DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code,
Section 122(1) and (3)h and
29 Delaware Code, Section 7904
(16 **Del.C.** §122(1)(3)h, 29 **Del.C.** §7904)

ORDER

FINAL

Regulations Pertaining to the Testing of Newborn Infants for Metabolic, Hematologic and Endocrinologic Disorders

NATURE OF THE PROCEEDINGS

Delaware Health and Social Services ("DHSS") initiated proceedings to adopt State of Delaware Regulations Pertaining to the Testing of Newborn Infants for Metabolic, Hematologic and Endocrinologic Disorders. The DHSS proceedings to adopt regulations were initiated pursuant to 29 **Del.C.** Ch. 101 and authority as prescribed by 16 **Del.C.** §122 (1), (3)h and 29 **Del.C.** §7904.

On April 1, 2004 (Volume 7, Issue 10), DHSS published in the Delaware Register of Regulations its notice of proposed regulations, pursuant to 29 Delaware Code Section 10115. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by April 30, 2004, or be presented at a public hearing on April 22, 2004, 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."

FINDINGS OF FACT

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. The proposed regulations include minor modifications from those published in the April 1, 2004, Register of Regulations, based on comments received during the public comment period. These modifications are deemed not to be substantive in nature.

THEREFORE, IT IS ORDERED, that the proposed State of Delaware Regulations Pertaining to the Testing of Newborn Infants for Metabolic, Hematologic and Endocrinologic Disorders are adopted and shall become effective July 10, 2004, after publication of the final regulation in the Delaware Register of Regulations.

Vincent P. Meconi,
Secretary, Department of Health and Social Services
Date of Signature 6.15.2004

SUMMARY OF EVIDENCE

A public hearing was held on April 22, 2004, at 1:00 p.m. in the Third Floor Conference Room of the Jesse Cooper Building located on Federal and Water Streets, Dover, Delaware before David P. Walton, Hearing Officer. The purpose of the hearing was to discuss the proposed amendments to the Department of Health and Social Services (DHSS) Regulations Pertaining to the Testing of Newborn Infants for Metabolic, Hematologic and Endocrinologic Disorders. Announcements regarding the public hearing were published in the Delaware State News, the News Journal and the Delaware Register of Regulations in accordance with Delaware Law. JoAnn Baker from Community Health Care Access (CHCA) Section of the Division of Public Health (DPH) made the agency's presentation. Although there was no testimony given at the hearing, three letters were received commenting on the proposed Regulations. All comments were received during the public comment period (April 1 through April 30, 2004). Organizations that commented included:

- **Delaware Developmental Disabilities Council**
- **State Council for Persons with Disabilities**
- **Governor's Advisory Council for Exceptional Citizens**

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

- **The regulations generally contain inconsistent references to "parents" and "parents or guardians".**

Agency Response: After a careful review, amendments were made throughout the regulations to correct this problem.

- **The definition of "IMF" in Section 1.0 is difficult to follow. Perhaps the italicized language was meant to be deleted.**

Agency Response: Based on this comment, the italicized language was removed from the definition of "IMF" in Section 1.0 for purposes of clarity.

- **Section 7.0 of the regulation contemplates that the parents will receive a copy of the test results only upon request. We strongly recommend that the reference be amended to affirmatively require disclosure of positive test results to the parents. If the screening is indicative of a covered disorder, the parent should be promptly informed, preferably by the primary health care provider or, in the absence of such a provider, by some other entity.**

Agency Response: Based on this comment, Section 7.0 was amended to reflect the Newborn Screening Program's process to ensure affirmative disclosure of positive test results to the parents or legal guardians.

- **The affidavit in Section 10.0 contains some ostensibly odd representations. For example, the parents are essentially required to affirm that they have an "unorthodox" belief in God. The Agency may wish to reassess the text of this affidavit.**

Agency Response: Based on this comment the Agency reviewed the affidavit in question. Although the language used may seem "ostensibly odd", it is intended to recognize the many culturally diverse belief systems that are represented in the United States. The affidavit has also been reviewed by the Agency's Deputy Attorney General and has been found to be legally sufficient.

