DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, Sections 122(1), 122(3)h, and Ch. 8C (16 **Del.C.** §§122(1), 122(3)h, & Ch. 8C)
16 **DE Admin. Code** 4107

FINAL

ORDER

4107 Screening of Newborn Infants for Metabolic, Hematologic, Endocrinologic, and Certain Structural Disorders

NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services ("DHSS") initiated proceedings to adopt the State of Delaware Regulations Governing Screening of Newborn Infants for Metabolic, Hematologic, Endocrinologic, and Certain Structural Disorders. The DHSS proceedings to adopt regulations were initiated pursuant to 29 Delaware Code Chapter 101 and authority as prescribed by 16 Delaware Code, subsections 122(1) and 122(3)h, and Ch. 8C.

On September 1, 2019 (Volume 23, Issue 3), DHSS published in the Delaware *Register of Regulations* its notice of proposed regulations, pursuant to 29 **Del.C.** §10115. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by October 2, 2019, after which time DHSS would review information, factual evidence and public comment to the said proposed regulations.

Written comments were received during the public comment period and evaluated. The results of that evaluation are summarized in the accompanying "Summary of Evidence."

SUMMARY OF EVIDENCE

In accordance with Delaware Law, public notices regarding proposed Department of Health and Social Services (DHSS) Regulations Governing Screening of Newborn Infants for Metabolic, Hematologic, Endocrinologic, and Certain Structural Disorders were published in the Delaware *Register of Regulations*. Written comments were received on the proposed regulations during the public comment period (September 1, 2019 through October 2, 2019).

Entities offering written comments include:

- Mr. Richard James, Member, Newborn Screening Advisory Committee
- Mr. Chris Manning, Nemours Children's Health System

Comments from Mr. Richard James

I am a member of the Newborn Screening Advisory Committee and would like to make the following comments on the proposed revisions. My appointment happened this year so when these revisions were discussed I was not a member of the committee and did not participate. The following comments should not be construed as any criticism of those discussions or the opinions of the Committee.

Re. Section 11: I would argue that this section should be deleted in total, and no exemption from screening be authorized for religious, personal, or any other reason. There is no circumstance in which screening compels parental/caregiver action that might conflict with beliefs of any kind, and there is no possibility that the screening procedure in itself creates any harm to the infant. This being the case it is unreasonable that any refusal to screen can be in the child's best interest and therefore there is no justification for providing the option to refuse. On receipt of screening results, the parents decisional autonomy is retained and they may make conscience- or beliefs-based decisions within normal bounds, but since there is no harm and no coercion in the screening in and of itself, and screening is important for epidemiological and other reasons, refusal should not be sanctioned or at least, should be much more burdensome than the proposed revisions allow.

- Response: The Agency appreciates and acknowledges these comments. The language referenced in your submitted comment was not included in the final regulation. Title 16, §805C of the Delaware Code governs the requirement for exemptions to newborn screening.

Comments from Mr. Chris Manning, Nemours Children's Health System

Nemours Children's Health System appreciates the opportunity to comment on proposed revisions to the Newborn Screening Program (16 **Del.C.** §122(1), 122(3)h, & Ch.8C).

Nemours supports the proposed changes which align with best clinical practice and reflect the recommendations by Delaware's Newborn Screening Advisory Committee. The National Institutes of Health and the Centers for Disease Control and Prevention validate the timely collection of the infant blood spot specimen by day two (48 hours) of life. Likewise, special consideration should be given to preterm or sick newborns to ensure accurate results, as clinical best practice warrants a second screen for this population[1].

Thank you for the opportunity to comment. Nemours remains committed to supporting optimal child health and development. We look forward to continued partnership in the future.

- Response: The Agency appreciates and acknowledges these comments.

FINDINGS OF FACT:

No changes were made to the regulations since publication as proposed. The Department finds that the proposed regulations, as set forth in the attached copy should be adopted in the best interest of the general public of the State of Delaware.

THEREFORE, IT IS ORDERED, that the proposed State of Delaware Regulations Governing Screening of Newborn Infants for Metabolic, Hematologic, Endocrinologic, and Certain Structural Disorders is adopted and shall become effective November 11, 2019 (ten days), after publication of the final regulation in the Delaware *Register of Regulations*.

10/9/19
Date

Kara Odom Walker, MD, MPH, MSHS
Cabinet Secretary

4107 Screening of Newborn Infants for Metabolic, Hematologic, Endocrinologic, and Certain Structural Disorders

1.0 Authority and Purpose

Under the authority granted the Department of Health and Social Services, Division of Public Health under 16 **Del.C.** §122(1), 16 **Del.C.** §122(3)(h), 16 **Del.C.** Ch. 8C and 29 **Del.C.** §7904 the Department adopts the following regulations pertaining to the screening of newborns for various disorders.

The purpose of these regulations is to describe the procedures for the Newborn Screening Program where each newborn delivered in the state must be provided a panel of screening tests to identify certain metabolic, hematologic, endocrinologic, and certain structural disorders that may result in developmental delay, cognitive disabilities, serious medical conditions, or death.

The responsibility for implementation of the regulations rests with the institution in which the infant is born. If an infant is born outside a facility, the responsibility for implementation of the regulations rests with the attending delivering physician or midwife, the newborn's primary health care provider and the parent or legal guardian.

16 DE Reg. 1182 (05/01/13)

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 metabolic, hematologic or endocrinologic disorders.

"Certain Structural Disorders" includes critical congenital 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 results 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.

"Kit" means any or all parts of the combined materials, laboratory filter ~~paper~~ paper, specimen forms, 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 screening.

1. Fabie N.A., Pappas, K.B., Feldman, G. L. The current state of newborn screening in the United States. Pediatric Clinics of North America 2019; 66: pp. 369-386

"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.

