

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, §122(1), 16 Delaware Code, §122(3)h, and 16 Delaware Code, §7904

(16 Del.C., §122(1), §122(3)h and §7904)
16 DE Admin. Code 4107

PROPOSED

PUBLIC NOTICE

4107 Testing Of Newborn Infants For Metabolic, Hematologic And Endocrinologic Disorders

On February 1, 2013, the Family Health Systems section, under the Division of Public Health, Department of Health and Social Services, plans to publish proposed regulations governing the State of Delaware Screening of Newborn Infants for Metabolic, Hematologic, Endocrinologic, and Certain Structural Disorders and hold them out for public comment per Delaware law.

In September 2011, the U.S. Department of Health and Human Services adopted the Advisory Committee on Heritable Disorders in Newborns and Children's recommendation to add screening for critical congenital heart disease (CCHD) to the Uniform Screening Panel. The proposed revisions to this regulation outline the process for collecting screening results for CCHD through pulse oximetry testing for newborns. Additionally, the revisions clarify the program's retention of blood spot results for a period of three years as well as update language to currently acceptable terms.

Copies of the proposed regulations are available for review in the February 1, 2013 edition of the Delaware *Register of Regulations*, accessible online at: <http://regulations.delaware.gov> or by calling the Family Health Systems Section at (302) 744-4821.

Any person who wishes to submit suggestions, briefs or other written materials concerning the proposed regulations must submit same to Deborah Harvey by March 4, 2013 at:

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Dover, DE 19901
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~~4107 Testing~~ Screening Of Newborn Infants For Metabolic, Hematologic, And Endocrinologic, and Certain Structural Disorders

1.0 Authority and Purpose

Under the authority granted to the Department of Health and Social Services, Division of Public Health under 16 Del.C. §122(1), 16 Del.C. §122(3)(h), and 29 Del.C. §7904 the Department of Health and Social Services, Division of Public Health, State of Delaware adopts the following regulations pertaining to the ~~testing~~ screening of newborns for various disorders.

~~These regulations describe~~ To regulate the procedures for the Newborn Screening Program administered by the Delaware Division of Public Health. Under the authorization of the statues listed above, where each newborn delivered in the state must be provided a panel of screening tests to identify certain metabolic, hematologic, ~~and endocrinologic, and certain structural~~ disorders that may result in developmental delay, ~~mental retardation, cognitive disabilities,~~ serious medical conditions, or death.

~~These regulations clarify responsibilities among the parties involved.~~

~~These regulations apply to each newborn infant born in the State. The responsibility for implementation of the regulations rests with the institution in which the infant is born, or if an infant is born outside an institution, with the person required to prepare and file the certificate of birth and with the newborn's primary care provider. If an infant is born outside an institution or facility, the responsibility for implementation of the regulations rests with the attending physician or midwife, the newborn's primary care provider and the parent or legal guardian.~~

2.0 Definitions

“Blood Specimen for Metabolic, Hematologic and Endocrinologic Disorders” means a dried blood spot on a special filter paper utilized for screening (not diagnostic) tests to establish the likely presence of certain metabolic, hematologic or endocrinologic disorders.

“Certain Structural Disorders” includes critical cardiac heart defects and other structural disorders.

“Designated Laboratory” is the laboratory or laboratories, which have been selected by the Division of Public Health to perform these services.

“Endocrinologic Disorder” means the absence or deficiency of a hormone resulting in interference with normal health, growth or development. These disorders include Congenital Hypothyroidism (CH) and Congenital Adrenal Hyperplasia (CAH).

“Hematologic Disorder” means, in these regulations, a condition in which a variation in one or more of the hemoglobin structural genes or in one or more of the genes involved in hemoglobin synthesis produces a variation in hemoglobin structure or synthesis, which result in variation in hemoglobin function. The term “hemoglobinopathies” includes sickle cell anemia, sickle cell hemoglobin C disease (SC disease), sickle beta thalassemia, beta thalassemia, alpha thalassemia, hemoglobin C disease and other clinically important variations in hemoglobin structure or synthesis.

