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Lieutenant Governor  
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**OFFICE OF THE LIEUTENANT GOVERNOR  
ALASKA**

**MEMORANDUM**

**TO:** Triptaa Surve  
Department of Health and Social Services

**FROM:** Scott Meriwether, Office of the Lieutenant Governor   
465.4081

**DATE:** May 25, 2018

**RE:** Filed Permanent Regulations: Department of Health and Social Services

Department of Health and Social Services regulations re: newborn bloodspot screening  
(7 AAC 12.416(a); 7 AAC 12.425(b); 7 AAC 27.510 - 7 AAC 27.570; 7 AAC 27.590; 7  
AAC 27.620(a)(2)(K); 7 AAC 80.030(a))

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Attorney General File:	2017200841
Regulation Filed:	5/24/2018
Effective Date:	7/1/2018
Print:	226, July 2018

cc with enclosures: Linda Miller, Department of Law  
Judy Herndon, LexisNexis

ORDER ADOPTING CHANGES TO REGULATIONS  
OF THE DEPARTMENT OF HEALTH & SOCIAL SERVICES

The attached 10 pages of regulations, dealing with the newborn bloodspot screening update, are adopted and certified to be a correct copy of the regulation changes that the Department of Health and Social Services adopts under the authority of AS 18.05.040, AS 18.15.200, AS 18.15.210, AS 44.29.020, AS 44.29.022, and after compliance with the Administrative Procedure Act (AS 44.62), specifically including notice under AS 44.62.190 and 44.62.200 and opportunity for public comment under AS 44.62.210.

This action is not expected to require an increased appropriation.

In considering public comments, the Department of Health and Social Services paid special attention to the cost to private persons of the regulatory action being taken.

The regulation changes adopted under this order take effect on July 1, 2018, as provided in AS 44.62.180.

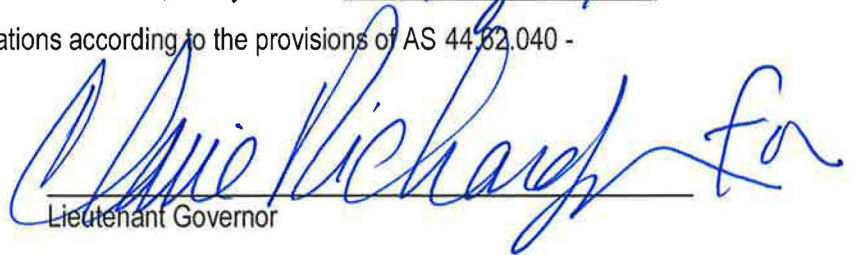
Date: 5-22-18

  
\_\_\_\_\_  
Jon Sherwood  
Deputy Commissioner  
Department of Health & Social Services

*Claire Richardson for*

FILING CERTIFICATION

I, Byron Mallott, Lieutenant Governor for the State of Alaska, certify that I on May 24  
18, at 3:44 p.m., I filed the attached regulations according to the provisions of AS 44.62.040 -  
44.62.120.

  
\_\_\_\_\_  
Lieutenant Governor

Effective: July 1, 2018

Register: 226, July 2018



THE STATE  
of ALASKA

GOVERNOR BILL WALKER

Department of  
Health and Social Services

OFFICE OF THE COMMISSIONER

Anchorage  
3601 C Street, Suite 902  
Anchorage, Alaska 99503-5923  
Main: 907.269.7800  
Fax: 907.269.0060

Juneau  
350 Main Street, Suite 404  
Juneau, Alaska 99801-1149  
Main: 907.465.3030  
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**DELEGATION OF AUTHORITY  
FOR ADOPTING REGULATIONS**

UNDER AS 44.17.010, THE AUTHORITY AND RESPONSIBILITY FOR ADOPTING REGULATIONS OF THE DEPARTMENT OF HEALTH & SOCIAL SERVICES UNDER THE ALASKA ADMINISTRATIVE PROCEDURE ACT ARE HEREBY DELEGATED TO JON SHERWOOD, DEPUTY COMMISSIONER.


SIGNED:

  
\_\_\_\_\_  
Commissioner

  
\_\_\_\_\_  
(Printed name)

SIGNED AND SWORN TO before me this 31<sup>st</sup> day of August, 2015.

