NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* first as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council or the Attorney General. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 13. DEPARTMENT OF HEALTH SERVICES
HEALTH PROGRAMS SERVICES

[R06-108]

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R9-13-201	Amend
R9-13-202	Repeal
R9-13-202	New Section
R9-13-203	Repeal
R9-13-203	New Section
R9-13-204	Repeal
R9-13-204	New Section
R9-13-205	Repeal
R9-13-205	New Section
R9-13-206	New Section
R9-13-207	New Section
R9-13-208	New Section

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 36-136(A)(7) and (F), and 36-132(A)(5)

Implementing statute: A.R.S. § 36-694, as amended by Laws 2005, Chapter 172

3. The effective date of the rules:

April 4, 2006

The Department requests an immediate effective date for these rules under A.R.S. § 41-1032(A)(1) and (4). These rules will enable the Department to initiate testing of newborns for a total of 28 disorders, 20 more than the eight disorders for which babies are tested under the current rules. Five of the 20 disorders will be added as of the effective date of the rules, with testing for groups of other disorders being added sequentially, according to a set schedule. Newborns with abnormal screening test results will receive follow-up services to help assure they receive diagnostic testing and any treatment they may need. The Department will also begin following up on abnormal hearing screening tests reported to the Department as of the effective date of these rules. Newborns and infants with one of the disorders detected through screening or with a hearing loss, their parents, third-party payers, and society in general will benefit from an immediate effective date for the rules.

In addition, the Department will benefit from the ability to collect increased fees to run the Newborn Screening Program, which will enable the Department to implement testing for additional disorders, as specified in R9-13-206(B), sooner than would otherwise be possible. Testing for the additional disorders will augment the benefit to the public. No penalties are assessed for a violation of the rules.

4. A list of all previous notices appearing in the *Register* addressing the final rule:

Notice of Recodification: 11 A.A.R. 3577, September 23, 2005

Notice of Rulemaking Docket Opening: 11 A.A.R. 3974, October 14, 2005

Notice of Proposed Rulemaking: 12 A.A.R. 18, January 6, 2006

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name:	Jan Kerrigan, RN, Program Manager
Address:	Arizona Department of Health Services Newborn Screening Program 150 N. 18th Ave., Suite 320 Phoenix, AZ 85007-3233
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Or	
Name:	Kathleen Phillips, Rules Administrator
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6. An explanation of the rule, including the agency's reason for initiating the rule:

A.R.S. § 36-694, as amended by Laws 2005, Chapter 172, contains requirements for ordering tests for certain congenital disorders and reporting congenital disorder test results and hearing test results to the Department, and establishes a newborn screening program, a central database for information about newborns and infants who are tested for hearing loss or congenital disorders, an educational program and follow-up services, and a newborn screening program committee. A.R.S. § 36-694 also contains requirements for contracting for the testing for congenital disorders and establishes fees for the operation of the newborn screening program. Current rules in 9 A.A.C. 13, Article 2, specify the congenital disorders being tested for, how a specimen is required to be collected from a newborn, who is responsible for collecting the specimen, educational program requirements, and fees. This rulemaking expands the number of tested congenital disorders from 8 to 28 disorders, with groups of disorders being added sequentially, according to a set schedule; adds requirements for reporting of hearing screening results; clarifies requirements for collecting specimens, reporting newborn bloodspot screening test results, and payment of fees; improves the organization, section headings, and syntax of the rules; and increases the fees to $30 for the submission of a first specimen for newborn bloodspot screening and $40 for the submission of a second specimen. All changes conform to rulemaking format and style requirements of the Governor's Regulatory Review Council and the Office of the Secretary of State.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on in its evaluation of or justification for the rule or did not 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 related to this rulemaking package.

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

Not applicable

9. The summary of the economic, small business, and consumer impact:

Annual costs/revenues changes are designated as minimal when less than $1,000, moderate when between $1,000 and $10,000, and substantial when $10,000 or greater in additional costs or revenues.

The Department will experience a substantial increase in costs associated with: contracting for laboratory services, due to the increase in the number of disorders for which testing will be performed; adequately following up on abnormal test results for the additional congenital disorders and on abnormal hearing test results; providing an educational program to health care providers, parents, and the general public about the additional congenital disorders being tested for and about newborn and infant hearing testing; and expanding the capacity of the current data system to enable the system to capture, store, report, and transfer an increased number of test results and other information about each specimen tested. These costs will be offset by increased fees.

Hospitals are expected to experience an increase in costs due to the increase in fees to operate the newborn screening program, and may experience an increase in costs for reporting hearing test results. These costs may range from minimal to substantial, depending on the number of specimens submitted for testing and whether a hospital is currently reporting hearing screening results, and may be offset by increases in the negotiated amounts received from AHCCCS,

other third-party payors, or parents. Hospitals may benefit from a decrease in liability for failing to detect a baby with a hearing loss because the Department will be assisting in the follow-up on abnormal hearing tests results. Hospitals may also benefit from additional revenue generated from outpatient hearing screening and diagnostic procedures that may be billed to third-party payors.

