U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Newborn Screening Contingency Plan Version II

August 2017

National Center on Birth Defects and Developmental Disabilities
Centers for Disease Control and Prevention

CDC

Newborn Screening Contingency Plan Version II

August 2017

DOCUMENT REVISIONS

DATE	REVISIONS	AGENCY REVISING
July 2010	***Version I*** Original document drafted and published online at: https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritable	CDC, HRSA, and associated partner organizations
August 2017	***Version II*** • Added point of care screening for critical congenital heart defects and newborn hearing • Streamlined text into a usable checklist tool for emergency planners at the state and local level	CDC, HRSA, and associated partner organizations

CONTENTS

EXECUTIVE SUMMARY

Background

More than 12,000 infants of nearly four million babies born in the United States each year are diagnosed with detectable and treatable disorders. Most babies are screened at birth by state newborn screening programs to detect certain conditions that may threaten their long-term health. If diagnosed timely, these conditions can be successfully managed or treated to prevent severe and often lifelong health consequences. Each state determines independently the conditions and screening procedures for its screening program. States varied widely on the number of conditions for which infants were tested prior to 2006. Moving toward standardization, the American College of Medical Genetics (ACMG) in 2006 completed a report commissioned by the U.S. Health Resources and Services Administration (HRSA). The ACMG report recommended that every baby born in the United States be screened for 29 specific core conditions, and each state should report test results for any of the additional 26 specific secondary conditions that may be identified incidentally during the course of screening for the core panel. The U.S. Department of Health and Human Services (HHS) Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) endorsed the report and its recommendations. HHS recommends that every newborn screening program include a Recommended Uniform Screening Panel (RUSP) that currently includes 34 core disorders and 26 secondary disorders. The RUSP is a list of conditions adopted by the Secretary of Health and Human Services (HHS). The ACHDNC provides recommendations to the Secretary of HHS with regard to which conditions ought to be included on the RUSP. The Secretary then makes the final decision on whether to add, or not add, a recommended condition to the RUSP.

The Newborn Screening Saves Lives Act of 2008 and Reauthorization Act of 2014

On April 24, 2008, *The Newborn Screening Saves Lives Act of 2008* became public law (H.R. 3825; Report No. 110-570). The Act was reauthorized in 2014 (P.L.113-240).

This law directs the Centers for Disease Control and Prevention (CDC), in consultation with HRSA and the State Departments of Health (or related agencies), to develop a national newborn screening contingency plan for use by a state, region, or consortia of states to ensure continuity of critical operations in the event of a public health emergency. The development of this framework for state and local planning was required within 180 days of enactment of the legislation. The Newborn Screening Saves Lives Reauthorization Act of 2014 stipulated that the plan was to be updated as needed and at least every five years.

A. Purpose

The Newborn Screening Contingency Plan Framework (known as the Framework) was developed in 2010 and the document was revised in 2015-16 in partnership with federal, state, local, and non-governmental organizations engaged in aspects of the newborn screening community. This is the first update to the Framework as it relates to newborn screening, which includes screening for hearing loss and Critical Congenital Heart Disease (CCHD).

The intent of the Framework is to facilitate collaboration among federal agencies and state, local, territorial, tribal, and regional efforts to screen newborns for identified conditions during a public health emergency. This effort is limited to those areas of the newborn screening system (screening test, diagnosis and follow-up, treatment and management, evaluation, and education), for which the state public health agency assumes an oversight role.

B. Mission Essential Tasks

- Developing a comprehensive continuity of operations plan to include blood spot, hearing, and CCHD screening.
- Contingency planning.
- Conducting hearing and CCHD screening using appropriate equipment and methodologies.
- Collecting blood spot specimens.
- Transporting blood spot specimens.
- Processing blood spot specimens.
- Reporting test results.
- Diagnostic testing of positive screen results.
- Ensuring appropriate follow-up and care prior to hospital discharge (or transfer) for newborns who fail a CCHD screen or do not pass a hearing screening.
- Locating affected and potentially displaced populations.
- Ensuring the availability of treatment and management resources.
- Educating families about newborn screening.
- Continuity of communications processes, such as Health Information Technology (HIT).
- Training newborn screening contingency respondents and stakeholders.
- Communicating newborn screening contingency plan details to partners and stakeholders.
- Coordinating the inclusion of state newborn screening contingency plans into the state's overall preparedness plan.

Concept of Operations

This document is intended to be used as a framework by state and local health agencies, laboratories, clinicians, and other organizations that are part of the newborn screening system in the United States. Each organization may use the applicable sections of this framework to create their plans.

The goal of newborn screening programs is improving the quality of life of newborns through early diagnosis and treatment. Newborn screening is organized as a system that includes the following:

- Education – ongoing education of the public, parents, and health professionals.
- Screening – testing newborns.
- Follow-up (including results reporting) – rapid location, follow-up, and referral of the screen-positive infant.
- Diagnostic confirmation – evaluation of the infant with a positive screening test (or fail/not pass) to make definitive diagnosis or exclude the disorder.
- Short-term and long-term management – rapid planning and implementation of long-term therapy, medical, or surgical intervention(s) as needed.
- Evaluation and continuous quality improvement – validation of testing procedures, assessment of the efficiency of follow-up and intervention, and assessment of the benefit to the patient, family, and society.

The screening component is performed the following three ways:

1) A heel stick should be done 24 to 48 hours after birth and before the baby leaves the birthing facility. Collect a small blood sample on special filter paper for laboratory analysis to detect metabolic/genetic disorders. If the baby is not born in a hospital, the midwife, doctor, or health professional should collect the blood sample within 48 hours of birth and send it to the newborn screening laboratory.

2) Screening for hearing loss should occur before the baby leaves the birthing facility. If not born in a hospital, the hearing test should occur no later than one month after birth.

3) Pulse oximetry to identify CCHD by measuring the proportion of hemoglobin that is oxygenated (e.g., the amount of oxygen in the baby's blood). Screening should be performed after 24 hours of age or prior to discharge from the birthing facility.

Members of the newborn screening community have developed a Continuity of Operations Plan (COOP), which provides information for state and local stakeholders to develop plans to ensure continuity in the event of disaster or emergency. The COOP for a newborn screening program and its public health laboratories should have two basic features:

1) Provide a comprehensive, pre-identified list of all core testing, support activities (including reporting), and supplies that must be maintained if the laboratory or birthing facility experiences a partial or complete operational disruption.

2) Provide a prearranged plan of action to ensure that all core activities are continued without delay.

Effective Date, Implementation, and Revisions

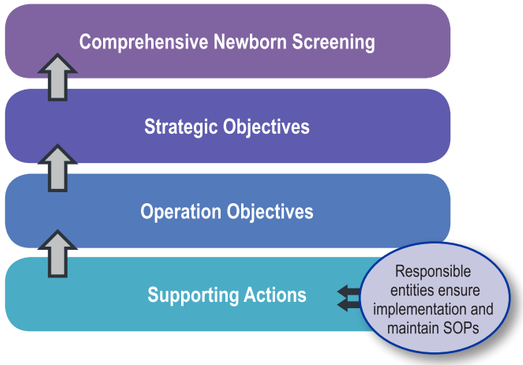
This Newborn Screening Contingency Plan Framework's effective date will be two weeks after final publication and following the signatures from the Director of CDC and the Administrator of HRSA. The Framework will be updated and renewed on an as-needed basis. This document is subject to amendments based on changes to the standard operating procedures in stable situations and based on information gathered during and after a disaster. Such amendments, shall however, be subject to the same level of scrutiny as in the preparation of the initial document.

Strategic and Operational Objectives and Supporting Actions

Strategic objectives broadly define what should be achieved to ensure comprehensive newborn screening. Operational objectives outline specific goals to achieve and require supporting actions that must be accomplished in order to fulfill the strategic objective. Each state should ensure that their newborn screening contingency plan is integrated into the overall state preparedness plan.

The Newborn Screening Contingency Planning Checklist provides the strategic and operational objectives and major activities in a checklist format. The responsible entities for each action are outlined in the Newborn Screening Contingency Planning Checklist. Each responsible entity must develop and maintain specific Standard Operating Procedures (SOPs) that detail how each activity is executed within their jurisdiction or scope of responsibility. SOPs should be reviewed and updated on a regular basis to ensure they reflect the current method the entity operates. The strategic objectives are supported by specific operational objectives, which are further supported by supporting actions (see Figure 1). Each action has an entity that is responsible for ensuring proper implementation of that supporting activity.

Figure 1: Newborn Screening Strategic Objectives. Operational Objectives and Actions



Common Roles and Responsibilities

Federal Responsibilities:

Office of the Assistant Secretary for Preparedness and Response (ASPR): The Office of the Assistant Secretary for Preparedness and Response was created under the *Pandemic and All Hazards Preparedness Act (PAHPA)* in the wake of Hurricane Katrina. ASPR focuses on preparedness planning and response; building federal emergency medical operational capabilities; countermeasures research, advance development, and procurement; and grants to strengthen the capabilities of hospitals and health care systems in public health emergencies and medical disasters. The office provides federal support and medical professionals through ASPR's National Disaster Medical System, which augments state and local capabilities during an emergency or disaster.

National Disaster Medical System (NDMS), Department of Health and Human Services (HHS): The NDMS is supplemented by state and local medical resources during disasters or major medical emergencies. Medical response is led by HHS that coordinates the Disaster Medical Assistance Teams, which are groups of intermittent federal employees who volunteer to be on a designated team for NDMS. Teams of 35 with a range of health and medical skills are typically deployed. Federalization of the program allows for addressing important issues, such as licensure and certification, liability, compensation, and coverage under the *Uniformed Services Employment and Reemployment Rights Act (USERRA)* regarding leave from employment and reemployment. Two pediatric teams in NDMS can address issues related to infants identified through newborn screening and specialty clinic patients. They are primarily generalist pediatricians with limited experience in the management of newborns and children living with a life-threatening disorder, whether or not identified through newborn screening.

