

## 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 endocrine patients identified through the Newborn Screening Program (NBSP). Vendor must be an approved Endocrine 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 Endocrine Centers and the California Newborn Screening Program. This includes the maintenance of CCS-approved status as an endocrine center including staffing requirements during the term of the agreement. It certifies that services provided meet the standards described in this agreement and other widely accepted professional treatment guidelines developed by endocrine professional organizations.

#### 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:

<p><b>California Department of Public Health</b>  Administrator  <a href="#">Janice Byers</a>  Telephone: (510) 412-5851  Fax: (510) 412-1556  Email: <a href="mailto:Janice.Byers@cdph.ca.gov">Janice.Byers@cdph.ca.gov</a></p>	<p><b>Vendor</b>  Agency Official   Telephone:  Fax:  Email:</p>
--	--

B. Direct all inquiries to:

<p><b>California Department of Public Health</b>  NBSP Endocrine Center Liaison  <a href="#">Genetic Disease Screening Program</a>  Attention: <a href="#">Beth McCoy</a>  Mail Station Code 8200  850 Marina Bay Parkway, Room F175  Richmond, CA 94804   Telephone: (510) 412-1489  Fax: (510) 412-1489  Email: <a href="mailto:Beth.McCoy@cdph.ca.gov">Beth.McCoy@cdph.ca.gov</a></p>	<p><b>Vendor</b>  Clinic Coordinator   Attention:   Telephone:  Fax:  Email:</p>
--	--

## **Exhibit A**

### Scope of Work

- 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 with positive endocrine newborn screening tests whenever requested by the Genetic Disease Screening Program (GDSP) Area Service Center (ASC) staff (see Attachment I). Respond within 48 hours to request for additional information that may be needed by the ASC.
- B. Contact Primary Medical Doctor (PMD) to discuss health status of newborn.
- C. Order follow-up confirmatory/diagnostic laboratory testing as appropriate to confirm or rule out a diagnosis. Provide information to PMD on laboratory results and any necessary follow-up within 24 hours of receiving the results.
- D. Forward a copy of the confirmatory test results to the referring NBS ASC.
- 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. In the event the family cannot be contacted, misses a scheduled appointment for an initial evaluation, or refuses care, the Vendor will notify the NBSP ASC as early as possible and no later than five (5) days after the occurrence.
- F. Assist family in completing CCS application form and fax it to the appropriate CCS office.
- 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. Bill family's insurance/HMO for services at the endocrine special care center. If a claim is denied for diagnostic services, submits it to CCS with written documentation of denial.
- L. Bill CCS for diagnostic services per CCS guidelines.
- M. When available for endocrine reporting, use the GDB Web-based computer Screening Information System (SIS) to view new cases referred to the endocrine center, schedule appointments for new clients, and record the initial appointment information in SIS. Assist GDB to test endocrine screens and files in SIS prior to implementation of endocrine reporting. Utilize other format developed by GDB for reporting prior to implementation of SIS reporting.

## Exhibit A

### Scope of Work

The manual/hard copy or on-line SIS **Endocrine Report form (ESR)**, (see Attachment III), is a mechanism for documenting significant contacts made regarding a referred infant up to the diagnosis and initiation of treatment. Significant contacts include the initial clinic visit, physician consultations and follow-up visits for diagnostic evaluation until the diagnosis is made and treatment initiated.

The Endocrine Services Report form (ESR) shall be completed as soon as a diagnosis is made, preferably within one (1) business day but no later than five (5) calendar days of the diagnosis confirmation or of ruling out a disorder. Included on this one ESR should be a record of all significant contacts made up to diagnosis. This should be submitted to GDSP along with the quarterly report. Once a diagnosis is confirmed or ruled out, an ESR is no longer required.

- 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 requested information and consultation to GDB staff, Area Service Center staff, newborns' primary care physicians, neonatologists and/or CCS authorizing agency regarding diagnosis and treatment of endocrine disorders.
- 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 11 for review and approval).

#### 6. Reporting Requirements

- A. Provide quarterly reports in the format specified by the NBSP (see Attachment II) to the NBSP Endocrine Center Liaison on a quarterly basis. Completed Quarterly Summary 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:

Beth McCoy, Newborn Screening Branch  
 Department of Public Health  
 Genetic Disease Screening Program  
 850 Marina Bay Parkway, MS 8200, Room F175  
 Richmond, CA 94804  
[Beth.McCoy@cdph.ca.gov](mailto:Beth.McCoy@cdph.ca.gov)

## **Exhibit A**

### Scope of Work

- B. The NBSP Endocrine 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 Polices/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.

#### **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.