[NOTARY SEAL]

  
\_\_\_\_\_  
Notary Public in and for the  
State of Alaska  
My commission expires: w/office



**FOR DELEGATION OF THE LIEUTENANT GOVERNOR'S AUTHORITY**

**I, BYRON MALLOTT, LIEUTENANT GOVERNOR OF THE STATE OF ALASKA, designate the following state employee to perform the Administrative Procedures Act filing functions of the Office of the Lieutenant Governor:**

**Claire Richardson, Special Assistant**

**IN TESTIMONY WHEREOF, I have signed and affixed the Seal of the State of Alaska, in Juneau, on January 7<sup>th</sup> 2015.**



**BYRON MALLOTT  
LIEUTENANT GOVERNOR**





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7 AAC 12.416(a)(10)(A) is amended to read:

(A) distribution of information to clients regarding availability of resources for vitamin K, erythromycin eye prophylaxis, newborn hearing screening tests, **bloodspot** [METABOLIC] screening, and other screening tests required by law;

7 AAC 12.416(a)(12) is amended to read:

(12) procedures for administering newborn **bloodspot** [METABOLIC] screening in compliance with 7 AAC 27.510 - 7 AAC 27.590 [7 AAC 27.5 10 - 7 AAC 27.590] (Screening of Newborn Children for **Congenital** [METABOLIC] Disorders);

(Eff. 5/14/82, Register 82; am 11/19/83, Register 88; am 9/30/2007, Register 183; am

7 / 1 / 2018, Register 226)

**Authority:** AS 47.32.010 AS 47.32.030

7 AAC 12.425(b)(3)(F) is amended to read:

(F) documentation that initial **bloodspot** [METABOLIC] screening was completed for the newborn;

7 AAC 12.425(b)(14) is amended to read:

(14) a plan for newborn health supervision, completion of the initial **bloodspot** [METABOLIC] screening, and required follow-up screening, including the provision for newborn hearing screening; and

(Eff. 5/14/82, Register 82; am 11/19/83, Register 88; am 9/30/2007, Register 183; am

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7/1/2018, Register 226)

**Authority:** AS 47.32.010 AS 47.32.100 AS 47.32.110  
AS 47.32.030

The article heading for 7 AAC 27, Article 10 is changed to read:

**Article 10. Screening of Newborn Children for Congenital [METABOLIC] Disorders.**

7 AAC 27.510 is amended to read:

**7 AAC 27.510. Uniform standards.** (a) The screening of newborn children for **congenital** [METABOLIC] disorders under **7 AAC 27.510 - 7 AAC 27.590** [7 AAC 27.510 - 7 AAC 27.580] must be performed at a single laboratory designated by the department. The screening must be performed on a specimen of the newborn child's blood collected as specified in 7 AAC 27.530. The screening must include tests for phenylketonuria, hypothyroidism, galactosemia, and congenital adrenal hyperplasia. Other conditions may be tested for if the designated laboratory has a test method suitable to the department.

(b) Unless the parent or guardian denies a request for specimens [AS DESCRIBED IN AS 18.15.210], screening under **7 AAC 27.510 - 7 AAC 27.590** [7 AAC 27.510 - 7 AAC 27.580] is required for a newborn child in the state. A newborn child who has not been screened must be reported to the department as prescribed in 7 AAC 27.530(c) [AND (d)]. (Eff. 12/30/77, Register 64; am 2/3/88, Register 105; am 7/13/94, Register 131; am 7/16/2011, Register 199; am 7/1/2018, Register 226)

**Authority:** AS 18.05.040 AS 18.15.200 AS 18.15.210

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7 AAC 27.520(a) is amended to read:

(a) Responsibility for collection and submission of specimens resides with the **health care provider** [PHYSICIAN OR CERTIFIED NURSE MIDWIFE UNDER AS 18.15.200, OR CERTIFIED DIRECT-ENTRY MIDWIFE UNDER 12 AAC 14.530] attending the newborn child. **If a** [A] newborn child [WHO] is not attended by **a** [ONE OF THESE] health care **provider, the department encourages** [PROVIDERS SHOULD BE PRESENTED BY] the newborn child's parent or guardian **to present the newborn child** as early as possible within the newborn child's first **48 hours** [WEEK] of life to a **health care provider** [PHYSICIAN OR PUBLIC HEALTH NURSE] for the required testing as described in 7 AAC 27.530.

(Eff. 12/30/77, Register 64; am 2/3/88, Register 105; am 7/13/94, Register 131; am 7/16/2011, Register 199; am 7 / 1 / 2018, Register 226)

**Authority:** AS 18.05.040 AS 18.15.200 AS 18.15.210

7 AAC 27.530 is repealed and readopted to read:

**7 AAC 27.530. Collection of blood specimen; refusal of collection.** (a) The minimum blood specimen collection requirements for the screening described in 7 AAC 27.510 are the following:

- (1) one specimen must be collected before the newborn child is 48 hours of age;
- (2) if the screening of the initial specimen shows an abnormal result for one or more of the tested conditions or the specimen was contaminated, spoiled, or otherwise not adequate for screening, a second specimen must be collected if requested by the department; and
- (3) a second specimen may be required if a newborn child is born prematurely,

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has a low birth weight, or is admitted to a specialty care unit according to the department's and the unit's screening procedures.

(b) The blood specimen must be collected using the procedure described on the test card for the screening provided by the department. The specimen must be submitted on the test card provided by the department. All information requested on the test card must be provided by the attending health care provider. The specimen must be shipped to the designated laboratory not later than 24 hours after the time the specimen is collected, according to the department's and facility's guidelines and at the department's expense.

