

**PA# 21-107**# PH-20-066

**COUNTY OF MENDOCINO  
STANDARD SERVICES AGREEMENT**

This Agreement is by and between the COUNTY OF MENDOCINO, hereinafter referred to as the "COUNTY", and **Redwood Community Services**, hereinafter referred to as the "CONTRACTOR".

**WITNESSETH**

WHEREAS, pursuant to Government Code Section 31000, COUNTY may retain independent contractors to perform special services to or for COUNTY or any department thereof; and,

WHEREAS, COUNTY desires to obtain CONTRACTOR for its participation in the Whole Person Care Pilot Project; and,

WHEREAS, CONTRACTOR is willing to provide such services on the terms and conditions set forth in this AGREEMENT and is willing to provide same to COUNTY.

NOW, THEREFORE it is agreed that COUNTY does hereby retain CONTRACTOR to provide the services described in Exhibit "A", and CONTRACTOR accepts such engagement, on the General Terms and Conditions hereinafter specified in this Agreement, the Additional Provisions attached hereto, and the following described exhibits, all of which are incorporated into this Agreement by this reference:

Exhibit A	Definition of Services
Exhibit B	Payment Terms
Exhibit C	Insurance Requirements
Exhibit D	Assurance of Compliance with Nondiscrimination in State and Federally Assisted Programs
Appendix A	Certification Regarding Debarment, Suspension, and Other Responsibility Matters -- Lower Tier Covered Transactions
Addendum A	Medi-Cal Data Privacy and Security Agreement
Addendum B	Business Associate Agreement
Attachment 1	Invoice
Attachment 2	Audit Checklist
Attachment 3	Whole Person Care Agreement
Attachment 4	Form 42 C.F.R. Part 2

The term of this Agreement shall be from January 1, 2021 (the "Effective Date"), and shall continue through June 30, 2021.

The compensation payable to CONTRACTOR hereunder shall not exceed Fifty Thousand Dollars (\$50,000) for the term of this Agreement.

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**IN WITNESS WHEREOF**

**DEPARTMENT FISCAL REVIEW:**

By:   
Jenine Miller, Psy.D. HHSA Assistant Director/  
Behavioral Health Director

Date: 2/22/21

Budgeted: ☒ Yes ☐ No

Budget Unit: 4072

Line Item: 86-2189

Org/Object Code: PC

Grant: ☒ Yes ☐ No

Grant No.: 17-14184-ME-23, DHCS

CARMEL J. ANGELO, Chief Executive Officer

By:   
PURCHASING AGENT  
**12/29/2020**

Date: \_\_\_\_\_


**INSURANCE REVIEW:**

By:   
Risk Management  
**12/29/2020**

Date: \_\_\_\_\_

**EXECUTIVE OFFICE/FISCAL REVIEW:**

APPROVAL RECOMMENDED

By:   
Deputy CEO

Date: **12/29/2020**

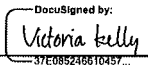
Signatory Authority: \$0-25,000 Department; \$25,001- 50,000 Purchasing Agent; \$50,001+ Board of Supervisors

Exception to Bid Process Required/Completed ☒ EB 20-79

Mendocino County Business License: Valid ☐

Exempt Pursuant to MCC Section: 501(c)(3)

**CONTRACTOR/COMPANY NAME**

By:   
Victoria Kelly, Chief Executive Officer

Date: 2/9/2021

**NAME AND ADDRESS OF CONTRACTOR:**

Redwood Community Services

PO Box 2077

Ukiah, CA 95482

707-467-2010:


kellyv@redwoodcommunityservices.org

By signing above, signatory warrants and represents that he/she executed this Agreement in his/her authorized capacity and that by his/her signature on this Agreement, he/she or the entity upon behalf of which he/she acted, executed this Agreement

**COUNTY COUNSEL REVIEW:**

APPROVED AS TO FORM:

CHRISTIAN M. CURTIS,  
County Counsel

By:   
Deputy

Date: **12/29/2020**

## **GENERAL TERMS AND CONDITIONS**

1. **INDEPENDENT CONTRACTOR:** No relationship of employer and employee is created by this Agreement; it being understood and agreed that CONTRACTOR is an Independent Contractor. CONTRACTOR is not the agent or employee of the COUNTY in any capacity whatsoever, and COUNTY shall not be liable for any acts or omissions by CONTRACTOR nor for any obligations or liabilities incurred by CONTRACTOR.

CONTRACTOR shall have no claim under this Agreement or otherwise, for seniority, vacation time, vacation pay, sick leave, personal time off, overtime, health insurance medical care, hospital care, retirement benefits, social security, disability, Workers' Compensation, or unemployment insurance benefits, civil service protection, or employee benefits of any kind.

CONTRACTOR shall be solely liable for and obligated to pay directly all applicable payroll taxes (including federal and state income taxes) or contributions for unemployment insurance or old age pensions or annuities which are imposed by any governmental entity in connection with the labor used or which are measured by wages, salaries or other remuneration paid to its officers, agents or employees and agrees to indemnify and hold COUNTY harmless from any and all liability which COUNTY may incur because of CONTRACTOR's failure to pay such amounts.

In carrying out the work contemplated herein, CONTRACTOR shall comply with all applicable federal and state workers' compensation and liability laws and regulations with respect to the officers, agents and/or employees conducting and participating in the work; and agrees that such officers, agents, and/or employees will be considered as Independent Contractors and shall not be treated or considered in any way as officers, agents and/or employees of COUNTY.

CONTRACTOR does, by this Agreement, agree to perform his/her said work and functions at all times in strict accordance with all applicable federal, state and COUNTY laws, including but not limited to prevailing wage laws, ordinances, regulations, titles, departmental procedures and currently approved methods and practices in his/her field and that the sole interest of COUNTY is to ensure that said service shall be performed and rendered in a competent, efficient, timely and satisfactory manner and in accordance with the standards required by the COUNTY agency concerned.

Notwithstanding the foregoing, if the COUNTY determines that pursuant to state and federal law CONTRACTOR is an employee for purposes of income tax withholding, COUNTY may upon two (2) week's written notice to CONTRACTOR, withhold from payments to CONTRACTOR hereunder federal and state income taxes and pay said sums to the federal and state governments.

2. **INDEMNIFICATION:** To the furthest extent permitted by law (including without limitation California Civil Code sections 2782 and 2782.8, if applicable), CONTRACTOR shall assume the defense of, indemnify, and hold harmless the COUNTY, its officers, agents, and employees, from and against any and all claims, demands, damages, costs, liabilities, and losses whatsoever alleged to be occurring or resulting in connection with the CONTRACTOR'S performance or its obligations under this AGREEMENT, unless arising out of the sole negligence or willful misconduct of COUNTY. "CONTRACTOR'S performance" includes CONTRACTOR'S action or inaction and the action or inaction of CONTRACTOR'S officers, employees, agents and subcontractors.
3. **INSURANCE AND BOND:** CONTRACTOR shall at all times during the term of the Agreement with the COUNTY maintain in force those insurance policies and bonds as designated in the attached Exhibit C, and will comply with all those requirements as stated therein.
4. **WORKERS' COMPENSATION:** CONTRACTOR shall provide Workers' Compensation insurance, as applicable, at CONTRACTOR's own cost and expense and further, neither the CONTRACTOR nor its carrier shall be entitled to recover from COUNTY any costs, settlements, or expenses of Workers' Compensation claims arising out of this Agreement.

CONTRACTOR affirms that s/he is aware of the provisions of Section 3700 of the California Labor Code which requires every employer to be insured against liability for the Workers' Compensation or to undertake self-insurance in accordance with the provisions of the Code and CONTRACTOR further assures that s/he will comply with such provisions before commencing the performance of work under this Agreement. CONTRACTOR shall furnish to COUNTY certificate(s) of insurance evidencing Worker's Compensation Insurance coverage to cover its employees, and CONTRACTOR shall require all subcontractors similarly to provide Workers' Compensation Insurance as required by the Labor Code of the State of California for all of subcontractors' employees.

5. **CONFORMITY WITH LAW AND SAFETY:**
  - a. In performing services under this Agreement, CONTRACTOR shall observe and comply with all applicable laws, ordinances, codes and regulations of governmental agencies, including federal, state, municipal, and local governing bodies, having jurisdiction over the scope of services, including all applicable provisions of the California Occupational Safety and Health Act. CONTRACTOR shall indemnify and hold COUNTY harmless from any and all liability, fines, penalties and consequences from any of CONTRACTOR's failures to comply with such laws, ordinances, codes and regulations.

- b. ACCIDENTS: If a death, serious personal injury or substantial property damage occurs in connection with CONTRACTOR's performance of this Agreement, CONTRACTOR shall immediately notify Mendocino County Risk Manager's Office by telephone. CONTRACTOR shall promptly submit to COUNTY a written report, in such form as may be required by COUNTY of all accidents which occur in connection with this Agreement. This report must include the following information: (1) name and address of the injured or deceased person(s); (2) name and address of CONTRACTOR's sub-contractor, if any; (3) name and address of CONTRACTOR's liability insurance carrier; and (4) a detailed description of the accident and whether any of COUNTY's equipment, tools, material, or staff were involved.
  - c. CONTRACTOR further agrees to take all reasonable steps to preserve all physical evidence and information which may be relevant to the circumstances surrounding a potential claim, while maintaining public safety, and to grant to the COUNTY the opportunity to review and inspect such evidence, including the scene of the accident.
6. PAYMENT: For services performed in accordance with this Agreement, payment shall be made to CONTRACTOR as provided in Exhibit "B" hereto as funding permits.

If COUNTY over pays CONTRACTOR for any reason, CONTRACTOR agrees to return the amount of such overpayment to COUNTY, or at COUNTY's option, permit COUNTY to offset the amount of such overpayment against future payments owed to CONTRACTOR under this Agreement or any other agreement.

In the event CONTRACTOR claims or receives payment from COUNTY for a service, reimbursement for which is later disallowed by COUNTY, State of California or the United States Government, the CONTRACTOR shall promptly refund the disallowance amount to COUNTY upon request, or at its option COUNTY may offset the amount disallowed from any payment due or that becomes due to CONTRACTOR under this Agreement or any other agreement.

All invoices, receipts, or other requests for payment under this contract must be submitted by CONTRACTOR to COUNTY in a timely manner and consistent with the terms specified in Exhibit B. In no event shall COUNTY be obligated to pay any request for payment for which a written request for payment and all required documentation was first received more than six (6) months after this Agreement has terminated, or beyond such other time limit as may be set forth in Exhibit B.

7. TAXES: Payment of all applicable federal, state, and local taxes shall be the sole responsibility of the CONTRACTOR.

8. **OWNERSHIP OF DOCUMENTS:** CONTRACTOR hereby assigns the COUNTY and its assignees all copyright and other use rights in any and all proposals, plans, specification, designs, drawings, sketches, renderings, models, reports and related documents (including computerized or electronic copies) respecting in any way the subject matter of this Agreement, whether prepared by the COUNTY, the CONTRACTOR, the CONTRACTOR's subcontractors or third parties at the request of the CONTRACTOR (collectively, "Documents and Materials"). This explicitly includes the electronic copies of all above stated documentation.

CONTRACTOR shall be permitted to retain copies, including reproducible copies and computerized copies, of said Documents and Materials. CONTRACTOR agrees to take such further steps as may be reasonably requested by COUNTY to implement the aforesaid assignment. If for any reason said assignment is not effective, CONTRACTOR hereby grants the COUNTY and any assignee of the COUNTY an express royalty – free license to retain and use said Documents and Materials. The COUNTY's rights under this paragraph shall apply regardless of the degree of completion of the Documents and Materials and whether or not CONTRACTOR's services as set forth in Exhibit "A" of this Agreement have been fully performed or paid for.

The COUNTY's rights under this Paragraph 8 shall not extend to any computer software used to create such Documents and Materials.

9. **CONFLICT OF INTEREST:** The CONTRACTOR covenants that it presently has no interest, and shall not have any interest, direct or indirect, which would conflict in any manner with the performance of services required under this Agreement.
10. **NOTICES:** All notices, requests, demands, or other communications under this Agreement shall be in writing. Notices shall be given for all purposes as follows:

**Personal Delivery:** When personally delivered to the recipient, notices are effective on delivery.

**First Class Mail:** When mailed first class to the last address of the recipient known to the party giving notice, notice is effective three (3) mail delivery days after deposit in a United States Postal Service office or mailbox. **Certified Mail:** When mailed certified mail, return receipt requested, notice is effective on receipt, if delivery is confirmed by a return receipt.

**Overnight Delivery:** When delivered by overnight delivery (Federal Express/Airborne/United Parcel Service/DHL WorldWide Express) with charges prepaid or charged to the sender's account, notice is effective on delivery, if delivery is confirmed by the delivery service.

**Facsimile Transmission:** When sent by facsimile to the facsimile number of the recipient known to the party giving notice, notice is effective on receipt, provided that, (a) a duplicate copy of the notice is promptly given by first-class or certified mail or by overnight delivery, or (b) the receiving party delivers a written confirmation of receipt. Any notice given facsimile shall be deemed received on the next business day if it is received after 5:00 p.m. (recipient's time) or on a non-business day.

Addresses for purpose of giving notice are as follows:

To COUNTY: COUNTY OF MENDOCINO  
HHSA Advocacy and Collaboration Team  
747 S. State St.  
Ukiah, CA 95482  
Attn: Heather Criss

To CONTRACTOR: Redwood Community Services  
PO Box 2077  
Ukiah, CA 95482  
Attn: Victoria Kelly

Any correctly addressed notice that is refused, unclaimed, or undeliverable because of an act or omission of the party to be notified shall be deemed effective as of the first date that said notice was refused, unclaimed, or deemed undeliverable by the postal authorities, messenger, or overnight delivery service.

Any party may change its address or facsimile number by giving the other party notice of the change in any manner permitted by this Agreement.