AHCCCS and other third-party payors as a whole will bear significant costs due to the increase in fees. They may also incur additional costs as a result of the rules for outpatient hearing screening and diagnostic testing for hearing loss for babies who may not otherwise have been tested until they were older. AHCCCS and other third-party payors are expected to benefit from screening for an increased number of congenital disorders through a reduction in the costs associated with diagnosing a disorder in a child once symptoms develop, and in treating the medical problems that late-diagnosed diseases can cause. AHCCCS and other third-party payors are also expected to benefit from an expected decrease in costs for long-term care for a child with one of the additional disorders, who was diagnosed early on the basis of screening results, rather than later when physiological problems had occurred. The benefit to AHCCCS and other third-party payors may range from minimal to substantial, depending on the number of babies with congenital disorders who are covered by a particular payor. AHCCCS and other third-party payors are also expected to benefit substantially from fewer children needing sedated diagnostic hearing tests. If a baby receives diagnostic hearing tests before the age of 3 months, the tests can be performed during the baby's natural sleep. If the tests are performed when a baby is older, the baby generally needs to be sedated for accurate results to be obtained. The Department assumes that follow-up by the Department's staff will allow further testing to be done before a baby is 3 months of age, and that diagnostic tests will not require sedation.

Physicians and outpatient treatment centers may experience a minimal to moderate decrease in revenue from a decrease in the number of office visits it may take to diagnose a baby with one of the added congenital disorders. Physicians and outpatient treatment centers may experience minimal to substantial benefit from a decrease in time to diagnose a baby with one of the rare congenital disorders being added to the bloodspot screening, as well as a decrease in liability associated with failing to detect a case of one of the disorders.

Those physicians, outpatient treatment centers, audiologists, and others that perform outpatient hearing screening or diagnostic hearing tests may experience a minimal to substantial benefit from performing an increased number of outpatient hearing screening or unsedated diagnostic hearing tests. Audiologists may experience a minimal to substantial decrease in revenue from a reduced number of sedated diagnostic hearing tests because babies are being tested before three months of age.

The contracted laboratory performing testing for the added congenital disorders will experience a significant increase in the amount paid to the contracted laboratory under the laboratory's contract, which will be offset by an increase in additional expenses.

If parents have no other payor source for newborn screening fees, they may bear the minimal costs of the fee increase. Parents who now pay independent of insurance for expanded screening tests for congenital disorders that will now be part of the bloodspot screening test panel will experience a decrease in cost for tests for these disorders. Parents with no other payor source may also bear minimal costs associated with the outpatient hearing screening and diagnostic hearing testing of a baby for suspected hearing loss. Most parents will benefit from knowing that their babies probably do not have a hearing loss or one of the congenital disorders tested for, while some parents will benefit substantially from early diagnosis of a hearing loss or congenital disorder, and treatment of their babies, saving the parents from the stress and expense of more physician visits and repeated diagnostic tests to determine the diagnosis, and enabling the babies to grow into healthy children with fewer catastrophic medical bills or learning disabilities.

Schools are expected to receive minimal to substantial benefit from these rules, since children with an early-identified and treated hearing loss or congenital disorder may require less accommodation to enable them to succeed in school. Reduced costs to schools for accommodation may result in a reduced cost to cities, municipalities, and school districts, and to the citizens supporting schools through tax monies. Society will benefit substantially from having a healthy and productive member of society because of timely identification and treatment of the added congenital disorders or a hearing loss.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

Minor technical and grammatical changes were made by the Department and at the suggestion of staff of the Council to improve clarity.

11. A summary of the comments made regarding the rule and the agency response to them:

There were no oral comments at the Oral Proceeding, and the Department received no written comments.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Incorporations by reference and their location in the rules:

None

14. Was this rule previously made as an emergency rule?
No.

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

**CHAPTER 13. DEPARTMENT OF HEALTH SERVICES
HEALTH PROGRAMS SERVICES**

ARTICLE 2. NEWBORN AND INFANT SCREENING

Section
R9-13-201. Definitions
R9-13-202. ~~Testing of Newborns~~ Tests for Congenital Disorders
R9-13-203. ~~Persons Responsible for Tests~~ General Requirements for Newborn and Infant Bloodspot Tests
R9-13-204. ~~Parent or Guardian Education~~ First Specimen Collection
R9-13-205. ~~Screening Fees~~ Second Specimen Collection
R9-13-206. ~~Repealed~~ Reporting Requirements for Specimens
R9-13-207. ~~Repealed~~ Reporting Requirements for Hearing Test Results
R9-13-208. Fees

