Summary of Express Terms

In April of 2015, the federal Department of Health and Human Services' (DHHS) Advisory Committee on Heritable Disorders in Newborns and Children recommended that initial newborn screening (NBS) specimens "should be collected in the appropriate time frame for the newborn's condition but no later than 48 hours after birth" and "NBS specimens should be received at the laboratory as soon as possible; ideally within 24 hours of collection." In 2015, 83.7% of initial NBS specimens in New York were collected within 48 hours of birth. According to NewSTEPs (Newborn Screening Technical assistance and Evaluation Program), New York State ranked 32 out of 37 states that reported data. Also, only 28.3% of the NBS specimens arrived at the New York State Department of Health (NYSDOH) within 24 hours of collection (New York ranked 29 out of 36 states). NYSDOH has endorsed the DHHS Advisory Committee's recommendations. However, the proposed amendments to Subpart 69-1 are necessary to enforce these standards and will support NYSDOH's efforts to improve timeliness by hospitals, birth attendants and responsible providers in New York State.

To reduce any confusion between diagnostic testing and "screening," the regulation title is amended from "*Testing* for Phenylketonuria and Other Diseases and Conditions" to "Newborn *Screening* for Phenylketonuria and Other Diseases" (emphasis added). The diseases to be screened will no longer be listed in the regulation and will instead be listed on the Department's web page. This will facilitate the addition of new conditions in the future and will provide an easily accessible list of the diseases that are screened. The timing for specimen collection will require collection in the first twenty-four (24) to thirty-six (36) hours after birth and require that specimens be submitted to the testing laboratory within twenty-four (24) hours following collection.

The regulation is also amended to reflect current practices. The requirements for the Chief Executive Officer (CEO) of a hospital are amended to require the CEO to appoint a designee who can receive and act on screening results and interface with the NBS Program. The amendments also require the CEO to provide the testing laboratory with current contact information related to the hospital appointed designee, on an annual basis.

The amendments add a requirement for initial and yearly education on specimen collection. Specimen drying time is updated to reflect the current recommendation of the Clinical Laboratory Standards Institute Guidelines. The provision regarding religious exemption is also amended to reflect similar language used by other New York State Department of Health Programs. Electronic reporting and documentation requirements have been updated.

Other changes have been made to simplify the regulations. For example, acronyms for diseases and the list of identifying information needed for the specimen collection form have been removed. In addition, the responsibilities of the CEO, birth attendant and responsible provider have been reorganized so that the required actions are consistent with the screening process.

Pursuant to the authority vested in the Commissioner of Health by sections 2500-a and 2500-f of the Public Health Law, Subpart 69-1 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is repealed and replaced, to be effective upon publication of a Notice of Adoption in the State Register, to read as follows:

SUBPART 69-1

NEWBORN SCREENING FOR PHENYLKETONURIA AND OTHER DISEASES

(Statutory authority: Public Health Law, sections 2500-a and 2500-f)

Section 69-1.1 Definitions. As used in this Part:

(a) *Administrative designee* means an individual employed by the hospital, and designated on a form prescribed by the Department, to assist with administrative aspects of compliance with this

Subpart and Subpart 69-6 of this Title, including but not limited to storing, handling, collecting and transporting specimens.

(b) *Birth attendant* means the physician, nurse practitioner, licensed midwife or other person who attends a non-hospital birth and who is required to register the birth of a child pursuant to section 4130 of the Public Health Law.

(c) *Chief executive officer* or *CEO* means the individual appointed by the governing body of a hospital to manage the hospital and its health care services.

(d) *Department* means the New York State Department of Health.

(e) *LAB I.D.* means the unique specimen identifier included on the specimen collection form.

(f) *Medical designee* means a licensed physician or other licensed healthcare provider employed by the hospital, and designated on a form prescribed by the Department, to receive and act upon newborn screening program results in the absence of the responsible provider.

(g) *Parent* means the newborn's parent, legal guardian or other person legally responsible for the health and well-being of the newborn.

(h) *Public health officer* means the Commissioner of Health, public health director, or equivalent officer of a county or of the City of New York.

(i) *Repeat specimen* means a satisfactory specimen taken subsequent to an initial satisfactory specimen.

(j) *Responsible provider* means the physician or other licensed health care provider named on the specimen collection form, or the newborn's primary health care provider as identified to the testing laboratory.

(k) *Satisfactory specimen* means a blood specimen submitted to the testing laboratory on a complete and legible specimen collection form prescribed by the Department, collected consistent with the guidance provided by the testing laboratory and submitted in a condition suitable for testing.

(l) *Specialty care center* means a health care facility established under Article 28 of the Public Health Law that is approved and certified by the Department to provide treatment and/or services to children.

(m) *Specimen collection form* means the current FDA approved medical device for blood specimen collection prescribed and provided by the Department for use in the newborn screening program.

(n) *Testing laboratory* means the New York State Department of Health Wadsworth Center Newborn Screening Program.

Section 69-1.2 Diseases screened.

(a) Unless a specific exemption is granted by the State Commissioner of Health, screening pursuant to this Subpart shall be performed by the testing laboratory and according to recognized clinical laboratory procedures.

