HIPAA Business Associate Exhibit

I. **Recitals**

A. This Contract (Agreement) has been determined to constitute a business associate relationship under the Health Insurance Portability and Accountability Act ("HIPAA") and its implementing privacy and security regulations at 45 CFR Parts 160 and 164 ("the HIPAA regulations:").

B. The California Department of Public Health ("CDPH") wishes to disclose to Business Associate certain information pursuant to the terms of this Agreement, some of which may constitute Protected Health Information ("PHI") pursuant to HIPAA regulations.

C. "Protected Health Information" or "PHI" means any information, whether oral or recorded in any form or medium that relates to the past, present, or future physical or mental condition of an individual, the provision of health and dental care to an individual, or the past, present, or future payment for the provision of health and dental care to an individual; and that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual. PHI shall have the meaning given to such term under HIPAA and HIPAA regulations, as the same may be amended from time to time.

D. "Security Incident" means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of PHI, or confidential data that is essential to the ongoing operation of the Business Associate's organization and intended for internal use; or interference with system operations in an information system.

E. As set forth in this Agreement Contractor is the Business Associate of CDPH that provides services, arranges, performs or assists in the performance of functions or activities on behalf of CDPH and creates, receives, maintains, transmits, uses or discloses PHI.

F. CDPH and Business Associate desire to protect the privacy and provide for the security of PHI created, received, maintained, transmitted, used or disclosed pursuant to this Agreement, in compliance with HIPAA and HIPAA regulations.

G. The purpose of this Exhibit is to satisfy certain standards and requirements of HIPAA and the HIPAA regulations, and other applicable laws.

H. The terms used in this Exhibit, but not otherwise defined, shall have the same meanings as those terms are defined in the HIPAA regulations.

In exchanging information pursuant to this Agreement, the parties agree as follows:

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II. Permitted Uses and Disclosures of PHI by Business Associate

A. ***Permitted Uses and Disclosures***. Except as otherwise indicated in this Exhibit, Business Associate may use or disclose PHI only to perform functions, activities or services specified in this Agreement, for, or on behalf of CDPH, provided that such use or disclosure would not violate the HIPAA regulations, if done by CDPH.

B. ***Specific Use and Disclosure Provisions***. Except as otherwise indicated in this Exhibit, Business Associate may:

1) ***Use and disclose for management and administration***. Use and disclose PHI for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate, provided that disclosures are required by law, or the Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and will be used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware that the confidentiality of the information has been breached.

2) ***Provision of Data Aggregation Services***. Use PHI to provide data aggregation services to CDPH. Data aggregation means the combining of PHI created or received by the Business Associate on behalf of CDPH with PHI received by the Business Associate in its capacity as the Business Associate of another covered entity, to permit data analyses that relate to the health care operations of CDPH.

III. Responsibilities of Business Associate

Business Associate agrees:

A. ***Nondisclosure.*** Not to use or disclose Protected Health Information (PHI) other than as permitted or required by this Agreement or as required by law.

B. ***Safeguards***. To implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the PHI, including electronic PHI, that it creates, receives, maintains, uses or transmits on behalf of CDPH; and to prevent use or disclosure of PHI other than as provided for by this Agreement. Business Associate shall develop and maintain a written information privacy and security program that includes administrative, technical and physical safeguards appropriate to the size and complexity of the Business Associate's operations and the nature and scope of its activities, and which incorporates the requirements of section C, Security, below. Business Associate will provide CDPH with its current and updated policies.

C. ***Security***. The Business Associate shall take any and all steps necessary to ensure the continuous security of all computerized data systems containing CDPH PHI. These steps shall include, at a minimum:

1) complying with all of the data system security precautions listed in the Business Associate Data Security Standards set forth in Attachment 1 to this Exhibit;
2) providing a level and scope of security that is at least comparable to the level and scope of security established by the Office of Management and Budget in OMB Circular No. A-130, Appendix III-Security of Federal Automated Information Systems, which sets forth guidelines for automated information systems in Federal agencies; and

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In case of a conflict between any of the security standards contained in any of these enumerated sources of security standards, the most stringent shall apply. The most stringent means that safeguard which provides the highest level of protection to CDPH PHI from breaches and security incidents.

