

Exhibit A
Scope of Work

1. Service Overview

Vendor agrees to provide to the California Department of Public Health (CDPH) the services described herein.

The Vendor shall provide diagnosis, treatment, and outcome data for metabolic patients identified through the Newborn Screening Program (NBSP). Vendor must be an approved Metabolic Special Care Center and maintain approval throughout the term of this Agreement.

The acceptance of this Agreement certifies that all work performed by the Vendor will comply with state standards, regulations, program policies, guidelines and protocols for the California Children's Services (CCS) Approved Metabolic Centers and the California Newborn Screening Program. This includes the maintenance of CCS-approved status as a metabolic center during the term of the Agreement. It certifies that services provided meet the standards described in this Agreement and national treatment guidelines as appropriate to California.

2. Service Location

The services shall be performed at various statewide facilities accessible to the Vendor.

3. Service Hours

The services shall be provided during normal Vendor working days and hours, and arrangements made for on call coverage during non-business hours.

4. Project Representatives

A. The project representatives during the term of this Agreement will be:

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| <p>California Department of Public Health Administrator Muslimah Jaavaid Telephone: (510) 412-6217 Fax: (510) 412-1548 Email: MJavaaid@dhs.ca.gov</p> | <p>Vendor Agency Official [Enter Name of Vendor's Contract Manager] Telephone: (XXX) XXX-XXXX Fax: (XXX) XXX-XXXX Email: XXXXXXXX@XXXXXXX</p> |
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B. Direct all inquiries to:

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| <p>California Department of Public Health NBSP Metabolic Center Liaison Genetic Disease Screening Program Attention: Karen Whitney, MS Mail Station Code 8200 850 Marina Bay Parkway Richmond, CA 94804 Telephone: (510) 412-1536 Fax: (510) 412-4657 Email: KWhitney@cdph.ca.gov</p> | <p>Vendor Project Director Section or Unit Name (if applicable) Attention: [Enter name, if applicable] Street address & room number, if applicable P.O. Box Number (if applicable) City, State, Zip Code Telephone: (XXX) XXX-XXXX Fax: (XXX) XXX-XXXX Email: XXXXXXXX@XXXXXXX</p> |
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- C. Either party may make changes to the information above by giving written notice to the other party. Said changes shall not require an amendment to this Agreement.

5. Services to be Performed

Vendor shall perform the following services:

- A. Accept referrals for newborns and pediatric patients under the age of five (5) with positive metabolic newborn screening test results whenever requested by the Genetic Disease Screening Program (GDSP) Newborn Screening Program (NBSP).
- B. Contact Primary Medical Doctor (PMD) to discuss health status of newborn.
- C. Using test request form (TRF) supplied by State or State Contract Metabolic Disorders Confirmatory Laboratory (Quest Diagnostics) or the State Contract Biotinidase Confirmatory Laboratory at Stanford University, order follow-up confirmatory/diagnostic laboratory testing when appropriate to confirm or rule out a diagnosis. Provide information to PMD or family on where and when to go for specimen collection including location of Quest Patient Service Centers, when appropriate. Provide information to PMD on laboratory results and any necessary follow-up within 24 hours of receiving the results.
- D. In the rare event that another laboratory is used for confirmatory/diagnostic testing forward a copy of the testing results per NBSP protocols to Steve Levine, PhD, GDB, Department of Health Services, 850 Marina Bay Parkway F175, Richmond CA 94804.
- E. When indicated, the Vendor agrees to arrange to have the baby and family seen at the next available clinic appointment or earlier when medically indicated. **Infants to be referred include those who test positive for galactosemia and over forty conditions, including PKU, detectable via tandem mass spectrometry (MS/MS) and biotinidase deficiency (see Attachment I).** In the event the family cannot be contacted, misses a scheduled appointment for an initial evaluation, or refuses care, the Vendor will notify the Area Service Centers NBS Coordinator as early as possible and no later than five (5) days after the occurrence.
- F. Assist family in completing CCS application form and faxes it to CCS office as appropriate.
- G. Perform a comprehensive clinical evaluation including family history, pedigree, physical examination, laboratory and/or other diagnostic tests per national and State treatment guidelines.
- H. Develop a treatment plan appropriate for the disorder.
- I. Educate the family with respect to management and treatment, including preventive health measures, and provide the family with appropriate health education materials approved, supplied, or recommended by the NBSP.
- J. Provide a copy of the history and physical, diagnostic evaluation and treatment plan to newborn's medical home, (i.e., primary care physician), and the CCS authorizing agency. Any other reports requested by the NBSP shall be submitted in a format defined or approved by the NBSP.
- K. If the family has other third-party coverage, bill family's insurance/HMO for services at Metabolic Special Care Center. If claim is denied for diagnostic services, submits to CCS with written documentation of denial.

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- L. If the family has no other third-party coverage bill CCS for diagnostic services per CCS guidelines.
- M. Provide timely documentation of contacts regarding a referred infant using the GDSP Web-based computer Screening Information System (SIS). New cases will appear in the top grid of the metabolic center SIS referral screen. After follow-up consultation activities have been initiated and documented on a SIS Metabolic Service Report indicating that the case has been received at the metabolic center the case will move to the "PENDING" grid. Once a diagnosis is confirmed or ruled out the case will move to the third grid, "RESOLVED CASES." The metabolic center agrees to schedule the initial appointment for newly diagnosed clients and record the status of the initial appointment in SIS.