(b) In accordance with section 2500-a of the Public Health Law, the State Commissioner of Health shall designate which diseases shall be screened for and shall list such diseases on the Department's website.

Section 69-1.3 Responsibilities of the CEO of a hospital. The CEO shall ensure that the hospital complies with the following procedures:

(a) The hospital shall inform the parent(s) of each newborn born in the hospital, or admitted to the hospital within the first twenty-eight (28) days of life, of the purpose and need for newborn screening, and shall provide newborn screening educational materials made available by the Department.

(b) Specimen collection forms shall be properly stored in a cool and dry environment prior to use.

(c) The hospital shall collect a satisfactory specimen from every newborn between twenty-four (24) and thirty-six (36) hours after birth, except under the following circumstances:

(1) If a newborn is less than twenty-four (24) hours of age at the time of discharge from the birth hospital, the birth hospital shall collect an initial satisfactory specimen prior to discharge. The birth hospital shall schedule and collect a repeat specimen from the newborn between forty-eight (48) and seventy-two (72) hours after birth.

(2) If a newborn is transferred to another hospital, the birth hospital shall collect an initial satisfactory specimen from the newborn prior to transfer, submit the satisfactory specimen to the testing laboratory, and provide written and/or electronic notification to the receiving hospital that a specimen was collected. The receiving hospital shall collect any repeat specimens from the newborn following transfer that are required by the testing laboratory. If the newborn is less than twenty-four (24) hours of age when the birth hospital collects the satisfactory specimen, the receiving hospital shall collect a repeat specimen from the newborn between forty-eight (48) and seventy-two (72) hours after birth.

(3) If a newborn requires admission to an intensive medical care unit prior to the collection of a satisfactory specimen, the hospital shall collect an initial satisfactory specimen upon admission to the unit and shall submit the satisfactory specimen to the testing laboratory. The hospital shall collect a repeat specimen between forty-eight (48) and seventy-two (72) hours after birth and shall submit the repeat specimen to the testing laboratory. The hospital shall collect a third satisfactory specimen upon discharge or at twenty-eight (28) days after birth, whichever comes first, designate it a "repeat specimen," and submit the repeat specimen to the testing laboratory.

(4) If a newborn requires transfusion or total parenteral nutrition (TPN), the hospital shall collect an initial satisfactory specimen prior to any transfusion or administration of TPN and shall

submit the satisfactory specimen to the testing laboratory. If a specimen is not collected prior to transfusion and/or TPN, the hospital shall wait to collect an initial satisfactory specimen until seventy-two (72) hours after administration of a transfusion and/or TPN and submit the specimen to the testing laboratory. The hospital shall schedule and collect a repeat specimen no later than 120 days after the date of final transfusion and/or TPN, and submit the repeat specimen to the testing laboratory.

(5) If a newborn is admitted to the hospital within the first twenty-eight (28) days of life and no specimen has been previously collected, the hospital shall collect a satisfactory specimen upon admission and submit it to the testing laboratory.

(d) All specimens shall be air dried thoroughly on a flat nonabsorbent surface for a minimum of three (3) hours prior to forwarding to the testing laboratory.

(e) All specimens, including repeat specimens, shall be submitted to the testing laboratory within twenty-four (24) hours of collection to ensure the specimens are received by the testing laboratory no later than forty-eight (48) hours after collection using the testing laboratory's delivery service or an equivalent arrangement.

(f) (1) When notified by the testing laboratory that a repeat specimen is required, the hospital shall notify the parent(s) and responsible provider within one (1) business day that a repeat specimen is required from the newborn. The hospital shall collect the repeat specimen, pursuant to guidance issued by the testing laboratory, and submit it to the testing laboratory as soon as practicable.

(2) If the responsible provider documented on the initial specimen collection form is no longer responsible for the newborn's care, the hospital shall identify a new provider, notify the new provider of the need for a repeat specimen, and submit the contact information for the new provider to the testing laboratory.

(3) If the hospital is unable to obtain a repeat specimen, the hospital shall submit written and/or electronic documentation to the testing laboratory describing the steps taken by the hospital to notify the parent(s) and responsible provider that a repeat specimen(s) was required. The hospital shall submit this documentation to the testing laboratory no later than ninety (90) days after receiving notification from the testing laboratory that a repeat specimen was required.

(g) If a satisfactory specimen or a repeat specimen is not collected due to newborn mortality, the hospital shall submit a written and/or electronic notification to the testing laboratory within five (5) days after death.

(h) The hospital shall submit all information required by the testing laboratory using an electronic format determined by the Department, provided that:

(1) specimen collection forms shall be submitted as directed by the testing laboratory; and

(2) a hospital may request an exemption from electronic submission by demonstrating, to the Department's satisfaction, that the requirement imposes an undue burden.

(i) The hospital shall document on the newborn's health record the LAB I.D., as it appears on the specimen collection form, the date and time of specimen collection, and all screening results.

(j) The hospital shall document the LAB I.D., as it appears on the specimen collection form, on any discharge summary, and shall transmit a copy of the screening results or a copy of the discharge summary to the responsible provider.

(k) Before performing any tasks relating to collection of specimens, an employee shall complete comprehensive specimen collection training. The employee shall complete such training annually thereafter. The hospital shall retain documentation of completion of all such training.

