

**SUBMITTAL TO THE BOARD OF SUPERVISORS  
COUNTY OF RIVERSIDE, STATE OF CALIFORNIA**

207



**SUBMITTAL DATE:**  
March 8, 2012

**FROM:** Community Health Agency/Department of Public Health

**SUBJECT:** Ratify the Agreement #T-1112-006-12 with the County of San Bernardino and the Community Health Agency, Department of Public Health Laboratory

**RECOMMENDED MOTION:** That the Board of Supervisors:

- 1) Ratify the Agreement between the County of San Bernardino and the Community Health Agency Department of Public Health in the amount of \$3,000 annually for the period of February 1, 2012 to January 31, 2015; and
- 2) Authorize the Chairperson of the Board to sign three (3) originals of the Agreement on behalf of the County of Riverside.

**BACKGROUND:** (continued)

SM:mc:td

*Susan D. Harrington*  
\_\_\_\_\_  
Susan D. Harrington, Director  
Department of Public Health

|                       |                               |          |                         |       |
|-----------------------|-------------------------------|----------|-------------------------|-------|
| <b>FINANCIAL DATA</b> | Current F.Y. Total Cost:      | \$ 3,000 | In Current Year Budget: | Yes   |
|                       | Current F.Y. Net County Cost: | \$ 3,000 | Budget Adjustment:      | No    |
|                       | Annual Net County Cost:       | \$ 0     | For Fiscal Year:        | 11/12 |

|   |   |                          |
|---|---|--------------------------|
| <b>SOURCE OF FUNDS:</b> 100% Department funds | <b>Positions To Be Deleted Per A-30</b> | <input type="checkbox"/> |
|   | <b>Requires 4/5 Vote</b>                | <input type="checkbox"/> |

**C.E.O. RECOMMENDATION:** APPROVE

BY: *Debra Cournoyer*  
Debra Cournoyer

**County Executive Office Signature**

FISCAL PROCEDURES APPROVED  
PAUL ANGULO, CPA, AUDITOR-CONTROLLER  
BY: *Samuel Wong* 3/12/12  
SAMUEL WONG

FORM APPROVED COUNTY COUNSEL  
*Nel R. Kipnis*  
DATE  
BY: NEL R. KIPNIS

Departmental Concurrence

ATTACHMENTS FILED WITH THE CLERK OF THE BOARD  
Dept't Recomm.  Consent  Policy   
Per Exec. Ofc.:  Consent  Policy

Prev. Agn. Ref.:

District: ALL

Agenda Number:

3.15

**SUBJECT:** Ratify the Agreement #T-1112-006-12 with the County of San Bernardino and the Community Health Agency, Department of Public Health Laboratory

**BACKGROUND:**

Since Fiscal Year 06/07 the Riverside County Community Health Agency Department of Public Health Laboratory has contracted with the County of San Bernardino Department of Public Health Laboratory for level B laboratory services, MTD testing and fungal/yeast identification services. The contracting was established annually through a Blanket Purchase Order.

This year, County of San Bernardino would like to establish a three (3) year agreement. Testing would be paid in accordance with the established charges per Attachment C, LABORATORY SERVICES, attached to the agreement. Compensation to County of San Bernardino Department of Public Health Laboratory will not exceed \$3,000 annually.



FOR COUNTY USE ONLY

County of San Bernardino

F A S

STANDARD CONTRACT

|   |                                    |                                 |  |                        |                                  |              |
|---|------------------------------------|---------------------------------|--|------------------------|----------------------------------|--------------|
| <input checked="" type="checkbox"/> New   | Vendor Code                        | SC                              | Depl. PHL                              | A                      | Contract Number<br>T-1112-006-12 |              |
| <input type="checkbox"/> Change   |                                    |                                 |  |                        | Contractor's License No.         |              |
| <input type="checkbox"/> Cancel   | County Department<br>Public Health | Dept. PHL                       | Orgn.                                  |                        | Total Contract Amount<br>\$      |              |
| County Department Contract Representative<br>Lisa Ordaz   |                                    |                                 | Telephone<br>(909)388-0222             |                        |                                  |              |
| Contract Type<br><input checked="" type="checkbox"/> Revenue <input type="checkbox"/> Encumbered <input type="checkbox"/> Unencumbered <input type="checkbox"/> Other Non-financial<br>If not encumbered or revenue contract type, provide reason: Template |                                    |                                 |  |                        |                                  |              |
| Commodity Code  |                                    | Contract Start Date<br>02/01/12 | Contract End Date<br>01/31/15          | Original Amount<br>\$  | Amendment Amount<br>\$           |              |
| Fund<br>AAA   | Dept.<br>PHL                       | Organization<br>1900            | Appr.                                  | Obj/Rev Source<br>9415 | GRC/PROJ/JOB No.                 | Amount<br>\$ |
| Fund  | Dept.                              | Organization                    | Appr.                                  | Obj/Rev Source         | GRC/PROJ/JOB No.                 | Amount<br>\$ |
| Fund  | Dept.                              | Organization                    | Appr.                                  | Obj/Rev Source         | GRC/PROJ/JOB No.                 | Amount<br>\$ |
| Project Name<br>Laboratory Testing Services   |                                    |                                 | Estimated Payment Total by Fiscal Year |                        |                                  |              |
|   |                                    |                                 | FY                                     | Amount                 | I/D                              | FY           |
|   |                                    |                                 |  |                        |                                  |              |
|   |                                    |                                 |  |                        |                                  |              |

THIS CONTRACT is entered into in the State of California by and between the County of San Bernardino, Department of Public Health, hereinafter called the County, and