~~“IMF” stands for Insufficient Milk Feeding, which is an inadequate time frame for milk feedings (<24 hours) prior to obtaining the blood spot specimen.~~

“Kit” means any or all parts of the combined materials, laboratory filter paper specimen forms, ~~lanets,~~ envelopes, Newborn Screening Program brochure, and/or other components provided by the State Newborn Screening Program for the purposes of collection of the blood spot specimen and for submission of the blood spot specimen for laboratory testing screening.

“Metabolic Disorder” means a disorder caused by a genetic alteration, which results in a defect in the structure or function of a specific enzyme or other protein. These disorders include, but are not limited to, Phenylketonuria (PKU), Galactosemia, Maple Syrup Urine Disease (MSUD), and Medium Chain Acyl-CoA Dehydrogenase (MCAD) Deficiency.

“Newborn Infant” means any infant born in the state who is under 4 weeks of age.

“Satisfactory Specimen” means a blood spot specimen on which an accurate laboratory analysis for the various disorders can be performed.

“The Newborn Screening Advisory Committee” means a committee, established through the Division of Public Health Newborn Screening Program, convened to provide advice and guidance to the ~~Newborn Screening~~ Program. Members include, but are not limited to: individuals or parents of individuals with one of the disorders for which screening is performed; physicians not employed by the Division of Public Health who have expertise in the disorders for which screening is performed; an attorney not employed by the Division of Public Health; an ethicist not employed by the Division of Public Health; representatives of relevant agencies within the Department of Health and Social Services. The Committee will ~~meets~~ at least semi-annually. The Director of the Division of Public Health will appoint members after recommendation by the Newborn Screening Program.

“Unsatisfactory Specimen” means a blood spot specimen which is of insufficient quantity; or a blood spot specimen on which an accurate analysis for the various disorders cannot be performed.

3.0 Determination of Required Screens

The Director of the Division of Public Health or designee shall determine the disorders subject to screening tests.

4.0 Persons Responsible for Submitting Blood Spot Specimens and Pulse Oximetry Results for Screening for Metabolic, Hematologic, ~~and~~ Endocrinologic, and Certain Structural Disorders

4.1 The person or institution responsible for assuring that a satisfactory blood spot specimen and pulse oximetry results is are submitted for testing screening newborns for metabolic, hematologic, ~~and~~ endocrinologic and certain structural disorders shall be, in order of responsibility:

- 4.1.1 the hospital, birthing facility or other licensed health care facility in which the newborn is born,
- 4.1.2 the newborn’s primary care provider; or, if no provider is identified;
- 4.1.3 the parent or legal guardian.

4.2 In cases of newborns entering a health care facility before 48 hours of age as result of transfer from another facility or of an infant not born in a hospital or other licensed health care facility, the receiving facility shall be responsible for the timely collection of the blood spot specimen and pulse oximetry screening results.

4.3 In cases of newborns not born in a hospital or other licensed health care facility, and not transferred to a

health care facility, the timely collection of the blood spot specimen and pulse oximetry screening results shall be the responsibility of the following, in order of responsibility:

- 4.3.1 the attending physician, or midwife, or in the absence of such a person;
- 4.3.2 the newborn's primary care provider; or, if no provider is identified;
- 4.3.3 the parent or legal guardian.

5.0 Manner of Submitting Blood Spot Specimens and Pulse Oximetry Results

- 5.1 All dried blood spot specimens submitted to the designated laboratory for testing shall be collected using kits available from the Newborn Screening Program office and/or designated laboratory.
- 5.2 Blood spot specimens collected for ~~testing~~ screening shall be forwarded from the institution ~~at which the specimen is collected~~ to the designated laboratory within 24 hours of collection, either by the designated Division of Public Health courier or by mail.
- 5.3 Pulse oximetry screening results shall be forwarded to the Division of Public Health electronically by the 15th of each month for births occurring in the previous calendar month.