(l) The hospital shall provide the testing laboratory with the names and contact information for its hospital administrative designee(s) and medical designee(s), annually; within ninety (90) days of any request from the testing laboratory; and within thirty (30) days of a change of designee. Such information shall be provided on a form prescribed by the Department.

(m) The hospital shall establish written policies and procedures, which shall be available for the Department's review, for:

(1) the collection, storage, tracking and shipping of specimens; and

(2) the tracking and disposition of test results.

(n) The hospital shall comply with the following additional requirements for HIV testing:

(1) the hospital shall obtain written documentation of any HIV testing and treatment during the current pregnancy and include such documentation in the mother's health record. The hospital shall counsel the mother consistent with such testing;

(2) if no HIV test result is documented in the health record of a mother and the mother's HIV status during the current pregnancy is unknown, the hospital shall immediately arrange an expedited HIV test of the mother with her consent, or if the mother declines testing for herself, arrange for expedited HIV antibody screen for the newborn with results available as soon as practicable, but no later than 12 hours after the mother provides consent for testing or, if she does not consent, 12 hours after the time of the newborn's birth;

(3) the hospital shall maintain in the newborn's health record the newborn's HIV test result in accordance with Article 27-F of the Public Health Law;

(4) the hospital shall determine the need for, and ensure provision of, HIV prophylaxis and/or treatment per standard of care to prevent transmission to the infant, and shall record such in both the mother's and newborn's health records;

(5) the hospital shall transmit a copy of the newborn's HIV test result to the responsible provider. For any newborn with a result indicating exposure to HIV, the hospital shall coordinate with the responsible provider to arrange appointments for follow up care with a provider experienced in the treatment of HIV;

(6) the hospital shall submit to the Department any specimen(s) necessary to confirm the HIV infection status of the newborn; or submit documentation of confirmatory test results from a laboratory permitted pursuant to section 574 of the Public Health Law;

(7) the hospital shall collect and provide authorized Department staff with such data as the Department may require for program evaluation and, in the case of HIV exposed newborns, patient follow-up;

(8) the hospital shall submit to the Department information related to HIV testing and treatment history of mothers and newborns for the purposes of medical audits. Such information shall be kept confidential as required by section 206(1)(j) of the Public Health Law; and

(9) the hospital shall provide the Department with the names and contact information for an HIV administrative designee(s) and a hospital appointed HIV medical designee(s):
(i) annually;
(ii) within ninety (90) days of any request from the testing laboratory; and
(iii) within thirty (30) days of a change of designee.

Section 69-1.4 Responsibilities of the birth attendant. Whenever a newborn is born outside of a hospital, the birth attendant shall be responsible for the collection of a satisfactory specimen and shall ensure compliance with the following procedures:

(a) The birth attendant shall inform the parent(s) of each newborn, of the purpose and need for newborn screening, and shall provide newborn screening educational materials made available by the Department.

(b) Specimen collection forms shall be properly stored in a cool and dry environment prior to use.

(c) The birth attendant shall collect a satisfactory specimen from every newborn between twenty-four (24) and thirty-six (36) hours after birth, and shall submit the satisfactory specimen to the testing laboratory within twenty-four (24) hours of collection, except under the following circumstances:

(1) If a newborn is transferred to a hospital before twenty-four (24) hours of age, the birth attendant shall collect an initial satisfactory specimen from the newborn prior to transfer, submit the satisfactory specimen to the testing laboratory, and provide written and/or electronic notification to the receiving hospital that a specimen was collected. The receiving hospital shall collect a repeat specimen from the newborn between forty-eight (48) and seventy-two (72) hours after birth.

(d) All specimens shall be air dried thoroughly on a flat nonabsorbent surface for a minimum of three (3) hours prior to forwarding to the testing laboratory. All specimens, including repeat specimens, shall be forwarded to the testing laboratory within twenty-four (24) hours of collection using the testing laboratory's delivery service or an equivalent arrangement designed to ensure delivery of specimens to the testing laboratory no later than forty-eight (48) hours after collection.

(e) (1) When notified by the testing laboratory that a repeat specimen is required, the birth attendant shall notify the parent(s) and responsible provider within one (1) business day that a repeat specimen is required from the newborn. The birth attendant shall collect the repeat specimen, pursuant to guidance issued by the testing laboratory, and submit it to the testing laboratory as soon as practicable.

(2) If the responsible provider documented on the initial specimen collection form is no longer responsible for the newborn's care, the birth attendant shall identify a new provider, notify the new provider of the need for a repeat specimen, and submit the contact information for the new provider to the testing laboratory.

(3) If the birth attendant is unable to obtain a repeat specimen, the birth attendant shall submit written and/or electronic documentation to the testing laboratory describing the steps by the birth attendant to notify the parent(s) and responsible provider that a repeat specimen(s) was required. The birth attendant shall submit this documentation to the testing laboratory no later than ninety (90) days after receiving notification from testing laboratory that a repeat specimen was required.

(f) If a satisfactory specimen or a repeat specimen is not collected due to newborn mortality, the birth attendant shall submit a written and/or electronic notification to the testing laboratory within five (5) days after death.

