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Newborn Screening Webinar Series: Birth Attendants

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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

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A JOURNAL SENTINEL WATCHDOG REPORT

Deadly Delays

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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: 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**



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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

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

Outline

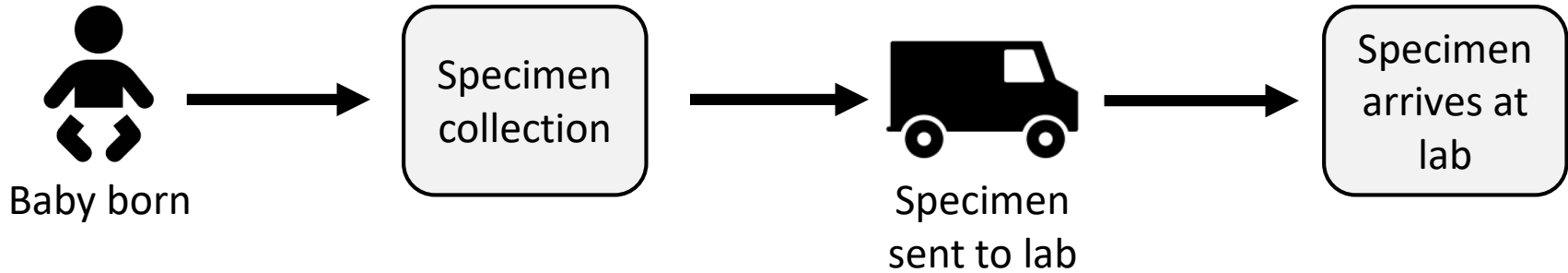
Up

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

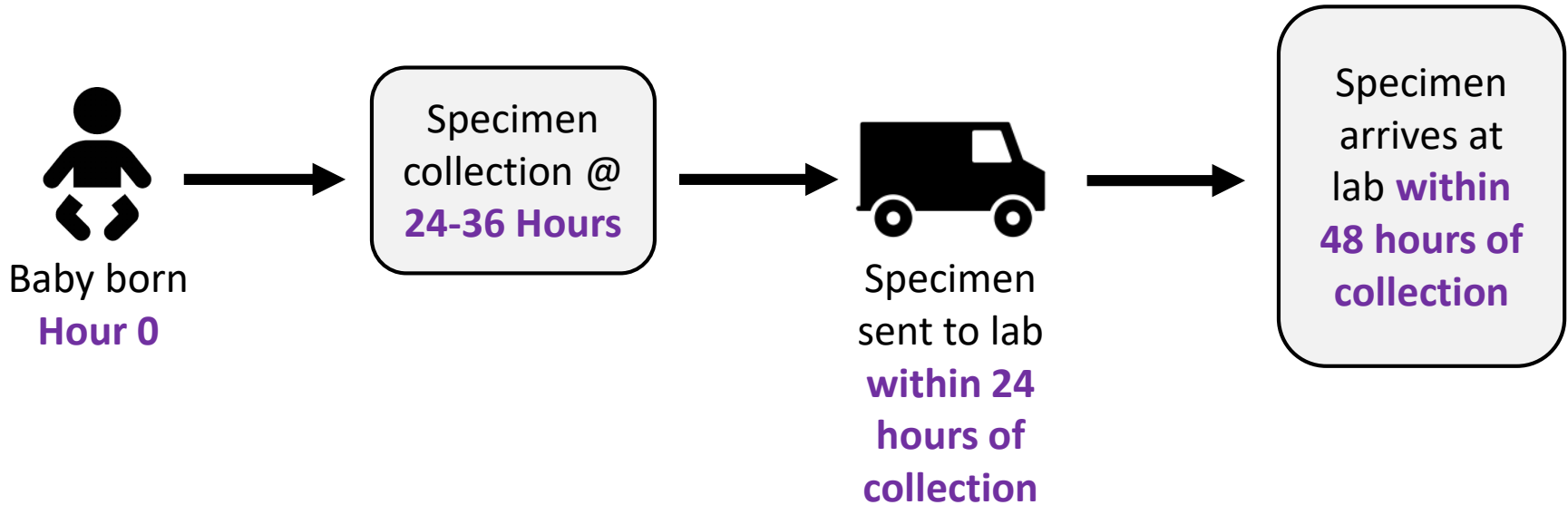


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Recommended Timing Under New Regulation