ARTICLE 2. NEWBORN AND INFANT SCREENING

R9-13-201. Definitions
In this Article, unless otherwise specified:

~~1. "Administrator" means an individual in charge of the onsite management of a health care facility.~~
~~2. "Abnormal" means a result of an analysis performed as part of a newborn screening test that deviates from the range of values established by the Department.~~
1. "Abnormal result" means an outcome that deviates from the range of values established by the Department for an analysis performed as part of a bloodspot test, or for a hearing test.
~~3.~~ 2. "Admitted" means ~~a written acceptance of a newborn by a health care facility~~ the same as in A.A.C. R9-10-201.
~~4.~~ 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. "Audiological equipment" means instruments used to measure a physiological response to determine the presence, type, or degree of hearing loss.
6. "Audiologist" means an individual licensed under A.R.S. Title 36, Chapter 17.
7. "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.
~~5.~~ 8. "Biotinidase deficiency" means a congenital ~~metabolic~~ disorder characterized by defective biotinidase activity that causes abnormal biotin metabolism.
~~6.~~ 9. "Birth center" means a health care facility that is not a hospital and is organized for the sole purpose of delivering newborns.
10. "Blood sample" means capillary or venous blood, but not cord blood, applied to the filter paper of a specimen collection kit.
11. "Bloodspot test" means multiple laboratory analyses performed on a blood sample to detect the presence of congenital disorders listed in R9-13-202.
12. "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.
13. "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.
~~7.~~ 14. "Classic galactosemia" means a congenital ~~metabolic~~ disorder characterized by abnormal galactose metabolism due to defective galactose-1-phosphate uridyltranferase activity.
~~8. "Committee" means the newborn screening program committee specified in A.R.S. § 36-694.~~
~~9.~~ 15. "Congenital adrenal hyperplasia" means ~~an endocrine~~ a congenital disorder characterized by decreased cortisol production and increased androgen production due to defective 21-hydroxylase activity.
16. "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.

~~10.~~ 17."Congenital hypothyroidism" means ~~an endocrine~~ a congenital disorder characterized by deficient thyroid hormone production.

18. "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.

~~11.~~ 19."Department" means the Arizona Department of Health Services.

~~12. "Director" means the Director of the Department of Health Services.~~

~~13.~~ 20."Discharge" means ~~the release of a patient from medical care by a health care facility~~ the termination of inpatient services to a newborn or infant.

~~14.~~ 21."Disorder" means a disease or medical condition that may be identified by a laboratory analysis.

~~15.~~ 22."Document" means to establish and maintain information in written, photographic, electronic, or other permanent form.

23. "Educational materials" means printed or electronic information provided by the Department, explaining newborn and infant screening, any of the congenital disorders listed in R9-13-202, or hearing loss.

~~16.~~ 24."Electronic" means ~~relating to technology that has electrical, digital, magnetic, wireless, optical, or electromagnetic capabilities or similar capabilities~~ the same as in A.R.S. § 44-7002.

~~17.~~ 25."First specimen" means the initial ~~satisfactory specimen on which the newborn screening laboratory performs an analysis to detect a disorder listed in R9-14-502(A)~~ specimen that is collected from a newborn who is less than five days of age and sent to the screening laboratory for testing and recording of demographic information.

26. "Glutaric acidemia type I" means a congenital disorder characterized by an accumulation of glutaric acid due to defective glutaryl-CoA dehydrogenase activity.

~~18.~~ 27."Guardian" means an individual appointed by a court under A.R.S. Title 14, Chapter 5, Article 2.

~~19.~~ 28."Health care facility" means a health care institution defined in A.R.S. § 36-401 where obstetrical care or newborn care is provided.

~~20.~~ 29."Health care provider" means a physician, physician assistant, ~~or~~ registered nurse practitioner, or midwife.

~~21.~~ 30."Health-related services" means the same as in A.R.S. § 36-401.

31. "Hearing test" means an evaluation of both ears of a newborn or infant, using audiological equipment, for the presence, type, or degree of hearing loss.

32. "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.

33. "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.

~~22.~~ 34."Hemoglobinopathy" means ~~any inherited abnormality in the production, structure, or function of hemoglobin~~ a congenital disorder characterized by abnormal production, structure, or functioning of hemoglobin.

~~23.~~ 35."Home birth" means delivery of a newborn, outside a health care facility, ~~for which~~ when the newborn is not hospitalized within 72 hours of delivery.

~~24.~~ 36."Homocystinuria" means a congenital ~~metabolic~~ disorder characterized by abnormal methionine and homocysteine metabolism due to defective cystathione-ß-synthase activity.

~~25.~~ 37."Hospital" means ~~a health care institution that provides hospital services for the diagnosis and treatment of patients~~ the same as in A.A.C. R9-10-201.