(c) If a parent or guardian of a newborn child refuses to permit collection of a specimen, the department encourages the parent or guardian to affirm that refusal by signing a refusal statement, including the same information requested on the test card. The health care provider shall send a copy of the refusal statement to the department. If the parents do not sign the refusal statement, the health care facility shall send the department a copy of the unsigned refusal statement and state in writing on the unsigned statement that the parent or guardian refused to permit collection of a specimen and refused to sign the refusal statement. (Eff. 12/30/77, Register 64; am 10/31/82, Register 84; am 2/3/88, Register 105; am 7/13/94, Register 131; am 12/13/97, Register 144; am 7/16/2011, Register 199; am 7/1/2018, Register 226)

**Authority:** AS 18.05.040 AS 18.15.200 AS 18.15.210

**Editor's note:** The address for reporting the information described in 7 AAC 27.530(c) is the Department of Health and Social Services, division of public health, section of women's, children's, and family health, [IS] 3601 C Street, Suite 322, Anchorage, AK 99503.



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7 AAC 27.540 is amended to read:

**7 AAC 27.540. Specimen collection materials.** The department will provide a **health care provider** [PHYSICIAN, CERTIFIED NURSE MIDWIFE, OR CERTIFIED DIRECT-ENTRY MIDWIFE] with specimen collection materials [, TEST FORMS, AND MAILING CONTAINERS] when ordered through the program manager for the newborn **bloodspot** [METABOLIC] screening (**NBS**) [(NBMS)] program. A request for these materials [, FORMS, AND CONTAINERS] must be directed to the **NBS** [NBMS] program. (Eff. 12/30/77, Register 64; am 10/31/82, Register 84; am 12/6/86, Register 100; am 2/3/88, Register 105; am 7/13/94, Register 131; am 7/16/2011, Register 199; am 7/1 2018, Register 226)

**Authority:** AS 18.05.040 AS 18.15.200 AS 18.15.210

**Editor's note:** The address for the newborn **bloodspot** [METABOLIC] screening (**NBS**) program in the department is the Department of Health and Social Services, division of public health, section of women's, children's, and family health, 3601 C Street, Suite 322, Anchorage, AK 99503.

7 AAC 27.550 is repealed and readopted to read:

**7 AAC 27.550. Results of screening test.** (a) Screening test results must be returned to the health care provider as indicated on the return address portion of the screening test form.

(b) Screening test results must indicate whether the specimen was normal or abnormal, for each test performed.

(c) The designated laboratory shall report to the health care provider and the department



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by the designated method any abnormal results requiring action. Normal results must be reported to the health care provider described in (a) of this section not later than seven days after the designated laboratory receives the results. (Eff. 12/30/77, Register 64; am 2/3/88, Register 105; am 7/13/94, Register 131; am 7/1/2018, Register 226)

**Authority:** AS 18.05.040 AS 18.15.200

7 AAC 27.560 is repealed and readopted to read:

**7 AAC 27.560. Confirmation.** (a) Diagnostic testing must be conducted on a newborn child with abnormal screening test results when required by the designated laboratory. A health care provider who ordered a screening test under 7 AAC 27.530 shall arrange for a newborn child with an abnormal result to have that diagnostic testing performed.

(b) A specimen must be obtained for the diagnostic testing upon request by the department. The department will pay for one or more of the following diagnostic tests required under (a) of this section if the testing is done by a laboratory designated by the department:

- (1) plasma amino acids;
- (2) plasma acylcarnitines;
- (3) urine organic acids;
- (4) total and free carnitine;
- (5) total plasma homocysteine;
- (6) urine acylglycines;
- (7) urine amino acids;
- (8) urine succinylacetone.

(c) The health care provider who ordered the screening test in 7 AAC 27.530 may choose to use a diagnostic laboratory other than the designated laboratory for a diagnostic test required under (a) of this section of the specimen. However, the department will not pay for costs incurred by use of a nondesignated laboratory for the testing.

(d) If diagnostic confirmatory testing is done through a nondesignated laboratory, the health care provider shall report, in writing, the results of the diagnostic testing to the newborn bloodspot screening program in the department, not later than two days after the date of receipt of results of the diagnostic testing.

(e) When a newborn child has an abnormal screening test result and a diagnostic report is not received by the department from the health care provider, the department will contact the child's health care provider.

(f) The department will provide the child's health care provider with a consultation with an appropriate medical specialist for a newborn child undergoing diagnostic testing due to abnormal screening results. (Eff. 12/30/77, Register 64; am 2/3/88, Register 105; am 7/13/94, Register 131; am 7/16/2011, Register 199; am 7/1 2018, Register 226)

**Authority:** AS 18.05.040 AS 18.15.200

**Editor's note:** The address for the newborn **bloodspot** [METABOLIC] screening (**NBS**) program in the department is the Department of Health and Social Services, division of public health, section of women's, children's, and family health, 3601 C Street, Suite 322, Anchorage, AK 99503.

