

# DEPARTMENT OF HEALTH & SOCIAL SERVICES



## PROPOSED CHANGES TO REGULATIONS

### NEWBORN BLOODSPOT SCREENING UPDATE

- 7 AAC 27.510-.570, .590. *Preventive Medical Services; Article 10. Screening of Newborn Children for Metabolic Disorders.*
- 7 AAC 80.030. *Fees for Department Services. Fee schedule and procedures.*



### PUBLIC REVIEW DRAFT

*January 31, 2018*

**COMMENT PERIOD ENDS: April 3, 2018**

***Please see the public notice for details about how to comment on these proposed changes.***

**Notes to reader:**

1. Except as discussed in note 2, new text that amends an existing regulation is **bolded and underlined**.
2. If the lead-in line above the text of each section of the regulations states that a new section, subsection, paragraph, or subparagraph is being added, or that an existing section, subsection, paragraph, or subparagraph is being repealed and readopted (replaced), *the new or replaced text is not bolded or underlined*.
3. [ALL-CAPS TEXT WITHIN BRACKETS] indicates text that is to be deleted.
4. When the word “including” is used, Alaska Statutes provide that it means “including, but not limited to.”
5. Only the text that is being changed within a section of the current regulations is included in this draft. Refer to the text of that whole section, published in the current Alaska Administrative Code, to determine how a proposed change relates within the context of the whole section and the whole chapter.

**Title 7 Health and Social Services.****Chapter 27  
Preventive Medical Services**

The title for Article 10 is amended to read:

**Article 10**

Screening of Newborn Children for **Congenital** [METABOLIC] Disorders

**7 AAC 27.510. Uniform standards.**

7 AAC 27.510(a) is amended to read:

(a) The screening of newborn children for **congenital** [METABOLIC] disorders under 7 AAC 27.510 - 7 AAC 27.580 must be performed at a single laboratory designated by the department.

...

(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 \_\_\_\_/\_\_\_\_/\_\_\_\_, Register \_\_\_\_)

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

**7 AAC 27.520. Persons required to collect specimens.**

7 AAC 27.520(a) is amended to read:

(a) Responsibility for collection and submission of specimens resides with the physician or certified nurse midwife under AS 18.15.200, or certified direct-entry midwife under 12 AAC 14.530 attending the newborn child. A newborn child who is not attended by one of these health care providers should be presented by the newborn child's parent or guardian 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 \_\_\_\_/\_\_\_\_/\_\_\_\_, Register \_\_\_\_\_)

**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

- (1) one specimen collected before the newborn child is 48 hours of age; or
- (2) if the screening of the initial specimen has shown 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 as requested by the department; or
- (3) a second specimen may be required if a newborn child is born prematurely, had a low birth weight, or is admitted to a specialty care unit per the department's and the unit's screening **procedures** [GUIDELINES].

(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 physician, certified nurse midwife, or certified direct-entry midwife. The specimen must be shipped to the designated laboratory within 24 hours of the time the specimen is collected per the department's guidelines, at the department's expense.

(c) A parent or guardian of a newborn child who refuses to permit collection of a specimen should affirm that refusal by signing a refusal statement, including the same information requested on the test form, a copy of which shall be sent to the department.

(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 \_\_\_\_/\_\_\_\_/\_\_\_\_, Register \_\_\_\_)

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

#### **7 AAC 27.540. Specimen collection materials.**

7 AAC 27.540 is amended to read:

The department will provide a 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 \_\_\_\_/\_\_\_\_/\_\_\_\_, Register \_\_\_\_)

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

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 [PHYSICIAN, CERTIFIED NURSE MIDWIFE, OR CERTIFIED DIRECT-ENTRY MIDWIFE ] 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 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 within 7 days.

(Eff. 12/30/77, Register 64; am 2/3/88, Register 105; am 7/13/94, Register 131; am \_\_\_\_/\_\_\_\_/\_\_\_\_, Register \_\_\_\_)

**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 per department standards. A newborn child with an abnormal result

shall be referred to a health care provider for the diagnostic testing by the practitioner who ordered the screening test under 7 AAC 27.530.

(b) A specimen must be obtained for the diagnostic testing per the department's request. The diagnostic testing [OF THE SPECIMEN SENT TO THE DESIGNATED LABORATORY] must be performed at no charge to the family or **health care provider** [PHYSICIAN] if the testing cannot be completed in Alaska. The physician may choose to use a diagnostic laboratory other than the designated laboratory for diagnostic testing of the specimen. The department will not pay for costs incurred by use of a non-designated laboratory for the testing.

(c) If diagnostic confirmatory testing is done through a laboratory other than a designated laboratory, the **health care provider** [PHYSICIAN] shall report, in writing, the results of the diagnostic testing to the newborn bloodspot screening program in the department, within two days after the date of receipt of results of the diagnostic testing.

(d) 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.

(e) 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 \_\_\_\_/\_\_\_\_/\_\_\_\_, Register \_\_\_\_)

**Authority:** AS 18.05.040 AS 18.15.200

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 \_\_\_\_/\_\_\_\_/\_\_\_\_, Register \_\_\_\_)

**Authority:** AS 18.05.040 AS 18.15.200

The Editor's note for 7 AAC 27.570 is amended to read:

**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**, 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, IL 60009-0927].

**7 AAC 27.590. Definitions.**

7 AAC 27.590(3) is amended to read:

In 7 AAC 27.510 - 7 AAC 27.590

...

(4) [(3)] "medical facility or service" means a hospital, birthing center, **primary care practice** or home birth services;

7 AAC 27.590 is amended by adding a new paragraph to read:

(3) "health care provider" means any licensed medical provider, including a physician, nurse practitioner, certified nurse midwife, certified direct-entry midwife, and physician assistant.

(Eff. 7/13/94, Register 131; am \_\_\_\_/\_\_\_\_/\_\_\_\_, Register \_\_\_\_)

**Authority:** AS 18.05.040 AS 18.15.200

**7 AAC 80.030. Fee schedule and procedures.**

7 AAC 80.030 is amended to read:

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

SERVICE	FEE
...	
<b><u>BLOODSPOT</u></b> [METABOLIC] SCREENING TEST FOR NEWBORNS	\$159.50 <b><u>per infant screened</u></b> [FOR DOUBLE-CARD KITS];  [\$100 FOR SINGLE-CARD KITS, FOR LOST OR DAMAGED CARDS]
...	



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**HEALTH AND SOCIAL SERVICES**

(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 \_\_\_\_/\_\_\_\_/2016, Register \_\_\_\_)

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