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Newborn Screening Webinar Series: Specimen Collection, Shipping, Tracking & Resulting

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New York State Newborn Screening Program

September 11, 2019

New Regulation: Webinar Series

- **Specimen collection, shipping, tracking and resulting**
- Babies in the NICU
- Requests for repeats
- Referrals to specialty care centers
- Birth attendants

- Process improvement



New Regulation: Webinar Series

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All webinars will be recorded and then posted on the NBS Program's website:
<https://www.wadsworth.org/programs/newborn/screening>



New Regulation: An Impetus for Change

JOURNAL SENTINEL



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

<http://www.jsonline.com/watchdog/watchdogreports/Deadly-Delays-Watchdog-Report-Delays-at-hospitals-across-the-country-undermine-newborn-screening-programs-putting-babies-at-risk-of-disability-and-death-228832111.html>

A JOURNAL SENTINEL WATCHDOG REPORT

Deadly Delays

The nation's newborn screening programs depend on speed and science to save babies from rare diseases. But thousands of hospitals fall short, deadly delays are ignored and failures are hidden from public view – while babies and their families suffer.



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New Regulation: Deadly Delays

JOURNAL SENTINEL



A JOURNAL SENTINEL WATCHDOG REPORT

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Findings:

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



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New Regulation: Federal Guidance

Recommendations from the Department of Health and Human Services' (DHHS) Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC)



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Discretionary Advisory Committee on
Heritable Disorders in Newborns and Children
5600 Fishers Lane, Room 18W68
Rockville, Maryland 20857
www.hrsa.gov/heritabledisorderscommittee

April 16, 2015

The Honorable Sylvia Mathews Burwell
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Burwell:

During the past eighteen months, the Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (Committee) has been reviewing current policies and practices relating to timeline [redacted] the United States. Prompted by a public comment during [redacted] committee determined that it

<https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/heritable-disorders/reports-recommendations/letter-to-sec-timely-newborn%20.pdf>



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New Regulation: SACHDNC Recommendations

- “To achieve the goals of timely diagnosis and treatment of screened conditions and to avoid associated disability, morbidity and mortality, the following timelines should be achieved by NBS systems for the initial newborn screening specimen:
 - Presumptive positive results for time-critical conditions should be communicated immediately to the newborns healthcare provider but 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.”



New Regulation: SACHDNC Recommendations

- “In order to achieve the above goals:
 - 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: Changes Needed

- In 2015 in New York State:
 - 83.7% of initial NBS specimens were collected within 48 hours of birth
 - New York ranked 32 out of 37 states that reported data to NewSTEPs (Newborn Screening Technical assistance and Evaluation Program)
- 28.3% of NBS specimens arrived at the NYSDOH within 24 hours of collection
- New York ranked 29 out of 36 states according to NewSTEPs data



New Regulation: Revision

- In New York State, newborn screening is mandated by Public Health Law, sections 2500-a and 2500-f.
- Due in part to the DHHS recommendations, the NYSDOH embarked on a multi-year process of revising the regulation that details how this public health law should be enacted



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**



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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>



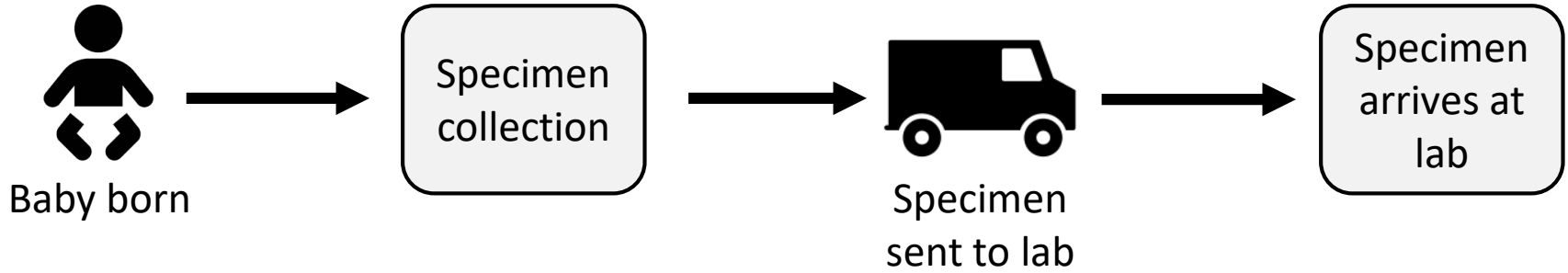
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New Regulation: Topics Covered

- Specimen collection, shipping, tracking and resulting
- Babies in the NICU
- Requests for repeats
- Referrals to specialty care centers
- Birth attendants