- **There was a general comment that the Newborn Screening Program screen for more genetic diseases.**

Agency Response: Currently, Delaware's Newborn Screening Program screens for 30 disorders, the majority of which are considered genetic disorders. In deciding what disorders to screen for, the Agency considers the recommended March of Dimes list of disorders and geographic prevalence data. As a result of this comment, The Newborn Screening Program will make direct contact with commenting organizations to clarify and consider their screening recommendations.

In addition to the changes made above, grammatical corrections were made to the regulation for purposes of clarity.

The public comment period was open from April 1, 2004 to April 30, 2004.

Verifying documents are attached to the Hearing Officer's record. The regulation has been approved by the Delaware Attorney General's office and the Cabinet Secretary of DHSS.

~~**REGULATIONS PERTAINING TO THE**~~
~~**TESTING OF NEWBORNS FOR HEREDITARY DISORDERS**~~
~~**STATE OF DELAWARE**~~
~~**State Board of Health Regulations adopted July 14, 1994.**~~
~~**REGULALTIONS PERTAINING TO THE TESTING OF NEWBORNS**~~
~~**FOR HEREDITARY DISORDERS**~~

Under the Authority granted to the State Board of Health under 16 **Del.C.** sec. 122 (1), 16 **Del.C.** sec. 122 (3) (h), and 29 **Del.C.** sec. 7904 the Board of Health of the State of Delaware hereby adopts the following regulations pertaining to the testing of newborns for hereditary disorders.

The Committee on Genetics of the American Academy of Pediatrics recognizes that newborn screening is a preventive public health procedure which should be available to all neonates. Newborn screening programs have proven to be one of our most valuable tools for preventing mental retardation.

PURPOSE: These regulations describe the Newborn Screening Program administered by the Delaware Division of Public Health. Under the authorization of the statutes listed above, each newborn delivered in the state must be provided a panel of screening tests to identify the newborn that may be at risk of having phenylketonuria, certain other heritable diseases or congenital hypothyroidism.

These regulations clarify responsibilities among the parties involved, and will bring the Delaware Newborn Screening Program into step with Newborn Screening System Guidelines published by the Council of Regional Genetics Networks. Vermont and Delaware are the only states that have no regulation or legislation on newborn screening. These regulations will increase the effectiveness of the Newborn Screening Program.

These regulations apply to each newborn child in the State, and the responsibility for implementation of the regulations rests with the institution in which the child is born, or, if a child 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.

SECTION I
DEFINITIONS

1. "Blood Specimen for Hereditary Metabolic and Hematologic Disorders" means blood obtained for a screening (not diagnostic) test, performed on the dried blood spot on a filter paper, to establish the likely presence of hereditary disorders specified by the Division of Public Health.
2. "Newborn Child" means any infant born in the state who is under 4 weeks of age.
3. "Hereditary 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 protein. These disorders include but are not limited to: Phenylketonuria (PKU), Galactosemia, and Maple Syrup Urine Disease (MSUD).
4. "Congenital Hypothyroidism" means absence of or deficiency of thyroid hormones.
5. "Hereditary Hemoglobin Disorder" in these regulations means a condition in which a mutation in the hemoglobin gene, or in genes involved in hemoglobin synthesis, produces a variation in the hemoglobin structure which results in variation in hemoglobin function. The term "Hemoglobinopathies" includes Sickle Cell Anemia, Sickle Cell Hemoglobin C Disease (SC Disease), Sickle Cell Beta Thalassemia, Beta Thalassemia, Alpha Thalassemia. Hemoglobin C Disease and other clinically important variations in hemoglobin structure.
6. "Kit" means any or all parts of the combined materials, laboratory slips, lancets, envelopes, Newborn Screening Program pamphlet or other components provided by the State Newborn Screening Program for the purposes of collection and submission of specimens for laboratory tests.
7. "Unsatisfactory Specimen" means
   a. a blood specimen on which an insufficient quantity of blood is obtained, or
   b. a blood specimen on which an accurate analysis cannot be performed due to some technical or laboratory variation.
8. "IMF" means Insufficient Milk Feeding prior to the taking of the specimen.
9. "Satisfactory Specimen" means a blood specimen on which an accurate laboratory analysis for hereditary disorders can be performed.
10. "Designated Laboratory" means a laboratory or laboratories, specified by the Division of Public Health, capable of performing the newborn screening tests. The designated laboratory is chosen by the Division of Public Health following Request for Proposals sent to qualified laboratories who compete for the contract.