Centers for Disease Control and Prevention (CDC): The Office of Public Health Preparedness and Response (OPHPR) within CDC has primary oversight and responsibility for all programs that comprise CDC's public health preparedness and response portfolio. OPHPR helps the nation prepare for and respond to urgent threats to the public's health, such as natural, biological, chemical, nuclear, and radiological events. OPHPR carries out its mission by emphasizing accountability through performance, progress through public health science, and collaboration through partnerships. CDC supports a Clinician Outreach and Communication Activity (COCA), which establishes partnerships with national clinician organizations to communicate information about emergency and disaster events.

CDC's National Center on Environmental Health (NCEH): The Newborn Screening Quality Assurance Program (NSQAP) within NCEH provides laboratory support to newborn screening programs and is devoted to ensuring the accuracy of newborn screening tests in every state for conditions that are evaluated through dried blood spot (DBS) testing. NSQAP's services include proficiency testing, development of quality control and reference blood spot materials, test development and transfer, filter paper evaluation, technical training, and consultation for recent and anticipated additions to the Recommended Uniform Screening Panel (RUSP). NSQAP also partners with the Association of Public Health Laboratories (APHL) to provide technical services and support for newborn screening laboratory practice, including oversight and administration of a filter paper repository for emergency use by newborn screening programs.

CDC's ***National Center on Birth Defects and Developmental Disabilities (NCBDDD).*** NCBDDD provides clinical genetic and public health surveillance and epidemiology expertise to states. NCBDDD provides funding to support the development and implementation of state-based Early Hearing Detection and Intervention (EHDI) tracking and surveillance systems, which help to ensure that newborns are screened for hearing loss and receive recommended follow-up. CDC also

funds 14 states to track major birth defects, including CCHDs, using population-based methods. State systems use the data to help direct birth defects prevention activities and refer children affected by birth defects to needed services.

Health Resources and Services Administration (HRSA): HRSA's Maternal and Child Health Bureau (MCHB) oversees the Title V Maternal and Child Health Services Block Grant, which includes State Formula Block Grants, Special Projects of Regional and National Significance grants, and Community Integrated Service Systems grants. The largest portion of Title V funding goes to the states to meet critical challenges in maternal and child health and for monitoring systems of care, such as newborn screening for infants, children, youth, women of all ages, and pregnant women and their families.

HRSA's funded services provide:

- Access to quality care, especially for people with low-incomes or limited availability of care
- Assistance in the reduction of infant mortality
- Access to comprehensive prenatal and postnatal care for women, especially low-income and at-risk pregnant women
- An increase in health assessments and follow-up diagnostic and treatment services
- Access to preventive and child care services as well as rehabilitative services for certain children
- Family-centered, community-based systems of coordinated care for children with special healthcare needs
- Toll-free hotlines and assistance in applying for services to pregnant women with infants and children who are eligible for Title XIX (Medicaid).

In addition, HRSA/MCHB funds various newborn screening programs:

- Improving the Timeliness of Newborn Screening Diagnosis Initiative seeks to ensure newborns receive timely screening, diagnosis, and treatment for heritable disorders.
- Newborn Screening Technical Assistance and Evaluation Program (NewSTEPS) provides technical assistance on the implementation of state-based public health newborn screening and other genetics programs.
- The Regional Genetics Networks with an associated national coordinating center to provide a regional infrastructure of public health genomics expertise to improve, expand, strengthen, evaluate access to a system of genetic services, to improve health outcomes for children, youth and adults across their lifespan.
- Severe Combined Immunodeficiency (SCID) Newborn Screening Implementation Program supports implementation of universal screening for SCID in every state, with all identified infants receiving appropriate screening and follow up care.
- Newborn Screening Implementation Program Regarding Conditions Added to the Recommended Uniform Screening Panel supports implementation of universal screening for Pompe disease, Mucopolysaccharidosis I (MPS I), and X-linked Adrenoleukodystrophy (X-ALD).
- Universal Newborn Hearing Screening and Intervention Program and two associated coordinating centers to support statewide and territorial Early Hearing and Detection and Intervention (EHDI) programs in their efforts to develop a comprehensive and coordinated system of care targeted towards ensuring that newborns and infants are receiving appropriate and timely services including screening, evaluation, diagnosis and early intervention.

Director's Critical Information Requirements (DCIRs): The CDC Director's and HRSA Administrator's Critical Information Requirements (DCIRs) are used as criteria or triggers to determine what information should to be communicated to CDC and HRSA leadership to assist in making critical decisions regarding both agencies' preparation for and response to an emergency. If one of the DCIRs is met, it might trigger an increased level of awareness, increased contact with partners, event-specific planning, or initiation of response activities. The DCIRs applicable to newborn screening include:

1. Report significant disruptions to state or regional newborn screening capabilities;
2. Report any requests for CDC or HRSA assets or assistance in coordinating newborn screening in the event of a public health emergency;
3. Report any significant disruptions in the availability of newborn screening treatment and management resources;
4. Report any requests made by the HHS Secretary regarding execution of newborn screening activities; and
5. Report any abnormal trends from newborn screening results.

Non-Federal Responsibilities

Newborn screening is a system cutting across governmental public health at all levels, hospitals and midwives, health plans, manufacturers, pharmacists, clinicians, advocacy organizations, couriers, and other entities. Staff members, who will provide newborn screening, should be made aware of the following:

1. State and local coordination requirements.
2. Non-governmental organization requirements.
3. Private sector coordination requirements.
4. Key federal decisions.
5. Actions required of or prohibited by the federal government.

Public health officials are subject to a host of laws and regulations. The following represents roles and responsibilities that should apply to a cross-section of all newborn screening partners:

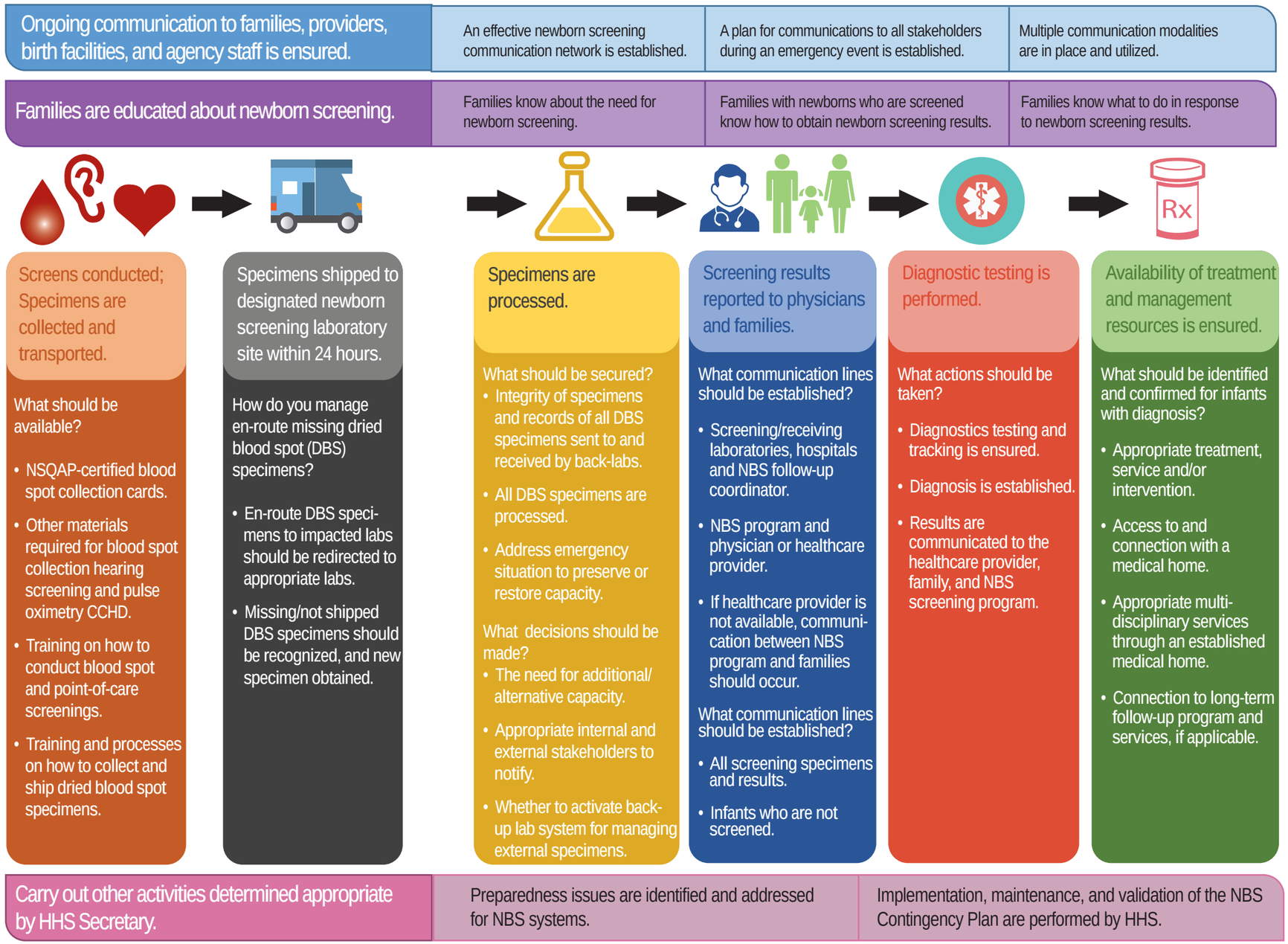
1. Establish policies and procedures to ensure continuous performance of critical testing and support activities.
2. Ensure sufficient stock of critical supplies.
3. Define requirements for continuous operations, then identify and prearrange for assistance from alternate states and laboratories, if needed.
4. Ensure safety of all laboratory employees and visitors.
5. Provide communication and direction to stakeholders.
6. Minimize the loss of assets, resources, critical records, and data.
7. Reduce or mitigate disruptions to the program's operation.
8. Build infrastructure to support a timely recovery.
9. Manage the immediate response to the emergency.
10. Provide prospective information and education for employees and stakeholders regarding roles and responsibilities during an emergency.
11. Maintain, exercise, or audit the COOP at least annually.