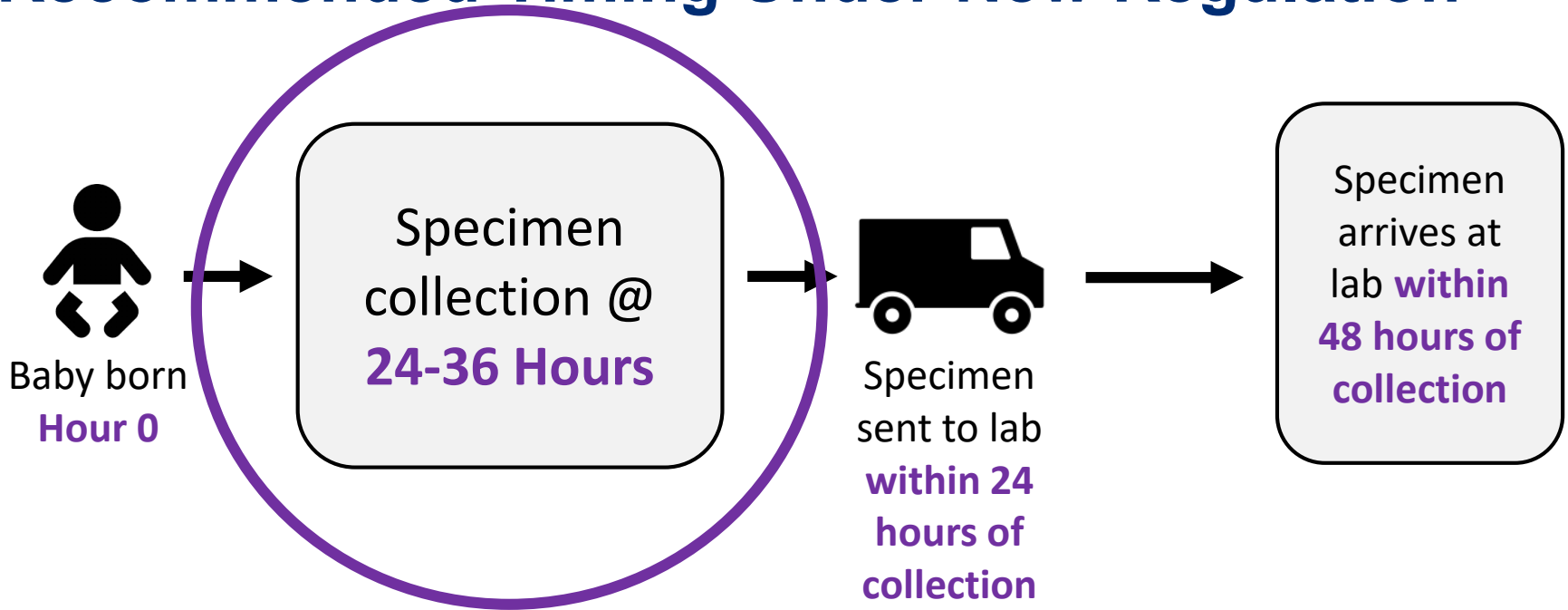
Specimen Collection



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Recommended Timing Under New Regulation



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



- 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>



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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



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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 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