11. **USE OF COUNTY PROPERTY:** CONTRACTOR shall not use COUNTY property (including equipment, instruments and supplies) or personnel for any purpose other than in the performance of his/her obligations under this Agreement.
12. **EQUAL EMPLOYMENT OPPORTUNITY PRACTICES PROVISIONS:** CONTRACTOR certifies that it will comply with all Federal, State, and local laws, rules and regulations pertaining to nondiscrimination in employment.
  - a. CONTRACTOR shall, in all solicitations or advertisements for applicants for employment placed as a result of this Agreement, state that it is an "Equal Opportunity Employer" or that all qualified applicants will receive consideration for employment without regard to their race, creed, color, pregnancy, disability, sex, sexual orientation, gender identity, ancestry, national origin, age, religion, Veteran's status, political affiliation, or any other factor prohibited by law.

- b. CONTRACTOR shall, if requested to so do by the COUNTY, certify that it has not, in the performance of this Agreement, engaged in any unlawful discrimination.
  - c. If requested to do so by the COUNTY, CONTRACTOR shall provide the COUNTY with access to copies of all of its records pertaining or relating to its employment practices, except to the extent such records or portions of such records are confidential or privileged under State or Federal law.
  - d. Nothing contained in this Agreement shall be construed in any manner so as to require or permit any act which is prohibited by law.
  - e. The CONTRACTOR shall include the provisions set forth in this paragraph in each of its subcontracts.
13. DRUG-FREE WORKPLACE: CONTRACTOR and CONTRACTOR's employees shall comply with the COUNTY's policy of maintaining a drug-free workplace. Neither CONTRACTOR nor CONTRACTOR's employees shall unlawfully manufacture, distribute, dispense, possess or use controlled substances, as defined in 21 U.S. Code § 812, including, but not limited to, marijuana, heroin, cocaine, and amphetamines, at any COUNTY facility or work site. If CONTRACTOR or any employee of CONTRACTOR is convicted or pleads *nolo contendere* to a criminal drug statute violation occurring at a COUNTY facility or work site, the CONTRACTOR, within five days thereafter, shall notify the head of the COUNTY department/agency for which the contract services are performed. Violation of this provision shall constitute a material breach of this Agreement.
14. ENERGY CONSERVATION: CONTRACTOR agrees to comply with the mandatory standards and policies relating to energy efficiency in the State of California Energy Conservation Plan, (Title 24, California Administrative Code).
15. COMPLIANCE WITH LICENSING REQUIREMENTS: CONTRACTOR shall comply with all necessary licensing requirements and shall obtain appropriate licenses. To the extent required by law, CONTRACTOR shall display licenses in a location that is reasonably conspicuous. Upon COUNTY's request, CONTRACTOR shall file copies of same with the County Executive Office.
- CONTRACTOR represents and warrants to COUNTY that CONTRACTOR and its employees, agents, and any subcontractors have all licenses, permits, qualifications, and approvals of whatsoever nature that are legally required to practice their respective professions.
16. AUDITS; ACCESS TO RECORDS: The CONTRACTOR shall make available to the COUNTY, its authorized agents, officers, or employees, for examination any and all ledgers, books of accounts, invoices, vouchers, cancelled checks, and

other records or documents evidencing or relating to the expenditures and disbursements charged to the COUNTY, and shall furnish to the COUNTY, within sixty (60) days after examination, its authorized agents, officers or employees such other evidence or information as the COUNTY may require with regard to any such expenditure or disbursement charged by the CONTRACTOR.

The CONTRACTOR shall maintain full and adequate records in accordance with COUNTY requirements to show the actual costs incurred by the CONTRACTOR in the performance of this Agreement. If such books and records are not kept and maintained by CONTRACTOR within the County of Mendocino, California, CONTRACTOR shall, upon request of the COUNTY, make such books and records available to the COUNTY for inspection at a location within COUNTY or CONTRACTOR shall pay to the COUNTY the reasonable, and necessary costs incurred by the COUNTY in inspecting CONTRACTOR's books and records, including, but not limited to, travel, lodging and subsistence costs. CONTRACTOR shall provide such assistance as may be reasonably required in the course of such inspection. The COUNTY further reserves the right to examine and reexamine said books, records and data during the four (4) year period following termination of this Agreement or completion of all work hereunder, as evidenced in writing by the COUNTY, and the CONTRACTOR shall in no event dispose of, destroy, alter, or mutilate said books, records, accounts, and data in any manner whatsoever for four (4) years after the COUNTY makes the final or last payment or within four (4) years after any pending issues between the COUNTY and CONTRACTOR with respect to this Agreement are closed, whichever is later.

17. **DOCUMENTS AND MATERIALS:** CONTRACTOR shall maintain and make available to COUNTY for its inspection and use during the term of this Agreement, all Documents and Materials, as defined in Paragraph 8 of this Agreement. CONTRACTOR's obligations under the preceding sentence shall continue for four (4) years following termination or expiration of this Agreement or the completion of all work hereunder (as evidenced in writing by COUNTY), and CONTRACTOR shall in no event dispose of, destroy, alter or mutilate said Documents and Materials, for four (4) years following the COUNTY's last payment to CONTRACTOR under this Agreement.
18. **TIME OF ESSENCE:** Time is of the essence in respect to all provisions of this Agreement that specify a time for performance; provided, however, that the foregoing shall not be construed to limit or deprive a party of the benefits of any grace or use period allowed in this Agreement.
19. **TERMINATION:** The COUNTY has and reserves the right to suspend, terminate or abandon the execution of any work by the CONTRACTOR without cause at any time upon giving to the CONTRACTOR notice. Such notice shall be in writing and may be issued by any COUNTY officer authorized to execute or amend the contract, the County Chief Executive Officer, or any other person designated by the County Board of Supervisors. In the event that the COUNTY

should abandon, terminate or suspend the CONTRACTOR's work, the CONTRACTOR shall be entitled to payment for services provided hereunder prior to the effective date of said suspension, termination or abandonment. Said payment shall be computed in accordance with Exhibit B hereto, provided that the maximum amount payable to CONTRACTOR for its services as listed in Exhibit A shall not exceed \$50,000 payment for services provided hereunder prior to the effective date of said suspension, termination or abandonment or lack of funding.

20. **NON APPROPRIATION:** If COUNTY should not appropriate or otherwise make available funds sufficient to purchase, lease, operate or maintain the products set forth in this Agreement, or other means of performing the same functions of such products, COUNTY may unilaterally terminate this Agreement only upon thirty (30) days written notice to CONTRACTOR. Upon termination, COUNTY shall remit payment for all products and services delivered to COUNTY and all expenses incurred by CONTRACTOR prior to CONTRACTOR'S receipt of the termination notice.
21. **CHOICE OF LAW:** This Agreement, and any dispute arising from the relationship between the parties to this Agreement, shall be governed by the laws of the State of California, excluding any laws that direct the application of another jurisdiction's laws.
22. **VENUE:** All lawsuits relating to this contract must be filed in Mendocino County Superior Court, Mendocino County, California.
23. **WAIVER:** No waiver of a breach, failure of any condition, or any right or remedy contained in or granted by the provisions of this Agreement shall be effective unless it is in writing and signed by the party waiving the breach, failure, right or remedy. No waiver of any breach, failure, right or remedy shall be deemed a waiver of any other breach, failure, right or remedy, whether or not similar, nor shall any waiver constitute a continuing waiver unless the writing so specifies.
24. **ADVERTISING OR PUBLICITY:** CONTRACTOR shall not use the name of COUNTY, its officers, directors, employees or agents, in advertising or publicity releases or otherwise without securing the prior written consent of COUNTY in each instance.
25. **ENTIRE AGREEMENT:** This Agreement, including all attachments, exhibits, and any other documents specifically incorporated into this Agreement, shall constitute the entire agreement between COUNTY and CONTRACTOR relating to the subject matter of this Agreement. As used herein, Agreement refers to and includes any documents incorporated herein by reference and any exhibits or attachments. This Agreement supersedes and merges all previous understandings, and all other agreements, written or oral, between the parties and sets forth the entire understanding of the parties regarding the subject matter

thereof. This Agreement may not be modified except by a written document signed by both parties. In the event of a conflict between the body of this Agreement and any of the Exhibits, the provisions in the body of this Agreement shall control.

26. HEADINGS: Herein are for convenience of reference only and shall in no way affect interpretation of this Agreement.
27. MODIFICATION OF AGREEMENT: This Agreement may be supplemented, amended or modified only by the mutual agreement of the parties. No supplement, amendment or modification of this Agreement shall be binding unless it is in writing and signed by authorized representatives of both parties.
28. ASSURANCE OF PERFORMANCE: If at any time the COUNTY has good objective cause to believe CONTRACTOR may not be adequately performing its obligations under this Agreement or that CONTRACTOR may fail to complete the Services as required by this Agreement, COUNTY may request from CONTRACTOR prompt written assurances of performance and a written plan acceptable to COUNTY, to correct the observed deficiencies in CONTRACTOR's performance. CONTRACTOR shall provide such written assurances and written plan within thirty (30) calendar days of its receipt of COUNTY's request and shall thereafter diligently commence and fully perform such written plan. CONTRACTOR acknowledges and agrees that any failure to provide such written assurances and written plan within the required time is a material breach under this Agreement.
29. SUBCONTRACTING/ASSIGNMENT: CONTRACTOR shall not subcontract, assign or delegate any portion of this Agreement or any duties or obligations hereunder without the COUNTY's prior written approval.
  - a. Neither party shall, on the basis of this Agreement, contract on behalf of or in the name of the other party. Any agreement that violates this Section shall confer no rights on any party and shall be null and void.
  - b. Only the department head or his or her designee shall have the authority to approve subcontractor(s).
  - c. CONTRACTOR shall remain fully responsible for compliance by its subcontractors with all the terms of this Agreement, regardless of the terms of any agreement between CONTRACTOR and its subcontractors.
30. SURVIVAL: The obligations of this Agreement, which by their nature would continue beyond the termination on expiration of the Agreement, including without limitation, the obligations regarding Indemnification (Paragraph 2), Ownership of Documents (Paragraph 8), and Conflict of Interest (Paragraph 9), shall survive termination or expiration for two (2) years.

31. **SEVERABILITY:** If a court of competent jurisdiction holds any provision of this Agreement to be illegal, unenforceable, or invalid in whole or in part for any reason, the validity and enforceability of the remaining provisions, or portions of them, will not be affected, unless an essential purpose of this Agreement would be defeated by the loss of the illegal, unenforceable, or invalid provision.
32. **INTELLECTUAL PROPERTY WARRANTY:** CONTRACTOR warrants and represents that it has secured all rights and licenses necessary for any and all materials, services, processes, software, or hardware ("CONTRACTOR PRODUCTS") to be provided by CONTRACTOR in the performance of this AGREEMENT, including but not limited to any copyright, trademark, patent, trade secret, or right of publicity rights. CONTRACTOR hereby grants to COUNTY, or represents that it has secured from third parties, an irrevocable license (or sublicense) to reproduce, distribute, perform, display, prepare derivative works, make, use, sell, import, use in commerce, or otherwise utilize CONTRACTOR PRODUCTS to the extent reasonably necessary to use the CONTRACTOR PRODUCTS in the manner contemplated by this agreement.

CONTRACTOR further warrants and represents that it knows of no allegations, claims, or threatened claims that the CONTRACTOR PRODUCTS provided to COUNTY under this Agreement infringe any patent, copyright, trademark or other proprietary right. In the event that any third party asserts a claim of infringement against the COUNTY relating to a CONTRACTOR PRODUCT, CONTRACTOR shall indemnify and defend the COUNTY pursuant to Paragraph 2 of this AGREEMENT

In the case of any such claim of infringement, CONTRACTOR shall either, at its option, (1) procure for COUNTY the right to continue using the CONTRACTOR Products; or (2) replace or modify the CONTRACTOR Products so that that they become non-infringing, but equivalent in functionality and performance.

33. **ELECTRONIC COPIES:** The parties agree that an electronic copy, including facsimile copy, email, or scanned copy of the executed Agreement, shall be deemed, and shall have the same legal force and effect as, an original document.
34. **COOPERATION WITH COUNTY:** CONTRACTOR shall cooperate with COUNTY and COUNTY staff in the performance of all work hereunder.
35. **PERFORMANCE STANDARD:** CONTRACTOR shall perform all work hereunder in a manner consistent with the level of competency and standard of care normally observed by a person practicing in CONTRACTOR's profession. COUNTY has relied upon the professional ability and training of CONTRACTOR as a material inducement to enter into this Agreement. CONTRACTOR hereby agrees to provide all services under this Agreement in accordance with generally

accepted professional practices and standards of care, as well as the requirements of applicable Federal, State, and local laws, it being understood that acceptance of CONTRACTOR's work by COUNTY shall not operate as a waiver or release. If COUNTY determines that any of CONTRACTOR's work is not in accordance with such level of competency and standard of care, COUNTY, in its sole discretion, shall have the right to do any or all of the following: (a) require CONTRACTOR to meet with COUNTY to review the quality of the work and resolve matters of concern; (b) require CONTRACTOR to repeat the work at no additional charge until it is satisfactory; (c) terminate this Agreement pursuant to the provisions of paragraph 19 (Termination) or (d) pursue any and all other remedies at law or in equity.

36. ATTORNEYS' FEES: In any action to enforce or interpret the terms of this agreement, including but not limited to any action for declaratory relief, each party shall be solely responsible for and bear its own attorneys' fees, regardless of which party prevails.