Strategic Objectives Flowchart

The flowchart (see Figure 2) provides an overview of strategic objectives and major actions that need to be sustained to ensure babies and their families receive these critically important services.

1. Ongoing communication to families, providers, birth facilities, and agency staff is ensured.
2. Families are educated about newborn screening.
3. A framework for screening (blood spot, hearing, and CCHD) and specimen collection is established.
4. Specimens are shipped to the designated newborn screening laboratory site.
5. Specimens are processed and tested.
6. Screening results are reported to the newborn screening follow-up program and physicians and families.
7. Diagnostic testing is performed for infants with positive screening results for time-critical disorders.
8. Availability of treatment and management resources is ensured.
9. Other activities determined appropriate by the HHS Secretary are carried out.

Figure 2: Newborn Screening Strategic Objective Flowchart



I. SITUATION

A. Background

Effective implementation of newborn screening has had a significant place in the United States public health arena for decades. Non-governmental organizations, such as the March of Dimes, have championed the cause of newborn health for almost a century. CDC's Newborn Screening Quality Assurance Program (NSQAP) which played an important role in the quality assurance aspect of newborn screening, celebrated its 30th anniversary in July 2008.

The Association of Public Health Laboratories (APHL) established a subcommittee of its Newborn Screening and Genetics in Public Health Committee to develop a framework to assist public health laboratories to prepare for, and respond to, disasters caused by nature, terrorism, and interruptions of testing materials and supplies in 2004. The subcommittee designed a checklist (*Appendix A*) that outlined the various elements public health laboratories must address to prepare for disasters that disrupt newborn blood spot screening program operations. A generic Model Memorandum of Understanding/Agreement (MOU/MOA) (Appendix B) was developed to include elements for consideration by states that may need assistance from other states using a mutual assistance agreement.

Hurricanes Katrina and Rita destroyed Louisiana's state public health laboratory and eliminated the state's ability to perform newborn blood spot screening in 2005. The chief of the Louisiana Public Health Laboratory determined that the state's newborn screening program was one of the state's highest public health priorities. Fortunately, the Iowa public health newborn screening laboratory, facilitated by the Emergency Management Assistance Compact (EMAC), was able to rapidly assume the screening of Louisiana's newborns. After the hurricanes, HRSA, the HRSA-funded Regional Genetic and Newborn Screening Service Collaboratives, their national coordinating center, and APHL initiated a process to create regional newborn screening emergency preparedness plans and the CONPLAN. These plans were essential for preparedness and recovery from the effects of Hurricane Sandy in New Jersey and New York in 2012. These plans provided a mandate for emergency preparedness for all state newborn screening programs.

EMAC provides a structure for emergency support between states and territories where requested resources can be shared. EMAC was established by a federal law (Public Law 104-321) and ratified by Congress in 1996. All 50 states, the District of Columbia, Puerto Rico, Guam, and the U.S. Virgin Islands are EMAC members. The National Emergency Management Association (NEMA) administrates this program. The CONPLAN considers EMAC an essential resource in supporting emergency preparedness and response for newborn screening.

APHL served as the central point of contact during these emergencies and assisted programs in maintaining services. Stakeholders, including the regional collaborations, HRSA, and the APHL Newborn Screening and Genetics in Public Health Committee, led to the development of the 2010 CONPLAN. This updated document was developed by an Advisory Committee of newborn screening experts and stakeholders, including federal, state, and local partners, and family representatives (*see Appendix F)*.

B. Authorities

- The Newborn Screening Saves Lives Reauthorization Act of 2014
- Title V of the Social Security Act of 1935
- Title XXVI of the Children's Health Act of 2000, "Screening for Heritable Disorders"
- Public Health Service Act of 1944

C. Threat

A state and site vulnerabilities analysis provide a list of threats that might disrupt normal public health functions, including newborn screening program operations within laboratory facilities (e.g., laboratory testing) and within the community (e.g., patient follow-up, treatment). Such threats fall into the following general categories:

- Extreme weather conditions
- Major equipment failure
- Prolonged personnel staffing issues
- Extensive building damage
- Compromised building utilities
- Failed communication systems
- Shortage of testing materials and supplies
- Civil disturbance
- Acts of terrorism

Each public health newborn screening program should develop a comprehensive list specific to its own facility. This could be coordinated and/or informed by other organization analyses, such as a health department's Hazard and Vulnerability Analysis (HVA).

D. Critical Considerations

(1) Many states lack sufficient resources to ensure self-sufficiency through internal back-up systems and redundancy through regionalization.

(2) Few states have the capacity to absorb a significant increase in hospital-based screens and screening volume for the laboratory and follow-up functions in the case of an emergency.

(3) Because of the variation among states in the disorders they screen for, contingency newborn screening programs in states that provide screening assistance to states in need might not have the capacity to screen for all of the same conditions.

Contingency newborn screening programs might not have the capacity needed to follow up with infants that tested positive.

E. Critical Assumptions

(1) National and/or regional back-up systems, including birthing facilities and redundancy, are required to ensure continuity of newborn screening operations.

(2) Preparations and drills for newborn screening contingencies must occur before the need for their implementation.

II. MISSION

CDC and HRSA will work with our public health newborn screening partners to assure continuity to newborn care and to develop a comprehensive and uniform system of screening infants born in the United States in the event of a public health emergency, as specified in the Newborn Screening Saves Lives Reauthorization Act of 2014.

III. EXECUTION

Concept of Operations

1. General

Federal Agencies and National Partners

- American Academy of Pediatrics (AAP)
- American College of Cardiology (ACC)
- American College of Medical Genetics and Genomics (ACMG)
- American Heart Association (AHA)
- Association of Maternal & Child Health Programs (AMCHP)
- Association of Public Health Laboratories (APHL)
- Association of State and Territorial Health Officials (ASTHO)
- Centers for Disease Control and Prevention (CDC)
- Emergency Management Assistance Compact (EMAC) / Federal Emergency Management Agency (FEMA)
- Health Resources and Services Administration (HRSA)
- National Center for Hearing Assessment and Management (NCHAM)

City, County and State Partners

- State and local public health departments
- State and local public health department laboratories (non-contract and contract)
- State newborn screening program directors
- State and local public health preparedness directors
- State Homeland Security Agency
- State Emergency Management Agency
- State and local emergency management officials
- State Title V Maternal Child Health / Children and Youth with Special Health Care Needs Directors
- Agency Communication/Press Offices

Non-Governmental Organizations

- Joint Committee on Infant Hearing (JCIH)
- March of Dimes (MOD)
- National Association of County and City Health Officials (NACCHO)
- NewSTEPs (Newborn Screening Technical assistance and Evaluation Program)
- National Coordinating Center (NCC) for the Regional Genetic Networks
- Patient Advocacy groups
- Manufacturers of newborn screening tests and supplies
- Regional disaster organizations
- Hospital associations

Healthcare Service Partners

- Hospitals
- Clinics
- Primary care and other physicians, nurses, and allied health practitioners
- Health professional associations
- Case managers
- Specimen delivery systems
- Reference laboratories
- Local disorder/family support groups

2. Pre-alert or Activation Responsibilities

A. Manufacturer or supplier responsibilities.

- Adequate forward stocking established.
- Alternate transportation plans established including disaster identification to allow travel in an emergency.
- Plan to provide equipment, training, and/or supplies as needed to alternate site(s) within a specific time frame.

B. State Health Official Responsibilities.

- Meet with EMAC coordinator to discuss newborn screening contingency planning.
- Establish contingency plan that includes newborn screening program and its laboratory capabilities.
- Amend or establish MOU/MOAs to include newborn screening contingency planning.
- Establish contract with partners and vendors to include newborn screening contingency planning.

It is outside the scope of this plan to address state specific details for newborn screening contingency planning. However, a state can ensure a much smoother assistance process being proactive and with a contingency plan in place. When developing a state newborn screening contingency plan, there are several key factors to consider:

- o Coordination at all levels is imperative. Consider pre-identifying potential reciprocal laboratories and/or entering into MOUs/MOAs with several partner states in different geographic regions. Identify hospitals that are appropriate to accept a transferred newborn needing immediate evaluation for a failed CCHD screen and a hospital or diagnostic center to diagnose hearing loss. Consider developing a shared response which could ease the testing load of any one state. Consider taking advantage of existing conferences, workshops, and training to discuss newborn screening contingency planning.

- o Redundancy is critical to ensure continuity. Redundancy should be planned in-depth, such as multiple methods to respond to a system or component failure or a secondary response identified should the primary backup fail. Evaluate every aspect of the newborn screening program and determine what would happen if each aspect failed. If an aspect is critical to the newborn screening system functioning, develop backups for team members, equipment, facilities, and supplies.

- o Communication is critical. Lateral (interstate) and vertical (interstate) communication is essential when reporting mechanisms for newborn screening results or when standard communication might be unavailable. It is important to include online reporting methods in the Standard Operating Procedures (SOP).

- o Training tests the response network. Regularly scheduled exercises and reviews of the contingency plan should be routine.

