MISSISSIPPI STATE DEPARTMENT OF HEALTH

REQUEST FOR PROPOSALS (RFP)

Testing for Genetic Conditions and Reporting

RFx# 3120002630

ISSUE DATE
Friday, February 10, 2023

CLOSING TIME AND DATE
Proposals must be received by:
Wednesday, March 15, 2023, 10:00 AM CT

Proposal Coordinator
Jennifer Dotson, Chief Procurement Officer
570 E. Woodrow Wilson Ave.
Jackson, MS 39216-4538
Telephone: 601.576.7627
Email: jennifer.dotson@msdh.ms.gov

GENERAL INSTRUCTIONS

Section 1 – Background, Authority, and Purpose

The Mississippi State Department of Health – Genetic Services is seeking to establish a contract for the purpose of selecting a qualified laboratory for the right to provide newborn screening laboratory testing and reporting services for Mississippi birthed newborns. This short-term follow-up process assist in the identification of certain serious or life-threatening conditions that may cause organ damage, developmental delay, or death if left undiagnosed and untreated. It is understood that any contract resulting from this solicitation requires approval by the Public Procurement Review Board. If any contract is not approved by the Public Procurement Review Board, it is void and no payment shall be made.

Term

MSDH intends to enter into a firm fixed price agreement. The initial term of the contract resulting from the RFP shall be for a period of three (3) years beginning July 1, 2023, through June 30, 2026. Upon written agreement of both parties at least 60 days prior to the end of the third year, a letter of agreement will be signed by both parties to utilize the option to renew for one (1) successive year under the same prices, terms, and conditions as in the original contract. The total number of renewal years permitted shall not exceed one.

A contract will be awarded to the Vendor whose proposal is determined to be the most advantageous to the State, taking into consideration the qualification factors set forth in the RFP.

Section 2 – Timeline

Event	**Date/Time**
Request for Proposal Issue Date	Friday, February 10, 2023
	Friday, February 17, 2023
Questions and Requests for Clarification	Tuesday, February 21, 2023
Anticipated Posting of Written Responses	Tuesday, February 28, 2023
Proposal Package Submission Deadline	**Wednesday, March 15, 2023, 10:00 AM CT**
Anticipated Date of the Public Notice of Intent to Award	Tuesday, March 28, 2023
Anticipated Formal Notice of Intent	Thursday, March 30, 2023
Anticipated Post-Award Debriefing Request	Tuesday, April 4, 2023
Anticipated Protest Deadline	Thursday, April 6, 2023
PPRB Meeting for Contract Approval	Wednesday, May 3, 2023

Section 3 – Contact and Questions/Requests for Clarification

3.1 Vendors must carefully review this solicitation, the Contract, risk management provisions, and all attachments for defects, questionable, or objectionable material. Following review, vendors may have questions to clarify or interpret the RFP in order to submit the best Proposals

possible. To accommodate the questions and requests for clarifications, vendors shall submit any such question via email by the deadline reflected in Section 2. All questions and requests for clarifications must be directed by email to:

Jennifer Dotson, Proposal Coordinator
E-mail: jennifer.dotson@msdh.ms.gov

3.2 Vendors should enter "**RFP RFx# 3120002630 - Questions**" as the subject for the email. Question submittals should include a reference to the applicable RFP section and be submitted in the format shown below:

	RFP Section, Page Number	**Vendor Question/Request for Clarification**
1.		

3.3 Official responses will be provided only for questions submitted as described above and only to clarify information already included in the RFP. The identity of the organization submitting the question(s) will not be revealed. All questions and answers will be published on the Mississippi Contract/Procurement Opportunity Search Portal website and the agency's website as an amendment to the RFP by the date and time reflected in Section 2.

3.4 The Agency will not be bound by any verbal or written information that is not contained within this RFP unless formally noticed and issued by the contact person as an RFP amendment. Vendors are cautioned that any statements made by agency personnel that materially change any portion of the proposal document shall not be relied upon unless subsequently ratified by a formal written amendment to the proposal document.

3.5 All vendor communications regarding this RFP must be directed to the Proposal Coordinator. Unauthorized contact regarding the RFP with other employees of the Agency may result in the vendor being disqualified, and the vendor may also be suspended, disbarred, or removed from consideration for award of contracts with the State of Mississippi for a period of two (2) years.

3.6 Pre-Proposal Conference, Tour, or Site Visit: No pre-proposal conference, tour, or site visit will be held for this RFP.

3.7 Acknowledgement of Amendments: Should an amendment to the RFP be issued, it will be posted on the Mississippi Contract/Procurement Opportunity Search Portal website and the agency's website in a manner that all vendors will be able to view. Vendors must acknowledge receipt of any amendment to the solicitation by signing and returning the amendment with the proposal package, by identifying the amendment number and date in the space provided for this purpose on the RFP amendment, or by letter. The acknowledgment should be received by the agency by the time, date, and at the place specified for receipt of Proposals. It is the vendor's sole responsibility to monitor the websites for any updates or amendments to the RFP. Questions and Answer document(s) and/or Summary of Pre-Proposal Conference, Tour, or Site Visit, if any are issued/posted on the Mississippi Contract/Procurement Opportunity Search Portal website and the agency's website, must be treated the same as an RFP Amendment.

3.8 Vendors must provide a signed Acknowledgements of RFP Amendment(s), Questions and Answer document(s), and/or Summary of Pre-Proposal Conference, Tour, or Site Visit, if any were issued/posted on the Mississippi Contract/Procurement Opportunity Search Portal website and the agency's website.

3.9 The RFP is comprised of the base RFP document, any attachments, any amendments issued prior to the submission deadline, and any other documents released before contract award.

Section 4 – Scope of Services

The selected laboratory will provide testing for the specified conditions in the Rules and Regulations governing Newborn Screening and Birth Defects modified and adopted by the Mississippi State Board of Health on October 7, 2014 (See Appendix A). Laboratories submitting proposals must be located within the United States and must test a minimum of 40,000 specimens per year. All regulated laboratories must be successfully participating in an acceptable commercial proficiency testing program that will monitor the performance of testing methodologies. Laboratories must have either a certificate of compliance or a certificate of accreditation from the Department of Health and Human Services, Health Care Financing Administration (HCFA) pursuant to Section 353 of the Public Health Service Act as revised by the Clinical Laboratory Improvement Amendments (CLIA) of 1988. Laboratories must adhere to all quality control measures listed in the Rules and Regulations governing Newborn Screening and Birth Defects. The Mississippi Board of Health must approve any exceptions. The current quality control measures in the Regulations Governing Newborn Screening and Birth Defects Registry (See Appendix A) may be amended in the future, as necessary, to accommodate any new testing protocols. All changes in testing protocol must be submitted to the Genetic Services Bureau for review and acceptance, prior to laboratory implementation. Laboratories must submit copies of proficiency testing/performance evaluations upon request by the program. Laboratories must submit copies of validation or verification documentation for all assays used if requested by the program. Any changes to the reference ranges/cut-off values or other indicators used to determine abnormal/presumptive positive results must be provided in writing to MSDH Genetic Services Bureau as they occur. The laboratory will provide up to twelve (12) training sessions and/or presentations for MSDH personnel and healthcare professionals each year, as requested by the MSDH. Times and locations will be determined by the MSDH Genetic Service.

Vendor shall perform and complete in a timely and satisfactory manner the services described in Attachment A captioned "Minimum Specification" which is attached hereto and made a part hereof by reference.

Section 5 – Proposal Evaluation and Basis for Award

5.1 All Proposals received in response to this RFP by the stated deadline will receive an evaluation. Agency will use an evaluation committee to review and evaluate the Proposals using a 100-point scale. The evaluation of any submission may be suspended and/or terminated at the Agency's discretion at any point during the evaluation process at which time the Agency determines that said proposal and/or vendor fails to meet any of the mandatory requirements

as stated in this RFP, the submission is determined to contain fatal deficiencies to the extent that the likelihood of selection for contract negotiations is minimal, or Agency receives reliable information that would make contracting with the vendor impractical or otherwise not in the best interests of the MSDH and/or the State of Mississippi.

5.2 Compliance Phase: In this initial phase of the evaluation process, all Proposals received are reviewed to determine if mandatory RFP requirements have been satisfied, meaning whether a vendor is responsive, responsible, and/or acceptable. Compliance requirements are not assigned a point percentage or score but are simply recorded as **Pass or Fail.**

5.2.1 Responsive Respondent
Respondent must submit a proposal which conforms in all material respects to this Request for Proposals as determined by MSDH.

5.2.2 Responsible Respondent
Respondent must have capability in all respects to perform fully the contract requirements and the integrity and reliability which will assure good faith performance, as determined by MSDH.

Proposals with errors that do not alter the substance of the submission can be accepted, and the Agency Chief Procurement Officer may allow the vendor to correct the problem as long as the irregularities are insignificant mistakes that can be waived or corrected without prejudice to other vendors. At its discretion, MSDH may conduct discussions may with vendors who submit Proposals, but Proposals may also be accepted without such discussions.

If any component received a Fail score (a "No" response) on any item or contains an item which for some reason cannot be evaluated, it shall be deemed as non-responsive and/or non-responsible. Failure to comply with these RFP requirements may result in the Proposal being eliminated from further consideration. All Proposals which are determined to be responsive, responsible, and/or acceptable will continue on to next phase.

5.3 Analysis Phase: In this phase of the evaluation process, the evaluation committee reviews to determine numerical scores for each proposal. The evaluation factors are listed in order of their relative importance and weight:

- **Cost (Weight/Value of 35%/Points)** – The point allocations for price on the other offers will be evaluated according to the following formula: Price of the lowest responsive and responsible offer divided by the price of the responsive and responsible offer being rated times the maximum 35 points allocated for price equals the awarded points.

$$\frac{X}{Y} * 35 = Z$$

X = Lowest bid price
Y = Offeror's bid price
Z = Assigned points

- **Technical (Weight/Value of 31%/Points) (*BLIND*)** – Technical factors are scored by the evaluation committee without knowledge of the identity of the vendor (blind) and generally aid in determining the vendor's technical ability to perform the service.

    - How well does the Offeror's proposal demonstrate a clear understanding of and appropriate response to the scope of work and related objectives? (10%)
    - How well do proposed specimen processing procedures (including collection, transportation, testing, retesting, storage, timeline, etc.) meet the agency's technical and timeliness requirements? (12%)
    - How well do proposed reporting procedures meet the agency's technical and timeliness requirements? (9%)

- **Management (Weight/Value of 34%/Points)** – Management factors are scored with knowledge of the identity of the vendor and generally aid in determining the vendor's past performance of the service or provision of the service. Management factors to be evaluated include personnel, experience, ability to provide timely services; the ability to technically implement and maintain the structure and resources for providing all services listed in this RFP, demonstrating where applicable the ability to perform the service reflected by technical training, education and general experience of staff and a documented record of past performance of providing marketing and communication services. The Management portion of the proposal must include substantial evidence of the Respondent and its staff's ability to undertake the services required and outlined in this RFP.

    (a) Comprehensive project management plan with identified activities, personnel, resources, and timelines (4%):
    (b) History and experience in performing the work (10%):
    (c) Proposal demonstrates availability of personnel, facilities, equipment, and other resources (10%):
        a. Consider to what extent does the offeror rely on in-house resources vs. contracted resources.
        b. Consider thoroughness of contingency planning to address potential disruptions.
    (d) Proposal demonstrates highly-qualified personnel with the experience necessary to meet the program requirements (10%):
        a. Consider all personnel, including laboratory, clerical, training, and counseling personnel
        b. Consider expertise of employees, sub-contractors, etc.
        c. Consider commitment to diversity and equity in hiring and training staff

5.4 Best and Final Offer (BAFO) – At the Agency's discretion, the top vendors may be given the opportunity to provide a BAFO. The Agency will notify offerors if a BAFO may be submitted and will establish a date and time for submission. If an offeror chooses to not make a BAFO,

its initial response to this RFP will be considered as the BAFO. Unsolicited BAFOs, including but not limited to such offers submitted by non-finalists, will not be accepted. The numerical scores for the Cost factor from the Analysis Phase will be adjusted for any BAFO received.

5.5 MSDH intends to award a single contract to the responsible and responsive vendor whose proposal is determined in writing to be the most advantageous to the State taking into consideration the evaluation factors set forth in this RFP. No other factors or criteria shall be used in the evaluation.

Section 6 – Minimum Vendor Qualifications

The following minimum Vendor requirements are mandatory. Failure to meet any of these requirements may result in disqualification of the proposal submitted by your company. Please respond by restating each minimum requirement, including the number, listed below with documentation that proves specifically how your company meets that minimum criterion. If, in the opinion of the procurement team, you fail to prove that your company meets any of these minimum requirements, the proposal will be disqualified from further evaluation. If this happens, you will be notified of the decision and will have an opportunity to provide additional information to prove your company does meet the minimum requirements. It is incumbent upon the disqualified Vendor to respond timely and completely to any such notice as unreasonable delays and/or non-responsive submissions may result in the disqualification being upheld without further review.

The Vendor must have:

6.1 Prior Experience: The Vendor must have ten (10) years of experience providing similar testing and reporting services.

6.2 Office and Staff Location: The Vendor must be currently located within the United States.

6.3 Minimum Testing Capacity: The Vendor must test a minimum of 40,000 specimen per year.

6.4 Proficiency Testing: The Vendor must be a regulated laboratory that is successfully participating in an acceptable commercial proficiency testing program that monitors compliance or a certificate of accreditation from the Department of Health and Human Services, Health Care Financing Administration (HCFA) pursuant to Section 353 of the Public Health Services, Act as revised by the Clinical Laboratory Improvement Amendments (CLIA) of 1988. This would exclude any laboratory that:

a. has been convicted, under Federal or State laws relating to fraud and abuse, false billing or kickbacks;
b. has had their CLIA certificate suspended, limited, or revoked;
c. employs persons who have been convicted of violating CLIA requirements, as specified in section 353(1) of the PHS Act;
d. had alternative sanctions imposed;
e. had its accreditation withdrawn or revoked; or
f. was/is excluded from participation in Medicare or Medicaid.

6.5 Quality Control and Testing Protocol: Agrees to requirements in quality control and testing protocol as stated in Attachment B.

6.6 Financial Stability: Vendor must certify that it is financially stable and provide supporting documentation as requested by MSDH.

Section 7 – Proposal Submission Requirements

7.1 Proposal Minimum Content

Written proposal shall contain the following minimum information:

(1) name of business, location of business, and the place of performance of the proposed contract, *(Vendor Questionnaire)*

(2) age of business and the average number of employees over the past three (3) years; *(Vendor Questionnaire)*

(3) resume listing abilities, qualifications and experience of all individuals who will be assigned to provide the required services; *(Management Submission)*

(4) a listing of other contracts under which services similar in scope, size, or discipline to the required services were performed or undertaken within a previous period of time, as specified in the RFP or RFQ; *(Vendor Questionnaire)* and,

(5) listing of three contracts under which services similar in scope, size, or discipline were performed or undertaken, including at least two (2) references for current contracts or those awarded during the past five (5) years. List three (3) projects to include the names and addresses of the projects, the scope of the project, and the names and telephone numbers of the clients for reference purposes. All information on the proposal form must be completed. Incomplete or unsigned proposal forms will be rejected.); *(Vendor Questionnaire)*

(6) a plan giving as much details as is practical explaining how the services will be provided. *(Technical Submission)*

7.1.1 Submission Format – Each vendor must submit their written proposal in the style and format outlined herein. No staples or bound documents. Clips and three ring binders are acceptable.

MSDH discourages overly lengthy and costly proposals. In preparing a proposal response, all narrative portions should be straightforward, detailed, and precise.

Proposals must be typewritten on 8.5" x 11" paper (charts or graphs may be provide on legal-sized paper) using Times New Roman font type, font size 12, with standard half-inch margins. Appendices, as well as samples and templates required of the proposal need not comply with font and margin restriction. **Technical Proposals shall not exceed 20 pages (back and front) total**. Each vendor must submit their written proposal in the style and format outlined herein.

The proposal shall consist of three (3) separate sections: technical, cost, and management. Pursuant to Mississippi Code Annotated §§ 27-104-7 and 31-7-401 through 31-7-423, the State of Mississippi requires a **blind evaluation** of certain factors not requiring knowledge of the name of an offeror. ***All Vendor-identifying information shall not be included or otherwise be removed and/or redacted. Identifying information includes, but is not limited to, any prior, current and future names or addresses of the offeror, any names of incumbent staff, any prior, current and future logos, watermarks, and company colors, any information, which identifies the offeror as an incumbent, and any other information, which would affect the blind evaluation of technical factors.*** The Technical Section **shall have no identifying information ("Blind")**.

MSDH has received permission to score price openly. Therefore, the Cost and Management Sections will be allowed to have identifying information. Any Proposals that do not adhere to these requirements of "Blind" submission will be deemed non-responsive and may be rejected on that basis. **MSDH reserves the right to cancel this solicitation and not make any contract award if any offeror(s) fail to adhere to blind submission requirements, or when it is in the best interest of the State as determined by MSDH.**

The three sections of the proposal shall be comprised as listed below. It is the Vendor's responsibility to organize and separate the information into the sections and tabs accordingly.