(g) The birth attendant shall submit all information required by the testing laboratory using an electronic format determined by the Department, provided that:

(1) specimen collection forms shall be submitted as directed by the testing laboratory; and

(2) the birth attendant may request an exemption from electronic submission by demonstrating, to the Department's satisfaction, that the requirement imposes an undue burden.

(h) The birth attendant shall document on the newborn's health record the LAB I.D., as it appears on the specimen collection form, the date and time of specimen collection, and all screening results.

(i) The birth attendant shall document the LAB I.D., as it appears on the specimen collection form, on any discharge summary, and shall transmit a copy of screening results or a copy of the discharge summary to the responsible provider.

(j) Before performing any tasks relating to collection of specimens, the birth attendant, and any staff under the birth attendant's supervision performing specimen collection, shall complete comprehensive specimen collection training, and shall complete such training annually thereafter. The birth attendant shall retain documentation of all such training.

(k) The birth attendant shall establish written policies and procedures, which shall be available for the Department's review, for:

(1) the collection, storage, and shipping of specimens; and

(2) the tracking and disposition of test results.

(l) The birth attendant shall comply with the following additional requirements for HIV testing:

(1) the birth attendant shall obtain written documentation of any HIV testing and treatment during the current pregnancy and include such documentation in the mother's health record. The birth attendant shall counsel the mother consistent with such testing;

(2) the birth attendant shall maintain in the newborn's health record the newborn's HIV test result in accordance with Article 27-F of the Public Health Law;

(3) the birth attendant shall transmit a copy of the newborn's HIV test result to the responsible provider. For any HIV exposed newborn, the birth attendant shall coordinate with the responsible provider to arrange appointments for follow up care with a provider experienced in the treatment of HIV; and

(4) the birth attendant shall collect and provide authorized Department staff with such data as the Department may require for program evaluation and, in the case of HIV exposed newborns, for patient follow-up.

69-1.5 Duties of the responsible provider. The responsible provider shall obtain initial screening results within fourteen (14) days of birth and shall ensure compliance with the following procedures:

(a) When notified by the testing laboratory that a repeat specimen is required, the responsible provider shall notify the parent(s) within one (1) business day that a repeat specimen is required from the newborn. The responsible provider, or his or her designee, shall collect the repeat specimen, pursuant to guidance issued by the testing laboratory, and submit it to the testing laboratory as soon as practicable.

(b) Specimen collection forms shall be properly stored in a cool and dry environment prior to use.

(c) All specimens shall be air dried thoroughly on a flat nonabsorbent surface for a minimum of three (3) hours prior to forwarding to the testing laboratory. All specimens shall be forwarded to the testing laboratory within twenty-four (24) hours of collection to ensure delivery of specimens to the testing laboratory no later than forty-eight (48) hours after collection.

(d) If a satisfactory specimen or repeat specimen is not collected due to newborn mortality, the responsible provider shall submit a written and/or electronic notification to the testing laboratory within five (5) days after death.

(e) The responsible provider shall document on the newborn's health record the LAB I.D., as it appears on the specimen collection form, the date and time of specimen collection, and all screening results. The responsible provider shall inform parents of the newborn screening result.

(f) Except when a newborn is under the care of a specialty care center, the responsible provider shall report diagnostic evaluation and test results, case management information, and follow-up

reviews to the testing laboratory no later than ninety (90) days following receipt of testing laboratory test results. The responsible provider shall arrange for a diagnostic evaluation and case management with an approved specialty care center as necessary.

(g) Before performing any tasks relating to collection of specimens, the responsible provider, and any staff under his or her supervision performing specimen collection, shall complete comprehensive specimen collection training, and shall complete such training annually thereafter. The responsible provider shall retain documentation of all such training.

(h) The responsible provider shall establish written policies and procedures, which shall be available for the Department's review, for:

(1) the collection, storage, and shipping of specimens; and

(2) the tracking and disposition of test results.

(i) The responsible provider shall comply with the following additional requirements for all newborns who test positive for HIV antibodies:

(1) the responsible provider shall arrange for follow-up care with a provider experienced in the treatment of HIV. The responsible provider shall also submit to the Department any specimen necessary to confirm the HIV infection status of the newborn; or submit documentation of confirmatory test results from a laboratory permitted pursuant to section 574 of the Public Health

Law;

(2) the responsible provider shall provide or arrange for post-test counseling for the birth mother or person authorized by law to give consent to health care for the newborn if the mother lacks capacity to consent;

(3) the responsible provider shall provide, or refer the newborn for, appropriate and/or specialized health care, case management and other social services as needed;

(4) the responsible provider shall provide the parent(s) with referrals for health and social services as needed and shall transfer a copy of the newborn's HIV test result to the mother's physician as permitted by Article 27-F of the Public Health Law; and

(5) the responsible provider shall maintain in the newborn’s health record the newborn’s HIV test result in accordance with Article 27-F of the Public Health Law.

69-1.6 Responsibilities of the public health officer. Public health officers shall ensure collection of a satisfactory specimen when directed by the testing laboratory and shall ensure compliance with the following procedures:

(a) The public health officer shall inform the newborn's parent(s) of the purpose and need for newborn screening, and shall provide newborn screening educational materials made available by the Department.