- o Conduct drills. Consider performing joint emergency drills with reciprocal agreement states. Practice drills provide opportunities to examine quality assurance parameters.

- Develop a state Continuity of Operations (COOP) Plan.

  - o Refer to Section 3, Considerations for COOP Development (below), for recommended considerations regarding COOP planning.

C. State Public Health Laboratory Responsibilities.

- Establish backup testing methods or plans.
- Obtain documentation that manufacturer or supplier has the following:

  - o Adequate forward stocking established.

  - o Alternate transportation plans established.

- Work with manufacturers or suppliers to address situations where materials are not delivered as scheduled, such as:

  o Cost of alternative testing instruments, materials, or outsourced testing, and

  o Cost of staff time to implement alternate testing.

- Collaborate with state and federal agencies to harmonize laboratory methods so that results are comparable between states.
- Establish interstate and regional agreements for ensuring backup of laboratory capacity in addition to EMAC (for situations where EMAC may not be activated).
- Establish back-up plans to ensure continuation of diagnosis and follow-up services for infants who test positive.
- Establish a public health laboratory COOP (See next section for recommended considerations when developing a COOP).

C. Birthing facilities

- Establish an EHDI and CCHD newborn screening, tracking and follow-up COOP.
- For responsibilities specific to EHDI or CCHD, please see Operational Objectives 2, 3, 6 and 7.

3. Considerations for COOP Development for the Laboratory

A COOP applies to all operations, infrastructure, and resources necessary to continue the laboratory activities deemed essential to fulfill governmental responsibilities. The nature of the work done in the public health laboratory requires that its COOP be developed as a special part of the business continuity plan of the agency within which it operates. A COOP for a public health laboratory should have two basic features:

1) A Newborn Screening COOP provides a comprehensive, pre-identified list of all core testing, support activities, supplies, and communications plans to report positive screening results to healthcare providers or families if the laboratory experiences a partial or complete operational disruption; and

2) A COOP provides a prearranged plan of action to ensure that all core activities are continued without delay.

The scope of the laboratory COOP should include all time-sensitive core activities of the public health laboratory, including technology and required support. The COOP should also have the capability to scale down to accommodate lesser disruptions. Specific plans of action should be developed, and groups of personnel should be identified and trained to implement these predefined actions to ensure timely recovery. Some items to consider in COOP planning include, but are not limited to, the following:

On-site Operation: Short-Term

(1) Emergency electrical power available for the following:
- Specimen accessioning;
- Demographic entry or test reporting;
- Instruments;
- Laboratory information management system;
- Refrigeration; and
- Heating and cooling work areas.

(2) Maintain a 3-month supply of testing materials.

(3) Identify alternate water sources.

(4) Ensure availability of data systems to record integrity and timely transmission of test results to providers and state programs and telephones for continuous access to communication.

On-site Operation: Long-Term

(1) Prioritize tests to be reported. (Refer to the ACHDNC timeliness recommendations and Society for Inherited Metabolic Disorders statement on defining time-critical conditions citations in Appendix E: References.)

(2) Identify states with same screening panels and methodology and consider backup plans in the event of an emergency.

(3) Identify states with similar reporting mechanisms (e.g., Web-based, fax, and voice response system).

Off-site Operation

(1) Identify contacts at offsite screening facility, if specimens are being tested at a different laboratory.

(2) Establish Memoranda of Understanding (MOU) with neighboring states.
* (See Appendix B for example)

(3) Establish a plan for compensation.*

(4) Establish a plan for specimen transport.

(5) Establish a plan for communication of positive tests results to submitters, providers or specialists.

(6) Establish a plan for communication of all test results to submitters.

(7) Prepare for temporary relocation of staff.
- Identify in-house staff, and plan for updated emergency contact information.

- Identify financial mechanisms for travel and housing.

(8) Establish a plan for access, retrieval, and entry of all data into local information system after local operation is reestablished.

(9) Establish a communication plan for the development and delivery of Public Service Announcements (PSAs) to inform hospitals, midwives, providers, and the public of process changes.

(10) Establish a plan for return to normal operations.

** EMAC, if activated, will provide for MOUs and reimbursement of eligible mission costs.*

4. Deployment

To be published by the State authority, as required.

5. Demobilization

Procedures for standing down the plan should be developed and issued by appropriate state authority (as required).

IV. OVERSIGHT, COORDINATION, AND COMMUNICATIONS

A. Oversight

Legal issues: Numerous legal issues have to be considered in developing a contingency plan for newborn screening emergency preparedness. Memoranda of Understanding with those involved to provide backup services, interstate compacts, and other agreements can cover issues the states' rules cover return and storage of materials, malpractice and liability of responders, and other factors.

Legal Issues Involved in Interjurisdictional Agreements for NBS Contingency Planning

The Emergency Management Assistance Compact (EMAC) is a national interstate mutual aid agreement that enables states to share resources during times of disaster. Initiating formal agreements (e.g., memoranda of understanding [MOU], contracts) is a useful mechanism to address questions and concerns regarding newborn screening prior to an emergency situation arising. When entering into an MOU or contract with another state, it might be useful to incorporate the following considerations.

These are drawn from the Association for Public Health Laboratories (APHL) / Centers for Disease Control and Prevention (CDC)'s Policy Guide for Public Health Laboratory Test Service Sharing and the CDC's guidance publication An Overview of Legal Considerations in Assessing Multijurisdictional Sharing of Public Health Laboratory Testing Services. The specific section where more information and specific examples can be obtained in either guide is noted.

1. Authority to Participate in Test Service Sharing[1]

Although there is no express legal authority to enter into formal test service sharing agreements across jurisdictions, this is generally not precluded. Moreover, some jurisdictions' EMAC agreements may include a provision for "temporary suspension of any statutes or ordinances that restrict the implementation of EMAC-authorized mutual aid." Therefore, EMAC could be used to enable a state to engage in test service sharing if a standing prohibition exists.

2. Liability and Payment [2, 3]

Two common concerns encountered in developing formal test service sharing agreements are the extent to which one state laboratory may be held liable for another state laboratory's actions or omissions to act (i.e., liability) and how funds are transferred from one state laboratory to another (i.e., payment). These rank high as frequent barriers to test service sharing and should be discussed in conversations to develop the agreement.

Liability. Negotiation of liability considerations should identify and allocate responsibility for possible risks involved in test service sharing between jurisdictions. For example, states may include indemnification provisions to specify which parties agree to compensate others for loss or damages incurred as a result of pre-defined incidents, such as inaccurate reporting of results, misuse or misplacement of specimens, and/or breaches of privacy.

Payment. The ways in which state laboratories charge for test services performed in another state vary widely. Some jurisdictions prohibit these charges, some specify a fixed amount, and some permit full cost recovery, with certain laws exempting specific tests from being charged.

3. Certification and Licensure [4]

Laboratories. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) designate the provisions needed to permit testing of human specimens, including newborn screening specimens, for the prevention, diagnosis, or treatment of diseases. While CLIA likely does not preclude shared service agreements, it may be helpful to include a provision that addresses all necessary laboratory certifications.

Personnel. Some states have laboratory personnel licensure requirements, and many of these states require out-of-state laboratories to comply with these requirements when sharing test services.

4. Emergency Management Assistance Compact [5]

Each state, the District of Columbia, Puerto Rico, Guam, and the U.S. Virgin Islands have each enacted essentially uniform Emergency Management Assistance Compact (EMAC) legislation which authorizes participating states to provide assistance during a state of emergency declared by the jurisdiction's governor.

Each jurisdiction's EMAC statutes contains provisions pertaining to liability, reimbursement, and licenses and related requirements for public health laboratories during a declared emergency. EMAC laws should be consulted in developing your plan as they can inform what is currently written in state law and what points remain to be addressed.

5. Privacy [6, 7, 8]

Public health laboratories are subject to federal and state laws that protect individuals' privacy and the confidentiality of information related to their health. Of particular note are federal laws – the Health Insurance Portability and Accountability Act (HIPAA) and Health Information Technology for Economic and Clinical Health Act (HITECH) – and state-specific laws.

HIPAA (1996) protects information that "identifies an individual or for which there is a reasonable basis to believe the information can be used to identify the individual" and was updated and strengthened in 2009 via HITECH. That act regulates the disclosure of patient-identifiable information by covered entities (e.g., health care providers, health plans, and health clearing houses) and their business associates (e.g., claims processors and data services) to public health entities. Public health laboratories are often considered covered entities (i.e., when located within a health department) or hybrid entities – and thus HIPAA compliance is mandatory. It will be important to clarify which state laboratories are covered entities, hybrid entities, or business associates when entering into shared service agreements.

State privacy laws also need to be considered. These laws often serve to supplement, and in many cases go above and beyond, HIPAA protections, so provisions may need to be set in place to ensure these laws do not impact implementation during an emergency.

[1] *Policy Guide for Public Health Laboratory Test Service Sharing*, Section 4.1, pp. 25.
[2] *Policy Guide for Public Health Laboratory Test Service Sharing*, Section 2.3, pp.7; Section 4.2, pp. 26; Section 4.3, pp. 28.
[3] *An Overview of Legal Considerations in Assessing Multijurisdictional Sharing of Public Health Laboratory Testing Services,* "Public Health Laboratory Fees", pp. 9.
[4] *An Overview of Legal Considerations in Assessing Multijurisdictional Sharing of Public Health Laboratory Testing Services,* "Laboratory Certification", pp. 6.
[5] *Policy Guide for Public Health Laboratory Test Service Sharing*, Section 4.8.2, pp. 35
[6] *Policy Guide for Public Health Laboratory Test Service Sharing*, Section 4.4, pp. 29
[7] *An Overview of Legal Considerations in Assessing Multijurisdictional Sharing of Public Health Laboratory Testing Services,* "Laboratory Certification", pp. 5, 10.
[8] *Policy Guide for Public Health Laboratory Test Service Sharing*, Section 4.4.1, pp. 29; Section 4.4.2, pp. 30

6. Disease Reporting Laws [9, 10]
Although state-specific reporting requirements (i.e., who is required to report, which diseases are reportable, to whom reports must be made, reporting time frames, report content, reporting methods, etc.) might influence shared service agreements and should be reviewed for potential implications, it is uncommon for these to raise specific challenges.

