

**Memorandum of Agreement
Between
The Florida Department of Health, Newborn Screening Program
And
The Texas Department of State Health Services, Newborn Screening Program
Regarding
The Continuity of Operations Plan (COOP)**

THIS MEMORANDUM OF AGREEMENT is entered into between the Florida Department of Health, Newborn Screening Program, located at 1217 Pearl Street, Jacksonville, Florida 32202 and the Texas Department of State Health Services, Newborn Screening Program, located at 1100 W. 49th St., Austin, Texas, 78756.

I. Scope of Services

A. Program Definitions.

1. Newborn Screening (NBS) - One or more tests to identify a newborn that may be at risk of having a disorder on the screening panel of either state.
2. Newborn screening specimen - Dried blood spot (DBS) sample used for newborn screen testing that consists of drops of blood collected on a specialized filter paper collection device. Other equivalent terms used include blood spot card, dried blood spot specimen, or blood spot.
3. Newborn Screening data (data) - Includes demographic information received on the NBS specimen collection form, the NBS test results, diagnosis and follow-up case data compiled as part of the clinical coordination of care of individual children (i.e. with positive NBS test results).
4. Unsatisfactory Specimen – a specimen that cannot be tested for one or more conditions.

B. Florida Specific Definitions

1. Florida Newborn Screening Follow-Up Program - The statewide program administered by Children's Medical Services by which all newborns with abnormal newborn screening test results are tracked and referred for appropriate follow-up and treatment if necessary.
2. Presumptive Positive Newborn Screening Test Result – A value outside of the anticipated range set for each test, indicating the importance of promptly referring the baby to a Children's Medical Services Referral Center for evaluation and diagnostic and confirmatory testing.
3. Borderline Result - A test result that is outside of the expected range of testing established for a particular condition, which the Florida Newborn Screening Follow-Up Program protocol requests a repeat specimen be collected.
4. Confirmatory testing – Testing that must be performed by the Children's Medical Services Referral Centers, on any infant identified through the Florida Newborn Screening Follow-Up Program with a presumptive positive newborn screening result, in order to diagnose the infant with a disorder or as normal.
5. Children's Medical Services Referral Centers - A facility designated by Florida Children's Medical Services through a contract or memorandum of agreement

as having a program specifically designed to provide evaluation, diagnostic and treatment services as well as counseling and education to families of newborns with presumptive positive newborn screening results.

C. Texas Specific Terms–

1. Clinical Care Coordination - The Texas Department of State Health Services Unit that provides linkage of children with out-of-range newborn screen results to medical resources, including primary and subspecialty care. The Unit provides short-term follow up for children with out-of-range results and long term follow up for children with confirmed diagnoses.
2. Follow-up – Notification of medical providers of out-of-range newborn screen results and tracking of the infant until confirmatory testing either clears infant of condition or confirms diagnosis. For confirmed diagnosis, long-term tracking of infant's medical course is included.
3. Panic Value Result – A laboratory value that is significantly out-of-range and is likely to require immediate medical intervention for the infant.
4. Borderline Result - A laboratory value that is minimally out-of-range.
5. Referral Center – Subspecialty medical providers who have expertise in the conditions that are identified by newborn screening (eg. metabolic, endocrine, hematology, and cystic fibrosis centers).

D. General Description

1. General Statement: The purpose of this Agreement is to provide a Continuity of Operations Plan ("COOP") framework and initial scope of work in the event that either state's newborn screening program is unable to perform its statutorily required duties related to laboratory testing and follow-up services due to any naturally occurring or man-made disaster or catastrophic information technology failure. The ability to exercise the plan is also covered by this agreement.
2. Authority:
 - a. The Florida Department of Health, Newborn Screening Program (hereinafter referred to as "Florida") is required to perform newborn screening in accordance with § 383.14, Florida Statutes. (<http://www.flsenate.gov/laws/statutes/2010/383.14>)
 - b. The Texas Department of State Health Services, Newborn Screening Program (hereinafter referred to as "Texas") is required to perform Newborn Screening, in accordance with Texas Health and Safety Code, Chapter 33. (<http://www.statutes.legis.state.tx.us/Docs/HS/pdf/HS.33.pdf>)
 - c. In addition any mutual aid agreement is required to be in accordance with the Texas Health and Safety Code, Chapter 12, Section 12.01221. (<http://www.statutes.legis.state.tx.us/Docs/HS/htm/HS.12.htm#12.01221>)

II. **Term**

This Agreement shall be effective from date of signed agreement through August 31, 2017.

A. Renewal

At the end of the five-year term a review, update, and a written renewal will be processed if the need remains and the parties so-agree.

B. Termination at Will

Either party may unilaterally terminate this Agreement with advance 30-day written notice. This contract may be terminated by either party, without cause, upon such written notice to the other party. Said notice shall be delivered by certified mail, return receipt requested, or in person with proof of delivery.

III. Request for Assistance

A. Emergency or Disaster: Either party threatened with impact from an impending or existing emergency or disaster either natural or man-made that precludes that party's laboratories from conducting analysis of newborn screening tests and/or to provide follow-up services required by law, may request assistance from the other party under this MOA to accomplish its statutory duties.

