STATE OF CONNECTICUT PROCUREMENT NOTICE

Request for Proposals (RFP)
Connecticut Newborn Screening Program

DPH RFP Log#: 2023-0901-0

RFP Name: Newborn Screening Program (NBS) RFP for the Provision of Diagnostic and Treatment Services and Long-term Follow-Up

Issued By:
Connecticut Department of Public Health
January 14, 2022

The Request For Proposal is available in electronic format on the State Contracting Portal by filtering by Organization for Department of Public Health https://portal.ct.gov/DAS/CTSource/BidBoard or from the Agency's Official Contact:

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The RFP is also available on the Department's website at http://www.ct.gov/dph/rfp

RESPONSES MUST BE RECEIVED NO LATER THAN

March 15, 2022 at 4:30 p.m. EST

The Connecticut Department of Public Health is an Equal Opportunity/Affirmative Action Employer.

The Agency reserves the right to reject any and all submissions or cancel this procurement at any time if deemed in the best interest of the State of Connecticut (State).

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I. GENERAL INFORMATION

A. INTRODUCTION

1. **RFP Name and Number.** DPH RFP Log#: 2023-0901-0 - Newborn Screening Program (NBS) RFP for the Provision of Diagnostic and Treatment Services and Long-term Follow-Up.

2. **RFP Summary.** The Connecticut (CT) Department of Public Health (DPH) Newborn Screening (NBS) program is seeking proposals from CT Medical Centers to respond to reports of presumptive positive results from CT NBS for infants who screen positive for metabolic, endocrine, hematologic, immunologic, peroxisomal, lysosomal, neuromuscular and other genetic disorders and to provide a comprehensive program that includes diagnostic and treatment services and care coordination for each infant with a presumptive positive result and long-term follow-up through the age of 21 for each infant who confirms positive for a disorder detected by NBS. The selected hospital/medical center will also provide direct consultation to the NBS program on the addition of new tests to the screening panel, the implementation of new testing platforms, the interpretation of newborn screening results (at the individual and population level) and assistance with improving the positive predictive value of screening tests. A total of $ 1,797,531 is available to support up one (1) award for a (3) year period from 7/1/2022 to 6/30/2025, with the opportunity to renew the contract for an additional two (2) year period subject to the availability of funds and satisfactory program performance.

3. **RFP Purpose.** NBS programs identify infants with potentially serious disorders who generally appear normal at birth but have an inherent condition that can lead to disability or death without intervention. U.S. NBS programs are very successful in identifying and preventing disability/death in of thousands of infants per year. The CT NBS Program began in 1964 with testing for one disorder, Phenylketonuria (PKU). As of 2021, the CT NBS Program is able to detect up to 70 different disorders through bloodspot screening. In 2019 alone, CT NBS screened 35,485 newborns and reported 400 presumptive positive results to the Connecticut Newborn Diagnosis and Treatment Network (the Network) for Follow-Up. This resulted in confirmation of a disorder in 83 infants. In addition, 947 newborns were identified with a Hemoglobin (Hb) trait in 2019. Newborn screening is not diagnostic. The medical center providing diagnostic and treatment services will work with the infant's family and medical provider to begin the diagnostic evaluation and will either confirm or rule out the disorder and will initiate treatment and long-term follow-up (LTFU) services for children diagnosed with a disorder.

4. **Commodity Codes.** The services that the Agency wishes to procure through this RFP are as follows:

   0098: Medical Services or Medical Testing Services
   0600: Services (Professional, Support, Consulting and Misc. Services)
   1000: Healthcare Services
   2000: Community and Social Services
   3000: Education and Training

B. INSTRUCTIONS

1. **Official Contact.** The Agency has designated the individual below as the Official Contact for purposes of this RFP. The Official Contact is the **only authorized contact** for this procurement and, as such, handles all related communications on behalf of the Agency. Proposers, prospective proposers, and other interested parties are advised that any communication with any other Agency employee(s) (including appointed officials) or personnel under contract to the Agency about this RFP is strictly prohibited. Proposers or prospective proposers who violate this instruction may risk disqualification from further consideration.

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   Katherine A. Kelley State Public Health Laboratory
   395 West Street
   Rocky Hill, CT 06067
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   E-Mail: Marie.Burlette@ct.gov

   Please ensure that e-mail screening software (if used) recognizes and accepts e-mails from the Official Contact.

2. **Registering with State Contracting Portal.** Respondents must register with the State of CT contracting portal at https://portal.ct.gov/DAS/CTSource/Registration if not already registered. Respondents shall submit the following information pertaining to this application to this portal (on their supplier profile), which will be checked by the Agency contact.
   - Secretary of State recognition – Click on appropriate response
   - Non-profit status, if applicable
   - Notification to Bidders, Parts I-V
   - Campaign Contribution Certification (OPM Ethics Form 1): https://portal.ct.gov/OPM/Fin-PSA/Forms/Ethics-Forms

3. **RFP Information.** The RFP, amendments to the RFP, and other information associated with this procurement are available in electronic format from the Official Contact or from the Internet at the following locations:

   - Agency's RFP Web Page
     http://www.ct.gov/dph/rfp

   - State Contracting Portal (go to CTsource bid board, filter by Department of Public Health)
     https://portal.ct.gov/DAS/CTSource/BidBoard

   It is strongly recommended that any proposer or prospective proposer interested in this procurement check the Bid Board for any solicitation changes. Interested proposers may receive additional e-mails from CTsource announcing addendums that are posted on the portal. This service is provided as a courtesy to assist in monitoring activities associated with State procurements, including this RFP.

4. **Procurement Schedule.** See below. Dates after the due date for proposals ("Proposals Due") are non-binding target dates only (*). The Agency may amend the schedule as needed. Any change to non-target dates will be made by means of an amendment to this RFP and will be posted on the State Contracting Portal and, if available, the Agency's RFP Web Page.

- RFP Released: January 14, 2022
- Letter of Intent Due: January 28, 2022
- Deadline for Questions: February 4, 2022
- Answers Released: February 11, 2022
- Proposals Due: March 15, 2022
- (*) Proposer Selection: March 31, 2022 (on or around)
- (*) Start of Contract Negotiations: April 15, 2022 (on or around)
- (*) Start of Contract: July 1, 2022 (optional to include)

5. **Contract Awards.** The award of any contract pursuant to this RFP is dependent upon the availability of funding to the Agency. The Agency anticipates the following:

- Total Funding Available: $1,797,531
- Number of Awards: 1
- Contract Cost: $1,797,531
- Contract Term: 7/1/2022 to 6/30/2025
- Funding Source: Genetics Fund

6. **Eligibility.** Private provider organizations (defined as state or non-state entities that are either nonprofit or proprietary corporations or partnerships), are eligible to submit proposals in response to this RFP. Individuals who are not a duly formed business entity are ineligible to participate in this procurement.

7. **Minimum Qualifications of Proposers.** To qualify for a contract award, a proposer must have the following minimum qualifications:

- Proposals must be complete and comply with all requirements specified in the RFP.
- Proposers must be in good standing with the Department and have no long-standing, significant unresolved issues on current or prior contracts with the Department.
- Proposers must have:
    - Demonstrated knowledge and experience in the interpretation of NBS results considering gestational age, birth weight, and treatment that the newborn is receiving, with particular emphasis on the interpretation of tandem mass spectrometry results (MS/MS).
    - Demonstrated knowledge and experience with the diagnosis and treatment of the types of metabolic, endocrine, hematologic, immunologic, peroxisomal, lysosomal, neuromuscular and genetic conditions detected by newborn bloodspot screening including knowledge of the American College of Medical Genetics and Genomics' (ACMG) Newborn Screening ACTion Sheets and Confirmatory Algorithms (ACT Sheets).
    - Knowledge of the community/area(s) to be served including any emerging trends, population needs and service gaps.
    - Demonstrated knowledge of NBS guidelines, research and trends on the national level including, but not limited to, the Centers for Disease Control and Prevention (CDC) recommendations, ACMG recommendations, the Clinical and Laboratory Standards Institute's (CLSI) Newborn Screening Laboratory Standards and the Advisory Committee on Heritable Disorders in Newborns and Children's (ACHDNC) Recommended Uniform Screening Panel (RUSP).
    - Demonstrated population health focus as evidenced by promotion of community-oriented programs and partnerships to address the critical health needs of children.

- Demonstrated ability to execute the proposed plan of service delivery, including accounting and financial reporting systems and sound fiscal stability.
- Sufficient experienced staff, or the ability to hire or subcontract qualified personnel, to execute the proposed plan of service delivery statewide.
- Technology and infrastructure to support data entry into the web-based Connecticut Electronic Surveillance System (CT SITE), more commonly referred to as "Maven" or the "NBS Follow-Up /tracking database". The minimum hardware/software configuration is for CT Site are:
  - Operating Systems: Windows 10.
  - Browsers: the latest supported version of the mostly commonly used browsers Microsoft Internet Explorer 11, but Edge preferred, Mozilla Firefox, Apple Safari and Google Chrome. All with JavaScript and CSS enabled.
  - Connection Speed: 56.6k modem or better (High speed Internet of 1 Mbps or better recommended).
  - Screen Resolution: Minimum 1024 x 768 monitor resolution.
- The ability to send and receive secure electronic documents.

