

**NOTICE OF PROPOSED EXPEDITED RULEMAKING**  
**TITLE 9. HEALTH SERVICES**  
**CHAPTER 13. DEPARTMENT OF HEALTH SERVICES**  
**HEALTH PROGRAM SERVICES**  
**ARTICLE 2. NEWBORN AND INFANT SCREENING**

**PREAMBLE**

- 1. Article, Part, of Section Affected (as applicable)      Rulemaking Action**

R9-13-201	Amend
R9-13-203	Amend
  
- 2. Citations to the agency’s statutory authority for the rulemaking to include the authorizing statute (general) and the implementing statute (specific):**

Authorizing Statutes: A.R.S. §§ 36-132(A)(1) and 36-136(G)  
Implementing Statutes: A.R.S. § 36-694
  
- 3. Citations to all related notices published in the Register as specified in R1-1-409(A) that pertain to the record of the proposed expedited rulemaking:**

Notice of Docket Opening: 27 A.A.R. XXXX, August XX, 2021 [to be completed by *Register* editor]
  
- 4. The agency’s contact person who can answer questions about the rulemaking:**

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**5. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, under A.R.S. § 41-1027, to include an explanation about the rulemaking:**

Arizona Revised Statutes (A.R.S.) § 36-694(D) requires the Arizona Department of Health Services (Department) to establish a Newborn Screening Program within the Department to ensure that the testing for congenital disorders required by A.R.S. § 36-694 is conducted in an effective and efficient manner. The Department has adopted rules to implement A.R.S. § 36-694 in Arizona Administrative Code (A.A.C.) Title 9, Chapter 13, Article 2. A.R.S. § 36-694(D), as amended in Laws 2021, Ch. 409, § 14, requires the Newborn Screening Program to include all congenital disorders that are included on the Recommended Uniform Screening Panel adopted by the Secretary of the United States Department of Health and Human Services (<https://www.hrsa.gov/advisory-committees/heritable-disorders/rusp/index.html>) for both core and secondary conditions, as well as make necessary changes related to fees. The Department has received an exception from the Governor's rulemaking moratorium to make these changes. Laws 2021, Chapter 409, § 32 requires the Department to add two disorders to the State's Newborn Screening panel by December 31, 2021. Through this expedited rulemaking, the Department is complying with the Legislative requirement. These changes do not increase the cost of regulatory compliance, increase a fee, or reduce procedural rights. Rather, they provide a public benefit and amend rules made obsolete by legislative action. The proposed changes conform to rulemaking format and style requirements of the Governor's Regulatory Review Council and the Office of the Secretary of State.

**6. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:**

The Department did not review or rely on any study for this rulemaking.

**7. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state.**

Not applicable

**8. The preliminary summary of the economic, small business, and consumer impact:**

Under A.R.S. § 41-1055(D)(2), the Department is not required to provide an economic, small

business, and consumer impact statement.

**9. The agency's contact person who can answer questions about the economic, small business, and consumer impact statement:**

Not applicable

**10. Where, when, and how persons may provide written comment to the agency on the proposed expedited rule under A.R.S. § 41-1027(C):**

Close of record: Thursday, September 30, 2021, 4:00 p.m.

A person may submit written comments on the proposed expedited rules no later than the close of record to either of the individuals listed in item 4.

**11. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:**

**a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:**

The rule does not require the issuance of a regulatory permit. Therefore, a general permit is not applicable.

**b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:**

Federal laws do not apply to the rule.

**c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:**

No such analysis was submitted.

**12. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules:**

None

**13. The full text of the rule follows:**

**TITLE 9. HEALTH SERVICES**  
**CHAPTER 13. DEPARTMENT OF HEALTH SERVICES**  
**HEALTH PROGRAM SERVICES**  
**ARTICLE 2. NEWBORN AND INFANT SCREENING**

Section

R9-13-201. Definitions

R9-13-203. Newborn and Infant Bloodspot Tests

**R9-13-201. Definitions**

In this Article, unless otherwise specified:

1. “Abnormal result” means an outcome that deviates from the range of values established by:
  - a. The Department for an analysis performed as part of a bloodspot test or for a hearing test, or
  - b. A health care facility or health care provider for critical congenital heart defect screening.
2. “Admission” or “admitted” means the same as in A.A.C. R9-10-101.
3. “AHCCCS” means the Arizona Health Care Cost Containment System.
4. “Argininosuccinic acidemia” means a congenital disorder characterized by an inability to metabolize the amino acid argininosuccinic acid due to defective argininosuccinate lyase activity.
5. “Arizona State Laboratory” means the entity operated according to A.R.S. § 36-251.
6. “Audiological equipment” means an instrument used to help determine the presence, type, or degree of hearing loss by:
  - a. Providing ear-specific and frequency-specific stimuli to an individual; or
  - b. Measuring an individual’s physiological response to stimuli.
7. “Audiologist” means the same as in A.R.S. § 36-1901.
8. “Beta-ketothiolase deficiency” means a congenital disorder characterized by an inability to metabolize 2-methyl-acetoacetyl-CoA due to defective mitochondrial acetoacetyl-CoA thiolase activity.
9. “Biotinidase deficiency” means a congenital disorder characterized by defective biotinidase activity that causes abnormal biotin metabolism.
10. “Birth center” means a health care facility that is not a hospital and is organized for the purpose of delivering newborns.
11. “Blood sample” means capillary or venous blood, but not cord blood, applied to the filter paper of a specimen collection kit.
12. “Bloodspot test” means multiple laboratory analyses performed on a blood sample to screen for the presence of congenital disorders listed in R9-13-203.
13. “Carnitine uptake defect” means a congenital disorder characterized by a decrease in the amount of free carnitine due to defective sodium ion-dependent carnitine transporter OCTN2 activity.

14. "Citrullinemia" means a congenital disorder characterized by an inability to convert the amino acid citrulline and aspartic acid into argininosuccinic acid due to defective argininosuccinate synthetase activity.
15. "Classic galactosemia" means a congenital disorder characterized by abnormal galactose metabolism due to defective galactose-1-phosphate uridylyltransferase activity.
16. "Congenital adrenal hyperplasia" means a congenital disorder characterized by decreased cortisol production and increased androgen production due to defective 21-hydroxylase activity.
17. "Congenital disorder" means an abnormal condition present at birth, as a result of heredity or environmental factors, that impairs normal physiological functioning of a human body.
18. "Congenital hypothyroidism" means a congenital disorder characterized by deficient thyroid hormone production.
19. "Critical congenital heart defect" means a heart abnormality or condition present at birth that places a newborn or infant at significant risk of disability or death if not diagnosed soon after birth.
20. "Cystic fibrosis" means a congenital disorder caused by defective functioning of a transmembrane regulator protein and characterized by damage to and dysfunction of various organs, such as the lungs, pancreas, and reproductive organs.
21. "Department" means the Arizona Department of Health Services.
22. "Diagnostic evaluation" means a hearing test performed by an audiologist or a physician to determine whether hearing loss exists, and, if applicable, determine the type or degree of hearing loss.
23. "Discharge" means the termination of inpatient services to a newborn or an infant.
24. "Disorder" means a disease or medical condition that may be identified by a laboratory analysis.
25. "Document" means to establish and maintain information in written, photographic, electronic, or other permanent form.
26. "Educational materials" means printed or electronic information provided by the Department, explaining newborn and infant screening, any of the congenital disorders listed in R9-13-203, hearing loss, or critical congenital heart defect.
27. "Electronic" means the same as in A.R.S. § 44-7002.

28. “First specimen” means the initial specimen that is collected from a newborn who is less than five days of age and sent to the Arizona State Laboratory for testing and recording of demographic information.
29. “Glutaric acidemia type I” means a congenital disorder characterized by an accumulation of glutaric acid due to defective glutaryl-CoA dehydrogenase activity.
30. “Guardian” means an individual appointed by a court under A.R.S. Title 14, Chapter 5, Article 2.
31. “Health care facility” means a health care institution defined in A.R.S. § 36-401 where obstetrical care or newborn care is provided.
32. “Health care provider” means a physician, physician assistant, registered nurse practitioner, or midwife.
33. “Health-related services” means the same as in A.R.S. § 36-401.
34. “Hearing screening” means a hearing test to determine the likelihood of hearing loss in a newborn or infant.
35. “Hearing test” means an evaluation of each of a newborn’s or an infant’s ears, using audiological equipment to:
  - a. Screen the newborn or infant for a possible hearing loss;
  - b. Determine that the newborn or infant does not have a hearing loss; or
  - c. Diagnose a hearing loss in the newborn or infant, including determining the type or degree of hearing loss.
36. “Hemoglobin S/Beta-thalassemia” means a sickle cell disease in which an individual has one sickle cell gene and one gene for beta thalassemia, another inherited hemoglobinopathy.
37. “Hemoglobin S/C disease” means a sickle cell disease in which an individual has one sickle cell gene and one gene for another inherited hemoglobinopathy called hemoglobin C.
38. “Hemoglobinopathy” means a congenital disorder characterized by abnormal production, structure, or functioning of hemoglobin.
39. “Home birth” means delivery of a newborn, outside a health care facility, when the newborn is not hospitalized within 72 hours of delivery.
40. “Homocystinuria” means a congenital disorder characterized by abnormal methionine and homocysteine metabolism due to defective cystathione-β-synthase activity.
41. “Hospital” means the same as in A.A.C. R9-10-101.
42. “Hospital services” means the same as in A.A.C. R9-10-201.