B. Exercise: Either party may request that a test run (COOP exercise) of this framework be executed to identify successes and gaps in the plan, provided that no patient record, patient identifying information or information that meets the definition of "protected health information", at 45 CFR § 160.103 will be provided as part of a test under this paragraph, without the express written consent of the patient or patient's legal representative.

IV. Scope of Work and Service Tasks

Exact services (participation level/activities) of parties will be determined at the time of the event based on the extent of assistance requested. The party in need of assistance shall notify the other party in writing of its request for assistance and shall identify in such notice the type of assistance required.

A. Specimen transportation/delivery is the responsibility of the state laboratory confronted with the emergency to arrange for transport of specimens/samples to the laboratory providing services.

B. In the event of an emergency rendering Texas unable to perform newborn screening tests, Florida shall provide the following services on an as-needed basis:

1. Receive newborn screening specimens and provide testing for all disorders tested in Florida at the time of the event. List of current disorders can be found at:

http://www.doh.state.fl.us/cms/NewbornScreening/35_screened_disorders.doc.

2. Report laboratory results as detailed at the time of the emergency.

C. In the event of an emergency rendering Texas unable to perform follow-up services, Florida shall provide follow-up service as specified in the protocol

documents separately developed and maintained by the TX/FL COOP planning team.

- D. In the event of an emergency rendering Florida unable to perform newborn screening tests, Texas shall provide the following services on an as-needed basis:
 - 1. Receive newborn screening specimens and provide testing for all disorders tested in Texas at the time of the event. List of current disorders can be found at <http://www.dshs.state.tx.us/newborn/quickreference.shtm>.
 - 2. Report laboratory results as detailed at the time of the emergency.
- E. In the event of an emergency rendering Florida unable to perform follow-up services, Texas shall provide follow-up service as specified in the protocol documents separately developed and maintained by the TX/FL COOP planning team.

V. Confidentiality

- A. All activities taken as part of this agreement involving any specimens or data which contain any information that directly or indirectly allows the linkage of a blood spot or data derived from the NBS blood spot back to the child or the parents of the child from which the specimen was collected will adhere to the federal Health Insurance Portability and Accountability Act (HIPAA) and the regulations issued by the United States Department of Health and Human Services under the Act, including the HIPAA security and privacy regulations (45CFR Parts 160, 162, and 164), and will also comply with the applicable state confidentiality laws concerning those specimens/data (eg. specimens/data from Texas infants must be handled in a manner consistent with Texas Health & Safety Code Sec. 33.017).
- B. Specimens and data will only be used for purpose of newborn screening tests and follow-up. A state conducting activities under this MOA on behalf of the other state will not allow any research to be conducted on the specimens and/or associated data, nor will it allow any external entity to utilize the specimens for quality assurance/quality control purposes.
- C. All specimens, demographic entry forms and data will be returned to the state receiving services. The timeline for return will be determined during or near the end of the event period.

VI. Reimbursement

The party in need of assistance bears any and all fiscal responsibility for the cost of services provided to it. It is the responsibility of the party in need of assistance to apply for all state and federal aid reasonably available to it.

Unless otherwise specified in this document, the reimbursement will be set at current market value to cover the services provided during the event.

Details of reimbursement will be determined at the time of the event.

VII. Subcontracts

Neither party shall subcontract for the services provided under this contract without the express advance written approval of the other party.

VIII. Liability

Each party agrees to be responsible for the negligence of its employees when acting within the scope of their employment, and agrees to be liable for damages resulting from said negligence to the extent permitted by law. Nothing herein is intended to serve as a waiver of sovereign immunity by any provider to whom sovereign immunity may be applicable. Nothing herein shall be construed as consent by a state agency or political subdivision of the State of Florida or the State of Texas to be sued in any matter arising out of this agreement.

IX. Modification

Neither this Agreement, nor any provision hereof, may be amended or otherwise modified, except by a written instrument signed by all parties hereto.

X. Notice

Any notices given by either party to the other party under this Agreement shall be in writing. Notice will be provided to the following addresses:

Florida: Florida Department of Health
Newborn Screening Program
1217 Pearl Street
Jacksonville, Florida 32202

Texas: Texas Department of State Health Services
Newborn Screening Program
PO Box 149347
Austin, Texas, 78714-9347.

XI. Authorizing Signatures:

IN WITNESS THEREOF, the parties hereto have caused this ___ page Agreement to be executed by their officials thereunto duly authorized.

2012-040232-001

STATE OF FLORIDA

Florida Department of Health

SIGNED

BY: 

NAME: Susanne R. Crowe, MHA
Interim Chief
TITLE: Bureau of Public Health Laboratories
Florida Department of Health

DATE: February 11, 2013

STATE OF TEXAS

Texas Department of State Health
Services

SIGNED

BY: 

NAME: Bob Burnette, CPM, CTPM
TITLE: Director
Client Services Contracting Unit

DATE: 2-27-13