Any proposal or proposing entity not meeting these minimum requirements shall be removed from further review.

8. **Letter of Intent.** A Letter of Intent (LOI) is required by this RFP. The LOI is non-binding and does not obligate the sender to submit a proposal. The LOI must be submitted to the Official Contact by e-mail by the deadline established in the Procurement Schedule. The LOI must clearly identify the sender, including name, postal address, telephone number, and e-mail address. It is the sender's responsibility to confirm the Agency's receipt of the LOI. Failure to submit the required LOI in accordance with the requirements set forth herein shall result in disqualification from further consideration.

9. **Inquiry Procedures.** All questions regarding this RFP or the Agency's procurement process must be directed, in writing, electronically, (e-mail) to the Official Contact before the deadline specified in the Procurement Schedule. The early submission of questions is encouraged. Questions will not be accepted or answered verbally – neither in person nor over the telephone. All questions received before the deadline(s) will be answered. However, the Agency will not answer questions when the source is unknown (i.e., nuisance or anonymous questions). Questions deemed unrelated to the RFP or the procurement process will not be answered. At its discretion, the Agency may or may not respond to questions received after the deadline. If this RFP requires a Letter of Intent, the Agency reserves the right to answer questions only from those who have submitted such a letter. The Agency may combine similar questions and give only one answer. All questions and answers will be compiled into a written amendment to this RFP. If any answer to any question constitutes a material change to the RFP, the question and answer will be placed at the beginning of the amendment and duly noted as such.

   The agency will release the answers to questions on the date(s) established in the Procurement Schedule. The Agency will publish any and all amendments to this RFP on the State Contracting Portal and, if available, on the Agency's RFP Web Page. At its discretion, the Agency may distribute any amendments to this RFP to prospective proposers who submitted a Letter of Intent.

10. **RFP Conference.** An RFP conference will not be held to answer questions from prospective proposers.

11. Proposal Due Date and Time. The Official Contact is the **only authorized recipient** of proposals submitted in response to this RFP. Proposals must be received by the Official Contact on or before the due date and time:

- Due Date: March 15, 2022
- Time: 4:30 p.m.

Proposals received after the due date and time will be ineligible and will not be evaluated. The Agency will send an official letter alerting late respondents of ineligibility.

An acceptable submission must include the following:

- One (1) conforming electronic copy of the original proposal.

  The proposal must be complete, properly formatted and outlined, and ready for evaluation by the Screening Committee.

  The electronic copy of the proposal must be emailed to official agency contact for this procurement. The subject line of the email must read: NBS RFP for the Provision of Diagnostic and Treatment Services and Long-term Follow-Up. Required forms and appendices may be scanned and submitted as PDFs at the end of the main proposal document. Please ensure the entire email submission is less than 25MB as this reflects The Agency's server limitations. Respondents should work to ensure there are not additional IT limitations from the provider side.

12. Multiple Proposals. The submission of multiple proposals is not an option for this procurement.

II. PURPOSE OF RFP AND SCOPE OF SERVICES

A. AGENCY OVERVIEW

DPH is the state's leader in public health policy and advocacy, the agency is the center of a comprehensive network of public health services and is a partner to local health departments. The agency provides advocacy, training and certification, technical assistance and consultation, and specialty services such as risk assessment that are not available at the local level. The agency is a source of accurate, up-to-date health information to the Governor, the Legislature, the Federal government and local communities. This information is used to monitor the health status of Connecticut's residents, set health priorities and evaluate the effectiveness of health initiatives. The agency is focused on health outcomes, maintaining a balance between assuring quality and administrative functions among personnel, facilities and programs. DPH is a leader on the national scene through direct input to Federal agencies and the United States Congress.

The mission of DPH is: To protect and improve the health and safety of the people of Connecticut by:

- assuring the conditions in which people can be healthy
- preventing disease, injury, and disability, and

- promoting the equal enjoyment of the highest attainable standard of health, which is a human right and a priority of the state.

B. PROGRAM OVERVIEW

The Connecticut Newborn Screening (CT NBS) Program works to ensure that every newborn, who is born or resides in Connecticut, has a valid newborn screening on record and that presumptive positive screening results are promptly reported to a specialty treatment center for further evaluation and treatment when needed. These comprehensive efforts help prevent unnecessary disability and premature death.

History & Description

In 1964, the CT Newborn Screening (NBS) Program began statewide bloodspot screening for Phenylketonuria (PKU). Between 1976 and 1993, many disorders were added CT's NBS panel, including Congenital Hypothyroidism (CH), Congenital Adrenal (CAH), Maple Syrup Urine Disease (MSUD), Homocystinuria (HCY), Biotinidase Deficiency (BIO), and Hemoglobinopathies, such as Sickle Cell disease (SCD), to name a few. In May 2004, the CT NBS program implemented Tandem Mass Spectrometry (TMS) instrumentation. This technology allowed the lab to detect over 60 conditions and disorders from a few bloodspots including Amino Acid (AA), Fatty Acid Oxidation (FAO), and Organic Acid (OA) disorders. Screening for Severe Combined Immune Deficiency (SCID) was added in 2011 and screening for Adrenoleukodystrophy (X-ALD) in 2016. The three disorders most recently added CT's panel, include Spinal Muscular Atrophy (SMA) in 2020 and Pompe and Mucopolysaccharidosis type 1 (MPS-1) in 2021.

Goals of the CT NBS Program are to:

- ensure that all newborns born and/or residing in the state receive a timely, valid NBS.
- ensure that all infants with a presumptive positive NBS result receive an appropriate diagnostic work-up in a timely manner.
- ensure that infants who confirm positive for a disorder have access to appropriate treatment and follow-up services.
- prevent serious illness, permanent disability and death in affected infants.
- provide cost-effective, reliable and sensitive NBS testing.
- educate hospital and community-based HCPs, parents and the general public on the importance of NBS.
- educate hospital and community-based HCPs regarding the management of disorders identified through NBS.
- reduce disability-related health care costs in the state.
- advance the science of NBS.

Regulations:

The Connecticut Department of Public Health (CT DPH) Regulations (Sec.19a-55-1-19a-55-3) require those overseeing the medical care of newborns to collect a bloodspot specimen from each newborn infant in their care for genetic and metabolic testing as prescribed by the CT DPH, in accordance with Sec. 19a-55 of the Connecticut General Statutes. This specimen must be collected before the second day of life (48 hours of age) or as soon as medically appropriate after birth. This bloodspot specimen must be shipped to the State Laboratory or designated facility within 24 hours of collection. Birthing facilities, NICU care providers, midwives and primary care providers have a responsibility to know the NBS status of each infant in their care, and to ensure that each infant has a valid newborn screen on record. This includes infants who may not have been born in the state but reside and/or receive medical care in the state.

Current System:
In 2018, CT NBS completely restructured its system for NBS Follow-Up and entered into agreement with one diagnostic treatment center to respond to reports of presumptive positive NBS results made by CT NBS under the guidance of genetics, endocrine, hematology, immunology and neurology specialty care teams. Under this centralized system, the contractor begins the diagnostic work-up and provides support to both the family and health care team following the report of a presumptive positive result. When an infant confirms positive for a disorder, the contractor coordinates treatment and LTFU care for the condition identified, working with PCPs, hospitals and specialists statewide. Using a population health approach, the contractor established a registry for measuring, tracking, and reporting of disorder specific outcomes for infants from birth to age 21 for children who confirm positive for a disorder identified through NBS. An interface between CT NBS's Follow-Up database and contractor's electronic health record (EHR) system Epic, allows the seamless exchange of results and outcome data between the two entities. The current agreement expires on 6/30/2022.

Today, CT NBS is able to detect up to 70 different disorders through bloodspot screening. In 2019 alone, CT NBS screened 35,485 newborns and reported 400 presumptive positive results through the centralized Follow-Up system. This resulted in confirmation of a disorder in 83 infants. The following is a breakdown of presumptive positive reports by specialty group (2019):

- 269 reports to Genetics.
- 93 reports to Endocrine.
- 32 reports to Hematology.
- 6 reports to Immunology.

Additionally:

- 188 children have been added to the confirmed case registry for LTFU since its inception.
- In 2020, CT NBS began reporting presumptive positive Spinal Muscular Atrophy (SMA) results to the Neurology specialty group.
- In 2021, CT began reporting presumptive positive Pompe results to the Neurology specialty group and presumptive positive MPS-I results to the Genetics specialty group.
- An average of 935 hemoglobin traits were reported per year between 2018 and 2020, genetic counseling services are made available through the contractor as needed to families of infants identified with a hemoglobin trait.

■ C. SCOPE OF SERVICE DESCRIPTION

CT NBS is soliciting proposals from vendors (CT Medical Centers) to provide services under the centralized model of NBS follow-up that is currently in place, with a focus on building on the progress that has been made.

The selected vendor (CT Medical Center) will respond to reports of presumptive positive results from CT NBS for infants who screen positive for metabolic, endocrine, hematologic, immunologic, peroxisomal, lysosomal, neuromuscular and other genetic disorders and to provide a comprehensive program that includes diagnostic and treatment services and care coordination for each infant with a presumptive positive result an through the age of 21 for each infant who confirms positive for a disorder detected by NBS. The selected hospital/medical center will also provide direct consultation to the NBS program on the addition of new tests to the screening panel, the implementation of new testing platforms, the interpretation of newborn screening results (at the individual and population level) and assistance with improving the positive predictive value of screening tests.