7. In-State vs. Out-of-State Testing
While most states conduct their own testing and follow-up of newborns within their jurisdiction, 14 jurisdictions participate in a contractual agreement in which specimens are sent to a centralized testing facility, and then results are sent back to the original state for follow-up.

For states that do have a standing, non-emergency agreement for inter-jurisdictional testing, the same agreements may apply during an emergency. For states that do not, it might be useful to define a plan of action for inter-jurisdictional test sharing during a declared emergency, such as agreeing to only test for disorders typically tested for in the original state. For example, if State A typically only screens for 30 disorders and has to send out to State B - which usually screens for 38 disorders - in an emergency, State B might agree only to test for those 30 on State A's screening panel.

8. Parental Consent
While newborn screening is opt-out across the country, jurisdictions vary in opt-out or refusal procedures (e.g., for what reasons one can opt out, forms required, etc.). Jurisdictions should review their own refusal procedures and the procedures of jurisdictions they plan to enter into an agreement with, which will inform the language and provisions used in any agreement vehicle (e.g., State A and State B agree that State A will abide by State B's refusal requirements to test for specific diseases in an emergency).

B. Coordination

Pre-event Planning and Exercises: Contingency plans are only as good as the preparation to employ them. Periodic conferences that discuss details of newborn screening contingency plans and MOU/MOAs are highly beneficial tools to maintain attention on these plans and allow for periodic updates as needs or situations warrant. Everyone with an interest in newborn screening programs, including the public, providers and their institutions, and emergency responders, must assume overlapping responsibility for the continuation of all aspects of the program.

C. Communications.
Effective newborn screening communications support involves addressing issues that arise during the course of normal operations and planning, as well as COOP. Recommendations for consideration and inclusion in planning are outlined in Strategic Objective 1.

Implementation requires immediate activation of the COOP notification team to contact all key individuals and groups to provide them with essential information and guidance. Among those that need to be contacted by the notification team are the following:

- All required response teams.
- State Health Officer.
- State epidemiologist.
- State Title V Maternal Child Health Director.
- State Emergency Management
- All affected agency leaders.
- All laboratory staff.
- All newborn screening program staff.
- All affected submitters of samples and specimens.
- All alternative laboratories and newborn screening programs that may be required to assume core functions.

[9] Policy Guide for Public Health Laboratory Test Service Sharing, Section 4.7, pp. 33
[10] An Overview of Legal Considerations in Assessing Multijurisdictional Sharing of Public Health Laboratory Testing Services, "Disease Reporting Requirements", pp. 10.

APPENDICES:

Appendix A:

Newborn Screening Contingency Planning Checklist Framework

This checklist includes the strategic objectives, operational objectives, and major supporting actions that should be considered when planning and preparing for newborn screening contingency operations. Not all emergency situations are the same and not all of the identified items may be needed. Additionally, there may be other items and issues that will need to be addressed that are not included in this plan.

Strategic Objective 1
Ongoing communication to families, providers, birth facilities, and agency staff is ensured.

Objectives	Are the following activities/plans in place?	Resources / Tips	Responsible Entities
1.1 Establish an effective newborn screening communication network.	External Communications: Establish relationships with and identify contact information for/established relationships with the following: ☐ Birth facilities – nursery and laboratory ☐ Known midwives ☐ Local family practice and pediatrician groups ☐ Appropriate specialists ☐ Families already identified with a newborn screening condition Employ multiple communication modalities: ☐ Phone: ☐ Emergency call-back systems ☐ Integrate with Health Alert Network ☐ Social Media (Facebook, Twitter) ☐ Text ☐ Email ☐ Family resource centers (e.g., Family Voices, Genetic Alliance) ☐ Radio & Television ☐ Program/Agency Website updates ☐ Streaming audio sessions Provide education and training on state newborn screening practices to the following: ☐ Families ☐ Providers ☐ Birthing facilities/midwifery practices ☐ Ensure education and preparedness messages are linguistically and culturally appropriate; communications are accessible to all populations; and that communication channels are in place for reaching all affected populations. ☐ Incorporate emergency processes into standard communications to stakeholders	☐ Ensure all stakeholders are aware of the existence of a contingency plan. ☐ Consider social media as an Internal communication mechanism. ☐ For websites, consider a designated area for emergency information.	State: • State Health Official • Newborn Screening Program Director • State Early Hearing Detection and Intervention (EHDI) Coordinator. • Title V MCH program • State Hospital Preparedness Director • State Preparedness Director • State Emergency Management Director or designee Local: • Jurisdictional public health authority • Newborn screening program • Laboratory(ies) • Local Emergency Management

Strategic Objective 1 Continued

Objectives	Are the following activities/plans in place?	Resources / Tips	Responsible Entities
	Internal Communications: ☐ Define a call-back system for in-house staff, partners, and stakeholders. ☐ Test the system at least annually. ☐ Review and update the system at least semiannually. ☐ Store critical data needed for activation of the COOP at an off-site location (or location accessible remotely) for ready access. ☐ Store necessary contact information for staff, stakeholders, couriers, alternate laboratories, vendors, emergency management personnel, and key contact information for APHL, CDC, and HRSA on a secure site available remotely and/or on back-up servers that are housed in other areas. ☐ Store any relevant standard operating procedures needed to carry out COOP activities on a secure site available remotely.		
1.2 **A plan for communications to all stakeholders during an emergency event is established.**	☐ Determine which types of emergency will require emergency communications and to whom. ☐ Create centralized communication hotline for newborn screening. ☐ Educate stakeholders on how they will receive information about newborn screening in an emergency. ☐ Incorporate the National Standards for Culturally and Linguistically Appropriate Services (CLAS) into preparedness activities: ☐ Perform needs assessment and gap analysis. ☐ Develop key messages in appropriate languages in advance of emergency situations. ☐ Establish a plan for communication that is accessible to all populations, including deaf and hard of hearing, blind and low vision consumers.	Consider developing a specific communication plan and channels with alternative/back-up screening entities. Other situations you may want to consider: ☐ Personnel shortages (e.g., strikes) ☐ Consider cross training ☐ Loss of supplies (NBS Kits) ☐ Hospital evacuation ☐ EMR goes down	**State:** • State Health Official • Newborn Screening Program Director • State EHDI Coordinator • Title V MCH program • State Hospital Preparedness Director • State Preparedness Director • State Emergency Management Director or designee **Local:** • Jurisdictional public health authority

Objectives	Are the following activities/plans in place?	Resources / Tips	Responsible Entities
			• Newborn screening program • Hospital Incident Command Staff • Birthing Facilities • Laboratory(ies) • Local Emergency Management
1.3 **Multiple communication modalities are in place and utilized.**	☐ Establish a variety of communication modalities, including: ☐ Agency email listserv ☐ Organizational listservs (e.g., APHL, AAP, etc.) ☐ Phone hotline (e.g., Health Alert Network or State HAN Coordinator) ☐ Social media (Facebook, Twitter) ☐ Text ☐ Family support groups and community networks ☐ Program/Agency Website	*Situations you may want to consider:* Maintaining email and/or contact lists can be challenging: ☐ Use a hotline ☐ Establish a master contact list and updating periodically Social media venues to consider could include: ☐ Agency/Program ☐ External stakeholders (Genetic Alliance, APHL, family support groups, etc.)	**State:** • State Health Official • Newborn Screening Program Director • State EHDI Coordinator • Title V MCH program • State Hospital Preparedness Director • State Preparedness Director • State Emergency Management Director or designee **Local:** • Jurisdictional public health authority • Newborn screening program • Hospital Incident Command Staff • Birthing Facilities • Laboratory(ies) • Local Emergency Management

Strategic Objective 2
Families are educated about newborn screening.

Objectives	Are the following activities/plans in place?	Resources / Tips	Responsible Entities
2.1 Families of newborns know about the need for newborn screening.	☐ Identify pregnant women and families with newborn babies. ☐ Deliver information about newborn screening at the time the specimen is obtained or point-of-care screening is performed. ☐ Ensure families understand the information. ☐ Raise awareness of the public health functions of the State newborn screening program.		**State:** • State Health Official • Newborn Screening Program Director • State EHDI Coordinator • Title V MCH program • State Hospital Preparedness Director **Local:** • Jurisdictional public health authority • Birthing or screening facility. • Newborn screening program • Families
2.2 Families with newborns who are screened know how to obtain newborn screening results.	☐ Provide families with information and education on how to obtain screening results. ☐ Request alternate/emergency contact information for family on the newborn screening specimen kit. ☐ Add additional contact options (healthcare provider, state health department, etc.) at the bottom of the state testing pamphlet and a statement to for parents to ask their pediatrician about newborn screening results at baby's first visit. ☐ Ensure that families know about point-of-care screening results prior to discharge. The baby with a failed CCHD screen will be evaluated prior to discharge from the hospital or birthing facility. If an infant fails a hearing screen, families should receive results and follow-up appointment information.		**State:** • State Health Official • Newborn Screening Program Director • State EHDI Coordinator • State Title V MCH program • State Hospital Preparedness Director **Local:** • Birthing or screening facility • Healthcare providers • Newborn screening program • Families
2.2 Families with newborns who are screened know how to obtain newborn screening results.	☐ Provide families with information and education on how to obtain screening results. ☐ Request alternate/emergency contact information for family on the newborn screening specimen kit. ☐ Add additional contact options (healthcare provider, state health department, etc.) at the bottom of the state testing pamphlet and a statement to for parents to ask their pediatrician about newborn screening results at baby's first visit. ☐ Ensure that families know about point-of-care screening results prior to discharge. The baby with a failed CCHD screen will be evaluated prior to discharge from the hospital or birthing facility. If an infant fails a hearing screen, families should receive results and follow-up appointment information.		**State:** • State Health Official • Newborn Screening Program Director • State EHDI Coordinator • State Title V MCH program • State Hospital Preparedness Director **Local:** • Birthing or screening facility • Healthcare providers • Newborn screening program • Families
2.3 Families know what to do in response to newborn screening results.	Assist families with appropriate course of action. o Provide families information about access to care. o Provide families with information on the potential meaning of a positive/not-pass/fail screen and need for confirmatory testing for diagnostic purposes. o If testing confirms a diagnosis, provide information on short-term follow-up and linkage to specialty care.		**State:** • State Health Official • Newborn Screening Program Director • State EHDI Coordinator • State Title V MCH program • State Hospital Preparedness Director **Local:** • Birthing or screening facility • Healthcare providers • Newborn screening program • Families

Strategic Objective 3
Screens are conducted and dried blood spot specimens are collected and transported.

