations; while prenatal ultrasound screenings can detect some major congenital heart defects, these screenings, alone, identify less than half of all CHD cases, and critical CHD cases are often missed during routine clinical exams performed prior to a newborn's discharge from a birthing facility;

d. Pulse oximetry is a non-invasive test that estimates the percentage of hemoglobin in blood that is saturated with oxygen; when performed on a newborn a minimum of 24 hours after birth, pulse oximetry screening is often more effective at detecting critical, life-threatening CHDs which otherwise go undetected by current screening methods; newborns with abnormal pulse oximetry results require immediate confirmatory testing and intervention; and

e. Many newborn lives could potentially be saved by earlier detection and treatment of CHDs if birthing facilities in the State were required to perform this simple, non-invasive newborn screening in conjunction with current CHD screening methods.

C.26:2-111.4 Birthing facilities required to perform pulse oximetry screening; rules, regulations.

2. a. The Commissioner of Health and Senior Services shall require each birthing facility licensed by the Department of Health and Senior Services to perform a pulse oximetry screening, a minimum of 24 hours after birth, on every newborn in its care.

b. As used in this section, "birthing facility" means an inpatient or ambulatory health care facility licensed by the Department of Health and Senior Services that provides birthing and newborn care services.

c. The commissioner shall adopt rules and regulations, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), necessary to carry out the purposes of this act.

3. This act shall take effect on the 90th day after enactment, but the commissioner may take such anticipatory administrative action in advance thereof as shall be necessary for the implementation of this act.

This Act directs the state commissioner of health and senior services to require each birthing facility licensed by the department of health and senior services to perform a pulse oximetry screening, a minimum of 24 hours after birth, on every newborn in its care.

Submitted as:

New Jersey

Chapter 74 of 2011

Status: Enacted into law in 2011.

GO TO TABLE OF CONTENTS

Comment:

First-in-the-Nation New Jersey Newborn Heart Defect
Screening Law Already Saving Lives

Trenton, NJ – Governor Chris Christie today toured Newton Medical Center and met with the Gordon family, whose two-month-old son, Dylan, is alive today because of detection and treatment resulting from New Jersey's first-in-the nation law requiring newborns to be screened for life-threatening heart defects before leaving the hospital.

On September 1, a day after the law mandating inclusion of pulse oximetry testing on newborns became effective, a hospital pediatrician informed Lisa and Bill Gordon of Newton that the test performed on their baby was abnormal and that he had a heart murmur. Dylan was rushed to Morristown Medical Center, where it was determined he needed specialized pediatric cardiac surgery. Dylan was transferred to Columbia University Medical Center; and several days later had the life-saving surgery correcting the abnormality discovered from the newly mandated newborn testing.

"As Governor, you sign a lot of bills into law, but it's a rare day when you know a piece of legislation you signed saved a life," said Governor Christie. "As a father of four children, I can just imagine the fear Lisa and Bill endured in those days after the diagnosis. But I can also imagine the relief and joy that overtook their fear when they realized Dylan would be fine. I'm proud to say that New Jersey has led the way in requiring this life-saving test, which demonstrates our commitment to early detection in children like Dylan."

"It is because of your law that our son's life was saved, and my husband and I are very grateful to you," the Gordons wrote in a letter to the Governor last month. "We just can't thank you enough for passing this law and we hope that other states will pass this law in the future. Our son Dylan is proof that the test is worth doing." Mrs. Gordon said she hoped to bring greater attention to this important new law by speaking publicly about Dylan's story.

"Congenital heart defects are not easily detected, but among birth defects, they are the leading cause of infant death, according to the federal Centers for Disease Control and Prevention (CDC)," said Health and Senior Services Commissioner Mary E. O'Dowd. Untreated, congenital birth defects may cause physical and mental disabilities, or even death.

"This new requirement solidifies New Jersey's position as a leader in early detection and treatment of children," said Commissioner O'Dowd. "More than 102,000 babies are born in New Jersey each year and we know this simple and inexpensive screening test will save other babies' lives."

Since Governor Christie signed the pulse oximetry law on June 2, U.S. Health and Human Services Secretary Katherine Sebelius last month added pulse oximetry to the list of nearly 60 recommended tests for newborns – a list states are not bound to follow but many do. Maryland and Indiana will implement pulse oximetry screening measures next year; other states currently considering legislation include New York, Pennsylvania, Missouri, Tennessee and Nebraska. Minnesota is operating a pulse oximetry screening pilot program at five hospitals in the state.