6.0 Timing of Collecting the Blood Spot Specimen and Pulse Oximetry Screening for Screening Infants

- 6.1 A blood spot specimen for screening for metabolic, hematologic, and endocrinologic disorders shall be collected prior to hospital discharge, but ~~in no event later than 3~~ three days after birth ~~from every newborn infant~~ as follows:
 - 6.1.1 For infants born inside or outside of a hospital or other health care facility, or infants born outside of a hospital or other health care facility and transferred to the hospital where they will remain for the next 24 hours, a specimen shall be collected ~~not sooner than~~ 24 hours after the onset of milk feeding, but no later than 3 days after birth, preferably between 36 and 72 hours of birth. A second specimen is to be collected between ~~7~~ seven and 28 days of age.
 - 6.1.2 For infants who are born in a hospital or health care facility or who are born outside and transferred into the hospital and who will remain in the hospital for 24 hours of milk feedings or more a blood spot specimen shall be collected ~~not sooner than 24 hours after the onset of milk feeding, but no later than 3 days after birth, preferably between 36 and 72 hours after birth. A second blood spot specimen is to be collected between 7 and 28 days of age.~~
 - 6.1.3~~2~~ For pre term or sick newborns, the initial blood spot specimen may be collected as late as ~~3~~ three days of age and ~~must be collected but~~ no later than 3 days regardless of birth weight, illness or nutritional status. The second dried blood spot specimen on preterm or sick newborns ~~is to be done~~ must be completed at hospital discharge or 28 days of life which ever comes first.
 - 6.1.4~~3~~ When an infant is discharged from a hospital or other health care facility before 24 hours of milk feedings a blood spot specimen shall be obtained immediately prior to discharge from the facility and a second dried blood spot specimen shall be obtained after 3 days of age and before 14 days of age.
- 6.2 Birth facilities or care providers responsible for screening newborns shall adopt protocols consistent with the scientific statement regarding the role of pulse oximetry from the American Heart Association and American Academy of Pediatrics (Pediatrics, Vol. 124, No. 2, August 1, 2009, pp. 823-836).
- 6.3 The data elements to be reported for pulse oximetry screening of newborns to the Division of Public Health are:
 - 6.3.1 The number of births in a birthing facility each month
 - 6.3.2 The number of pulse oximetry screenings on newborn infants performed each month
 - 6.3.3 The number of positive and negative screens recorded
 - 6.3.4 For those infants who do not receive a screen, a reason for not being screened
 - 6.3.5 The identity of the infants who fail the screen including their diagnostic evaluation and disposition

7.0 Procedures for Follow Up of Dried Blood Spot Specimens ~~that were obtained prior to 24 Hours Of Milk Feeding (Imf)~~ and for those whose Results are Designated as Abnormal or Suspicious

- 7.1 ~~The hospital or institution of birth or the hospital to which a newborn is transferred~~ The hospital/institution of birth/hospital to which a newborn is transferred shall develop adequate procedures to insure that a satisfactory blood spot specimen is collected by the time each newborn is ~~2 weeks old~~ three days of age. The sample must be taken from ~~each every~~ newborn who is described by one or more of the following categories:
 - 7.1.1 ~~a newborn that is discharged from the institution prior to~~ within 24 hours of milk feedings (IMF).
 - 7.1.2 ~~a newborn on which the blood-spot specimen is reported by the laboratory as~~ “designated unsatisfactory” by the laboratory.

7.2 The hospital/institution of birth/hospital or ~~institution of birth, the hospital~~ to which a newborn is transferred and the primary care provider of the newborn shall cooperate with the Newborn Screening Program in completing follow up of newborns whose blood spot specimen result is designated as "abnormal" or "suspicious." This cooperation shall include:

7.2.1 ~~pro~~Providing appropriate demographic information to the Newborn Screening Program as requested on each baby ~~whose blood spot specimen result is designated as "abnormal" or "suspicious,"~~

7.2.2 providing the Newborn Screening Program with clinical information on each newborn as necessary for interpretation of the results of the testing screening of the ~~blood spot specimen~~.