SECTION II
INFANTS TESTED FOR METABOLIC AND HEMOGLOBIN DISORDERS

Every newborn infant in Delaware shall be tested for at least the following metabolic and hemoglobin disorders by a designated laboratory.

(a) Phenylketonuria
(b) Galactosemia
(c) Congenital Hypothyroidism
(d) Hemoglobinopathies

Analysis of the blood specimens for the required screening tests must be performed by the laboratory identified by the Division of Public Health.

Other hereditary disorders may be added and changes made in testing procedures and timing of testing as recommended by the Delaware Newborn Screening Program with the approval of the Director of the Division of Public Health.

SECTION III

INFORMATION TO MOTHER ABOUT NEWBORN SCREENING PROGRAM

Each pregnant woman shall be supplied with a Newborn Screening Program pamphlet.

The person responsible for providing a Newborn Screening Program pamphlet, shall be in order of responsibility:

(a) the health care facility or practitioner responsible for care of the pregnant woman,

(b) the hospital, alternate birthing facility, other health care facility, or practitioner responsible for obtaining the specimen.

The Newborn Screening Program pamphlet is available from the Newborn Screening Program Office.

SECTION IV

PERSONS RESPONSIBLE FOR SUBMITTING SPECIMENS FOR METABOLIC AND HEMOGLOBIN DISORDERS

The person or institution responsible for assuring that a satisfactory specimen is submitted for testing the infant for metabolic and hemoglobin disorders, shall be in order of responsibility:

(a) the hospital, alternate birth facility, or other licensed health care facility where the infant is born, and

(b) the newborn's primary care provider; or if no provider is identified;

(c) the parent or legal guardian.

In the case of infants entering a health care facility before 48 hours of age as a result of transfer from another health care facility or an infant not born in a hospital or other licensed health care facility, the receiving health care facility shall be responsible for the timely collection of specimens.

SECTION V

MANNER OF SUBMITTING SPECIMENS

1. All specimens submitted to the designated laboratory for testing for Metabolic and Hemoglobin Disorders shall be collected using kits available from the Newborn Screening Program Office.

2. Specimens collected for testing for Metabolic and Hemoglobin disorders shall be forwarded within 24 hours of collection.

SECTION VI

TIMING OF COLLECTING SPECIMENS FOR TESTING INFANTS

A specimen for testing for hereditary disorders shall be collected prior to hospital discharge where applicable, but in no event later than 5 days after birth from every infant surviving more than two days, as follows:

(1) In the case of infants born outside a hospital or other health care facility a specimen shall be collected not sooner than 24 hours after the onset of milk feeding, but no later than 3 days after birth, preferable between 36 and 72 hours after birth. A second specimen is to be collected between one and four weeks of age.

In the case of 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 specimen shall be collected not sooner than 24 hours after the onset of milk feeding, but no later than 3 days after birth, preferable between 36 and 72 hours after birth. A second specimen is to be collected between one and four weeks of age.

In the case of preterm or sick newborns, the initial specimen may be collected as late as 5 days of age. The second specimen on preterm or sick newborns is to be done at hospital discharge, at one month of age or when the newborn attains a weight of 2500 grams, whichever comes first.

(4) In the case of infants discharged from a hospital or other health care facility before 24 hours of milk feedings, a specimen shall be obtained immediately prior to discharge from the facility, and a second specimen shall be collected from such infants after 72 hours but before 14 days of age.

SECTION VII

PROCEDURES FOR FOLLOW-UP OF SPECIMENS COLLECTED PRIOR TO 24 HOURS SPECIMENS, AND THOSE THAT SHOW ABNORMAL RESULTS

A. The appropriate institution shall develop adequate procedures to insure that a satisfactory blood specimen for hereditary disorders is collected (preferably by the time the child is 2 weeks old) from each newborn child who is described by one or more of the following categories:

(1) A newborn child who is discharged from the institution sooner than 24 hours after the onset of milk feedings (IMF).