Name  
Riverside County Department of Public Health hereinafter called Contractor

Address  
P.O. Box 7600/4650 County Circle Drive

Riverside, CA 92513-7600

Telephone Federal ID No. or Social Security No.  
(951) 358-5070

**IT IS HEREBY AGREED AS FOLLOWS:**

WHEREAS, the County desires to provide laboratory testing services for human infectious diseases of public health importance; and

WHEREAS, the Contractor has the need of laboratory testing services for human infectious disease of public health importance; and

WHEREAS, the County operates a Public Health laboratory suitable to provide such testing services; and

WHEREAS, it is of mutual benefit to the parties that the Public Health laboratory provides testing services for Contractor;

NOW THEREFORE, the parties hereto enter into this Agreement as a full statement of their respective responsibilities during the term of this Agreement, and in consideration of the representations made above and the covenants and conditions set forth herein, the parties agree as follows:

**Auditor/Controller-Recorder Use Only**

|  |                              |
|--|------------------------------|
| <input type="checkbox"/> Contract Database | <input type="checkbox"/> FAS |
| Input Date                                 | Keyed By                     |

I. County Responsibilities

The County shall:

- A. Provide all equipment, materials, supplies, personnel, licenses, and permits to provide full service public health laboratory services related to communicable diseases and other conditions of public health importance, on blood, urine, and other body fluids.
- B. Provide the Contractor with a current Specimen Collection Manual describing tests available, appropriate specimens for testing, specimen transportation criteria, critical values for each test, and expected test turnaround time.
- C. Provide most routine supplies necessary for collection of specimens free of charge. In most cases these supplies will be transported by Contractor's courier within one week of request.
- D. Perform the necessary medical laboratory tests, upon request of the Contractor's ordering physician, unless the specimen is unsatisfactory for testing.
  - In the event a specimen is unsatisfactory for testing, the Contractor will be notified within 24 hours by fax or phone. The unsatisfactory specimen will be held at the laboratory for one week before disposal or return to the Contractor at the Contractor's request. Contractor contact information must be on file or on the requisition.
- E. For some testing algorithms, initially positive tests will be confirmed with further tests. Additional charges may apply. If the submitting physician does not want confirmation or follow-up tests, this must be indicated on the original laboratory test request form, under "Submitter comments."
- F. Only be open during regular business hours: Monday through Friday, 8:00am to 5:00pm. The lab is closed on weekends and county holidays.
- G. Ensure laboratory reports meet the following specifications:
  1. Computer printed on 8.5 by 11-inch paper.
  2. Faxed to the Contractor within 1 business day of test completion.
  3. Results outside established reference range will be marked or separated from normal results for easy identification. Abnormal results will be reported to the Contractor on the day the results are obtained.
  4. Results of tests from separate individuals will be on separate report forms.
  5. If sufficient sample exists, specimens shall be retained for at least ten (10) days after the results are reported, to allow for repeat or additional testing.
- H. Maintain, in effect at all times during the term of the agreement, current licenses, certifications, and permits in accordance with Federal, State, and local government requirements as follows:
  1. Certified by the California Department of Public Health as a public health and environmental health laboratory.
  2. Medicare certified laboratory with average proficiency at least 95%. A copy of the graded proficiency test results will be available on request.
  3. Current and valid Clinical Laboratory Improvement Amendments (CLIA) Certificate of Compliance, copy available on request.
- I. Provide technical support on an as needed basis.

II. Contractor Responsibilities

Contractor shall:

- A. Ensure all test request forms are filled out completely and legibly.

1. Specimen Requisition Forms: All laboratory test requests must be submitted on a "Laboratory Test Request" form. This form is available upon request by submitting a "Laboratory Supplies and Forms" Requisition.
  2. The Laboratory Test Request forms are triple copy – The white original and yellow copy are returned to the lab. The pink copy stays with the Contractor. Laboratory Test Request forms are submitted for immunological evidence of infection from blood and cerebrospinal fluid (CSF) specimens and for isolation and/or identification of bacteria, fungi, parasites, or viruses.
- B. Order supplies as needed: Use Attachment A – Supplies Request Form. All orders may be mailed, faxed, or delivered to the Public Health Laboratory at the address below for delivery that week.

Department of Public Health  
Laboratory Services  
799 E. Rialto Avenue  
San Bernardino, CA 92415-0011  
Fax: (909) 383-3094

- C. Ensure Specimens are correctly labeled, stored and transported.
1. Contractor will obtain specimens using standard methods. Specimens will be obtained by the Contractor's personnel and transported by courier to the Public Health laboratory for testing per the instructions on Attachment B – Specimen Transportation.
  2. Contractor will arrange for timely transport of the specimens to the laboratory during regular business hours. Special arrangements will need to be made for delivery outside regular business hours.
  3. Test Reporting: Requests for copies of final reports must be submitted to the Public Health Laboratory office staff in writing.
- D. Contact the Public Health Laboratory office at (909) 383-3000, if additional information on patient test results is required.

### III. Payment of Fees

- A. The total dollar amount of this Agreement will be determined by the total number and nature of the requests made by the Contractor to the County. There is no guaranteed maximum or minimum number of requests to be made under this Agreement.
- B. Contractor will be invoiced every two months on a fee-for-service basis for testing services requested and completed, based on fees established in Attachment C – Laboratory Services. Contractor will be invoiced using the most current rates established by the County, updated July 1 of each year.
- C. Contractor shall remit payment to County within 30 days of receipt of invoice from County.
- D. Specimens or cultures may be submitted to the California Department of Public Health (CDPH) Laboratory for follow-up testing at no additional cost.