SECTION I
TECHNICAL

Tab 1 – Technical Proposal (Blind Submission-no identifying information)

The written proposal should clearly and fully explain how the laboratory plans to provide the required laboratory testing and reporting services, in particular the requirements of the Detailed Minimum Specifications and Deliverables attached hereto as Attachment A. Any proposed services that are offered in addition to those services specified in Attachment A, and for which there would be no additional charge, (for example: testing of compulsory repeat specimens, consultation services regarding need for further testing of individuals with positive screen results, DNA testing, performing confirmatory tests) may be included under the heading "Additional No Cost Services".

The proposal must be prepared and organized in a clear and concise manner that is easily understandable. It should be prepared without any identifying information. It should be plain and straight forward without any unnecessary designs, symbols, colors. In the proposal, the offeror shall address all aspects of each component listed in Attachment A and provide a comprehensive description of how the bidder proposes to ensure effective integration of activities within the existing service delivery structure.

SECTION II
MANAGEMENT

Tab 2 – Proposal Cover Sheet (Attachment C) and narrative questionnaire (Attachment C-1): Failure to complete and/or sign may result in Vendor being determined nonresponsive. **Unauthorized modification or addition to any portion of the Attachment C or C-1may be cause for rejection of the proposal.**

In preparing your written response to the narrative questionnaire, repeat each question, including the number, or requirement followed by your response. Please provide complete answers and explain all issues in a concise, direct manner.

Tab 3–Minimum Vendor Requirements Confirmation: Self Attestation of Minimal Qualifications- Attachment B and supporting information.

Tab 4 – References- Each vendor must furnish at least three (3) references for contracts under which services similar in scope, size, or discipline were performed or undertaken, including at least two (2) references for current contracts or those awarded during the past five (5) years. Include the name of the organization, the length of the contract, a brief summary of the work, and the name(s), telephone numbers, and email information of a responsible contact person for reference purposes. MSDH reserves the right to contact, at its discretion, references submitted.

Tab 5 –Management Summary- Provides a comprehensive project management plan with identified activities, personnel, resources, and timelines**.**

Qualifications/Experience of Staff- Vendor shall include its background and relevant experience as well as any of the vendor's subsidiaries and subcontractors expected to be involved in the provision of these services. Qualifications, experience, and length of service of all personnel involved in performing these services shall be provided along with their titles and responsibilities. Specify for all key professional staff their roles and responsibilities. Identify numbers and qualifications of staff maintained for laboratory operations by area, e.g. specimen accessioning/processing, data entry, testing (by area), reporting, initial notifications, filter paper management, etc.).

Résumés for Key Staff - Provide a complete résumé of key vendor staff who will be assigned to render services to the Agency, including detailed information on any special training or designations. Include what role and responsibilities each individual will fulfill throughout the length of the contract. Also, specifically identify the project manager and/or executive who will serve as the primary contact for the Agency. Provide each person's total number of years of experience related to the services being requested in the RFP.

The laboratory shall maintain a listing of qualified specialists in pediatric endocrine, metabolic, hemoglobin disorders, immunodeficiencies, pulmonology, molecular genetics and a laboratory specialist who have agreed to provide medical consultation to the laboratory. This medical consultation may be related to establishing and monitoring screening test algorithms, and test performance, interpretation of screening test results, and recommendations for further evaluation.

Tab 6 –Laboratory Certifications- Provide copies of certificates and other forms of documentation that indicate the laboratory meets all specifications, terms, and conditions for professional services as stated in Attachment A. Vendor shall submit copies of all proficiency testing submissions/performance evaluations for the last two years. Where no external proficiency testing program is available, the vendor shall submit the results of the laboratory's semi-annual proficiency evaluations for the last two years.

Tab 7 – Attachment E- Standard Certifications

Tab 8 – Signed Acknowledgment(s) of RFP Amendment(s) (if any were posted)

Tab 9 – Contract Exceptions - The vendor may submit a list of contract exceptions along with suggested language. However, exceptions are discouraged as many clauses are required and non-negotiable. Any requests for exceptions or changes will need to be submitted with the proposal for review and approved by MSDH legal. Any changes must be finalized prior to contract submission to PPRB for approval before the contract can be executed. If MSDH and vendor cannot reach an agreement regarding terms, MSDH reserves the right to reject the suggested changes and proposal submission as nonresponsive and move to the next qualified vendor for contract award.

SECTION III
COST

Tab 10 –Cost Proposal (Attachment D) - Failure to complete and/or sign the Price Acknowledgment Form may result in Vendor being determined non-responsive. **Modification or addition to any portion of the Attachment may be cause for rejection of the proposal.**

7.2 Submission Requirements

7.2.1 Proposals must be submitted in writing. One (1) signed original and six (6) hard (paper) color copies of the proposal package, and an electronic copy (on CD, DVD or flash drive) of its proposal package submitted in a sealed envelope or package to the place identified for receipt of Proposals no later than the time and date specified for receipt of Proposals. The electronic files shall not be password protected, shall be in Portable Document Format (PDF®) or Microsoft Word and/or Microsoft Excel format, and shall be capable of being copied to other media including readable in Microsoft Word and/or Microsoft Excel. The procurement team, not the evaluation committee, will be the only ones with access to this electronic copy, which shall consist of the following:

a. One (1) electronic copy of the complete proposal including all attachments in a searchable Microsoft Office® format, preferably in Word® or PDF®;

b. One (1) REDACTED FOR PUBLICATION electronic copy of the complete proposal including all attachments and referenced documents in a searchable Microsoft Office® format, preferably in Word® or PDF®, ***if the proposal contains confidential or proprietary information, pursuant to RFP Section 7.2.13 below***.

7.2.2 The sealed envelope or package shall be marked with the proposal opening date and time, and the number of the Request for Proposals **Wednesday, March 15, 2023, 10:00 AM RFx# 3120002630.**

7.2.3 Proposals are subject to rejection unless submitted with the information included on the outside the sealed proposal envelope or package.

7.2.4 Sealed Proposals should be mailed or hand-delivered to and labeled as follows:
RFP for Genetic Testing and Reporting RFx# 3120002630

Submission Deadline: **Wednesday, March 15, 2023, 10:00 AM**
Attention: Jennifer Dotson, Proposal Coordinator
MISSISSIPPI STATE DEPARTMENT OF HEALTH
570 E. Woodrow Wilson Ave.
Jackson, MS 39216-4538
SEALED PROPOSAL – DO NOT OPEN

7.2.5 All proposal packages must be received by the Agency no later than **Wednesday, March 15, 2023, 10:00 AM CT**. Proposals submitted via facsimile (fax) machine **will not** be accepted. It is suggested that if a proposal is mailed to the Agency, it should be posted in certified mail with a return receipt requested. The Agency will not be responsible for mail delays or lost mail. All risk of late arrival due to unanticipated delay – whether delivered by hand, USPS, courier or other delivery service or method – is entirely on the Vendor. All vendors are urged to take the possibility of delay into account when submitting a proposal.

7.2.6 In addition to the paper copy, vendors may also submit a proposal package on-line in the State of Mississippi electronic procurement system, the State of Mississippi's Accountability System for Governmental Information and Collaboration (MAGIC). **Submission through MAGIC, however, it is not mandatory.** In order to submit electronically vendors must be registered as a vendor in MAGIC system and have an I.D. number and password assigned at the time of registration. Registering as a supplier with the State of Mississippi allows businesses to register for upcoming RFx opportunity notifications by the products they supply, search the system for upcoming RFxs, respond to RFxs electronically, and receive purchase orders by email. To register, please go to the following website: http://www.DFA.ms.gov/DFA-offices/mmrs/mississippi-suppliers-vendors/supplier-self-service/. Technical assistance may be found at http://www.dfa.ms.gov/dfa-offices/mmrs/mississippi-suppliers-vendors/.

7.2.7 If submitting via MAGIC, the documents are required to be uploaded in the same format required for the paper submission. The paper submission will take precedence if there is a discrepancy between the two.

7.2.8 Timely submission of the proposal package is the responsibility of the Vendor. Proposals received after the specified time will be rejected and maintained unopened in the procurement file. A proposal received at the place designated in the solicitation for receipt of Proposals after the exact time specified for receipt will not be considered unless it has been determined by the Agency that the late receipt was due solely to mishandling by the Agency after receipt at the specified address.

7.2.9 The time and date of receipt will be indicated on the sealed proposal envelope or package by Agency staff. The only acceptable evidence to establish the time of receipt at the office identified for proposal opening is the time and date stamp of that office on the proposal wrapper or other documentary evidence of receipt used by that office.

7.2.10 Each page of the proposal must be numbered. Multiple page attachments and samples should be numbered internally within each document, and not necessarily numbered in the overall page number sequence of the entire proposal. The intent of this requirement is for the Vendor to submit all information in a manner that it is clearly referenced and easily located.

7.2.11 Failure to submit cost on the cost proposal form provided may be considered cause for rejection of the proposal. **Modifications or additions to any portion of the proposal document may be cause for rejection of the proposal.** The Agency reserves the right to decide, on a case-by-case basis, whether to reject a proposal with modifications or additions as non-responsive.

7.2.12 A proposal response that includes terms and conditions that do not conform to the terms and conditions in the proposal document is subject to rejection as non-responsive. The Agency reserves the right to permit the Vendor to withdraw nonconforming terms and conditions from its proposal response prior to a determination by the Agency of non-responsiveness based on the submission of nonconforming terms and conditions.

7.2.13 As a precondition to proposal acceptance, the Agency may request the Vendor to withdraw or modify those portions of the proposal deemed non-responsive that do not affect quality, quantity, price, or delivery of the service.

7.2.14 Any Vendor claiming that its response contains information exempt from the Mississippi Public Records Act (Miss. Code Ann. §§ 25-61-1 *et seq.* and 79-23-1), shall segregate and mark the information as ***"Confidential"*** and provide the specific statutory authority for the exemption.

If the proposal contains ***confidential information***, one (1) REDACTED FOR PUBLIC RECORD electronic copy of the complete proposal including all attachments shall be labeled ***"PUBLIC RECORD"*** and submitted in a searchable Microsoft Office® format, preferably in Word® or Portable Document Format (PDF®).

If a redacted copy is not submitted, the Agency shall consider the entire Proposal to be public record. The redacted copy should include a separate list that identifies which section or information has been redacted (including page number) and the Vendor shall provide the specific statutory authority for the exemption. Per Mississippi Code Annotated § 25-61-9(7), the type of service to be provided, the price to be paid, and the term of the Contract cannot be deemed confidential.

The redacted copy shall be considered public record and immediately released, without notification to Vendor, pursuant to any request under the Mississippi Public Records Act, Mississippi Code Annotated §§ 25-61-1 *et seq.* and 79-23-1. Redacted copies shall also be used/released for any reason deemed necessary by the Agency, including but not limited to, submission to a regulatory entity, posting to the Transparency Mississippi website, etc.

Section 8 – Vendor Certification

The Vendor agrees that submission of a signed Proposal and all required attachments, is certification that the Vendor will accept an award made to it as a result of the submission. Under no circumstances, shall the maximum time for proposal acceptance by the State extend beyond one (1) year from the date of opening.

Section 9 – Debarment

By submitting a proposal, the Vendor certifies that it is not currently debarred from submitting Proposals for contracts issued by any political subdivision or agency of the State of Mississippi and that it is not an agent of a person or entity that is currently debarred from submitting Proposals for contracts issued by any political subdivision or agency of the State of Mississippi.

Section 10 – Registration with Mississippi Secretary of State

By submitting a proposal, the Vendor certifies that it is registered to do business in the State of Mississippi as prescribed by Mississippi law and the Mississippi Secretary of State or, if not already registered, that it will do so within seven (7) business days of being notified by the Agency that it has been selected for contract award. Sole proprietors are not required to register with the Mississippi Secretary of State.

Section 11 – Insurance, Bonds, or Other Sureties

11.1 Each successful vendor shall, at its own expense, obtain and maintain insurance, bond, or other surety which shall include the following types and coverage limits:

11.1.1 Workers Compensation coverage as required by the State of Mississippi. The policy shall provide coverage for all states of operation that apply to the performance of scope of work.

11.1.2 Comprehensive General Liability or Professional Liability insurance, with minimum limits of $2,000,000.00 per occurrence.

11.2 Additionally:

11.2.1 In no event shall the requirement for an insurance, bond, or other surety be waived.

11.2.2 All insurances policies will list the State of Mississippi as an additional insured.

11.2.3 All insurance policies shall be issued by companies authorized to do business under the laws of the State of Mississippi, meaning insurance carriers must be licensed or hold a Certificate of Authority from the Mississippi Insurance Department.

11.2.4 Vendor shall submit to the Agency within 15 days of notification of intent-to-award, a certificate of insurance and/or bond which outlines the coverage and limits defined in the procurement and Contract. There are no provisions for exceptions to this requirement. Failure to provide the certificates of insurance within 15 day period may be cause for your proposal to be declared non-responsive or for your contract to be cancelled.

11.2.5 Vendor shall obtain at the Vendor's expense the insurance and/or bond requirements specified in the procurement and Contract prior to performing under this Contract, and the Vendor shall maintain the required insurance and/or bond coverage throughout the duration of this Contract and all warranty periods. There are no provisions for exceptions to this requirement.

11.2.6 Vendor shall not commence work under this Contract until it obtains all insurance and/or bond required under this provision and furnishes a certificate or other form showing proof of current coverage to the State. After work commences, the Vendor will keep in force all required insurance and/or bond until the Contract is terminated or expires.

11.2.7 Vendor shall submit renewal certificates as appropriate during the term of the Contract.

11.2.8 Vendor shall instruct the insurers to provide the Agency 30 days advance notice of any insurance cancellation.

11.2.9 Vendor shall ensure that should any of the above described policies be cancelled before the expiration date thereof, or if there is a material change, potential exhaustion of

aggregate limits or intent not to renew insurance and/or bond coverage(s), that written notice will be delivered to the Agency.

11.2.10 There shall be no cancellation, material change, potential exhaustion of aggregate limits or non-renewal of insurance and/or bond coverage(s) to the Agency. Any failure to comply with the reporting provisions of this clause shall constitute a material breach of Contract and shall be grounds for immediate termination of this Contract by the Agency.

Section 12 – Proposal Opening

Submitted Proposals shall be opened at the time/date designated for bid submission in Section 2. The proposal opening is not open to the public.

Section 13 – Award Notification

Award for this procurement will be posted on the Mississippi Contract/Procurement Opportunity Search Portal website at https://www.ms.gov/dfa/contract_bid_search/Bid?autoloadGrid=False and the Agency website at http://www.msdh.ms.gov under RFPs/Grants in the bottom left corner of the webpage for 48 hours prior to Official award notices. After public posting, MSDH will notify in writing the responsible Offeror(s) whose proposal is determined to be the most advantageous to the State taking into consideration evaluation factors set for herein. Notice of intended Contract award will be sent via e-mail.

Section 14 – Procurement Methodology

14.1 Restrictions on Communications with Agency and Agency Staff

At no time shall any vendor or its personnel contact, or attempt to contact, any Agency staff regarding this RFP except the contact person as set forth and, in the manner, prescribed in RFP Section 3.

14.2 Vendor Investigations

Before submitting a proposal, each vendor shall make all investigations and examinations necessary to ascertain all site conditions and requirements affecting the full performance of the Contract and to verify any representations made by the Agency upon which the Vendor will rely. If the Vendor receives an award as a result of its proposal submission, failure to have made such investigations and examinations will in no way relieve the Vendor from its obligation to comply in every detail with all provisions and requirements of the Contract documents, nor will a plea of ignorance of such conditions and requirements be accepted as a basis for any claim whatsoever for additional compensation.

14.3 Expenses Incurred in Preparing a Proposal

The Agency accepts no responsibility for any expense incurred by any vendor in the preparation and presentation of a proposal. Such expenses shall be borne exclusively by the Vendor.

14.4 Property of MSDH

All Proposals submitted become the property of MSDH upon receipt and will not be returned to the Respondent once opened. MSDH has the right to use any and all ideas or adaptations of ideas contained in any proposal received as a result of this RFP. Selection or rejection of the Proposal will not affect this right. Proposals become public documents upon submission.

14.5 News Releases

The MSDH is the only entity authorized to issue news releases relating to this RFP, its evaluation, and award of any contract and performance thereunder.

14.6 Ownership of Materials

All materials and data produce for MSDH under a contract resulting from this RFP shall be owned by MSDH. This agency does not share original produced content.

14.7 Informalities and Irregularities

The Agency has the right to waive minor defects or variations of a proposal from the exact requirements of the specifications that do not affect the price, quality, quantity, delivery, or performance time of the services being procured. If insufficient information is submitted by a vendor with the submission for the Agency to properly evaluate it, the Agency has the right to require such additional information as it may deem necessary after the time set for receipt of Proposals, provided that the information requested does not change the price, quality, quantity, delivery, or performance time of the services being procured.