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7 AAC 27.570 is amended to read:

**7 AAC 27.570. Annual review and report.** The department will appoint a committee to annually review the results of the newborn **bloodspot** [CHILD METABOLIC DISORDER] screening program, consider addition or deletion of tests based on experience in this state and on newly developed tests recommended by the **United States Department of Health and Human Services Secretary's Advisory Committee on Heritable Disorders in Newborns and Children** [AMERICAN ACADEMY OF PEDIATRICS, COMMITTEE ON GENETICS], and report to [HEALTH CARE PROVIDERS AND] the public on these matters. (Eff. 2/3/88, Register 105; am 7/13/94, Register 131; am 7/1/2018, Register 226)

**Authority:** AS 18.05.040 AS 18.15.200

**Editor's note:** Information on newly developed [METABOLIC] screening tests recommended by the **United States Department of Health and Human Services Secretary's Advisory Committee on Heritable Disorders in Newborns and Children**, [AMERICAN ACADEMY OF PEDIATRICS] may be obtained by contacting the **Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, MD 20857** [AMERICAN ACADEMY OF PEDIATRICS, 141 NORTHWEST POINT BLVD., P.O. BOX 927, ELK GROVE VILLAGE, ILLINOIS 60009-0927].

7 AAC 27.590 is repealed and readopted to read:

**7 AAC 27.590. Definitions.** In 7 AAC 27.510 - 7 AAC 27.590,

(1) "department" means the Department of Health and Social Services;

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(2) "designated laboratory" means a laboratory designated by the department to perform screening of blood specimens for congenital disorders;

(3) "health care provider" means any of the following providers licensed under AS 08:

(A) a physician;

(B) an advanced practice registered nurse, including a certified nurse midwife;

(C) a certified direct-entry midwife. (Eff. 7/13/94, Register 131; am

7/1/2018, Register 226)

**Authority:** AS 18.05.040 AS 18.15.200

7 AAC 27.620(a)(2)(K) is amended to read:

(K) any additional information that the department considers necessary to match the results or status of **bloodspot** [NEWBORN METABOLIC DISORDER] screening conducted under **7 AAC 27.510 - 7 AAC 27.590 for newborn congenital disorders** [7 AAC 27.510 - 7 AAC 27.580] with the appropriate child reported under the newborn hearing screening program.

(Eff. 1/17/2008, Register 185; am 7/1/2018, Register 226)

**Authority:** AS 18.05.040 AS 47.20.310 AS 47.20.320  
AS 47.20.300

7 AAC 80.030(a) is amended to read:

(a) Following are the fees for the listed public health services:

SERVICE	FEE
<p>• • •</p> <p><b><u>BLOODSPOT</u></b> [METABOLIC] SCREENING TEST FOR NEWBORNS</p> <p>• • •</p>	<p>• • •</p> <p>\$159.50 for <b><u>each infant screened for specimens required under 7 AAC 27.530</u></b> [DOUBLE-CARD KITS];</p> <p>\$100 for <b><u>each submitted specimen not required under 7 AAC 27.530</u></b> [SINGLE-CARD KITS, FOR LOST OR DAMAGED CARDS]</p> <p>• • •</p>

(Eff. 12/6/86, Register 100; am 2/3/88, Register 105; am 4/28/94, Register 130; am 8/19/98, Register 147; am 10/1/2003, Register 167; am 12/24/2006, Register 180; am 1/1/2009, Register 188; am 6/16/2016, Register 218; am 7 / 1 / 2018, Register 226)

**Authority:** AS 18.05.040 AS 44.29.020 AS 44.29.022



# MEMORANDUM


State of Alaska  
Department of Law

**To:** Hon. Byron Mallott  
Lieutenant Governor

**Date:** May 24, 2018

**File No.:** 2017200841

**Tel. No.:** 465-3600

**From:** Steven C. Weaver   
Sr. Assistant Attorney General  
and Assistant Regulations Attorney  
Legislation and Regulations Section

**Re:** Department of Health and Social  
Services regulations re: newborn  
bloodspot screening (7 AAC  
12.416(a); 7 AAC 12.425(b); 7 AAC  
27.510 - 7 AAC 27.570; 7 AAC  
27.590; 7 AAC 27.620(a)(2)(K);  
7 AAC 80.030(a))

We have reviewed the attached regulations from the Department of Health and Social Services against the statutory standards of the Administrative Procedure Act. I have reviewed this project under a specific delegation dated May 23, 2018 from the Regulations Attorney. The regulations update procedures and requirements for the newborn bloodspot screening program for congenital disorders.

We find no legal problems. This memorandum constitutes the written statement of approval under AS 44.62.060(b) and (c) that authorizes your office to file the attached regulations.

Please alert the publisher that, for the amendment to 8 AAC 80.030(a), the attached regulations display only the single row that the agency is amending within a larger table, and that the rest of the table is unchanged.

Also, please note that the adoption order for these regulations sets out a special effective date of July 1, 2018.