### IV. Indemnification

Each party to this agreement agrees to indemnify and hold harmless the other party and its officers, employees, agents and volunteers from any and all claims or actions arising from the other party's acts, errors or omissions and for any costs or expenses incurred by the party on account of any claim therefore.

### V. Health Insurance Portability and Accountability Act of 1996

Pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), regulations have been promulgated governing the privacy of individually identifiable health information. The HIPAA Privacy Regulations specify requirements with respect to contracts between an entity covered under the HIPAA Privacy Regulations and its Business Associates. A Business Associate is defined as a party that performs

certain services on behalf of, or provides certain services for, a Covered Entity and, in conjunction therewith, gains access to individually identifiable health information. Therefore, in accordance with the HIPAA Privacy Regulations, County shall comply with the terms and conditions as set forth in the Business Associate Agreement (Attachment D), hereby incorporated by this reference.

VI. Confidentiality

County shall protect from unauthorized use or disclosure names and other identifying information concerning persons receiving services pursuant to this Contract, except for statistical information not identifying any participant. The County shall not use or disclose any identifying information for any other purpose other than carrying out the Public Health Laboratory's obligations under this Contract, except as may be otherwise required by law. This provision will remain in force even after the termination of the Contract.

VII. Term and Termination

This Agreement shall be effective for a three (3) year term, commencing on the execution of the Agreement by both parties and shall automatically renew for successive one year terms thereafter.

However, this Agreement may be terminated at any time, with or without cause, by either party after giving the other party 30 days advance written notice of its intention to terminate.

Written notice issued pursuant to this Section by the Assistant Director of Public Health on behalf of the County shall be sent by registered mail to the Contractor contact. Written notice issued pursuant to this Section by the Contractor shall be sent by registered mail to the Public Health Laboratory Director.

VIII. Modification

This Agreement may only be altered, changed, or amended by mutual agreement of the parties in writing.

IX. Governing Law

This Agreement is made and entered into the State of California and shall in all respects be interpreted, enforced and governed by and under the laws of the State of California.

X. Attorney's Fees and Costs

In any legal action to enforce or declare any party's rights hereunder, each party, including the prevailing party, shall bear its own costs and attorneys' fees. This section shall not apply to those costs and attorneys' fees directly arising from any third party legal action against a party hereto and payable under the indemnification requirement of this Contract.

IN WITNESS WHEREOF, the Board of Supervisors of the County of San Bernardino has granted authorization to the Assistant Director of the Department of Public Health to subscribe to this contract, and Contractor has caused this Contract to be subscribed in its behalf by its duly authorized officers, the day, month and year written.

COUNTY:OF SAN BERNARDINO

COUNTY OF RIVERSIDE

Riverside County Department of Public Health  
*(Print or type name of corporation, company, contractor, etc.)*

▶  
\_\_\_\_\_  
Department of Public Health Assistant Director

Dated \_\_\_\_\_

By ▶ \_\_\_\_\_  
*(Authorized signature - sign in blue ink)*

Name \_\_\_\_\_  
*(Print or type name of person signing contract)*

Title \_\_\_\_\_  
*(Print or Type)*

Dated \_\_\_\_\_

Address P.O. Box 7600/4650 County Circle Dr.  
Riverside, CA 92513-7600

ATTEST: Kecia Harper-Ihem, Clerk

By \_\_\_\_\_

FORM APPROVED COUNTY COUNSEL  
BY: Neal R. Kipnis DATE 3/12/12

RECEIVED:

FILLED/INITIALS:

**LABORATORY SUPPLIES REQUISITION**

San Bernardino County Public Health Laboratory

799 East Rialto Ave., San Bernardino, Ca. 92415

Phone (909) 383-3000 Fax (909) 383-3094

Mail Code: 0011

AGENCY: \_\_\_\_\_ ATTN: \_\_\_\_\_  
 ADDRESS: \_\_\_\_\_ PHONE: (\_\_\_\_) \_\_\_\_\_  
 CITY: \_\_\_\_\_ DATE: \_\_\_\_\_

| QTY | UNIT     | <u>COLLECTION MATERIALS</u>  |
|-----|----------|--|
| [ ] | EACH     | Bacterial Culture Swab (Misc. Culture)                                     |
| [ ] | EACH     | Blood Transport Tubes  |
| [ ] | FLAT/100 | Blood Tubes for CD4/PCR w/o separator ( <b>Purple Top</b> )                |
| [ ] | FLAT/50  | Blood Tubes for PCR w/ plasma separator ( <b>Purple w/ Yellow center</b> ) |
| [ ] | EACH     | Blood Tubes for AFB ( <b>Yellow Tube/Black Top</b> )                       |
| [ ] | SET      | Blood Tubes for QuantiFERON ( <b>Set of 3 color-coded tubes per test</b> ) |
| [ ] | BOX/100  | Chlamydia/Gonorrhea Collection Kits w/ specimen bags ( <b>Genital</b> )    |
| [ ] | BOX/100  | Chlamydia/Gonorrhea Collection Kits w/ specimen bags ( <b>URINE</b> )      |
| [ ] | EACH     | Enteric Stool Container (Orange Top)                                       |
| [ ] | EACH     | Gonorrhea Culture Swabs  |
| [ ] | EACH     | Hemocult Fecal Test Kit w/ Mailing Envelope                                |
| [ ] | EACH     | Ova & Parasite Container (Pink & Grey Top)                                 |
| [ ] | PACK/100 | Specimen Bags (Biohazard Labeled 6 x 9")                                   |
| [ ] | PACK/100 | Specimen Bags (Biohazard Labeled 6 x 10" - TB Use Only)                    |
| [ ] | EACH     | TB Collection tubes 50ml. blue top (sputum or stool)                       |
| [ ] | EACH     | Urine Cups   |
| [ ] | EACH     | *Viral Culture Swab ( <b>HSV CULTURE &amp; FLU TRANSPORT</b> )             |
|     |          | <i>(*order in quantities of each for viral culture swabs)</i>              |