(b) Specimen collection forms shall be properly stored in a cool and dry environment prior to use.

(c) All specimens shall be air dried thoroughly on a flat nonabsorbent surface for a minimum of three (3) hours prior to forwarding to the testing laboratory. All specimens shall be forwarded to the testing laboratory within twenty-four (24) hours of collection to ensure delivery of specimens to the testing laboratory no later than forty-eight (48) hours after collection.

(d) If a satisfactory specimen or a repeat specimen is not collected due to newborn mortality, the public health officer shall submit a written and/or electronic notification to the testing laboratory within five (5) days after death.

(e) The public health officer shall submit all information required by the testing laboratory using an electronic format determined by the Department, provided that:

(1) specimen collection forms shall be submitted as directed by the testing laboratory; and

(2) the public health officer may request an exemption from electronic submission by demonstrating, to the Department's satisfaction, that the requirement imposes an undue burden.

(f) If the public health officer is unable to obtain a repeat specimen, the public health officer shall submit written and/or electronic documentation to the testing laboratory describing the steps taken by the public health officer to notify the parent(s) and responsible provider that a repeat specimen(s) was required. The public health officer shall submit this documentation to

the testing laboratory no later than ninety (90) days after receiving notification from the testing laboratory that a repeat specimen was required.

(g) Before performing any tasks relating to collection of specimens, the public health officer, and any staff under his or her supervision performing specimen collection, shall complete comprehensive specimen collection training, and shall complete such training annually thereafter. The public health officer shall retain documentation of all such training.

(h) The public health officer shall establish written policies and procedures, which shall be available for the Department's review, for:

(1) the collection, storage, and shipping of specimens; and

(2) the tracking and disposition of test results.

Section 69-1.7 - Responsibilities of the specialty care center director. The specialty care center director shall be responsible for submitting to the testing laboratory, within the time frame for each condition as directed by the testing laboratory, the diagnostic evaluation, test results and treatment plan for each newborn referred to the specialty care center based on the newborn screening panel results. The specialty care center director shall ensure compliance with the following procedures:

(a) The specialty care center shall provide education, identify resources and any additional assistance to the newborn's parent(s).

(b) The specialty care center shall provide consultation and assistance to hospitals, responsible providers, the testing laboratory and other health care providers upon request.

(c) The specialty care center shall provide initial and subsequent case information, case management, treatment plan, specimens and other information for tracking and follow-up reviews to the testing laboratory, when requested.

(d) The specialty care center shall submit written and/or electronic notification to the testing laboratory thirty (30) days prior to the effective date of appointment of a new Director or change in the location of the specialty care center. Such information shall be provided on a form prescribed by the Department.

(e) The specialty care center shall provide the testing laboratory with the names and contact information for all personnel, annually, and within ninety (90) days of any request from the testing laboratory for such information. Such information shall be provided on a form prescribed by the Department.

69-1.8 Follow-up review, tracking and educational activities. The testing laboratory may:

(a) request case follow-up information from hospitals, birth attendants, responsible providers and specialty care centers;

(b) record diagnoses and case follow-up information;

(c) maintain tracking records on identified cases; and

(d) provide educational activities and materials.

69-1.9 Inapplicability of this Subpart. The testing requirements of this Subpart shall not apply if the chief executive officer of a hospital providing care to the newborn or the newborn's birth attendant determines that the newborn's parent(s) hold genuine and sincere religious beliefs contrary to the testing required by this Subpart, and the parent(s) have provided satisfactory written documentation of such religious beliefs. In such instances, within five (5) days of a newborn's birth the chief executive officer or birth attendant shall submit such documentation to the testing laboratory, along with an attestation that the parent(s) received education regarding the benefits of newborn screening.

Regulatory Impact Statement

Statutory Authority:

Public Health Law (PHL) section 2500-a requires institutions caring for infants 28 days of age or less to have newborns tested for phenylketonuria, branched-chain ketonuria, homocystinuria, galactosemia, homozygous sickle cell disease, hypothyroidism, and other diseases and conditions designated by the Commissioner of Health in regulation. Since initial enactment of this statute, 44 genetic/congenital conditions and one infectious disease have been added to the newborn testing panel. The proposed amendments are designed to improve the timely diagnosis and treatment of these conditions.

Legislative Objectives:

PHL section 2500-a was enacted in 1965 with the legislative objective of promoting public health by mandating that every newborn in New York State receives screening to detect harmful or potentially fatal conditions not otherwise apparent at birth. Today, newborn screening (NBS) is nationally recognized as an important public health tool used to successfully screen newborns for these conditions. NBS allows these babies to be identified and treated before they get sick, preventing serious health problems or even death. These amendments further the legislative objective of identifying and treating affected newborns by ensuring that regulated parties will properly prepare, collect and deliver samples to the testing laboratory at the New York State Department of Health's Wadsworth Center.

Needs and Benefits:

Every year over 250,000 newborn children in New York State receive a newborn screen. Most newborns will screen negative; however, without early detection the small number of newborns who screen positive may suffer serious and irreversible damage. Annually, the Wadsworth Center reports more than 12 million newborn screening results to hospitals of birth and supervising physicians.

