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

FINAL

ORDER

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

NATURE OF THE PROCEEDINGS:

The Delaware Department of Health and Social Services ("DHSS") initiated proceedings to amend the State of Delaware Regulations Governing Screening of Newborn Infants for Metabolic, Hematologic, Endocrinologic, and Certain Structural Disorders. The DHSS proceedings to amend regulations were initiated pursuant to 16 **Del.C.** §122(1), 16 **Del.C.** §122(3)(h), and 29 **Del.C.** §7904.

On February 1, 2013 (Volume 16, Issue 8), DHSS published in the Delaware *Register of Regulations* its notice of proposed regulations. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by March 4, 2013, after which time the 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 State News*, the *News Journal* and the Delaware *Register of Regulations*.

Entities offering written comments include:

- The Birth Center, Kathleen McCarthy and Dorinda Dove, Co-Owners, Co-Directors
- American Heart Association, Julie Brackett, Vice President of Advocacy
- State Council for Persons with Disabilities, Daniese McMullin-Powell, Chairperson
- Governor's Advisory Council for Exceptional Citizens, Terri A. Hancharick, Chairperson

Public comments and the DHSS (Agency) responses are as follows:

The Birth Center, Kathleen McCarthy and Dorinda Dove, Co-Owners, Co-Directors:

Regarding: Pulse Oximetry Screen for CCHD and DDPH Billing.

This is a follow up to our telephone conversation and your email inquiring about our policy for pulse oximetry screening for CCHD. We are presently not providing this screening measure. We were not aware of the policy nor do we have the funds or the staff to perform the screening.

Our ladies at TBC (The Birth Center) are discharged from our center on average between six and eight hours postpartum. We do a home visit on day two or day three. The home visiting nurse performs the first newborn metabolic screening at that visit. The metabolic screening requirements dictate this timeframe for the home visit. It is not feasible for us to do an earlier home visit for oximetry screening. The parents typically see their baby's pediatrician around the twenty-four hour post partum point; however, it is our understanding that the pediatricians will not be equipped to do this screening.

From a financial perspective we cannot afford the equipment, supplies and maintenance requirements of the equipment. We are just keeping our head above water. It is very difficult to recoup our costs from the third party payers. Many times the insurance payers will not pay for these additional services. They often say that it is included in the global charge. We are rarely able to get the insurance companies to increase their global fee. Thus each time your department increases the rates and screening requirements we are losing more money.

I was in touch with other birth centers in the country and was told that they were able to be exempt from the screening requirement. We are asking for an exemption.

Agency Response: The Agency appreciates and acknowledges these comments. While we realize that freestanding birth centers and nurse midwives who perform home deliveries may be impacted by the implementation of pulse oximetry

screening, these groups will have the option to either perform the screening at the home visit within 72 hours after birth or refer an infant to the primary care provider for screening.

We are also asking that your department bill the third party payers for the services that you test for. As noted above when your departments increase their charges we are not able to recoup the cost from the third party payers. If you billed the insurance companies for your services I am sure you would receive your payment quickly.

Agency Response: The Agency appreciates and acknowledges these comments, however for the purposes of these regulations, third party payment issues for professional/medical services are not addressed and we respectfully decline to comment on this issue.

American Heart Association, Julie Brackett, Vice President of Advocacy

Subject: Pulse Oximetry Screening in Delaware

As Jonathan mentioned, he and I work together in advocacy for the Great Rivers Affiliate of the American Heart Association. I work in a five-state region that includes Delaware, Kentucky, Ohio, Pennsylvania, and West Virginia. We were pleased to be able to pass pulse oximetry legislation early in 2012 in West Virginia, and we are currently working on this policy in the other four states in our affiliate. In Kentucky, Ohio, and Pennsylvania, we will soon be introducing legislation on this topic.

The American Heart Association is delighted that the State of Delaware is planning to move forward with regulations to ensure that newborns in the state receive pulse oximetry screening prior to leaving a birthing facility. As you know, this non-invasive, economical test is critical in identifying congenital heart defects early in infants, enabling lifesaving therapy to take place as early as possible.

Based on your discussions and correspondence with Jonathan, we have had our national experts review the proposed regulatory language. Our only concern is with section 5.2 in that it seems to stop short of actually specifying that every infant shall receive pulse oximetry screening prior to discharge. In order to assure that pulse oximetry screening is indeed a requirement for every infant, may we suggest that section 5.2 be amended as follows:

> 5.2 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) and ensure that such screening is performed for each infant prior to discharge from the birth facility.

The American Heart Association is working across the country to ensure that this life-saving screening is available for every infant, and we have been successful in several states already. If the Department is not able to require this of all Delaware hospitals, we will work with our volunteer advocates to introduce and support legislation to accomplish this goal.

We would be happy to discuss any further concerns or to review alternate proposed language.

Agency Response: The Agency appreciates and acknowledges these comments, however we respectfully disagree. We feel that the language, as it stands already charges the Division of Public Health with oversight of this screening requirement. The Newborn Screening Program Medical Director will ensure that training for pulse oximetry screening is provided to those facilities that request such assistance.