FORMS

|     |         |   |
|-----|---------|---|
| [ ] | PKG/167 | Culture/Immunology Test Request (3 copy form)                 |
| [ ] | PKG/200 | Clinical Technology Test Request (799 E. Rialto Only – Green) |
| [ ] | PKG/20  | Medical Waste Stickers (Delivery to Laboratory for Discard)   |
| [ ] | PKG/20  | Medical Waste Stickers (Site Code) _____                      |

OTHER

|     |      |   |
|-----|------|---|
| [ ] | EACH | Duospore/ProTest Steam (Autoclave Test Strips/Ampoules) |
| [ ] | EACH | Other: _____  |

\*\* For Laboratories mailing specimens, please use the cardboard box with the plastic insert (i.e., Saf-T-Pak) that conform to Department of Transportation and USPS mailing regulations. Laboratories providing return postage will have their Saf-T-Pak boxes returned to them. \*\*



## Specimen Transportation

Use the following guidelines to properly transport specimens to the laboratory.

### Temperature Requirements

Specific temperature transport requirements are provided under each assay description. Unless otherwise indicated specimens should be transported at 2-8°C.

### Diagnostic Specimens

Specimens that are to be sent through the Contractor's courier should be placed in the appropriate bag or container. Make sure the primary container is tightly sealed to avoid leaking.

Vacutainers containing blood specimens should be sent in the plastic screw cap 50-ml transport containers provided by the laboratory with the requisition form wrapped *outside* the transport container.

**Important:** The request form should not be wrapped around the blood tube itself or inside the transport container.

Other specimens should be sent in their appropriate specimen containers and placed inside the plastic resealable bag provided. The request form should be placed in the front pocket of the plastic resealable bag (if available) or wrapped *around* the resealable bag. *Please, do not place the request form inside the specimen compartment.*

Any specimens sent through the US mail need to meet federal and postal regulations.

## LABORATORY SERVICES

| Name of Test                                   | Fee      | CPT   |
|--|----------|-------|
| <b><u>Bacteriology</u></b>                     |          |       |
| Chlamydia Amplification Probe                  | \$50.00  | 87491 |
| Culture - Primary Gonorrhea                    | \$15.00  | 87070 |
| Culture - Stool Salmonella-Shigella            | \$30.00  | 87045 |
| Culture - Stool Campylobacter                  | \$20.00  | 87046 |
| Culture - Stool E.coli O 157: H7               | \$20.00  | 87046 |
| Culture - Misc Bacterial                       | \$15.00  | 87070 |
| Culture - Urine                                | \$15.00  | 87086 |
| Culture - B-Strep with typing                  | \$15.00  | 87070 |
| NG Amplification Probe                         | \$50.00  | 87591 |
| Aerobic Bacteria Identification                | \$50.00  | 87077 |
| <b><u>Mycology</u></b>                         |          |       |
| Specimen Concentration                         | \$15.00  | 87015 |
| Culture - Fungal                               | \$30.00  | 87102 |
| Fungus ID Mold                                 | \$50.00  | 87107 |
| Fungus ID Yeast                                | \$50.00  | 87106 |
| KOH Prep - Fungal                              | \$9.00   | 87220 |
| Systemic Fungus DNA Probe                      | \$100.00 | 87797 |
| Pneumocystis Exam                              | \$60.00  | 87281 |
| Aerobic Bacteria ID                            | \$50.00  | 87077 |
| <b><u>Mycobacteriology</u></b>                 |          |       |
| AFB Smear (Rhodamine-Auramine)                 | \$10.00  | 87206 |
| Culture - Mycobacteria Screening               | \$54.00  | 87116 |
| Definitive Mycobacteria ID by Biochemicals     | \$75.00  | 87118 |
| M. Kansasii Probe                              | \$35.00  | 87550 |
| MAC Nucleic Acid Probe                         | \$35.00  | 87560 |
| MTB Amplification Probe (NAAT)                 | \$75.00  | 87556 |
| MTB Nucleic Acid Probe                         | \$35.00  | 87555 |
| M. Gordonae Nucleic Acid Probe                 | \$35.00  | 87149 |
| Hospital Lab Culture Screening (incl. MB/MGIT) | \$25.00  | none  |
| Specimen Concentration                         | \$15.00  | 87015 |
| TB Susceptibility Agar Method (per drug)       | \$20.00  | 87190 |
| TB Susceptibility Broth Method (per drug)      | \$25.00  | 87188 |
| HPLC Isolate Identification                    | \$75.00  | 87143 |
| <b><u>Parasitology</u></b>                     |          |       |
| Blood Smear - Parasite Exam                    | \$20.00  | 87207 |