Blood specimens are collected by pricking the newborn infant's heel and applying the blood onto a numbered, standardized filter paper that is attached to a form where demographic and specimen information is also provided. Specimens are dried and shipped to the Wadsworth Center, where metabolic, endocrine, and genetic screening is conducted. Timely collection, transport and screening of all specimens and timely reporting of positive screening test results are critical.

In 2015, the United States Department of Health and Human Services' (HHS) Advisory Committee on Heritable Disorders in Newborns and Children (the Committee) recommended certain time frames for newborn screening. Additionally, in December 2016, a Report to Congressional Committees by the United States Government Accountability Office found that most states that reported timeliness data had not screened newborns within the recommended time frames for detecting conditions that may require treatment. The Committee concluded that the best outcomes for newborn infants and their families will be achieved when state NBS programs, birthing facilities, and hospitals adopt recommended policies designed to improve the timely diagnosis and treatment of screened conditions. More specifically, the Committee recommended that initial NBS specimens should be collected no later than 48 hours after birth,

and that NBS specimens should be received at the testing laboratory within 24 hours of collection. These timelines will serve to avoid associated disability, morbidity and mortality.

In 2015, the Wadsworth Center processed 265,537 specimens collected from 237,501 infants. Of those specimens collected, 58% were collected within 48 hours after birth, 36% of collected specimens arrived within 24 hours of collection. After considerable educational effort by the Department, the number of submissions within 48 hours has improved significantly but remains at 88% (March 2018). Because more than 28,000 specimens are received outside of the optimal timeframe, further efforts are necessary. These data support the proposed amendments that would update requirements specific to timeframes for collection and transport and the proposed amendments would be consistent with recommendations made by the Committee.

One of the greatest challenges to NBS programs is obtaining a repeat specimen from a child when the initial screen is abnormal, borderline, or inadequate. In 2015, the Wadsworth Center identified 7% of specimens as presumed positive and 3,009 infants were referred for confirmatory testing and diagnosis. Timely action taken by providers to obtain repeat specimens will improve health outcomes for presumed positive babies. The proposed amendments will specify requirements for obtaining repeat specimens, including but not limited to, requiring providers to give notice to parents and responsible providers within one business day that a repeat specimen is required, and submitting written and/or electronic documentation to the testing laboratory describing the steps taken by the provider to notify the parents and responsible provider that a repeat specimen(s) was required.

Costs

Costs to Regulated Parties:

The majority of the proposed amendments clarify existing requirements and are not expected to increase costs for regulated parties. This includes the revision and reordering of provisions and definitions; removal of outdated acronyms from the list of diseases; addition of streamlined directions for completing the blood specimen collection form; a requirement to submit legible and complete forms; additional detail related to specimen collection protocols; detailed instructions on the storage and handling of specimen collection forms; revised guidance for drying time post specimen collection; establishment of uniform reporting duties and timeframes; revisions on the timing of specimen collection when there is an early discharge or transfer of an infant; and inclusion of revised language providing a religious exemption from newborn screening that mirrors the more current and practical New York immunization program exemption model.

The proposed amendment also includes new requirements for regulated parties. These include revised time frames indicating that a specimen shall be collected from every infant between twenty-four (24) and thirty-six (36) hours after birth and submitted to the testing laboratory within twenty-four (24) hours of collection; requirements related to the reporting of infant mortality; establishment of policies and procedures for the collection, storage and shipping of specimens and the tracking and disposition of results; requirements that employees performing specimen collection must complete comprehensive specimen collection training prior to performing any specimen collection tasks and on an annual basis after the initial training; requirements for obtaining specimens for repeat testing; and requirements that the Chief Executive Officer of a hospital identify hospital-appointed administrative and medical

designee(s) who will be tasked with serving as program liaison, receiving and acting on newborn screening results and ensuring the testing laboratory receives current contact information for the hospital appointee designee(s). It is anticipated that regulated parties affected by these new requirements would incur minimal costs limited to human resource hours as a result of adoption of these new requirements.

Costs for Implementation and Administration of the Rule:

Costs to State Government and the New York State Department of Health

The cost of the NBS program, including shipping costs for transporting specimens from the birthing hospital, is already fully borne by New York State, unlike most other states where facilities assume the costs. Neither providers nor parents are charged for this service. The NBS program had not previously covered costs for the shipping of specimens submitted by midwives. Steps are being taken to allow midwives to use the Wadsworth Center's submission system to facilitate timely delivery of samples and to ensure that midwives will be able to meet new requirements for timely submission. These additional costs to the NBS program are anticipated to be minimal and will result in more timely delivery of samples.

Costs to Local Government:

Hospitals and birthing centers operated by local governments will not incur additional costs related to collection and submission of blood specimens to the NBS program, since the number of specimens collected and mailed to the NBS program will not change. However, such facilities will incur minimal costs related to enhanced follow up activities and training requirements. Local public health officers already play an integral role in reporting infant mortality and

supporting specimen collection efforts. The proposed amendments simply define and clarify these ongoing practices.

Local Government Mandates:

Language has been added to outline the protocols for handling and storing specimen collection forms and specimen collection. New administrative requirements include an obligation to report infant mortality, have policies and procedures in place, complete comprehensive training and document activities undertaken in notifying parents when additional specimen are needed.