D. ***Mitigation of Harmful Effects***. To mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate or its subcontractors in violation of the requirements of this Exhibit.

E. ***Business Associate's Agents***. To ensure that any agents, including subcontractors, to whom Business Associate provides PHI received from or created or received by Business Associate on behalf of CDPH, agree to the same restrictions and conditions that apply to Business Associate with respect to such PHI, including implementation of reasonable and appropriate administrative, physical, and technical safeguards to protect such PHI; and to incorporate, when applicable, the relevant provisions of this Exhibit into each subcontract or subaward to such agents or subcontractors.

F. ***Availability of Information to CDPH and Individuals***. To provide access as CDPH may require, and in the time and manner designated by CDPH (upon reasonable notice and during Business Associate's normal business hours) to PHI in a Designated Record Set, to CDPH (or, as directed by CDPH), to an Individual, in accordance with 45 CFR Section 164.524. Designated Record Set means the group of records maintained for CDPH that includes medical, dental and billing records about individuals; enrollment, payment, claims adjudication, and case or medical management systems maintained for CDPH health care component health plans; or those records used to make decisions about individuals on behalf of CDPH. Business Associate shall use the forms and processes developed by CDPH for this purpose and shall respond to requests for access to records transmitted by CDPH within fifteen (15) calendar days of receipt of the request by producing the records or verifying that there are none.

G. ***Amendment of PHI***. To make any amendment(s) to PHI that CDPH directs or agrees to pursuant to 45 CFR Section 164.526, in the time and manner designated by CDPH.

H. ***Internal Practices***. To make Business Associate's internal practices, books and records relating to the use and disclosure of PHI received from CDPH, or created or received by Business Associate on behalf of CDPH, available to CDPH or to the Secretary of the U.S. Department of Health and Human Services in a time and manner designated by CDPH or by the Secretary, for purposes of determining CDPH's compliance with the HIPAA regulations.

I. ***Documentation of Disclosures***. To document and make available to CDPH or (at the direction of CDPH) to an Individual such disclosures of PHI, and information related to such disclosures, necessary to respond to a proper request by the subject Individual for an accounting of disclosures of PHI, in accordance with 45 CFR 164.528.

J. ***Notification of Breach***. During the term of this Agreement:

1) ***Discovery of Breach***. To notify CDPH ***immediately by telephone call plus email or fax*** upon the discovery of breach of security of PHI in computerized form if the PHI was, or is reasonably believed to have been, acquired by an unauthorized person, or ***within 24 hours by email or fax*** of the discovery of any suspected security incident, intrusion or unauthorized use or disclosure of PHI in violation of this Agreement and this Exhibit, or potential loss of confidential data affecting this Agreement. Notification shall be provided to the CDPH Program Contract Manager, the CDPH Privacy Officer and the CDPH Chief Information

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Security Officer. If the incident occurs after business hours or on a weekend or holiday and involves electronic PHI, notification shall be provided by calling the CDPH ITSD Help Desk. Business Associate shall take:

i. Prompt corrective action to mitigate any risks or damages involved with the breach and to protect the operating environment and

ii. Any action pertaining to such unauthorized disclosure required by applicable Federal and State laws and regulations.

2) ***Investigation of Breach***. To immediately investigate such security incident, breach, or unauthorized use or disclosure of PHI or confidential data. ***Within 72 hours of the discovery***, to notify the CDPH Program Contract Manager(s), the CDPH Privacy Officer, and the CDPH Chief Information Security Officer of:

i. What data elements were involved and the extent of the data involved in the breach,

ii. A description of the unauthorized persons known or reasonably believed to have improperly used or disclosed PHI or confidential data,

iii. A description of where the PHI or confidential data is believed to have been improperly transmitted, sent, or utilized,

iv. A description of the probable causes of the improper use or disclosure; and

v. Whether Civil Code sections 1798.29 or 1798.82 or any other federal or state laws requiring individual notifications of breaches are triggered.