State Council for Persons with Disabilities, Daniese McMullin-Powell, Chairperson

RE: 16 DE Reg. 827 [DPH Proposed Newborn Screening Regulation]

The State Council for Persons with Disabilities (SCPD) has reviewed the Department of Health and Social Services/ Division of Health's (DPHs) proposal to adopt extensive revisions to its regulation covering screening of newborn infants for metabolic, hematologic, endocrinologic, and certain structural disorders. The proposed regulation was published as 16 DE Reg. 827 in the February 1, 2013 issue of the *Register of Regulations*. SCPD has the following observations.

First, in §1.0, the original regulation contained a second "sentence" beginning "(T)hese regulations describe...". The superseding revision is grammatically incorrect. It is not a sentence: "To regulate 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."

Agency Response: The Agency appreciates and acknowledges these comments. The Agency has changed the section to read, "The purpose of these regulations is s 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 metabolic, hematologic, endocrinologic and certain structural disorders that may result in developmental delay, cognitive disabilities, serious medical conditions, or death."

Second, in the same "sentence", SCPD recommend deletion of the word "certain" between "identify" and "metabolic". Compare comparable provisions in title to §4.0, §4.1, and 6.1. The definitions of "endocrinologic disorder", "hematologic disorder", and "metabolic disorder" are not restrictive. Indeed, the definition of "metabolic disorder" refers to "include, but are not limited to...".

Agency Response: The Agency appreciates and acknowledges these comments. The word certain has been

removed before “metabolic.”

Third, the regulation sometimes refers to an “institution” and sometimes refers to a “facility”. The term “institution is used in §§1.0, 5.2, 7.2, 9.1, 9.2, and 10.1. The term “facility” is used in §§1.0, 4.1.1, 4.3, 6.1.1, 6.1.3, 6.2, and 6.3.1. The Delaware Manual for Drafting Regulations issued by the *Register of Regulations* offers the following guidance:

> 6.2.2. Strive for consistency in terminology, expression and arrangement. Avoid using the same word or term in more than one sense. Conversely, avoid using different words to denote the same idea. ...

SCPD recommends using the term “facility”.

Agency Response: The Agency appreciates and acknowledges these comments. We have made the terminology consistent and have replaced “institution” with “facility” throughout the regulations.

Fourth, in §2.0, definition of “hematologic disorder”, the term “result” should be “results”.

Agency Response: The Agency appreciates and acknowledges these comments. The Agency has changed “result” to “results.”

Fifth, the structure of §4.0 merits overhaul. Both §§4.1 and 4.3 purport to establish a sequence of responsibility for assuring collection and submission of results. Both sections contemplate parental responsibility. Query whether a parent of a child born in a hospital should be made responsible for collection and submission of results if “overlooked” by the hospital. Section 4.1 covers hospitals and non-hospitals. Section 4.3 overlaps, covering non-hospitals. An undefined “primary care provider” is made responsible before a parent or guardian. Thus, a grandparent providing most general care for an infant would be responsible for ensuring the screening before a parent or legal guardian. SCPD suspects the Division intended to refer to “primary health care provider”. Compare §8.3.

Agency Response: The Agency appreciates and acknowledges these comments. The Agency has added “health” to read “primary health care provider.”

Sixth, §6.1.1 refers to “no later than ~~3~~ days after birth...” The strikeout of “3" results in a confusing reference.

Agency Response: The Agency appreciates and acknowledges these comments. The word “three” has been added for clarification.

Seventh, in §7.1, some words are ostensibly missing from the following sentence: “The sample must be taken from every newborn who one or more of the following categories:...”

Agency Response: The Agency appreciates and acknowledges these comments. This section has been reworded for clarification.

Eighth, §11.0 refers only to “Hereditary Disorders”. This may not be co-extensive with “metabolic, hematologic, endocrinologic, and certain structural disorders”. It is unclear if abnormalities in any of these contexts could be non-hereditary (e.g. induced by oxygen deprivation during birth). If so, the reference to “Hereditary Disorders” may be too narrow.

Agency Response: The Agency appreciates and acknowledges these comments. The Agency has removed the terminology “hereditary disorders” so that the language refers to newborn screening, in general.

Governor’s Advisory Council for Exceptional Citizens, Terri A. Hancharick, Chairperson

RE: DPH Proposed Newborn Screening Regulation [16 DE Reg. 827 (February 1, 2013)]

The Governor’s Advisory Council for Exceptional Citizens (GACEC) has reviewed the Division of Public Health (DPH) proposal to adopt extensive revisions to its regulation covering screening of newborn infants for metabolic, hematologic, endocrinologic, and certain structural disorders. The GACEC would like to share the following observations.

First, in §1.0, the original regulation contained a second “sentence” beginning “(T)hese regulations describe...”. The superseding revision is grammatically incorrect. It is not a sentence: “To regulate 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.”

Agency Response: The Agency appreciates and acknowledges these comments. The Agency has changed the section to read, “The purpose of these regulations is s 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 metabolic, hematologic, endocrinologic and certain structural disorders that may result in developmental delay, cognitive disabilities, serious medical conditions, or death.”