[END OF GENERAL TERMS AND CONDITIONS]

## **EXHIBIT A**

### **DEFINITION OF SERVICES**

- I. Overview of the Whole Person Care (WPC) Pilot Program – Mendocino County
  - A. Target population: Medi-Cal beneficiaries who have Serious Mental Illness (SMI). The project will prioritize services to those who are high users of mental health and/or medical services, and those with additional barriers including homelessness or housing instability, co-occurring Substance Use Disorders, and/or recent interactions with the criminal justice system.
  - B. Theory of Change: People with SMI who have access to integrated services, stable housing, and strong social support will increase their participation in prevention and early intervention services, resulting in improved health and social outcomes.
  - C. Funding parameters: The WPC project will provide funding for services and activities that are not billable to Medi-Cal.
- II. CONTRACTOR shall:
  - A. Provide office/meeting space and facility usage for Wellness Coaches, two (2) coaches at Stepping Stones in Ukiah, and one (1) at the Healing Center in Fort Bragg, to meet with WPC enrollees, Care Managers, and other members of the care team.
  - B. Attend and participate in at least 75% of WPC Steering Committee meetings.
  - C. Ensure that the Behavioral Health Care Manager meets with WPC Wellness Coaches, at least once per month, to coordinate care for each WPC enrollee assigned to Behavioral Health Services. The Behavioral Health Care Manager must document care coordination meetings in Exym, a software system for mental health services maintained by Redwood Quality Management Company (RQMC).
  - D. Ensure that the Behavioral Health Care Manager participates in quarterly WPC case conferences with each WPC enrollee, unless the needs of the WPC enrollee require more frequent conferences. The Behavioral Health Care Manager must document all quarterly case conferences in Exym.
  - E. Collaborate with RQMC regarding information entered into Exym, enabling RQMC to verify and provide documentation to the COUNTY for monitoring.

- F. Ensure that there is at least one (1) Behavioral Health Medi-Cal billable client service (other than Care Coordination listed in item C. above) with all clients who are dually enrolled in WPC and Behavioral Health Services. WPC should be an enhancement to Behavioral Health and not supersede Behavioral Health activities.
- G. Provide winter shelter services to WPC enrollees, as needed and as capacity allows; report to COUNTY and RQMC regarding all WPC enrollees who utilize winter shelter services.
- H. Ensure Medi-Cal billable services are maximized, not billing WPC for any currently billable Medi-Cal services, and meeting related terms and conditions of the WPC Pilot Project (Attachment 3).

III. COUNTY shall:

- A. Retain Steering Committee agendas and sign-in sheets, and monitor attendance.
- B. Log and track CONTRACTOR's use of Exym, and monitor compliance with quarterly and monthly requirements.

IV. Payments made through this Agreement are not for Behavioral Health Services that are billable to Medi-Cal. Payments made through this Agreement are for supporting coordination of care, and not to supplant other programs or funding streams.

[END OF DEFINITION OF SERVICES]

**EXHIBIT B****PAYMENT TERMS****I. COUNTY will pay CONTRACTOR as per the following instructions:****A. Submission of claims and reports will comply as follows:**

1. CONTRACTOR shall submit one (1) invoice quarterly (Attachment 1) within thirty (30) days of the conclusion of each quarter. First quarter is January 1, 2021 through March 31, 2021. Second quarter is April 1, 2021 through June 30, 2021. Invoice template is subject to change at COUNTY's discretion. COUNTY will provide electronic invoice template to CONTRACTOR.
2. Invoice must be accompanied by Audit Checklist (Attachment 2).
3. Invoices submitted ninety (90) days after the due date must be accompanied by a letter explaining why the invoice is late. COUNTY has the sole authority to determine whether to approve or disapprove payment of the late invoice.
4. COUNTY shall not approve payment of funds until CONTRACTOR has filed all reports required under this Agreement.

**B. Reimbursement for services will be structured as follows:**

Payment Structure Type	Criteria	Payment Terms
<b>Tiered<sup>1</sup></b>  <b>Attendance at Whole Person Care (WPC) Case Conferences:</b> <b>Max payment \$9,000</b>	<u>Full Participation</u> - Care Managers attend 90% or more of WPC enrollees' quarterly case conferences.	Full: 100% of payment
	<u>Meaningful Participation</u> - Care Managers attend 60-89% of WPC enrollees' quarterly case conferences.	Meaningful: 75% of payment
	<u>Partial Participation</u> - Care Managers attend 45-59% of WPC enrollees' quarterly case conferences.	Partial: 50% of payment
	<u>Limited Participation</u> - Care Managers attend 25-44% of WPC enrollees' quarterly case conferences.	Limited: 25% of payment
	<u>Incomplete Participation</u> - Care Managers attend less than 25% of WPC enrollees' quarterly case conferences.	Incomplete: 0% of payment

<p>Tiered<sup>2</sup></p> <p>Documentation of Care Coordination: <b>Max payment \$9,000</b></p>	<p><u>Full Participation</u> - Care Managers document 90% or more of WPC enrollees' monthly coordination of care.</p> <p><u>Meaningful Participation</u> - Care Managers document 60-89% of WPC enrollees' monthly coordination of care.</p> <p><u>Partial Participation</u> - Care Managers document 45-59% of WPC enrollees' monthly coordination of care.</p> <p><u>Limited Participation</u> - Care Managers document 25-44% of WPC enrollees' monthly coordination of care.</p> <p><u>Incomplete Participation</u> - Care Managers document less than 25% of WPC enrollees' monthly coordination of care.</p>	<p>Full: 100% of payment</p> <p>Meaningful: 75% of payment</p> <p>Partial: 50% of payment</p> <p>Limited: 25% of payment</p> <p>Incomplete: 0% of payment</p>
<p>Tiered<sup>3</sup></p> <p>Documentation of Behavioral Health (BH) Services: <b>Max payment \$9,000</b></p>	<p><u>Full Participation</u> - Care Managers document 90% or more of WPC enrollees' charts, and at least one monthly BH service in Exym.</p> <p><u>Meaningful Participation</u> - Care Managers document 60-89% of WPC enrollees' charts, and at least one monthly BH service in Exym.</p> <p><u>Partial Participation</u> - Care Managers document 45-59% of WPC enrollees' charts, and at least one monthly BH service in Exym.</p> <p><u>Limited Participation</u> - Care Managers document 25-44% of WPC enrollees' charts, and at least one monthly BH service in Exym.</p> <p><u>Incomplete Participation</u> - Care Managers document less than 25% of WPC enrollees' charts, and at least one monthly BH service in Exym.</p>	<p>Full: 100% of payment</p> <p>Meaningful: 75% of payment</p> <p>Partial: 50% of payment</p> <p>Limited: 25% of payment</p> <p>Incomplete: 0% of payment</p>

Actual Costs	Shelter Services - Payment will be provided for each WPC enrollee receiving a shelter bed.	\$50 per member per day
Homeless Services Infrastructure: Max payment \$23,000		
		<b>Total Maximum Payment Allowed: \$50,000</b>

C. Invoices and receipts shall be submitted to:

Heather Criss  
Advocacy and Collaboration Team  
Mendocino County Health and Human Services Agency  
747 South State Street  
Ukiah, CA 95482

- II. Payments under this Agreement shall not exceed Fifty Thousand Dollars (\$50,000) for the term of this Agreement.
- III. Additional funding is not committed or guaranteed in future years beyond the terms of this contract.

[END OF PAYMENT TERMS]

## **EXHIBIT C**

### **INSURANCE REQUIREMENTS**

Insurance coverage in a minimum amount set forth herein shall not be construed to relieve CONTRACTOR for liability in excess of such coverage, nor shall it preclude COUNTY from taking such other action as is available to it under any other provisions of this Agreement or otherwise in law. Insurance requirements shall be in addition to, and not in lieu of, CONTRACTOR's indemnity obligations under Paragraph 2 of this Agreement.

CONTRACTOR shall obtain and maintain insurance coverage as follows:

- a. Combined single limit bodily injury liability and property damage liability - \$1,000,000 each occurrence.
- b. Vehicle / Bodily Injury combined single limit vehicle bodily injury and property damage liability - \$500,000 each occurrence.

CONTRACTOR shall furnish to COUNTY certificates of insurance evidencing the minimum levels described above.

[END OF INSURANCE REQUIREMENTS]

EXHIBIT D  
**CONTRACTOR ASSURANCE OF COMPLIANCE WITH**  
**THE MENDOCINO COUNTY**  
**HEALTH & HUMAN SERVICES AGENCY**  
**NONDISCRIMINATION IN STATE**  
**AND FEDERALLY ASSISTED PROGRAMS**

---

NAME OF CONTRACTOR: **Redwood Community Services**

HEREBY AGREES THAT it will comply with Title VI and VII of the Civil Rights Act of 1964 as amended; Section 504 of the Rehabilitation Act of 1973 as amended; the Age Discrimination Act of 1975 as amended; the Food Stamp Act of 1977, as amended and in particular section 272.6; Title II of the Americans with Disabilities Act of 1990; California Civil Code Section 51 et seq., as amended; California Government Code section 11135-11139.5, as amended; California Government Code section 12940 (c), (h) (1), (i), and (j); California Government Code section 4450; Title 22, California Code of Regulations section 98000 – 98413; Title 24 of the California Code of Regulations, Section 3105A(e); the Dymally-Alatorre Bilingual Services Act (California Government Code Section 7290-7299.8); Section 1808 of the Removal of Barriers to Interethnic Adoption Act of 1996; and other applicable federal and state laws, as well as their implementing regulations [including 45 Code of Federal Regulations (CFR) Parts 80, 84, and 91, 7 CFR Part 15, and 28 CFR Part 42], by ensuring that employment practices and the administration of public assistance and social services programs are nondiscriminatory, to the effect that no person shall because of ethnic group identification, age, sex, sexual orientation, color, disability, medical condition, national origin, race, ancestry, marital status, religion, religious creed or political belief be excluded from participation in or be denied the benefits of, or be otherwise subject to discrimination under any program or activity receiving federal or state financial assistance; and HEREBY GIVE ASSURANCE THAT it will immediately take any measures necessary to effectuate this agreement.

THIS ASSURANCE is given in consideration of and for the purpose of obtaining any and all federal and state assistance; and THE CONTRACTOR HEREBY GIVES ASSURANCE THAT administrative methods/procedures which have the effect of subjecting individuals to discrimination or defeating the objectives of the California Department of Social Services (CDSS) Manual of Policies and Procedures (MPP) Chapter 21, will be prohibited.

BY ACCEPTING THIS ASSURANCE, CONTRACTOR agrees to compile data, maintain records and submit reports as required, to permit effective enforcement of the aforementioned laws, rules and regulations and permit authorized CDSS and/or federal government personnel, during normal working hours, to review such records, books and accounts as needed to ascertain compliance. If there are any violations of this assurance, CDSS shall have the right to invoke fiscal sanctions or other legal remedies in accordance with Welfare and Institutions Code section 10605, or Government Code section 11135-11139.5, or any other laws, or the issue may be referred to the appropriate federal agency for further compliance action and enforcement of this assurance.

THIS ASSURANCE is binding on CONTRACTOR directly or through contract, license, or other provider services, as long as it receives federal or state assistance.

2/9/2021

Date  
PO Box 2077 Ukiah, CA 95482  
Address of CONTRACTOR

DocuSigned by:  
*Victoria Kelly*  
CONTRACTOR Signature

**Appendix A**  
**CERTIFICATION REGARDING**  
**DEBARMENT, SUSPENSION, and OTHER RESPONSIBILITY MATTERS**  
**LOWER TIER COVERED TRANSACTIONS**

This certification is required by the regulations implementing Executive Order 12549, Debarment and Suspension, 29 CFR Part 98, Section 98.510, Participants' responsibilities. The regulations were published as Part VII of the May 26, 1988 Federal Register (pages 19160-19211).

- (1) The primary principal certifies to the best of its knowledge and belief, that it and its principals:
  - (a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;
  - (b) Have not within a three-year period preceding this proposal been convicted of or had a civil judgment tendered against them for commission of fraud or a criminal offence in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsifications or destruction of records, making false statements, or receiving stolen property;
  - (c) Are not presently indicted for or otherwise criminally or civilly charged by a government entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph (1) (b) of this certification, and
  - (d) Have not, within a three-year period preceding this application/proposal, had one or more public transactions (Federal, State, or local) terminated for cause or default.
- (2) Where the primary principal is unable to certify to any of the statements in this certification, such principal shall attach an explanation.

Victoria Kelly  
 (Type Name)

Redwood Community Services  
 (Organization Name)

Chief Executive Officer  
 (Title)

PO Box 2077  
 Ukiah, CA 95482  
 (Organization Address)

DocuSigned by:  
 Victoria Kelly  
 (Signature)

2/9/2021  
 (Date)

## **Addendum A**

### **Medi-Cal Data Privacy and Security Agreement**

The California Department of Health Care Services (DHCS) and the County of Mendocino Health and Human Services Agency (MC-HHSA) have entered into a Medi-Cal Data Privacy and Security Agreement in order to ensure the privacy and security of Medi-Cal Personally Identifiable Information (PII).

Medi-Cal PII is information directly obtained in the course of performing an administrative function on behalf of Medi-Cal, such as determining Medi-Cal eligibility or conducting IHSS operations, that can be used alone, or in conjunction with any other information, to identify a specific individual. PII includes any information that can be used to search for or identify individuals, or can be used to access their files, such as name, social security number, date of birth, driver's license number or identification number. PII may be electronic or paper.

### **AGREEMENTS**

**NOW THEREFORE**, County and the Contractor mutually agree as follows:

#### **I. Privacy and Confidentiality**

- A. Contractors may use or disclose Medi-Cal PII only to perform functions, activities or services directly related to the administration of the Medi-Cal program in accordance with Welfare and Institutions Code section 14100.2 and 42 Code of Federal Regulations section 431.300 et.seq, or as required by law.

Disclosures which are required by law, such as a court order, or which are made with the explicit written authorization of the Medi-Cal client, are allowable. Any other use or disclosure of Medi-Cal PII requires the express approval in writing of DHCS. Contractor shall not duplicate, disseminate or disclose Medi-Cal PII except as allowed in the Agreement.