Dylan was released from Columbia University Medical Center on September 18 and requires a follow-up visit with his pediatric cardiologist every two months.

"Screening all newborns for pulse oximetry allows us the ability to better respond in delivering high-quality care to the most vulnerable of our patients," said Joseph DiPaolo, Director of Operations for Newton Medical Center. "With this simple, non-invasive test meaning the difference between tragedy or a healthy life for this little boy, there's no question that the law mandating pulse oximetry testing has already proved its necessity," said Sue Calvert, RN, the nurse in Newton Medical Center's Maternity Center who performed the test on Dylan. "Performing this test on each of our newborns simply makes sense."

Sponsors of the legislation in the Assembly include Assemblypersons Jason O'Donnell (D-Hudson), Connie Wagner (D-Bergen) and Ruben J. Ramos, Jr. (D-Hudson). Senate version sponsors are Senators Richard J. Codey (D-Essex) and Joseph F. Vitale (D—Middlesex).

Disposition: 21-33B-10

CSG policy task force recommendations to The Committee on Suggested State Legislation:
2013B

- Include in Volume
- Defer consideration to next task force meeting
- Reject
- No action

Comments/Note to staff:

SSL Committee Meeting: 2013B

- Include in Volume
- Defer consideration
 - next task force mtg.
 - next SSL mtg.
 - next SSL cycle
- Reject

Comments/Note to staff:

February 8, 2013 – Responses to Inquiry

The State of Alaska, Division of Public Health, Section of Women's, Children's, and Family Health (WCFH) has assembled a steering committee of healthcare providers in Alaska related to the implementation of pulse oximetry screening of newborns for critical congenital heart defects in Alaska. We are creating a toolkit for birthing centers which will include a State of Alaska position statement on pulse oximetry screening in newborns, resources for health care providers and birthing centers on this practice, the American Academy of Pediatrics/American Heart Association recommendations, and a procedural flowchart for pulse oximetry screening. This steering committee will provide feedback and recommendations on this toolkit and help WCFH promote this practice throughout the state. Many of the larger birthing hospitals in the state have already implemented this testing such as: Samuel Simmonds, Kakanak, Fairbanks Memorial, Bassett Army Hospital, Mat-su Regional, Alaska Regional, Alaska Native Medical Center, Providence Alaska Medical Center, and Mt. Edgecombe Hospital.

1. Is the list of tests from the third party website (Baby's First Test) accurate?

The list on the Baby's First Test website is accurate. The list on our public website notes the categories of conditions we screen for, along with some of the most common disorders. Both sets of information are accurate. For health care providers in Alaska, The State of Alaska and Oregon Public Health Lab created the "Alaska Practitioner's Manual" which lists all of disorders tested on the newborn screening blood spot. The link can be found here:

<http://dhss.alaska.gov/dph/wcfh/Pages/metabolic/resources/manual.aspx>.

2. Why are the following disorders not tested for? (Using the American College of Medical Genetics code)

The State of Alaska has a contract with the State of Oregon Public Health Laboratory (OPHL) to run our blood spot tests. The number and type of tests we screen for are guided by the states that are served by OPHL. OPHL bases their screening on the national recommendations of the federal Secretary's Advisory Committee on Heritable Disorders in Newborns and Children and has generally been one of the first labs in the country to implement new screening recommendations as they are published. There are some tests that are on the list that are not able to be detected during the newborn period and so are not currently on the panel. The physician consultants and lab director participate on national committees that advise the Secretary's Advisory Committee.

- SCID (Severe Combined Immunodeficiencies) – OPHL will be adding this disorder to the newborn screening panel in 2013. They are finalizing plans to ramp up to screen for this as a large scale process. Once OPHL is able to screen for this disorder (as it requires a different method of testing), it will be included in the Alaska panel as well.