3) ***Written Report***. To provide a written report of the investigation to the CDPH Program Contract Managers, the CDPH Privacy Officer, and the CDPH Chief Information Security Officer within ten (10) working days of the discovery of the breach or unauthorized use or disclosure. The report shall include, but not be limited to, the information specified above, as well as a full, detailed corrective action plan, including information on measures that were taken to halt and/or contain the improper use or disclosure.

4) ***Notification of Individuals***. To notify individuals of the breach or unauthorized use or disclosure when notification is required under state or federal law and to pay any costs of such notifications, as well as any costs associated with the breach. The CDPH Program Contract Managers, the CDPH Privacy Officer, and the CDPH Chief Information Security Officer shall approve the time, manner and content of any such notifications.

5) ***CDPH Contact Information***. To direct communications to the above referenced CDPH staff, the Contractor shall initiate contact as indicated herein. CDPH reserves the right to make changes to the contact information below by giving written notice to the Contractor. Said changes shall not require an amendment to this Exhibit or the Agreement to which it is incorporated.

CDPH Program Contract Manager	**CDPH Privacy Officer**	**CDPH Chief Information Security Officer**
See the Scope of Work exhibit for	Privacy Officer Privacy Office, c/o Office of Legal	Chief Information Security Officer Information Security Office

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Program Contract Manager information	Services California Department of Public Health P.O. Box 997377, MS 0505 Sacramento, CA 95899-7377 Email: privacy@cdph.ca.gov Telephone: (916) 440-7700	California Department of Public Health P.O. Box 997413, MS 6302 Sacramento, CA 95899-7413 Email: cdphiso@cdph.ca.gov Telephone: IT Service Desk (916) 440-7000 or (800) 579-0874

K. ***Employee Training and Discipline***. To train and use reasonable measures to ensure compliance with the requirements of this Exhibit by employees who assist in the performance of functions or activities on behalf of CDPH under this Agreement and use or disclose PHI; and discipline such employees who intentionally violate any provisions of this Exhibit, including by termination of employment. In complying with the provisions of this section K, Business Associate shall observe the following requirements:

1) Business Associate shall provide information privacy and security training, at least annually, at its own expense, to all its employees who assist in the performance of functions or activities on behalf of CDPH under this Agreement and use or disclose PHI.

2) Business Associate shall require each employee who receives information privacy and security training to sign a certification, indicating the employee's name and the date on which the training was completed.

3) Business Associate shall retain each employee's written certifications for CDPH inspection for a period of three years following contract termination.

IV. Obligations of CDPH

CDPH agrees to:

A. ***Notice of Privacy Practices***. Provide Business Associate with applicable and relevant Notice(s) of Privacy Practices that CDPH HIPAA-covered healthcare components produce in accordance with 45 CFR 164.520, as well as any changes to such notice(s).

B. ***Permission by Individuals for Use and Disclosure of PHI***. Provide the Business Associate with any changes in, or revocation of, permission by an Individual to use or disclose PHI, if such changes affect the Business Associate's permitted or required uses and disclosures.

C. ***Notification of Restrictions***. Notify the Business Associate of any restriction to the use or disclosure of PHI that CDPH has agreed to in accordance with 45 CFR 164.522, to the extent that such restriction may affect the Business Associate's use or disclosure of PHI.

D. ***Requests Conflicting with HIPAA Rules***. Not request the Business Associate to use or disclose PHI in any manner that would not be permissible under the HIPAA regulations if done by CDPH.

V. Audits, Inspection and Enforcement

From time to time, CDPH may inspect the facilities, systems, books and records of Business Associate to monitor compliance with this Agreement and this Exhibit. Business Associate shall promptly remedy any violation of any provision of this Exhibit and shall certify the same to the CDPH Privacy Officer or the CDPH

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Chief Information Security Officer in writing. The fact that CDPH inspects, or fails to inspect, or has the right to inspect, Business Associate's facilities, systems and procedures does not relieve Business Associate of its responsibility to comply with this Exhibit, nor does CDPH's:

A. Failure to detect or

B. Detection, but failure to notify Business Associate or require Business Associate's remediation of any unsatisfactory practices constitute acceptance of such practice or a waiver of CDPH's enforcement rights under this Agreement and this Exhibit.