- B. Access to Medi-Cal PII shall be restricted to only contractor personnel who need the Medi-Cal PII to perform their official duties in connection with the administration of the Medi-Cal program.
- C. Contractor and/or their personnel who access, disclose or use Medi-Cal PII in a manner or for a purpose not authorized by this Agreement may be subject to civil and criminal sanctions contained in applicable Federal and State statutes.

#### **II. Employee Training and Discipline**

Contractor agrees to advise its personnel who have access to Medi-Cal PII of the confidentiality of the information, the safeguards required to protect the information, and the civil and criminal sanctions for non-compliance contained in applicable Federal and State laws. Contractor shall:

## **Addendum A – Page 2**

- A. Train and use reasonable measures to ensure compliance with the requirements of this Agreement by their personnel who assist in the administration of the Medi-Cal program and use or disclose Medi-Cal PII; and take corrective action against such personnel who intentionally violate any provisions of this Agreement, up to and including by termination of employment. New employees will receive privacy and security awareness training from Contractor within 30 days of employment and receive regular reminders throughout their employment. This information will be recorded in employee records with dates of each training/reminder. These records are to be retained and available for inspection for a period of three years after completion of the training/reminders.

### **III. Management Oversight and Monitoring**

The Contractor agrees to establish and maintain ongoing management oversight and quality assurance for monitoring workforce compliance with the privacy and security safeguards in this Agreement when using or disclosing Medi-Cal PII and ensure that ongoing management oversight includes periodic self-assessments.

### **IV. Confidentiality Statement**

Contractor agrees to ensure that all contractor personnel who assist in the administration of the Medi-Cal program and use or disclose Medi-Cal PII sign a confidentiality statement. The statement shall include at a minimum, General Use, Security and Privacy Safeguards, Unacceptable Use, and Enforcement Policies. The statement shall be signed by the Contractor and their personnel prior to access to Medi-Cal PII.

### **V. Physical Security**

Contractor shall ensure that Medi-Cal PII is used and stored in an area that is physically safe from access by unauthorized persons during working hours and non-working hours. Contractor agrees to safeguard Medi-Cal PII from loss, theft or inadvertent disclosure and, therefore, agrees to:

- A. Secure all areas of Contractor facilities where personnel assist in the administration of the Medi-Cal program and use or disclose Medi-Cal PII. The Contractor shall ensure that these secure areas are only accessed by authorized individuals with properly coded key cards, authorized door keys or access authorization; and access to premises is by official identification.
- B. Ensure that there are security guards or a monitored alarm system with or without security cameras 24 hours a day, 7 days a week at Contractor facilities and leased facilities where a large volume of Medi-Cal PII is store
- C. Issue Contractor personnel who assist in the administration of the Medi-Cal program identification badges and require County Workers to wear the identification badges at facilities where Medi-Cal PII is stored or used.

### **Addendum A – Page 3**

- D. Store paper records with Medi-Cal PII in locked spaces, such as locked file cabinets, locked file rooms, locked desks or locked offices in facilities which are multi-use (meaning that there are personnel other than contractor personnel using common areas that are not securely segregated from each other.) The contractor shall have policies which indicate that Contractor and their personnel are not to leave records with Medi-Cal PII unattended at any time in vehicles or airplanes and not to check such records in baggage on commercial airlines.
- E. Use all reasonable measures to prevent non-authorized personnel and visitors from having access to, control of, or viewing Medi-Cal PII.

#### **VI. Computer Security Safeguards**

The Contractor agrees to comply with the general computer security safeguards, system security controls, and audit controls in this section. In order to comply with the following general computer security safeguards, the Contractor agrees to:

- A. Encrypt portable computer devices, such as laptops and notebook computers that process and/or store Medi-Cal PII, with a solution using a vendor product that is recognized as an industry leader in meeting the needs for the intended solution. One source of recommended solutions is specified on the California Strategic Sourced Initiative (CSSI) located at the following link: [www.pd.dgs.ca.gov/masters/EncryptionSoftware.html](http://www.pd.dgs.ca.gov/masters/EncryptionSoftware.html). The Contractor shall use an encryption solution that is full-disk unless otherwise approved by DHCS.
- B. Encrypt workstations where Medi-Cal PII is stored using a vendor product that is recognized as an industry leader in meeting the needs for the intended solution, such as products specified on the CSSI.
- C. Ensure that only the minimum necessary amount of Medi-Cal PII is downloaded to a laptop or hard drive when absolutely necessary for current business purposes.
- D. Encrypt all electronic files that contain Medi-Cal PII when the file is stored on any removable media type device (i.e. USB thumb drives, floppies, CD/DVD, etc.) using a vendor product that is recognized as an industry leader in meeting the needs for the intended solution, such as products specified on the CSSI.
- E. Ensure that all emails sent outside the Contractor's e-mail environment that include Medi-Cal PII are sent via an encrypted method using a vendor product that is recognized as an industry leader in meeting the needs for the intended solution, such as products specified on the CSSI.
- F. Ensure that all workstations, laptops and other systems that process and/or store Medi-Cal PII have a commercial third-party anti-virus software solution and are updated when a new anti-virus definition/software release is available.

## **Addendum A – Page 4**

- G. Ensure that all workstations, laptops and other systems that process and/or store Medi-Cal PII have current security patches applied and up-to-date.
- H. Ensure that all Medi-Cal PII is wiped from systems when the data is no longer legally required. The Contractor shall ensure that the wipe method conforms to Department of Defense standards for data destruction.
- I. Ensure that any remote access to Medi-Cal PII is established over an encrypted session protocol using a vendor product that is recognized as an industry leader in meeting the needs for the intended solution, such as products specified on the CSSI. The Contractor shall ensure that all remote access is limited to minimum necessary and least privilege principles.

### **VII. System Security Controls**

In order to comply with the following system security controls, the Contractor agrees to:

- A. Ensure that all Contractor systems containing Medi-Cal PII provide an automatic timeout after no more than 20 minutes of inactivity.
- B. Ensure that all Contractor systems containing Medi-Cal PII display a warning banner stating that data is confidential, systems are logged, and system use is for business purposes only. User shall be directed to log off the system if they do not agree with these requirements.
- C. Ensure that all Contractor systems containing Medi-Cal PII log successes and failures of user authentication and authorizations granted. The system shall log all data changes and system accesses conducted by all users (including all levels of users, system administrators, developers, and auditors). The system shall have the capability to record data access for specified users when requested by authorized management personnel. A log of all system changes shall be maintained and be available for review by authorized management personnel.
- D. Ensure that all Contractor systems containing Medi-Cal PII use role based access controls for all user authentication, enforcing the principle of least privilege.
- E. Ensure that all Contractor data transmissions over networks outside of the Contractor's control are encrypted end-to-end using a vendor product that is recognized as an industry leader in meeting the needs for the intended solution, such as products specified on the CSSI, when transmitting Medi-Cal PII. The Contractor shall encrypt Medi-Cal PII at the minimum of 128 bit AES or 3DES (Triple DES) if AES is unavailable.
- F. Ensure that all Contractor systems that are accessible via the Internet or store Medi-Cal PII actively use either a comprehensive third-party real-time host based intrusion detection and prevention program or be protected at the perimeter by a network based IDS/IPS solution.

## **Addendum A – Page 5**

### **VIII. Audit Controls**

Contractor agrees to an annual system security review by the County to assure that systems processing and/or storing Medi-Cal PII are secure. This includes audits and keeping records for a period of at least three (3) years. A routine procedure for system review to catch unauthorized access to Medi-Cal PII shall be established by the Contractor.

### **IX. Paper Document Controls**

In order to comply with the following paper document controls, the Contractor agrees to:

- A. Dispose of Medi-Cal PII in paper form through confidential means, such as crosscut shredding and pulverizing.
- B. Not remove Medi-Cal PII from the premises of the Contractor except for identified routine business purposes or with express written permission of DHCS.
- C. Not leave faxes containing Medi-Cal PII unattended and keep fax machines in secure areas. The Contractor shall ensure that faxes contain a confidentiality statement notifying persons receiving faxes in error to destroy them. Contractor personnel shall verify fax numbers with the intended recipient before sending.
- D. Use a secure, bonded courier with signature of receipt when sending large volumes of Medi-Cal PII. The Contractor shall ensure that disks and other transportable media sent through the mail are encrypted using a vendor product that is recognized as an industry leader in meeting the needs for the intended solution, such as products specified on the CSSI.

### **X. Notification and Investigation of Breaches**

The Contractor agrees to notify John Martire, Chief Welfare Investigator, at 467-5856.

### **XI. Assessments and Reviews**

In order to enforce this Agreement and ensure compliance with its provisions, the Contractor agrees to inspections of its facilities, systems, books and records, with reasonable notice from the County, in order to perform assessments and reviews.

### **XII. Assistance in Litigation or Administrative Proceedings**

In the event of litigation or administrative proceedings involving DHCS based upon claimed violations, the Contractor shall make all reasonable effort to make itself and its personnel who assist in the administration of the Medi-Cal program and using or disclosing Medi-Cal PII available to DHCS at no cost to DHCS to testify as witnesses.

Addendum A – Page 6

Signature Page

Victoria Kelly  
Contractor Name (printed)

DocuSigned by:  
Victoria Kelly  
Contractor Signature

Chief Executive Officer  
Contractor Title

Redwood Community Services  
Contractor's Agency Name

2/9/2021  
Date

## ADDENDUM B

### Business Associate Agreement

**THIS HIPAA BUSINESS ASSOCIATE AGREEMENT** (the "Agreement") is entered into effective January 1, 2021 (the "Effective Date"), by and between **Redwood Community Services** ("Business Associate") and **Mendocino County Behavioral Health & Recovery Services** (the "Covered Entity").

Business Associate and Covered Entity have a business relationship (the "Relationship" or the "Agreement") in which Business Associate may perform functions or activities on behalf of Covered Entity involving the use and/or disclosure of protected health information received from, or created or received by, Business Associate on behalf of Covered Entity. ("PHI"). Therefore, if Business Associate is functioning as a business associate to Covered Entity, Business Associate agrees to the following terms and conditions set forth in this HIPAA Business Associate Agreement.

1. **Definitions.** For purposes of this Agreement, the terms used herein, unless otherwise defined, shall have the same meanings as used in the Health Insurance Portability and Accountability Act of 1996, and any amendments or implementing regulations ("HIPAA"), or the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009), and any amendments or implementing regulations ("HITECH").
2. **Compliance with Applicable Law.** The parties acknowledge and agree that, beginning with the relevant effective dates, Business Associate shall comply with its obligations under this Agreement and with all obligations of a business associate under HIPAA, HITECH and other related laws, as they exist at the time this Agreement is executed and as they are amended, for so long as this Agreement is in place.
3. **Permissible Use and Disclosure of Protected Health Information.** Business Associate may use and disclose PHI to carry out its duties to Covered Entity pursuant to the terms of the Relationship. Business Associate may also use and disclose PHI (i) for its own proper management and administration, and (ii) to carry out its legal responsibilities. If Business Associate discloses Protected Health Information to a third party for either above reason, prior to making any such disclosure, Business Associate must obtain: (i) reasonable assurances from the receiving party that such PHI will be held confidential and be disclosed only as required by law or for the purposes for which it was disclosed to such receiving party; and (ii) an agreement from such receiving party to immediately

notify Business Associate of any known breaches of the confidentiality of the PHI.

4. **Limitations on Uses and Disclosures of PHI.** Business Associate shall not, and shall ensure that its directors, officers, employees, and agents do not, use or disclose PHI in any manner that is not permitted or required by the Relationship, this Agreement, or required by law. All uses and disclosures of, and requests by Business Associate, for PHI are subject to the minimum necessary rule of the Privacy Standards and shall be limited to the information contained in a limited data set, to the extent practical, unless additional information is needed to accomplish the intended purpose, or as otherwise permitted in accordance with Section 13405(b) of HITECH and any implementing regulations.
5. **Required Safeguards To Protect PHI.** Business Associate agrees that it will implement appropriate safeguards in accordance with the Privacy Standards to prevent the use or disclosure of PHI other than pursuant to the terms and conditions of this Agreement.
6. **Reporting of Improper Use and Disclosures of PHI.** Business Associate shall report within 24 business hours to Covered Entity a use or disclosure of PHI not provided for in this Agreement by Business Associate, its officers, directors, employees, or agents, or by a third party to whom Business Associate disclosed PHI. Business Associate shall also report within 24 business hours to Covered Entity a breach of unsecured PHI, in accordance with 45 C.F.R. §§ 164.400-414, and any security incident of which it becomes aware. Report should be made to:  
  
Compliance Officer  
Mendocino County Behavioral Health  
1-866-791-9337
7. **Mitigation of Harmful Effects.** Business Associate agrees to mitigate, to the extent practicable, any harmful effect of a use or disclosure of PHI by Business Associate in violation of the requirements of this Agreement, including, but not limited to, compliance with any state law or contractual data breach requirements. Business Associate shall cooperate with Covered Entity's breach notification and mitigation activities, and shall be responsible for all costs incurred by Covered Entity for those activities.
8. **Agreements by Third Parties.** Business Associate shall enter into an agreement with any agent or subcontractor of Business Associate that will have access to

PHI. Pursuant to such agreement, the agent or subcontractor shall agree to be bound by the same restrictions, terms, and conditions that apply to Business Associate under this Agreement with respect to such PHI.