14.8 Discussions/ Competitive Negotiations

MSDH is seeking the best combination of price, experience and quality of services. Discussions may be conducted with vendors who submit Proposals determined to be reasonably susceptible of being selected for the award, but Proposals may also be accepted without such discussions. Likewise, MSDH also reserves the right to accept any proposal as submitted for contract award, without substantive negotiation of offered terms, services or prices. For these reasons, all parties are advised to propose their most favorable terms initially.

If any component received a Fail score (a “No” response) on any item or contains an item which for some reason cannot be evaluated, it shall be deemed as non-responsive and/or non-responsible. Failure to comply with these RFP requirements may result in the Qualification

being eliminated from further consideration. All Proposals which are determined to be responsive, responsible, and/or acceptable will continue on to next phase.

14.9 RFP Does Not Constitute Acceptance of Offer

The release of the RFP does not constitute an acceptance of any offer, nor does such release in any way obligate MSDH to execute a contract with any other party. The Agency reserves the right to accept, reject, or negotiate any or all offers on the basis of the evaluation criteria contained herein. The final decision to execute a contract with any party rests solely with MSDH.

15.0 Rejection of Proposals

A proposal that includes terms and conditions that do not conform to the terms and conditions in the RFP document is subject to rejection as non-responsive. Further, submission of a proposal that is not complete and/or signed is subject to rejection as non-responsive. The Agency reserves the right to permit the Vendor to withdraw nonconforming terms and conditions from its proposal prior to a determination by the Agency staff of non-responsiveness based on the submission of nonconforming terms and conditions. Furthermore, if a Vendor's price is substantially higher or lower than those of other vendors, meaning those in excess or deficient of a twenty-five percent (25%) differential, the Vendor's price may be deemed non-responsive.

MSDH reserves the right to reject any or all proposal received in response to the RFP, cancel the RFP in its entirety, and/or issue another RFP.

15.1 Withdrawal of Proposals

If the price bid/offered is substantially lower than those of other vendors, a mistake may have been made. A vendor may withdraw its proposal from consideration if certain conditions are met:

(1) The proposal is submitted in good faith;
(2) The price bid/offered is substantially lower than those of other vendors because of a mistake;
(3) The mistake is a clerical error, not an error of judgment; and,
(4) Objective evidence drawn from original work papers, documents, and other materials used in the preparation of the proposal demonstrates clearly that the mistake was an unintentional error in arithmetic or an unintentional omission of a quantity of labor or material.

To withdraw a proposal that includes a clerical error after proposal opening, the Vendor must give notice in writing to the Agency of claim of right to withdraw a proposal. Within two (2) business days after the proposal opening, the Vendor requesting withdrawal must provide to the Agency all original work papers, documents, and other materials used in the preparation of the bid/offer.

A Vendor may also withdraw a bid/offer, prior to the time set for the opening of Proposals, by simply making a request in writing to the Agency. No explanation is required.

No vendor who is permitted to withdraw a proposal shall, for compensation, supply any material or labor to or perform any subcontract or other work for the person to whom the contract is awarded, or otherwise benefit from the Contract.

No partial withdrawals of a proposal are permitted after the time and date set for the proposal opening; only complete withdrawals are permitted.

14.10 Post-Award Vendor Debriefing

An offeror, successful or unsuccessful, has the right to request a post-award debriefing, in writing, by U.S. mail, postage prepaid, or electronic submission.

A debriefing must be requested within three (3) business days of the Notice of Intent to Award. A debriefing is "requested" when the written request is received by MSDH, specifically, Jennifer Dotson, Proposal Coordinator and Chief Procurement Officer. The responsibility to timely deliver the request to MSDH lies entirely with the bidder.

Unless good cause exists for a delay, a debriefing typically occurs within three (3) business days of receipt of the written request.

A post-award debriefing is a meeting and not a hearing; therefore, legal representation is not required. If a bidder prefers to have legal representation present, the bidder must notify MSDH in writing and identify its attorney by name, address, and telephone number. MSDH will schedule and/or suspend and reschedule the meeting at a time when a Representative of the Office of the Mississippi Attorney General can be present. MSDH reserves the right to provide a written debriefing memorandum.

At a minimum, the debriefing information shall include:

a. The agency's evaluation of significant weaknesses or deficiencies in the debriefed vendor's bid;
b. The overall evaluated cost or price of the successful vendor(s) and the debriefed vendor;
c. The overall ranking of all vendors, if the OPSCR develops a ranking during the selection process;
d. A summary of the rationale for the contract award; and
e. Reasonable responses to relevant questions about selection procedures contained in the solicitation, applicable regulations, and other applicable authorities that were followed.

The debriefing shall not include a point-by-point comparison of the debrief vendor's bid with those of other bidders.

For additional information regarding Post-Award Vendor Debriefing, as well as the information that may be provided and excluded, please see Section 7-113 through 7-113.07,

Post-Award Vendor Debriefing, of the *PPRB OPSCR Rules and Regulations* as updated and replaced by PPRB, located at: https://www.dfa.ms.gov/personal-service-contract-review .

14.11 Protest of Solicitation or Award

Any actual or prospective Offeror who is aggrieved in connection with this solicitation or the outcome of this RFP may file a protest with the Jennifer Dotson, Chief Procurement Officer. The protest must be submitted within seven (7) calendar days of the Notice of Intent to Award the contract, in writing after such aggrieved person or entity knows or should have known of the facts giving rise thereto. The protesting Offeror must provide facts and evidence to support the protest. *A protest is considered filed when received by Jennifer Dotson, Chief Procurement Officer, Mississippi State Department of Health via either U.S. Postal Service mail, postage prepaid, or by personal delivery*. **Protests filed after 5:00 PM CST, seven (7) calendar days of Notice of Intent to Award, will not be considered.**

Content of Protest
A protest must be in writing, dated, and signed by the protestor. It must also include:

a. The name and address of the protestor;
b. An appropriate identification of the procurement and, if a contract has been awarded, its number;
c. A statement of the specific basis for the protest and a statement of the reason(s) for protest, citing the law(s), rule(s), regulation(s), or procedure(s) on which the protest is based;
d. Supporting exhibits, evidence, or documents to substantiate any claims unless not available within the filing time, in which case the expected availability date shall be indicated, and
e. Be submitted in an envelope labelled "PROTEST"

In the event of a timely protest, MSDH will not proceed further with the solicitation or the award of the contract until the Public Procurement Review Board approves the determination that continuation of the solicitation or award of the contract without delay is necessary to protect substantial interests of the State.

Protestors should seek resolution of their complaints initially with MSDH, and such protest shall be decided by the State Health Officer who will issue a statement in writing.

Any person adversely affected by the protest decision of the State Health Officer may appeal administratively to the Public Procurement Review Board. Any such appeal must be filed within seven (7) calendars days of receipt of a protest decision.

Should a protestor wish to, instead, seek resolution of their protest directly to the PPRB, the protest must be submitted to the Director of OPSCR and shall clearly state, "PROTEST SUBMITTED DIRECTLY TO PPRB."

Any party filing a protest directly to PPRB shall file the protest with the Director of OPSCR within seven (7) calendar days after the aggrieved party knew or should have known of the facts and circumstances upon which the protest is based, but in no event later than within seven (7) calendar days of the solicitation posting or award.

The PPRB shall decide whether the solicitation or award was in accordance with the Constitution, statutes, rules and regulations, and the terms and conditions of the solicitation.

For additional information regarding Protests, please see Section 7-112 through 7-112.04, Protest of Solicitations or Awards, of the *PPRB OPSCR Rules and Regulations* as updated and replaced by PPRB located at: https://www.dfa.ms.gov/personal-service-contract-review.

Section 15 –Contract, Terms and Conditions

The release of this RFP does not constitute an acceptance of any submitted proposal, nor does such release in any way obligate MSDH to execute a contract with any offeror. MSDH reserves the right to accept, reject, or negotiate any and all offers on the basis of the evaluation criteria contained within this document. The final decision to execute a Contract with any party rests solely with MSDH, including the decision to make no award of Contract.
A draft Contract has been included as **Attachment F** to this RFP for your review. Any contract entered into with the Agency pursuant to this RFP shall include clauses required pursuant to the *PPRB OPSCR Rules and Regulations* as updated and replaced by PPRB. These required clauses are mandatory and are nonnegotiable. A copy of the required contract clauses can be found at https://www.dfa.ms.gov/media/9413/pprb-opscr-rules-and-regulations-efficetive-01182020.pdf

MSDH discourages exceptions from the draft contract content, regardless of content being required or not. Such exceptions may cause a proposal to be rejected as non-responsive. Proposals which condition the proposal based upon the State accepting other terms and conditions not found in the RFP, or which take exception to the State's terms and conditions, may be found non-responsive, and no further consideration of the proposal will be given.

Any contract resulting from this RFP shall consist of the contract, this RFP, its amendments, the offeror's proposal and the Best and Final Offer where applicable.

Section 16 – Agency Website

This RFP, any amendment thereto, such as Questions and Answer document(s) and Summary of Pre-Proposal Conference, Tour, or Site Visit, if any were issued, the Notice of Intent-To-Award, and the Evaluation Report will be posted on the Agency website Agency website at http://www.msdh.ms.gov under RFPs/Grants in the bottom left corner of the webpage and on the Mississippi Contract/Procurement Opportunity Search Portal website at https://www.ms.gov/dfa/contract_bid_search/Bid?autoloadGrid=False.

Section 17 – Attachments

The attachments to this RFP are made a part of this RFP as if copied herein in words and figures.

Attachment A

MINIMUM SPECIFICATIONS AND DELIVERABLES

A. Minimum Specifications:

The written proposal should be such that it clearly and fully explains how the laboratory plans to:

(1) Receive specimens directly from the birthing hospitals and county health departments located in Mississippi. The applicant shall describe their current protocols for receiving and processing specimens and describe their plan to incorporate the approximately 40,000 Newborn Screening (NBS) collection cards (See Appendix B) to be received annually from Mississippi. The contractor will arrange for daily courier pick-up service at designated locations within each Mississippi birthing hospital for next day delivery to the contractor's laboratory and provide for tracking of such specimens (with exceptions for weekend and holiday days when no transport service is available). A minimum of six (6) day a week pick up and overnight delivery is expected for all birthing hospitals. Saturday delivery to the laboratory shall be provided for specimens shipped Fridays. The contractor shall also monitor the courier service for performance and timeliness. **Contractor may also receive specimens from other (non-hospital) birthing facilities within Mississippi and must include those results in the data sent to MSDH Genetic Services Bureau if the mother's address is within Mississippi.**

(2) Enter all demographic data fields from the NBS collection card (see Appendix B) in a format suitable for electronic transfer to the MSDH Genetic Services Bureau, according to program specifications. The Genetic Services Bureau will supply the collection card to the birthing hospitals and county health departments. **Collection cards are hand-written documents, so they will require data entry expertise to process.**

(3) Describe in detail their current laboratory information management system including an explanation of their capacity to capture and segregate Mississippi data. The following information shall be captured if provided on the collection card:

- Specimen status (i.e., first specimen, repeat specimen) **and reason for repeat**
- Infant's first and last name, previous last name, date of birth, time of birth in military time, sex, race, ethnicity, weight in grams at time of specimen collection, and feeding status at time of specimen collection, meconium ileus status at birth, **NICU, Hyperalimentation and Carnitine statuses at birth, gestational age, weeks' gestation, and baby's name at discharge**
- Birth information (i.e., single birth, twin A or B, or other multiple births, and whether or not the infant was premature)
- Date of collection of specimen, and time of collection in military time **and who collected the sample**
- Infant's transfusion status and date of last transfusion

- Hospital of birth, county health department, or hospital where specimen was collected (using the 3-digit designated hospital codes to be supplied by the MSDH Genetic Services Bureau)
- Hospital medical record number for the infant
- Mother's first and last name, mother's date of birth, residence (street address, city, state, Zip code, county) telephone number, social security number and Medicaid number **and mother's medical history**
- Name of infant's physician and contact information
- Submitter's name and address
- Universal Newborn Hearing Screening Test (UNHS) results
- Critical Congenital Heart Defects (CCHD) Screening results
- **Emergency contact name and phone number**

(4) Provide a secure portal where MSDH Genetic Services Bureau personnel can look up results by patient date of birth, patient last name, patient sex, filter paper number, AKA name, and submitter name. The search results should be able to be sorted by filter paper number, submitter name, patient last name. From the search list, we should be able to view the original NBS card that was submitted as well as the result, and the demographics that were entered from the NBS card.

a) The portal should provide ability to run reports listed in the deliverables on demand and allowing for manipulation of the reporting period dates.

b) Portal should also provide access for submitter hospitals to enter updates to information on the DBS cards, as well as additional status updates related to Critical Congenital Heart Disease (CCHD) and to report birth defects.

c) Portal must provide a way for users to update their password and should automatically prompt users to update passwords that have not been changed in the last 90 days.

d) Portal must provide the ability for a system administrator at MSDH to enter new users and inactivate users who no longer need access.

e) Conduct testing for specified conditions on specimens received. The offeror shall describe their current protocols and procedures for processing and testing specimens, and describe their ability to test for the following conditions:

- Argininemia
- Argininosuccinic Aciduria (ASA Lyase Deficiency)
- Biotinidase Deficiency
- Carbamoylphosphate Synthetase Deficiency (CPS Deficiency)
- Carnitine Palmitoyltransferase I Deficiency (CPT I)
- Carnitine Palmitoyltransferase II Deficiency (CPT II)
- Carnitine/Acylcarnitine Translocase Deficiency (Translocase)
- Citrullinemia (ASA Synthetase Deficiency)

- Cystic Fibrosis (CF)
- Glutaric Aciduria Type I (GA I)
- Homocystinuria
- 3-Hydroxy-3-Methylglutaryl-CoA Lyase Deficiency (HMG)
- Hyperammoninemia, Hyperornithinemia, Homocitrullinemia Syndrome (HHH)
- Hypermethioninemia
- Isobutyryl-CoA Dehydrogenase Deficiency
- Isovaleric Acidemia (IVA)
- Long-Chain 3-hydroxyacyl-CoA Dehydrogenase Deficiency (LCHAD)
- Malonic Aciduria
- Maple Syrup Urine Disease (MSUD)
- Medium-Chain Acyl-CoA Dehydrogenase Deficiency (MCAD)
- 2-Methylbutyryl-CoA Dehydrogenase Deficiency
- 3-Methylcrotonyl-CoA Carboxylase Deficiency (3MCC Def)
- 3-Methylglutaconyl-CoA Hydratase Deficiency
- Methylmalonic Acidemia (MMA)
- Mitochondrial Acetoacetyl-CoA Thiolase Deficiency
- Mucopolysaccharidosis I (MPS I)
- Multiple Acyl-CoA Dehydrogenase Deficiency (MADD or GA II)
- Multiple CoA Carboxylase Deficiency
- 5-Oxoprolinuria (Pyroglutamic aciduria)
- Propionic Acidemia (PPA)
- Severe Combined Immunodeficiency (SCID)
- Short-Chain Acyl-CoA Dehydrogenase Deficiency (SCAD)
- Short-Chain Hydroxy Acyl-CoA Dehydrogenase Deficiency (SCHAD)
- Spinal Muscular Atrophy (SMA)
- Trifunctional Protein Deficiency (TFP Deficiency)
- Tyrosinemia Type I (TYR I)
- Tyrosinemia Type II (TYR II)
- Very Long-Chain Acyl-CoA Dehydrogenase Deficiency (VLCAD)
- X-linked adrenoleukodystrophy (X-ALD)

(5) Report the results of all tests to the MSDH Genetic Services Bureau electronically according to program specified format and time frames **(i.e., a real-time HL7 interface).** Certain inconclusive and presumptive positive test result must also be reported by telephone and fax. **Interface must also be able to send a pdf copy of the result report.**

(6) Provide MSDH with written emergency backup plan for temporary laboratory support services in the event of a natural disaster, terrorist event, an emergency, or other hazards preventing testing at the contracted laboratory.

(7) Provide written laboratory policy on storage of dried blood spot specimens (e.g., use, storage, and destruction where, and how long). The use, storage and destructions of specimens must be approved by MSDH Genetic Services Bureau.

(8) Report test results to the MSDH Genetic Services Bureau via electronic transmission and allow electronic access to test results and other data via a secure connection. All electronic transmissions of data must meet all State and Federal security requirements including those in the Health Information Protection and Portability Assurance Act (HIPPAA) and regulations and be compatible with provisions of the Health Information Technology for Economic and Clinical Health (HITECH Act). The laboratory IT personnel will provide training to the Program Manager and Follow-up personnel on how to use the applications. The bidder shall provide documentation of their ability to submit test results electronically according to the program specified format and to report inconclusive and presumptive positive results by telephone and fax as specified by the program.

(9) Report test results to the facility where the specimen originated. The applicant shall provide documentation of their ability to provide electronic reports and/ or mail hard copy reports of all tests to the hospital, county health department, or other site where the dried blood specimen was collected within one workday after completion of all tests.