Objectives	Are the following activities/plans in place?	Resources / Tips	Responsible Entities
3.1 NSQAP-certified blood spot collection cards with the ability to capture appropriate demographics that also allow follow-up are available for use by any U.S. Newborn screening program.	☐ Identify a repository of blood spot collection cards for use by any U.S. newborn screening program. ☐ Ensure cards are not expired. ☐ Facilitate redistribution of locally available cards until supplies are exhausted. ☐ Notify and activate national repository to deliver cards in anticipation of local supplies being depleted. ☐ Facilitate distribution of cards to jurisdiction. ☐ Facilitate distribution of cards to collection points.		**State:** • State Health Official • Newborn Screening Program Director • State Hospital Preparedness Director • APHL **Local:** • Jurisdictional health official or designee • Newborn screening program, in accordance with jurisdictional rules • Hospitals and other potential collection sites
3.2 Other materials required for blood spot collection, hearing screening and CCHD screening are available.	☐ Ensure availability of materials required for blood spot collection, including lancets, alcohol pads, and packaging at hospitals and other potential collection sites. ☐ Ensure availability of materials for CCHD screening, including pulse oximeters and probes designed for use in newborns, equipment and personnel for follow-up echocardiogram (on-site or by telemedicine), or identification of an alternate site with proper materials for further evaluation. ☐ Ensure availability of materials for hearing screening, such as OAE and ABR screening equipment and necessary supplies (e.g., probes).		**State:** • State Health Official • Newborn Screening Program DirectorState EHDI Coordinator • State Hospital Preparedness Director **Local:** • Hospitals and other potential collection and screening sites
3.3 A valid, adequate, or satisfactory blood spot specimen has been collected. A hearing screening is performed and CCHD screening is conducted for all eligible newborns before leaving the birthing facility.	☐ Train medical professionals who may be involved in dried blood spot collection. ☐ Train professionals who may be involved in conducting a CCHD screen on the jurisdiction's defined protocol. ☐ Train professionals who may be involved in conducting a hearing screen using physiologic measures, such as OAE and/or automated ABR testing. ☐ Collect appropriate specimens and conduct appropriate point-of-care screens. ☐ Record accurate demographics and results of point-of-care screenings (to allow complete screening, including follow-up testing). ☐ Maintain a log of all dried blood spot specimens collected or refused at the collection site. ☐ Make a decision about which laboratory to use. ☐ Identify alternate courier (if necessary) who will work in any emergency/disaster conditions (e.g., National Guard, state police, FedEx or UPS, local couriers, etc.). ☐ Inform hospitals and follow-up providers about changes in laboratory and/or couriers. ☐ Forward completed and dried blood spot specimen to shipping location. ☐ Report CCHD and hearing screening results to appropriate state program. ☐ Evaluate any newborn with a failed CCHD screen for the cause of low blood oxygen levels including CCHD prior to hospital discharge. Establish plans for transfer to another facility when indicated.		**State:** • State Health Official • State Preparedness Director • Newborn Screening Program Director • State EHDI Coordinator • Title V/MCH Director • State Hospital Preparedness Coordinator **Local:** • Hospitals and other potential collection and screening sites • Newborn screening program; state hospital preparedness coordinator • Newborn • screening • program • Hospital or • alternate • evaluation • facility

Strategic Objective 4
Specimens are shipped to the designated newborn screening laboratory site.

Objectives	Are the following activities/plans in place?	Resources / Tips	Responsible Entities
4.1 Specimens are shipped to the appropriate laboratory within 24 hours of collection.	☐ Assess the situation and the operational status of laboratories and transport system. ☐ Ship to primary laboratory, if available. Ship to secondary or tertiary laboratories when necessary. ☐ Operationalize tracking system to document chain of custody of specimens. ☐ Notify courier of any special pick-up or delivery issues (e.g., timing, or location).	*Situations you may want to consider:* ☐ Weather and need for alternate couriers ☐ Strikes by couriers ☐ Consider local and state public entities, such as the National Guard, local police and fire personnel, the State Highway Patrol, and Sheriff's Department as potential alternative couriers.	**State:** • State Health Official • Newborn Screening Program Director • State Preparedness Director • State Hospital Preparedness Director **Local:** • Jurisdictional health official • Newborn Screening Program Coordinator(s) • Public Health and Hospital Preparedness Coordinators • Hospital and other potential collection facilities • Laboratory(ies) • Local Emergency Management
4.2 Specimens en-route to impacted laboratories are redirected to alternate laboratories.	☐ Notify courier of any special pick-up or delivery issues. ☐ Contact transport system provider and execute change of address.	☐ Consider centralized courier pick-up site.	**State:** • State Health Official • Newborn Screening Program Director **Local:** • Newborn screening programs • Hospitals and other potential collection sites • Laboratory(ies) • Courier Services • Local Emergency Management
4.3 Track and identify missing specimens (including those not shipped) and obtain a new specimen, as needed.	☐ Identify missing specimens. ☐ Locate the newborn and his/her family. ☐ Collect a second specimen. ☐ Use Public Service Announcements (PSAs) to aid in advising parents of newborns affected by an emergency incident when necessary.		**State:** • State Health Official • Newborn Screening Program Director • State Hospital Preparedness Director **Local:** • Hospitals and other potential collection facilities • Laboratory (ies) • Newborn screening program staff • Health care providers • Joint Information Center (JIC)

Strategic Objective 5
Specimens are processed.

Objectives	Are the following activities/plans in place?	Resources / Tips	Responsible Entities
5.1 Laboratory capability and capacity are assessed.	☐ Assess facilities, supplies, utilities, staff, informatics, supply chain, transport systems, safety issues or working environment, and communication systems. ☐ Assess potential duration of interruption and disruption of lab capacity or service. ☐ Document assessment.	*Situations you may want to consider:* **Reagents running out/other supplies missing** **Power outage:** ☐ Back-up power (batteries, generator) ☐ Be on priority list with power company **Machines break:** ☐ Examine maintenance contracts **Personnel shortage (illness, inability to get into office, detailed elsewhere):** ☐ ID essential personnel ☐ Provide letter/card to identify essential personnel ☐ Identify back-up staff ☐ Identify emergency transportation assets	**State:** • State Health Official • Newborn Screening Program Director • State Preparedness Director • State Hospital Preparedness Director **Local:** • Jurisdictional health official • Newborn Screening Program Coordinator(s) • Public Health and Hospital Preparedness Coordinators • Hospital and other potential collection facilities • Laboratory(ies) • Local Emergency Management
5.2 Integrity of specimens and records are secured.	☐ Evaluate potential risk to specimens and records. ☐ Take appropriate corrective actions to ensure integrity of specimens and records. ☐ Make a record of damaged or compromised specimens and records.		**State:** • State Health Official • Newborn Screening Program Director **Local:** • Hospitals and other potential collection facilities • Laboratory (ies) • Newborn screening program staff • Health care providers
5.3 Structural and equipment repairs are made as indicated, if possible, to preserve or restore capacity.	☐ Contact vendors, tech support, facilities, and maintenance to determine if emergency repair support is available. ☐ Estimate time required to complete repairs. ☐ Initiate repairs as feasible. ☐ Maintain record of any repairs made.		**State:** • State Health Official • Newborn Screening Program Director **Local:** • Jurisdictional Health Official • Newborn screening program • Laboratory(ies) • Local Emergency Management
5.4 Decision is made regarding whether additional or alternative capacity is needed.	☐ Make a timely judgment whether existing resources are sufficient or if a back-up lab is needed. ☐ Identify the appropriate resources that are needed to achieve capacity.		**State:** • State Health Official • Newborn Screening Program Director **Local:** • Jurisdictional Health Official • Newborn screening program • Laboratory(ies) • Local Emergency Management
5.5 If additional capacity is needed, seek assistance or activate back-up plan.	☐ Contact APHL and NewSTEPs. ☐ Contact State Emergency Manager with recommendations on the need to activate EMAC, if applicable. ☐ Identify and contact back-up laboratory. ☐ Ensure that the back-up laboratory is CLIA approved and participates in the CDC NSQAP. ☐ Establish disorder panel needs. ☐ Identify and address or resolve major algorithm, IT, and methodological or protocol differences.	☐ Ensure the back-up laboratory tests for the same disorders as the primary laboratory, especially if crossing state lines for testing.	**State:** • State Health Official • Newborn Screening Program Director **Local:** • Jurisdictional Health Official • Newborn screening program • Laboratory(ies) • Local Emergency Management

