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# **Newborn Screening Webinar Series: Babies in the NICU**

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**September 19, 2019**

# New Regulation: SACHDNC Recommendations

- Recommendations from the Department of Health and Human Services' (DHHS) Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC)
  - “Initial 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.”
- New York State Department of Health (NYSDOH) endorses these recommendations, although the new regulation is actually more stringent (collection at < 36 hours).



# New Regulation: It's Here!

- “Newborn Screening for Phenylketonuria and Other Diseases,” Subpart 69-1 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations went into effect on **February 13, 2019**



# New Regulation: Where to Find It



Services News Government Local

New York Codes, Rules  
and Regulations

Home Title 10 Title 18 Laws & Regulations

Home / VOLUME A-1a (Title 10) / SubChapter H - Maternal and Child Health  
/ Part 69 - Testing for Phenylketonuria and Other Diseases and Conditions/Early Intervention Program/Newborn Hearing Screening  
/ Title: SubPart 69-1 - Newborn Screening for Phenylketonuria and Other Diseases

## Title: SubPart 69-1 - Newborn Screening for Phenylketonuria and Other Diseases

Printer-friendly version

Outline

Up

### Effective Date

02/13/2019

### SubPart 69-1 - Newborn Screening for Phenylketonuria and Other Diseases

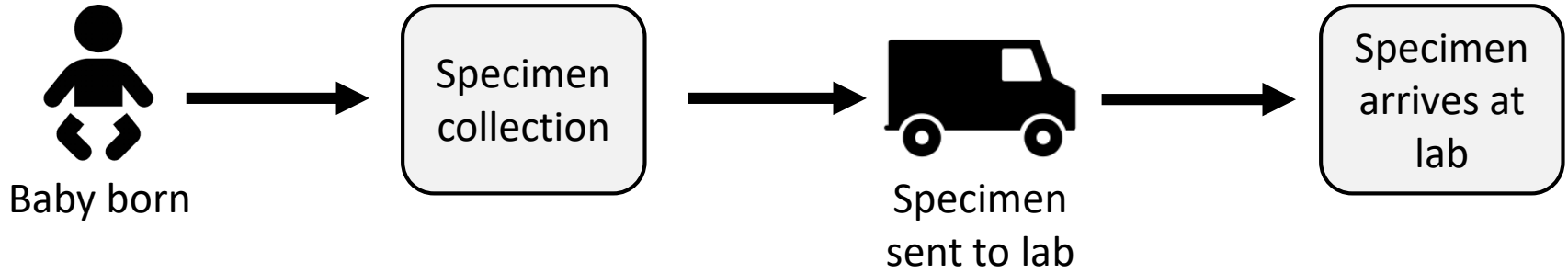
- Section 69-1.1 - Definitions
- Section 69-1.2 - Diseases screened
- Section 69-1.3 - Responsibilities of the CEO of a Hospital
- Section 69-1.4 - Responsibilities of the birth attendant
- Section 69-1.5 - Duties of the responsible provider
- Section 69-1.6 - Responsibilities of the public health officer
- Section 69-1.7 - Responsibilities of the specialty care center director
- Section 69-1.8 - Follow-up review, tracking and educational activities
- Section 69-1.9 - Inapplicability of this Subpart