- M/SCHAD (Medium/Short-chain L-3-hydroxyacyl-CoA dehydrogenase deficiency) – Not screened for by OPHL or in most other states as it is unlikely to be detected on the newborn screen. It is also considered a secondary condition and not part of the core newborn metabolic conditions.
- MCAT (Medium-chain ketoacyl-CoA thiolase deficiency) – Not screened for by OPHL or in most other states as it is unlikely to be detected on the newborn screen. It is also considered a secondary condition and not part of the core conditions.
- DE RAD (2,4 Dienoyl-CoA reductase deficiency) -- Not screened for by OPHL or in most other states as it is unlikely to be detected on the newborn screen. It is also considered a secondary condition and not part of the core conditions.
- BIOPT (BS) (Biopterin defect in cofactor biosynthesis) -- Not screened for by OPHL as this is done as a follow-up if there is a positive screen. This is also called reflex testing which would be done through diagnostic testing at a different laboratory.
- BIOPT (REG) (Biopterin defect in cofactor regeneration) -- Not screened for by OPHL as this is done as a follow-up if there is a positive screen. This is also called reflex testing which would be done through diagnostic testing at a different laboratory.
- TYR III (Tyrosinemia, type III) -- Not screened for by OPHL as it is extremely rare.
- GALE (Galactosepimerase deficiency) -- Not screened for by OPHL as this is reflex testing which would be done through diagnostic testing at a different laboratory.
- GALK (Galactokinase deficiency) -- Not screened for by OPHL as this is reflex testing which would be done through diagnostic testing at a different laboratory.

3. Do you have the statutory or regulatory authority to require these tests?

The Division of Public Health does not have statutory or regulatory authority to require these tests. Our interpretation has been that the current regulations only cover the blood spot test. Please see the link below for the statutes (AS.18.15.200 and AS.18.15.210) related to newborn bloodspot screening:

<http://www.legis.state.ak.us/basis/statutes.asp?title=18#18.15.200>.

4. Do you have the statutory or regulatory authority to require pulse oximetry (PO) testing for CCHDs? From my reading of the statutes and regulations, it is unclear.

The Division of Public Health does not have the statutory or regulatory authority to require pulse oximetry testing for CCHD. At this time, our approach has been to engage the birthing hospitals and birthing centers in adopting this screening as a best practice and this approach has been widely accepted.

5. Can Medicaid cover the cost of the whole screening program, or just part?

Currently, Medicaid does pay for the cost of the newborn screening blood spot test for newborns eligible for coverage. We also confirmed with State of Alaska Medicaid program that pulse oximetry screening is covered. They reimburse for the CPT code 94760 at \$4.08.

6. Do most major health insurance plans cover the cost of newborn screening?

We suspect that most private health insurance plans cover the newborn screening blood spot test. The State of Alaska distributes and pre-charges the blood spot kits to birthing centers in the state. The birthing facilities in turn bill the patient for this screening as a part of their hospital or birthing center stay. The charge covers the required two blood spot screens.

As a part of our contractual relationship with OPHL, OPHL provides metabolic genetic medical consultation to health care providers in Alaska regarding children with abnormal newborn screening results who need further testing or follow-up. In addition, the metabolic geneticist comes to Alaska four times per year with a specialty Registered Dietician to conduct state-sponsored clinics specially designed for individuals diagnosed with metabolic disorders. These patients are followed through adulthood.

7. Is there a way for low-income families, or families with no insurance, to receive newborn screening for low or no cost?

For low-income families on Medicaid, this cost would be covered. For those families who are self pay or underinsured, most birthing centers work with the family on their health care costs associated with a delivery, postpartum and newborn care.

8. If PO testing is required, do you have an idea of how much this would cost the family?

The hospitals and birthing centers will be charging the family for this testing. The State of Alaska does not set facility fees thus this is not information that we capture.

9. If PO testing is required, do you know how much would it cost the average hospital or birthing facility to set up the instrumentation to screen for CCHDs?

The average cost for the instrumentation is around \$200. This will vary depending on the type of instrument the birthing centers choose to purchase. The cost will also vary

depending on the size of the facility and the number of births they have annually. There would also be some costs related to training hospital personnel. Some instruments contain training videos but it takes an average of two hours per nurse for training. There are also costs related to consultation and referrals, data entry, quality assurance activities, and working with the State of Alaska on developing a system to report abnormal results.

Mindy Rowland

From: Christiansen, James <james.christiansen@seattlechildrens.org>
Sent: Thursday, March 28, 2013 9:23 AM
To: Sen. Peter Micciche
Subject: Pulse oximetry screening legislation

Dear Senator Micciche,

I was surprised but heartened at the announcement of your legislation aimed at improving the detection of critical congenital heart disease in Alaska newborns. I have a very strong passion for this endeavor and would be happy to offer any assistance to you or your staff to educate and enlighten your fellow legislators about this important project. Recently we were involved with a baby who failed screening in the Fairbanks area who was discovered to have critical congenital heart disease. He subsequently had life-saving surgery and is doing very well.

Thank you for this important effort. Please don't hesitate to call me.

Sincerely,
James L. Christiansen MD
Pediatric Cardiology of Alaska
907-212-3655

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