1. The selected vendor (CT Medical Center) will have the knowledge and experience necessary:
    a. to interpret bloodspot screening results in light of gestational age, birth weight, and treatment that the newborn is receiving, with particular emphasis on the interpretation of tandem mass spectrometry results (MS/MS) and the use of post-analytical tools, such as the Collaborative Laboratory Integrated Reports (CLIR) developed by Mayo Clinical Laboratories.
    b. to oversee the diagnosis, treatment and follow-up of metabolic, endocrine, hematologic, immunologic, peroxisomal, lysosomal, neuromuscular and genetic conditions detected by newborn bloodspot screening.
    c. to provide culturally competent, family centered, holistic care to meet the needs of families with infants undergoing diagnostic work-up and treatment for conditions identified through NBS.
    d. to provide support to primary care providers and other community-based health care providers around the diagnosis and treatment of conditions identified through NBS.
    e. to provide access to specialists in the areas of genetics, metabolics, neonatology, immunology, endocrinology, hematology, neurology, and transplant services for children throughout the state.
    f. to coordinate care for infants who confirm positive for a metabolic, endocrine, hematologic, immunologic, peroxisomal, lysosomal, neuromuscular or genetic condition identified through NBS, including coordination of:
        i. inpatient and outpatient care.
        ii. genetic counseling.
        iii. disease education.
        iv. LTFU.
    g. to maintain a population health focus and implement community-oriented programs with a newborn screening focus.

2. When a screen positive result is reported by CT NBS the vendor's care team will consult with the infant's current primary care provider (PCP) or hospital-based medical provider (HBMP) for the purpose of:
    a. providing recommendations for care pending the results of the diagnostic work-up.
    b. recommending/referring for diagnostic work-up.
    c. arranging for evaluation the newborn by the care team as part of the diagnostic work up, when indicated.
    d. providing ongoing information/education on the screen positive condition.
    e. obtaining a family health history.
    f. assuring that the diagnostic work-up is completed.
    g. interpreting of the results of the diagnostic work-up.
    h. communicating the results of the diagnostic work-up to the PCP/HBMP and when appropriate directly to the family.

3. The selected vendor (CT Medical Center) will establish a system for care coordination for infants who confirm positive for a disorder detected through NBS. This includes making recommendations on the appropriate location(s) for the infant and family to receive Follow-Up care, taking into account considerations such as geographic location, family preference, potential barriers to care, and the institution's expertise/experience with the disorder and current and emerging treatment modalities and ability to provide:
    a. ongoing collaboration with the child's primary care provider.
    b. ongoing education about the disease process to the provider, the parent and the child/adolescent when developmentally appropriate.
    c. ongoing nutritional counseling for parents of infants identified with a metabolic disorder and the child, when developmentally appropriate.

d. appropriate treatment.
e. coordination of the evaluation of the child, as appropriate, by other specialists including but not limited to specialists in the area of genetics, metabolics, endocrinology, hematology, transplant services, neurology, and immunology.
f. psycho-social evaluation and support as needed over time.
g. support through appropriate community-based support groups such as disease advocacy groups, etc.
h. referrals for family members for appropriate genetic testing and follow-up as needed.
i. oversight of inpatient and outpatient management of the disorder throughout infancy, childhood, adolescence and young adulthood, including coordination with specialty groups.
j. identification of needs and referral to programs that can help meet the meet the psycho-social needs of the family and child, such as support groups, camps for children with special health care needs, disease advocacy groups, etc.
k. assistance to families of children with metabolic disorders identified through NBS without insurance coverage or with inadequate insurance coverage for whom the purchase of medical foods would create a financial hardship.
l. genetic counseling for the child when developmentally appropriate.
m. identification and referral to programs that can help meet the meet the psycho-social needs of the family and child, such as support groups, camps for children with special health care needs, disease advocacy groups, etc.
n. facilitation of the transition from pediatric specialty care to adult specialty care.

4. The selected vendor (CT Medical Center) will develop a establish a system to track demographic information, referrals and outcomes measures to be reported to CT NBS via the electronic NBS database and used to support short and long-term follow-up of children identified through NBS and the science of newborn screening. Information to be electronically reported to DPH includes, but is not limited to:
    a. select demographic information such as:
        - insurance coverage.
        - exclusion or confirmation of a diagnosis for every child referred through CT NBS.
        - false negative cases.
        - referral to other specialty groups including consideration for bone marrow or stem cell transplant when related to the disorder identified through NBS.
        - the name and contact information of the provider who is assuming responsibility for the on-going LTFU related to the child's condition (either PCP or specialist).
        - infants/children who are lost to follow-up at any point in the continuum of care. beginning with diagnostic work up and the reason they are lost to follow-up (for example: moved out of state, unable to make contact with family, parent refusal, etc.).
        - select disease specific outcome measures for children who confirm positive for certain disorders.
        - biochemical diagnostic results, mutational analysis diagnostic results and interpretation, and other related diagnostic testing results.

The CT NBS Program has changed from paper-based reporting system to an entirely electronic reporting system in order to increase efficiency and lessen the potential for mistakes. The selected vendor (CT Medical Center) must have the ability to send and receive secure results, outcome data and via HL7 messaging and other HIPAA

compliant electronic formats and a willingness to implement data sharing agreements with the CT NBS program and other diagnostic Treatment Centers (Yale/UConn/Connecticut Children's, etc.).

5. The selected vendor (CT Medical Center) will:
    a. establish a fund utilizing monies granted as a result of this RFP to assist established metabolic treatment programs operating in Connecticut, outside of the proposer's organization, involved in the treatment of infants, children and adolescents with metabolic disorders detected by NBS, with the provision of the following:
        - the purchase of formula and/or metabolic foods to assist families without insurance coverage or with inadequate insurance coverage for whom the purchase of medical foods items would create a financial hardship.
    b. Establish a system for tracking distribution and utilization of these funds including how many children/families receive formula supplied through the program.
    c. provide access to a board-certified biochemical geneticist who in addition to providing support to the genetics care team, will provide consultation to CT NBS on the addition of conditions to the screening panel, implementation of new testing platforms, the interpretation of newborn screening results and improving the positive predictive value of screening tests.

6. The selected vendor (CT Medical Center) will establish:
    a. Genetics Care Team(s) under the direction of a board-certified geneticist with experience in the interpretation of NBS results.
    b. Endocrine Care Team(s) under the direction of a board-certified pediatric endocrinologist.
    c. Hematology Care Team(s) under the direction of a board-certified pediatric hematologist.
    d. Immunology Care Team(s) under the direction of a board-certified pediatric immunologist.
    e. Neurology Care Team(s) under the direction of a board-certified pediatric neurologist.

■ D. PERFORMANCE MEASURES

The following performance metrics highlight key priorities that will be analyzed with providers collaboratively during the life of the contract. This is not an exhaustive list, but rather an indication of significant performance metrics of interest to The Agency. The Agency looks forward to working with providers to define additional important performance metrics.

The Contractor shall implement the program and services described herein to result in the following outcomes on behalf of clients. Outcomes must be tracked and measured by reports as required by the department.

Outcomes	Measures
The percentage of infants with a time critical NBS result whose PCP or HBCP is contacted by the care team to initiate an appropriate evaluation within 24 hours of report of the abnormal CT NBS result to the diagnostic treatment center.	95% of infants with a time critical CT NBS result have had an appropriate evaluation initiated within 24 hours of report of the NBS result to the diagnostic treatment center.
The percentage of infants with a time sensitive CT NBS result whose PCP or HBCP is contacted by the care team to initiate an appropriate evaluation within 48 hours of the report of the abnormal NBS result to the diagnostic treatment center.	95% of infants with a time sensitive CT NBS result will be evaluated within 48 hours of report of the NBS result to the diagnostic treatment center.

E. CONTRACT MANAGEMENT/DATA REPORTING

As part of the State's commitment to becoming more outcomes-oriented, the Department of Public Health, seeks to actively and regularly collaborate with providers to enhance contract management, improve results, and adjust service delivery and policy based on learning what works. Reliable and relevant data is necessary to ensure compliance, inform trends to be monitored, evaluate results and performance, and drive service improvements. As such, the Department of Public Health reserves the right to request/collect other key data and metrics from providers.

The selected contractor will:

1) implement a secure computer database to track the following:
    a. client demographics.
    b. results of diagnostic workup including the results of genetic testing.
    c. treatment(s) initiated.
    d. appointments scheduled.
    e. consultations with PCPs.
    f. distribution and utilization of state funded metabolic formulas and foods.
2) Develop an electronic interface between the Contractor's electronic health record and the Maven database for the purpose of reporting short and long-term follow-up data.
3) Report the following on an ongoing basis:
    a. all data as required by the CT DPH Policy on Collecting Sociodemographic Data.
    b. the date of diagnosis/exclusion of a disorder.
    c. information on conditions/treatments contributing to false positive CT NBS results including, but not limited to:
        i. maternal health, behavioral, medical, societal, or environmental factors.
        ii. newborn client conditions and procedures/treatments, including, but not limited to:
        iii. premature birth.
        iv. very low birth weight.

v. other existing medical conditions.

vi. parenteral nutrition.

vii. transfusions.

d. date /time of initial contact with PCP following report of abnormal result by CT NBS (updated within 30 days of contact).

e. the name of the specialty care team(s) overseeing the diagnostic workup.

f. name(s) and contact information of PCPs and other parties responsible for long term coordination of the client's medical care related to the disorder (updated as needed).

g. the insurance status of client.

h. select interventions (updated regularly) such as:

i. metabolic diet.

ii. stem cell transplant.

iii. gene therapy.

iv. enzyme replacement therapy.

v. hydroxyurea therapy.

vi. other disorder specific treatments (to be determined).

vii. referrals made to a specialist in the medical field of the identified disorder.

viii. genetic counseling received.