(2) A newborn child on whom the blood specimen for hereditary disorders is reported by the laboratory as "unsatisfactory."

B. The Division of Public Health, Office of Women's and Infants' Health, Newborn Screening Program staff will be responsible for:

(1) maintaining an ongoing system of monitoring, which will identify the time period during which each newborn infant has a specimen taken and submitted for testing and for following up of those specimen results.

(a) Where the specimen is taken prior to 24 hours of milk feedings, and a follow-up specimen must be taken, the monitoring system will track individual infants through the screening process to ensure timely and complete follow-up.

(b) Where specimens are reported by the designated laboratory as "unsatisfactory," a repeat specimen will be requested by the Division of Public Health, Newborn Screening Program.

(c) Where specimens are reported by the designated laboratory as "abnormal," results will be reported to the identified primary care provider and the newborn's parents in a timely manner. Arrangements for repeat screening and/or appropriate confirmatory testing and diagnosis will be made with the primary care provider and the parent. These arrangements will be made by the Newborn Screening Program by letter or telephone call followed by letter, depending upon the urgency of the situation. The Newborn Screening Program Office will make available, in a timely manner, information regarding appropriate referral and treatment recommendations to the primary health care provider. If no primary health care provider has been identified, the Newborn Screening Program will contact the family directly and assist in obtaining a health care provider and completion of the testing.

(d) The Newborn Screening Program Office will be notified in writing of the final resolution and confirmation of each case by the primary health care provider or consultant.

(2) tracking and follow-up of infants who do not have a primary care provider identified or whose identified primary care provider has indicated he/she is not caring for the child.

(3) reviewing and reporting on various aspects of the program including but not limited to:

- Specimen transit times;
- Specimen collection timing;
- Frequency of inadequate specimens;
- Completeness of laboratory slip;
- Quality of Newborn Screening case record; and
- Timing to treatment of identified abnormals.

SECTION VIII
DEMOGRAPHIC DATA

The Newborn Screening Program Office will maintain demographic data records on all newborn infants to be used for the purposes of deriving incidence/prevalence rates, and monitoring statistical trends and screening practices in hospitals, birthing facilities, and individual practices. This monitoring will enable the Newborn Screening Program Office to:

(1) Assure that the most effective newborn screening program for the State of Delaware be maintained;

(2) Periodically evaluate the overall effectiveness of the screening program;

(3) Monitor and assure timely and complete follow-up of children with abnormal results; and

(4) Identify facilities and health care providers that have patterns of submitting unsatisfactory specimens which can be corrected through training.

SECTION IX
REPORTING OF RESULTS OF NEWBORN SCREENING TESTS

The laboratory making the analysis shall report the results of the test to the Newborn Screening Program Office, within 5 days after receipt of the specimen. Abnormal test results shall be reported immediately, by phone or facsimile, to the Newborn Screening Program Office with written or electronic data transfer confirmation sent within 5 days after receipt of the specimen.

All test results shall be reported to the health care facility of birth and to the person specified as the primary care provider on the screening collection form, for entry into the medical record.

The results shall be available to the parent upon request through the Newborn Screening Program Office.

Positive or suspicious test results shall be reported to the parent, the identified primary health care provider and the authorized Newborn Screening Program Consultant.

All newborns who have been screened and have been found to be presumptively positive through the screening program will be referred to the Division's Child WATCH program.

SECTION X
CONFIDENTIALITY OF RECORDS

The Office of Women's and Infants' Health, Newborn Screening Program, shall maintain and treat as confidential all newborn screening records, including a register of every newborn child in whom a diagnosis of a hereditary disorder has been confirmed.

Information may be disclosed by the Newborn Screening Program in summary, statistical, or other forms which do not identify particular individuals. Individuals or groups requesting data for purposes of research must submit proposals for review.

SECTION XI
AVAILABILITY OF COUNSELING SERVICES

The Office of Women's and Infants' Health shall, if so requested, assist each participant in the Newborn Screening Program and their families in gaining access to genetic counseling services that (i) are nondirective, (ii) emphasize informing the individual, and (iii) do not require restrictions in childbearing.

SECTION XII
FEES FOR NEWBORN SCREENING TESTS PERFORMED IN THE DESIGNATED LABORATORY

The Division of Public Health shall bill the institution for services provided to the institution 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.