MSR Reporting

The on-line SIS **Metabolic Services Report form (MSR)** is a mechanism for documenting significant contacts made regarding a referred infant up to diagnosis and initiation of treatment or of ruling out a disorder. This important information gained from the MSR is used by the Genetic Disease Branch, Newborn Screening Program to evaluate the effectiveness of the screening program and the MSR forms need to be completed fully including the Global Health Assessment and the Health Profile. Significant contacts needing a MSR include physician telephone consultations, contact with the family in person or by telephone, initial clinic visit, other physician consultations and follow-up visits for diagnostic evaluation until the diagnosis is made and treatment initiated. After completing the MSR case notes should be added when additional information is needed to augment or clarify that MSR. For example, date of diagnosis, doctor making the diagnosis and the date treatment is initiated should be added to the case notes until this function is available through the on-line MSR. Often reasons for case notes include brief explanations of reasons for unusual delays in diagnosis, or when contact type is checked as "Other". For a diagnosis taking over a month, case notes should be written periodically in SIS (at least monthly). However, case notes do not replace the need for a MSR when a significant contact is made that provides information about the referred NBS case.

The on-line SIS Metabolic Services Report form (MSR) shall be completed as **soon as possible preferably within one (1) business day but no later than five (5) calendar days** of each significant contact, diagnosis confirmation or of ruling out a disorder.

Annual Patient Summary

Once a diagnosis is confirmed or ruled out SIS MSRs are no longer required, however, a SIS Annual Patient Summary must be completed in SIS once a year for each diagnosed child up until the child is five years of age. The Annual Patient Summary should be completed by the end of the month in which it appears on the summary list. Each month metabolic centers will receive a list in SIS of referred cases of children who had a birthday in the previous month and who will need an Annual Patient Summary. We are requesting that the Annual Patient Summary be completed by the end of the following month (the month after the child's birthday). Guidelines for completing the Annual Patient Summary will be provided to all metabolic centers. Any questions about SIS and completing the MSRs or the Annual Patient Summary should be directed to the Metabolic Vendor Liaison.

Most metabolic cases taking more than 120 days to resolve at the metabolic center will be followed directly by staff at the Genetic Disease Branch. Metabolic centers will be contacted directly by GDB staff concerning extended case follow-up and given instructions about any additional information that is needed. MSRs still need to be kept current on these cases until they are resolved.

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- N. Provide the family with genetic counseling with respect to the cause of the disorder, recurrence risk and reproductive options.
- O. Attend periodic meetings convened and funded by the NBSP to review and consult on the effectiveness of newborn screening, reference ranges, patterns and reporting of results, and follow-up protocols.
- P. Upon request, provide consultation to NBSP staff, Area Service Center staff, newborns' primary care physicians, and/or CCS authorizing agency regarding diagnosis and treatment of metabolic conditions screened for by the NBSP.
- Q. Provide to the NBSP upon request, an accounting of how State funds were utilized to support the personnel and other patient care needs required for completion and documentation of follow-up of newborns in accordance with the attached budget.
- R. Use only written patient educational materials supplied or approved by the NBSP (see Exhibit D, Item 10 for review and approval).

6. Reporting Requirements

- A. Provide quarterly reports in the format specified by the NBSP (see Attachment II) to the NBSP Metabolic Center Liaison on a quarterly basis. Completed Quarterly Report Forms, shall be submitted by the following dates:

| Quarter | Report Submission Date |
|--|------------------------|
| #1 - July 1, 2008 – September 30, 2008 | November 1, 2008 |
| #2 - October 1, 2008 – December 31, 2008 | February 1, 2009 |
| #3 - January 1, 2009 – March 31, 2009 | May 1, 2009 |
| #4 - April 1, 2009 – June 30, 2009 | August 1, 2009 |

All reports and other communications are to be delivered or mailed to:

Karen Whitney, Newborn Screening Branch
California Department of Public Health
Genetic Disease Screening Program
850 Marina Bay Parkway, Room F175
Richmond, CA 94804
KWhitney@cdph.ca.gov

- B. The NBSP Metabolic Center Liaison must approve any changes in personnel that impact the budget after reviewing the Personnel Change Request form. Resumes of new hires shall be included with the Personnel Change Request form. See Administrative Policies/Guidelines for more information.

7. Representation and Participation

The Vendor shall release staff specified by the NBSP to attend regional or statewide meetings planned and convened by the NBSP. Vendor staff shall assist the GDB in the further development of the NBSP by recommending and responding to proposed policy changes and providing information as requested.

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8. Confidential and Privileged Information

The Vendor shall keep all information provided by the NBSP confidential. The confidentiality of patient files and records shall be protected by the Vendor and the NBSP in accordance with existing State and Federal laws and regulations.

Confidential and privileged information includes, but is not limited to, any and all information, instructions, calculations, tables, graphs, programming instructions, software, computer discs, and any other materials designated by the NBSP. The Vendor shall ensure that all personnel, including vendors, shall not release any such information to unauthorized persons except as required by law. Such information is not to be used for private gain or profit. The Vendor agrees to notify the NBSP in the event any confidential and privileged information is released without proper authorization. The Vendor agrees to reimburse the NBSP for the costs of enforcing this clause, including any legal fees.

9. Allowable Informal Scope of Work Changes

- A. The Vendor or the State may propose informal changes or revisions to the activities, tasks, deliverables and/or performance time frames specified in the Scope of Work, provided such changes do not alter the overall goals and basic purpose of the agreement.
- B. Informal SOW changes may include the substitution of specified activities or tasks; the alteration or substitution of agreement deliverables and modifications to anticipated completion/target dates.
- C. Informal SOW changes processed hereunder, shall not require a formal agreement amendment, provided the Vendor's annual budget does not increase or decrease as a result of the informal SOW change.
- D. Unless otherwise stipulated in this agreement, all informal SOW changes and revisions are subject to prior written approval by the State.
- E. In implementing this provision, the State may provide a format for the Vendor's use to request informal SOW changes. If no format is provided by the State, the Vendor may devise its own format for this purpose.