4) report the following aggregate data to the CT NBS three times per year in accordance with the reporting schedule, including:

a. number of infant clients with a time critical NBS result whose PCP or HBCP is contacted by the care team to initiate an appropriate evaluation:

i. within 24 hours of initial report of abnormal NBS result to the diagnostic treatment center.

ii. within 48 hours of initial report of abnormal NBS result to the diagnostic treatment center.

iii. greater than 48 hours of initial report of abnormal NBS result to the diagnostic treatment center.

b. number of infant clients with a time sensitive NBS result whose PCP or HBCP is contacted by the care team to initiate an appropriate evaluation:

i. at 48 hours or less of initial report of abnormal NBS result to the diagnostic treatment center.

ii. between 3-5 days of initial report of abnormal NBS result to the diagnostic treatment center.

iii. greater than 5 days of initial report of abnormal NBS result to the diagnostic treatment center.

c. number of new confirmed cases referred by the diagnostic treatment center for follow-up to each specialty care team.

d. number of new confirmed cases evaluated by a registered dietitian of each specialty care team.

e. number of new confirmed cases receiving genetic counseling by each specialty care team.

f. Details of each false negative case.

5) report the following aggregate data and information to the CT NBS annually, in accordance with the reporting schedule:

a. number of infant clients identified through CT NBS.

b. whose parents refused initial diagnostic testing.

c. whose follow-up was managed out of state.

d. who were lost to follow-up prior to diagnosis/exclusion of a disorder.

e. who were lost follow-up following confirmation of a disorder.

f. morbidity/mortality statistics related to specific disorders identified through CT NBS by specialty care team.

g. number and age of infant/child clients treated by each specialty care team who received:

i. free or reduced cost metabolic formula/foods made available as a result of this contract.

ii. travel assistance.

iii. total cost of metabolic formula/foods provided to families as a result of this contract.

h. number of infant clients who have the following insurance coverage:

i. state sponsored insurance.

ii. private insurance.

iii. no insurance.

i. number of calls for consultation made by:

i. HBMPs.

ii. by PCPs.

iii. by parents.

j. number of PCP and HBMP requests for consultation received by specialty care team s following identification of a hemoglobin trait through CT NBS.

6) Provide a narrative of:

a. new program activities.

b. family centered services provided to clients.

c. educational activities provided to clients, client families, practitioners, and other stakeholders.

d. quality assurance activities undertaken.

III. PROPOSAL SUBMISSION OVERVIEW

A. SUBMISSION FORMAT INFORMATION

1. **Required Outline.** All proposals must follow the required outline presented in Section IV – Proposal Outline. Proposals that fail to follow the required outline will be deemed non-responsive and not evaluated.

2. **Cover Sheet.** The Cover Sheet is Page 1 of the proposal. Proposers must complete and use the Cover Sheet form provided by the Agency in the Appendix.

3. **Table of Contents.** All proposals must include a Table of Contents that conforms with the required proposal outline.

1. **Executive Summary.** Proposals must include a high-level summary, not exceeding 1 page, of the main proposal and cost proposal. The summary must also include the organization's eligibility and qualifications to respond to this RFP.

5. **Attachments.** Attachments other than the required Appendices or Forms identified in the RFP are not permitted and will not be evaluated. Further, the required Appendices or Forms must not be altered or used to extend, enhance, or replace any component required by this RFP. Failure to abide by these instructions will result in disqualification.

5. **Style Requirements.**
   - Include *the following language: THIS IS AN ELECTRONIC SUBMISSION.*
   - Page Limit: 30 pages maximum. Required forms and attachments do not count towards page limit
   - Font Size: No smaller than 11-point type
   - Font Type: Arial, Times New Roman, Verdana or Calibri
   - Margins: No less than 0.5" top, bottom, left and right margins
   - Line Spacing: 1.0 line spacing

7. **Pagination.** The proposer's name must be displayed in the header of each page. All pages, including the required Appendices and Forms, must be numbered in the footer.

9. **Declaration of Confidential Information.** Proposers are advised that all materials associated with this procurement are subject to the terms of the Freedom of Information Act (FOIA), the Privacy Act, and all rules, regulations and interpretations resulting from them. If a proposer deems that certain information required by this RFP is confidential, the proposer must label such information as CONFIDENTIAL prior to submission. In subsection C of the proposal submission, the proposer must reference where the information labeled CONFIDENTIAL is located in the proposal. *EXAMPLE: Section G.1.a.* For each subsection so referenced, the proposer must provide a convincing explanation and rationale sufficient to justify an exemption of the information from release under the FOIA. The explanation and rationale must be stated in terms of (a) the prospective harm to the competitive position of the proposer that would result if the identified information were to be released and (b) the reasons why the information is legally exempt from release pursuant to C.G.S. § 1-210(b).

10. **Conflict of Interest - Disclosure Statement.** Proposers must include a disclosure statement concerning any current business relationships (within the last

three (3) years) that pose a conflict of interest, as defined by C.G.S. § 1-85. A conflict of interest exists when a relationship exists between the proposer and a public official (including an elected official) or State employee that may interfere with fair competition or may be adverse to the interests of the State. The existence of a conflict of interest is not, in and of itself, evidence of wrongdoing. A conflict of interest may, however, become a legal matter if a proposer tries to influence, or succeeds in influencing, the outcome of an official decision for their personal or corporate benefit. The Agency will determine whether any disclosed conflict of interest poses a substantial advantage to the proposer over the competition, decreases the overall competitiveness of this procurement, or is not in the best interests of the State. In the absence of any conflict of interest, a proposer must affirm such in the disclosure statement. *Example: "[name of proposer] has no current business relationship (within the last three (3) years) that poses a conflict of interest, as defined by C.G.S. § 1-85."*

■ B. EVALUATION OF PROPOSALS

1. **Evaluation Process.** It is the intent of the Agency to conduct a comprehensive, fair, and impartial evaluation of proposals received in response to this RFP. When evaluating proposals, negotiating with successful proposers, and awarding contracts, the Agency will conform with its written procedures for POS and PSA procurements (pursuant to C.G.S. § 4-217) and the State's Code of Ethics (pursuant to C.G.S. §§ 1-84 and 1-85). Final funding allocation decisions will be determined during contract negotiation.

2. **Evaluation Review Committee.** The Agency will designate a Review Committee to evaluate proposals submitted in response to this RFP. The Review Committee will be composed of individuals, Agency staff or other designees as deemed appropriate. The contents of all submitted proposals, including any confidential information, will be shared with the Review Committee. Only proposals found to be responsive (that is, complying with all instructions and requirements described herein) will be reviewed, rated, and scored. Proposals that fail to comply with all instructions will be rejected without further consideration. The Review Committee shall evaluate all proposals that meet the Minimum Submission Requirements by score and rank ordered and make recommendations for awards. The Commissioner of the Connecticut Department of Public Health will make the final selection. Attempts by any proposer (or representative of any proposer) to contact or influence any member of the Review Committee may result in disqualification of the proposer.

3. **Minimum Submission Requirements.** To be eligible for evaluation, proposals must (1) be received on or before the due date and time; (2) meet the Proposal Format requirements; (3) meet the Eligibility and Qualification requirements to respond to the procurement, (4) follow the required Proposal Outline; and (5) be complete. Proposals that fail to follow instructions or satisfy these minimum submission requirements will not be reviewed further The Agency will reject any proposal that deviates significantly from the requirements of this RFP.

4. **Evaluation Criteria (and Weights).** Proposals meeting the Minimum Submission Requirements will be evaluated according to the established criteria. The criteria are the objective standards that the Review Committee will use to evaluate the technical merits of the proposals. Only the criteria listed below will be used to evaluate proposals. The weights are disclosed below.

    - Executive Summary (5 points)

- Applicant Organizational Profile (10 points)
- Scope of Services (30 points)
- Staffing Plan and Work Plan (30 points)
- Data and Technology Requirements (10 points)
- Cost Proposal Component (10 points)
- Appendices (5 points)

Note: As part of its evaluation of the Staffing Plan, the Review Committee will review the proposer's demonstrated commitment to affirmative action, as required by the Regulations of CT State Agencies § 46A-68j-30(10).

5. **Proposer Selection.** Upon completing its evaluation of proposals, the Review Committee will submit the rankings of all proposals to the Commissioner or Agency Head. The final selection of a successful proposer is at the discretion of the Commissioner or Agency Head. Any proposer selected will be so notified and awarded an opportunity to negotiate a contract with the Agency. Such negotiations may, but will not automatically, result in a contract. Any resulting contract will be posted on the State Contracting Portal. All unsuccessful proposers will be notified by e-mail or U.S. mail, at the Agency's discretion, about the outcome of the evaluation and proposer selection process. The Agency reserves the right to decline to award contracts for activities in which the Commissioner or Agency Head considers there are not adequate respondents.