8.0 Reporting of Results of Newborn Screening Tests

8.1 The designated laboratory shall report the results to the Newborn Screening Program as designated in the contract.

8.2 The Newborn Screening Program shall contact with abnormal results the parent or legal guardian and primary health care provider in writing and/or by telephone.

8.3 A copy of the Newborn Screening laboratory report shall be available to the parent or legal guardian upon request made to the birth hospital medical record department or their primary health care provider.

9.0 Confidentiality of Records

9.1 The Newborn Screening Program shall maintain and treat as confidential all newborn screening communications with institutions, families and health care providers. The Newborn Screening Program shall maintain and treat as confidential a record of every newborn in whom a diagnosis of one or more of the various metabolic, hematologic, or endocrinologic disorders is confirmed.

9.2 Information may be disclosed by the Newborn Screening Program in summary forms, which do not identify individuals. Individuals or institutions requesting summary data must submit a proposal to the Newborn Screening Program and to the Institutional Review Board of the Division of Public Health.

9.3 Dried blood-spots will be retained for a period of three years under appropriate conditions. The stored specimens will only be used for activities to improve the screening program and/or develop new screening tests.

10.0 Fees for Newborn Screening Tests Performed in the Designated Laboratory

10.1 The Division of Public Health Newborn Screening Program shall bill the institution or individual for services provided ~~to the institution or individual~~ for each newborn screened under these regulations including but not limited to, the cost of the kits for collection of specimens, the laboratory fee for analysis, and administrative costs. The fee will be determined annually (in July) based on cost of the program.

10.2 No Delaware newborn shall be denied testing for hereditary disorders because of inability of the newborn's parent or legal guardian to pay the fee. A "Statement of Fee Exemption" form will be provided to the practitioner or parent requesting exemption from fees. This form must be completed and submitted to the Newborn Screening Program Office within 30 days of birth.

11.0 Religious Exemption from ~~Testing~~ Screening

11.1 A newborn may be excused from screening if the parent or legal guardian objects to the tests because the screening tests conflict with the religious tenets or practices of the parent or legal guardian.

11.2 In the event a religious exemption is claimed from the requirements for testing for Hereditary Disorders, the person otherwise responsible for submitting the specimen for testing screening shall be responsible for submitting a completed affidavit to the Delaware Newborn Screening Program Office, signed by the infant's parent or legal guardian, using the following language:

1. (I) (We) (am) (are) the (parent(s)) (legal guardian(s)) of (name of child)

2. (I) (We) hereby (swear) (affirm) that (I) (we) subscribe to a belief in a relation to a Supreme Being involving duties superior to those arising from any human relation.

3. (I) (We) further (swear) (affirm) that our belief is sincere and meaningful and occupies a place in (my) (our) life parallel to that filled by the orthodox belief in God.

4. This belief is not a political, sociological or philosophical view of a merely personal moral code.

5. This belief causes (me) (us) to request an exemption from the requirements for testing for Hereditary Disorders by the Delaware Newborn Screening Program for _____ (name of child).

Signature of Parent (s) or

Legal Guardian(s)

SWORN TO AND SUBSCRIBED before me, a registered Notary Public, this ____ day of _____, 200__.

(Seal)

Notary Public

My Commission Expires:

11.3 The Newborn Screening Refusal Form will be provided through the Newborn Screening Program Office.

12.0 Penalty for Non-compliance

Under the Authority granted to the Department of Health and Social Services, Division of Public Health under 16 Del.C §107, "whoever refuses, fails or neglects to perform the duties required under this chapter, or violates, neglects or fails to comply with the duly adopted regulations or orders of the Division shall be fined not less than \$100 and not more than \$1,000, together with costs, unless otherwise provided by law."

8 DE Reg. 100 (7/1/04)

16 DE Reg. 827 (02/01/13) (Prop.)