

## 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 cystic fibrosis patients identified through the Newborn Screening Program (NBSP). Vendor must be an approved Cystic Fibrosis Special Care Center, use a CFF accredited lab for sweat testing, 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 and Cystic Fibrosis Foundation accredited cystic fibrosis centers and the California Newborn Screening Program (NBSP). This includes maintaining the standards of CCS cystic fibrosis centers including staffing requirements during the term of the agreement. It certifies that services provided meet the standards described in this agreement and other professional treatment guidelines as outlined in the Cystic Fibrosis Foundation Consensus Conference on Infection Control<sup>1</sup> and the Cystic Fibrosis Foundation's current *Clinical Practice Guidelines for Cystic Fibrosis*.

### 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:

<b>California Department of Health Services</b> Administrator Muslimah Jaavaid Telephone: (510) 412-1476 Fax: (510) 412-1548 Email: MJavaaid@dhs.ca.gov	<b>Vendor</b> Agency Official [Enter Name of Vendor's Contract Manager] Telephone: (XXX) XXX-XXXX Fax: (XXX) XXX-XXXX Email: XXXXXXXX@XXXXXXXX
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1. *Infection Control and Hospital Epidemiology (ICHE)*: May 2003, Vol. 24, No. 5 and *American Journal of Infection Control (AJIC)*: May 2003, Vol. 31, No. 3.

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B. Direct all inquiries to:

<b>California Department of Health Services</b> NBSP Cystic Fibrosis Center Liaison Genetic Disease Screening Program Attention: Tracey Bishop Mail Station Code 8200 850 Marina Bay Parkway, F175 Richmond, CA 94804  Telephone: (510) 412-6213 Fax: (510) 412-1552 Email: Tracey.Bishop@cdph.ca.gov	<b>Vendor Name</b> 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@XXXXXXXX
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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**

The Vendor shall perform the following services:

- A. Accept referrals for newborns with initial positive cystic fibrosis newborn screening test results (also referred to as interesting cases or cases) whenever requested by the Genetic Disease Screening Program (GDSP) Newborn Screening Program (NBSP) Area Service Center (ASC) staff. Respond within 48 hours to requests for additional information that may be needed by the ASC.
- B. Contact Primary Medical Doctor (PMD) to discuss health status of newborn.
- C. The CF Center will order follow-up sweat test as soon as possible within 2 weeks of referral. Other diagnostic laboratory testing should be ordered 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. Enter sweat chloride test results into confirmatory tests result section of SIS when received within 24 hours of receipt.
- E. 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.

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- 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.
- 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 the cystic fibrosis special care center. If a claim is denied for diagnostic services, submits it to CCS with written documentation of denial.
- L. If the family has no other third-party coverage, bill CCS for diagnostic services per CCS guidelines.
- M. Provide timely documentation of significant contacts regarding a referred infant using the GDSP Web-based computer Screening Information System (SIS). New cases with CF positive screening results will appear in the top grid of the cystic fibrosis center SIS referral screen. After follow-up consultation activities have been initiated and documented on a SIS Cystic Fibrosis Service Report (CFSR), indicating that the referred case has been received at the CF Center the case information will move to the SIS "PENDING" grid. Once a diagnosis is confirmed or ruled out patient information will appear on the third grid, "RESOLVED CASES."

**In the course of following up patients at your center, if the patient's diagnosis changes, please complete a new Cystic Fibrosis Service Report (CFSR) and enter the case status to the appropriate category (e.g. cystic fibrosis, suspect cystic fibrosis, no disorder/carrier) and notify the CF Contract Liaison, the NBSP ASC Coordinator, and the CF Monitor.**

### **CFSR Reporting**

The on-line SIS Cystic Fibrosis Services Report form (CFSR) is a mechanism for documenting significant contacts made regarding a referred infant up to the

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diagnostic decision and initiation of treatment or of ruling out a disorder. The important information gained from the CFSR is used by the Genetic Disease Screening Program to evaluate the effectiveness of the screening program and the CFSR forms need to be completed fully including the Global Health Assessment and the Health Profile. Significant contacts needing a CFSR include physician telephone consults, contacts with the family in person or by telephone, the initial clinic visit, other physician consultations and follow-up visits for diagnostic evaluation until the diagnostic decision is made and treatment initiated. After completing a CFSR, case notes should be added when additional information is needed to augment or clarify that CFSR. 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 CFSR. 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 CFSR when a significant contact is made that provides information about the referred NBS case.

The on-line SIS Cystic Fibrosis Services Report forms (CFSR) 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.

### **Cystic Fibrosis Annual Patient Summary**

Once a diagnostic decision is made CFSRs are no longer required, however, a SIS CF Annual Patient Summary must be completed in SIS once a year for each diagnosed child up until the child is 5 years of age. Each month cystic fibrosis 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 cystic fibrosis centers. Any questions about SIS and completing the CFSRs or the Annual Patient Summary should be directed to Ruth Koepke, the CF monitor.

- N. Fax copies of laboratory reports with the results of CF DNA mutation analysis of the newborn's parents to the GDSP for entry into SIS to Ruth Koepke, fax #: 510-412-1511.
- O. Provide the family with genetic counseling with respect to the cause of the disorder, recurrence risk and reproductive options.
- P. Accept referrals from GDSP CF Carrier Follow-up program for parents of newborns with a single CF gene mutation identified via the NBSP who have already received

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phone counseling from NBSP's Genetic Counselor or who have requested face to face counseling in lieu of telephone counseling.

- Q. Notify the GDSP by telephone or e-mail (Ruth Koepke, 510-412-1471, or [Ruth.Koepke@cdph.ca.gov](mailto:Ruth.Koepke@cdph.ca.gov)) each time a new diagnosis of CF is made at your Center or a new case is referred to your Center, on a patient not referred by the California NBSP, regardless of patient age. Provide information on names, birth date, demographic characteristics, and the results of confirmatory and CFTR mutation testing. Within five (5) days, Centers shall complete pertinent information on the CFSR screen in SIS on encounters with each new patient up to the point of diagnosis and treatment initiation. Centers also shall complete a SIS Annual Patient Summary once a year on each new patient until the child is 5 years of age.
- R. 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.
- S. Upon request, provide requested information and consultation to GDSPstaff, Area Service Center staff, newborns' primary care physicians, neonatologists and/or CCS authorizing agency regarding diagnosis and treatment of cystic fibrosis.
- T. 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.
- U. Use only written patient educational materials supplied or approved by the NBSP (see Exhibit D, Item 10 for review and approval).

**6. CYSTIC FIBROSIS VENDOR QUARTERLY SUMMARY REPORTING REQUIREMENTS**

- A. Provide quarterly reports in the format specified by the NBSP to the Cystic Fibrosis Center vendor agreement liaison.

Completed Quarterly Summary Reports shall be submitted by the following dates:

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

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

Tracey Bishop, Newborn Screening Branch,  
California Department of Public Health  
Genetic Disease Screening Program  
850 Marina Bay Parkway, Room F175  
Richmond, CA 94804  
E-mail: Tracey.Bishop@cdph.ca.gov

- B. The NBSP cystic fibrosis center vendor agreement liaison must approve any changes in personnel that impact the budget after reviewing the Request for Personnel Change Form. Resumes of new hires **and confidentiality oaths** shall be included with the Request for Personnel Change 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.

### 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. A copy of the HIPAA business associate addendum is located in the Vendor Agreement Exhibit E.

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 contractors, 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

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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.