|   |          |              |
|---|----------|--------------|
| Cryptosporidium / Giardia Exam                | \$40.00  | 87328        |
| Cyclospora / Isospora /<br>Microsporidia Exam | \$20.00  | 87206        |
| Helminth / Arthropod                          | \$10.00  | 87168        |
| O&P Trichome or Other Stain                   | \$30.00  | 87209        |
| Stool Conc for O&P Exam                       | \$30.00  | 87177        |
| <b>Serology</b>                               |          |              |
| Hepatitis A - Antibody, IgM                   | \$25.00  | 86709        |
| Hepatitis A - Antibodies Total                | \$25.00  | 86708        |
| Hepatitis B - Core Antibody Total             | \$25.00  | 86704        |
| Hepatitis B - Surface Antibody                | \$25.00  | 86706        |
| Hepatitis B - Surface Antigen                 | \$25.00  | 87340        |
| HbsAg Confirmation                            | \$25.00  | 87341        |
| Hepatitis C - Antibody By EIA                 | \$50.00  | 86803        |
| HIV-1/2 Antibody, EIA                         | \$20.00  | 86703        |
| HIV-1 Antibody, IFA                           | \$50.00  | 86689        |
| HIV -1 Drug Resist Genotyping                 | \$400.00 | 87901        |
| HIV-1 PCR Quantitative                        | \$125.00 | 87536        |
| Mumps, IgM IFA                                | \$30.00  | 86735        |
| Mumps, IgG IFA                                | \$30.00  | 86735        |
| Measles, IgM IFA                              | \$30.00  | 86765        |
| Measles, IgG IFA                              | \$30.00  | 86765        |
| RPR or VDRL - Qualitative                     | \$7.00   | 86592        |
| RPR or VDRL - Quantitative                    | \$10.00  | 86593        |
| Treponema Pallidum - Antibodies               | \$20.00  | 86780        |
| Varicella-Zoster, IgM IFA                     | \$30.00  | 86787        |
| Varicella-Zoster, IgG IFA                     | \$30.00  | 86787        |
| Quantiferon                                   | \$89.00  | 86480        |
| West Nile Ab                                  | \$25.00  | 86789        |
| West Nile IgM                                 | \$25.00  | 86788        |
| West Nile IFA                                 | \$30.00  |              |
| <b>Virology</b>                               |          |              |
| Culture - Chlamydia with FA                   | \$90.00  | 87110        |
| Culture - Virus / Herpes                      | \$40.00  | 87252        |
| Herpes Simplex Typing by FA                   | \$25.00  | 87273, 87274 |
| Virus Isolate ID by FA                        | \$25.00  | 87253        |
| Influenza Virus ID by FA                      | \$25.00  | 87275, 87276 |
| Culture - Virus / Respiratory                 | \$45.00  | 87252        |
| Culture - Enterovirus                         | \$45.00  | 87252        |
| Culture - Virus / Other                       | \$40.00  | 87252        |
| Virus Direct PCR: each agent                  | \$54.00  | 87798        |
| Influenza PCR: each agent                     | \$54.00  | 87798        |
| Bordatella PCR                                | \$54.00  | 87798        |
| Norovirus PCR                                 | \$54.00  | 87798        |

## BUSINESS ASSOCIATE AGREEMENT

Except as otherwise provided in this Agreement, THE COUNTY OF SAN BERNARDINO DEPARTMENT OF PUBLIC HEALTH, hereinafter referred to as BUSINESS ASSOCIATE, may use, access or disclose Protected Health Information to perform functions, activities or services for or on behalf of Riverside County Health, hereinafter referred to as the COVERED ENTITY, as specified in this Agreement and the attached CONTRACT, provided such use, access or disclosure does not violate the Health Insurance Portability and Accountability Act (HIPAA), 42 United States Code (USC) 1320d et seq., and its implementing regulations, including but not limited to, 45 Code of Federal Regulations (CFR) Parts 160, 162, and 164, hereinafter referred to as the Privacy and Security Rules and patient confidentiality regulations, including but not limited to, California Civil Code 56 – 56.16, 56.20, 56.36, and Health and Safety Codes 1280.1, 1280.3, 1280.15, 130200 and the requirements of the Health Information Technology for Economic and Clinical Health Act, as incorporated in the American Recovery and Reinvestment Act of 2009, Public Law 111-5 (the "HITECH Act") and any regulations adopted or to be adopted pursuant to the HITECH Act that relate to the obligations of business associates. Business Associate recognizes and agrees it is obligated by law to meet the applicable provisions of the HITECH Act.

### I. Definitions.

- a. "Breach" means the acquisition, access, use or disclosure of Protected Health Information (PHI) in a manner not permitted under HIPAA (45 CFR Part 164, Subpart E), and/or CA Civil Code 56.36 which compromises the security or privacy of the Protected Health Information. For the purposes of HITECH, a breach shall not include:
1. Any unintentional acquisition, access or use of PHI by a workforce member or person acting under the authority of Covered Entity or the Business Associate, if such acquisition, access or use was made in good faith and within the scope of authority and does not result in further use or disclosure in a manner not permitted under the HIPAA Privacy Rule; or
  2. Any inadvertent disclosure by a person who is authorized to access PHI at Covered Entity or Business Associate to another person authorized to access Protected Health Information at Covered Entity or Business Associate, respectively, and the information received as a result of such disclosure is not further used or disclosed in a manner not permitted under the HIPAA Privacy Rule; or
  3. A disclosure of PHI where Covered Entity or Business Associate has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.
- b. "Business Associate" means with respect to a Covered Entity, a person who:
1. On behalf of such Covered Entity, but other than in the capacity of a member of the workforce of such Covered Entity performs or assists in the performance of :
    - (a) a function or activity involving the use or disclosure of Personally Identifiable Health Information, including claims processing or administration, data analysis, utilization review, quality assurance, billing, benefit management, practice management, and repricing; or
    - (b) any other function or activity regulated by the HIPAA Privacy or HIPAA Security Regulations; or
  2. Provides, other than in the capacity of a member of the workforce of such Covered Entity, legal, actuarial, accounting, consulting, data Aggregation, management, administrative, accreditation or financial services to or for such Covered Entity where the provision of the service involves the disclosure of Personally Identifiable Health Information from such Covered Entity to the person.
- c. "Patient/Client" means Covered Entity funded person who is the patient or client of the Business Associate.