(10) Ensure availability of a Health Level Seven (HL7) interface engine to interface with Mississippi hospitals and/or Mississippi State Department of Health divisions. The various uses of the HL7 engine will be determined by the Bureau.

(11) Inform the MSDH Genetic Services Bureau of invalid/unacceptable specimens received. The Genetic Services Bureau shall be notified of all invalid/unacceptable specimens. The applicant shall describe their current criteria for invalid/unacceptable specimen designation and provide historical data monthly to indicate the number of invalid/unacceptable specimens for each criterion.

(12) Provide a plan, in the Management sections, that shall include the personnel to be involved in each process, the qualifications of the individuals, and their length of service and experience. Additional information regarding staffing and personnel may be included if pertinent.

(13) The applicant shall include details such as the primary screen assay for each condition that includes reference ranges/cut-off values or other indicators used to determine abnormal/presumptive positive results. The applicant shall also include details on the secondary assay used when to be performed, the control that will be included, and the expected turnaround time from date of birth to collection lab to date of results.

- Any variations in testing that differ from the methods for specimen analysis or quality control measures listed in the MSDH Rules and Regulations Governing Newborn Screening and Birth Defects shall be noted and explained. All changes in testing protocol must be submitted to the Genetics Services Bureau for review and acceptance and prior to lab implementation.

- A detailed description of the entire testing process including specimen preparation, testing method with all instruments and reagents specified, a description of all

control samples, the reportable reference ranges, and other pertinent information to be provided upon request by MSDH Genetic Services Bureau.

- Laboratories should be prepared to submit copies of their current Standard Operating Procedure Manuals that pertain to testing for the specified conditions if requested by the MSDH Genetic Services Bureau.

B. Deliverables:

The selected respondent will provide reports to the MSDH Genetic Services Bureau pertaining to its operations in support of the newborn screening program as indicated below. All reports will identify the period being reported, will be submitted electronically, and are to be submitted in the timeframe and format requested by MSDH Genetics Bureau.

The selected respondent will be required to submit reports detailed below to MSDH Genetic Services Bureau as noted (i.e., monthly, quarterly, or annually). In addition, the MSDH Genetic Services Bureau may request additional reports of the selected respondent as needed to complete national surveys and statistical reports or for quality assurance or improvement efforts. The selected respondent is expected, as part of its internal quality assurance program, to maintain an electronic database containing all the information required for each report and to regularly evaluate these reports. MSDH Genetic Services Bureau reserves the right to request additional reports or remove reports from these lists at any time.

Monthly NBS Statistics Report
This report will include the following information:

- Time period covered by the report
- Number of initial screens conducted, listed by collection source
- Number of repeat screens conducted, listed by collection source
- Number of unacceptable specimens, listed by collection source
- Number of confirmed abnormal results, listed by collection source
- Number of presumptive positive results, listed by collection source
- Number of confirmed positive results, listed by collection source

Monthly Transit Turnaround Time Report
This report will list the number of screening specimens, by collection source, received by the selected respondent after being collected by the collection source within the given time period. All transit reports should include the following:

- Number of newborns born in the facility with a NBS collection card
- Initial newborn specimens submitted
- Total Specimens (includes initial and repeat specimens)
- Unacceptable specimens
- Specimens drawn early (<24 hours)
- Initial specimens collected post-transfusion
- Average turn-around time from birth to report (days)
- Average time from birth to collection

- Average time collection to receipt at the screening lab
- Average time from receipt to report
- Upper range value of turn-around time from birth to report
- Lower range value of turn-around time from birth to report

Monthly Transit Turnaround Time – Patient Detail Report
This report will include the following information for all screening specimens that were received by the selected respondent more than two (2) days after being collected by the collection source within the given time period.

- Time period covered by the report
- Name of collection source and ID number
- Infant's name
- Date of birth
- Date specimen was drawn
- Date specimen was received by the selected respondent
- Was the specimen quality/quantity acceptable (Yes or No)?
- Were the screen results normal (Yes or No)?

Monthly CCHD Statistics Report
This report will include the following information:

- Number of newborns born in the facility with a NBS collection card
- Number of CCHD screens conducted, listed by collection source
- Number of infants passed screens, listed by collection source
- Number of infants failed screens, listed by collection source
- Number of infants not screened/no screening results, listed by collection source

Monthly UNHS Statistics Report
This report will include the following information:

- Number of newborns born in the facility with a NBS collection card
- Number of initial hearing screens conducted, listed by collection source
- Number of repeat screens conducted, listed by collection source
- Number of infants passed screens, listed by collection source
- Number of infants failed screens, listed by collection source
- Number of infants not screened/no screening results, listed by collection source

Quarterly Hospital Performance Report
This report will include the following information by hospital:

- Time period covered by the report
- Number of newborns born in the facility with a NBS collection card
- Number of initial bloodspot screens conducted
- Number of initial CCHD screens conducted
- Number of initial hearing screens conducted
- Number of infants not screened/no screening results for CCHD
- Number of infants not screened/no screening results for hearing
- Number of unacceptable specimens

- Percent of unacceptable specimens
- Number of infants transfused
- Percent of infants transfused
- Number of specimens drawn early (<24 hours) without transfusion or transfer
- Percent of specimens drawn early (<24 hours) without transfusion or transfer
- Number of specimens drawn early (<24 hours) due to transfusion
- Number of specimens drawn early (<24 hours) due to transfer to different facility
- Number of infants missing demographics
- Percent of infants missing demographics
- Average turn-around time from birth to report (days)
- Average time from birth to collection
- Average time collection to receipt at the screening lab
- Average time from receipt to report
- Upper range value of turn-around time from birth to report
- Lower range value of turn-around time from birth to report

Annual NBS Statistical Report

The selected respondent will submit an annual report covering January through December to the MSDH Genetic Services Bureau no later than the following March. This report will also include cumulative statistics for the entire calendar year, listed by collection source.

- Time period covered by the report
- Number of newborns born in the facility with a NBS collection card
- Number of initial screens conducted
- Number of repeat screens conducted
- Total specimens (includes initial and repeat specimens)
- Total number of all screens conducted
- Percentage of infants who did not require any repeat screens
- Number of unacceptable specimens
- Number of initial specimens collected post-transfusion
- Number of specimens drawn early (<24 hours)
- Number of confirmed abnormal results
- Number of presumptive positive results
- Number of confirmed positive results
- Average age of infants when initial specimen collected
- Average turn-around time from birth to report (days)
- Average time from birth to collection
- Average time collection to receipt at the screening lab
- Average time from receipt to report
- Upper range value of turn-around time from birth to report
- Lower range value of turn-around time from birth to report

The selected respondent, as part of its internal quality assurance program, is expected to maintain statistics on its own laboratory operations, as well as on the NBS activities of the birthing facilities/collection sources that submit newborn screening specimens.

In addition to the statistical compilation listed above, respondents are encouraged to submit additional statistical indices they feel would contribute to an assessment of the MSDH Genetic Services Bureau.

Attachment B

SELF-ATTESTATION OF MINIMAL QUALIFICATIONS

1. CERTIFICATION OF LOCATION

Laboratories submitting proposals must be located within the United States.

Proposer certifies that it meets this requirement.

Indicate: Yes [ ] No [ ]

The laboratory is located at:

2. PROFICIENCY TESTING

This laboratory is successfully participating in a commercial proficiency testing program that will monitor the performance of testing methodologies.

Proposer certifies that it meets this requirement.

Indicate: Yes [ ] No [ ]

The laboratory is participating in the following proficiency testing program(s) that will monitor the performance of testing methodologies:

3. CERTIFICATE(S) OF COMPLIANCE OR ACCREDITATION

The laboratory has either a certificate of compliance and/or a certificate of accreditation from the Department of Health and Human Services, Health Care Financing Administration (HCFA) pursuant to Section 353 of the Public Health Service Act as revised by the Clinical Laboratory Improvement Amendments (CLIA) of 1988.

A copy of these certificates has been provided in the Management Section of the Proposal

Proposer certifies that it meets this requirement.

Indicate: Yes [ ] No [ ]

4. QUALITY CONTROL AND TESTING PROTOCOL

The laboratory will adhere to all quality control measures listed in the Rules and Regulations governing Newborn Screening and Birth Defects. The Mississippi Board of Health must approve any exceptions. The current quality control measures in the Regulations Governing Newborn Screening and Birth Defects Registry (See Appendix A) may be amended in the future, as necessary, to accommodate any new testing protocols. All changes in testing protocol must be submitted to the Genetic Services Bureau for review and acceptance, prior to laboratory implementation. Laboratories must submit copies of proficiency testing/performance evaluations upon request by the program. Laboratories must submit copies of validation or verification documentation for all assays used if requested by the program. Any changes to the reference ranges/cut-off values or other indicators used to determine abnormal/presumptive positive results must be provided in writing to MSDH Genetic Services Bureau as they occur.

The laboratory will provide up to twelve (12) training sessions and/or presentations for MSDH personnel and healthcare professionals each year, as requested by the MSDH. Times and locations will be determined by the MSDH Genetic Services.

Proposer accepts this requirement.

Indicate: Yes [ ] No [ ]

5. Financial Stability or Solvency:

Vendor must be financially stable or solvent. *MSDH cannot prepay for services rendered or goods delivered. Therefore, all invoices must be submitted in arrears.* MSDH reserves the right to request information relative to a vendor's financial status. MSDH also reserves the right to request a current financial statement, prepared and certified by an independent auditing firm and/or require that Vendors document their financial ability to provide the products and services proposed up to the Vendor's cost proposal's total dollar amount.

Proposer certifies that it is financially solvent and will comply with MSDH request for financial information.

Indicate: Yes [ ] No [ ]

By signing below, the company Representative certifies that he/she has authority to bind the company, and further acknowledges and certifies that this information is accurate and correct.

_____ _____

Signature **Date**

_____

Print Name/Title

Attachment C

PROPOSAL COVER SHEET

Proposals are to be submitted as listed below, on or before **Wednesday, March 15, 2023, 10:00 AM CT.**

PLEASE MARK YOUR ENVELOPE:

RFP for Newborn Screen Laboratory Services **RFx# 3120002630**
Submission Deadline: **Wednesday, March 15, 2023, 10:00 AM**
Attention: Jennifer Dotson, Proposal Coordinator
MISSISSIPPI STATE DEPARTMENT OF HEALTH
570 E. Woodrow Wilson Ave.
Jackson, MS 39216-4538
SEALED PROPOSAL – DO NOT OPEN

Name of Company: _____

Proposal By: _____

Signature: _____

Address: _____

City/State/Zip: _____

Telephone: _____

Fax Number: _____

Email Address: _____

Name, title, phone number, and email address of Company Representative to be contacted by Agency, if different than person identified above: _____
_____

Attachment C-1

Vendor Questionnaire

In addition to providing the above contact information, please answer the following questions regarding your company. You may prepare a separate document labeled as Attachment C-1 Vendor Questionnaire by restating the question and providing your response.

1. The name of the Offeror, the physical location and mailing address of your company's home office, principal place of business, and place of incorporation of the Offeror's principal place of business, and, if different, the place of performance of the proposed contract;

2. What is the age of the Offeror's business and average number of employees over the past five years (5), as specified in the RFP;

3. Please provide a listing of other contracts under which services similar in scope, size, or discipline to the required services were performed or undertaken within the past four years (5), as specified in the RFP;

4. How many years has your company been in the business of performing the services called for in this RFP?

5. Has your company ever been involved in a lawsuit involving any area covered by this RFP? If yes, provide details including dates and outcomes.

6. Has your company been cited or threatened with citation within the last three (3) years by federal or state regulators for violations of any federal, state, or local law or federal, state or local regulation? If yes, please describe the circumstances in detail.

7. Confirm that your company is not presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from covered transaction by any federal department or agency, or by any political subdivision or agency of the State of Mississippi.

8. Please confirm the proposal is valid for at least one (1) year subsequent to the date of submission.

9. List up to three (3) governmental clients for whom your company has provided one or more of the services requested in this RFP. If possible, please list three additional clients besides any previously listed references. For each client, specify the type of work performed by your company and the period of time retained as a client. For each client, the list must specify:

    a. Client information, including the name, title, address, email address, and phone number of a person whom we may contact to confirm as needed,
    b. The type of work your company provided to the client,

c. Contract effective dates for the time period(s) (beginning and end dates) your company provided services to the client.

10. List all clients that have discontinued use of your services in the past three (3) years and your understanding of their discontinued use of your services. For each client, the list must specify:
    a. Client information, including the name, title, address, email address, and phone number of a person whom we may contact to confirm as needed,
    b. The type of work your company provided to the client,
    c. Contract effective dates for the time period(s) (beginning and end dates) your company provided services to the client.
    d. Reason services were discontinued.

Attachment D

COST PROPOSAL

Company	
Contact Person	
Telephone Number	
Email Address	

The price quoted shall be ALL INCLUSIVE. The price includes, but is not limited to, the following:

1. All required equipment/material(s);
2. All required insurance, bond, or other surety;
3. All required overhead/profit;
4. All required applicable taxes;
5. All required vehicles;
6. All required travel;
7. All required labor and supervision;
8. All required training;
9. All required business and professional certifications, licenses, permits, or fees; and,
10. Any and all other direct or indirect costs, incurred or to be incurred.

Offeror will perform the services required by the RFP for the period specified at the following price per specimen:

_____/specimen

Printed Name of Representative/Title:_____

Date: _____

Signature: _____

Note: ***Failure to sign the Cost Proposal may result in the proposal being rejected as non-responsive. Modifications or additions to any portion of this document may be cause for rejection of the proposal.***

Attachment E

Standard Certifications and Acknowledgements

By signing below, the company Representative certifies that he/she has authority to bind the company, and further acknowledges and certifies the following on behalf of the company:

1. That he/she has thoroughly read and understands the Request for Proposals and Attachments thereto;

2. That the company meets all requirements and acknowledges all certifications contained in the Request for Proposals and Attachments thereto;

3. That the company agrees to all provisions of the Request for Proposals and Attachments thereto including, but not limited to, those to be included in any contract resulting from this RFP (Attachment E);

4. That the company will perform the services required at the prices quoted above;

5. That, to the best of its knowledge and belief, the cost or pricing data submitted is accurate, complete, and current as of the submission date;

6. The Contractor represents that its workers are licensed, certified **and/or** possess the requisite credentials to perform the services; and,

7. **NON-DEBARMENT:** By submitting a proposal, the vendor certifies that it is not currently debarred from submitting Proposals for contracts issued by any political subdivision or agency of the State of Mississippi and that it is not an agent of a person or entity that is currently debarred from submitting Proposals for contracts issued by any political subdivision or agency of the State of Mississippi.

8. **INDEPENDENT PRICE DETERMINATION:** The vendor certifies that the prices submitted in response to the solicitation have been arrived at independently and without, for the purpose of restricting competition, any consultation, communication, or agreement with any other vendor or competitor relating to those prices, the intention to submit a proposal, or the methods or factors used to calculate the prices bid/offered.

9. **PROSPECTIVE CONTRACTOR'S REPRESENTATION REGARDING CONTINGENT FEES:** The prospective contractor represents as a part of such Contractor's proposal that such Contractor ***has not*** retained any person or agency on a percentage, commission, or other contingent arrangement to secure this contract.

10. **REPRESENTATION REGARDING CONTINGENT FEES:** Contractor represents that it ***has not*** retained a person to solicit or secure a State contract upon an agreement or understanding for a commission, percentage, brokerage, or other contingent fee, except as disclosed in the Contractor's proposal.

11. **REPRESENTATION REGARDING GRATUITIES:** Contractor represents that it ***has not*** violated, *is not* violating, and promises that it *will not* violate the prohibition against gratuities set forth in Section 6-204 (Gratuities) of the *PPRB OPSCR Rules and Regulations*.

Company Name: _____

Printed Name of Representative: _____

Date: _____

Signature: _____

Note: ***Failure to sign these Certifications and Acknowledgements may result in the Proposals being rejected as non-responsive. Modifications or additions to any portion of this document may be cause for rejection of the Proposals.***

Attachment F

MISSISSIPPI STATE
DEPARTMENT OF HEALTH
CONTRACT FOR PROFESSIONAL SERVICES

1. Parties. This contractual agreement is entered into by and between the Mississippi State Department of Health (hereinafter "MSDH" or "Agency") and [Company Name] (hereinafter "Contractor").

2. Purpose. The purpose of this contract is for MSDH to engage Contractor to provide certain professional services.

3. Period of Performance. This contract will become effective for the beginning [Month Day, 20XX] and ending on [Month Day, 20XX], upon the approval and signature of the parties hereto.

4. General Terms and Conditions. This contract is hereby made subject to the terms and conditions included in Attachment A, captioned "General Terms and Conditions", attached hereto and incorporated herein.

5. Acknowledgements, Special Terms and Compliance. This contract is hereby made subject to the terms and conditions included in Attachment B, captioned "Acknowledgements and Special Terms", and Attachment C, captioned "Federal Procurement Compliance", attached hereto and incorporated herein.

6. Scope of Services. Contractor will perform and complete in a timely and satisfactory manner the services described in Attachment D, captioned "Services and Compensation", and Attachment E, captioned "Statement of Work", which are attached hereto and made a part hereof by reference.