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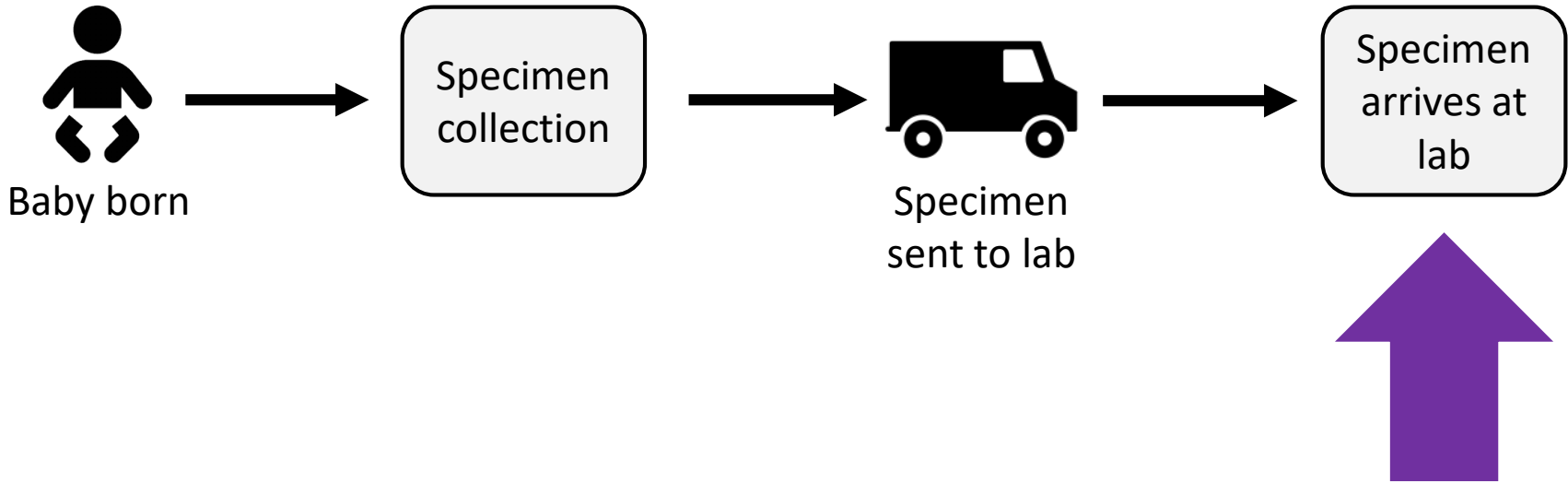
Specimen Resulting: Documentation

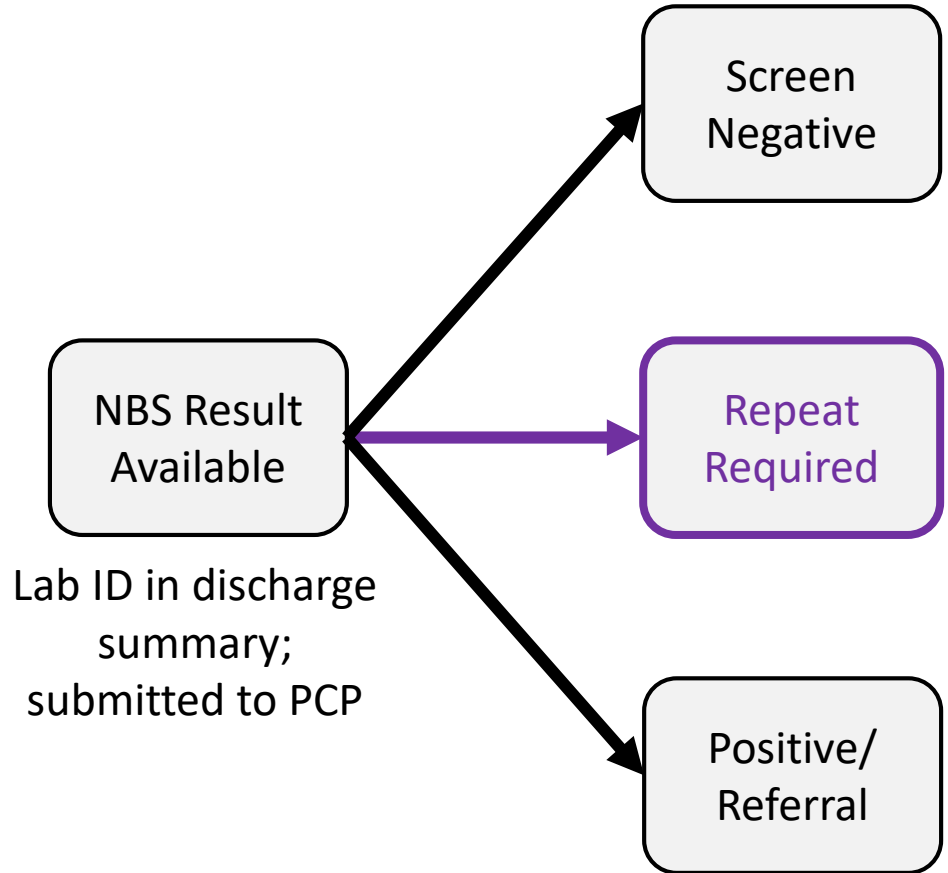
- Each newborn's NBS results should be documented in the baby's health record
- Discharge summary containing Lab ID or copy of NBS result should be transmitted to the responsible provider