No Delaware newborn shall be denied testing for hereditary disorders because of inability of the newborn's parents 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.

SECTION XIII
RELIGIOUS EXEMPTION FROM TESTING

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

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 shall be responsible for submitting a completed affidavit to the Delaware Newborn Screening Program Office, signed by the infant's parents, using the following language:

1. (I) (We) (am) (are) the (parent(s)) (legal guardian 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 _____, 19__.

~~_____ (Seal)~~

~~Notary Public~~

~~My Commission Expires:~~

~~_____~~

~~**SECTION XIV**~~

~~**PENALTY FOR NON-COMPLIANCE**~~

~~Under the Authority granted to the State Board of Health under 16 **Del.C** sec. 107, "(w)hoever 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 Board shall be fined not less than $100 and not more than $1,000, together with costs, unless otherwise provided by law."~~

107 Regulations Pertaining To The Testing Of Newborn Infants For Metabolic, Hematologic And Endocrinologic Disorders

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

PURPOSE: These regulations describe the Newborn Screening Program administered by the Delaware Division of Public Health. Under the authorization of the statues listed above, each newborn delivered in the state must be provided a panel of screening tests to identify certain metabolic, hematologic and endocrinologic disorders that may result in developmental delay, mental retardation, 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.

1.0 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.

"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 ~~***[means that insufficient time had passed (24 hours) between the time of the first milk feeding and the time at which the bloodspot specimen was obtained]***~~ 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.

"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 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.

2.0 Determination Of Required Screens

2.1 The Director of the Division of Public Health or designee shall determine **[~~what disorders will be tested for.~~ the disorders subject to screening tests.]**

3.0 Persons Responsible For Submitting Blood Spot Specimens For Screening For Metabolic, Hematologic And Endocrinologic Disorders

3.1 The person or institution responsible for assuring that a satisfactory blood spot specimen is submitted for testing newborns for metabolic, hematologic and endocrinologic disorders shall be, in order of responsibility:

3.1.1 the hospital, birthing facility or other licensed health care facility in which the newborn is born,

3.1.2 the newborn's primary care provider; or, if no provider is identified;

3.1.3 the parent or legal guardian.

3.2 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.

4.0 Manner Of Submitting Blood Spot Specimens

4.1 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.

4.2 Blood spot specimens collected for testing 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.

5.0 Timing Of Collecting The Blood Spot Specimen For Screening Infants

5.1 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 days after birth from every newborn infant as follows:

5.1.1 For infants born outside of a hospital or other health care facility 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 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.

5.1.3 For pre term or sick newborns, the initial blood spot specimen may be collected as late as 3 days of age *and must be collected 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 at hospital discharge or 28 days of life *which ever comes first.*

5.1.4 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.

6.0 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

6.1 The hospital or institution of birth or the 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 from each newborn who is described by one or more of the following categories:

6.1.1 a newborn that is discharged from the institution prior to 24 hours of milk feedings (IMF).

6.1.2 a newborn on which the blood spot specimen is reported by the laboratory as "unsatisfactory".

6.2 The 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:

6.2.1 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,"

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

7.0 Reporting Of Results Of Newborn Screening Tests

7.1 The designated laboratory shall report the results to the Newborn Screening Program as designated in the contract. **[~~All test results shall be available to the parent upon request through the birth hospital medical record department or their primary health care provider.~~]**

[7.2 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.

7.3 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.]

8.0 Confidentiality Of Records

8.1 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.

8.2 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.

9.0 Fees For Newborn Screening Tests Performed In The Designated Laboratory

9.1 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.

9.2 No Delaware newborn shall be denied testing for hereditary disorders because of inability of the newborn's parent**[~~s~~ 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.

10.0 Religious Exemption From Testing

10.1 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**[~~s~~ or legal guardian]**.

10.2 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 shall be responsible for submitting a completed affidavit to the Delaware Newborn Screening Program Office, signed by the infant's parent**[~~s~~ 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:

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

11.0 Penalty For Non-compliance

Under the Authority granted to the Department of Health and Social Services, Division of Public Health under 16 **Del.C** sec. 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."