9. **Access to Information.** Within five (5) days of a request by Covered Entity for access to PHI about an individual contained in a Designated Record Set, Business Associate shall make available to Covered Entity such PHI for so long as such information is maintained by Business Associate in the Designated Record Set, as required by 45 C.F.R. § 164.524. In the event any individual delivers directly to Business Associate a request for access to PHI, Business Associate shall within two (2) days forward such request to Covered Entity.
10. **Availability of PHI for Amendment.** Within five (5) days of receipt of a request from Covered Entity for the amendment of an individual's PHI or a record regarding an individual contained in a Designated Record Set (for so long as the PHI is maintained in the Designated Record Set), Business Associate shall provide such information to Covered Entity for amendment and incorporate any such amendments in the PHI as required by 45 C.F.R. § 164.526. In the event any individual delivers directly to Business Associate a request for amendment to PHI, Business Associate shall within two (2) days forward such request to Covered Entity.
11. **Documentation of Disclosures.** Business Associate agrees to document disclosures of PHI 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 PHI in accordance with 45 C.F.R. § 164.528.
12. **Accounting of Disclosures.** Within five (5) days of notice by Covered Entity to Business Associate that it has received a request for an accounting of disclosures of PHI regarding an individual during the six (6) years prior to the date on which the accounting was requested, Business Associate shall make available to Covered Entity information to permit Covered Entity to respond to the request for an accounting of disclosures of PHI, as required by 45 C.F.R. § 164.528. In the case of an electronic health record maintained or hosted by Business Associate on behalf of Covered Entity, the accounting period shall be three (3) years and the accounting shall include disclosures for treatment, payment and healthcare operations, in accordance with the applicable effective date of Section 13402(a) of HITECH. In the event the request for an accounting is delivered directly to Business Associate, Business Associate shall within two (2) days forward such request to Covered Entity.

**13. Electronic PHI.** To the extent that Business Associate creates, receives, maintains or transmits electronic PHI on behalf of Covered Entity, Business Associate shall:

- (a) Comply with 45 C.F.R. §§164.308, 301, 312, and 316 in the same manner as such sections apply to Covered Entity, pursuant to Section 13401(a) of HITECH, and otherwise implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of electronic PHI;
- (b) Ensure that any agent to whom Business Associate provides electronic PHI agrees to implement reasonable and appropriate safeguards to protect it; and
- (c) Report to Covered Entity any security incident of which Business Associate becomes aware.

**14. Judicial and Administrative Proceedings.** In the event Business Associate receives a subpoena, court or administrative order or other discovery request or mandate for release of PHI, Covered Entity shall have the right to control Business Associate's response to such request. Business Associate shall notify Covered Entity of the request as soon as reasonably practicable, but in any event within two (2) days of receipt of such request.

**15. Availability of Books and Records.** Business Associate shall make its internal practices, books, and records relating to the use and disclosure and privacy protection of PHI received from Covered Entity, or created, maintained or received by Business Associate on behalf of the Covered Entity, available to the Covered Entity, the State of California, and the Secretary of the Department of Health and Human Services, in the time and manner designated by the Covered Entity, State or Secretary, for purposes of determining Covered Entity's compliance with the Privacy Standards. Business Associate shall notify the Covered Entity upon receipt of such a request for access by the State or Secretary, and shall provide the Covered Entity with a copy of the request as well as a copy of all materials disclosed.

**16. Breach of Contract by Business Associate.** In addition to any other rights Covered Entity may have in the Relationship, this Agreement or by operation of law or in equity, Covered Entity may i) immediately terminate the Relationship if

Covered Entity determines that Business Associate has violated a material term of this Agreement, or ii) at Covered Entity's option, permit Business Associate to cure or end any such violation within the time specified by Covered Entity. Covered Entity's option to have cured a breach of this Agreement shall not be construed as a waiver of any other rights Covered Entity has in the Relationship, this Agreement or by operation of law or in equity.

- 17. Effect of Termination of Relationship.** Upon the termination of the Relationship or this Agreement for any reason, Business Associate shall return to Covered Entity or, at Covered Entity's direction, destroy all PHI received from Covered Entity that Business Associate maintains in any form, recorded on any medium, or stored in any storage system, unless said information has been de-identified and is no longer PHI. This provision shall apply to PHI that is in the possession of Business Associates or agents of Business Associate. Business Associate shall retain no copies of the PHI. Business Associate shall remain bound by the provisions of this Agreement, even after termination of the Relationship or the Agreement, until such time as all PHI has been returned, de-identified or otherwise destroyed as provided in this Section.
- 18. Injunctive Relief.** Business Associate stipulates that its unauthorized use or disclosure of PHI while performing services pursuant to this Agreement would cause irreparable harm to Covered Entity, and in such event, Covered Entity shall be entitled to institute proceedings in any court of competent jurisdiction to obtain damages and injunctive relief.
- 19. Indemnification.** Business Associate shall indemnify and hold harmless Covered Entity and its officers, trustees, employees, and agents from any and all claims, penalties, fines, costs, liabilities or damages, including but not limited to reasonable attorney fees, incurred by Covered Entity arising from a violation by Business Associate of its obligations under this Agreement.
- 20. Exclusion from Limitation of Liability.** To the extent that Business Associate has limited its liability under the terms of the Relationship, whether with a maximum recovery for direct damages or a disclaimer against any consequential, indirect or punitive damages, or other such limitations, all limitations shall exclude any damages to Covered Entity arising from Business Associate's breach of its obligations relating to the use and disclosure of PHI.

**21. Owner of PHI.** Under no circumstances shall Business Associate be deemed in any respect to be the owner of any PHI used or disclosed by or to Business Associate by Covered Entity.

**22. Third Party Rights.** The terms of this Agreement do not grant any rights to any parties other than Business Associate and Covered Entity.

**23. Independent Contractor Status.** For the purposed of this Agreement, Business Associate is an independent contractor of Covered Entity, and shall not be considered an agent of Covered Entity.

**24. Changes in the Law.** The parties shall amend this Agreement to conform to any new or revised legislation, rules and regulations to which Covered Entity is subject now or in the future including, without limitation, HIPAA, HITECH, the Privacy Standards, Security Standards or Transactions Standards.

IN WITNESS WHEREOF, each Party hereby executes this Agreement as of the Effective Date.

**Redwood Community Services**

By:  \_\_\_\_\_  
DocuSigned by:  
Victoria Kelly  
37E085248810457...

Name: Victoria Kelly

Title: Chief Executive Officer

**Mendocino County**

By:  \_\_\_\_\_  
*Psy.D.*

Name: Jenine Miller, Psy.D.

Title: HHSA Assistant Director/Behavioral Health Director

## Attachment 1

Mendocino County Whole Person Care Pilot Program  
PROVIDER AGENCY INVOICE

Bill to: County of Mendocino HHS  
Attn: Heather Criss  
747 S State Street  
Ukiah, CA 95482

Remit to: Agency Name/Address  
[ ] Check if remittance address changed since last invoice  
Name  
Address  
Telephone

Date: \_\_\_\_\_

Check for Final Invoice: [ ]  
Contract Number: TBD  
Contract Term: 1/1/2021-6/30/2021  
Invoice Quarter: Qtr 1

Budget Category	Approved Budget	Amount Allocated per Qtr	Percentage of Deliverable Provided	Invoiced Amount Jan - March Qtr 1	Percentage of Deliverable Provided	Invoiced Amount Apr - June Qtr 2	Percentage of Deliverable Provided	Invoiced Amount July - Sept Qtr 3	Percentage of Deliverable Provided	Invoiced Amount Oct - Dec Qtr 4	Cumulative Expenses to Date	Unexpended Balance
Attendance WPC Case Conferences			n/a			\$0		\$0		\$0	\$0	-
Percentage of case conference meetings attended and documented for billing cycle												
Documentation of Care Coordination			n/a			\$0		\$0		\$0	\$0	-
Percentage of meetings documented for care coordination during billing cycle												
Documentation of BH Services			n/a			\$0		\$0		\$0	\$0	-
Percentage of services documented during billing cycle												
TOTAL EXPENSES	\$0			\$0								\$0
TOTAL PAYMENT REQUESTED				\$0								

I certify that this claim is in all respects true, correct, supportable by available documentation, and in compliance with all terms/conditions, laws, and regulations governing its payment.

Signature of Authorized Accounting Representative

Date

## FOR COUNTY USE ONLY

I certify that this claim is in all respects true, correct, supportable by available documentation, and in compliance with all terms/conditions, laws, and regulations governing its payment.

Signature of Authorized County of Mendocino Staff

Date

## Attachment 2

## Whole Person Care SUB-CONTRACTOR Audit Checklist

M: MET

PM: PARTIALLY MET

NM: NOT MET

DC: DATE CORRECTED

Measure	M	PM	NM	Explanation or Correction	DC
1. Provide client written information about WPC services at enrollment					
2. Provide client written copy of service plan each time it is updated					
3. Written information is provided at an appropriate literacy level					
4. Written information is available in both Spanish and English					
5. All workforce members who assist in the performance of functions or activities on behalf of DHCS, or access or disclose DHCS PHI/PI, complete information privacy and security training, at least annually					
6. All persons that will be working with DHCS PHI/PI sign a confidentiality statement that includes, 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 DHCS PHI/PI. <u>The statement must be renewed annually</u>					

## Attachment 3

County of Mendocino  
Contract No. 17-14184-ME-23

DOS AGREEMENT # 17-042\*

### **WHOLE PERSON CARE AGREEMENT**

The overarching goal of the Whole Person Care (WPC) Pilot program is the coordination of health, behavioral health, and social services, as applicable, in a patient-centered manner with the goals of improved beneficiary health and wellbeing through more efficient and effective use of resources.

The Department of Health Care Services (DHCS) published a Request for Application (RFA) relating to the WPC Pilot Program on January 13, 2017. County of Mendocino submitted its WPC application (Attachment A), in response to DHCS' RFA on March 1, 2017. DHCS accepted County of Mendocino's WPC application to the RFA on June 12, 2017 with an allocation of (see table below) in federal financial participation available for each calendar year for the WPC pilot beginning in program year one through program year five subject to the signing of this Agreement.

Total Funds PY 1 - PY 5			
PY	Federal Financial Participation	Local Non-federal Funds	Total Funds
PY 1	\$675,295	\$675,295	\$1,350,590
PY 2	\$675,295	\$675,295	\$1,350,590
PY 3	\$1,350,590	\$1,350,590	\$2,701,180
PY 4	\$1,350,590	\$1,350,590	\$2,701,180
PY 5	\$1,350,590	\$1,350,590	\$2,701,180

The parties agree:

**A. That "Section 6: Attestations and Certification" of Attachment A shall be amended and replaced by the following:**

#### **Section 6: Attestations and Certification**

##### **6.1 Attestation**

I certify that, as the representative of the WPC pilot lead entity, I agree to the following conditions:

1. The WPC pilot lead entity will help develop and participate in regular learning collaboratives to share best practices among pilot entities, per STC 119.
2. The intergovernmental transfer (IGT) funds will qualify for federal financial participation per 42 CFR 433, subpart B, and will not be derived from impermissible sources, such as recycled Medicaid payments, federal money excluded from use as a state match, impermissible taxes, and non-bona fide provider-related donations, per STC 126.a. Sources of non-federal funding shall not include provider taxes or donations impermissible under section 1903(w), impermissible intergovernmental transfers from providers, or federal funds

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received from federal programs other than Medicaid (unless expressly authorized by federal statute to be used for claiming purposes, and the federal Medicaid funding is credited to the other federal funding source). For this purpose, federal funds do not include PRIME payments, patient care revenue received as payment for services rendered under programs such as the Designated State Health Programs, Medicare, or Medicaid

3. Within 30 days determining the interim or final payments due based on the mid-year and annual reports, DHCS will issue requests to the WPC pilot for the necessary IGT amounts. The WPC pilot shall make IGT of funds to DHCS in the amount specified within 7 days of receiving the state's request. If the IGTs are made within the requested timeframe, the payment will be paid within 14 days after the transfers are made.
4. This Agreement between DHCS and the WPC pilot lead entity constitutes the agreement that specifies the WPC pilot requirements, including a data sharing agreement, per STC 118. [See Exhibit A "HIPAA Business Associate Addendum (BAA)" of this Application.] The BAA will apply to the transfer and access of Protected Health Information (PHI) and Personal Information (PI) should the need for sharing such data arise. The DHCS BAA applies to any entity that is acting in a business associate capacity as defined by HIPAA specifically for the purpose of the WPC pilot's operation and evaluation.
5. The WPC pilot will report and submit timely and complete data to DHCS in a format specified by the state. Incomplete and/or non-timely data submissions may lead to a financial penalty after multiple occurrences and technical assistance is provided by the state.
6. The WPC pilot shall submit mid-year and annual reports in a manner specified by DHCS and according to the dates outlined in Attachment GG. The WPC pilot payments shall be contingent on whether progress toward the WPC pilot requirements approved in this application has been made.
7. The WPC pilot will meet with evaluators to assess the WPC pilot.
8. Payments for WPC pilots will be contingent on certain deliverables or achievements; payments will not be distributed, or may be recouped, if pilots fail to demonstrate achievement or submission of deliverables. Funding for PY1 will be available for this submitted and approved WPC pilot application and for reporting baseline data; this funding is in support of the initial identification of the target population and other coordination and planning activities that were necessary for the submission of a successful application. Funding for PY2 through PY5 shall be made available based on the activities and interventions described in the approved WPC Pilot application. (STC 126). Federal funding received shall be returned if the WPC pilot, or a component of it as determined by the state, is not subsequently implemented.