"Pulse Oximetry Screening" is non-evasive test allowing for determination of the oxygen saturation of a patient's hemoglobin to screen for a critical congenital heart defect.

"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 Program. Members are appointed by the Governor and include~~, but are not limited to~~: three individuals or parents of individuals ~~with one of the disorders for which screening is performed~~ affected by disorders identified by the screening panel; ~~physicians not employed by the Division of Public Health who have expertise in the disorders for which screening is performed;~~ an ethicist; an attorney not employed by the ~~Division of Public Health~~ State; ~~an ethicist not employed by the Division of Public Health;~~ three pediatric physicians; the Medical Director for the Division of Public Health, or their designee; the Laboratory Director for the Division of Public Health, or their designee; a representative from the Department of Services for Children, Youth, and Their Families; the Chair of the Midwifery Advisory Council, or their designee; and a member of the public. ~~representatives of relevant agencies within the Department of Health and Social Services.~~ The Committee will ~~meets~~ meet 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~~ that is of insufficient quantity; or a blood spot specimen on which an accurate analysis for the various disorders cannot be performed.

16 DE Reg. 1182 (05/01/13)

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, Endocrinologic, and Certain Structural Disorders

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

4.1.1 ~~the~~ The hospital, birthing facility or other licensed health care facility in which the newborn is ~~born,~~ born;

4.1.2 ~~the~~ The newborn's primary health care provider; or, if no provider is identified;

4.1.3 ~~the~~ 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~~ The attending delivering physician, or ~~midwife,~~ midwife; or in the absence of such a person;

4.3.2 ~~the~~ The newborn's primary health care provider; or, if no provider is identified;

4.3.3 ~~the~~ The parent or legal guardian.

16 DE Reg. 1182 (05/01/13)

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 screening shall be forwarded from the collecting facility to the designated laboratory within 24 hours of collection, either by the designated Division of Public Health ~~courier or~~ courier, by ~~mail.~~ mail, or via the service provided by the designated laboratory.

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.

16 DE Reg. 1182 (05/01/13)

6.0 Timing of Collecting the Blood Spot Specimen and Pulse Oximetry Screening for Screening Infants By Hospitals, Birth Centers or Midwives

6.1 A blood spot specimen for screening for metabolic, hematologic, and endocrinologic disorders shall be collected ~~prior to hospital discharge, but no later than three days after birth as follows:~~ by the hospital, birth center, or midwife by 72 hours of age regardless of feeding history or medical condition unless the newborn falls into one of the following categories:

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 24 hours after the onset of milk feeding, but no later than three days after birth, preferably between 36 and 72 hours of birth. A second specimen is to be collected between seven and 28 days of age.~~ for continuing care prior to 48 hours of age, the hospital to which the newborn child has been transferred shall collect a specimen from the newborn child, regardless of feeding history or medical condition, as close to arrival as possible.

6.1.2 For pre-term or sick newborns, the initial blood spot specimen shall be collected between 24 ~~hours~~ and 48 hours after birth~~, if possible~~. The ~~second dried blood spot~~ specimen ~~on pre-term or sick newborns must be completed at hospital discharge or transfer if within seven days from birth, or otherwise~~ may be collected prior to 24 hours of age if the infant is receiving blood products. If the first specimen is collected prior to 24 hours of age, a second specimen shall be collected at 8 – 10 days of age or prior to discharge, whichever occurs first. ~~A third specimen on pre-term or sick newborns shall be collected between 21-24 days or at discharge, whichever comes first.~~ For infants weighing less than 1800 grams at birth, a second specimen shall be collected at 28 days of life or prior to discharge, whichever comes first.

6.1.3 ~~When an infant is~~ For infants discharged from a hospital or other health care facility before 24 hours of ~~milk feedings~~ age, 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)~~ 2012: 129 (1) pp. 190-192).

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~~ month;

6.3.2 The number of pulse oximetry screenings on newborn infants performed each ~~month~~ month;

6.3.3 The number of positive and negative screens ~~recorded~~ recorded;

6.3.4 For those infants who do not receive a screen, a reason for not being screened; and

6.3.5 The identity of the infants who fail the screen including their diagnostic evaluation and ~~disposition~~ disposition.

16 DE Reg. 1182 (05/01/13)

7.0 Procedures for Follow Up of Dried Blood Spot Specimens Designated as Abnormal or Suspicious

7.1 The hospital/facility of birth/midwife to which a newborn is transferred shall develop adequate procedures to ~~insure~~ ensure a satisfactory blood spot specimen is collected by the time each newborn is ~~three~~ two days of age. The sample must be taken from every newborn unless a refusal form signed by the parent or legal guardians is obtained.

7.2 The hospital/facility of birth/midwife to which a newborn is transferred and the primary health 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."~~ "unacceptable", "presumptive positive" or "inconclusive." This cooperation shall include:

7.2.1 Providing appropriate demographic information to the Newborn Screening Program as requested on each ~~baby.~~ baby; and

7.2.2 Providing the Newborn Screening Program with clinical information on each newborn as necessary for interpretation of the results of the screening.

16 DE Reg. 1182 (05/01/13)

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 primary health care provider, the birth facility or midwife, and upon request 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 facilities, 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.

16 DE Reg. 1182 (05/01/13)

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 facility or individual for services provided 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 ~~parentor~~ 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.

16 DE Reg. 1182 (05/01/13)

11.0 ~~Religious~~ Exemption from 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~~ for any reason.

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

~~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~~11.2.1 The Newborn Screening Refusal Form will be provided through the Newborn Screening Program Office.

16 DE Reg. 1182 (05/01/13)

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 (07/01/04)
16 DE Reg. 1182 (05/01/13)
23 DE Reg. 378 (11/01/19) (Final)