Paperwork:

The paperwork that needs to be submitted by regulated parties will not change significantly as a consequence of the proposed amendments. Submission of specimen collection forms is not a new requirement; however, the proposed regulation includes additional directions for completing specimen collection forms and mandates the submission of complete and legible forms. In addition, regulated parties will experience a minimal increase in paperwork related to improved documentation and follow-up activities. Specifically, additional paperwork may be required related to documentation of: the steps taken to notify parents and responsible providers of the need for repeat specimens; the referral of newborns with abnormal screening results; parents who opt out of screening based on religious beliefs; and specimen collection training.

Duplication:

These rules do not duplicate any other law, rule or regulation.

Alternative Approaches:

An alternative to the proposed amendments would be to keep the current regulations. However, this approach would be insufficient because there is significant evidence that early detection and intervention drastically improves affected infants' survival chances as well as the infants' quality of life. The proposed amendments to Subpart 69-1 are necessary to adopt and implement the standards established by the federal Department of Health and Human Services' (DHHS) Advisory Committee on Heritable Disorders in Newborns and Children. In addition, the proposed changes will support the NBS Program's initiatives to improve timeliness. Therefore, the Department rejected this alternative.

Federal Standards:

As discussed above, the HHS Advisory Committee on Heritable Disorders in Newborns and Children Committee recently conducted a comprehensive review of state policies and practices relating to timeliness in newborn screening across the nation. In collaboration with state programs, review of independent research, public comments, deliberation and findings, the Committee identified the following goals directly related to improving timeliness:

- Presumptive positive results for time-critical conditions should be communicated immediately to the newborn's healthcare provider and no later than five days of life.
- Presumptive positive results for all other conditions should be communicated to the newborn's healthcare provider as soon as possible but no later than seven days of life.
- All NBS tests should be completed within seven days of life with results reported to the healthcare provider as soon as possible.

Importantly, the Committee stated the best health outcomes for newborns and their families will be achieved when state NBS programs, birthing facilities and hospitals adopt and implement

recommended policy revisions which meet the goals of timely diagnosis, as well as treatment of screened conditions. The Committee further concluded the following timelines, when achieved by NBS systems, will serve to reduce associated disability, morbidity and mortality:

- Initial NBS specimens should be collected in the appropriate time frame for specific conditions but no later than 48 hours after birth, and
- NBS specimens should be received at the testing laboratory as soon as possible; optimally within 24 hours of collection.

Additionally, a December 2016 Report to Congressional Committees by the United States Government Accountability Office reported that most states that reported timeliness data had not screened newborns within recommended goals to detect conditions that may require treatment. Amendments to Subpart 69-1 reflect the recommendations of the HHS Advisory Committee on Heritable Disorders in Newborns and Children Committee and will include additional amendments to revise and reorder several provisions.

Compliance Schedule:

This regulation will be effective upon publication of the Notice of Adoption in the State Register. The infrastructure and mechanisms to support the newborn screening program are established and operational statewide. Consequently, regulated parties should be able to comply with the proposed regulation as of its effective date.

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Regulatory Flexibility Analysis for Small Business and Local Governments

Effect on Small Businesses and Local Governments:

These proposed amendments will improve the effectiveness of the NBS program by revising timelines for specimen collection and submission, and by clarifying the role of health care providers and their responsibilities to the newborn, the newborn's parent or guardian, and the testing laboratory. It is anticipated that regulated parties operating as a small business and local governments will incur minimal additional costs related to meeting the revised timeframes, notifying parents, and securing specimens.

The State Education Department of New York reports that approximately 95,000 physicians and 1,000 midwives are currently licensed in the State, some of whom, specifically those in private practice, operate as small businesses. The Department does not have data concerning the number of these medical professionals that are operating small businesses and deliver infants. The Department estimates that three hospitals and one birthing center in the State meet the definition of a small business. Improvements in timeliness of specimen collection and submission will serve to avoid potentially deadly delays in diagnosis and health intervention and will not place economic or regulatory burden on affected small parties.

Compliance Requirements:

The majority of the proposed amendments provide additional details and clarify existing requirements which are not expected to increase costs for regulated parties. This includes the revision and reordering of provisions and definitions; removal of outdated acronyms from the list of diseases; addition of streamlined directions for completing the blood specimen collection

form; a requirement to submit legible and complete forms; additional detail related to specimen collection protocols; detailed instructions on the storage and handling of specimen collection forms; revised guidance for drying time post specimen collection; establishment of uniform reporting duties and timeframes; revisions on the timing of specimen collection when there is an early discharge or transfer of an infant; and inclusion of revised language providing a religious exemption from newborn screening that mirrors the more current and practical New York immunization program exemption model.

The proposed amendment also includes new requirements for regulated parties. These include revised time frames indicating that a specimen shall be collected from every infant between twenty-four (24) and thirty-six (36) hours after birth and submitted to the testing laboratory within twenty-four (24) hours of collection; requirements related to the reporting of infant mortality; establishment of policies and procedures for the collection, storage and shipping of specimens and the tracking and disposition of results; requirements that employees performing specimen collection must complete comprehensive specimen collection training prior to performing any specimen collection tasks and on an annual basis after the initial training; requirements for obtaining specimens for repeat testing; and requirements that the Chief Executive Officer of a hospital identify a hospital appointed administrative and medical designee(s) who will be tasked with serving as program liaison, receiving and acting on newborn screening results and ensuring the testing laboratory receives current contact information for the hospital appointee designee(s). It is anticipated that regulated parties affected by these new requirements would incur minimal costs limited to human resource hours as a result of adoption of these new requirements.