Strategic Objective 5 Continued

Objectives	Are the following activities/plans in place?	Resources / Tips	Responsible Entities
5.6 Appropriate internal and external stakeholders (including personnel) are notified of change in process during an emergency.	☐ Notify personnel according to internal procedures. ☐ Notify external stakeholders, State Health Officer, State Title V Director, providers and sub-specialists, and the public, as needed.		**State:** • State Health Official • Newborn Screening Program Director **Local:** • Newborn screening programs • Hospitals and other potential collection sites • Laboratory(ies) • Courier Services • Local Emergency Management
5.7 A record of all dried blood spot specimens sent to and received by the back-up laboratory is maintained.	☐ All entities submitting specimens keep a log of specimens submitted. ☐ All entities receiving specimens keep a log of specimens received. ☐ When possible and as feasible, compare records of transported specimens. ☐ Identify missing specimens.		**State:** • State Health Official • Newborn Screening Program Director **Local:** • Newborn screening programs • Hospitals and other potential collection sites • Laboratory(ies) • Courier Services
5.8 A system at the back-up lab for managing external specimens from routine collections is activated.	☐ Back-up laboratories sort external specimens.		**State:** • State Health Official • Newborn Screening Program Director **Local:** • Back-up labs
5.9 Specimens are analyzed and results are reported.	☐ Analyze specimens. ☐ Report results to submitters. ☐ Report the positive results to the follow-up system. ☐ Unsatisfactory and out-of-range are reported to appropriate follow-up system. ☐ Request second specimen, if needed. ☐ Return specimen to originating state.		**State:** • State Health Official • Newborn Screening Program Director **Local:** • Back-up labs • Newborn screening program • Health care providers

Strategic Objective 6
Screening results are reported to physicians and families.

Objectives	Are the following activities/plans in place?	Resources / Tips	Responsible Entities
6.1 -6.3 Communication lines are established and utilized to ensure reporting of results.	**Between sending and receiving laboratories, hospitals, and newborn screening follow-up coordinators:** ☐ Assess options for communication among laboratories, hospitals performing CCHD and hearing screenings, and newborn screening follow-up coordinator. ☐ Formulate communication strategy. ☐ Implement strategies for communication. **Between newborn screening follow-up program and physicians/providers:** ☐ Determine if newborn screening card submitter or physician of record is available. ☐ Identify alternative provider to report results, if needed. ☐ Report result to submitter or physician of record or alternative provider. ☐ Healthcare provider confirms to newborn screening coordinator that infant is in care. **Between newborn screening program and families (if healthcare provider is not available):** ☐ Locate family. ☐ Inform family of newborn screening results and need for additional care. ☐ Link family to healthcare provider, ultimately a primary care provider/medical home.	*To address variability in how results are reported, consider:* ☐ Discussing data definitions, reporting verbiage and interpretations when formulating communications strategy. *If database for laboratory is unavailable, consider:* ☐ Developing alternate method to report results to short term follow-up and to health care providers. *If contact numbers for healthcare providers and specialists are electronic only:* ☐ Develop and maintain alternate method to store contact information for healthcare providers and sub-specialists.	**State:** • State Health Official • Newborn Screening Program Director • State EHDI Coordinator • Title V MCH program • Emergency management **Local:** • Newborn screening program • Healthcare provider • Newborn screening follow-up coordinator • Families • Emergency management

Strategic Objective 6 Continued

Objectives	Are the following activities/plans in place?	Resources / Tips	Responsible Entities
6.4 All screening specimens and results are tracked.	☐ Develop a registry of specimens collected, and hearing and CCHD screens performed or refused. ☐ Record all results – positive, not-pass/fail, unsatisfactory, pass, and negative – in registry. ☐ Resolve all open newborn screening follow-up cases.		**State:** • State Health Official • Newborn Screening Program Director • State EHDI Coordinator • State Title V MCH program **Local:** • Hospitals and other potential collection and screening sites • Health care providers • Newborn screening follow-up coordinator
6.5 Infants who are not screened are identified.	☐ Match screening records with birth records to identify infants not screened. ☐ Contact families of infants who did not receive newborn screening.	*Depending on the emergency event and systems impacted, getting birth records could be difficult. Consider:* ☐ Documenting alternative approaches *To contact families, consider:* ☐ PSAs for those who did not know if their baby was screened to call a hotline where the data can be queried to see if the baby was actually screened and valid results were obtained. ☐ Consider PSAs in your state and surrounding states which residents may relocated.	**State:** • State Health Official • Newborn Screening Program Director • State EHDI Coordinator • State Title V MCH program **Local:** • Hospitals and other potential collection and screening sites • Newborn screening program • Vital Records • Newborn screening follow-up coordinator

Strategic Objective 7
Diagnostic testing is performed for infants with urgent positive screening results.

Objectives	Are the following activities/plans in place?	Resources / Tips	Responsible Entities
7.1 Appropriate diagnostic testing occurs and is tracked in a timely way.	☐ Healthcare provider consults with appropriate sub-specialist. ☐ Identify indicated diagnostic test(s) and laboratories. ☐ CCHD should be ruled out by a medical evaluation, which may include the use of diagnostic echocardiography that may involve transport to another facility if the birthing hospital is not equipped with echocardiography or telemedicine. ☐ Collect and send samples to diagnostic laboratories. ☐ Report infants not passing the hearing screening to the state EHDI program along with information about if and to whom a referral was made. ☐ Report diagnostic test results to appropriate healthcare professionals, sub-specialists, designated state programs, or sample submitters.	*Situations you may want to consider:* Database for documentation of short term follow-up is unavailable. Cannot access LIMS remotely. **Consider:** ☐ Developing an alternate plan to document follow-up actions until database is re-established. ☐ Transport issues for family to get to clinics for follow-up. If access is an issue, consider telehealth options as needed, if available.	**State:** • State Health Official • Newborn Screening Program Director • State EHDI Coordinator • Title V MCH program **Local:** • Healthcare provider(s) • Newborn screening follow-up coordinator Laboratory(ies)
7.2 Diagnosis is established.	Healthcare provider and sub-specialist confer regarding diagnostic test results and establish diagnosis, as appropriate. ☐ Identify and conduct additional diagnostic evaluations, as appropriate. ☐ Communicate results to family. ☐ Notify newborn screening program of results and diagnosis.		**State:** • State Health Official • Newborn Screening Program Director • State EHDI Coordinator • Title V MCH program **Local:** • Healthcare provider(s) • Newborn screening follow-up coordinator • Families

Strategic Objective 8
Availability of treatment and management resources is ensured.

Objectives	Are the following activities/plans in place?	Resources / Tips	Responsible Entities
8.1 Appropriate treatment and services are identified for infants with a confirmed diagnosis.	☐ Identify a primary care provider and specialist(s). ☐ Appropriate healthcare provider and sub-specialist confer and discuss treatment recommendations and services and discuss with family. ☐ Provide acute or urgent care, if needed. ☐ Ensure infants identified with hearing loss are referred to the state early intervention (Part C) program. ☐ Confirm each child's access to and connection with a medical home.	• In an emergency, it can be challenging to identify or confirm a medical home. Once the immediate situation resolves, the need for a reconnection to a medical home can be emphasized. • The medical home is the source for a complete and accessible record of a baby's medical history and can provide this information in an emergency. • Consider telehealth options as needed, if available.	**State:** • State Health Official • Newborn Screening Program Director • State EHDI Coordinator • Title V MCH program **Local:** • Healthcare provider(s) • Newborn screening follow-up coordinator • Laboratory(ies) • Families
8.2 Infants with diagnoses receive appropriate multidisciplinary services through an established medical home.	☐ Establish a mechanism to track affected displaced populations. ☐ Initiate chronic condition management. ☐ Initiate care coordination between primary care provider and specialist(s). ☐ Refer to State Title V health department, CYSHCN services, early intervention and/or community-based organization(s), and local resources to ensure access to needed services and family support. ☐ Develop a treatment plan. ☐ Facilitate access to counseling and social services. ☐ Facilitate access to medical foods, pharmaceuticals, and devices. ☐ Establish reimbursement mechanisms for services. ☐ Ensure these efforts and plans are connected to the State CYSHCN and/or long term follow-up program, where such follow-up programs exist.	*Consider reaching out to the following partners:* ☐ WIC ☐ Family Voices (health insurance concerns) ☐ P2PUSA for emotional support through state Parent-to-Parent organization ☐ Metabolic centers ☐ Medical food vendors ☐ Pharmaceutical vendors	**State:** • State Health Official • Newborn Screening • Program Director • State EHDI Coordinator • Title V MCH program **Local:** • Jurisdictional public health authority • Newborn screening follow-up coordinator • Healthcare providers • Local pharmacies • Medical food manufacturers • Non-governmental organizations • Emergency Mgmt.

Strategic Objective 9
Carry out other activities determined appropriate by the HHS Secretary.