38. "Hospital services" means the same as in A.A.C. R9-10-201.

39. "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.

~~26.~~ 40."Identification code" means ~~an account number~~ a unique set of numbers or letters, or a unique set of both numbers and letters, assigned by the ~~newborn screening laboratory~~ Department to a health care facility, a health care provider, an audiologist, or another person submitting specimen collection kits to the screening laboratory or hearing test results to the Department.

41. "Infant" means the same as in A.R.S. § 36-694.

42. "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.

43. "Inpatient services" means medical services, nursing services, or other health-related services provided to an inpatient in a health care facility.

44. "Isovaleric acidemia" means a congenital disorder characterized by an accumulation of isovaleric acid due to defective isovaleryl-CoA dehydrogenase activity.

45. "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.

~~27.~~ 46.“Maple syrup urine disease” means a congenital ~~metabolic~~ disorder of branched chain amino acid metabolism due to defective branched chain-keto acid dehydrogenase activity.
~~28.~~ 47.“Medical services” means the same as in A.R.S. § 36-401.
48. “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.
49. “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.
50. “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.
51. “Methylmalonic acidemia (mutase deficiency)” means a congenital disorder characterized by an accumulation of methylmalonic acid due to defective methylmalonyl-CoA mutase activity.
~~29.~~ 52.“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.
53. “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.
~~30.~~ 54.“Newborn” means ~~a human from birth through 28 days of age for whom a certificate of live birth is required to be filed under A.R.S. § 36-322~~ the same as in A.R.S. § 36-694.
~~31.~~ 55.“Newborn care” means medical services, nursing services, and health-related services provided to a newborn.
~~32. “Newborn screening laboratory” means an entity contracted with the Department under A.R.S. § 36-694(C) to perform the newborn screening test.~~
~~33. “Newborn screening test” means multiple laboratory analyses performed on a first specimen and a second specimen to detect the presence of endocrine disorders, metabolic disorders, or hemoglobinopathies listed in R9-14-502(A).~~
~~34.~~ 56.“Nursing services” means the same as in A.R.S. § 36-401.
~~35.~~ 57.“Obstetrical care” means ~~the~~ medical services, nursing services, and health-related services provided to a woman throughout her pregnancy, labor, delivery, and postpartum.
58. “Organ” means a somewhat independent part of a human body, such as a salivary gland, kidney, or pancreas, which performs a specific function.
~~36.~~ 59.“Parent” means a natural, adoptive, or custodial mother or father of a newborn or infant.
~~37.~~ 60.“Person” means the state, a municipality, district, or other political subdivision, a cooperative, institution, corporation, company, firm, partnership, individual, or other legal entity.
~~38.~~ 61.“Phenylketonuria” means a congenital ~~metabolic~~ disorder characterized by abnormal phenylalanine metabolism due to defective phenylalanine hydroxylase activity.
~~39.~~ 62.“Physician” means an individual licensed under A.R.S. Title 32, Chapters 13, 14, 17, or 29.
~~40.~~ 63.“Physician assistant” means an individual licensed under A.R.S. Title 32, Chapter 25.
64. “Propionic acidemia” means a congenital disorder characterized by an accumulation of glycine and 3-hydroxypropionic acid due to defective propionyl-CoA carboxylase activity.
~~41.~~ 65.“Registered nurse practitioner” means the same as in A.R.S. § 32-1601.
~~42. “Satisfactory specimen” means a specimen collection kit, on which demographic information has been written and blood applied to the filter paper of that specimen collection kit, that meets the newborn screening test requirements.~~
66. “Screening laboratory” means an entity contracted with the Department under A.R.S. § 36-694(I) to perform the bloodspot test.
~~43.~~ 67.“Second specimen” means a ~~satisfactory specimen collected after a first specimen, on which the newborn screening laboratory performs analyses to detect the presence of all of the disorders listed in R9-14-502(A)~~ specimen that is sent to the screening 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.
68. “Sickle cell anemia” means a sickle cell disease in which an individual has two sickle cell genes.
~~44.~~ 69.“Sickle cell disease” means a hemoglobinopathy characterized by ~~the distortion of the red blood cells~~ an abnormally shaped red blood cell resulting from the abnormal structure of the protein hemoglobin.
70. “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.
~~45.~~ 71.“Specimen” means ~~capillary or venous blood, but not cord blood, applied to the filter paper of the specimen collection kit~~ a blood sample obtained from and demographic information about a newborn or infant.
~~46.~~ 72.“Specimen collection kit” means ~~a form supplied by the Department for obtaining information specified in R9-14-502(C), with an attached strip of filter paper for collecting a specimen~~ a strip of filter paper for collecting a blood

sample attached to a form for obtaining the information specified in R9-13-203(A)(3) about a newborn or infant.