7. Consideration. As consideration for the performance of the services referenced above, MSDH agrees to compensate Contractor as provided in Attachments D and E.

8. Notices. All notices required or permitted to be given under this agreement must be in writing and personally delivered or sent by certified United States mail, postage prepaid, return receipt requested, to the party to whom the notice should be given at the address set forth below. Notice shall be deemed given when actually received or when refused. The parties agree to promptly notify each other in writing of any change of address.

For MSDH: Daniel Edney, MD, FACP, FASAM
State Health Officer
Mississippi State Department of Health
Post Office Box 1700
Jackson, Mississippi 39215-1700

[with Copy to Teselyn Melton Funches, Procurement Coordinator]

For the Contractor: [Name of Authorized Signer], [Title]
[Company Name]
[Mailing Address]
[City], Mississippi [Zip Code]
[Email Address]
[Phone Number]

Any other correspondence concerning this agreement shall be directed as follows:

For MSDH: [Name of MSDH Employee], [Title]
Mississippi State Department of Health
[Mailing Address]
[City], [State] [Zip Code]
[Email Address]@msdh.ms.gov

9. Entire Agreement. This document and all incorporated attachments constitute the entire agreement of the parties with respect to the subject matter contained herein and supersedes and replaces any and all prior negotiations, understandings and agreements, written or oral, between the parties relating thereto.

In witness whereof, the parties hereto have affixed, on duplicate originals, their signatures on the date indicated below, after first being authorized so to do.

_____
ATE

By:_____
Daniel Edney, MD, FACP, FASAM
State Health Officer
Mississippi State Department of Health

_____
DATE

By:_____
[Name of Authorized Signer], [Title]
[Company Name]

ATTACHMENT A: GENERAL TERMS AND CONDITIONS

1. Assignment and Receipt of Amounts Payable. This section applies only to a Contractor which serves as a clinical or healthcare provider for the Department, as follows:

    a. The Contractor authorizes the Department to accept assignment and receive any amounts payable under Part B of Title XVII and Title XIX of the Social Security Act and/or any monies collected for service rendered by the Contractor under the terms of this contract, including but not limited to private insurance, third-party arrangements, or such other payment or reimbursement mechanisms as may be applicable or available. The Contractor agrees that the Department shall be the payor or financial reimbursement mechanism of last resort when other sources are mandated or are available.

    b. The Contractor agrees that no additional charges will be made to patients/clients to whom services are provided under the terms of this contract.

2. Anti-assignment/subcontracting. Contractor acknowledges that it was selected by the State to perform the services required hereunder based, in part, upon Contractor's special skills and expertise. Contractor shall not assign, subcontract, or otherwise transfer this agreement, in whole or in part, without the prior written consent of the State, which the State may, in its sole discretion, approve or deny without reason. Any attempted assignment or transfer of its obligations without such consent shall be null and void. No such approval by the State of any subcontract shall be deemed in any way to provide for the incurrence of any obligation of the State in addition to the total fixed price agreed upon in this agreement. Subcontracts shall be subject to the terms and conditions of this agreement and to any conditions of approval that the State may deem necessary. Subject to the foregoing, this agreement shall be binding upon the respective successors and assigns of the parties.

3. Applicable Law. The contract shall be governed by and construed in accordance with the laws of the State of Mississippi, excluding its conflicts of laws, provisions, and any litigation with respect thereto shall be brought in the courts of the State. Contractor shall comply with applicable federal, state, and local laws and regulations.

4. Approval Clause. It is understood that if this contract requires approval by the Public Procurement Review Board and/or the Mississippi Department of Finance and Administration Office of Personal Service Contract Review and this contract is not approved by the PPRB and/or OPSCR, it is void and no payment shall be made hereunder.

5. Attorneys' Fees and Expenses. Subject to other terms and conditions of this agreement, in the event Contractor defaults in any obligations under this agreement, Contractor shall pay to the State all costs and expenses (including, without limitation, investigative fees, court costs, and attorney's fees) incurred by the State in enforcing this agreement or otherwise reasonably related thereto. Contractor agrees that under no circumstances shall the customer be obligated to pay any attorney's fees or costs of legal action to Contractor.

6. Authority to Contract. Contractor warrants: (a) that it is a validly organized business with valid authority to enter into this agreement; (b) that it is qualified to do business and in good standing in the State of Mississippi; (c) that entry into and performance under this agreement is not restricted or prohibited by any loan, security, financing, contractual, or other agreement of any kind; and, (d) notwithstanding any other provision of this agreement to the contrary, that there are no existing legal proceedings or prospective legal proceedings, either voluntary or otherwise, which may adversely affect its ability to perform its obligations under this agreement.

7. Availability of Funds. It is expressly understood and agreed that the obligation of the Mississippi State Department of Health (MSDH) to proceed under this agreement is conditioned upon the appropriation of funds by the Mississippi State Legislature and the receipt of state and/or federal funds. If the funds anticipated for the continuing fulfillment of the agreement are, at any time, not forthcoming or insufficient, either through the failure of the federal government to provide funds or of the State of Mississippi to appropriate funds or the discontinuance or material alteration of the program under which funds were provided or if funds are not otherwise available to MSDH, MSDH shall have the right upon ten (10) working days written notice to Contractor, to terminate this agreement without damage, penalty, cost or expenses to MSDH of any kind whatsoever. The effective date of termination shall be as specified in the notice of termination.

8. Compliance with Laws. Contractor understands that the Mississippi State Department of Health (MSDH) is an equal opportunity employer and therefore, maintains a policy which prohibits unlawful discrimination based on race, color, creed, sex, age, national origin, physical handicap, disability, genetic information, or any other consideration made unlawful by federal, state, or local laws. All such discrimination is unlawful and Contractor agrees during the term of the agreement that Contractor will strictly adhere to this policy in its employment practices and provision of services. Contractor shall comply with, and all activities under this agreement shall be subject to, all applicable federal, State of Mississippi, and local laws and regulations, as now existing and as may be amended or modified.

9. Confidential Information. Confidential Information shall be defined as (1) those materials, documents, data, and other information which the Contractor has designated in writing as proprietary and confidential; and (2) all materials, documents, data and information which the Contractor acquires as a result of its contact with and efforts on behalf of MSDH, and any other information designated in writing as confidential by MSDH or the State of Mississippi.

   Each party to this contract agrees to protect all Confidential Information provided by one party to the other, to treat all such Confidential Information as confidential to the extent that confidential treatment is allowed under State and/or Federal law, and, except as otherwise required by law, not to publish or disclose such information to any third party without the other party's written permission, and to do so by using those methods and procedures normally used to protect the party's own confidential information. Any liability resulting from the wrongful disclosure of confidential information on the part of the Contractor or its Subcontractors shall rest with the Contractor. Disclosure of any confidential

information by the Contractor or its Subcontractors without the express written approval of MSDH shall result in the immediate termination of this contract.

10. Confidentiality. Notwithstanding any provision to the contrary contained herein, it is recognized that MSDH is a public agency of the State of Mississippi and is subject to the Mississippi Public Records Act. Mississippi Code Annotated §§ 25-61-1 *et seq*. If a public records request is made for any information provided to MSDH pursuant to the agreement and designated by the Contractor in writing as trade secrets or other proprietary confidential information, MSDH shall follow the provisions of Mississippi Code Annotated §§ 25-61-9 and 79-23-1 before disclosing such information. The MSDH shall not be liable to the Contractor for disclosure of information required by court order or required by law.

11. Disclosure of Confidential Information. In the event that either party to this agreement receives notice that a third party requests divulgence of confidential or otherwise protected information and/or has served upon it a subpoena or other validly issued administrative or judicial process ordering divulgence of confidential or otherwise protected information that party shall promptly inform the other party and thereafter respond in conformity with such subpoena to the extent mandated by law. This section shall survive the termination or completion of this agreement. The parties agree that this section is subject to and superseded by Mississippi Code Annotated §§ 25-61-1 *et seq*.

12. Exceptions to Confidential Information. Contractor and the State shall not be obligated to treat as confidential and proprietary any information disclosed by the other party ("disclosing party") which:

    (1) is rightfully known to the recipient prior to negotiations leading to this agreement, other than information obtained in confidence under prior engagements;

    (2) is generally known or easily ascertainable by nonparties of ordinary skill in the business of the customer; is released by the disclosing party to any other person, firm, or entity (including governmental agencies or bureaus) without restriction;

    (3) is independently developed by the recipient without any reliance on confidential information;

    (4) is or later becomes part of the public domain or may be lawfully obtained by the State or Contractor from any nonparty; or,

    (5) is disclosed with the disclosing party's prior written consent.

13. Disputes. Any dispute concerning a question of fact arising under this Contract shall be disposed of by good faith negotiation between duly authorized representative of MSDH and the Contractor. Disputes that cannot be resolved in this manner shall be determined by a court of competent jurisdiction in Hinds County, Mississippi. Pending final decision of a dispute, the Contractor shall proceed diligently with the performance of its obligation in this agreement.

14. E-Payment. Contractor agrees to accept all payments in United States currency via the State of Mississippi's electronic payment and remittance vehicle. The agency agrees to make payment in accordance with Mississippi law on "Timely Payments for Purchases by Public Bodies," which generally provides for payment of undisputed amounts by the agency within forty-five (45) days of receipt of invoice. Mississippi Code Annotated § 31-7-301 et seq.

15. E-Verification. If applicable, Contractor represents and warrants that it will ensure its compliance with the Mississippi Employment Protection Act of 2008 and will register and participate in the status verification system for all newly hired employees. Mississippi Code Annotated §§ 71-11-1 et seq. The term "employee" as used herein means any person that is hired to perform work within the State of Mississippi. As used herein, "status verification system" means the Illegal Immigration Reform and Immigration Responsibility Act of 1996 that is operated by the United States Department of Homeland Security, also known as the E-Verify Program, or any other successor electronic verification system replacing the E-Verify Program. Contractor agrees to maintain records of such compliance. Upon request of the State and after approval of the Social Security Administration or Department of Homeland Security when required, Contractor agrees to provide a copy of each such verification. Contractor further represents and warrants that any person assigned to perform services hereafter meets the employment eligibility requirements of all immigration laws. The breach of this agreement may subject Contractor to the following:

    a. termination of this contract for services and ineligibility for any state or public contract in Mississippi for up to three (3) years with notice of such cancellation/termination being made public;

    b. the loss of any license, permit, certification or other document granted to Contractor by an agency, department or governmental entity for the right to do business in Mississippi for up to one (1) year; or,

    c. both.

    In the event of such cancellation/termination, Contractor would also be liable for any additional costs incurred by the State due to Contract cancellation or loss of license or permit to do business in the State.

16. Failure to Deliver. In the event of failure of Contractor to deliver services in accordance with the contract terms and conditions, MSDH, after due oral or written notice, may procure the services from other sources and hold Contractor responsible for any resulting additional purchase and administrative costs. This remedy shall be in addition to any other remedies that MSDH may have.

17. Failure to Enforce. Failure by MSDH at any time to enforce the provisions of the contract shall not be construed as a waiver of any such provisions. Such failure to enforce shall not affect the validity of the contract or any part thereof or the right of MSDH to enforce any provision at any time in accordance with its terms.

18. Force Majeure. Each party shall be excused from performance for any period and to the extent that it is prevented from performing any obligation or service, in whole or in part, as a result of causes beyond the reasonable control and without the fault or negligence of such party and/or its subcontractors. Such acts shall include without limitation acts of God, strikes, lockouts, riots, acts of war, epidemics, governmental regulations superimposed after the fact, fire, earthquakes, floods, or other natural disasters ("force majeure events"). When such a cause arises, Contractor shall notify the State immediately in writing of the cause of its inability to perform, how it affects its performance, and the anticipated duration of the inability to perform. Delays in delivery or in meeting completion dates due to force majeure events shall automatically extend such dates for a period equal to the duration of the delay caused by such events, unless the State determines it to be in its best interest to terminate the agreement.

19. HIPAA Compliance. Contractor agrees to comply with the "Administrative Simplification" provisions of the Health Insurance Portability and Accountability Act of 1996, including electronic data interchange, code sets, identifiers, security, and privacy provisions, as may be applicable to the services under this contract.

20. Indemnification.

    a. If Contractor is another agency or entity of the State of Mississippi, the following shall apply:

       Contractor's tort liability, as an entity of the State of Mississippi, is determined and controlled in accordance with Mississippi Code Annotated §§ 11-46-1 *et seq*., including all defenses and exceptions contained therein. Nothing in this agreement shall have the effect of changing or altering this liability or of eliminating any defense available to the State under statute.

    b. For all other Contractors, the following shall apply:

       To the fullest extent allowed by law, Contractor shall indemnify, defend, save and hold harmless, protect, and exonerate the agency, its commissioners, board members, officers, employees, agents, and representatives, and the State of Mississippi from and against all claims, demands, liabilities, suits, actions, damages, losses, and costs of every kind and nature whatsoever including, without limitation, court costs, investigative fees and expenses, and attorney's fees, arising out of or caused by Contractor and/or its partners, principals, agents, employees and/or subcontractors in the performance of or failure to perform this agreement. In the State's sole discretion, Contractor may be allowed to control the defense of any such claim, suit, etc. In the event Contractor defends said claim, suit, etc., Contractor shall use legal counsel acceptable to the State. Contractor shall be solely responsible for all costs and/or expenses associated with such defense, and the State shall be entitled to participate in said defense. Contractor shall not settle any claim, suit, etc. without the State's concurrence, which the State shall not unreasonably withhold.

21. Independent Contractor Status. Contractor shall, at all times, be regarded as and shall be legally considered an independent contractor and shall at no time act as an agent for the State. Nothing contained herein shall be deemed or construed by the State, Contractor, or any third party as creating the relationship of principal and agent, master and servant, partners, joint ventures, employer and employee, or any similar such relationship between the State and Contractor. Neither the method of computation of fees or other charges, nor any other provision contained herein, nor any acts of the State or Contractor hereunder creates, or shall be deemed to create a relationship other than the independent relationship of the State and Contractor. Contractor's personnel shall not be deemed in any way, directly or indirectly, expressly or by implication, to be employees of the State. Neither Contractor nor its employees shall, under any circumstances, be considered servants, agents, or employees of MSDH, and MSDH shall be at no time legally responsible for any negligence or other wrongdoing by Contractor, its servants, agents, or employees. MSDH shall not withhold from the contract payments to Contractor any federal or state unemployment taxes, federal or state income taxes, Social Security tax, or any other amounts for benefits to Contractor. Further, MSDH shall not provide to Contractor any insurance coverage or other benefits, including Worker's Compensation, normally provided by the State for its employees.

22. Modification or Renegotiation. This agreement may be modified only by written agreement signed by the parties hereto. The parties agree to renegotiate the agreement if federal and/or state revisions of any applicable laws or regulations make changes in this agreement necessary.

23. No Limitation of Liability. Nothing in this agreement shall be interpreted as excluding or limiting any tort liability of Contractor for harm caused by the intentional or reckless conduct of Contractor or for damages incurred through the negligent performance of duties by Contractor or the delivery of products that are defective due to negligent construction.

24. Non-Discrimination for HIV/AIDS. As a recipient of Federal funds, directly or indirectly through payments from the Department, the Contractor agrees that no person(s) who are otherwise qualified shall be denied employment, funds, education, or care in the program(s) funded in whole or in part by the Department on account of affliction with Acquired Immune Deficiency Syndrome (AIDS)-related conditions, or on the basis of their infection with the Human Immunodeficiency Virus (HIV). This non-discrimination agreement and policy shall likewise apply to those individuals or groups who may be perceived as having AIDS or the aforementioned AIDS-related conditions, or who are perceived as being infected with HIV.

25. Ownership of Documents and Work Papers. MSDH shall own all documents, files, reports, work papers and working documentation, electronic or otherwise, created in connection with the project which is the subject of this agreement, except for Contractor's internal administrative and quality assurance files and internal project correspondence. Contractor shall deliver such documents and work papers to MSDH upon termination or completion of the agreement. The foregoing notwithstanding, Contractor shall be entitled to retain a set of such work papers for its files. Contractor shall be entitled to use such work papers only after receiving written permission from MSDH and subject to any copyright protections.

Additionally, Contractor assures that any and all information regarding clients of MSDH will be kept strictly confidential and will become the property of MSDH. Contractor assures that MSDH shall have full access to all information collected. The Contractor is prohibited from use of the above described information and/or materials without the express written approval of MSDH.

Paper documents and electronic devices and media containing Personally Identifiable Information must be returned or, if approved by MSDH, destroyed in a preapproved manner. Contractor agrees to contact MSDH for further guidance on approved methods on destroying electronic devices and related media.

26. Paymode. Payments by state agencies using the State's accounting system shall be made and remittance information provided electronically as directed by the State. These payments shall be deposited into the bank account of Contractor's choice. The State may, at its sole discretion, require Contractor to electronically submit invoices and supporting documentation at any time during the term of this Agreement. Contractor understands and agrees that the State is exempt from the payment of taxes. All payments shall be in United States currency.