6. **Debriefing.** Within ten (10) days of receiving notification from the Agency, unsuccessful proposers may contact the Official Contact and request information about the evaluation and proposer selection process. The e-mail sent date or the postmark date on the notification envelope will be considered "day one" of the ten (10) days. If unsuccessful proposers still have questions after receiving this information, they may contact the Official Contact and request a meeting with the Agency to discuss the evaluation process and their proposals. If held, the debriefing meeting will not include any comparisons of unsuccessful proposals with other proposals. The Agency may schedule and hold the debriefing meeting within fifteen (15) days of the request. The Agency will not change, alter, or modify the outcome of the evaluation or selection process as a result of any debriefing meeting.

7. **Appeal Process.** Proposers may appeal any aspect the Agency's competitive procurement, including the evaluation and proposer selection process. Any such appeal must be submitted to the Agency head. A proposer may file an appeal at any time after the proposal due date, but not later than thirty (30) days after an agency notifies unsuccessful proposers about the outcome of the evaluation and proposer selection process. The e-mail sent date or the postmark date on the notification envelope will be considered "day one" of the thirty (30) days. The filing of an appeal shall not be deemed sufficient reason for the Agency to delay, suspend, cancel, or terminate the procurement process or execution of a contract. More detailed information about filing an appeal may be obtained from the Official Contact.

8. **Contract Execution.** Any contract developed and executed as a result of this RFP is subject to the Agency's contracting procedures, which may include approval by the Office of the Attorney General. Fully executed and approved contracts will be posted on State Contracting Portal and the Agency website.

IV. REQUIRED PROPOSAL SUBMISSION OUTLINE AND REQUIREMENTS

A. Cover Sheet

B. Table of Contents

C. Executive Summary

D. Main Proposal

E. Attachments (clearly referenced to summary and main proposal where applicable)

F. Declaration of Confidential Information

G. Conflict of Interest - Disclosure Statement

H. Statement of Assurances

A: Cover Sheet

The Respondent must use a Cover Sheet capturing the following information:

- RFP Name and Number:
- Legal Name:
- FEIN (not required for currently contracted providers/vendors):
- Street Address:
- Town/City/State/Zip:
- Contact Person:
- Title:
- Phone Number:
- E-Mail Address:
- Authorized Official:
- Title:
- Signature:

Legal Name is defined as the name of private provider organization, CT State agency, or municipality submitting the proposal. *Contact Person* is defined as the individual who can provide additional information about the proposal or who has immediate responsibility for the proposal. *Authorized Official* is defined as the individual empowered to submit a binding offer on behalf of the proposer to provide services in accordance with the terms and provisions described in this RFP and any amendments or attachments hereto.

B: Table of Contents

Respondents must include a Table of Contents that lists sections and subsections with page numbers that follow the organization outline and sequence for this proposal.

C: Proposer Executive Summary (5 points)

The page limitation for this section is 2 pages briefly describing how the Respondent meets the eligibility and qualification criteria outlined in the Proposal Overview and a brief

overview of why the Respondent should be selected for the activities highlighted in the scope of services.

D: SCOPE OF SERVICE DESCRIPTION/MAIN PROPOSAL COMPONENTS

***Please note the maximum total page length for this section is 30 pages (all appendices and other attachments should be referred to in section D and then placed in section E). The Agency Review Committee will not read answers longer than 30 pages in this section.

1. **Applicant Organizational Profile (10 points)***:*
    i. provide an overview of the history and structure of your organization.
    ii. describe how this proposal will fit into the organization's overall mission and meet the intent of this RFP.
    iii. describe how you meet the following proposer requirements
        - knowledge and experience with the interpretation of NBS results in light of gestational age, birth weight, and treatment that the newborn is receiving, with particular emphasis on the interpretation of tandem mass spectrometry results (MS/MS).
        - an understanding of the usage of post-analytical tools, such as the Collaborative Laboratory Integrated Reports (CLIR) developed by Mayo Clinical Laboratories, for the interpretation of newborn screening results.
        - knowledge and experience with the diagnosis and treatment of the types of metabolic, endocrine, hematologic, immunologic, peroxisomal, lysosomal, neuromuscular and genetic conditions detected by newborn bloodspot screening including knowledge of the American College of Medical Genetics and Genomics' (ACMG) Newborn Screening ACTion Sheets and Confirmatory Algorithms (ACT Sheets).
        - knowledge of the community/area(s) to be served including any emerging trends, population needs and service gaps.
        - demonstrated population health focus as evidenced by promotion of community-oriented programs and partnerships to address the critical health needs of children.
        - knowledge of NBS guidelines, research and trends on the national level including, but not limited to, the Centers for Disease Control and Prevention (CDC) recommendations, ACMG recommendations, the Clinical and Laboratory Standards Institute's (CLSI) Newborn Screening Laboratory Standards and the Advisory Committee on Heritable Disorders in Newborns and Children's (ACHDNC) Recommended Uniform Screening Panel (RUSP).
        - demonstrated ability to execute the proposed plan of service delivery, including accounting and financial reporting systems and sound fiscal stability.
        - sufficient experienced staff, or the ability to hire or subcontract qualified personnel, to execute the proposed plan of service delivery statewide.
    iv. Describe your organization's ability to provide culturally competent, family centered, multidisciplinary, holistic care to meet the needs of families with infants undergoing diagnostic work-up and treatment for conditions identified through NBS.
    v. Infants diagnosed with a metabolic, endocrine, hematologic, immunologic, peroxisomal, lysosomal, neuromuscular or other genetic condition as a result of newborn screening frequently require multi-specialty care. Describe your organization's ability to provide access to specialists in the areas of genetics, metabolics, neonatology, immunology, endocrinology, hematology, neurology, and transplant services for children throughout the state. Include information about collaborations with other healthcare organizations across the state.

vi. Describe how your organization collaborates with and supports primary care providers and other community-based health care providers.
vii. Provide the name, title, address, telephone and FAX number of staff persons responsible for the completion and submittal of:
- contract and legal documents/forms.
- program progress reports.
- financial expenditure reports.

vii. Location of Office(s) or Facilities / Hours of Operation:
- the proposer must define all locations where services will be provided and hours of operation, including nontraditional locations and hours.

viii. Accreditation / Certification / Licensure (if applicable):
- please define any organizational accreditations, certifications or licensure.

2. Service Requirements – Scope of Services (30 points):

Describe in detail how your organization will accomplish the following:

i. establish multi-disciplinary, culturally competent care teams responsible for:
- overseeing the diagnostic workup on infants with presumptive positive results reported by CT NBS program and other responsibilities described below.
- providing and coordinating inpatient and outpatient care, genetic counseling, disease education and follow-up for those who confirm positive for metabolic, endocrine, hematologic, immunologic, peroxisomal, lysosomal, neuromuscular or other genetic condition.
- providing the services outlined below.

When a screen positive result is reported by CT NBS, care team will consult with the infant's current primary care provider (PCP) or hospital-based medical provider (HBMP) for the purpose of:
- providing recommendations for care pending the results of the - diagnostic work-up.
- recommending/referring for diagnostic work-up.
- arranging for evaluation the newborn by the care team as part of the diagnostic work up, when indicated.
- providing general information/education on the screen positive condition.
- obtaining a family health history.
- assuring that the diagnostic work-up is completed.
- interpreting of the results of the diagnostic work-up.
- communicating the results of the diagnostic work-up to the PCP/HBMP and when appropriate directly to the family.

Describe a model for care coordination for infants who confirm positive for a disorder detected through NBS. This includes determining the best location(s) for the infant and family to receive Follow-Up care, taking into account considerations such as geographic location, family preference, potential barriers to care, and the institution's expertise/experience with the disorder and current and emerging treatment modalities and ability to provide:
- ongoing collaboration with the child's primary care provider.
- ongoing education about the disease process for the provider, parent and for the child/adolescent when developmentally appropriate.
- ongoing nutritional counseling for parents of infants identified with a metabolic disorder and the child, when developmentally appropriate.
- appropriate treatment.
- coordination of the evaluation of the child, as appropriate, by other specialists including but not limited to specialists in the area of

genetics, metabolics, endocrinology, hematology, transplant services, neurology, and immunology.
- psycho-social evaluation and support as needed over time.
- support through appropriate community-based support groups such as disease advocacy groups, etc.
- referrals for family members for appropriate genetic testing and follow-up as needed.
- oversight of inpatient and outpatient management of the disorder throughout infancy, childhood, adolescence and young adulthood, including coordination with specialty groups
- identification of needs and referral to programs that can help meet the meet the psycho-social needs of the family and child, such as support groups, camps for children with special health care needs, disease advocacy groups, etc.
- assistance to families of children with metabolic disorders identified through NBS without insurance coverage or with inadequate insurance coverage for whom the purchase of medical foods would create a financial hardship.
- genetic counseling for the child when developmentally appropriate.
- identification and referral to programs that can help meet the meet the psycho-social needs of the family and child, such as support groups, camps for children with special health care needs, disease advocacy groups, etc.
- facilitation of the transition from pediatric specialty care to adult specialty care.