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9. If the individual WPC pilot applicant receives its maximum approved pilot year budget funding before the end of the pilot year, the individual WPC pilot will continue to provide WPC pilot services to enrolled WPC pilot participants at levels established in the approved WPC pilot application through the end of the pilot year.
  10. WPC Pilot payments shall not be earned or payable for activities otherwise coverable or directly reimbursable by Medi-Cal.
  11. The WPC lead entity has reviewed and compared the activities in the proposed WPC pilot application to its county's Medi-Cal Targeted Case Management Program (TCM), and has made appropriate adjustments to reduce the request for WPC funds as necessary to ensure that the WPC pilot funding for activities and interactions of their care coordination teams do not duplicate payments under the county's TCM benefit. The WPC lead entity has provided documentation for the adjustment(s) in the approved application which was accepted in accordance with DHCS guidance provided to the lead entity during the DHCS application review process.
  12. The lead entity will respond to general inquiries from the state pertaining to the WPC pilot within one business day after acknowledging receipt, and provide requested information within five business days, unless an alternate timeline is approved or determined necessary by DHCS. DHCS will consider reasonable timelines that will be dependent on the type and severity of the information when making such requests.
  13. The lead entity understands that the state of California must abide by all requirements outlined in the STCs and Attachments GG, HH, and MM. The state may suspend or terminate a WPC pilot if corrective action has been imposed and persistent poor performance continues. Should a WPC pilot be terminated, the state shall provide notice to the pilot and request a close-out plan due to the state within 30 calendar days, unless significant harm to beneficiaries is occurring, in which case the state may request a close-out plan within 10 business days. All state requirements regarding pilot termination can be found in Attachment HH.
- ☒ I hereby certify that all information provided in this application is true and accurate to the best of my knowledge, and that this application has been completed based on a good faith understanding of WPC pilot program participation requirements as specified in the Medi-Cal 2020 waiver STCs, Attachments GG, HH and MM, and the DHCS Frequently Asked Questions document.

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**B. WPC Pilot Program Agreement**

**Notice**

All inquiries and notices relating to this Agreement should be directed to the representatives listed below. Either party may make changes to the information below by giving written notice to the other party. Said changes shall not require an amendment to this Contract.

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The Agreement representatives during the term of this Agreement will be:

Department of Health Care Services	WPC Pilot Lead Entity
Managed Care Quality & Monitoring Division	County of Mendocino
Attention: Bob Baxter	Attention: Tammy Moss Chandler
Telephone: (916) 319-9707	Telephone: (707) 472-2631

As a condition for participation in the WPC Pilot program, the WPC pilot lead entity (referred to as "Contractor" below) agrees to comply with all of the following terms and conditions, and with all of the terms and conditions included on any attachment(s) hereto, which is/are incorporated herein by reference:

1. **Nondiscrimination.** Pursuant to Affordable Care Act section 1557 (42 U.S.C. section 18116), during the performance of this Contract, Contractor shall not, and shall also require and ensure its subcontractors, providers, agents, and employees to not, cause an individual, beneficiary, or applicant to be excluded on the grounds prohibited under Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), or subject to any other applicable State and Federal laws, from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity offered through DHCS.
2. **Term and Termination.** This Agreement will be effective from the date both DHCS and Contractor have executed this Agreement and terminate on June 30, 2021 unless the application is renewed or the WPC Pilot program is extended, or the WPC pilot is terminated in accordance with procedures established pursuant to STC 120 and Attachment HH thereof.
3. **Compliance with Laws and Regulations.** Contractor agrees to, and shall also require and ensure its subcontractors to, comply with all applicable provisions of Chapters 7 and 8 of the Welfare and Institutions Code, and any applicable rules or regulations promulgated by DHCS pursuant to these chapters. Contractor agrees to, and shall also requires its subcontractors to, comply with all federal laws and regulations governing and regulating the Medicaid program.
4. **Fraud and Abuse.** Contractor agrees, and shall also require its subcontractors to agree, that it shall not engage in or commit fraud or abuse. "Fraud" means intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or herself or some other person. "Abuse" means provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care.

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5. **Governing Law.** This Agreement shall be governed by and interpreted in accordance with the laws of the State of California.
6. **Complete Integration.** This Agreement, including any attachments or documents incorporated herein by express reference is intended to be a complete integration and there are no prior or contemporaneous different or additional agreements pertaining to the subject matters of this Agreement.
7. **Amendment.** No alteration or variation of the terms or provisions of this Agreement shall be valid unless made in writing and signed by the parties to this Agreement, and no oral understanding or agreement not set forth in this Agreement, shall be binding on the parties to this Agreement.
8. **Discrepancy or Inconsistency.** If there is a discrepancy or inconsistency in the terms of this Agreement and Attachment A, then this Agreement controls.

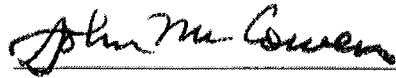
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Signature of WPC Lead Entity Representative

Date 6/21/17

Name: John McCowen

Title: Chairperson, Board of Supervisors

Signature of DHCS Representative

Date

Name: Mari Cantwell

Title: Chief Deputy Director, Health Care Programs

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**Whole Person Care Agreement**

**Exhibit A – Health Insurance Portability and Accountability Act (HIPAA Business Associate Addendum (BAA))**

**I. Recitals**

- A. This Contract (Agreement) has been determined to constitute a business associate relationship under the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act, Public Law 111-005 ("the HITECH Act"), 42 U.S.C. section 17921 et seq., and their implementing privacy and security regulations at 45 CFR Parts 160 and 164 ("the HIPAA regulations").
- B. The Department of Health Care Services ("DHCS") wishes to disclose to Business Associate certain information pursuant to the terms of this Agreement, some of which may constitute Protected Health Information ("PHI"), including protected health information in electronic media ("ePHI"), under federal law, and personal information ("PI") under state law.
- C. As set forth in this Agreement, Contractor, here and after, is the Business Associate of DHCS acting on DHCS' behalf and provides services, arranges, performs or assists in the performance of functions or activities on behalf of DHCS and creates, receives, maintains, transmits, uses or discloses PHI and PI. DHCS and Business Associate are each a party to this Agreement and are collectively referred to as the "parties."
- D. The purpose of this Addendum is to protect the privacy and security of the PHI and PI that may be created, received, maintained, transmitted, used or disclosed pursuant to this Agreement, and to comply with certain standards and requirements of HIPAA, the HITECH Act and the HIPAA regulations, including, but not limited to, the requirement that DHCS must enter into a contract containing specific requirements with Contractor prior to the disclosure of PHI to Contractor, as set forth in 45 CFR Parts 160 and 164 and the HITECH Act, and the Final Omnibus Rule as well as the Alcohol and Drug Abuse patient records confidentiality law 42 CFR Part 2, and any other applicable state or federal law or regulation. 42 CFR section 2.1(b)(2)(B) allows for the disclosure of such records to qualified personnel for the purpose of conducting management or financial audits, or program evaluation. 42 CFR Section 2.53(d) provides that patient identifying information disclosed under this section may be disclosed only back to the program from which it was obtained and used only to carry out an audit or evaluation purpose or to investigate or prosecute criminal or other activities, as authorized by an appropriate court order.

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- E. The terms used in this Addendum, but not otherwise defined, shall have the same meanings as those terms have in the HIPAA regulations. Any reference to statutory or regulatory language shall be to such language as in effect or as amended.

**II. Definitions**

- A. Breach shall have the meaning given to such term under HIPAA, the HITECH Act, the HIPAA regulations, and the Final Omnibus Rule.
- B. Business Associate shall have the meaning given to such term under HIPAA, the HITECH Act, the HIPAA regulations, and the final Omnibus Rule.
- C. Covered Entity shall have the meaning given to such term under HIPAA, the HITECH Act, the HIPAA regulations, and Final Omnibus Rule.
- D. Electronic Health Record shall have the meaning given to such term in the HITECH Act, including, but not limited to, 42 U.S.C Section 17921 and implementing regulations.
- E. Electronic Protected Health Information (ePHI) means individually identifiable health information transmitted by electronic media or maintained in electronic media, including but not limited to electronic media as set forth under 45 CFR section 160.103.
- F. Individually Identifiable Health Information means health information, including demographic information collected from an individual, that is created or received by a health care provider, health plan, employer or health care clearinghouse, and relates to the past, present or future physical or mental health or 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, that identifies the individual or where there is a reasonable basis to believe the information can be used to identify the individual, as set forth under 45 CFR section 160.103.
- G. Privacy Rule shall mean the HIPAA Regulation that is found at 45 CFR Parts 160 and 164.
- H. Personal Information shall have the meaning given to such term in California Civil Code section 1798.29.
- I. Protected Health Information means individually identifiable health information that is transmitted by electronic media, maintained in electronic media, or is transmitted or maintained in any other form or medium, as set forth under 45 CFR section 160.103.

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- J. Required by law, as set forth under 45 CFR section 164.103, means a mandate contained in law that compels an entity to make a use or disclosure of PHI that is enforceable in a court of law. This includes, but is not limited to, court orders and court-ordered warrants, subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information, and a civil or an authorized investigative demand. It also includes Medicare conditions of participation with respect to health care providers participating in the program, and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.
- K. Secretary means the Secretary of the U.S. Department of Health and Human Services ("HHS") or the Secretary's designee.
- L. Security Incident means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of PHI or PI, 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.
- M. Security Rule shall mean the HIPAA regulation that is found at 45 CFR Parts 160 and 164.
- N. Unsecured PHI shall have the meaning given to such term under the HITECH Act, 42 U.S.C. section 17932(h), any guidance issued pursuant to such Act, and the HIPAA regulations.

**III. Terms of Agreement**

**A. Permitted Uses and Disclosures of PHI by Business Associate**

Permitted Uses and Disclosures. Except as otherwise indicated in this Addendum, Business Associate may use or disclose PHI only to perform functions, activities or services specified in this Agreement, for, or on behalf of DHCS, provided that such use or disclosure would not violate the HIPAA regulations, if done by DHCS. Any such use or disclosure must, to the extent practicable, be limited to the limited data set, as defined in 45 CFR section 164.514(e)(2), or, if needed, to the minimum necessary to accomplish the intended purpose of such use or disclosure, in compliance with the HITECH Act and any guidance issued pursuant to such Act, the HIPAA regulations, the Final Omnibus Rule and 42 CFR Part 2.

- 1. Specific Use and Disclosure Provisions. Except as otherwise indicated in this Addendum, Business Associate may:

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- a. Use and disclose for management and administration. Use and disclose PHI for the proper management and administration of the Business Associate provided that such 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.
- b. Provision of Data Aggregation Services. Use PHI to provide data aggregation services to DHCS. Data aggregation means the combining of PHI created or received by the Business Associate on behalf of DHCS 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 DHCS.

**B. Prohibited Uses and Disclosures**

1. Business Associate shall not disclose PHI about an individual to a health plan for payment or health care operations purposes if the PHI pertains solely to a health care item or service for which the health care provider involved has been paid out of pocket in full and the individual requests such restriction, in accordance with 42 U.S.C. section 17935(a) and 45 CFR section 164.522(a).
2. Business Associate shall not directly or indirectly receive remuneration in exchange for PHI, except with the prior written consent of DHCS and as permitted by 42 U.S.C. section 17935(d)(2).

**C. Responsibilities of Business Associate**

Business Associate agrees:

1. Nondisclosure. Not to use or disclose Protected Health Information (PHI) other than as permitted or required by this Agreement or as required by law.
2. 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 DHCS, in compliance with 45 CFR sections 164.308, 164.310 and 164.312, and to prevent use or disclosure of PHI other than as provided for by this Agreement. Business Associate shall implement reasonable and appropriate policies and procedures to comply with the standards, implementation specifications and other requirements of 45 CFR section 164, subpart C, in compliance with 45 CFR section 164.316. Business Associate shall develop and maintain a written information privacy

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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 3, Security, below. Business Associate will provide DHCS with its current and updated policies.

3. Security. To take any and all steps necessary to ensure the continuous security of all computerized data systems containing PHI and/or PI, and to protect paper documents containing PHI and/or PI. These steps shall include, at a minimum:
  - a. Complying with all of the data system security precautions listed in Attachment A, the Business Associate Data Security Requirements;
  - b. Achieving and maintaining compliance with the HIPAA Security Rule (45 CFR Parts 160 and 164), as necessary in conducting operations on behalf of DHCS under this Agreement;
  - c. 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
  - d. 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 PHI from unauthorized disclosure. Further, Business Associate must comply with changes to these standards that occur after the effective date of this Agreement.

Business Associate shall designate a Security Officer to oversee its data security program who shall be responsible for carrying out the requirements of this section and for communicating on security matters with DHCS.

- 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 Addendum.
- E. Business Associate's Agents and Subcontractors.
  1. To enter into written agreements with any agents, including subcontractors and vendors, to whom Business Associate provides PHI or PI received from or created or received by Business Associate on behalf of DHCS, that impose

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the same restrictions and conditions on such agents, subcontractors and vendors that apply to Business Associate with respect to such PHI and PI under this Addendum, and that comply with all applicable provisions of HIPAA, the HITECH Act the HIPAA regulations, and the Final Omnibus Rule, including the requirement that any agents, subcontractors or vendors implement reasonable and appropriate administrative, physical, and technical safeguards to protect such PHI and PI. Business associates are directly liable under the HIPAA Rules and subject to civil and, in some cases, criminal penalties for making uses and disclosures of protected health information that are not authorized by its contract or required by law. A business associate also is directly liable and subject to civil penalties for failing to safeguard electronic protected health information in accordance with the HIPAA Security Rule. A "business associate" also is a subcontractor that creates, receives, maintains, or transmits protected health information on behalf of another business associate. Business Associate shall incorporate, when applicable, the relevant provisions of this Addendum into each subcontract or subaward to such agents, subcontractors and vendors, including the requirement that any security incidents or breaches of unsecured PHI or PI be reported to Business Associate.