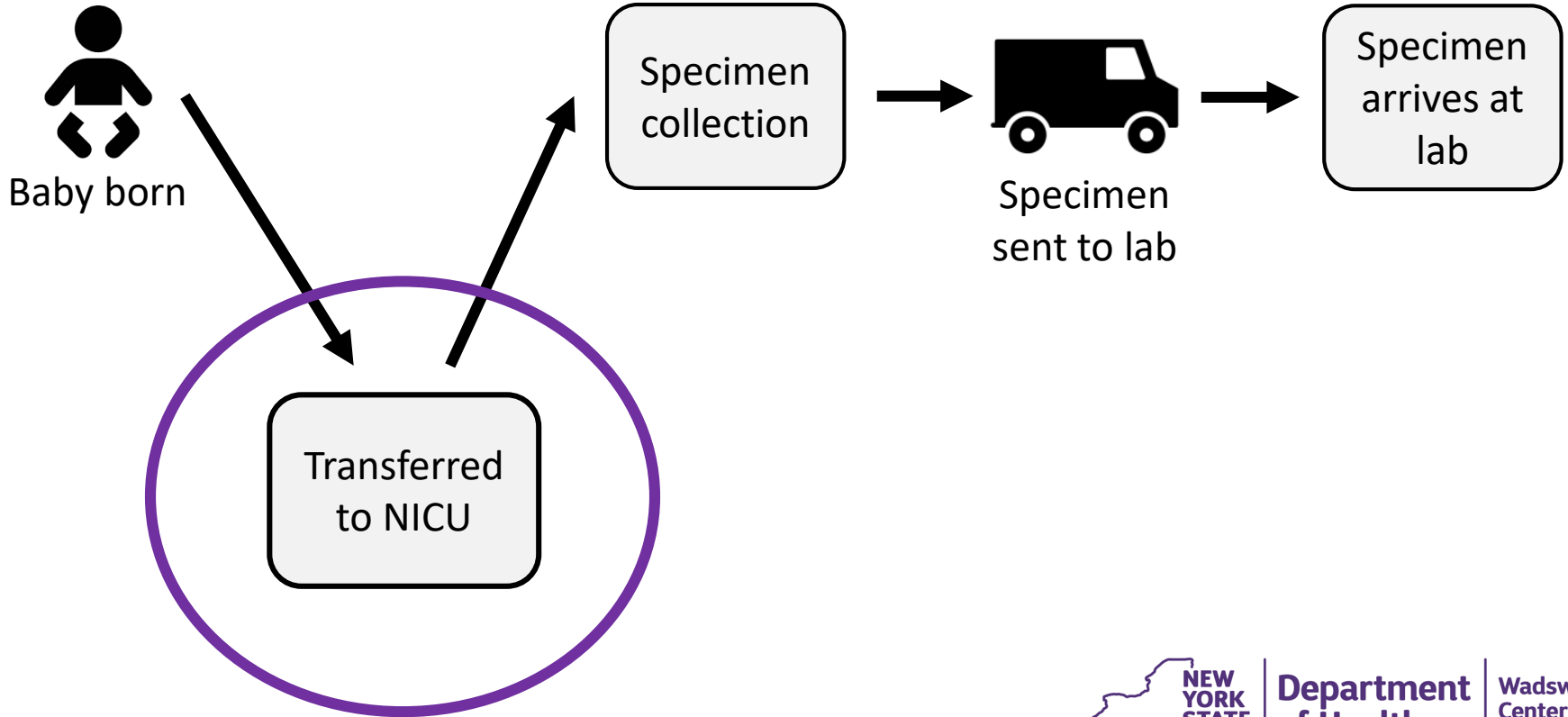
<https://regs.health.ny.gov/volume-1a-title-10/1384929965/subpart-69-1-newborn-screening-phenylketonuria-and-other-diseases>



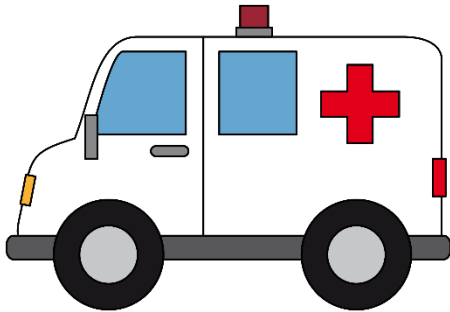
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# Transfer to Another Hospital



- If a newborn is transferred to another hospital, the birth hospital should collect initial screen and notify receiving hospital that specimen was collected
- Receiving hospital is responsible for collecting any repeat screens needed
- Receiving hospital should follow recommended procedure for NICU admissions

# NICU Admission

- If newborn requires admission to NICU prior to collection of initial screen, specimen should be collected at admission prior to interventions (blood transfusion/TPN)
- Repeat screen at 48-72 hours after birth
- Third screen done at discharge or at 28 days after birth (whichever comes first)





# NICU Admission

- If newborn requires admission to NICU prior to collection of initial screen, specimen should be collected at admission
- Repeat screen at 48-72 hours after birth
- Third screen done at discharge or at 28 days after birth (whichever comes first)
- **Please check the 'Repeat Specimen' box on the filter paper when submitting these and fill out the prior lab ID field!**



No change from the guidelines on specimen collection for premature and/or sick infants, approved by the Clinical and Laboratory Standards Institute (CLSI; ILA31-A), which is posted on our website.

<https://www.wadsworth.org/programs/newborn/screening/providers/specimen-collection>



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**Specimen Collection**

Home > Public Health Programs > Newborn Screening and Bloodspot > Newborn Screening Program > Information for Healthcare Providers > Specimen Collection

Newborn screening is the practice of testing or greatly improving the life of newborns. Newborn screening is necessary to New York State's Public Health Goals (2012-16), NY State's Strategic Plan (2014-18) and the state's commitment to its citizens.

There are several circumstances where newborn screening is required:

1. When the parent or guardian of the infant is a member of a recognized religious organization whose beliefs are contrary to the testing requirement, or who may choose to opt out of testing of their child. The parent or guardian indicates in writing (signed and witnessed) their refusal to participate in the newborn screening program.
  - Fully informed consent is required from the parent or guardian.
  - The parent or guardian must be given the opportunity to discuss the consequences of refusal.
  - The parent or guardian must be given the opportunity to discuss the consequences of a signed refusal of newborn screening for religious reasons in a written document.
    - "Refusal to be tested" is not an endorsement and testing should be carried out as a member of a recognized religious organization and has been fully informed of the benefits of screening as well as the possible consequences of not having the newborn tested.
    - Subsequent Newborn Screening Medical Collectors Form with complete demographic information, but without the blood sample for the screening program.
    - "Refusal to be tested" should be written across the top, the parent's copy should be retained by the hospital, and the child's copy given to the parent.
2. If a newborn is severely compromised (concurrently) and only, and is not expected to survive, screening may be declined by the parent or guardian. In these circumstances, the attending physician must use a Newborn Screening Medical Collectors Form with complete demographic information, but without a blood sample. This is to be accompanied by written documentation of the reasons for non-participation and any medical considerations of screening. It should be required for the parent or guardian that written such a case. It may be returned to the newborn screening program, screening results may shed light on the cause of the newborn's medical condition and the remaining blood sample should be stored, pending the opportunity for future testing if the appropriate services receive.