ii. Establish a system to track demographic information, referrals and outcomes measures to be reported to CT NBS via the electronic NBS database and used to support short and long-term follow-up of children identified through NBS and the science of newborn screening. Information to be electronically reported to DPH includes, but is not limited to:
- select demographic information.
- insurance coverage.
- exclusion or confirmation of a diagnosis for every child referred through CT NBS.
- false negative cases.
- referral to other specialty groups including consideration for bone marrow or stem cell transplant when related to the disorder identified through NBS.
- the name and contact information of the provider who is assuming responsibility for the on-going LTFU related to the child's condition (either PCP or specialist).
- infants/children who are lost to follow-up at any point in the continuum of care. beginning with diagnostic work up and the reason they are lost to follow-up (for example: moved out of state, unable to make contact with family, parent refusal, etc.)
- select disease specific outcome measures for children who confirm positive for certain disorders
- biochemical diagnostic results, mutational analysis diagnostic results and interpretation, and other related diagnostic testing results.

iii. Describe a system for reporting on required performance measures (see section D. PERFORMANCE MEASURES)

iv. Establish a fund utilizing monies granted as a result of this RFP to assist established metabolic treatment programs operating in Connecticut, outside of the proposer's organization, involved in the treatment of infants, children and adolescents with metabolic disorders detected by NBS, with the provision of the following:
- on-going nutritional counseling.
- psycho-social consultation.
- the purchase of formula and/or metabolic foods to assist families without insurance coverage or with inadequate insurance coverage for whom the purchase of medical foods items would create a financial hardship.
- Establish a system for tracking distribution and utilization of these funds including how many children/families receive formula supplied through the program, receive nutritional counseling and/or psycho-social consultation.

4. Staffing Requirements – Staffing Plan and Work Plan (30 points):

The organization will determine the most effective means of staffing to provide the scope of services outlined in this document in addition to the following staffing requirements:

i. The organization will provide access to a board-certified biochemical geneticist who in addition to providing support to the genetics care team will to providing direction to team, will provide consultation to CT NBS on the addition of conditions to the screening panel, implementation of new testing platforms, the interpretation of newborn screening results and improving the positive predictive value of screening tests.
ii. The Genetics Care Team will be under the direction of a board-certified geneticist with experience in the interpretation of NBS results.
iii. The Endocrine Care Team will be under the direction of a board-certified pediatric endocrinologist.
iv. Hematology Care Team will be under the direction of a board-certified pediatric hematologist.
v. Immunology Care Team will be under the direction of a board-certified pediatric immunologist.
vi. Neurology Care Team will be under the direction of a board-certified pediatric neurologist.

The composition of the care teams will be determined by the organization.

Taking the previously described staffing requirements into consideration, please describe your staffing and work plan in detail and how your organization's specialty care groups will collaborate with CT NBS and encourage collaboration of other specialty care groups statewide the development of a coordinated NBS response.

Subcontractors
If subcontractors are utilized for the provision or delivery of a service, the purpose of this subsection is to specify the information to be provided about the administrative and operational capabilities of each such subcontractor. Such as:

i. Legal Name of Agency, Address, FEIN
ii. Contact Person, Title, Phone, Fax, E-mail
iii. Services Currently Provided

iv. Services to Be Provided Under Subcontract
v. Subcontractor Oversight
vi. Subcontract Cost and Term

NOTE: The proposal must include a completed Subcontractor Schedule A—Detail Form for each subcontractor proposed (If known at application time, otherwise, will be required to submit during contract negotiations; see Attachments Section V. A. 7. Application Forms).

5. **Data and Technology Requirements (10 points):**
The organization must have the necessary technology and infrastructure to support data entry into the web-based Connecticut Electronic Surveillance System (CT SITE), more commonly referred to as "Maven" or the "NBS Follow-Up /tracking database". The minimum hardware/software configuration is for CT Site is as follows:
   i. Operating Systems: Windows 10.
   ii. Browsers: the latest supported version of the mostly commonly used browsers Microsoft Internet Explorer 11, but Edge preferred, Mozilla Firefox, Apple Safari and Google Chrome. All with JavaScript and CSS enabled.
   iii. Connection Speed: 56.6k modem or better (High speed Internet of 1 Mbps or better recommended).
   iv. Screen Resolution: Minimum 1024 x 768 monitor resolution.

   In recent years, the CT NBS Program has changed from paper-based reporting system to an entirely electronic reporting system in order to increase efficiency and lessen the potential for mistakes.

   The organization must have the ability to send and receive secure results, outcome data and via HL7 messaging and other HIPAA compliant electronic formats.

   Data sharing agreements or a willingness to implement data sharing agreements with other CT NBS diagnostic Treatment Centers (Yale/Connecticut Children's)

6. **COST PROPOSAL COMPONENT (10 points)**:
   - **Financial Requirements – Profile**
   The CT NBS Program is aware that the funds that may be provided through this prospective agreement cover only a portion of the expense incurred in providing such services. Please describe your other sources of funding available to your organization and your experience working with third party payers for reimbursement for services.

   - **Budget Requirements – Budget and Budget Narrative**
   The organization is required to submit a budget narrative including a budget summary and justification and a line item budget.

E: Attachments

Attachments other than the required attachments identified are not permitted and will not be evaluated. See the Proposal Checklist in Appendix C for a list of relevant attachments. Further, the required attachments must not be altered or used to extend, enhance, or replace any component required by this RFP. Failure to abide by these instructions may result in disqualification.

F: Declaration of Confidential Information

If a proposer deems that certain information required by this RFP is confidential, the proposer must label such information as CONFIDENTIAL prior to submission. The proposer must reference where the information labeled CONFIDENTIAL is located in the proposal. *EXAMPLE: Section G.1.a.* For each subsection so referenced, the proposer must provide a convincing explanation and rationale sufficient to justify an exemption of the information from release under the FOIA. The explanation and rationale must be stated in terms of (a) the prospective harm to the competitive position of the proposer that would result if the identified information were to be released and (b) the reasons why the information is legally exempt from release pursuant to C.G.S. § 1-210(b).

G: Conflict of Interest – Disclosure Statement

Proposers must include a disclosure statement concerning any current business relationships (within the last three (3) years) that pose a conflict of interest, as defined by C.G.S. § 1-85. A conflict of interest exists when a relationship exists between the proposer and a public official (including an elected official) or State employee that may interfere with fair competition or may be adverse to the interests of the State. The existence of a conflict of interest is not, in and of itself, evidence of wrongdoing. A conflict of interest may, however, become a legal matter if a proposer tries to influence, or succeeds in influencing, the outcome of an official decision for their personal or corporate benefit. In the absence of any conflict of interest, a proposer must affirm such in the disclosure statement. *Example: "[name of proposer] has no current business relationship (within the last three (3) years) that poses a conflict of interest, as defined by C.G.S. § 1-85."*

H: Statement of Assurances

Place after Conflict of Interest-Disclosure Statement. Sign and return Appendix _.

V. MANDATORY PROVISIONS

A. POS STANDARD CONTRACT, PARTS I AND II

By submitting a proposal in response to this RFP, the proposer implicitly agrees to comply with the provisions of Parts I and II of the State's "standard contract" for POS:

Part I of the standard contract is maintained by the Department and will include the scope of services, contract performance, quality assurance, reports, terms of payment, budget, and other program-specific provisions of any resulting POS contract. A sample of Part I is available from the Department's Official Contact upon request.

Part II of the standard contract is maintained by OPM and includes the mandatory terms and conditions of the POS contract. Part II is available on OPM's website at: http://www.ct.gov/opm/fin/standard_contract

Note:
Included in Part II of the standard contract is the State Elections Enforcement Commission's notice (pursuant to C.G.S. § 9-612(g)(2)) advising executive branch State contractors and prospective State contractors of the ban on campaign contributions and solicitations. If a proposer is awarded an opportunity to negotiate

a contract with the Department and the resulting contract has an anticipated value in a calendar year of $50,000 or more, or a combination or series of such agreements or contracts has an anticipated value of $100,000 or more, the proposer must inform the proposer's principals of the contents of the SEEC notice.

Part I of the standard contract may be amended by means of a written instrument signed by the Department, the selected proposer (contractor), and, if required, the Attorney General's Office. Part II of the standard contract may be amended only in consultation with, and with the approval of, the Office of Policy and Management and the Attorney General's Office.

■ B. ASSURANCES

By submitting a proposal in response to this RFP, a proposer implicitly gives the following assurances:

1. **Collusion.** The proposer represents and warrants that the proposer did not participate in any part of the RFP development process and had no knowledge of the specific contents of the RFP prior to its issuance. The proposer further represents and warrants that no agent, representative, or employee of the State participated directly in the preparation of the proposer's proposal. The proposer also represents and warrants that the submitted proposal is in all respects fair and is made without collusion or fraud.

2. **State Officials and Employees.** The proposer certifies that no elected or appointed official or employee of the State has or will benefit financially or materially from any contract resulting from this RFP. The Agency may terminate a resulting contract if it is determined that gratuities of any kind were either offered or received by any of the aforementioned officials or employees from the proposer, contractor, or its agents or employees.