The February 8, 2018 public notice and the May 22, 2018 adoption order both state that this action is not expected to require an increased appropriation. Therefore, a fiscal note under AS 44.62.195 is not required.

SCW

cc w/enc: (via email)

Hon. Valerie "Nurr'araaluk" Davidson, Commissioner  
Department of Health and Social Services

Triptaa Surve, Regulations Contact  
Department of Health and Social Services

Jon Sherwood, Deputy Commissioner  
Department of Health and Social Services

Jay C. Butler, M.D., Director  
Division of Public Health  
Department of Health and Social Services

Sabra Anckner  
Division of Public Health  
Department of Health and Social Services

April Simpson  
Office of the Lieutenant Governor

Kelly E. Henriksen, Senior Assistant Attorney General  
Human Services Section

# MEMORANDUM

## State of Alaska Department of Law

**TO:** Hon. Byron Mallott  
Lieutenant Governor

**DATE:** May 23, 2018

**FILE NO.:** 2017200841

**TELEPHONE NO.:** (907) 465-3600

**FROM:** Susan R. Pollard *SPP*  
Chief Assistant Attorney General  
and Regulations Attorney  
Legislation/Regulations Section

**SUBJECT:** Specific delegation of authority regarding regulations review on Department of Health and Social Services regulations re: newborn bloodspot screening (7 AAC 12.416(a); 7 AAC 12.425(b); 7 AAC 27.510 - 7 AAC 27.570; 7 AAC 27.590; 7 AAC 27.620(a)(2)(K); 7 AAC 80.030(a))

By this memorandum, I am delegating my authority as Regulations Attorney under AS 44.62 to Assistant Attorney General Steven C. Weaver for the above-referenced regulations project. Under this delegation of authority, Steven Weaver has my full authority under AS 44.62 to conduct the legal review under AS 44.62 and take necessary actions on this regulations project.

If you have questions, please let me know.

SCW

cc w/enc: Scott C. Meriwether, AAC Coordinator  
Office of the Lieutenant Governor

Steven C. Weaver  
Sr. Assistant Attorney General and  
Assistant Regulations Attorney  
Legislation/Regulations Section

NOTICE OF PROPOSED CHANGES ON NEWBORN BLOODSPOT SCREENING  
IN THE REGULATIONS OF THE DEPARTMENT OF HEALTH & SOCIAL SERVICES

BRIEF DESCRIPTION

The Department of Health & Social Services proposes to change regulations on newborn bloodspot screening.

The Department of Health & Social Services proposes to adopt regulation changes in Title 7 of the Alaska Administrative Code, dealing with screening of newborn infants for congenital disorders, including the following:

(1) 7 AAC 27.510- .580 is proposed to be changed as follows:

- Reduce the number of required screens per infant.
- Propose that the Department pay for shipping costs related to Newborn Bloodspot Screening specimens.
- Clarify procedures for notifying the Department of screening refusals.
- Clarify procedures for completing diagnostic testing after an abnormal screening result.
- Eliminate the fee for single-card kits.
- Change the program name from Newborn Metabolic Screening to Newborn Bloodspot Screening.
- Change the title of Article from Screening of Newborn Children for Metabolic Disorders to Congenital Disorders.

(2) 7 AAC 27.530(a)(1), is proposed to be repealed. The intended effect of this repeal is to eliminate the requirement to collect specimens on infants who die before 48 hours of life.

(3) 27.530 (c) is proposed to be repealed. The intended effect of this repeal is to eliminate the burdensome requirement that birth providers submit weekly birth lists to the Department. The required information is obtained through an agreement with the Division of Health Analytics and Vital Records.

You may comment on the proposed regulation changes, including the potential costs to private persons of complying with the proposed changes, by submitting written comments to Sabra Anckner, Nurse Consultant, Women's, Children's, and Family Health, 3601 C Street, Suite 322, Anchorage, AK 99503. Additionally, the Department of Health and Social Services will accept comments by facsimile at (907) 754-3455 and by electronic mail at [sabra.anckner@alaska.gov](mailto:sabra.anckner@alaska.gov). The comments must be received not later than 5 p.m. on April 3, 2018.

Oral or written comments also may be submitted at a hearing to be held on March 16, 2018, at the Frontier Building, 3601 C Street, Suite 300 Conference Room, Anchorage, AK 99503. The hearing will be held from 11:00 a.m. to 1:00 p.m. and might be extended to accommodate those present before 12:30 p.m. who did not have an opportunity to comment. If you are unable to attend in person, but would like to comment during the oral public hearing, you can call the teleconference number 1-800-897-4662 (toll free).

You may submit written questions relevant to the proposed action to Sabra Anckner by e-mail at [sabra.anckner@alaska.gov](mailto:sabra.anckner@alaska.gov) or at the Department of Health & Social Services, Division of Public Health,

Women's, Children's, and Family Health, 3601 C Street, Suite 322, Anchorage, AK 99503. The questions must be received at least 10 days before the end of the public comment period. The Department of Health & Social Services will aggregate its response to substantially similar questions and make the questions and responses available on the Alaska Online Public Notice System and agency website at <http://dhss.alaska.gov/dph/wcfh/Pages/bloodspot/default.aspx>.

