

Exhibit A
Scope of Work

1. Service Overview

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

Vendor must be a California Children's Services (CCS) approved Metabolic Special Care Center providing multidisciplinary care at the clinic site. CCS approval must be maintained throughout the term of the agreement.

Vendor shall provide a timely diagnosis for cases referred by the CDPH, Genetic Disease Screening Program (GDSP) Newborn Screening Program (NBSP) to prevent morbidity or mortality associated with a metabolic disorder for which NBSP screens as well as document the referral and diagnostic decision into the GDSP Screening Information System (SIS). **Infants to be referred to the Vendor include those who test positive for galactosemia, biotinidase deficiency and over forty conditions, including Phenylketonuria (PKU), detectable via tandem mass spectrometry (MS/MS). (See Exhibit A-Attachment I)**

The acceptance of this Agreement certifies that services provided by the Vendor will comply with GDSP program policies, guidelines and protocols for the California Newborn Screening Program. It also certifies that services provided meet national treatment guidelines as appropriate to California.

2. Service Location

The services shall be performed at clinic locations and any CCS approved satellite clinics.

3. Service Hours

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

4. Project Representatives

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

<p>California Department of Public Health Administrator Janice Byers Telephone: (510) 412-5851 Fax: (510) 412-1548 Email: Janice.byers@cdph.ca.gov</p>	<p>Vendor's Name Agency Official {Enter name of Vendor's Contract Mgr) Telephone: (XXX) XXX-XXXX Fax: (XXX) XXX-XXXX Email: Xxxxxxxx@xxxx.xxx</p>
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B. Direct all inquiries to:

<p>California Department of Public Health NBSP Metabolic Center Liaison Genetic Disease Screening Program Attention: Carole Klein, MPH Mail Station Code 8200 850 Marina Bay Parkway Richmond, CA 94804</p> <p>Telephone: (510) 412-1481 Fax: (510) 412-4657 Email: Carole.Klein@cdph.ca.gov</p>	<p>Vendor's Name</p> <p>Project Director Section or Unit Name (if applicable) Attention: (Enter Name) Street Address & room number P.O. Box Number (if applicable) City, State, Zip Code</p> <p>Telephone: (XXX) XXX-XXXX Fax: (XXX) XXX-XXXX Email: XXXXXXXX@XXXX.XXX</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. Enter short-term and long-term reportable data on the referred and diagnosed newborn cases into SIS. Reportable data encompasses information related to the consultation with the newborn's Primary Medical Doctor (PMD), Newborn Screening Area Service Centers (ASCs), and the NBSP staff regarding cases referred to the Metabolic Center with a positive newborn screening result, as well as providing clinical information to GDSP on conditions screened for by the California NBSP.
- B. Participate in 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.
- C. Contact the PMD to discuss health status of referred newborns and determine whether it is necessary for the baby to be seen immediately by a specialist. Communicate by telephone, secure fax or E-mail with PMD as needed regarding the status and treatment of the baby.
- D. Respond to ASC or NBSP staff requests for information on referred cases within two (2) business days of request.

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E. Upon request, provide consultation to NBSP staff, ASC staff, newborns' PMD, and/or CCS authorizing agency regarding diagnosis and treatment of metabolic conditions screened for by the GDSP.

F. SIS Documentation

Provide timely documentation of significant contacts pertaining to a referred infant using the GDSP Web-based SIS. New cases will appear in the top grid of the SIS Follow Up Center Cases Referred 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."

SIS Metabolic Service Report

The on-line **SIS Metabolic Services Report form (MSR)** is a mechanism for documenting significant contacts made regarding a referred infant from the time of initial referral until the diagnostic decision is made and any necessary treatment is initiated. The information gained from the MSR is used by the GDSP to evaluate the effectiveness of the screening program. It is important that the Metabolic Center enter information into all the fields of the MSR form, including the Health Profile. An MSR should be completed for significant contacts. This data includes physician telephone consultations, contact with the family in person or by telephone, the initial clinic visit, other physician consultations and follow-up visits for diagnostic evaluation. The final MSR shall document the diagnostic decision and information on the treatment initiated.

The SIS 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 and the diagnostic decision. After a diagnosis is confirmed or ruled out, treatment (if indicated) initiated, and this information entered in an MSR, further MSRs are no longer required for that patient.

SIS Genotype Entry

If genotyping or mutation analysis results are available, enter these in the Confirmatory Test Results section of SIS by selecting 'DNA' as the Test Type.

SIS Case Notes

After entering the MSR, case notes may be added when additional information is needed to augment or clarify that MSR. For example, when the contact type checked on the MSR is "Other", for brief explanations for unusual

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delays in diagnosis, or estimate of time until confirmatory results will be available. Other reasons for case notes include notes about the date of the next appointment, additional testing ordered or case status since the last MSR. However, **case notes do not replace the need for an MSR when a significant contact is made that provides information about the referred NBS case.**

For a diagnosis taking over a month, the Center should communicate at least monthly with the ASC regarding the case status. The Center can discuss with the ASC the best way to communicate updates, using one or more modes of contact: email, telephone, or SIS case notes.

SIS Metabolic Center Annual Patient Summary

A SIS Metabolic Center Annual Patient Summary (MCAPS) must be completed in SIS once a year for each child diagnosed with a metabolic disorder for which GDSP screens until the child is five years of age. Each month metabolic centers will receive a list in SIS of referred cases of children who had a birthday in the previous month who are due to have an MCAPS. The MCAPS should be completed by the end of the following month (the month after the child's birthday). Guidelines for completing the MCAPS can be found in the Data Entry Manual. Any questions about SIS and completing the MSRs or the MCAPS should be directed to the Metabolic Center Vendor Liaison.

Some metabolic cases taking more than 6 months to resolve at the Metabolic Center will be followed directly by staff at the GDSP. Metabolic Centers will be contacted directly by GDSP 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.

- G. Notify the GDSP by telephone or email each time a new diagnosis of a metabolic disorder for which NBSP screens is made at your Center for a patient who was *screened but not identified as screen positive by the California NBSP, regardless of patient age.*

- H. Notify the GDSP by telephone or email each time a new diagnosis of a metabolic disorder for which NBSP screens is made at your Center for a patient up to 5 years of age, who was **not** *screened by the California NBSP.* Provide information on name, birthdate, demographic characteristics, and the results of confirmatory testing. Within five (5) days, Center shall complete pertinent information on the MSR screen in SIS on encounters with each new patient who was not initially screened by GDSP, up to the point of diagnosis and initiation of treatment. Centers also shall complete a SIS MCAPS once a year on each of these new patients until the child is 5 years of age.

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- I. The NBSP Metabolic Center Vendor Liaison must be notified regarding any changes in the Metabolic Center core clinic team members or staff who will be entering information into SIS.

6. Reimbursement

The GDSP shall reimburse the Vendor using a unit-cost methodology for each new case referred and for each annual follow-up for diagnosed cases as reported in SIS. See Exhibit B for a detailed outline of the rate schedule. GDSP will provide a report quarterly that contains the number of new referrals and completed Annual Patient Summaries to be used in completing the quarterly invoice for the associated time period.

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, i.e., statewide planning meetings, guideline subcommittees, Maternal Phenylketonuria Camp, (MPKU Camp), etc. Vendor staff shall assist the GDSP in the further development of the NBSP by recommending and responding to proposed policy changes and providing information as requested.

8. Confidential and Privileged Information

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

Confidential or 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 NBSB. 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 or 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.