27. Personally Identifiable Information. Contractor will not disclose or release any Personally Identifiable Information (PII) to which the Contractor has access except as required to do so to authorized employees and officials within the scope of the Contractor's duties under this contract. Furthermore, Contractor acknowledges that any unauthorized disclosure of the information provided under this contract may violate Federal and/or State laws and subject the Contractor to penalties.

28. Procurement Regulations. The contract shall be governed by the applicable provisions of the *Mississippi Public Procurement Review Board Office of Personal Service Contract Review Rules and Regulations*, a copy of which is available at 501 North West Street, Suite 701E, Jackson, Mississippi 39201 for inspection, or downloadable at www.dfa.ms.gov.

29. Record Retention and Access to Records. Provided Contractor is given reasonable advance written notice and such inspection is made during normal business hours of Contractor, the State or any duly authorized representatives shall have unimpeded, prompt access to any of Contractor's books, documents, papers, and/or records which are maintained or produced as a result of the project for the purpose of making audits, examinations, excerpts, and transcriptions. Unless mandated by federal or state law for a longer retention period, all records related to this agreement shall be retained by Contractor for three (3) years after final payment is made under this agreement and all pending matters are closed; however, if any audit, litigation or other action arising out of or related in any way to this project is commenced before the end of the three (3) year period, the records shall be retained for one (1) year after all issues arising out of the action are finally resolved or until the end of the three (3) year period, whichever is later. Unless mandated by federal or state law for a longer retention period, all records related to this agreement that contain, or are associated with, protected health information (PHI) shall be retained by Contractor for at least six (6) years after final payment is made under this agreement and all pending matters are closed;

however, if any audit, litigation or other action arising out of or related in any way to this project is commenced before the end of the six (6) year period, the records shall be retained for one (1) year after all issues arising out of the action are finally resolved or until the end of the six (6) year period, whichever is later.

30. Recovery of Money. Whenever, under the contract, any sum of money shall be recoverable from or payable by Contractor to MSDH, the same amount may be deducted from any sum due to Contractor under the contract or under any other contract between Contractor and MSDH. The rights of MSDH are in addition and without prejudice to any other right MSDH may have to claim the amount of any loss or damage suffered by MSDH on account of the acts or omissions of Contractor.

31. Reimbursement. MSDH agrees to provide reimbursement for the contract period. For contracts that include the use of Federal funds, MSDH agrees to provide reimbursement for the contract period in accordance with the requirements set forth in OMB Circular A-87. Such reimbursement will be made upon receipt of the necessary billing listing salaries, Social Security, retirement, and other items provided in this contract, including copies of payroll requisitions and invoice copies for materials, equipment, or supplies. Any final billings shall be submitted to MSDH no later than thirty (30) days after the close of the contract. Failure to submit final billings within the stated timeframe for this contract may be grounds for MSDH to reject such reimbursements. It is agreed by both parties that the following items will be made only when approved by both parties:

    a. Reimbursement in excess of the amount budgeted for any item; or

    b. Reimbursement of items not included in the budget; or

    c. The transfer of monies between items within the budget.

    It is agreed by both parties that no reimbursement will be made by MSDH until this contract has been signed by the appropriate personnel of both parties and until a budget for expenditures pursuant to the contract has been approved by MSDH.

32. Requirements Contract. During the period of the contract, Contractor shall provide all the service described in the contract. Contractor understands and agrees that this is a requirements contract and that MSDH shall have no obligation to Contractor if no services are required. Any quantities that are included in the scope of work reflect the current expectations of MSDH for the period of the contract. The amount is only an estimate and Contractor understands and agrees that MSDH is under no obligation to Contractor to buy any amount of the services as a result of having provided this estimate or of having any typical or measurable requirement in the past. Contractor further understands and agrees that MSDH may require services in an amount less than or in excess of the estimated annual contract amount and that the quantity actually used, whether in excess of the estimate or less than the estimate, shall not give rise to any claim for compensation other than the total of the unit prices in the contract for the quantity actually used.

33. Right to Audit. Contractor shall maintain such financial records and other records as may be prescribed by MSDH or by applicable federal and state laws, rules, and regulations. Unless mandated by federal or state law for a longer retention period, Contractor shall retain these records for a period of three (3) years after final payment, or until they are audited by MSDH, whichever event occurs first. These records shall be made available during the term of the contract and the subsequent three-year period for examination, transcription, and audit by the Mississippi State Auditor's Office, its designees, or other authorized bodies. Unless mandated by federal or state law for a longer retention period, Contractor shall retain these records for a period of six (6) years after final payment if such records contain, or are associated with, PHI. These records shall be made available during the term of the contract and the subsequent six (6) year period for examination, transcription, and audit by the Mississippi State Auditor's Office, its designees, or other authorized bodies.

34. Severability. If any part of this agreement is declared to be invalid or unenforceable, such invalidity or unenforceability shall not affect any other provision of the agreement that can be given effect without the invalid or unenforceable provision, and to this end the provisions hereof are severable. In such event, the parties shall amend the agreement as necessary to reflect the original intent of the parties and to bring any invalid or unenforceable provisions in compliance with applicable law.

35. State Property. Contractor will be responsible for the proper custody and care of any state-owned property furnished for Contractor's use in connection with the performance of this agreement. Contractor will reimburse the State for any loss or damage, normal wear and tear excepted.

36. Stop Work Order.

    a. *Order to Stop Work*: The Chief Procurement Officer, may, by written order to Contractor at any time, and without notice to any surety, require Contractor to stop all or any part of the work called for by this contract. This order shall be for a specified period not exceeding 90 days after the order is delivered to Contractor, unless the parties agree to any further period. Any such order shall be identified specifically as a stop work order issued pursuant to this clause. Upon receipt of such an order, Contractor shall forthwith comply with its terms and take all reasonable steps to minimize the occurrence of costs allocable to the work covered by the order during the period of work stoppage. Before the stop work order expires, or within any further period to which the parties shall have agreed, the Chief Procurement Officer shall either:

        i. cancel the stop work order; or,
        ii. terminate the work covered by such order as provided in the Termination for Default clause or the Termination for Convenience clause of this contract.

    b. *Cancellation or Expiration of the Order:* If a stop work order issued under this clause is canceled at any time during the period specified in the order, or if the period of the order or any extension thereof expires, Contractor shall have the right to resume work. An appropriate adjustment shall be made in the delivery schedule or Contractor price, or both, and the contract shall be modified in writing accordingly, if:

i. the stop work order results in an increase in the time required for, or in Contractor's cost properly allocable to, the performance of any part of this contract; and,
ii. Contractor asserts a claim for such an adjustment within 30 days after the end of the period of work stoppage; provided that, if the Chief Procurement Officer decides that the facts justify such action, any such claim asserted may be received and acted upon at any time prior to final payment under this contract.

c. *Termination of Stopped Work:* If a stop work order is not canceled and the work covered by such order is terminated for default or convenience, the reasonable costs resulting from the stop work order shall be allowed by adjustment or otherwise.

d. *Adjustments of Price:* If permissible, any adjustment in contract price made pursuant to this clause shall be determined in accordance with the Price Adjustment clause of this contract.

37. Termination for Convenience.

a. *Termination*. The Agency Head or designee may, when the interests of the State so require, terminate this contract in whole or in part, for the convenience of the State. The Agency Head or designee shall give written notice of the termination to Contractor specifying the part of the contract terminated and when termination becomes effective.

b. *Contractor's Obligations*. Contractor shall incur no further obligations in connection with the terminated work and on the date set in the notice of termination Contractor will stop work to the extent specified. Contractor shall also terminate outstanding orders and subcontracts as they relate to the terminated work. Contractor shall settle the liabilities and claims arising out of the termination of subcontracts and orders connected with the terminated work. The Agency Head or designee may direct Contractor to assign Contractor's right, title, and interest under terminated orders or subcontracts to the State. Contractor must still complete the work not terminated by the notice of termination and may incur obligations as are necessary to do so.

38. Termination for Default.

a. *Default.* If Contractor refuses or fails to perform any of the provisions of this contract with such diligence as will ensure its completion within the time specified in this contract or any extension thereof, or otherwise fails to timely satisfy the contract provisions, or commits any other substantial breach of this contract, the Agency Head or designee may notify Contractor in writing of the delay or nonperformance and if not cured in ten (10) days or any longer time specified in writing by the Agency Head or designee, such officer may terminate Contractor's right to proceed with the contract or such part of the contract as to which there has been delay or a failure to properly perform. In the event of termination in whole or in part, the Agency Head or designee may procure similar supplies or services in a manner and upon terms deemed appropriate by the Agency Head or designee. Contractor shall continue performance of the contract to the extent it is not

terminated and shall be liable for excess costs incurred in procuring similar goods or services.

b. *Contractor's Duties.* Notwithstanding termination of the contract and subject to any directions from the Chief Procurement Officer, Contractor shall take timely, reasonable, and necessary action to protect and preserve property in the possession of Contractor in which the State has an interest.

c. *Compensation.* Payment for completed services delivered and accepted by the State shall be at the contract price. The State may withhold from amounts due Contractor such sums as the Agency Head or designee deems to be necessary to protect the State against loss because of outstanding liens or claims of former lien holders and to reimburse the State for the excess costs incurred in procuring similar goods and services.

d. *Excuse for Nonperformance or Delayed Performance.* Except with respect to defaults of subcontractors, Contractor shall not be in default by reason of any failure in performance of this contract in accordance with its terms (including any failure by Contractor to make progress in the prosecution of the work hereunder which endangers such performance) if Contractor has notified the Agency Head or designee within 15 days after the cause of the delay and the failure arises out of causes such as: acts of God; acts of the public enemy; acts of the State and any other governmental entity in its sovereign or contractual capacity; fires; floods; epidemics; quarantine restrictions; strikes or other labor disputes; freight embargoes; or unusually severe weather. If the failure to perform is caused by the failure of a subcontractor to perform or to make progress, and if such failure arises out of causes similar to those set forth above, Contractor shall not be deemed to be in default, unless the services to be furnished by the subcontractor were reasonably obtainable from other sources in sufficient time to permit Contractor to meet the contract requirements. Upon request of Contractor, the Agency Head or designee shall ascertain the facts and extent of such failure, and, if such officer determines that any failure to perform was occasioned by any one or more of the excusable causes, and that, but for the excusable cause, Contractor's progress and performance would have met the terms of the contract, the delivery schedule shall be revised accordingly, subject to the rights of the State under the clause entitled (in fixed-price contracts, "Termination for Convenience," in cost-reimbursement contracts, "Termination"). (As used in this Paragraph of this clause, the term "subcontractor" means subcontractor at any tier).

e. *Erroneous Termination for Default.* If, after notice of termination of Contractor's right to proceed under the provisions of this clause, it is determined for any reason that the contract was not in default under the provisions of this clause, or that the delay was excusable under the provisions of Paragraph (4) (Excuse for Nonperformance or Delayed Performance) of this clause, the rights and obligations of the parties shall, if the contract contains a clause providing for termination for convenience of the State, be the same as if the notice of termination had been issued pursuant to such clause.

f. *Additional Rights and Remedies.* The rights and remedies provided in this clause are in addition to any other rights and remedies provided by law or under this contract.

39. Termination upon Bankruptcy. This contract may be terminated in whole or in part by the Mississippi State Department of Health upon written notice to Contractor, if Contractor should become the subject of bankruptcy or receivership proceedings, whether voluntary or involuntary, or upon the execution by Contractor of an assignment for the benefit of its creditors. In the event of such termination, Contractor shall be entitled to recover just and equitable compensation for satisfactory work performed under this contract, but in no case shall said compensation exceed the total contract price.

40. Third Party Action Notification. Contractor shall give the customer prompt notice in writing of any action or suit filed, and prompt notice of any claim made against Contractor by any entity that may result in litigation related in any way to this agreement.

41. Trade Secrets, Commercial and Financial Information. It is expressly understood that Mississippi law requires that the provisions of this contract which contain the commodities purchased or the personal or professional services provided, the price to be paid, and the term of the contract shall not be deemed to be a trade secret or confidential commercial or financial information and shall be available for examination, copying, or reproduction.

42. Transparency. This contract, including any accompanying exhibits, attachments, and appendices, is subject to the "Mississippi Public Records Act of 1983," and its exceptions. See Mississippi Code Annotated §§ 25-61-1 et seq. and Mississippi Code Annotated § 79-23-1. In addition, this contract is subject to the provisions of the Mississippi Accountability and Transparency Act of 2008. Mississippi Code Annotated §§ 27-104-151 et seq. Unless exempted from disclosure due to a court-issued protective order, a copy of this executed contract is required to be posted to the Department of Finance and Administration's independent agency contract website for public access at http://www.transparency.mississippi.gov. Information identified by Contractor as trade secrets, or other proprietary information, including confidential vendor information or any other information which is required confidential by state or federal law or outside the applicable freedom of information statutes, will be redacted.

43. Unsatisfactory Work. If, at any time during the contract term, the service performed or work done by Contractor is considered by MSDH to create a condition that threatens the health, safety, or welfare of the citizens and/or employees of the State of Mississippi, Contractor shall, on being notified by MSDH, immediately correct such deficient service or work. In the event Contractor fails, after notice, to correct the deficient service or work immediately, MSDH shall have the right to order the correction of the deficiency by separate contract or with its own resources at the expense of Contractor.

44. Waiver. No delay or omission by either party to this agreement in exercising any right, power, or remedy hereunder or otherwise afforded by contract, at law, or in equity shall constitute an acquiescence therein, impair any other right, power or remedy hereunder or otherwise afforded by any means, or operate as a waiver of such right, power, or remedy. No waiver by either party to this agreement shall be valid unless set forth in writing by the party making said waiver. No waiver of or modification to any term or condition of this agreement will void, waive, or change any other term or condition. No waiver by one party to this

agreement of a default by the other party will imply, be construed as or require waiver of future or other defaults.

ATTACHMENT B: FEDERAL PROCUREMENT COMPLIANCE (WHERE APPLICABLE)

As this contract may be eligible for reimbursement from the Federal Emergency Management Agency, the following clauses are applicable where MSDH will seek reimbursement for funds spent carrying out the purpose of this agreement.

ACCESS. MSDH, the subgrantees (counties and communities), FEMA, the Comptroller General of the United States, and any other duly authorized representatives to any of these bodies shall have access to any and all books, documents, papers, and records of the Contractor which are directly pertinent to this specific contract for the purpose of making audit, examination, excerpts, and transcriptions.

BYRD ANTI-LOBBYING AMENDMENT. Contractor shall certify that it will not and has not used Federal appropriated funds to pay any person or organization for influencing or attempting to influence an officer or employee of any agency, a member of Congress, officer or employee of Congress, or an employee of a member of Congress in connection with obtaining any Federal contract, grant or any other award covered by 31 U.S. C. 1352. Contract shall also disclose any lobbying with non-Federal funds that takes place in connection with obtaining any Federal Award. Contractor shall require all subcontractors to submit these same certifications. Contractor shall adhere to mandatory standards and policies on energy efficiency which are contained in the state energy conservation plan issued in compliance with the Energy Policy and Conservation Act (42 U.S.C. 6201).

CLEAN AIR AND WATER ACTS COMPLIANCE.

1) The Contractor agrees to comply with all applicable standards, orders or regulations issued pursuant to the Clean Air Act, as amended, 42 U.S.C. 7401 et seq. and the Federal Water Pollution Control Act, as amended, 33 U.S.C. 1251 et seq.
2) The Contractor agrees to report each violation to the (name of the state agency or local or Indian tribal government) and understands and agrees that the (name of the state agency or local or Indian tribal government) will, in turn, report each violation as required to assure notification to the (name of recipient), Federal Emergency Management Agency, and the appropriate Environmental Protection Agency Regional Office.
3) The Contractor agrees to include these requirements in each subcontract exceeding $150,000 financed in whole or in part with Federal assistance provided by FEMA.

ENERGY EFFICIENCY. Contractor shall adhere to mandatory standards and policies on energy efficiency which are contained in the state energy conservation plan issued in compliance with the Energy Policy and Conservation Act (42 U.S.C. 6201).

PROCUREMENT OF RECOVERED MATERIALS.

1) In the performance of this contract, the Contractor shall make maximum use of products containing recovered materials that are EPA-designated items unless the product cannot be acquired—
    (i) Competitively within a timeframe providing for compliance with the contract performance schedule;
    (ii) Meeting contract performance requirements; or

(iii) At a reasonable price.

2) Information about this requirement, along with the list of EPA designate items, is available at EPA's Comprehensive Procurement Guidelines website, https://www.epa.gov/smm/comprehensiveprocurementguideline-cpg-program.

SUSPENSION AND DEBARMENT.