Second, in the same “sentence”, Council recommend deletion of the word “certain” between “identify” and “metabolic”. Compare comparable provisions in title to §4.0, §4.1, and 6.1. The definitions of “endocrinologic disorder”, “hematologic disorder”, and “metabolic disorder” are not restrictive. Indeed, the definition of “metabolic disorder” refers to “include, but are not limited to...”.

Agency Response: The Agency appreciates and acknowledges these comments. The word certain has been removed before “metabolic.”

Third, the regulation sometimes refers to an “institution” and sometimes refers to a “facility”. The term “institution is used in §§1.0, 5.2, 7.2, 9.1, 9.2, and 10.1. The term “facility” is used in §§1.0, 4.1.1, 4.3, 6.1.1, 6.1.3, 6.2, and 6.3.1. The

Delaware Manual for Drafting Regulations issued by the *Register of Regulations* offers the following guidance:

> 6.2.2. Strive for consistency in terminology, expression and arrangement. Avoid using the same word or term in more than one sense. Conversely, avoid using different words to denote the same idea. ...

The GACEC recommends using the term “facility”.

Agency Response: The Agency appreciates and acknowledges these comments. We have made the terminology consistent and have replaced “institution” with “facility” throughout the regulations.

Fourth, in §2.0, definition of “hematologic disorder”, the term “result” should be “results”.

Agency Response: The Agency appreciates and acknowledges these comments. The Agency has changed “result” to “results.”

Fifth, the structure of §4.0 merits overhaul. Both §§4.1 and 4.3 purport to establish a sequence of responsibility for assuring collection and submission of results. Both sections contemplate parental responsibility. Council queries whether a parent of a child born in a hospital should be made responsible for collection and submission of results if “overlooked” by the hospital. Section 4.1 covers hospitals and non-hospitals. Section 4.3 overlaps, covering non-hospitals. An undefined “primary care provider” is made responsible before a parent or guardian. Thus, a grandparent providing most general care for an infant would be responsible for ensuring the screening before a parent or legal guardian. The Council suspects the Division intended to refer to “primary health care provider”. Compare §8.3.

Agency Response: The Agency appreciates and acknowledges these comments. The Agency has added “health” to read “primary health care provider.”

Sixth, §6.1.1 refers to “no later than ~~3~~ days after birth...” The strikeout of “3" results in a confusing reference.

Agency Response: The Agency appreciates and acknowledges these comments. The word “three” has been added for clarification.

Seventh, in §7.1, some words are ostensibly missing from the following sentence: “The sample must be taken from every newborn who one or more of the following categories:...”

Agency Response: The Agency appreciates and acknowledges these comments. This section has been reworded for clarification.

Eighth, in §7.1 and §7.2, - ‘hospital/institution of birth hospital – one of the ‘hospitals’ is redundant.

Agency Response: The Agency appreciates and acknowledges these comments. The redundant language has been removed.

Ninth, in §7.1.2, there is a typographical error on the second line, “designated unsatisfactory” by the laboratory. The quotation marks should be around “unsatisfactory”. The hyphen before ‘by’ may be the continuation of a strikethrough and should be clarified.

Agency Response: The Agency appreciates and acknowledges these comments. This section has been removed.

Tenth, §11.0 refers only to “Hereditary Disorders”. This may not be co-extensive with “metabolic, hematologic, endocrinologic, and certain structural disorders”. It is unclear if abnormalities in any of these contexts could be non-hereditary (e.g. induced by oxygen deprivation during birth). If so, the reference to “Hereditary Disorders” may be too narrow.

Agency Response: The Agency appreciates and acknowledges these comments. The Agency has removed the terminology “hereditary disorders” so that the language refers to newborn screening, in general.

The public comment period was open from February 1, 2013 through March 4, 2013.

FINDINGS OF FACT:

Based on public comments received, non-substantive changes were made to the proposed regulations. 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 are adopted and shall become effective May 11, 2013, after publication of the final regulation in the Delaware *Register of Regulations*.

Rita M. Landgraf, Secretary

4107 ~~Testing~~ Screening ~~O~~of Newborn Infants ~~F~~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 purpose of these regulations is to describe 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~~ 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.

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~~ 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 result**[s]** 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, ~~lancets, 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.\

["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 ~~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 meet~~s~~ 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~~ facility]** 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 **[health]** 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 **[delivering]** physician, or midwife, or in the absence of such a person;

4.3.2 the newborn's primary **[health]** 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~~ collecting facility]** ~~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.

~~5.1.2 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 shall be collected between 24 hours and 48 hours after birth, if possible]**. 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~~ or transfer if within seven days from birth, or otherwise at 8 – 10 days**. **A third specimen on pre-term or sick newborns shall be collected between 21-24 days or at discharge, whichever comes first.]**

6.1.43 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~~ facility]** 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~~ facility]** of birth**[~~/hospital~~]** ~~or institution of birth, the hospital~~ 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." This cooperation shall include:

7.2.1 ~~p~~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~~ 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.

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~~ facility]** 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 parentor 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~~ screening]**, 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. 1182 (05/01/13) (Final)