Newborn Screening Webinar Series:
Birth Attendants

Sarah Bradley, MS, CGC
Follow-up Supervisor
New York State Newborn Screening Program

October 17, 2019
New Regulation: An Impetus for Change

“Deadly Delays” article in Milwaukee Journal Sentinel in November, 2013

New Regulation: Deadly Delays

Findings:
• Labs closed on weekends & holidays
• Delays in specimen shipping
• Little standardization between newborn screening systems
• Hospital data not made available
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

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

Effective Date
03/3/2015

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

October 17, 2019

Baby born → Specimen collection → Specimen sent to lab → Specimen arrives at lab
Recommended Timing Under New Regulation

1. Baby born Hour 0
2. Specimen collection @ 24-36 Hours
3. Specimen sent to lab within 24 hours of collection
4. Specimen arrives at lab within 48 hours of collection
Specimen Collection
Recommended Timing Under New Regulation

- Baby born Hour 0
- Specimen collection @ 24-36 Hours
- Specimen sent to lab within 24 hours of collection
- Specimen arrives at lab within 48 hours of collection
Specimen Collection: Drying Time

Specimens should be air dried on a flat, nonabsorbent surface for at least 3 hours prior to shipment.
Specimen Collection: NBS Documentation

- Specimen collection forms shall be submitted as directed by the testing laboratory:
  - Fill out ALL fields as clearly as possible
  - ‘Infant’s Last Name’ should be filled out with the newborn’s new, legal name if known at time of sample collection
Specimen Collection: NBS Documentation

• Missing, incomplete, or incorrect demographic information on the specimen collection form can delay screen results and reporting.

• Please make every effort to ensure this information is on the filter paper and correct before submitting to NBS lab.
Specimen Collection: Transfer to a Hospital

- If a newborn is transferred to a hospital, the birth attendant should collect initial screen and notify receiving hospital that specimen was collected.
- Hospital is then responsible for collecting any repeat screens needed.
Specimen Collection: Training

- Birth attendants should complete comprehensive specimen collection training prior to collecting any samples
- Training annually
- Birth attendants should retain records of training completion
- Resources available on NBS website:
  - Video
  - Specimen collection guide

https://www.wadsworth.org/programs/newborn/screening/providers/specimen-collection
Specimen Collection: Procedures

- Birth attendants should establish written policies and procedures for:
  - Specimen collection, storage, tracking and shipping
  - Tracking and disposition of results
Specimen Shipping
Recommended Timing Under New Regulation

1. Baby born (Hour 0)
2. Specimen collection @ 24-36 Hours
3. Specimen sent to lab within 24 hours of collection
4. Specimen arrives at lab within 48 hours of collection
Specimen Shipping

• All specimens should be submitted to the NBS lab within 24 hours of collection using the lab’s courier (UPS) or an equivalent service

• Specimens should arrive at the NBS lab within 48 hours of sample collection
Specimen Resulting: Documentation

- Each newborn’s NBS results should be documented in the baby’s health record

- Discharge summary containing Lab ID or copy of NBS result should be transmitted to the responsible provider
Repeat Requests
October 17, 2019

1. Baby born
2. Specimen collection
3. Specimen sent to lab
4. Specimen arrives at lab
NBS Result Available

- Screen Negative
- Repeat Required
- Positive/Referral

Lab ID in discharge summary; submitted to PCP
Reasons for Repeat Screens

• Unsuitable for testing
  • Poor quality (clotted, serum rings, insufficient quantity, etc.)
  • Collected at less than 24 hours
• Borderline result(s)
• Indeterminate
Repeat Required

Parent & PCP notified within 1 day

Repeat specimen collected

Unable to obtain repeat

Documentation of steps taken to notify parents & PCP submitted within 90 days
NBS Repeat Notifications

- Phone calls, faxes, and letters to the birth attendant
- Letters and phone calls to the pediatrician
- Letters to the parents
Birth Attendant Repeat Notifications

• Birth attendant should notify the parents and responsible provider within one business day that repeat is needed

• Birth attendant should be prepared to collect the repeat specimen
Change of Provider

• If the responsible provider documented on the initial specimen changes, the birth attendant should identify a new provider and notify NBS Program
Repeat Documentation

• If the birth attendant is unable to obtain a repeat, they should submit written and/or electronic documentation to the NBS Program
  • Describe steps taken to notify parent(s) and responsible provider
  • Documentation should be submitted within 90 days of notification that a repeat is required
New Regulation: Summary

- The NYS NBS Program has a new regulation which went into effect on February 13, 2019
- The new regulation contains changes that will affect birth attendants in the following areas:
  - Collection
  - Shipping
  - Resulting
  - Repeat requests

Questions?

• Please email questions to 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.