1) This contract is a covered transaction for purposes of 2 C.F.R. pt. 180 and 2 C.F.R. pt. 3000. As such the Contractor is required to verify that none of the Contractor, its principals (defined at 2 C.F.R. 180.995), or its affiliates (defined at 2 C.F.R. 180.905) are excluded (defined at 2 C.F.R. § 180.940) or disqualified (defined at 2 C.F.R. 180.935).
2) The Contractor must comply with 2 C.F.R. pt. 180, subpart C and 2 C.F.R. pt. 3000, subpart C and must include a requirement to comply with these regulations in any lower tier covered transaction it enters into.
3) This certification is a material representation of fact relied upon by MSDH. If it is later determined that the Contractor did not comply with 2 C.F.R. pt. 180, subpart C and 2 C.F.R. pt. 3000, subpart C, in addition to remedies available to MSDH, the Federal Government may pursue available remedies, including but not limited to suspension and/or debarment.
4) The bidder or proposer agrees to comply with the requirements of 2 C.F.R. pt. 180, subpart C and 2 C.F.R. pt. 3000, subpart C while this offer is valid and throughout the period of any contract that may arise from this offer. The bidder or proposer further agrees to include a provision requiring such compliance in its lower tier covered transactions.

RETENTION OF RECORDS. Contractor shall retain all records associated with this contract for three (3) years after MSDH or the subgrantees (the counties and communities) make final payments and all other pending matters are closed.

DHS SEAL, LOGO, AND FLAGS. The Contractor shall not use the DHS seal(s), logos, crests, or reproductions of flags or likenesses of DHS agency officials without specific FEMA pre-approval.

COMPLIANCE WITH FEDERAL LAW, REGULATIONS, AND EXECUTIVE ORDERS. This is an acknowledgement that FEMA financial assistance will be used to fund the contract. The Contractor will comply with all applicable federal law, regulations, executive orders, FEMA policies, procedures, and directives.

NO OBLIGATION BY FEDERAL GOVERNMENT. The Federal Government is not a party to this contract and is not subject to any obligations or liabilities to the non-Federal entity, Contractor, or any other party pertaining to any matter resulting from the contract.

PROGRAM FRAUD AND FALSE OR FRAUDULENT STATEMENTS OR RELATED ACTS. The Contractor acknowledges that 31 U.S.C. Chap. 38 (Administrative Remedies for False Claims and Statements) applies to its actions pertaining to the contract.

COMPLIANCE WITH THE CONTRACT WORK HOURS AND SAFETY STANDARDS ACT.

1) Overtime requirements. No Contractor or subcontractor contracting for any part of the contract work which may require or involve the employment of laborers or mechanics shall require or permit any such laborer or mechanic in any workweek in which he or she is

employed on such work to work in excess of forty hours in such workweek unless such laborer or mechanic receives compensation at a rate not less than one and one-half times the basic rate of pay for all hours worked in excess of forty hours in such workweek.

2) Violation: Liability For Unpaid Wages and Liquidated Damages. In the event of any violation of the clause set forth in paragraph (1) of this section the Contractor and any subcontractor responsible therefor shall be liable for the unpaid wages. In addition, such contractor and subcontractor shall be liable to the United States (in the case of work done under contract for the District of Columbia or a territory, to such District or to such territory), for liquidated damages. Such liquidated damages shall be computed with respect to each individual laborer or mechanic, including watchmen and guards, employed in violation of the clause set forth in paragraph (l) of this section, in the sum of $10 for each calendar day on which such individual was required or permitted to work in excess of the standard workweek of forty hours without payment of the overtime wages required by the clause set forth in paragraph (l) of this section.
3) Withholding for unpaid wages and liquidated damages. The Mississippi State Department of Health shall upon its own action or upon written request of an authorized representative of the Department of Labor withhold or cause to be withheld, from any moneys payable on account of work performed by the Contractor or subcontractor under any such contract or any other Federal contract with the same prime contractor, or any other federally-assisted contract subject to the Contract Work Hours and Safety Standards Act, which is held by the same prime Contractor, such sums as may be determined to be necessary to satisfy any liabilities of such contractor or subcontractor for unpaid wages and liquidated damages as provided in the clause set forth in paragraph (2) of this section.
4) Subcontracts. The Contractor or subcontractor shall insert in any subcontracts the clauses set forth in paragraph (1) through (4) of this section and, also a clause requiring the subcontractors to include these clauses in any lower tier subcontracts. The prime contractor shall be responsible for compliance by any subcontractor or lower tier subcontractor with the clauses set forth in paragraphs (1) through (4) of this section.

COMPLIANCE WITH THE DAVIS-BACON ACT.

1) All transactions regarding this contract shall be done in compliance with the Davis-Bacon Act (40 U.S.C. 3141- 3144, and 3146-3148) and the requirements of 29 C.F.R. pt. 5 as may be applicable. The contractor shall comply with 40 U.S.C. 3141-3144, and 3146-3148 and the requirements of 29 C.F.R. pt. 5 as applicable.
2) Contractors are required to pay wages to laborers and mechanics at a rate not less than the prevailing wages specified in a wage determination made by the Secretary of Labor.
3) Additionally, contractors are required to pay wages not less than once a week.

ATTACHMENT C: ACKNOWLEDGEMENTS AND SPECIAL TERMS

The following acknowledgements and conditions shall be made a part of this agreement:

CONFLICT OF INTEREST. To the best of his or her knowledge, Contractor certifies that no MSDH employee, or spouse, parent or child of an MSDH employee, serves as a member of its governing body, project staff or has an ownership or pecuniary interest in the Contractor. Contractor agrees that should this condition change during the period of this contract, Contractor shall notify MSDH within 30 days. Notification should be sent by certified mail to the following:

Mississippi State Department of Health
Attention: MSDH Legal Department
Post Office Box 1700
Jackson, Mississippi 39215-1700

Furthermore, Contractor represents, to the best of his or her knowledge and belief, that this contract does not present the Contractor with a conflict of interest with respect to any past, current, or potential contract or employment such that the Contractor would be unable to perform impartially and without bias.

DEBARMENT AND SUSPENSION. Contractor certifies to the best of its knowledge and belief, that it:

1. is not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transaction by any federal department or agency or any political subdivision or agency of the State of Mississippi;
2. has not, within a three-year period preceding this proposal, been convicted of or had a civil judgment rendered against it for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (federal, state, or local) transaction or contract under a public transaction;
3. has not, within a three-year period preceding this proposal, been convicted of or had a civil judgment rendered against it for a violation of federal or state antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;
4. is not presently indicted for or otherwise criminally or civilly charged by a governmental entity (federal, state or local) with commission of any of these offenses enumerated in paragraphs two (2) and (3) of this certification; and,
5. has not, within a three-year period preceding this proposal, had one or more public transactions (federal, state, or local) terminated for cause or default.

REPRESENTATION REGARDING CONTINGENT FEES. Contractor represents that it has not retained a person to solicit or secure a state contract upon an agreement or understanding for a commission, percentage, brokerage, or contingent fee, except as disclosed in Contractor's bid or proposal.

REPRESENTATION REGARDING GRATUITIES. Contractor represents that it has not violated, is not violating, and promises that it will not violate the prohibition against gratuities set forth in Section 6-204 (Gratuities) of the *Mississippi Public Procurement Review Board Office of Personal Service Contract Review Rules and Regulations*.

ATTACHMENT D: SERVICES AND COMPENSATION

SCOPE OF SERVICES

In fulfillment of the purposes of this Agreement, the Contractor shall provide MSDH with the professional services detailed below and further described in Attachment E. Services shall include, but are not limited to, the following:

[Insert a description of services being as detailed as possible. Include location where services are to be rendered, frequency of performance, specific tasks or duties, etc.]

COMPENSATION

In furtherance of the performance of the services referenced above, MSDH agrees to compensate the Contractor the estimated amount of $XX,XXX.XX. Rates and purchases under this Agreement shall be subject to any limitations contained in Attachment E. Contractor agrees to ensure the funds subject to this Agreement are used in accordance with any applicable conditions, requirements and restrictions of federal, state and local laws.

The Contractor shall invoice MSDH monthly as needed. The final invoice to MSDH shall be sent within thirty (30) days after the Agreement ending date. The invoice should have appropriate documentation substantiating actual expenses. MSDH will pay all invoices within forty-five (45) days following the approval of the same. All invoices should be submitted to the following:

[Name], [Title]
Mississippi State Department of Health
[Post Office Box XXXX]
[City], Mississippi [Zip Code]
[email@MSDH.ms.gov]

It is expressly understood and agreed that, while the amount noted above is based on an estimated budget and may be subject to change, in no event will the total compensation to be paid hereunder exceed the specified amount of $XX,XXX.XX.

[The final contract document may include terms and/or conditions in addition to those provided in this template.]

ATTACHMENT E: STATEMENT OF WORK

Contractor's services shall be in accordance with the [below/attached] documentation submitted to MSDH as a quote or statement of work. A reasonable allowance for contingencies shall be included for market conditions at the time of the written quote and for unanticipated changes required in the work of this project.

[Attach a copy of Contractor's Quote or Statement of Work or insert a pdf or image of the document.]

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APPENDIX A

Title 15: Mississippi State Department of Health

Part 4: Office of Health Services

Subpart 1: Bureau of Genetics

Chapter 1. NEWBORN SCREENING AND BIRTH DEFECTS REGISTRY

Subchapter 1. AUTHORITY

Rule 1.1.1. **Statutory Authority**

1. Sections 41-21-201 and 41-21-203 of the Mississippi Code of 1972, Annotated, authorizes the State Department of Health to adopt rules and regulations to carry out the Newborn Screening and Follow-up Program for hypothyroidism, phenylketonuria (PKU), hemoglobinopathy, congenital adrenal hyperplasia (CAH), galactosemia, and other such conditions listed on the Recommended Uniform Screening Panel (RUSP) and as specified by the State Board of Health as stated herein below in Rule 1.1.2.

2. Section 41-24-1 of the Mississippi Code of 1972, Annotated, authorizes the State Department of Health to adopt rules and regulations to establish a program of testing to determine the presence of sickle cell trait or sickle cell anemia.

SOURCE: Miss. Code Ann. §41-21-201

Rule 1.1.2. **Legal Requirements**

1. Under the statutory authority, conditions listed on the RUSP will be included in the comprehensive newborn screening program within three (3) years after being added to the RUSP and adopt any rules and regulations necessary to accomplish the program.

    a. If any RUSP-listed conditions are not added to the comprehensive newborn screening program within three (3) years, a report on the status and reasons for the delay will be submitted to the House and Senate Public Health Committees once a year after the three-year period.

2. Under the statutory authority, a list of each of the conditions included in the comprehensive newborn screening program and made available to physicians and other health care providers who are required to provide for newborn screening testing under Section 41-21-203.

3. Under the statutory authority, informational materials about newborn screening tests will be available for use by physicians and other health care providers to inform pregnant women and parents.

4. Under the statutory authority, ongoing epidemiologic surveillance of the comprehensive newborn screening program will be used determine the efficacy and cost effectiveness of screening newborn infants.

5. Under the statutory authority, the physician attending a newborn child, or the persons attending a newborn child who was not attended by a physician, is held responsible for ensuring that the child is tested for the newborn screening tests as described in these rules and regulations. State law exempts from these tests any child whose parents object thereto on the grounds that such tests conflict with their religious practices or tenets.

6. Under the statutory authority, screening for congenital hypothyroidism (TSH), phenylketonuria (PKU), hemoglobinopathies (Hgb), congenital adrenal hyperplasia (CAH), and galactosemia (GAL) will be conducted statewide. Screening for the following conditions, as determined and specified by the State Board of Health, will also be conducted:

    a. 2-Methylbutyryl-CoA Dehydrogenase Deficiency

    b. 3-Hydroxy-3-Methylglutaryl-CoA Lyase Deficiency (HMG)

    c. 3-Methylcrotonyl-CoA Carboxylase Deficiency (3MCC Def)

    d. 3-Methylglutaconyl-CoA Hydratase Deficiency

    e. 5-Oxoprolinuria (Pyroglutamic aciduria)

    f. Argininemia

    g. Argininosuccinic Aciduria (ASA Lyase Deficiency)

    h. Biotinidase Deficiency

    i. Carbamoylphosphate Synthetase Deficiency (CPS Deficiency)

    j. Carnitine Palmitoyltransferase I Deficiency (CPT I)

    k. Carnitine Palmitoyltransferase II Deficiency (CPT II)

    l. Carnitine/Acylcarnitine Translocase Deficiency (Translocase)

    m. Citrullinemia (ASA Synthetase Deficiency)

    n. Critical Congenital Heart Defects (CCHD) - Under the statutory authority, all licensed hospitals and other state licensed birthing

facilities must test every newborn for CCHD statewide. All CCHD screenings must be performed prior to discharge and in accordance with current standards of care. Screening results must be reported to the Mississippi State Department of Health Newborn Screening Program. (Point of care testing which does not require blood)

o. Cystic Fibrosis (CF)

p. Glutaric Aciduria Type I (GA I)

q. Homocystinuria

r. Hyperammoninemia, Hyperornithinemia, Homocitrullinemia Syndrome (HHH)

s. Hypermethioninemia

t. Isobutyryl-CoA Dehydrogenase Deficiency

u. Isovaleric Acidemia (IVA)

v. Long-Chain 3-hydroxyacyl-CoA Dehydrogenase Deficiency (LCHAD)

w. Malonic Aciduria

x. Maple Syrup Urine Disease (MSUD)

y. Medium-Chain Acyl-CoA Dehydrogenase Deficiency (MCAD)

z. Methylmalonic Acidemia (MMA)

aa. Mitochondrial Acetoacetyl-CoA Thiolase Deficiency

bb. Mucopolysaccharidosis I (MPS1)

cc. Multiple Acyl-CoA Dehydrogenase Deficiency (MADD or GA II)

dd. Multiple CoA Carboxylase Deficiency

ee. Pompe

ff. Propionic Acidemia (PPA)

gg. Severe Combined Immunodeficiency (SCID)

hh. Short-Chain Acyl-CoA Dehydrogenase Deficiency (SCAD)

ii. Short-Chain Hydroxy Acyl-CoA Dehydrogenase Deficiency (SCHAD)

jj. Spinal Muscular Atrophy (SMA)

kk. Trifunctional Protein Deficiency (TFP Deficiency)

ll. Tyrosinemia Type I (TYR I)

mm. Tyrosinemia Type II (TYR II)

nn. Very Long-Chain Acyl-CoA Dehydrogenase Deficiency (VLCAD)

oo. X-linked adrenoleukodystrophy (X-ALD) (starts July 1, 2023)

SOURCE: Miss. Code Ann. §41-21-201

Subchapter 2. SPECIMEN COLLECTION

Rule 1.2.1. **Specimen Collection Requirements**

1. The specimen must be dried blood spots for screening and whole blood for confirmatory testing. Specimen should be collected according to the instructions issued by the Newborn Screening Program and as specified in the Child Health and Public Health Nursing Manuals.

2. Newborn screening should be performed prior to hospital discharge. Any specimen collected prior to 24 hours of age will require repeat specimen collection.

3. Newborn screening collection for Hgb is accepted for testing under the assumption that the infant has not been transfused. This statement is noted on Mississippi's newborn screening collection card. The most recent transfusion date must be appropriately documented on the collection card.

4. The performing laboratory must receive the specimen within five working days of the date of collection. All specimens requiring repeat testing will be monitored by the Newborn Screening Program as follows:

   a. Specimen repeated due to lack of information will be the responsibility of the originating hospital.

   b. All other repeat specimen will be followed by the patient's local county health department unless there is a special circumstance

5. A Mississippi State Department of Health newborn screening collection card must be completed in full and accompany the specimen. It is critical that the data on the collection card be accurate; the information entered must be compatible with that recorded on the infant's birth certificate. The

collection card must be completed according to the instructions issued by the Newborn Screening Program.

Subchapter 3. CCHD Reporting

Rule 1.3.1 Reporting Requirements

1. All infants will receive a CCHD screening after 24 hours of age or before discharge.

    a. All infants should be on room-air for at least 24 hours and asymptomatic, including those in the NICU.

    b. Neonatal intensive care unit (NICU) infants who are stable and preparing for discharge.

    c. Infants with a prenatal diagnosis of a cardiac defect or infants who have already had a complete postnatal echocardiogram performed should be excluded.

    d. CCHD results must be entered on the collection card for all screens done.

        i. If the CCHD screening results are not available and the bloodspot is ready to be shipped. Ship the bloodspot specimen once it is dried.

SOURCE: Miss. Code Ann. §41-21-201

Rule 1.3.2. **Fees**

1. A charge will be assessed for every infant screened to defray the cost of maintaining a central registry, lab testing and health department follow-up on positive and repeat tests, for all conditions.

SOURCE: Miss. Code Ann. §41-21-201

Subchapter 4. FOLLOW-UP

Rule 1.4.1. **Documentation of Screening Outcomes**

1. The Newborn Screening Program will be responsible for assuring that all infants have a CCHD screening outcome documented.

    a. Each healthcare facility is responsible for providing additional information on all infants that failed the CCHD Screening or did not have a “passed” result documented on the Newborn Screening Collection Card.

i. Except in the case where the card is marked as expired.