- d. "Covered Entity" means a health plan, a health care clearinghouse or a health care provider who transmits any health information in electronic form in connection with a transaction covered by HIPAA Privacy and Security Regulations.
- e. "Data Aggregation" means, with respect to PHI created or received by a Business Associate in its capacity as the Business Associate of a Covered Entity, the combining of such PHI by the Business Associate with the PHI received by the Business Associate in its capacity as a Business Associate of another Covered Entity, to permit data analyses that relate to the health care operations of the respective Covered Entities.
- f. "Discovered" means a breach shall be treated as discovered by Covered Entity or Business Associate as the first day on which such breach is known to such Covered Entity or Business Associate, respectively, (including any person, other than the individual committing the breach, that is an employee, officer or other agent of such entity or associate, respectively) or should reasonably have been known to such Covered Entity or Business Associate (or person) to have occurred.
- g. "Electronic Protected Health Information" or "Electronic PHI" means PHI that is transmitted by or maintained in electronic media as defined in the HIPAA Security Regulations.
- h. "HIPAA" means the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.
- i. "HIPAA Privacy Rule" means the regulations promulgated under HIPAA by the United States Department of Health and Human Services to protect the privacy of Protected Health Information, including, but not limited to, 45 CFR Part 160 and 45 CFR Part 164, Subpart A and Subpart E.
- j. "HIPAA Security Rule" means the regulations promulgated under HIPAA by the United States Department of Health and Human Services to protect the security of Electronic Protected Health Information, including, but not limited to, 45 CFR Part 160 and 45 CFR Part 164, Subpart A and Subpart C.
- k. "HITECH Act" means the privacy, security and security Breach notification provisions applicable to Business Associate under Subtitle D of the Health Information Technology for Economic and Clinical Health Act ("HITECH"), which is Title XIII of the American Recovery and Reinvestment Act of 2009 (Public Law 111-5), and any regulations promulgated thereunder.
- l. "Personally Identifiable Health Information" means information that is a subset of health information, including demographic information collected from an individual, and;
  1. is created or received by a health care provider, health plan, employer or health care clearinghouse; and
  2. relates to the past, present or future physical or mental health condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and
    - (a) that identifies the individual; or
    - (b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.
- m. "Protected Health Information" or "PHI" means Personally Identifiable Health Information transmitted or maintained in any form or medium that (i) is received by Business Associate from Covered Entity, (ii) Business Associate creates for its own purposes from Personally Identifiable Health Information that Business Associate received from Covered Entity, or (iii) is created, received, transmitted or maintained by Business Associate on behalf of Covered Entity. Protected Health Information excludes Personally Identifiable Health Information in education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. Section 1232(g), records described at 20 U.S.C. Section 1232g(a)(4)(B)(iv), and employment records held by the Covered Entity in its role as employer.

- n. "Secured PHI" means PHI that was rendered unusable, unreadable or indecipherable to unauthorized individuals through the use of technologies or methodologies specified under Section 13402 (h)(2) of the HITECH Act under ARRA.
- o. "Unsecured PHI" means PHI that is not secured through the use of a technology or methodology specified by the Secretary of the U.S. Department of Health and Human Services.
- p. Any terms capitalized, but not otherwise defined, in this Agreement shall have the same meaning as those terms have under HIPAA, the HIPAA Privacy Rule, the HIPAA Security Rule and the HITECH Act.

## II. Obligations and Activities of Business Associate.

- a. **Permitted Uses.** Business Associate shall not use, access or further disclose Protected Health Information other than as permitted or required by this Agreement and as specified in the attached **CONTRACT** or as required by law. Further, Business Associate shall not use Protected Health Information in any manner that would constitute a violation of the Privacy Rule or the HITECH Act. Business Associate shall disclose to its employees, subcontractors, agents, or other third parties, and request from Covered Entity, only the minimum Protected Health Information necessary to perform or fulfill a specific function required or permitted hereunder.
- b. **Prohibited Uses and Disclosures.** Business Associate shall not use or disclose Protected Health Information for fundraising or marketing purposes. Business Associate shall not disclose Protected Health Information to a health plan for payment or health care operations purposes if the patient has requested this special restriction, and has paid out of pocket in full for the health care item or service to which the Protected Health Information solely relates; 42 U.S.C. Section 17935(a) and 45 C.F.R. section 164.522(a)(1)(i)(A). Business Associate shall not directly or indirectly receive remuneration in exchange for Protected Health Information, except with the prior written consent of Covered Entity and as permitted by the HITECH Act, 42 U.S.C. Section 17935(d)(2); however, this prohibition shall not affect payment by Covered Entity to Business Associate for services provided pursuant to this Agreement.
- c. **Appropriate Safeguards.** Business Associate shall implement the following administrative, physical, and technical safeguards in accordance with the Security Rule under 45 C.F.R., Sections 164.308, 164.310, 164.312 and 164.316:
  - 1. Implement policies and procedures to prevent, detect, contain and correct security violations; identify the security official who is responsible for the development and implementation of the policies and procedures required by this subpart for the entity; implement a security awareness and training program for all members of its workforce; implement P&Ps to prevent those workforce members who do not have access from obtaining access to electronic PHI; implement policy and procedures to address security incidents; establish policies and procedures for responding to an emergency or other occurrence that damages systems that contain electronic PHI; and perform a periodic technical and nontechnical evaluation in response to environmental or operational changes affecting the security of electronic PHI that establishes the extent to which an entity's security policies and procedures meet the requirements of this subpart.
  - 2. Implement policies and procedures to limit physical access to its electronic information systems and the facility or facilities in which they are housed, while ensuring that properly authorized access is allowed; implement policies and procedures that specify the proper functions to be performed, and the physical attributes of the surroundings of a specific workstation or class of workstations that can access electronic PHI; implement physical safeguards for all workstations that access electronic PHI; restrict access to authorized users; implement policies and procedures that govern the receipt and removal of hardware and electronic media that contain electronic PHI into and out of a facility and the movement of these items within the facility.