2. In accordance with 45 CFR section 164.504(e)(1)(ii), upon Business Associate's knowledge of a material breach or violation by its subcontractor of the agreement between Business Associate and the subcontractor, Business Associate shall:
    - a. Provide an opportunity for the subcontractor to cure the breach or end the violation and terminate the agreement if the subcontractor does not cure the breach or end the violation within the time specified by DHCS; or
    - b. Immediately terminate the agreement if the subcontractor has breached a material term of the agreement and cure is not possible.
- F. Availability of Information to DHCS and Individuals. To provide access and information:
1. To provide access as DHCS may require, and in the time and manner designated by DHCS (upon reasonable notice and during Business Associate's normal business hours) to PHI in a Designated Record Set, to DHCS (or, as directed by DHCS), to an Individual, in accordance with 45 CFR section 164.524. Designated Record Set means the group of records maintained for DHCS that includes medical, dental and billing records about individuals; enrollment, payment, claims adjudication, and case or medical management systems maintained for DHCS health plans; or those records used to make decisions about individuals on behalf of DHCS. Business Associate shall use the forms and processes developed by DHCS for this purpose and shall respond to requests for access to records transmitted by

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DHCS within fifteen (15) calendar days of receipt of the request by producing the records or verifying that there are none.

2. If Business Associate maintains an Electronic Health Record with PHI, and an individual requests a copy of such information in an electronic format, Business Associate shall provide such information in an electronic format to enable DHCS to fulfill its obligations under the HITECH Act, including but not limited to, 42 U.S.C. section 17935(e).
  3. If Business Associate receives data from DHCS that was provided to DHCS by the Social Security Administration, upon request by DHCS, Business Associate shall provide DHCS with a list of all employees, contractors and agents who have access to the Social Security data, including employees, contractors and agents of its subcontractors and agents.
- G. Amendment of PHI. To make any amendment(s) to PHI that DHCS directs or agrees to pursuant to 45 CFR section 164.526, in the time and manner designated by DHCS.
- H. Internal Practices. To make Business Associate's internal practices, books and records relating to the use and disclosure of PHI received from DHCS, or created or received by Business Associate on behalf of DHCS, available to DHCS or to the Secretary of the U.S. Department of Health and Human Services in a time and manner designated by DHCS or by the Secretary, for purposes of determining DHCS' compliance with the HIPAA regulations. If any information needed for this purpose is in the exclusive possession of any other entity or person and the other entity or person fails or refuses to furnish the information to Business Associate, Business Associate shall so certify to DHCS and shall set forth the efforts it made to obtain the information.
- I. Documentation of Disclosures. To document and make available to DHCS or (at the direction of DHCS) 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 the HITECH Act and its implementing regulations, including but not limited to 45 CFR section 164.528 and 42 U.S.C. section 17935(c). If Business Associate maintains electronic health records for DHCS as of January 1, 2009, Business Associate must provide an accounting of disclosures, including those disclosures for treatment, payment or health care operations, effective with disclosures on or after January 1, 2014. If Business Associate acquires electronic health records for DHCS after January 1, 2009, Business Associate must provide an accounting of disclosures, including those disclosures for treatment, payment or health care operations, effective with disclosures on or after the date the electronic health record is acquired, or on or after January 1, 2011, whichever date is later. The

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electronic accounting of disclosures shall be for disclosures during the three years prior to the request for an accounting.

J. Breaches and Security Incidents. During the term of this Agreement, Business Associate agrees to implement reasonable systems for the discovery and prompt reporting of any breach or security incident, and to take the following steps:

1. Notice to DHCS. (1) To notify DHCS immediately upon the discovery of a suspected security incident that involves data provided to DHCS by the Social Security Administration. This notification will be by telephone call plus email or fax upon the discovery of the breach. (2) To notify DHCS within 24 hours by email or fax of the discovery of unsecured PHI or PI in electronic media or in any other media if the PHI or PI was, or is reasonably believed to have been, accessed or acquired by an unauthorized person, any suspected security incident, intrusion or unauthorized access, use or disclosure of PHI or PI in violation of this Agreement and this Addendum, or potential loss of confidential data affecting this Agreement. A breach shall be treated as discovered by Business Associate as of the first day on which the breach is known, or by exercising reasonable diligence would have been known, to any person (other than the person committing the breach) who is an employee, officer or other agent of Business Associate.

Notice shall be provided to the DHCS Program Contract Manager, the DHCS Privacy Officer and the DHCS Information Security Officer. If the incident occurs after business hours or on a weekend or holiday and involves data provided to DHCS by the Social Security Administration, notice shall be provided by calling the DHCS EITS Service Desk. Notice shall be made using the "DHCS Privacy Incident Report" form, including all information known at the time. Business Associate shall use the most current version of this form, which is posted on the DHCS Privacy Office website ([www.dhcs.ca.gov](http://www.dhcs.ca.gov), then select "Privacy" in the left column and then "Business Use" near the middle of the page) or use this link: <http://www.dhcs.ca.gov/formsandpubs/laws/priv/Pages/DHCSBusinessAssociatesOnly.aspx>

Upon discovery of a breach or suspected security incident, intrusion or unauthorized access, use or disclosure of PHI or PI, Business Associate shall take:

- a. Prompt corrective action to mitigate any risks or damages involved with the breach and to protect the operating environment; and
  - b. Any action pertaining to such unauthorized disclosure required by applicable Federal and State laws and regulations.
2. Investigation and Investigation Report. To immediately investigate such security incident, breach, or unauthorized access, use or disclosure of PHI

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or PI. If the initial report did not include all of the requested information marked with an asterisk, then within 72 hours of the discovery, Business Associate shall submit an updated "DHCS Privacy Incident Report" containing the information marked with an asterisk and all other applicable information listed on the form, to the extent known at that time, to the DHCS Program Contract Manager, the DHCS Privacy Officer, and the DHCS Information Security Officer:

3. Complete Report. To provide a complete report of the investigation to the DHCS Program Contract Manager, the DHCS Privacy Officer, and the DHCS Information Security Officer within ten (10) working days of the discovery of the breach or unauthorized use or disclosure. If all of the required information was not included in either the initial report, or the Investigation Report, then a separate Complete Report must be submitted. The report shall be submitted on the "DHCS Privacy Incident Report" form and shall include an assessment of all known factors relevant to a determination of whether a breach occurred under applicable provisions of HIPAA, the HITECH Act, the HIPAA regulations and/or state law. The report shall also include a full, detailed corrective action plan, including information on measures that were taken to halt and/or contain the improper use or disclosure. If DHCS requests information in addition to that listed on the "DHCS Privacy Incident Report" form, Business Associate shall make reasonable efforts to provide DHCS with such information. If necessary, a Supplemental Report may be used to submit revised or additional information after the completed report is submitted, by submitting the revised or additional information on an updated "DHCS Privacy Incident Report" form. DHCS will review and approve or disapprove the determination of whether a breach occurred, is reportable to the appropriate entities, if individual notifications are required, and the corrective action plan.
4. Notification of Individuals. If the cause of a breach of PHI or PI is attributable to Business Associate or its subcontractors, agents or vendors, Business Associate shall notify individuals of the breach or unauthorized use or disclosure when notification is required under state or federal law and shall pay any costs of such notifications, as well as any costs associated with the breach. The notifications shall comply with the requirements set forth in 42 U.S.C. section 17932 and its implementing regulations, including, but not limited to, the requirement that the notifications be made without unreasonable delay and in no event later than 60 calendar days. The DHCS Program Contract Manager, the DHCS Privacy Officer, and the DHCS Information Security Officer shall approve the time, manner and content of any such notifications and their review and approval must be obtained before the notifications are made.

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5. **Responsibility for Reporting of Breaches.** If the cause of a breach of PHI or PI is attributable to Business Associate or its agents, subcontractors or vendors, Business Associate is responsible for all required reporting of the breach as specified in 42 U.S.C. section 17932 and its implementing regulations, including notification to media outlets and to the Secretary. If a breach of unsecured PHI involves more than 500 residents of the State of California or its jurisdiction, Business Associate shall notify the Secretary of the breach immediately upon discovery of the breach. If Business Associate has reason to believe that duplicate reporting of the same breach or incident may occur because its subcontractors, agents or vendors may report the breach or incident to DHCS in addition to Business Associate, Business Associate shall notify DHCS, and DHCS and Business Associate may take appropriate action to prevent duplicate reporting. The breach reporting requirements of this paragraph are in addition to the reporting requirements set forth in subsection 1, above.
6. **DHCS Contact Information.** To direct communications to the above referenced DHCS staff, the Contractor shall initiate contact as indicated herein. DHCS 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 Addendum or the Agreement to which it is incorporated.

DHCS Contract Contact	DHCS Privacy Officer	DHCS Information Security Officer
Chief, Coordinated Care Program Section	Privacy Officer c/o: Office of HIPAA Compliance Department of Health Care Services P.O. Box 997413, MS 4722 Sacramento, CA 95899-7413  Email: <a href="mailto:privacyofficer@dhcs.ca.gov">privacyofficer@dhcs.ca.gov</a>  Telephone: (916) 445-4646  Fax: (916) 440-7680	Information Security Officer DHCS Information Security Office P.O. Box 997413, MS 6400 Sacramento, CA 95899-7413  Email: <a href="mailto:iso@dhcs.ca.gov">iso@dhcs.ca.gov</a> Fax: (916) 440-5537  Telephone: EITS Service Desk (916) 440-7000 or (800) 579-0874

- K. **Termination of Agreement.** In accordance with Section 13404(b) of the HITECH Act and to the extent required by the HIPAA regulations, if Business Associate knows of a material breach or violation by DHCS of this Addendum, it shall take the following steps:

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1. Provide an opportunity for DHCS to cure the breach or end the violation and terminate the Agreement if DHCS does not cure the breach or end the violation within the time specified by Business Associate; or
  2. Immediately terminate the Agreement if DHCS has breached a material term of the Addendum and cure is not possible.
- L. Due Diligence. Business Associate shall exercise due diligence and shall take reasonable steps to ensure that it remains in compliance with this Addendum and is in compliance with applicable provisions of HIPAA, the HITECH Act and the HIPAA regulations, and that its agents, subcontractors and vendors are in compliance with their obligations as required by this Addendum.
- M. Sanctions and/or Penalties. Business Associate understands that a failure to comply with the provisions of HIPAA, the HITECH Act and the HIPAA regulations that are applicable to Business Associate may result in the imposition of sanctions and/or penalties on Business Associate under HIPAA, the HITECH Act and the HIPAA regulations.

#### IV. Obligations of DHCS

DHCS agrees to:

- A. Notice of Privacy Practices. Provide Business Associate with the Notice of Privacy Practices that DHCS produces in accordance with 45 CFR section 164.520, as well as any changes to such notice. Visit the DHCS Privacy Office to view the most current Notice of Privacy Practices at: <http://www.dhcs.ca.gov/formsandpubs/laws/priv/Pages/default.aspx> or the DHCS website at [www.dhcs.ca.gov](http://www.dhcs.ca.gov) (select "Privacy in the left column and "Notice of Privacy Practices" on the right side of the page).
- 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 DHCS has agreed to in accordance with 45 CFR section 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 DHCS.

#### V. Audits, Inspection and Enforcement

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- A. From time to time, DHCS may inspect the facilities, systems, books and records of Business Associate to monitor compliance with this Agreement and this Addendum. Business Associate shall promptly remedy any violation of any provision of this Addendum and shall certify the same to the DHCS Privacy Officer in writing. The fact that DHCS 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 Addendum, nor does DHCS':
1. Failure to detect or
  2. 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 DHCS' enforcement rights under this Agreement and this Addendum.
- B. If Business Associate is the subject of an audit, compliance review, or complaint investigation by the Secretary or the Office of Civil Rights, U.S. Department of Health and Human Services, that is related to the performance of its obligations pursuant to this HIPAA Business Associate Addendum, Business Associate shall notify DHCS and provide DHCS with a copy of any PHI or PI that Business Associate provides to the Secretary or the Office of Civil Rights concurrently with providing such PHI or PI to the Secretary. Business Associate is responsible for any civil penalties assessed due to an audit or investigation of Business Associate, in accordance with 42 U.S.C. section 17934(c).

**VI. Termination**

- A. Term. The Term of this Addendum shall commence as of the effective date of this Addendum and shall extend beyond the termination of the contract and shall terminate when all the PHI provided by DHCS to Business Associate, or created or received by Business Associate on behalf of DHCS, is destroyed or returned to DHCS, in accordance with 45 CFR 164.504(e)(2)(ii)(I).
- B. Termination for Cause. In accordance with 45 CFR section 164.504(e)(1)(ii), upon DHCS' knowledge of a material breach or violation of this Addendum by Business Associate, DHCS 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 DHCS; or
  2. Immediately terminate this Agreement if Business Associate has breached a material term of this Addendum and cure is not possible.