VI. Termination

A. ***Termination for Cause***. Upon CDPH's knowledge of a material breach of this Exhibit by Business Associate, CDPH shall:

1) Provide an opportunity for Business Associate to cure the breach or end the violation and terminate this Agreement if Business Associate does not cure the breach or end the violation within the time specified by CDPH;

2) Immediately terminate this Agreement if Business Associate has breached a material term of this Exhibit and cure is not possible; or

3) If neither cure nor termination is feasible, report the violation to the Secretary of the U.S. Department of Health and Human Services.

B. ***Judicial or Administrative Proceedings***. Business Associate will notify CDPH if it is named as a defendant in a criminal proceeding for a violation of HIPAA. CDPH may terminate this Agreement if Business Associate is found guilty of a criminal violation of HIPAA. CDPH may terminate this Agreement if a finding or stipulation that the Business Associate has violated any standard or requirement of HIPAA, or other security or privacy laws is made in any administrative or civil proceeding in which the Business Associate is a party or has been joined.

C. ***Effect of Termination***. Upon termination or expiration of this Agreement for any reason, Business Associate shall promptly return or destroy all PHI received from CDPH (or created or received by Business Associate on behalf of CDPH) that Business Associate still maintains in any form, and shall retain no copies of such PHI or, if return or destruction is not feasible, shall continue to extend the protections of this Exhibit to such information, and shall limit further use of such PHI to those purposes that make the return or destruction of such PHI infeasible. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate.

VII. Miscellaneous Provisions

A. ***Disclaimer***. CDPH makes no warranty or representation that compliance by Business Associate with this Exhibit, HIPAA or the HIPAA regulations will be adequate or satisfactory for Business Associate's own purposes or that any information in Business Associate's possession or control, or transmitted or received by Business Associate, is or will be secure from unauthorized use or disclosure. Business Associate is solely responsible for all decisions made by Business Associate regarding the safeguarding of PHI.

B. ***Amendment***. The parties acknowledge that federal and state laws relating to electronic data security and privacy are rapidly evolving and that amendment of this Exhibit may be required to provide for procedures to ensure compliance with such developments. The parties specifically agree to take such

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action as is necessary to implement the standards and requirements of HIPAA, the HIPAA regulations and other applicable laws relating to the security or privacy of PHI. Upon CDPH's request, Business Associate agrees to promptly enter into negotiations with CDPH concerning an amendment to this Exhibit embodying written assurances consistent with the standards and requirements of HIPAA, the HIPAA regulations or other applicable laws. CDPH may terminate this Agreement upon thirty (30) days written notice in the event:

1) Business Associate does not promptly enter into negotiations to amend this Exhibit when requested by CDPH pursuant to this Section or

2) Business Associate does not enter into an amendment providing assurances regarding the safeguarding and security of PHI that CDPH in its sole discretion, deems sufficient to satisfy the standards and requirements of HIPAA and the HIPAA regulations.

C. ***Assistance in Litigation or Administrative Proceedings****.* Business Associate shall make itself and any subcontractors, employees or agents assisting Business Associate in the performance of its obligations under this Agreement, available to CDPH at no cost to CDPH to testify as witnesses, or otherwise, in the event of litigation or administrative proceedings being commenced against CDPH, its directors, officers or employees based upon claimed violation of HIPAA, the HIPAA regulations or other laws relating to security and privacy, which involves inactions or actions by the Business Associate, except where Business Associate or its subcontractor, employee or agent is a named adverse party.

D. ***No Third-Party Beneficiaries****.* Nothing express or implied in the terms and conditions of this Exhibit is intended to confer, nor shall anything herein confer, upon any person other than CDPH or Business Associate and their respective successors or assignees, any rights, remedies, obligations or liabilities whatsoever.