3. Implement technical policies and procedures for electronic information systems that maintain electronic PHI to allow access only to those persons or software programs that have been granted access rights as specified in 45 C.F.R., Section 164.208; implement hardware, software and/or procedural mechanisms that record and examine activity in information systems that contain or use electronic PHI; implement policies and procedures to protect electronic PHI from improper alteration, destruction, unauthorized access or loss of integrity or availability.
- d. **Mitigation.** Business Associate shall have procedures in place to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use, access or disclosure of Protected Health Information by Business Associate in violation of the requirements of this Agreement.
- e. **Reporting of Improper Access, Use or Disclosure or Breach.** Business Associate shall report to Covered Entity's Office of Compliance any unauthorized use, access or disclosure of unsecured Protected Health Information or any other security incident with respect to Protected Health Information no later than two (2) business days upon the discovery of potential breach. Additionally, effective February 17, 2010, the Business Associate shall report to the Covered Entity's Office of Compliance any breach consistent with the regulations promulgated under HITECH by the United States Department of Health and Human Services, 45 CFR Part 164, Subpart D, within two (2) business days of discovery of the potential breach. Upon discovery of the potential breach, the Business Associate shall complete the following actions:
- (1) Provide Covered Entity's Office of Compliance with the following information to include but not limited to:
    - (a) Date the potential breach occurred;
    - (b) Date the potential breach was discovered;
    - (c) Number of staff, employees, subcontractors, agents or other third parties and the titles of each person allegedly involved;
    - (d) Number of potentially affected patients/clients; and
    - (e) Description of how the potential breach allegedly occurred.
  - (2) Conduct and document a risk assessment by investigating without reasonable delay and in no case later than twenty (20) calendar days of discovery of the potential breach to determine the following:
    - (a) Whether there has been an impermissible use, acquisition, access or disclosure of PHI under the Privacy Rule;
    - (b) Whether an impermissible use or disclosure compromises the security or privacy of the PHI by posing a significant risk of financial, reputational or other harm to the patient/client; and
    - (c) Whether the incident falls under one of the breach exceptions.
  - (3) Provide completed risk assessment and investigation documentation to Covered Entity's Office of Compliance within twenty-five (25) calendar days of discovery of the potential breach with decision whether a breach has occurred:
    - (a) If a breach has not occurred, notification to patient/client(s) is not required.
    - (b) If a breach has occurred, notification to the patient/client(s) is required, and Business Associate must provide Covered Entity with affected patient/client names and contact information so the Covered Entity can provide notification.
  - (4) Make available to Covered Entity and governing State and Federal agencies in a time and manner designated by Covered Entity or governing State and Federal agencies, any policies, procedures, internal practices and records relating to a potential breach for the purposes of audit or should the Covered Entity reserve the right to conduct its own investigation and analysis.
- f. **Permitted Disclosures.** If Business Associate discloses Protected Health Information to a third party, including any agent or subcontractor, Business Associate must obtain, prior to making any such disclosure, (i) reasonable assurances from such third party that such



Protected Health Information will be held confidential as provided pursuant to this Agreement and only disclosed as required by law or for the purposes for which it was disclosed to such third party, and (ii) an agreement from such third party to immediately notify Business Associate of any breach of confidentiality of the Protected Health Information, to the extent it has obtained knowledge of such breach [42 U.S.C. Section 17932; 45 C.F.R. Sections 164.504(e)].