~~47.~~ 73. "Test" means a laboratory analysis performed on body fluid, tissue, or excretion to determine the presence or absence of a disorder.

~~48.~~ 74. "Transfer" means ~~discharging and relocating a newborn from a health care facility to another health care facility~~ a health care facility 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.

~~49.~~ 75. "Transfusion" means the infusion of blood or blood products into the body of an individual.

76. "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.

77. "Tyrosinemia type I" means a congenital disorder characterized by an accumulation of the amino acid tyrosine due to defective fumarylacetoacetate hydrolase activity.

~~50. "Unsatisfactory specimen" means a specimen collection kit, on which demographic information has been written and blood applied to the filter paper of that specimen collection kit that is rejected by the newborn screening laboratory for any of the reasons specified in R9-14-502(B).~~

~~51.~~ 78. "Verify" means ~~to obtain information through sources that include the newborn screening program, a health care provider, a health care facility, or a documented record~~ 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.

79. "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.

~~52.~~ 80. "Working day" means 8:00 a.m. through 5:00 p.m. Monday through Friday, excluding state holidays.

R9-13-202. ~~Testing of Newborns~~ Tests for Congenital Disorders

~~A.~~ ~~A newborn screening test shall screen for the presence of the following disorders:~~

~~1. Biotinidase deficiency;~~
~~2. Classic galactosemia;~~
~~3. Congenital adrenal hyperplasia;~~
~~4. Congenital hypothyroidism;~~
~~5. Hemoglobinopathy;~~
~~6. Homocystinuria,~~
~~7. Maple syrup urine disease, and~~
~~8. Phenylketonuria.~~

~~B.~~ ~~A health care facility's designee, a health care provider, or the health care provider's designee shall:~~

~~1. Collect a satisfactory specimen;~~
~~2. Complete the information on the specimen collection kit; and~~
~~3. Submit the specimen collection kit to the newborn screening laboratory no later than 24 hours, or the next working day, after the specimen is collected.~~

~~C.~~ ~~A health care facility's designee, a health care provider, or the health care provider's designee shall provide the following information on the specimen collection kit provided by the Department:~~

~~1. The newborn's name, gender, ethnicity, medical record number, and if applicable, AHCCCS identification number;~~
~~2. The newborn's type of food;~~
~~3. Whether the newborn is a single or multiple birth;~~
~~4. Whether the newborn has a medical condition that may affect the newborn screening test results;~~
~~5. Whether the newborn received antibiotics or a blood transfusion and, if applicable, the date of the last blood transfusion;~~
~~6. The method of specimen collection;~~
~~7. The date and time of birth and newborn's weight at birth;~~
~~8. The date and time of specimen collection and the newborn's weight when the specimen is collected;~~
~~9. The name and identification code of the person submitting the specimen;~~
~~10. The name, identification code, and address of the newborn's health care provider;~~
~~11. The mother's name, date of birth, address, and if applicable, AHCCCS identification number; and~~
~~12. Whether the parent or guardian refused the newborn screening test.~~

~~D.~~ ~~If a parent or guardian refuses the newborn screening test, a health care facility's designee, a health care provider, or the health care provider's designee shall:~~

~~1. Document the refusal in the newborn's medical record; and~~
~~2. Submit the specimen collection kit, with the form completed, to the newborn screening laboratory no later than 24 hours or the next working day after the form is completed.~~

~~E.~~ ~~A health care facility's designee, a health care provider, or the health care provider's designee shall collect a first specimen according to whichever of the following occurs first:~~

~~1. A newborn is 48 to 72 hours old;~~

~~2. Before and proximate to a newborn's discharge time; or~~
~~3. Before a transfusion, unless specified otherwise by a physician, physician assistant, or registered nurse practitioner.~~

~~**F.** A birth center is exempt from the requirement in R9-14-502(E)(2) to collect a first specimen before and proximate to a newborn's discharge time.~~

~~**G.** After a first specimen is collected, a health care facility's designee, a health care provider, or the health care provider's designee shall collect a second specimen according to whichever of the following occurs first:~~
~~1. If a home birth attended by a health care provider, when the newborn is seven through 14 days old;~~
~~2. If a newborn is in a health care facility, when the newborn is seven through 14 days old; or~~
~~3. At the time of a newborn's first visit to a health care provider after discharge.~~

~~**H.** Before a newborn is discharged, a health care facility's designee, a health care provider, or the health care provider's designee shall inform the newborn's parent or guardian of the requirement for a second specimen if the second specimen has not been collected.~~

~~**I.** If a health care facility's designee, a health care provider, or the health care provider's designee cannot verify that a first specimen has been collected on an individual who is one-year old or less, the health care provider or the health care provider's designee shall collect a specimen and submit the specimen to the newborn screening laboratory.~~