Repeat Requests



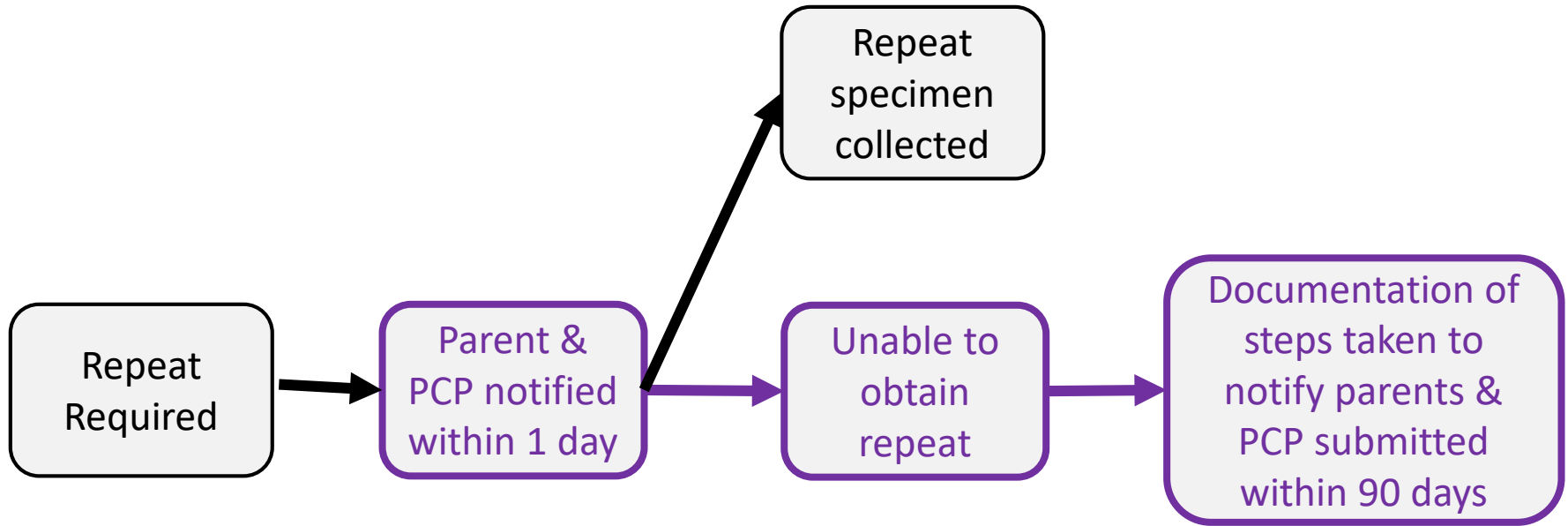




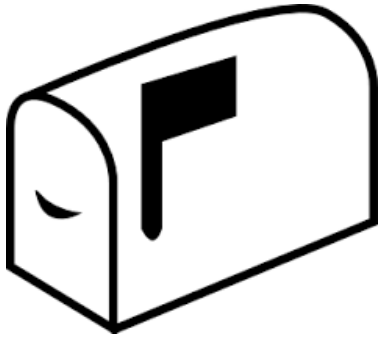
Reasons for Repeat Screens

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





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

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



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.