Objectives	Are the following activities/plans in place?	Resources / Tips	Responsible Entities
9.1 Preparedness issues are identified and addressed for NBS systems.	☐ Establish and maintain a national blood spot collection card repository communication strategy. ☐ Establish contingency plans for transfer of care (for affected individuals) from one health care system to another. ☐ Educate families about the need for individualized emergency response plans. ☐ Search the NBS contingency plan for instructions to "activate" various mechanisms and make sure those mechanisms have already been established and are in place. ☐ Develop and follow a plan to periodically hold drills or practice the NBS contingency plan. ☐ Establish communications with state EMAC (i.e., each NBS program should establish these communication channels). ☐ Assess the NBS emergency operations plans that states have developed, and maintain an electronic library of such documents. ☐ Develop the mechanism or ability to assist with information, data, or results management among states for NBS systems. ☐ Establish relationships (among jurisdictions) related to mutual aid for NBS systems.		**Federal:** • HHS **State:** • State Health Official • Newborn Screening Program Director • State EHDI Coordinator • Title V MCH program • State Hospital Preparedness Director • State Preparedness Director • State Emergency Management Director or designee **Local:** • Jurisdictional public health authority • Newborn screening program • Hospital Incident Command Staff • Birthing Facilities • Laboratory(ies) • Local Emergency Management
9.2 –Implementation, maintenance, and validation of the NBS contingency plan are performed by HHS.			**Federal:** • HHS

Appendix B:

Model Memorandum of Understand/Agreement (MOU/MOA)

MODEL MEMORANDUM OF UNDERSTANDING
(Some states prefer Memoranda of Agreements)
Between
State A Department of Health and
State B Department of Health

Purpose
This Memorandum of Understanding (MOU) is being established between State A Department of Health and State B Department of Health to provide reciprocal coverage, to the extent facilities and materials are available, for each other in the case of natural disasters, terrorism, or other emergencies that could temporarily cause a discontinuation of laboratory services to the citizens of the state.

Emergency Support Services
State A and State B agree to provide, on a temporary basis, laboratory support services to each other and/or permit the affected Laboratory's staff to work in the other's public health laboratory to perform testing in the event of a natural disaster, terrorist event, or other emergency that could close down mission critical functions of State A or State B.
Laboratory services provided on a temporary basis means no more than four (4) weeks of continuous service for a single occurrence, unless the parties mutually agree in writing to extend the time period. Where appropriate, laboratory staff from the affected laboratory may be assigned to work in the public health laboratory that is designated to provide the support service s. Assigned employees will comply with rules and regulations of the support laboratory.

Funding
The state laboratory that is confronted with a temporary emergency caused by a disaster agrees to reimburse at a reasonable cost the laboratory providing the support services for the cost of reagents, supplies, reproduction of laboratory reports, telephone costs, and shipping and postage fees upon submission of an itemized invoice.

Transportation and Delivery of Specimens or Samples
It shall be the responsibility of the state laboratory confronted with the emergency to arrange for transport of specimens or samples to the laboratory providing support services or space for laboratory testing.

Chain of Custody
All samples or specimens and physical evidence received under chain of custody will be maintained under secure conditions during storage, testing, and retention of evidence until the case is resolved. Laboratory staff involved in receipt of samples or specimens, or storage and testing agree to respond to court-ordered subpoenas related to these samples or specimens and to testify in court if necessary. The state agency or attorney(s) who requested the subpoenas will pay for all expenses associated with court appearances. Disposal of samples or specimens and physical evidence received under chain of custody must be approved in writing by the submitter or returned to the submitter for disposal.

Contact Persons
A contact person will be identified for laboratory testing in the cooperating laboratories named in this MOU to allow immediate interaction, assessment of the situation, and appropriate arrangements necessary for the unimpeded flow of services. The contact persons for each laboratory will be the Laboratory Director whose signature is on this MOU or his/her successor or designated representative.

Liability
Nothing in this MOU will create any right of indemnification for the benefit of either party, and each party shall be responsible for its conduct as provided by law. Nothing in this MOU will be deemed to waive any immunity available to either party, including sovereign immunity.

Terms and Termination
Subject to any rights of termination hereinafter set forth, this MOU shall become effective immediately upon all parties signing and shall remain valid for 12 months. This MOU may be reviewed, and it may be renewed annually.
This MOU may be terminated by either party with or without cause upon thirty (30) days advance written notice. This MOU shall not be altered, changed, modified, or amended except by written consent of all parties to the MOU.

Signatories
The signatories of this Memorandum of Understanding will be responsible for activating this MOU whenever a disaster occurs in the Public Health Laboratory operation.

For their respective State Laboratories:

_____	_____
Laboratory Director	Laboratory Director
Date: _____	Date: _____

For the State Agencies:

_____	_____
Commissioner Department of Health	Commissioner Department of Health
Date: _____	Date: _____

Appendix C:
Acronyms

AAP ..... American Academy of Pediatrics
ACC..... American College of Cardiology
ACMG ..... American College of Medical Genetics
AHCP ..... Appropriate Health Care Provider
AMCHP..... Association of Maternal & Child Health Programs
APHL ..... Association of Public Health Laboratories
ASTHO ..... Association of State and Territorial Health Officials
CCHD..... Critical Congenital Heart Defect
CDC ..... Centers for Disease Control and Prevention
CLIA..... Clinical Laboratory Improvement Amendments
COCA ..... Clinician Outreach and Communication Activity
COOP ..... Continuity of Operations Plan
CONOPS..... Concept of Operations
CONPLAN ..... Contingency Plan
CYSHCN ..... Children &Youth with Special Health Care Needs
OPHPR ..... Office of Public Health Preparedness and Response
DBS..... Dried Blood Spot
DCIRs..... CDC Director's Critical Information Requirements
DOH..... Department of Health
EHDI ..... Early Hearing and Detection and Intervention
EMAC..... Emergency Management Assistance Compact
FEMA..... Federal Emergency Management Agency
NCBDD ..... National Center on Birth Defects and Developmental Disabilities
HCP ..... Health Care Provider
HIT..... Health Information Technology
HHS ..... U.S. Department of Health and Human Services
HRSA ..... Health Resources and Services Administration
LRN..... Laboratory Response Network
MCH ..... Maternal Child Health
MCHB ..... Maternal and Child Health Bureau
MOA ..... Memoranda of Agreement
MOU..... Memoranda of Understanding
NBS ..... Newborn Screening
NCBDDD ..... National Center on Birth Defects and Developmental Disabilities
NCC ..... National Coordinating Center (Regional Genetic and Newborn Screening Collaboratives)
NDMS..... National Disaster Medical System
New STEPs ..... Newborn Screening Technical assistance and Evaluation Program
NGO ..... Nongovernmental Organization
NSQAP ..... CDC's Newborn Screening Quality Assurance Program
PH..... Public Health
POR ..... Physician of Record
PSA..... Public Service Announcement
SOP ..... Standard Operating Procedure
U.S. ..... United States of America
USERRA..... Uniformed Services Employment and Reemployment Rights Act
VOIP ..... Voice Over Internet Protocol

Appendix D:
Additional Resources

This appendix contains resources, templates, case studies, state examples and other information that may be helpful to states developing, updating, and/or implementing their newborn screening contingency plans. This list is neither comprehensive nor exhaustive.

Additional Background Resources
Emergency Management Assistance Compact (EMAC) – Background Resources:

- Overview: https://www.fema.gov/pdf/emergency/nrf/EMACoverviewForNRF.pdf
  EMAC's 13 Articles: https://www.leg.state.nv.us/nrs/NRS-415.html
- **Emergency Preparedness for Children with Special Health Care Needs.** (Website) American Academy of Pediatrics. Available from: https://www2.aap.org/advocacy/emergprep.htm
- **Planning & Record Keeping > Emergency Preparedness for Children with Special Needs.** (Webpage). Seattle Children's Center for Children with Special Needs. Available from: http://cshcn.org/planning-record-keeping/emergency-preparedness-for-children-with-special-needs/
- **Preparedness for Pediatric Practices – Newborn Screening in Emergencies.** American Academy of Pediatrics. Available from: https://www.aap.org/en-us/Documents/disasters_newborn_screening_handout.pdf
- **Public Health Preparedness Tools.** (Website) Agency for Healthcare Research and Quality, U.S. Dept. of Health and Human Services. Available from: http://archive.ahrq.gov/prep/.
- **Women, Infants and Children (WIC) - Detailed Policy Guidance in Disaster Situations.**
  Available from: http://www.fns.usda.gov/wic/detailed-policy-guidance-disaster-situations

Case Examples:

- **Genetic/metabolic health care delivery during and after hurricanes Katrina and Rita** - Andersson HC, Narumanchi TC, Cunningham A, Bowdish B, Thoene J. Available at: http://www.ncbi.nlm.nih.gov/pubmed/16311054
- **New Jersey Prioritizes Newborn Screening Program in the Face of Hurricane Sandy.** Association of State & Territorial Health Officials. Available at: http://www.astho.org/Maternal-and-Child-Health/New-Jersey-Prioritizes-Newborn-Screening-Program-During-Hurricane/
- **"Lab technician braves blizzard for results that save newborn's life"** (2015, WCBV.com) – news story highlighting importance of contingency planning during a blizzard in Massachusetts: http://www.wcvb.com/health/lab-technician-braves-blizzard-for-results-that-save-newbornslife/31879152?absolute=true&utm_source=dlvr.it&utm_medium=twitter&utm_campaign=wcvb

State Examples and Templates:

- The Heartland NBS Back-up Testing and Quality Assurance Project – 2012 Poster
- Missouri Newborn Screening Laboratory Emergency Response Plan – 2010
- Southeast Regional Genetics Collaborative Emergency Management Strategic Plan
- Income Contract Template (Word Document) - editable example of a state income contract, which could be used to contract with another state's laboratory in situations that may not be deemed a state emergency.
- Sample Emergency Management Assistance (EMAC) Interstate Mutual Aid Request for Assistance – Newborn Screening Example, Kansas

Appendix E:
References

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- SIMD Position Statement: Identifying abnormal newborn screens requiring immediate notification of the health care provider, 2014. Society for Inherited Metabolic Disorders. Available from: http://www.simd.org/Issues/index.asp.
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Appendix F:
CONPLAN Update Advisory Committee Members 2015-16

2015-16 Newborn Screening Contingency Plan Update

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