~~**J.** A specimen is unsatisfactory for the newborn screening test if:~~
~~1. There is an insufficient quantity of blood to complete the newborn screening test;~~
~~2. The blood is clotted or layered;~~
~~3. The blood has serum rings;~~
~~4. The blood is diluted or discolored;~~
~~5. The blood will not elute from the filter paper;~~
~~6. The blood has been applied to both sides of the filter paper;~~
~~7. The blood or the filter paper is contaminated;~~
~~8. The filter paper is scratched or abraded; or~~
~~9. The specimen is received by the newborn screening laboratory 14 days or more after the specimen is collected.~~

~~**K.** The newborn screening laboratory shall report results from all newborn screening tests:~~
~~1. In writing, to the person submitting the specimen and the health care provider identified on the specimen collection kit, and~~
~~2. To the Department.~~

~~**L.** A health care facility's designee, a health care provider, or the health care provider's designee who orders a test, shall send the results in writing to the Department, if the test is:~~
~~1. Performed by a laboratory other than the newborn screening laboratory, and~~
~~2. In response to an abnormal newborn screening test.~~

~~**M.** Newborn screening test results are confidential subject to the disclosure provisions of A.A.C. Title 9, Chapter 1, Article 3.~~
A bloodspot test shall include laboratory analyses for the following congenital disorders:

1. Argininosuccinic acidemia,
2. Biotinidase deficiency,
3. Citrullinemia,
4. Classic galactosemia,
5. Congenital adrenal hyperplasia,
6. Congenital hypothyroidism,
7. Hemoglobin S/Beta-thalassemia,
8. Hemoglobin S/C disease,
9. Homocystinuria,
10. Maple syrup urine disease,
11. Phenylketonuria,
12. Sickle cell anemia,
13. Tyrosinemia type I,
14. 3-Methylcrotonyl-CoA carboxylase deficiency,
15. 3-Hydroxy-3-methylglutaric aciduria,
16. Beta-ketothiolase deficiency,
17. Carnitine uptake defect,
18. Glutaric acidemia type I,
19. Isovaleric acidemia,
20. Long-chain 3-hydroxy acyl-CoA dehydrogenase deficiency,
21. Medium chain acyl-CoA dehydrogenase deficiency,
22. Methylmalonic acidemia (Cbl A,B),
23. Methylmalonic acidemia (mutase deficiency),
24. Multiple carboxylase deficiency,

25. Propionic acidemia,
26. Trifunctional protein deficiency,
27. Very long-chain acyl-CoA dehydrogenase deficiency, and
28. Cystic fibrosis.

R9-13-203. ~~Persons Responsible for Tests~~ General Requirements for Newborn and Infant Bloodspot Tests

~~**A.** An administrator shall ensure that a first specimen is collected from each newborn born at the health care facility unless the newborn is transferred before the newborn is three days old or the newborn dies before the specimen is collected.~~

~~**B.** If a newborn is admitted to a health care facility or transferred to another health care facility, the administrator of the receiving facility shall verify that the first specimen has been collected before admission or transfer. If the administrator cannot verify that the first specimen has been collected, the administrator shall ensure that a health care provider or the health care provider's designee collects the specimen.~~

~~**C.** Unless an administrator can verify that a second specimen has been collected from a newborn who is seven to 14 days old, the administrator shall ensure that a second specimen is collected from a newborn who is:~~

~~1. Not discharged;~~
~~2. Admitted to the health care facility; or~~
~~3. Transferred to the health care facility.~~

~~**D.** If a specimen is collected, the administrator shall ensure that all the information requested on the specimen collection kit is completed.~~

~~**E.** If a home birth is attended by a health care provider, the health care provider or health care provider's designee shall:~~

~~1. Collect the first specimen from the newborn;~~
~~2. Complete the information requested on the specimen collection kit; and~~
~~3. Submit the specimen collection kit to the newborn screening laboratory within 24 hours after the specimen is collected.~~

~~**F.** If a home birth is not attended by a health care provider and a local or state registrar of vital statistics is notified under A.R.S. § 36-322(D), the local or state registrar shall inform the health officer of the county identified by the address of the newborn's parent or guardian of the birth.~~

A. 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 antibiotics or a blood transfusion and, if applicable, the date of the last blood transfusion;
   g. The method of blood sample collection;
   h. The date and time of birth, and the newborn's or infant's weight at birth;
   i. The date and time of blood sample collection, and the newborn's or infant's weight when the blood sample is collected;
   j. The name and identification code of the health care facility or health care provider submitting the specimen collection kit;
   k. The name, identification code, and address of the health care provider responsible for the management of medical services provided to the newborn or infant;
   l. Except as provided in subsection (A)(3)(m), the mother's first and last names, date of birth, name before first marriage, mailing address, phone number, and if applicable, AHCCCS identification number; and
   m. 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 phone number of the person who has physical custody of the newborn or infant; and
4. Submit the specimen collection kit to the screening laboratory no later than 24 hours or the next working day after the blood sample is collected.