43. “3-Hydroxy-3-methylglutaric aciduria” means a congenital disorder characterized by the accumulation of 3-hydroxy-3-methylglutaric acid due to a defective 3-hydroxy-3-methylglutaryl-CoA lyase activity.
44. “Identification code” means a unique set of numbers or letters, or a unique set of both numbers and letters, assigned by the Department to a health care facility, a health care provider, an audiologist, or another person submitting specimen collection kits to the Arizona State Laboratory or hearing test results to the Department.
45. “Infant” means the same as in A.R.S. § 36-694.
46. “Inpatient” means an individual who:
  - a. Is admitted to a hospital,
  - b. Receives hospital services for 24 consecutive hours, or
  - c. Is admitted to a birth center.
47. “Inpatient services” means medical services, nursing services, or other health-related services provided to an inpatient in a health care facility.
48. “Isovaleric acidemia” means a congenital disorder characterized by an accumulation of isovaleric acid due to defective isovaleryl-CoA dehydrogenase activity.
49. “Long-chain 3-hydroxy acyl-CoA dehydrogenase deficiency” means a congenital disorder characterized by an inability to metabolize fatty acids that are 12 to 16 carbon atoms in length due to defective long-chain 3-hydroxy acyl-CoA dehydrogenase activity.
50. “Maple syrup urine disease” means a congenital disorder of branched chain amino acid metabolism due to defective branched chain-keto acid dehydrogenase activity.
51. “Medical services” means the same as in A.R.S. § 36-401.
52. “Medium chain acyl-CoA dehydrogenase deficiency” means a congenital disorder characterized by an inability to metabolize fatty acids that are 6 to 10 carbon atoms in length due to defective medium-chain acyl-CoA dehydrogenase activity.
53. “3-Methylcrotonyl-CoA carboxylase deficiency” means a congenital disorder characterized by an accumulation of 3-methylcrotonyl-glycine due to defective 3-methylcrotonyl-CoA carboxylase activity.
54. “Methylmalonic acidemia (Cbl A,B)” means a congenital disorder characterized by an accumulation of methylmalonic acid due to defective activity of methylmalonyl-CoA racemase or adenosylcobalamin synthetase.
55. “Methylmalonic acidemia (mutase deficiency)” means a congenital disorder characterized by an accumulation of methylmalonic acid due to defective methylmalonyl-CoA mutase activity.



56. “Midwife” means an individual licensed under A.R.S. Title 36, Chapter 6, Article 7, or certified under A.R.S. Title 32, Chapter 15.
57. “Multiple carboxylase deficiency” means a congenital disorder characterized by an inability to transport or metabolize biotin that leads to defective activity of propionyl-CoA carboxylase, beta-methylcrotonyl-CoA carboxylase, and pyruvate carboxylase.
58. “Newborn” means the same as in A.R.S. § 36-694.
59. “Newborn care” means medical services, nursing services, and health-related services provided to a newborn.
60. “Nursing services” means the same as in A.R.S. § 36-401.
61. “Obstetrical care” means medical services, nursing services, and health-related services provided to a woman throughout her pregnancy, labor, delivery, and postpartum.
62. “Organ” means a somewhat independent part of a human body, such as a salivary gland, kidney, or pancreas, which performs a specific function.
63. “Parent” means a natural, adoptive, or custodial mother or father of a newborn or an infant.
64. “Parenteral nutrition” means the feeding of an individual intravenously through the administration of a formula containing glucose, amino acids, lipids, vitamins, and minerals.
65. “Person” means the state, a municipality, district, or other political subdivision, a cooperative, institution, corporation, company, firm, partnership, individual, or other legal entity.
66. “Phenylketonuria” means a congenital disorder characterized by abnormal phenylalanine metabolism due to defective phenylalanine hydroxylase activity.
67. “Physician” means an individual licensed under A.R.S. Title 32, Chapters 13, 14, 17, or 29.
68. “Physician assistant” means an individual licensed under A.R.S. Title 32, Chapter 25.
69. “Propionic acidemia” means a congenital disorder characterized by an accumulation of glycine and 3-hydroxypropionic acid due to defective propionyl-CoA carboxylase activity.
70. “Pulse oximetry” means a non-invasive method of measuring the percentage of hemoglobin in the blood that is saturated with oxygen using a device approved by the U.S. Food and Drug Administration for use with newborns or infants less than six weeks of age.
71. “Registered nurse practitioner” means the same as in A.R.S. § 32-1601.