Rule 1.4.2. **Follow-up for Positive Results, Questionable Results, and Repeat Screening**

1. The Newborn Screening Program will be responsible for assuring that all infants with positive, questionable, and repeat screening tests are appropriately followed. Follow-up on infants who have a primary care provider will be coordinated with the provider. The local health department will provide repeat follow-up on all specimens that have been collected too early or improperly.

Rule 1.4.3. **Repeat Screening Outside of the Health Department**

1. Special cases where the infant may have a repeat completed outside of the health department are: (1) Infant has not been discharged from the birthing facility or (2) parent/guardian request to return to birthing facility due to parent preference, location, or health department scheduling conflict.

SOURCE: Miss. Code Ann. §41-21-201

Rule 1.4.4. **Repeat Screening Due to Incomplete Collection Card**

1. If the newborn screening tests have to be repeated due to lack of information on the collection card, the hospital will be charged with finding the newborn and repeating the newborn screening tests.

SOURCE: Miss. Code Ann. §41-21-201

Subchapter 5. LABORATORY REQUIREMENTS

Rule 1.5.1. **Compliance with Standards**

1. Any laboratory which offers this testing must meet the standards outlined in this section and, if requested, provide the agency with a written statement that they will comply with these standards. All specimens must be tested in an approved laboratory located in the United States.

2. The results of hemoglobinopathies, galactosemia, and congenital adrenal hyperplasia screening are not always clear cut and this type of screening requires extensive input from a recognized reference laboratory. Screening by tandem mass spectrometry requires extensive expertise and experience in this testing methodology.

3. A single control laboratory is required for screening. The laboratory should be proficient in all required testing methodologies.

SOURCE: Miss. Code Ann. §41-21-201

Rule 1.5.2. **Specimen Requirements:**

1. Specimen acceptable for analysis includes only dried blood spots for newborn screening, and whole blood or serum for confirmatory testing.

SOURCE: Miss. Code Ann. §41-21-201

Rule 1.5.3. **Method for Specimen Analysis**

1. **Argininemia**: Method: fluorometric assay or by tandem mass spectrometry analysis

2. **Biotinidase Deficiency**: Method: continuous flow enzyme assay

3. **Congenital Hypothyroidism**: Method: Enzyme Immunoassay (EIA)

4. **Cystic Fibrosis (CF)**: Immunoreactive Trypsinogen (IRT) Method: Immunoassay

5. **Congenital Adrenal Hyperplasia (CAH)**: Method: Enzyme Immunoassay (EIA)

6. **Galactosemia**: Method: continuous flow chemistry analysis for Galactose-1-Phospahte Uridyltransferase deficiency

7. **Hemoglobinopathies**: Method: isoelectric focusing

8. **Phenylketonuria (PKU)**: Method: continuous flow chemistry analysis or tandem mass spectrometry analysis

9. **Other Disorders**: Method: tandem mass spectrometry analysis, or biochemical and other established technologies.

SOURCE: Miss. Code Ann. §41-21-201

Rule 1.5.4. **Quality Control**

1. The laboratory must be successfully participating in an acceptable proficiency testing program that will monitor the performance of all testing methodologies. Acceptable testing programs include the following:

    a. College of American Pathologists (CAP)

    b. American Association of Clinical Chemists (AACC)

    c. Centers for Disease Control (CDC)

2. Test methods used by the laboratory must be FDA cleared/approved and must be used according to the manufacturers' directions. Documentation must be provided upon request for any appropriate and necessary test used by the laboratory that is not FDA cleared/approved.

3. The laboratorian must examine the quality and integrity of blood spots and must have a written procedure for rejection of those specimen judged to be unacceptable.

4. The laboratory must test a minimum of 40,000 specimens per year for each disorder.

5. Standard curves must be done with each assay of TSH and CAH.

6. Since interpretation of 17-OHP levels for CAH is weight dependent, a birth weight and current weight in grams must be documented for all specimen submitted for CAH testing.

7. Laboratories must be Medicare approved.

8. Hemoglobinopathies

    a. Control(s) containing AFSC must be included in each assay.

    b. All samples that are not normal (not FA or AF) must be sent to a recognized reference laboratory as liquid blood unless a diagnosis has been determined by DNA analysis or other valid means.

    c. If transfused, a repeat blood spot specimen or a liquid blood sample will be collected and tested between two and twelve weeks post last transfusion.

SOURCE: Miss. Code Ann. §41-21-201

Rule 1.5.5. **Disorders being Screened by Biochemical and Other Technologies**

1. **Biotinidase Deficiency:** Biotinidase Deficiency is caused by the complete or partial lack of the enzyme biotinidase. This condition can lead to seizures, developmental delay, eczema, and hearing loss.

2. **Congenital Adrenal Hyperplasia:** Congenital Adrenal Hyperplasia (CAH) is a genetic endocrine disorder caused primarily by a deficiency of enzymes needed for the adrenal glands to make the hormones cortisol and aldosterone. It can result in masculinization of female genitalia as well as adrenal crisis and early infant death.

3. **Cystic Fibrosis:** Cystic Fibrosis (CF) is an inherited condition that affects the glands that produce mucus, tears, sweat, saliva, and digestive juices. It

causes severe lung damage and nutritional deficiencies. Respiratory failure is the most dangerous consequence.

4. **Congenital Hypothyroidism:** Hypothyroidism is a disorder in which there is a decrease in the production of thyroid hormone, possibly resulting in brain damage and mental retardation in the absence of prompt treatment.

5. **Galactosemia:** Galactosemia is an inborn error of metabolism, inherited as an autosomal-recessive trait, in which the hepatic enzyme galactose-1-phosphate uridyl transferase is absent, preventing the conversion of the milk sugar galactose to glucose. If untreated death can occur in the first month of life.

6. **Hemoglobinopathies:** Hemoglobinopathy, which includes sickle cell diseases, thalassemia, and other variants are blood disorders resulting from change in the structure of hemoglobin. Sickle Cell Disease, the most common hemoglobinopathy in Mississippi, is an inherited disease found primarily in African-Americans and people of Mediterranean descent. Although there is no cure for sickle cell disease, early detection is important for effective treatment and prevention of complications. Infection due to Streptococcus pneumonia is a significant cause of death during the first few years of life for patients with sickle cell disease.

SOURCE: Miss. Code Ann. §41-21-201

Rule 1.5.6. **Disorders Screened by Tandem Mass Spectrometry**

A tandem mass spectrometer is an analytical instrument consisting of two mass spectrometers in series connected by a reaction chamber or collision cell. It can identify a compound by its mass and determine how much of the compound is present. Through tandem mass spectrometry analysis, many genetic disorders can be detected from one blood specimen.

1. **Medium Chain Acyl-CoA Dehydrogenase Deficiency:** Medium Chain Acyl-CoA Dehydrogenase Deficiency (MCAD) is a hereditary condition that is caused by a lack of an enzyme required to convert fat to energy. For individuals with this condition, prolonged fasting can lead to hypoglycemia, vomiting, lethargy, seizures, coma, apnea, cardiac arrest, or sudden unexplained death.

2. **Phenylketonuria:** Phenylketonuria (PKU) is a genetic disorder inherited as an autosomal-recessive trait caused by the absence of an enzyme that is necessary for metabolism of the essential amino acid phenylalanine. If untreated, neurologic deterioration, seizures, and severe mental retardation will occur.

3. **Other Disorders:** Other less prevalent conditions are detectable by tandem mass spectrometry. They are grouped into amino acid disorders, organic

acid disorders, and fatty acid disorders (See Attachment A). Many of these conditions can be life threatening if appropriate and timely interventions are not initiated.

SOURCE: Miss. Code Ann. §41-21-201

Rule 1.5.7. **Record Retention**

1. Records of standardization, quality control, and patient values must be kept for at least two years. It is advisable for laboratories to retain these records until the statute of limitations regarding medical malpractice actions expires as stipulated by Mississippi state law.

SOURCE: Miss. Code Ann. §41-21-201

Rule 1.1.1. **Specimen Retention**

1. Specimen must be retained for at least 365 days. Under no circumstances will the retained specimen be used for research or purposes other than confirmation of previous test results.

SOURCE: Miss. Code Ann. §41-21-201

Chapter 2. BIRTH DEFECTS REGISTRY

Subchapter 1. Authority

Rule 2.1.1. **Statutory Authority**

1. Section 41-21-205 of the Mississippi Code of 1972, Annotated, authorizes the State Department of Health (the department) to adopt rules and regulations to govern the operation of the Birth Defects Registry.

SOURCE: Miss. Code Ann. §41-21-205

Rule 2.1.2. **Legal Requirements**

Under the statutory authority, the Board of Health (the board) shall:

1. Establish in the department a birth defects surveillance program to:

   a. identify and investigate birth defects, and

   b. maintain a central registry of cases of birth defects

2. Design a birth defects data system that will:

   a. provide information to identify risk factors and causes of birth defects,

b. provide information on other possible causes of birth defects,

c. provide for the development of strategies to prevent birth defects,

d. provide for interview studies about the causes of birth defects, and

e. provide for the collection of birth defect information

3. Adopt rules, regulations and procedures to govern the operation of the registry program and to carry out the intent of this action

4. Specify the types of information to be provided to the birth defects registry and the persons and entities who are required to provide such information to the birth defects registry

5. Prescribe the manner in which records and other information are made available to the department

6. Obtain records and/or test results of individuals with birth defects not previously reported or observed for inclusion in the central registry.

7. Collect, analyze and place data in the central registry to facilitate epidemiological studies/ reviews and to maintain security

8. Use the registry to:

a. investigate the causes of birth defects and other health conditions as authorized by statute,

b. design and evaluate measures to prevent the occurrence of birth defects, and other conditions, and

c. refer and track children with special health care needs

d. conduct other investigations and activities necessary for the board and the department to fulfill their obligation to protect the public health

SOURCE: Miss. Code Ann. §41-21-205

Rule 2.1.3. **The Genetics Advisory Committee**

1. The State Health Officer may appoint or delegate his authority for the purposes of this section to an advisory committee, not to exceed (13) persons, to assist in the design and implementation of this central registry with representation from relevant groups including, but not limited to, hospitals, two (2) pediatricians, board-certified clinical geneticists, personnel of the department, personnel of other appropriate state agencies, and one (1) consumer representative from a family that has experience with

a newborn infant with an abnormal screening test. . If a central registry advisory committee is created by the State Health Officer, the board shall consult and be advised by the committee on the promulgation of rules, regulations and procedures for the purposes of this section.

SOURCE: Miss. Code Ann. §41-21-205

Chapter 3. Identifying Reportable Cases

Rule 3.1.1. Definition of Birth Defect

1. **Birth Defect:** A birth defect is an abnormality of structure, function or metabolism, whether genetically determined or a result of environmental influences during embryonic or fetal life. A birth defect may present from the time of conception through one year after birth, or later in life.

   a. From birth to one year of age certain principal birth defects shall be reported.

   b. Other birth defects found later in life may be reported at any time up to age twenty-one.

2. **Reportable Birth Defects:** Live Births and Reportable Fetal Deaths with birth defects (fetal death of 20 completed weeks of gestation or more, or a weight of 350 grams or more) shall be reported. Birth Defects of the following categories must be reported:

Craniofacial	GI/GU
Neural Tube	Teratogen
Cardiac	Skeletal
Genetic Disorders	Skin
Congenital Tumors	Central Nervous System

3. **Persons and Entities Required to Provide Information to the Registry**

   a. The physician must report every birth defect case the first time the patient is seen, for individuals born on or after January 1, 2000. A reporting form or its equivalent as determined by the Mississippi State Department of Health is required when reporting a suspected or diagnosed birth defect. If the patient is seen for another birth defect on another occasion, that defect shall also be reported.

   b. Appropriate birth certificate data will be reported.

   c. Appropriate data from other department registries such as the Cancer Registry, Newborn Hearing Registry will be reported.

d. The state (s) tertiary care center and other hospitals will report data through newborn discharge summaries or by completing and submitting individual reporting forms.

e. Appropriate data on specified disorders detected through newborn screening will be reported.

4. **Criteria for Inclusion as a Case**

a. The infant/fetus must have a reportable structural defect, newborn screening disorder, functional or metabolic disorder, genetically determined or a defect resulting from an environmental influence during embryonic or fetal life.

b. The defect optimally should be diagnosed or its signs and symptoms recognized within the first year of life, but defects can be recognized and included up to twenty-one years of age.

c. An infant must have been born alive or a fetus must have gestational age of at least 20 weeks or a birth weight of at least 350 grams to be included in the Birth Defects Registry.

5. **Process for Making Records and Other Information Available to The Birth Defects Registry**

a. Hospitals, physicians, and other health care professionals may submit records and birth defect information electronically or by completing and submitting individual reporting forms.

b. The following persons who act in compliance with this section are not civilly or criminally liable for furnishing the information required under this section:

i. A hospital, clinical laboratory, genetic treatment center or other health care facility;

ii. An administrator, officer or employee of a hospital, clinical laboratory, genetic treatment center or other health care facility; and

iii. A physician or employee of a physician.

c. The department field staff will visit health care facilities to gather medical and other required information of children with birth defects. This information will be recorded on registry data report forms.

d. The department may obtain records and/or test results of individuals with known or potential birth defects not previously reported.

6. **Confidentiality and Security**

a. Information collected and analyzed by the department under this section shall be placed in the central registry to facilitate epidemiological studies/ reviews and to maintain security.

i. Data obtained under this section directly from the medical records of a patient is for the confidential use of the department and the persons or public or private entities that the department determines are necessary to carry out the intent of this section. The data is privileged and may not be divulged or made public in a manner that discloses the identity of an individual whose medical records have been used for obtaining data under this section.

ii. Information that may identify an individual whose medical records have been used for obtaining data under this section is not available for public inspection under the Mississippi Public Records Act of 1993.

iii. Statistical information collected under this section is public information.

b. Misuse of the Registry Data: Any person or entity who misuses the information provided to the registry shall be subject to a civil penalty of Five Hundred Dollars ($500.00) for each such failure or misuse. Such penalty shall be assessed and levied by the board after a hearing, and all such penalties collected shall be deposited into the State General Fund.

7. **Policies and Procedures** The department will maintain written policies and procedures to guide the operations of the Birth Defects Registry.

SOURCE: Miss. Code Ann. §41-21-205

APPENDIX B

TOP COPY FOR LAB; SUBMITTER MAY KEEP BLUE COPY

ALL INFORMATION MUST BE PRINTED ☐ Transferred to: _____

TO AVOID RECOLLECTION- Accurately complete the entire form

☐ Initial Specimen ☐ Home Birth ☐ Repeat Specimen → Initial FP#: Reason: ☐ <24 hr. ☐ Unsatisfactory ☐ Abnormal ☐ Transfused ☐ Inconclusive

Birth Facility Name | Code

Submitter Name | Code

Address if no CODE given

MOTHER'S Name (Last) | MOTHER'S Name (First, MI)

Street (PO Box)

City | State | Zip

Mother's E-mail | Mother's Phone # ( ) -

Emergency Contact | Emergency Contact # ( ) -

☐ Female ☐ Male ☐ Unknown

BABY'S Name (Last) | BABY'S Name (First)

Baby's Last Name at Discharge | Baby's First Name at Discharge

☐ Single Birth ☐ Multiple Birth → If Multiple: ☐ A ☐ B ☐ C ☐ Other: ____

Birth Date: ___/___/___ Time (Military) ___:___ Birth Wt.: _____ ☐ gms. ☐ lbs.oz.

Collection Date: ___/___/___ Time (Military) ___:___ Current Wt.: _____ ☐ gms. ☐ lbs.oz.

Drawn By: _____

Weeks Gestation: | Medical Record #:

☐ Transfused Date: ___/___/___ Time (Military) ___:___ Gest. Age _____

☐ NICU ☐ Hyperalimentation ☐ Carnitine ☐ Meconium ileus

Race (check all that apply): Hispanic: ☐ Yes ☐ No

☐ White ☐ Black ☐ Pac. Isl. ☐ Asian ☐ Am. Ind. ☐ Other

Mother's Date of Birth ___/___/___

Mother's Medical History:

☐ Hypertension ☐ Opioid Use

☐ Maternal PKU ☐ Diabetes

☐ Thyroid Disease

☐ Other: _____

HBsAg:

☐ Pos. ☐ Neg. ☐ Unknown

Feeding:

☐ Breast ☐ Soy ☐ TPN

☐ I.V. ☐ Lactose

Hearing Screening completed:

☐ Yes ☐ No ☐ Delayed

Hearing Screen: ☐ ABR ☐ OAE

R Ear: ☐ Pass ☐ Refer

L Ear: ☐ Pass ☐ Refer

Newborn PCP / Practice Name | PCP Phone Number ( ) -

Street (PO Box)

City | State | Zip

Final O2 Result ☐ Passed ☐ WBN ☐ Failed ☐ NICU Date: ___/___/___ Time (Military) ___:___

If not performed, √ reason: ☐ Prenatal fetal echocardiogram ☐ On O2 ☐ Expired ☐ Other ☐ Postnatal echocardiogram performed ☐ Refused ☐ Transferred

Results are based on the assumption that the infant has not been transfused

GIVE TO PARENT / LEGAL GUARDIAN

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SN