E. ***Interpretation***. The terms and conditions in this Exhibit shall be interpreted as broadly as necessary to implement and comply with HIPAA, the HIPAA regulations and applicable state laws. The parties agree that any ambiguity in the terms and conditions of this Exhibit shall be resolved in favor of a meaning that complies and is consistent with HIPAA and the HIPAA regulations.

F. ***Regulatory References***. A reference in the terms and conditions of this Exhibit to a section in the HIPAA regulations means the section as in effect or as amended.

G. ***Survival****.* The respective rights and obligations of Business Associate under Section VII.C of this Exhibit shall survive the termination or expiration of this Agreement.

H. ***No Waiver of Obligations***. No change, waiver or discharge of any liability or obligation hereunder on any one or more occasions shall be deemed a waiver of performance of any continuing or other obligation, or shall prohibit enforcement of any obligation, on any other occasion.

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Attachment 1
Business Associate Data Security Standards

1. General Security Controls

A. ***Confidentiality Statement.*** All persons that will be working with CDPH PHI must sign a confidentiality statement. The statement must include at a minimum, General Use, Security and Privacy safeguards, Unacceptable Use, and Enforcement Policies. The statement must be signed by the workforce member prior to access to CDPH PHI. The statement must be renewed annually. The Business Associate shall retain each person's written confidentiality statement for CDPH inspection for a period of three (3) years following contract termination.

B. ***Background check.*** Before a member of the Business Associate's workforce may access CDPH PHI, Business Associate must conduct a thorough background check of that worker and evaluate the results to assure that there is no indication that the worker may present a risk for theft of confidential data. The Business Associate shall retain each workforce member's background check documentation for a period of three (3) years following contract termination.

C. ***Workstation/Laptop encryption.*** All workstations and laptops that process and/or store CDPH PHI must be encrypted using a FIPS 140-2 certified algorithm, such as Advanced Encryption Standard (AES), with a 128bit key or higher. The encryption solution must be full disk unless approved by the CDPH Information Security Office.

D. ***Server Security.*** Servers containing unencrypted CDPH PHI must have sufficient administrative, physical, and technical controls in place to protect that data, based upon a risk assessment/system security review.

E. ***Minimum Necessary.*** Only the minimum necessary amount of CDPH PHI required to perform necessary business functions may be copied, downloaded, or exported.

F. ***Removable media devices.*** All electronic files that contain CDPH PHI data must be encrypted when stored on any removable media or portable device (i.e. USB thumb drives, floppies, CD/DVD, Blackberry, backup tapes etc.). Must be encrypted using a FIPS 140-2 certified algorithm, such as Advanced Encryption Standard (AES), with a 128bit key or higher

G. ***Antivirus software.*** All workstations, laptops and other systems that process and/or store CDPH PHI must install and actively use comprehensive anti-virus software solution with automatic updates scheduled at least daily.

H. ***Patch Management.*** All workstations, laptops and other systems that process and/or store CDPH PHI must have security patches applied, with system reboot if necessary. There must be a documented patch management process which determines installation timeframe based on risk assessment and vendor recommendations. At a maximum, all applicable patches must be installed within 30 days of vendor release.

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I. ***User IDs and Password Controls.*** All users must be issued a unique user name for accessing CDPH PHI. Username must be promptly disabled, deleted, or the password changed upon the transfer or termination of an employee with knowledge of the password. Passwords are not to be shared. Must be at least eight characters. Must be a non-dictionary word. Must not be stored in readable format on the computer. Must be changed every 60 days. Must be changed if revealed or compromised. Must be composed of characters from at least three of the following four groups from the standard keyboard:

- Upper case letters (A-Z)
- Lower case letters (a-z)
- Arabic numerals (0-9)
- Non-alphanumeric characters (punctuation symbols)

J. ***Data Sanitization.*** All CDPH PHI must be sanitized using NIST Special Publication 800-88 standard methods for data sanitization when the CDPH PSCI is no longer needed.

2. System Security Controls

A. ***System Timeout.*** The system must provide an automatic timeout, requiring re-authentication of the user session after no more than 20 minutes of inactivity.