72. “Second specimen” means a specimen that is sent to the Arizona State Laboratory for testing and recording of demographic information, after being collected:
- a. From a newborn after a first specimen; or
  - b. From an individual at least five days and not older than one year of age, regardless of whether a first specimen was collected.
73. “Severe combined immunodeficiency” means a congenital disorder usually characterized by a defect in both the T- and B-lymphocyte systems, which typically results in the onset of one or more serious infections within the first few months of life.
74. “Sickle cell anemia” means a sickle cell disease in which an individual has two sickle cell genes.
75. “Sickle cell disease” means a hemoglobinopathy characterized by an abnormally shaped red blood cell resulting from the abnormal structure of the protein hemoglobin.
76. “Sickle cell gene” means a unit of inheritance that is involved in producing an abnormal type of the protein hemoglobin, in which the amino acid valine is substituted for the amino acid glutamic acid at a specific location in the hemoglobin.
77. “Specimen” means a blood sample obtained from and demographic information about a newborn or an infant.
78. “Specimen collection kit” means a strip of filter paper for collecting a blood sample attached to a form for obtaining the information specified in R9-13-203(B)(3) about a newborn or an infant.
- 79. "Spinal muscular atrophy " means a congenital disorder characterized by the loss of nerve cells in the spinal cord that control muscle movement due to the deletion of exon 7 in the survival motor neuron 1 (SMN1) gene.**
- ~~79~~.80. “Transfer” means a health care facility or health care provider discharging a newborn and sending the newborn to a hospital for inpatient medical services without the intent that the patient will be returned to the sending health care facility or health care provider.
- ~~80~~.81. “Transfusion” means the infusion of blood or blood products into the body of an individual.
- ~~81~~.82. “Trifunctional protein deficiency” means a congenital disorder characterized by an inability to metabolize fatty acids that are 12 to 18 carbon atoms in length due to defective mitochondrial trifunctional protein activity.
- ~~82~~.83. “Tyrosinemia type I” means a congenital disorder characterized by an accumulation of the amino acid tyrosine due to defective fumarylacetoacetate hydrolase activity.

- ~~83-84.~~ “Verify” means to confirm by obtaining information through a source such as the newborn screening program, a health care provider, a health care facility, or a documented record.
- ~~84-85.~~ “Very long-chain acyl-CoA dehydrogenase deficiency” means a congenital disorder characterized by an inability to metabolize fatty acids that are 14 to 18 carbon atoms in length due to defective very long-chain acyl-CoA dehydrogenase activity.
- ~~85-86.~~ “Working day” means 8:00 a.m. through 5:00 p.m. Monday through Friday, excluding state holidays.
- 87.** “X-linked adrenoleukodystrophy” means a congenital disorder characterized by the build-up in the body of very long-chain fatty acids due to a deficiency in the amount of adrenoleukodystrophy protein, caused by a defective ABCD1 gene.

**R9-13-203. Newborn and Infant Bloodspot Tests**

- A.** A bloodspot test shall screen for the following congenital disorders:
1. 3-Hydroxy-3-methylglutaric aciduria,
  2. 3-Methylcrotonyl-CoA carboxylase deficiency,
  3. Argininosuccinic acidemia,
  4. Beta-ketothiolase deficiency,
  5. Biotinidase deficiency,
  6. Carnitine uptake defect,
  7. Citrullinemia,
  8. Classic galactosemia,
  9. Congenital adrenal hyperplasia,
  10. Congenital hypothyroidism,
  11. Cystic fibrosis,
  12. Glutaric acidemia type I,
  13. Hemoglobin S/Beta-thalassemia,
  14. Hemoglobin S/C disease,
  15. Homocystinuria,
  16. Isovaleric acidemia,
  17. Long-chain 3-hydroxy acyl-CoA dehydrogenase deficiency,
  18. Maple syrup urine disease,
  19. Medium chain acyl-CoA dehydrogenase deficiency,
  20. Methylmalonic acidemia (Cbl A,B),
  21. Methylmalonic acidemia (mutase deficiency),