B. A health care facility or a health care provider submitting a first specimen to the screening laboratory shall pay the Department the fee in R9-13-208(A).

C. A person who submits a second specimen to the screening laboratory shall:
1. Pay the fee in R9-13-208(B) to the Department, or
2. Provide the following information to the screening laboratory for billing purposes:
   a. The name, mailing address, and phone 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.

D. When a health care insurance company or an individual responsible for paying is identified as specified in subsection (C)(2), the health care insurance company or the individual responsible for paying shall pay the Department the fee in R9-13-208(B).

E. The screening laboratory shall perform a bloodspot test on a blood sample from a specimen collection kit if:
1. The blood sample on the specimen collection kit:
a. Contains a sufficient quantity of blood to complete the bloodspot test,
b. Is not clotted or layered,
c. Does not have serum rings,
d. Is not diluted or discolored,
e. Will elute from the filter paper,
f. Has not been applied to both sides of the filter paper, and
g. Is not contaminated;
2. The filter paper on the specimen collection kit is not contaminated, scratched, or abraded;
3. The information on the specimen collection kit is sufficient to identify:
a. The newborn or infant, and
b. The person who ordered the bloodspot test or caused the bloodspot test to be ordered; and
4. The screening laboratory receives the specimen collection kit within 14 days after the blood sample is collected.

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 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 infant for whom a bloodspot test is ordered.

R9-13-204. ~~Parent or Guardian Education~~ First Specimen Collection

~~**A.** The Department shall provide written educational materials about the newborn screening test to a health care facility or health care provider upon request.~~

~~**B.** An administrator shall ensure that the educational materials provided by the Department are given to a newborn's parent or guardian before the newborn is discharged.~~

~~**C.** For a home birth, a health care provider or health care provider's designee shall give the educational materials provided by the Department to a newborn's parent or guardian before a first specimen is collected.~~

~~**D.** A health care provider or health care provider's designee shall explain the purpose for the newborn screening test, as stated in the educational materials, to a newborn's parent or guardian before a specimen is collected.~~

A. When a newborn is born in a hospital, the hospital's designee shall collect a first specimen from the newborn according to whichever of the following occurs first:
1. Before a transfusion, unless specified otherwise by a physician, physician assistant, or registered nurse practitioner;
2. When the newborn is at least 24 but not more than 72 hours old; or
3. Before the newborn is discharged, unless the newborn:
a. Is transferred to another hospital before the newborn is 48 hours old; or
b. Dies before the newborn is 72 hours old.

B. If a newborn is admitted or transferred to a hospital before the newborn is 48 hours old, the receiving hospital's designee shall:
1. Verify that the first specimen was collected before admission or transfer, or
2. Collect a first specimen from the newborn according to the requirements in subsection (A).

C. When a newborn is born in a birth center, the birth center's designee shall collect a first specimen from the newborn according to subsections (A)(1) or (A)(2).

D. For a home birth attended by a health care provider, the health care provider or the health care provider's designee shall collect a first specimen from the newborn according the requirements in subsection (A)(2).

R9-13-205. ~~Screening Fees~~ Second Specimen Collection

~~A person who submits a specimen to the newborn screening laboratory shall pay $20.00 for each specimen analyzed for all the disorders listed in R9-14-502(A).~~

A. After discharge from a health care facility or after a home birth, a health care provider or the health care provider's designee shall:
1. Collect a second specimen from a newborn or infant:
   a. When the newborn is at least 5 but not more than 10 days old; or
   b. At the time of a newborn's or infant's first visit to the health care provider; or
2. Verify that a different health care provider has collected the second specimen from the newborn or infant.

B. If a newborn is an inpatient of a health care facility at 5 days of age, the health care facility's designee shall collect a second specimen from the newborn:
1. When the newborn is at least 5 but not more than 10 days old; or
2. If the newborn is discharged from the facility when the newborn is at least 5 but not more than 10 days old, before discharge.

C. For a home birth not attended by a health care provider, a local health department's designee shall collect a specimen from a newborn or infant if a second specimen has not already been collected from the newborn or infant.

D. A health care provider or the health care provider's designee shall ensure that a subsequent specimen is ordered for a newborn or child one year of age or less, according to the requirements in R9-13-203, when the health care provider or the health care provider's designee:
1. Begins providing health care to the newborn or child, and
2. Cannot verify the results of a bloodspot test that was conducted on a second specimen from the newborn or child.