If you are a person with a disability who needs a special accommodation in order to participate in this process, please contact Sabra Anckner at [sabra.anckner@alaska.gov](mailto:sabra.anckner@alaska.gov) or at (907) 334-2295 not later than March 7, 2018, to ensure that any necessary accommodations can be provided.

A copy of the proposed regulation changes is available on the Alaska Online Public Notice System and by contacting Sabra Anckner at [sabra.anckner@alaska.gov](mailto:sabra.anckner@alaska.gov) or at (907) 334-2295.

A copy of material proposed for adoption by reference may be viewed at the agency's office at Women's, Children's, and Family Health, 3601 C Street, Suite 322, Anchorage, AK 99503.

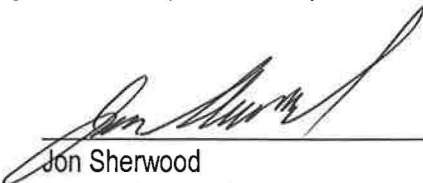
After the public comment period ends, the Department of Health & Social Services will either adopt the proposed regulation changes or other provisions dealing with the same subject, without further notice, or decide to take no action. The language of the final regulation may be different from that of the proposed regulation. **You should comment during the time allowed if your interests could be affected.**

**Statutory authority:** AS 18.05.040; AS 18.15.200; AS 18.15.210; AS 44.29.020; AS 44.29.022.

**Statutes being implemented, interpreted, or made specific:** AS 18.05.040; AS 18.15.200; AS 18.15.210; AS 44.29.020; AS 44.29.022.

**Fiscal information:** The proposed regulation changes are not expected to require an increased appropriation.

DATE: 2-2-18

  
\_\_\_\_\_  
Jon Sherwood  
Deputy Commissioner  
Department of Health & Social Services



NOTICE OF PROPOSED CHANGES ON NEWBORN BLOODSPOT SCREENING  
IN THE REGULATIONS OF THE DEPARTMENT OF HEALTH & SOCIAL SERVICES

The Department of Health & Social Services proposes to adopt regulation changes in Title 7 of the Alaska Administrative Code, dealing with screening of newborn infants for congenital disorders, including the following:

(1) 7 AAC 27.510- .580 is proposed to be changed as follows:

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You may comment on the proposed regulation changes, including the potential costs to private persons of complying with the proposed changes, by submitting written comments to Sabra Anckner, Nurse Consultant, Women's, Children's, and Family Health, 3601 C Street, Suite 322, Anchorage, AK 99503. Additionally, the Department of Health and Social Services will accept comments by facsimile at (907) 754-3455 and by electronic mail at [sabra.anckner@alaska.gov](mailto:sabra.anckner@alaska.gov) . The comments must be received not later than 5 p.m. on April 3, 2018.

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You may submit written questions relevant to the proposed action to Sabra Anckner by e-mail at [sabra.anckner@alaska.gov](mailto:sabra.anckner@alaska.gov) or at the Department of Health & Social Services, Division of Public Health, Women's, Children's, and Family Health, 3601 C Street, Suite 322, Anchorage, AK 99503. The questions must be received at least 10 days before the end of the public comment period. The Department of Health & Social Services will aggregate its response to substantially similar questions and make the questions and responses available on the Alaska Online Public Notice System and agency website at <http://dhss.alaska.gov/dph/wcfh/Pages/bloodspot/default.aspx> .

If you are a person with a disability who needs a special accommodation in order to participate in this process, please contact Sabra Anckner at [sabra.anckner@alaska.gov](mailto:sabra.anckner@alaska.gov) or at (907) 334-2295 not later than March 7, 2018, to ensure that any necessary accommodations can be provided.

A copy of the proposed regulation changes is available on the Alaska Online Public Notice System and by contacting Sabra Anckner at [sabra.anckner@alaska.gov](mailto:sabra.anckner@alaska.gov) or at (907) 334-2295.

A copy of material proposed for adoption by reference may be viewed at the agency's office at Women's, Children's, and Family Health, 3601 C Street, Suite 322, Anchorage, AK 99503.

After the public comment period ends, the Department of Health & Social Services will either adopt the proposed regulation changes or other provisions dealing with the same subject, without further notice, or decide to take no action. The language of the final regulation may be different from that of the proposed regulation. **You should comment during the time allowed if your interests could be affected.**

**Statutory authority:** AS 18.05.040; AS 18.15.200; AS 18.15.210; AS 44.29.020; AS 44.29.022.

**Statutes being implemented, interpreted, or made specific:** AS 18.05.040; AS 18.15.200; AS 18.15.210; AS 44.29.020; AS 44.29.022.