3. **Competitors.** The proposer assures that the submitted proposal is not made in connection with any competing organization or competitor submitting a separate proposal in response to this RFP. No attempt has been made, or will be made, by the proposer to induce any other organization or competitor to submit, or not submit, a proposal for the purpose of restricting competition. The proposer further assures that the proposed costs have been arrived at independently, without consultation, communication, or agreement with any other organization or competitor for the purpose of restricting competition. Nor has the proposer knowingly disclosed the proposed costs on a prior basis, either directly or indirectly, to any other organization or competitor.

4. **Validity of Proposal.** The proposer certifies that the proposal represents a valid and binding offer to provide services in accordance with the terms and provisions described in this RFP and any amendments or attachments hereto. The proposal shall remain valid for a period of 180 days after the submission due date and may be extended beyond that time by mutual agreement. At its sole discretion, the Agency may include the proposal, by reference or otherwise, into any contract with the successful proposer.

5. **Press Releases.** The proposer agrees to obtain prior written consent and approval of the Agency for press releases that relate in any manner to this RFP or any resultant contract.

C. TERMS AND CONDITIONS

By submitting a proposal in response to this RFP, a proposer implicitly agrees to comply with the following terms and conditions:

1. **Equal Opportunity and Affirmative Action.** The State is an Equal Opportunity and Affirmative Action employer and does not discriminate in its hiring, employment, or business practices. The State is committed to complying with the Americans with Disabilities Act of 1990 (ADA) and does not discriminate on the basis of disability in admission to, access to, or operation of its programs, services, or activities.

2. **Preparation Expenses.** Neither the State nor the Agency shall assume any liability for expenses incurred by a proposer in preparing, submitting, or clarifying any proposal submitted in response to this RFP.

3. **Exclusion of Taxes.** The Agency is exempt from the payment of excise and sales taxes imposed by the federal government and the State. Proposers are liable for any other applicable taxes.

4. **Proposed Costs.** No cost submissions that are contingent upon a State action will be accepted. All proposed costs must be fixed through the entire term of the contract.

5. **Changes to Proposal.** No additions or changes to the original proposal will be allowed after submission. While changes are not permitted, the Agency may request and authorize proposers to submit written clarification of their proposals, in a manner or format prescribed by the Agency, and at the proposer's expense.

6. **Supplemental Information.** Supplemental information will not be considered after the deadline submission of proposals, unless specifically requested by the Agency. The Agency may ask a proposer to give demonstrations, interviews, oral presentations or further explanations to clarify information contained in a proposal. Any such demonstration, interview, or oral presentation will be at a time selected and in a place provided by the Agency. At its sole discretion, the Agency may limit the number of proposers invited to make such a demonstration, interview, or oral presentation and may limit the number of attendees per proposer.

7. **Presentation of Supporting Evidence.** If requested by the Agency, a proposer must be prepared to present evidence of experience, ability, data reporting capabilities, financial standing, or other information necessary to satisfactorily meet the requirements set forth or implied in this RFP. The Agency may make onsite visits to an operational facility or facilities of a proposer to evaluate further the proposer's capability to perform the duties required by this RFP. At its discretion, the Agency may also check or contact any reference provided by the proposer.

8. **RFP Is Not An Offer.** Neither this RFP nor any subsequent discussions shall give rise to any commitment on the part of the State or the Agency or confer any rights on any proposer unless and until a contract is fully executed by the necessary parties. The contract document will represent the entire agreement between the proposer and the Agency and will supersede all prior negotiations, representations or agreements, alleged or made, between the parties. The State shall assume no liability for costs incurred by the proposer or for payment of services under the terms of the contract until the successful proposer is notified that the contract has been

accepted and approved by the Agency and, if required, by the Attorney General's Office.

D. RIGHTS RESERVED TO THE STATE

By submitting a proposal in response to this RFP, a proposer implicitly accepts that the following rights are reserved to the State:

1. **Timing Sequence.** The timing and sequence of events associated with this RFP shall ultimately be determined by the Agency.

2. **Amending or Canceling RFP.** The Agency reserves the right to amend or cancel this RFP on any date and at any time, if the Agency deems it to be necessary, appropriate, or otherwise in the best interests of the State.

3. **No Acceptable Proposals.** In the event that no acceptable proposals are submitted in response to this RFP, the Agency may reopen the procurement process, if it is determined to be in the best interests of the State.

4. **Award and Rejection of Proposals.** The Agency reserves the right to award in part, to reject any and all proposals in whole or in part, for misrepresentation or if the proposal limits or modifies any of the terms, conditions, or specifications of this RFP. The Agency may waive minor technical defects, irregularities, or omissions, if in its judgment the best interests of the State will be served. The Agency reserves the right to reject the proposal of any proposer who submits a proposal after the submission date and time.

5. **Sole Property of the State.** All proposals submitted in response to this RFP are to be the sole property of the State. Any product, whether acceptable or unacceptable, developed under a contract awarded as a result of this RFP shall be the sole property of the State, unless stated otherwise in this RFP or subsequent contract. The right to publish, distribute, or disseminate any and all information or reports, or part thereof, shall accrue to the State without recourse.

6. **Contract Negotiation.** The Agency reserves the right to negotiate or contract for all or any portion of the services contained in this RFP. The Agency further reserves the right to contract with one or more proposer for such services. After reviewing the scored criteria, the Agency may seek Best and Final Offers (BFO) on cost from proposers. The Agency may set parameters on any BFOs received.

7. **Clerical Errors in Award.** The Agency reserves the right to correct inaccurate awards resulting from its clerical errors. This may include, in extreme circumstances, revoking the awarding of a contract already made to a proposer and subsequently awarding the contract to another proposer. Such action on the part of the State shall not constitute a breach of contract on the part of the State since the contract with the initial proposer is deemed to be void *ab initio* and of no effect as if no contract ever existed between the State and the proposer.

8. **Key Personnel.** When the Agency is the sole funder of a purchased service, the Agency reserves the right to approve any additions, deletions, or changes in key personnel, with the exception of key personnel who have terminated employment. The Agency also reserves the right to approve replacements for key personnel who have terminated employment. The Agency further reserves the right to require the

removal and replacement of any of the proposer's key personnel who do not perform adequately, regardless of whether they were previously approved by the Agency.

■ E. STATUTORY AND REGULATORY COMPLIANCE

By submitting a proposal in response to this RFP, the proposer implicitly agrees to comply with all applicable State and federal laws and regulations, including, but not limited to, the following:

1. **Freedom of Information, C.G.S. § 1-210(b).** The Freedom of Information Act (FOIA) generally requires the disclosure of documents in the possession of the State upon request of any citizen, unless the content of the document falls within certain categories of exemption, as defined by C.G.S. § 1-210(b). Proposers are generally advised not to include in their proposals any confidential information. If the proposer indicates that certain documentation, as required by this RFP, is submitted in confidence, the State will endeavor to keep said information confidential to the extent permitted by law. The State has no obligation to initiate, prosecute, or defend any legal proceeding or to seek a protective order or other similar relief to prevent disclosure of any information pursuant to a FOIA request. The proposer has the burden of establishing the availability of any FOIA exemption in any proceeding where it is an issue. While a proposer may claim an exemption to the State's FOIA, the final administrative authority to release or exempt any or all material so identified rests with the State. In no event shall the State or any of its employees have any liability for disclosure of documents or information in the possession of the State and which the State or its employees believe(s) to be required pursuant to the FOIA or other requirements of law.

2. **Contract Compliance, C.G.S. § 4a-60 and Regulations of CT State Agencies § 46a-68j-21 thru 43, inclusive.** CT statute and regulations impose certain obligations on State agencies (as well as contractors and subcontractors doing business with the State) to ensure that State agencies do not enter into contracts with organizations or businesses that discriminate against protected class persons.

3. **Consulting Agreements, C.G.S. § 4a-81. Consulting Agreements Representation, C.G.S. § 4a-81.** Pursuant to C.G.S. §§ 4a-81 the successful contracting party shall certify that it has not entered into any consulting agreements in connection with this Contract, except for the agreements listed below. "Consulting agreement" means any written or oral agreement to retain the services, for a fee, of a consultant for the purposes of (A) providing counsel to a contractor, vendor, consultant or other entity seeking to conduct, or conducting, business with the State, (B) contacting, whether in writing or orally, any executive, judicial, or administrative office of the State, including any department, institution, bureau, board, commission, authority, official or employee for the purpose of solicitation, dispute resolution, introduction, requests for information, or (C) any other similar activity related to such contracts. "Consulting agreement" does not include any agreements entered into with a consultant who is registered under the provisions of chapter 10 of the Connecticut General Statutes as of the date such contract is executed in accordance with the provisions of section 4a-81 of the Connecticut General Statutes. Such representation shall be sworn as true to the best knowledge and belief of the person signing the resulting contract and shall be subject to the penalties of false statement.