Recommended Timing Under New Regulation



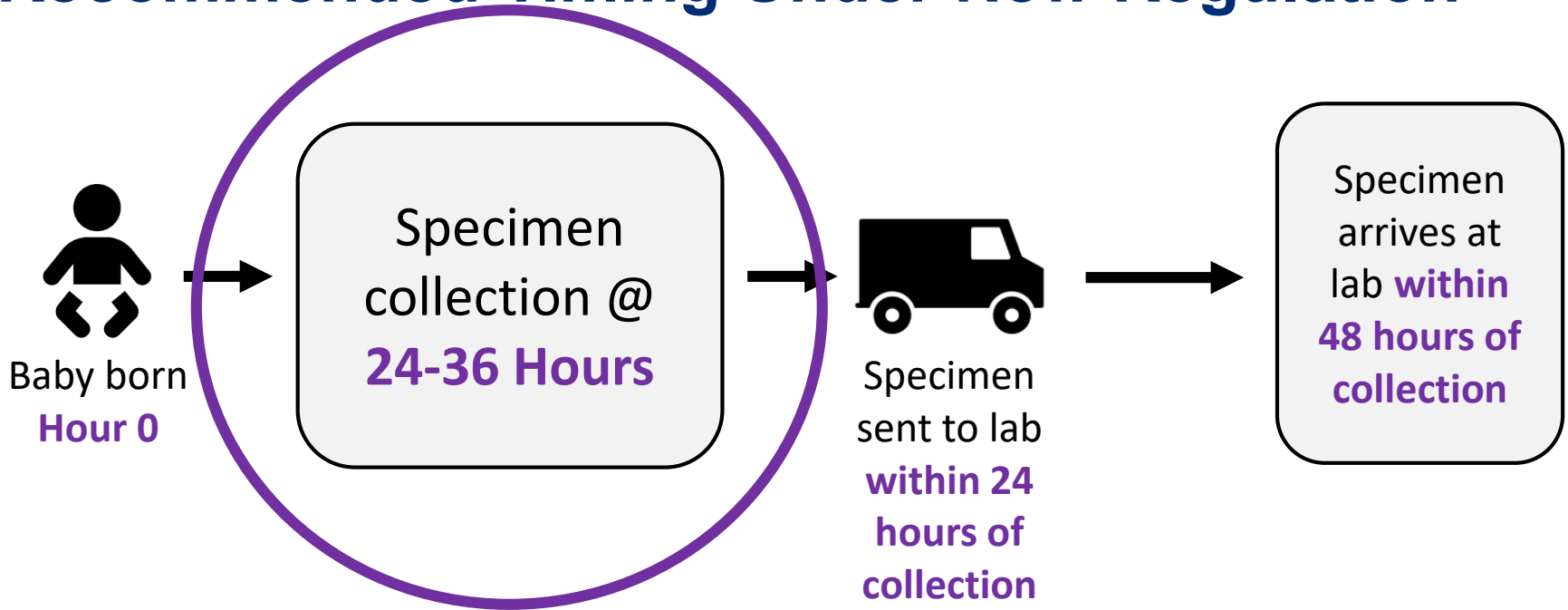
Specimen Collection



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Recommended Timing Under New Regulation



Specimen Collection: Early Discharge



- If a newborn is less than 24 hours old at the time of discharge, the hospital should collect a specimen prior to discharge
- Hospital should schedule and collect a second screen from the newborn between 48-72 hours of age



Specimen Collection: Late Admission

- If a newborn is admitted to the hospital within the first 28 days of life and no specimen was previously collected, the hospital should collect one



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

NEWBORN SCREENING BLOOD COLLECTION FORM
DO NOT USE AFTER JULY 2019

PRINT CLEARLY DO NOT WRITE IN OR COVER SHADED AREA

Infant's Last Name: _____ Initial Specimen
 Infant's First Name: _____ Placental Specimen
 Sex: Male Female
 Single Birth
 Twin (A) or (B)
 Other

Date of Birth: _____ Time of Birth: _____ Gestational Age: _____
 MM DD YYYY Millen Year: Millen: Secen:
 Date of Expiration: _____ Time of Collection: _____ Infant's Age When Collected: _____
 MM DD YYYY Millen Year: Less Than 24 hours More Than 24 hours

Infant's Medical Record # _____ Birth Weight: _____
 Sex: _____

Mother's Name and Address: _____
 Last: First: _____
 Address: _____ Apt. # _____
 City: _____ Zip: _____
 Tel. # () _____
 Mother's Date of Birth: _____
 MM DD YYYY
 Hospital Name and Address: _____
 City: _____
 Infant's Primary Care Physician: _____
 Name: _____
 Address: _____
 City: _____ Zip: _____
 Tel. # () _____
 Notes: _____

MSL LAB COPY **477943031**

1 ACCURATELY
FURNISH
ALL INFORMATION
ON FORM

2 HEAR OUT AND
PROOF UP
YOUR AS YOUR
SPECIMEN
COLLECTION

3 COLLECT BLOOD

4 USE BLOOD FOR
NEWBORN BLOOD
SCREENING

5 SUBMITTER
ONLY
KEEP COPY
FOR YOUR RECORDS

- 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: Staff Training

- Hospital staff should complete comprehensive specimen collection training prior to collecting any samples
- Training annually
- Hospital 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: Hospital Procedures

- Hospitals should establish written policies and procedures for:
 - Specimen collection, storage, tracking and shipping
 - Tracking and disposition of results



Hospital Contacts

- Hospitals should provide the NBS Program with the names and contact information for it's hospital administrative designee(s) and medical designee(s) annually
 - The NBS Program should be notified within 30 days of a change of designee

Health Electronic Response Data System (HERDS)

Level Selector | Home | **Data Entry** | Reports

Data Entry

Activity:* ▼



Specimen Shipping



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Recommended Timing Under New Regulation



Specimen Shipping

- All specimens should be submitted to the NBS lab within 24 hours of collection
- Specimens should arrive at the NBS lab within 48 hours of sample collection



Specimen Tracking



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Specimen Tracking: Hospital Documentation

- The Lab ID should be documented in the baby's discharge summary and medical record, including the date & time of collection



Lab IDs are unique identifiers for each baby/specimen



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Specimen Resulting



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Specimen Resulting: Hospital Documentation

- Each newborn's NBS results should be documented in the baby's medical record at the hospital
- Discharge summary containing Lab ID or copy of NBS result should be transmitted to the responsible provider



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.



Upcoming Webinars



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New Regulation: Webinar Series

- Babies in the NICU: September 12, 2019 @ noon
- 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