**Fiscal information:** The proposed regulation changes are not expected to require an increased appropriation.

DATE: 2-2-18

  
\_\_\_\_\_  
Jon Sherwood  
Deputy Commissioner  
Department of Health & Social Services

ADDITIONAL REGULATION NOTICE INFORMATION  
(AS 44.62.190(d))<sup>1</sup>

1. Adopting agency: Department of Health & Social Services
2. General subject of regulation: Newborn bloodspot screening.
3. Citation of regulation (may be grouped): 7 AAC 27.510-.570, 7AAC 80.030.
4. Department of Law file number, if any: 2017200841
  
5. Reason for the proposed action:  
 Compliance with federal law or action (identify): \_\_\_\_\_  
 Compliance with new or changed state statute  
 Compliance with federal or state court decision (identify): \_\_\_\_\_  
 Development of program standards  
 Other (identify): \_\_\_\_\_
  
6. Appropriation/Allocation: N/A
  
7. Estimated annual cost to comply with the proposed action to:  
A private person: None  
Another state agency: None  
A municipality: None
  
8. Cost of implementation to the state agency and available funding (in thousands of dollars): None.

	Initial Year FY _____	Subsequent Years
Operating Cost	\$ _____	\$ _____
Capital Cost	\$ _____	\$ _____
1002 Federal receipts	\$ _____	\$ _____
1003 General fund match	\$ _____	\$ _____
1004 General fund	\$ _____	\$ _____
1005 General fund/ program	\$ _____	\$ _____
Other (identify)	\$ _____	\$ _____


9. The name of the contact person for the regulation:

Name: Sabra Anckner, RN, BSN  
Title: Perinatal Nurse Consultant  
Address: 3601 C St., Suite 322, Anchorage, AK 99503.  
Telephone: (907) 334-2295

E-mail address: [sabra.anckner@alaska.gov](mailto:sabra.anckner@alaska.gov)

10. The origin of the proposed action:

- Staff of state agency
- Federal government
- General public
- Petition for regulation change
- Other (identify): \_\_\_\_\_

11. Date: 2/1/2018 Prepared by:  \_\_\_\_\_

[signature]

Name (printed): Sabra Anckner, RN, BSN \_\_\_\_\_

Title (printed): Perinatal Nurse Consultant \_\_\_\_\_

Telephone: (907) 334-2295 \_\_\_\_\_



AFFIDAVIT OF NOTICE OF PROPOSED REGULATION  
AND FURNISHING OF ADDITIONAL INFORMATION


I, Triptaa Surve, Project Coordinator, of the Department of Health & Social Services, being sworn, state the following:

As required by AS 44.62.190, notice of the proposed adoption of changes to the Newborn Bloodspot Screening (7 AAC 27.510-.570, 7 AAC 80.030), has been given by being

- (1) published in a newspaper or trade publication;
- (2) furnished to interested persons;
- (3) furnished to appropriate state officials;
- (4) furnished to the Department of Law, along with a copy of the proposed regulation;
- (5) furnished electronically to incumbent State of Alaska legislators;
- (6) furnished to the Legislative Affairs Agency, Division of Legal and Research Services;
- (7) posted on the Alaska Online Public Notice System as required by AS 44.62.175(a)(1) and (b) and 44.62.190(a)(1);
- (8) furnished electronically, along with a copy of the proposed regulation, to the Legislative Affairs Agency, the chair of the Health & Social Services and Finance Committees of the Alaska Senate and House of Representatives, the Administrative Regulation Review Committee, and the legislative council.

As required by AS 44.62.190, additional regulation notice information regarding the proposed adoption of the regulation changes described above has been furnished to interested persons and those in (5) and (6) of the list above. The additional regulation notice information also has been posted on the Alaska Online Public Notice System.

Date: April 13, 2018 4

  
\_\_\_\_\_  
Triptaa Surve, Project Coordinator

Subscribed and sworn to before me at Anchorage AK on 4-13-18  
(date)

Cheryl Patterson  
\_\_\_\_\_  
Notary Public in and for the State of Alaska

[NOTARY SEAL]



AFFIDAVIT OF ORAL HEARING

I, Sabra Anckner, Nurse Consultant II, of Department of Health and Social Services, being sworn, state the following:

On March 16, 2018, from 11:00 AM – 1:00 PM, in Suite 300 Conference Room, 3601 C St, Anchorage, AK, I presided over a public hearing held under AS 44.62.210 for the purpose of taking testimony in connection with the adoption of changes to Newborn Bloodspot Screening, 7 AAC 27.510-.580.

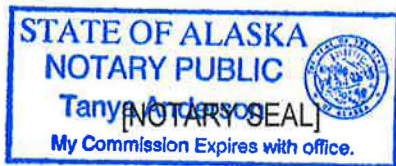
Date: 4/11/18

*Sabra Anckner*  
Sabra Anckner, Nurse Consultant II

Subscribed and sworn to before me at Anchorage, Alaska

4/11/2018  
(date)

*Tanya Anderson*  
Notary Public in and for the State of Alaska



AFFIDAVIT OF AGENCY RECORD OF PUBLIC COMMENT

I, Sabra Anckner, Perinatal Nurse Consultant for the Department of Health and Social Services, being duly sworn, state the following:

In compliance with AS 44.62.215, the Department of Health and Social Services has kept a record of its use or rejection of factual or other substantive information that was submitted in writing and orally as public comment and that was relevant to the accuracy, coverage, or other aspect of the Department of Health and Social Services regulation on the newborn blood spot screening update.