B. ***Warning Banners.*** All systems containing CDPH PHI must display a warning banner stating that data is confidential, systems are logged, and system use is for business purposes only. User must be directed to log off the system if they do not agree with these requirements.

C. ***System Logging*****.** The system must maintain an automated audit trail which can identify the user or system process which initiates a request for CDPH PHI, or which alters CDPH PHI. The audit trail must be date and time stamped, must log both successful and failed accesses, must be read only, and must be restricted to authorized users. If CDPH PHI is stored in a database, database logging functionality must be enabled. Audit trail data must be archived for at least 3 years after occurrence.

D. ***Access Controls.*** The system must use role based access controls for all user authentications, enforcing the principle of least privilege.

E. ***Transmission encryption.*** All data transmissions of CDPH PHI outside the secure internal network must be encrypted using a FIPS 140-2 certified algorithm, such as Advanced Encryption Standard (AES), with a 128bit key or higher. Encryption can be end to end at the network level, or the data files containing CDPH PHI can be encrypted. This requirement pertains to any type of CDPH PHI in motion such as website access, file transfer, and E-Mail.

F. ***Intrusion Detection***. All systems involved in accessing, holding, transporting, and protecting CDPH PHI that are accessible via the Internet must be protected by a comprehensive intrusion detection and prevention solution.

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3. Audit Controls

A. ***System Security Review.*** All systems processing and/or storing CDPH PHI must have at least an annual system risk assessment/security review which provides assurance that administrative, physical, and technical controls are functioning effectively and providing adequate levels of protection. Reviews shall include vulnerability scanning tools.

B. ***Log Reviews.*** All systems processing and/or storing CDPH PHI must have a routine procedure in place to review system logs for unauthorized access.

C. ***Change Control.*** All systems processing and/or storing CDPH PHI must have a documented change control procedure that ensures separation of duties and protects the confidentiality, integrity and availability of data.

4. Business Continuity / Disaster Recovery Controls

a. ***Disaster Recovery.*** Business Associate must establish a documented plan to enable continuation of critical business processes and protection of the security of electronic CDPH PHI in the event of an emergency. Emergency means any circumstance or situation that causes normal computer operations to become unavailable for use in performing the work required under this agreement for more than 24 hours.

Data Backup Plan. Business Associate must have established documented procedures to backup CDPH PHI to maintain retrievable exact copies of CDPH PHI. The plan must include a regular schedule for making backups, storing backups offsite, an inventory of backup media, and the amount of time to restore CDPH PHI should it be lost. At a minimum, the schedule must be a weekly full backup and monthly offsite storage of CDPH data.

5. Paper Document Controls

A. ***Supervision of Data.*** CDPH PHI in paper form shall not be left unattended at any time, unless it is locked in a file cabinet, file room, desk or office. Unattended means that information is not being observed by an employee authorized to access the information. CDPH PHI in paper form shall not be left unattended at any time in vehicles or planes and shall not be checked in baggage on commercial airplanes.

B. ***Escorting Visitors.*** Visitors to areas where CDPH PHI is contained shall be escorted and CDPH Protected Health Information shall be kept out of sight while visitors are in the area.

C. ***Confidential Destruction.*** CDPH PHI must be disposed of through confidential means, using NIST Special Publication 800-88 standard methods for data sanitization when the CDPH PSCI is no longer needed.

D. ***Removal of Data.*** CDPH PHI must not be removed from the premises of the Business Associate except with express written permission of CDPH.

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E. ***Faxing.*** Faxes containing CDPH PHI shall not be left unattended and fax machines shall be in secure areas. Faxes shall contain a confidentiality statement notifying persons receiving faxes in error to destroy them. Fax numbers shall be verified with the intended recipient before sending.

F. ***Mailing.*** CDPH PHI shall only be mailed using secure methods. Large volume mailings of CDPH Protected Health Information shall be by a secure, bonded courier with signature required on receipt. Disks and other transportable media sent through the mail must be encrypted with a CDPH approved solution, such as a solution using a vendor product specified on the CSSI.