- g. Access to Protected Health Information.** Business Associate shall provide access to Protected Health Information in a Designated Record Set to Covered Entity or to an Individual, at the request or direction of Covered Entity and in the time and manner designated by the Covered Entity, as required by of 45 CFR 164.524.
- h. Amendment of Protected Health Information.** If Business Associate maintains a Designated Record Set on behalf of the Covered Entity, Business Associate shall make any amendment(s) to Protected Health Information in a Designated Record Set that the Covered Entity directs or agrees to, pursuant to 45 CFR 164.526, in the time and manner designated by the Covered Entity.
- i. Access to Records.** Business Associate shall make internal practices, books, and records, including policies and procedures and Protected Health Information, relating to the use, access and disclosure of Protected Health Information received from, or created or received by Business Associate on behalf of, Covered Entity available to the Covered Entity, and/or to the Secretary for the U.S. Department of Health and Human Services, in a time and manner designated by the Covered Entity or the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy and Security Rules and patient confidentiality regulations.
- j. Audit and Monitor.** Covered Entity reserves the right to audit and monitor all records, policies, procedures and other pertinent items related to the use, access and disclosure of Protected Health Information of the Business Associate as requested to ensure Business Associate is in compliance with this Agreement. Covered Entity has the right to monitor Business Associate in the delivery of services provided under this Agreement. Business Associate shall give full cooperation in any auditing or monitoring conducted.
- k. Accounting for Disclosures.** Business Associate shall document such disclosures of Protected Health Information and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information. Further, Business Associate shall provide to Covered Entity or an Individual, in the time and manner designated by the Covered Entity, information collected in accordance with provision (i), above, to permit Covered Entity to respond to a request by the Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528 and the HITECH Act.
- l. Destruction of Protected Health Information.** Upon termination of this Agreement, Business Associate shall return all Protected Health Information required to be retained and return or destroy all other Protected Health Information received from the Covered Entity, or created or received by the Business Associate or its subcontractors, employees or agents on behalf of the Covered Entity. In the event the Business Associate determines that returning the Protected Health Information is not feasible, the Business Associate shall provide the Covered Entity with written notification of the conditions that make return not feasible. Business Associate further agrees to extend any and all protections, limitations, and restrictions contained in this Agreement, to any Protected Health Information retained by Business Associate or its subcontractors, employees or agents after the termination of this Agreement, and to limit any further use, access or disclosures to the purposes that make the return or destruction of the Protected Health Information infeasible.
- m. Breach Pattern or Practice by Covered Entity.** Pursuant to 42 U.S.C. Section 17934(b), if the Business Associate knows of a pattern of activity or practice of the Covered Entity that constitutes a material breach or violation of the Covered Entity's obligations under this Agreement, the Business Associate must take reasonable steps to cure the breach or end the



violation. If the steps are unsuccessful, the Business Associate must terminate the Agreement if feasible, or if termination is not feasible, report the problem to the Secretary of DHHS.

- n. **Costs Associated to Breach.** Business Associate shall be responsible for reasonable costs associated with a breach. Costs shall be based upon the required notification type as deemed appropriate and necessary by the Covered Entity and shall not be reimbursable under the contract at any time. Covered Entity shall determine the method to invoice the Business Associate for said costs. Costs shall incur at the current rates and may include, but are not limited to the following:

1. Postage;
2. Alternative means of notice;
3. Media notification; and
4. Credit monitoring services.

### III. Specific Use and Disclosure Provisions.

- a. Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.
- b. Except as otherwise limited in this Agreement, Business Associate may disclose Protected Health Information for the proper management and administration of the Business Associate, provided that disclosures are required by law.
- c. Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information to provide Data Aggregation service to Covered Entity as permitted by 42 CFR 164.504(e)(2)(i)(B).
- d. Business Associate may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with 42 CFR 164.502(j)(1).

### IV. Obligations of Covered Entity.

- a. Covered Entity shall notify Business Associate of any limitation(s) in its notice of privacy practices of Covered Entity in accordance with 45 CFR 164.520, to the extent that such limitation may affect Business Associate's use, access or disclosure of Protected Health Information.
- b. Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by an individual to use, access or disclose Protected Health Information, to the extent that such changes may affect Business Associate's use, access or disclosure of Protected Health Information.
- c. Covered Entity shall notify Business Associate of any restriction to the use, access or disclosure of Protected Health Information that Covered Entity has agreed to in accordance with 45 CFR 164.522, to the extent that such restriction may affect Business Associate's use, access or disclosure of Protected Health Information.
- d. Covered Entity shall complete the following in the event that the Covered Entity has determined that Business Associate has a breach:
  - a. Determine appropriate method of notification to the patient/client(s) regarding a breach as outlined under Section 13402(e) of the HITECH Act;
  - b. Send notification to the patient/client(s) without unreasonable delay but in no case later than sixty (60) days of discovery of the breach with at least the minimal required elements as follows:
    - i. Brief description of what happened, including the date of the breach and the date of discovery;
    - ii. Description of the types of unsecured PHI involved in the breach (such as name, date of birth, home address, Social Security number, medical insurance, etc.);

- iii. Steps patient/client(s) should take to protect themselves from potential harm resulting from the breach;
  - iv. Brief description of what is being done to investigate the breach, to mitigate harm to patient/client(s) and to protect against any further breaches; and
  - v. Contact procedures for patient/client(s) to ask questions or learn additional information, which must include a toll-free telephone number, an e-mail address, Web site or postal address.
- c. Determine if notice is required to Secretary of the U.S. Department of Health and Human Services.
  - d. Submit breach information to the Secretary of the U.S. Department of Health and Human Services within the required timeframe, in accordance with 164.408(b).

V. General Provisions.

- a. **Remedies.** Business Associate agrees that Covered Entity shall be entitled to seek immediate injunctive relief as well as to exercise all other rights and remedies which Covered Entity may have at law or in equity in the event of an unauthorized use, access or disclosure of Protected Health Information by Business Associate or any agent or subcontractor of Business Associate that received Protected Health Information from Business Associate.
- b. **Ownership.** The Protected Health Information shall be and remain the property of the Covered Entity. Business Associate agrees that it acquires no title or rights to the Protected Health Information.
- c. **Regulatory References.** A reference in this Agreement to a section in the Privacy and Security Rules and patient confidentiality regulations means the section as in effect or as amended.
- d. **Amendment.** The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy and Security Rules and the Health Insurance Portability and Accountability Act and patient confidentiality regulations.
- e. **Interpretation.** Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Privacy and Security Rules and patient confidentiality regulations.

The undersigned affirms that he/she is a duly authorized representative of the Business Associate for which he/she is signing and has the authority to execute this Agreement on behalf of the Business Associate.

Business Associate

\_\_\_\_\_

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Dated

\_\_\_\_\_  
Name

\_\_\_\_\_  
Title