**Resources**

The following educational materials are available for state and local public health practitioners. Collection of a specimen suitable for testing is a pre-requisite for successful early detection.

- The New York State Newborn Screening Program has produced a video that provides proper specimen collection techniques (DVD available upon request).



- The public "Single Spot Check" facilitates sampling of an available specimen of the possible causes (available upon request).
- Instructions for specimen collection can also be found on the back of the specimen collection form.



**Specimen Collection Table** (updated July 2019)

- Blood Collection Cards
- Completing the Blood Collection Form
- Timing of Specimen Collection
- Responsibility for Specimen Collection
- **Special Circumstances Surrounding Specimen Collection**

**Information for Healthcare Providers**

Director of Laboratory Testing

Specimen Collection

Obtaining Results

Follow-up Process

Form

Request Newborn Screening Materials

Residual Blood Spot Usage

Prepayment/Refund Conditions

Hospital Contacts and Designation

Notes for Hospital

**Contact Us**

**Newborn Screening Program**  
 112 Park Boulevard  
 Albany, NY 12242  
 United States  
 New York: 518-473-7833  
 Fax: 518-473-7228  
[screen@health.ny.gov](mailto:screen@health.ny.gov)

**• Special Circumstances Surrounding Specimen Collection**

**Premature and/or Sick Infants:** Guidelines on specimen collection for premature and/or sick infants, approved by the [Clinical and Laboratory Standards Institute](#) (CLIA31-A), recommend specimen collection upon admission to a neonatal intensive care or special baby care unit. If the specimen is collected when the infant is less than 24 hours of age, collect another specimen when the infant is 48 - 72 hours of age. A third specimen is required at discharge or 28 days of age, whichever comes first. Every effort should be made to obtain a specimen prior to transfusion and/or administration of Total Parenteral Nutrition (TPN) or other treatments which can affect screening results.

**Guidelines for Collecting Specimens for Babies in the NICU:**

- First Newborn Screening Specimen
  - Collect upon admission to the Neonatal Intensive Care Unit, if not already collected
  - Newborn will probably be less than 24 hours of age
  - Ensure specimen is collected prior to starting TPN or transfusion
- Second Newborn Screening Specimen
  - Collect at 48 to 72 hours of life
  - Collect if first specimen was collected at < 24 hours of age or if newborn weighed < 2000 grams at birth
- Third Newborn Screening Specimen
  - Collect at 28 days of life, or discharge, whichever comes first
  - Collect if newborn weighed < 2000 grams at birth

**Transfusion:** The optimum specimen collection time is when the newborn is older than 24 hours of age. However, transfusions may invalidate some screening results by masking the presence of a hemoglobinopathy or galactosemia. If the infant is to receive a transfusion, every effort must be made to collect a specimen prior to transfusion. Infants receiving transfusions with no prior newborn screening test need two specimens collected: one at three days or more after the most recent transfusion and one at four months after the final transfusion.

**Total Parenteral Nutrition (TPN) - Hyperalimentation:** The optimum collection time is when the newborn is older than 24 hours of age. However, even small amounts of TPN may invalidate some screening results for the acylcarnitines and amino acids. If the infant is to receive TPN every effort must be made to collect a specimen prior to treatment. Infants receiving



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# NICU Interventions



- If newborn requires transfusion or TPN, the hospital should collect a NBS specimen prior to any transfusion or administration of TPN
- If specimen is not done prior to transfusion and/or TPN, the hospital should wait to collect initial screen until 72 hours after administration of transfusion and/or TPN
  - Hospital should schedule repeat specimen for no later than 120 days after final transfusion and/or TPN



# Transfusions

- If newborn screen is collected prior to RBC transfusion, was screen negative or detected a trait, no follow-up is needed
- If a specimen was NOT collected prior to RBC transfusion, the baby was NOT screened for Hemoglobinopathies, Galactosemia, or Biotinidase Deficiency
  - These babies should be monitored for clinical signs of these disorders
  - To evaluate for Hemoglobinopathies, submit a specimen 120 days after final transfusion or determine maternal trait status



# Special Care Nursery

- Some babies are admitted to Special Care Nursery for sepsis work-up, hypoglycemia or monitoring
- If these babies are not receiving TPN or transfusions, they may follow the standard newborn screen collection protocol



# Questions?

- Please email questions to [nbsinfo@health.ny.gov](mailto:nbsinfo@health.ny.gov)
- We will do our best to respond individually, and will also compile all the questions in a 'Frequently Asked Questions' document which will be posted on the NBS website.



# Upcoming Webinars



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# New Regulation: Webinar Series

- Requests for repeats: September 19, 2019 @ noon
- Process improvement: October 3, 2019 @ noon
- Referrals to specialty care centers: October 10, 2019 @ noon
- Birth attendants: October 17, 2019 @ noon