4. **Campaign Contribution Restriction, C.G.S. § 9-612.** For all State contracts, defined in section 9-612 of the Connecticut General Statutes as having a value in a calendar year of $50,000 or more, or a combination or series of such agreements or

contracts having a value of $100,000 or more, the authorized signatory to the resulting contract must represent that they have received the State Elections Enforcement Commission's notice advising state contractors of state campaign contribution and solicitation prohibitions, and will inform its principals of the contents of the notice, as set forth in "Notice to Executive Branch State Contractors and Prospective State Contractors of Campaign Contribution and Solicitation Limitations." Such notice is available at https://seec.ct.gov/Portal/data/forms/ContrForms/seec_form_11_notice_only.pdf

5. Gifts, C.G.S. § 4-252. Pursuant to section 4-252 of the Connecticut General Statutes and Acting Governor Susan Bysiewicz's Executive Order No. 21-2, the Contractor, for itself and on behalf of all of its principals or key personnel who submitted a bid or proposal, represents:

(1) That no gifts were made by (A) the Contractor, (B) any principals and key personnel of the Contractor, who participate substantially in preparing bids, proposals or negotiating State contracts, or (C) any agent of the Contractor or principals and key personnel, who participates substantially in preparing bids, proposals or negotiating State contracts, to (i) any public official or State employee of the State agency or quasi- public agency soliciting bids or proposals for State contracts, who participates substantially in the preparation of bid solicitations or requests for proposals for State contracts or the negotiation or award of State contracts, or (ii) any public official or State employee of any other State agency, who has supervisory or appointing authority over such State agency or quasi-public agency;
(2) That no such principals and key personnel of the Contractor, or agent of the Contractor or of such principals and key personnel, knows of any action by the Contractor to circumvent such prohibition on gifts by providing for any other principals and key personnel, official, employee or agent of the Contractor to provide a gift to any such public official or State employee; and

(3) That the Contractor is submitting bids or proposals without fraud or collusion with any person.
Any bidder or proposer that does not agree to the representations required under this section shall be rejected and the State agency or quasi-public agency shall award the contract to the next highest ranked proposer or the next lowest responsible qualified bidder or seek new bids or proposals.

6. Iran Energy Investment Certification C.G.S. § 4-252(a). Pursuant to C.G.S. § 4-252(a), the successful contracting party shall certify the following: (a) that it has not made a direct investment of twenty million dollars or more in the energy sector of Iran on or after October 1, 2013, as described in Section 202 of the Comprehensive Iran Sanctions, Accountability and Divestment Act of 2010, and has not increased or renewed such investment on or after said date. (b) If the Contractor makes a good faith effort to determine whether it has made an investment described in subsection (a) of this section it shall not be subject to the penalties of false statement pursuant to section 4-252a of the Connecticut General Statutes. A "good faith effort" for purposes of this subsection includes a determination that the Contractor is not on the list of persons who engage in certain investment activities in Iran created by the Department of General Services of the State of California pursuant to Division 2, Chapter 2.7 of the California Public Contract Code. Nothing in this subsection shall be construed to impair the ability of the State agency or quasi-public agency to pursue a breach of contract action for any violation of the provisions of the resulting contract.

7. Nondiscrimination Certification, C.G.S. § 4a-60 and 4a-60a. If a bidder is

awarded an opportunity to negotiate a contract, the proposer must provide the State agency with *written representation* in the resulting contract that certifies the bidder complies with the State's nondiscrimination agreements and warranties. This nondiscrimination certification is required for all State contracts – regardless of type, term, cost, or value. Municipalities and CT State agencies are exempt from this requirement. The authorized signatory of the contract shall demonstrate his or her understanding of this obligation by either (A) initialing the nondiscrimination affirmation provision in the body of the resulting contract, or (B) providing an affirmative response in the required online bid or response to a proposal question, if applicable, which asks if the contractor understands its obligations. If a bidder or vendor refuses to agree to this representation, such bidder or vendor shall be rejected and the State agency or quasi-public agency shall award the contract to the next highest ranked vendor or the next lowest responsible qualified bidder or seek new bids or proposals.

8. Access to Data for State Auditors. The Contractor shall provide to OPM access to any data, as defined in C.G.S. § 4e-1, concerning the resulting contract that are in the possession or control of the Contractor upon demand and shall provide the data to OPM in a format prescribed by OPM [or the Client Agency] and the State Auditors of Public Accounts at no additional cost.

VI. APPENDICES

A. ABBREVIATIONS / ACRONYMS / DEFINITIONS

ACHDNC	Advisory Committee on Heritable Disorders in Newborns and Children
ACMG	American College of Medical Genetics and Genomics
ACT Sheets	Newborn Screening ACTion Sheets and Confirmatory Algorithms
BFO	Best and Final Offer
CDC	Centers for Disease Control and Prevention
C.G.S.	Connecticut General Statutes
CHRO	Commission on Human Rights and Opportunity (CT)
CT	Connecticut
DAS	Department of Administrative Services (CT)
DPH	Department of Public Health (CT)
DHHS	U.S. Department of Health and Human Services
FOIA	Freedom of Information Act (CT)
HBMP	Hospital Based Medical Provider
HCP	Health Care Provider
Hb	Hemoglobin
IRS	Internal Revenue Service (US)
LOI	Letter of Intent
NBS	Newborn Screening
MS/MS	Tandem Mass Spectrometry
OAG	Office of the Attorney General
OPM	Office of Policy and Management (CT)
OSC	Office of the State Comptroller (CT)
PCP	Primary Care Provider
PKU	Phenylketonuria
POS	Purchase of Service
P.A.	Public Act (CT)
RFP	Request for Proposal
RUSP	Recommended Uniform [Newborn]Screening Panel
SEEC	State Elections Enforcement Commission (CT)
U.S.	United States

- *contractor:* a private provider organization, CT State agency, or municipality that enters into a POS contract with the Agency as a result of this RFP

- *proposer:* a private provider organization, CT State agency, or municipality that has submitted a proposal to the Agency in response to this RFP. This term may be used interchangeably with respondent throughout the RFP.

- *prospective proposer:* a private provider organization, CT State agency, or municipality that may submit a proposal to the Agency in response to this RFP, but has not yet done so

- *subcontractor*: an individual (other than an employee of the contractor) or business entity hired by a contractor to provide a specific health or human service as part of a POS contract with the Agency as a result of this RFP

B. **STATEMENT OF ASSURANCES**

Agency Name

The undersigned Respondent affirms and declares that:

1) General

a. This proposal is executed and signed with full knowledge and acceptance of the RFP CONDITIONS stated in the RFP.

b. The Respondent will deliver services to the Agency the cost proposed in the RFP and within the timeframes therein.

c. The Respondent will seek prior approval from the Agency before making any changes to the location of services.

d. Neither the Respondent of any official of the organization nor any subcontractor the Respondent of any official of the subcontractor organization has received any notices of debarment or suspension from contracting with the State of CT or the Federal Government.

e. Neither the Respondent of any official of the organization nor any subcontractor to the Respondent of any official of the subcontractor's organization has received any notices of debarment or suspension from contracting with other states within the United States.

Legal Name of Organization:

_____ _____

Authorized Signatory Date

C. PROPOSAL CHECKLIST

To assist respondents in managing proposal planning and document collation processes, this document summarizes key dates and proposal requirements for this RFP. Please note that this document does not supersede what is stated in the RFP. Please refer to the Proposal Submission Overview, Required Proposal Submission Outline, and Mandatory Provisions (Sections II, III, and IV of this RFP) for more comprehensive details. It is the responsibility of each respondent to ensure that all required documents, forms, and attachments, are submitted in a timely manner.

Key Dates

Procurement Timetable The Agency reserves the right to modify these dates at its sole discretion.		
Item	Action	Date
1	RFP Released	January 14, 2022
2	Letter of Intent Due	January 28, 2022
3	Deadline for Questions	February 4, 2022
4	Answers Released:	February 11, 2022
5	Proposer Selection	March 31, 2022
6	Start of Contract Negotiations	April 15, 2022

Registration with State Contracting Portal (if not already registered):

☐ Register at: https://portal.ct.gov/DAS/CTSource/Registration

☐ Submit Campaign Contribution Certification (OPM Ethics Form 1): https://portal.ct.gov/OPM/Fin-PSA/Forms/Ethics-Forms

Proposal Content Checklist

☐ **Cover Sheet** including required information:
- RFP Name or Number
- Legal Name
- FEIN
- Street Address
- Town/City/State/Zip
- Contact Person
- Title
- Phone Number
- E-Mail Address
- Authorized Official
- Title
- Signature

☐ **Table of Contents**

☐ **Executive Summary**: high-level summary of proposal and cost

☐ **Main proposal body answering all questions with relevant attachments**.

☐ **IRS Determination Letter** (for nonprofit proposers)

☐ **Two years of most recent annual audited financial statements; OR any financial statements prepared by a Certified Public Accountant** for proposers whose organizations have been incorporated for less than two years.

☐ **Proposed budget**, including budget narrative and cost schedules for planned subcontractors if applicable.

☐ **Conflict of Interest Disclosure Statement**

☐ **Statement of Assurances**

Formatting Checklist

☐ Is the proposal formatted to fit 8 ½ x 11 (letter-sized) paper?
☐ Is the main body of the proposal within the page limit?
☐ Is the proposal in no smaller than 11-point Arial, Times New Roman, Verdana or Calibri Font?
☐ Does the proposal format follow normal (1 inch) margins and 1 line spacing?
☐ Does the proposer's name appear in the header of each page?
☐ Does the proposal include page numbers in the footer?
☐ Are confidential labels applied to sensitive information (if applicable)?