R9-13-206. ~~Repealed~~ Reporting Requirements for Specimens

A. The screening laboratory shall:
1. Report in written or electronic format:
   a. The results of a bloodspot test on a specimen; and
   b. For a specimen that does not meet the requirements for testing specified in R9-13-203(E):
      i. That the bloodspot test was not performed on the specimen; and
      ii. The reason the bloodspot test was not performed; and
2. Send the report to:
   a. The health care provider identified on the specimen collection kit;
   b. If applicable, the health care facility identified on the specimen collection kit; and
   c. The Department.

B. The screening laboratory shall begin reporting bloodspot test results for the congenital disorders specified in:
1. R9-13-202 (1) through (13), on the effective date of these rules;
2. R9-13-202 (14) through (27), no later than August 31, 2006; and
3. R9-13-202 (28), no later than June 30, 2007.

C. A health care facility's designee, a health care provider, or the health care provider's designee, who orders a subsequent test on a newborn or infant in response to an abnormal result on a bloodspot test, shall send the results of the subsequent test in writing to the Department, if the subsequent test is not performed by the screening laboratory.

D. Bloodspot test results are confidential subject to the disclosure provisions of 9 A.A.C. 1, Article 3, and A.R.S. §§ 12-2801 and 12-2802.

R9-13-207. ~~Repealed~~ Reporting Requirements for Hearing Test Results

A. When an initial hearing test is performed on a newborn, a health care facility's designee, a health care provider, or the health care provider's designee shall provide to the Department, as specified in subsection (E), the following information:
1. The newborn's name, date of birth, gender, and medical record number;
2. Whether the newborn is from a single or multiple birth;
3. If the newborn is from a multiple birth, the birth order of the newborn;
4. The newborn's mother's first and last names;
5. The name and identification code of the health care facility or health care provider submitting the hearing test results;
6. The name and identification code of the health care facility of birth;
7. The name of the health care provider responsible for the coordination of medical services for the newborn;
8. The date of the hearing test;
9. Whether or not the hearing test was performed when the newborn was an inpatient;
10. The audiological equipment used for the hearing test and the type of hearing test performed;

11. The hearing test result for each of the newborn's ears; and
12. The name, address, and phone number of the contact person for the health care facility or health care provider.

B. In addition to the information in subsection (A), if the reported results of an initial hearing test on a newborn include an abnormal result, a health care facility's designee, a health care provider, or the health care provider's designee shall provide to the Department, as specified in subsection (E), the following information:
1. The newborn's race, ethnicity, and if applicable, AHCCCS identification number;
2. Except as provided in subsection (B)(3), the mother's date of birth, name before first marriage, mailing address, and phone number;
3. If the newborn's mother does not have physical custody of the newborn, the first and last names, mailing address, and phone number of the person who has physical custody of the newborn;
4. The name of the health care provider who will be responsible for the coordination of medical services for the newborn after the newborn is discharged from the health care facility; and
5. The name and phone number of the person to whom the newborn's mother or other person who has physical custody of the newborn was referred for a subsequent hearing test.

C. When a hearing test is performed on a newborn or an infant after an initial hearing test, the designee of the health care facility, health care provider, or other person that performs the subsequent hearing test shall provide to the Department, as specified in subsection (E), the following information:
1. The newborn's or infant's name, date of birth, and gender;
2. Whether the newborn or infant is from a single or multiple birth;
3. If the newborn or infant is from a multiple birth, the birth order of the newborn or infant;
4. The newborn's or infant's mother's first and last names and date of birth;
5. The name of the health care facility where the initial hearing test was performed, or the name and address of the health care provider who performed the initial hearing test;
6. The name of the health care facility of birth;
7. The name and identification code of the person submitting the subsequent hearing test results;
8. The date of the subsequent hearing test;
9. The audiological equipment used for the subsequent hearing test and the type of hearing test performed;
10. The result for each of the newborn's or infant's ears on the subsequent hearing test; and
11. The name, address, and phone number of the contact person for the health care facility, health care provider, or other person that performed the subsequent hearing test.

D. In addition to the information in subsection (C), if the reported results of a subsequent hearing test on a newborn or infant include an abnormal result, the person submitting the report on the subsequent hearing test shall provide to the Department, as specified in subsection (E), the following information:
1. Except as provided in subsection (D)(2), the newborn's or infant's mother's mailing address and phone number;
2. 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 phone number of the person who has physical custody of the newborn or infant;
3. The name of the health care provider who is responsible for the coordination of medical services for the newborn or infant; and
4. If applicable, the name and phone number of the person to whom the newborn's or infant's parent was referred for further hearing tests, evaluation services, specialty care, or early intervention.

E. A health care facility's designee, health care provider, health care provider's designee, or other person required to report under subsections (A), (B), (C), or (D) shall submit, in an electronic format specified by the Department, the information specified in subsections (A), (B), (C), or (D) for hearing tests performed each week by the sixth day of the subsequent week.

R9-13-208. Fees

A. The fee for a first specimen is $30.00.

B. The fee for a second specimen is $40.00.