- 22. Multiple carboxylase deficiency,
- 23. Phenylketonuria,
- 24. Propionic acidemia,
- 25. Severe combined immunodeficiency,
- 26. Sickle cell anemia,
- 27. Spinal muscular atrophy.
- ~~27-28.~~ Trifunctional protein deficiency,
- ~~28-29.~~ Tyrosinemia type I, ~~and~~
- ~~29-30.~~ Very long-chain acyl-CoA dehydrogenase deficiency, and
- 31. X-linked adrenoleukodystrophy.

**B.** When a bloodspot test is ordered for a newborn or an infant, a health care facility's designee, a health care provider, or the health care provider's designee shall:

- 1. Only use a specimen collection kit supplied by the Department;
- 2. Collect a blood sample from the newborn or infant on a specimen collection kit;
- 3. Complete the following information on the specimen collection kit:
  - a. The newborn's or infant's name, gender, race, ethnicity, medical record number, and, if applicable, AHCCCS identification number;
  - b. The newborn's or infant's type of food or food source;
  - c. Whether the newborn or infant is from a single or multiple birth;
  - d. If the newborn or infant is from a multiple birth, the birth order of the newborn or infant;
  - e. Whether the newborn or infant has a medical condition that may affect the bloodspot test results;
  - f. Whether the newborn or infant received a blood transfusion and, if applicable, the date of the last blood transfusion;
  - g. The date and time of birth, and the newborn's or infant's weight at birth;
  - h. The date and time of blood sample collection, and the newborn's or infant's weight when the blood sample is collected;
  - i. The identification code or the name and address of the health care facility or health care provider submitting the specimen collection kit;
  - j. The name, address, and telephone number or the identification code of the health care provider responsible for the management of medical services provided to the newborn or infant;

- k. Except as provided in subsection (B)(3)(l), the mother's first and last names, date of birth, name before first marriage, mailing address, telephone number, and if applicable, AHCCCS identification number; and
      - l. If the newborn's or infant's mother does not have physical custody of the newborn or infant, the first and last names, mailing address, and telephone number of the person who has physical custody of the newborn or infant; and
    - 4. Submit the specimen collection kit to the Arizona State Laboratory no later than 24 hours or the next working day after the blood sample is collected.
- C. A health care facility or a health care provider submitting a first specimen to the Arizona State Laboratory shall pay the Department the fee in R9-13-208(A).
- D. A person who submits a second specimen to the Arizona State Laboratory shall:
  - 1. Pay the fee in R9-13-208(B) to the Department, or
  - 2. Provide the following information to the Arizona State Laboratory for billing purposes:
    - a. The name, mailing address, and telephone number of the newborn's or infant's parent or the individual responsible for paying, if not the parent; and
    - b. If the individual responsible for paying has health care insurance for the newborn or infant, information about the health care insurance, including:
      - i. The policyholder's name;
      - ii. The name and billing address of the health care insurance company;
      - iii. The member identification number;
      - iv. The group number, if applicable; and
      - v. The effective date of the health care insurance; or
    - c. That the individual responsible for paying has no health care insurance for the newborn or infant.
- E. When a health care insurance company or an individual responsible for paying is identified as specified in subsection (D)(2), the health care insurance company or the individual responsible for paying shall pay the Department the fee in R9-13-208(B).
- F. When a home birth not attended by a health care provider is reported to a local registrar, a deputy local registrar, or the state registrar under A.R.S. § 36-333:
  - 1. The local registrar, deputy local registrar, or state registrar shall notify the local health department of the county where the birth occurred; and
  - 2. The local health department's designee shall collect a specimen from the newborn or infant according to the requirements in R9-13-204(A)(2) or R9-13-205(C).

- G.** A health care facility's designee, a health care provider, or the health care provider's designee shall ensure that:
1. Educational materials are provided to the parent or guardian of a newborn or an infant for whom a bloodspot test is ordered, and
  2. The newborn's or infant's parent or guardian is informed of the requirement for a second specimen if the second specimen has not been collected.
- H.** For a home birth, a health care provider or the health care provider's designee shall provide educational materials to the parent or guardian of a newborn or an infant for whom a bloodspot test is ordered.