Professional Services:

No need for additional professional services is anticipated. Professional staff of regulated parties affected by the proposed regulation can implement the revised timelines, enhanced follow-up activities and training requirements.

Compliance Costs:

Hospitals, birthing centers, and physician and midwifery practices operating as small businesses will not incur additional costs related to collection and submission of blood specimens to the NBS program, since the number of specimens collected and mailed to the NBS program will not change. However, such facilities, and, to a lesser extent, at-home birth attendants, will incur minimal costs related to enhanced follow up activities and training requirements.

Economic and Technological Feasibility:

The proposed regulation would present no economic or technological difficulties to any small businesses and local governments affected. The infrastructure for specimen collection and referrals of affected infants are already in place.

Minimizing Adverse Impact:

The revised timeline for collection of specimens will not impose a unique burden on hospitals, birthing centers, and physician and midwifery practices operating as small businesses.

Small Business and Local Government Participation:

Small businesses and local governments will have the opportunity to participate in the rulemaking process by submitting comments during the public comment period following the

publication of the Notice of Proposed Rulemaking. In addition, the Department of Health will be holding webinars to help regulated parties better understand the new regulations.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010 (http://quickfacts.census.gov). Approximately 17% of small health care facilities are located in rural areas.

Allegany County	Greene County	Schoharie County
Cattaraugus County	Hamilton County	Schuyler County
Cayuga County	Herkimer County	Seneca County
Chautauqua County	Jefferson County	St. Lawrence County
Chemung County	Lewis County	Steuben County
Chenango County	Livingston County	Sullivan County
Clinton County	Madison County	Tioga County
Columbia County	Montgomery County	Tompkins County
Cortland County	Ontario County	Ulster County
Delaware County	Orleans County	Warren County
Essex County	Oswego County	Washington County
Franklin County	Otsego County	Wayne County
Fulton County	Putnam County	Wyoming County
Genesee County	Rensselaer County	Yates County
	Schenectady County	

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2010.

Albany County	Monroe County	Orange County
Broome County	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	

Reporting, Recordkeeping, Other Compliance Requirements and Professional Services:

The Department expects that hospitals, birthing centers, and physician and midwifery practices in rural areas will not experience significant regulatory burdens in complying with the amendment's requirements, as functions related to mandatory newborn screening are already embedded in established policies and practices of affected institutions and individuals. Activities related to collection and submission of blood specimens and communication among parents and providers will not change, however the timing in which those activities are conducted is affected. It is anticipated that there will be some increased burden for completing specimen collection training, reporting of infant mortality, conducting additional follow up activities and meeting new timelines. However, this will affect facilities in rural communities no differently than elsewhere in the state.

Compliance Costs:

The majority of the proposed amendments provide additional details and clarify existing requirements which are not expected to increase costs for regulated parties. This includes the revision and reordering of provisions and definitions; removal of outdated acronyms from the list of diseases; addition of streamlined directions for completing the blood specimen collection form; a requirement to submit legible and complete forms; additional detail related to specimen collection protocols; detailed instructions on the storage and handling of specimen collection forms; revised guidance for drying time post specimen collection; establishment of uniform reporting duties and timeframes; revisions on the timing of specimen collection when there is an early discharge or transfer of an infant; and inclusion of revised language providing a religious exemption from newborn screening that mirrors the more current and practical New York immunization program exemption model.

The proposed amendment also includes new requirements for regulated parties. These include revised time frames indicating that a specimen shall be collected from every infant between twenty-four (24) and thirty-six (36) hours after birth and submitted to the testing laboratory within twenty-four (24) hours of collection; requirements related to the reporting of infant mortality; establishment of policies and procedures for the collection, storage and shipping of specimens and the tracking and disposition of results; requirements that employees performing specimen collection must complete comprehensive specimen collection training prior to performing any specimen collection tasks and on an annual basis after the initial training; requirements for obtaining specimens for repeat testing; and requirements that the Chief Executive Officer of a hospital identify hospital-appointed administrative and medical designee(s) who will be tasked with serving as program liaison, receiving and acting on newborn screening results and ensuring the testing laboratory receives current contact information for the hospital appointee designee(s). It is anticipated that regulated parties affected by these new requirements would incur minimal costs limited to human resource hours as a result of adoption of these new requirements.

Minimizing Adverse Impact:

The revised timeline for collection of specimens will not impose a unique burden on hospitals, birthing centers, and physician and midwifery practices located in rural areas.

Rural Area Participation:

Public and private interests in rural areas will have the opportunity to participate in the rulemaking process by submitting comments during the public comment period following the

publication of the Notice of Proposed Rulemaking. In addition, the Department of Health will be holding webinars to help regulated parties better understand the new regulations.

Statement in Lieu of Job Impact Statement

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and employment opportunities is expected as a result of this proposed regulation.