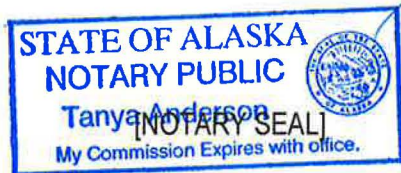
Date: 4/11/18

Sabra Anckner  
Sabra Anckner, Perinatal Nurse Consultant

Subscribed and sworn to before me at Anchorage, Alaska on

4/11/2018  
(date)

Tanya Anderson  
Notary Public in and for the State of Alaska





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# AFFIDAVIT OF PUBLICATION

STATE OF ALASKA  
THIRD JUDICIAL DISTRICT

Joleesa Stepetin  
being first duly sworn on oath deposes and says that he/she is a representative of the Anchorage Daily News, a daily newspaper. That said newspaper has been approved by the Third Judicial Court, Anchorage, Alaska, and it now and has been published in the English language continually as a daily newspaper in Anchorage, Alaska, and it is now and during all said time was printed in an office maintained at the aforesaid place of publication of said newspaper. That the annexed is a copy of an advertisement as it was published in regular issues (and not in supplemental form) of said newspaper on

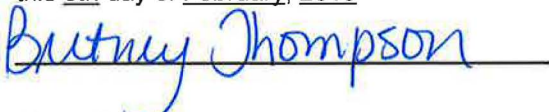
February 08, 2018

and that such newspaper was regularly distributed to its subscribers during all of said period. That the full amount of the fee charged for the foregoing publication is not in excess of the rate charged private individuals.

Signed



Subscribed and sworn to before me  
this 8th day of February, 2018



Notary Public in and for  
The State of Alaska.  
Third Division  
Anchorage, Alaska  
MY COMMISSION EXPIRES

2/23/2019

Notary Public  
BRITNEY L. THOMPSON  
State of Alaska  
My Commission Expires Feb 23, 2019

## NOTICE OF PROPOSED CHANGES ON NEWBORN BLOODSPOT SCREENING IN THE REGULATIONS OF THE DEPARTMENT OF HEALTH & SOCIAL SERVICES

The Department of Health & Social Services proposes to adopt regulation changes in Title 7 of the Alaska Administrative Code, dealing with screening of newborn infants for congenital disorders, including the following:

- (1) 7 AAC 27.510-.580 is proposed to be changed as follows:
- Reduce the number of required screens per infant.
  - Propose that the Department pay for shipping costs related to Newborn Bloodspot Screening
  - Clarify procedures for notifying the Department of screening refusals.
  - Clarify procedures for completing diagnostic testing after an abnormal screening result.
  - Eliminate the fee for single-card kits.
  - Change the program name from Newborn Metabolic Screening to Newborn Bloodspot Screening.
  - Change the title of Article from Screening of Newborn Children for Metabolic Disorders to Congenital Disorders.

(2) 7 AAC 27.530(a)(1), is proposed to be repealed. The intended effect of this repeal is to eliminate the requirement to collect specimens on infants who die before 48 hours of life.

(3) 7 AAC 27.530 (c) is proposed to be repealed. The intended effect of this repeal is to eliminate the burdensome requirement that birth providers submit weekly birth lists to the Department. The required information is obtained through an agreement with the Division of Health Analytics and Vital Records.

You may comment on the proposed regulation changes, including the potential costs to private persons of complying with the proposed changes, by submitting written comments to Sabra Anckner, Nurse Consultant, Women's, Children's, and Family Health, 3601 C Street, Suite 322, Anchorage, AK 99503.

Additionally, the Department of Health and Social Services will accept comments by facsimile at (907) 754-3455 and by electronic mail at [sabra.anckner@alaska.gov](mailto:sabra.anckner@alaska.gov). The comments must be received not later than 5 p.m. on April 3, 2018.

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If you are a person with a disability who needs a special accommodation in order to participate in this process, please contact Sabra Anckner at [sabra.anckner@alaska.gov](mailto:sabra.anckner@alaska.gov) or at (907) 334-2295 not later than March 7, 2018, to ensure that any necessary accommodations can be provided.

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**Statutes being implemented, interpreted, or made specific:** AS 18.05.040; AS 18.15.200; AS 18.15.210; AS 44.29.020; AS 44.29.022.

**Fiscal information:** The proposed regulation changes are not expected to require an increased appropriation.

DATE: February 2, 2018  
/s/ Jon Sherwood  
Deputy Commissioner  
Department of Health & Social Services

Published: February 8, 2018