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- C. **Judicial or Administrative Proceedings.** Business Associate will notify DHCS if it is named as a defendant in a criminal proceeding for a violation of HIPAA. DHCS may terminate this Agreement if Business Associate is found guilty of a criminal violation of HIPAA. DHCS 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.
- D. **Effect of Termination.** Upon termination or expiration of this Agreement for any reason, Business Associate shall return or destroy all PHI received from DHCS (or created or received by Business Associate on behalf of DHCS) that Business Associate still maintains in any form, and shall retain no copies of such PHI. If return or destruction is not feasible, Business Associate shall notify DHCS of the conditions that make the return or destruction infeasible, and DHCS and Business Associate shall determine the terms and conditions under which Business Associate may retain the PHI. Business Associate shall continue to extend the protections of this Addendum to such PHI, 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.** DHCS makes no warranty or representation that compliance by Business Associate with this Addendum, 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 Addendum may be required to provide for procedures to ensure compliance with such developments. The parties specifically agree to take such action as is necessary to implement the standards and requirements of HIPAA, the HITECH Act, the HIPAA regulations and other applicable laws relating to the security or privacy of PHI. Upon DHCS' request, Business Associate agrees to promptly enter into negotiations with DHCS concerning an amendment to this Addendum embodying written assurances consistent with the standards and requirements of HIPAA, the HITECH Act, the HIPAA regulations or other applicable laws. DHCS 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 Addendum when requested by DHCS pursuant to this Section; or

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2. Business Associate does not enter into an amendment providing assurances regarding the safeguarding of PHI that DHCS 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 DHCS at no cost to DHCS to testify as witnesses, or otherwise, in the event of litigation or administrative proceedings being commenced against DHCS, 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 Addendum is intended to confer, nor shall anything herein confer, upon any person other than DHCS or Business Associate and their respective successors or assignees, any rights, remedies, obligations or liabilities whatsoever.
- E. Interpretation. The terms and conditions in this Addendum shall be interpreted as broadly as necessary to implement and comply with HIPAA, the HITECH Act, the HIPAA regulations and applicable state laws. The parties agree that any ambiguity in the terms and conditions of this Addendum shall be resolved in favor of a meaning that complies and is consistent with HIPAA, the HITECH Act and the HIPAA regulations.
- F. Regulatory References. A reference in the terms and conditions of this Addendum 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 VI.D of this Addendum 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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**HIPAA BAA  
Attachment A  
Business Associate Data Security Requirements**

**I. Personnel Controls**

- A. **Employee Training.** All workforce members who assist in the performance of functions or activities on behalf of DHCS, or access or disclose DHCS PHI or PI must complete information privacy and security training, at least annually, at Business Associate's expense. Each workforce member who receives information privacy and security training must sign a certification, indicating the member's name and the date on which the training was completed. These certifications must be retained for a period of six (6) years following contract termination.
- B. **Employee Discipline.** Appropriate sanctions must be applied against workforce members who fail to comply with privacy policies and procedures or any provisions of these requirements, including termination of employment where appropriate.
- C. **Confidentiality Statement.** All persons that will be working with DHCS PHI or PI must sign a confidentiality statement that includes, 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 DHCS PHI or PI. The statement must be renewed annually. The Contractor shall retain each person's written confidentiality statement for DHCS inspection for a period of six (6) years following contract termination.
- D. **Background Check.** Before a member of the workforce may access DHCS PHI or PI, a thorough background check of that worker must be conducted, with evaluation of the results to assure that there is no indication that the worker may present a risk to the security or integrity of confidential data or a risk for theft or misuse of confidential data. The Contractor shall retain each workforce member's background check documentation for a period of three (3) years following contract termination.

**II. Technical Security Controls**

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

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- B. **Server Security.** Servers containing unencrypted DHCS PHI or PI must have sufficient administrative, physical, and technical controls in place to protect that data, based upon a risk assessment/system security review.
- C. **Minimum Necessary.** Only the minimum necessary amount of DHCS PHI or PI required to perform necessary business functions may be copied, downloaded, or exported.
- D. **Removable media devices.** All electronic files that contain DHCS PHI or PI data must be encrypted when stored on any removable media or portable device (i.e. USB thumb drives, floppies, CD/DVD, smartphones, backup tapes etc.). Encryption must be a FIPS 140-2 certified algorithm which is 128bit or higher, such as AES.
- E. **Antivirus software.** All workstations, laptops and other systems that process and/or store DHCS PHI or PI must install and actively use comprehensive anti-virus software solution with automatic updates scheduled at least daily.
- F. **Patch Management.** All workstations, laptops and other systems that process and/or store DHCS PHI or PI must have critical 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.
- G. **User IDs and Password Controls.** All users must be issued a unique user name for accessing DHCS PHI or PI. Username must be promptly disabled, deleted, or the password changed upon the transfer or termination of an employee with knowledge of the password, at maximum within 24 hours. Passwords are not to be shared. Passwords must be at least eight characters and must be a non-dictionary word. Passwords must not be stored in readable format on the computer. Passwords must be changed every 90 days, preferably every 60 days. Passwords must be changed if revealed or compromised. Passwords 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)
- H. **Data Destruction.** When no longer needed, all DHCS PHI or PI must be cleared, purged, or destroyed consistent with NIST Special Publication 800-88, Guidelines for Media Sanitization such that the PHI or PI cannot be retrieved.

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- I. **System Timeout.** The system providing access to DHCS PHI or PI must provide an automatic timeout, requiring re-authentication of the user session after no more than 20 minutes of inactivity.
- J. **Warning Banners.** All systems providing access to DHCS PHI or PI must display a warning banner stating that data is confidential, systems are logged, and system use is for business purposes only by authorized users. User must be directed to log off the system if they do not agree with these requirements.
- K. **System Logging.** The system must maintain an automated audit trail which can identify the user or system process which initiates a request for DHCS PHI or PI, or which alters DHCS PHI or PI. 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 DHCS PHI or PI is stored in a database, database logging functionality must be enabled. Audit trail data must be archived for at least 3 years after occurrence.
- L. **Access Controls.** The system providing access to DHCS PHI or PI must use role based access controls for all user authentications, enforcing the principle of least privilege.
- M. **Transmission encryption.** All data transmissions of DHCS PHI or PI outside the secure internal network must be encrypted using a FIPS 140-2 certified algorithm which is 128bit or higher, such as AES. Encryption can be end to end at the network level, or the data files containing PHI can be encrypted. This requirement pertains to any type of PHI or PI in motion such as website access, file transfer, and E-Mail.
- N. **Intrusion Detection.** All systems involved in accessing, holding, transporting, and protecting DHCS PHI or PI that are accessible via the Internet must be protected by a comprehensive intrusion detection and prevention solution.

**III. Audit Controls**

- A. **System Security Review.** All systems processing and/or storing DHCS PHI or PI 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 should include vulnerability scanning tools.
- B. **Log Reviews.** All systems processing and/or storing DHCS PHI or PI must have a routine procedure in place to review system logs for unauthorized access.
- C. **Change Control.** All systems processing and/or storing DHCS PHI or PI must have a documented change control procedure that ensures separation of duties and protects the confidentiality, integrity and availability of data.

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**IV. Business Continuity / Disaster Recovery Controls**

- A. **Emergency Mode Operation Plan.** Contractor must establish a documented plan to enable continuation of critical business processes and protection of the security of electronic DHCS PHI or PI 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.
- B. **Data Backup Plan.** Contractor must have established documented procedures to backup DHCS PHI to maintain retrievable exact copies of DHCS PHI or PI. The plan must include a regular schedule for making backups, storing backups offsite, an inventory of backup media, and an estimate of the amount of time needed to restore DHCS PHI or PI should it be lost. At a minimum, the schedule must be a weekly full backup and monthly offsite storage of DHCS data.

**V. Paper Document Controls**

- A. **Supervision of Data.** DHCS PHI or PI 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. DHCS PHI or PI 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 DHCS PHI or PI is contained shall be escorted and DHCS PHI or PI shall be kept out of sight while visitors are in the area.
- C. **Confidential Destruction.** DHCS PHI or PI must be disposed of through confidential means, such as cross cut shredding and pulverizing.
- D. **Removal of Data.** DHCS PHI or PI must not be removed from the premises of the Contractor except with express written permission of DHCS.
- E. **Faxing.** Faxes containing DHCS PHI or PI 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 the fax.
- F. **Mailing.** Mailings of DHCS PHI or PI shall be sealed and secured from damage or inappropriate viewing of PHI or PI to the extent possible. Mailings which include 500 or more individually identifiable records of DHCS PHI or PI in a single package shall be sent using a tracked mailing method which includes verification of delivery and receipt, unless the prior written permission of DHCS to use another method is obtained.

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## Attachment 4

### Title 42: Public Health

#### PART 2—CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

##### Section Contents

##### **Subpart A—Introduction**

- § 2.1 Statutory authority for confidentiality of drug abuse patient records.
- § 2.2 Statutory authority for confidentiality of alcohol abuse patient records.
- § 2.3 Purpose and effect.
- § 2.4 Criminal penalty for violation.
- § 2.5 Reports of violations.

##### **Subpart B—General Provisions**

- § 2.11 Definitions.
- § 2.12 Applicability.
- § 2.13 Confidentiality restrictions.
- § 2.14 Minor patients.
- § 2.15 Incompetent and deceased patients.
- § 2.16 Security for written records.
- § 2.17 Undercover agents and informants.
- § 2.18 Restrictions on the use of identification cards.
- § 2.19 Disposition of records by discontinued programs.
- § 2.20 Relationship to State laws.
- § 2.21 Relationship to Federal statutes protecting research subjects against compulsory disclosure of their identity.
- § 2.22 Notice to patients of Federal confidentiality requirements.
- § 2.23 Patient access and restrictions on use.

##### **Subpart C—Disclosures With Patient's Consent**

- § 2.31 Form of written consent.
- § 2.32 Prohibition on redisclosure.
- § 2.33 Disclosures permitted with written consent.
- § 2.34 Disclosures to prevent multiple enrollments in detoxification and maintenance treatment programs.
- § 2.35 Disclosures to elements of the criminal justice system which have referred patients.

##### **Subpart D—Disclosures Without Patient Consent**

- § 2.51 Medical emergencies.
- § 2.52 Research activities.
- § 2.53 Audit and evaluation activities.

##### **Subpart E—Court Orders Authorizing Disclosure and Use**

- § 2.61 Legal effect of order.
- § 2.62 Order not applicable to records disclosed without consent to researchers, auditors and evaluators.
- § 2.63 Confidential communications.
- § 2.64 Procedures and criteria for orders authorizing disclosures for noncriminal purposes.
- § 2.65 Procedures and criteria for orders authorizing disclosure and use of records to criminally investigate or prosecute patients.

§ 2.66 Procedures and criteria for orders authorizing disclosure and use of records to investigate or prosecute a program or the person holding the records.

§ 2.67 Orders authorizing the use of undercover agents and informants to criminally investigate employees or agents of a program.

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**Authority:** Sec. 408 of Pub. L. 92–255, 86 Stat. 79, as amended by sec. 303 (a), (b) of Pub L. 93–282, 83 Stat. 137, 138; sec. 4(c)(5)(A) of Pub. L. 94–237, 90 Stat. 244; sec. 111(c)(3) of Pub. L. 94–581, 90 Stat. 2852; sec. 509 of Pub. L. 96–88, 93 Stat. 695; sec. 973(d) of Pub. L. 97–35, 95 Stat. 598; and transferred to sec. 527 of the Public Health Service Act by sec. 2(b)(16)(B) of Pub. L. 98–24, 97 Stat. 182 and as amended by sec. 106 of Pub. L. 99–401, 100 Stat. 907 (42 U.S.C. 290ee–3) and sec. 333 of Pub. L. 91–616, 84 Stat. 1853, as amended by sec. 122(a) of Pub. L. 93–282, 88 Stat. 131; and sec. 111(c)(4) of Pub. L. 94–581, 90 Stat. 2852 and transferred to sec. 523 of the Public Health Service Act by sec. 2(b)(13) of Pub. L. 98–24, 97 Stat. 181 and as amended by sec. 106 of Pub. L. 99–401, 100 Stat. 907 (42 U.S.C. 290dd–3), as amended by sec. 131 of Pub. L. 102–321, 106 Stat. 368, (42 U.S.C. 290dd–2).

**Source:** 52 FR 21809, June 9, 1987, unless otherwise noted.

## Subpart A—Introduction

### § 2.1 Statutory authority for confidentiality of drug abuse patient records.

The restrictions of these regulations upon the disclosure and use of drug abuse patient records were initially authorized by section 408 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1175). That section as amended was transferred by Pub. L. 98–24 to section 527 of the Public Health Service Act which is codified at 42 U.S.C. 290ee–3. The amended statutory authority is set forth below:

#### §290ee–3. Confidentiality of patient records.

##### (a) *Disclosure authorization*

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

##### (b) *Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent*

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

*(c) Prohibition against use of record in making criminal charges or investigation of patient*

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

*(d) Continuing prohibition against disclosure irrespective of status as patient*

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

*(e) Armed Forces and Veterans' Administration; interchange of records; report of suspected child abuse and neglect to State or local authorities*

The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

*(f) Penalty for first and subsequent offenses*

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than \$500 in the case of a first offense, and not more than \$5,000 in the case of each subsequent offense.

*(g) Regulations; interagency consultations; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders*

Except as provided in subsection (h) of this section, the Secretary, after consultation with the Administrator of Veterans' Affairs and the heads of other Federal departments and agencies substantially affected thereby, shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(Subsection (h) was superseded by section 111(c)(3) of Pub. L. 94-581. The responsibility of the Administrator of Veterans' Affairs to write regulations to provide for confidentiality of drug abuse patient records under Title 38 was moved from 21 U.S.C. 1175 to 38 U.S.C. 4134.)

§ 2.2 Statutory authority for confidentiality of alcohol abuse patient records.

The restrictions of these regulations upon the disclosure and use of alcohol abuse patient records were initially authorized by section 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4582). The section as amended was transferred by Pub. L. 98–24 to section 523 of the Public Health Service Act which is codified at 42 U.S.C. 290dd–3. The amended statutory authority is set forth below:

§290dd–3. Confidentiality of patient records

*(a) Disclosure authorization*

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to alcoholism or alcohol abuse education, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

*(b) Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent*

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

*(c) Prohibition against use of record in making criminal charges or investigation of patient*

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

*(d) Continuing prohibition against disclosure irrespective of status as patient*

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

*(e) Armed Forces and Veterans' Administration; interchange of record of suspected child abuse and neglect to State or local authorities*

The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

*(f) Penalty for first and subsequent offenses*

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than \$500 in the case of a first offense, and not more than \$5,000 in the case of each subsequent offense.

*(g) Regulations of Secretary; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders*

Except as provided in subsection (h) of this section, the Secretary shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection(b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(Subsection (h) was superseded by section 111(c)(4) of Pub. L. 94-581. The responsibility of the Administrator of Veterans' Affairs to write regulations to provide for confidentiality of alcohol abuse patient records under Title 38 was moved from 42 U.S.C. 4582 to 38 U.S.C. 4134.)

## § 2.3 Purpose and effect.

(a) *Purpose.* Under the statutory provisions quoted in §§2.1 and 2.2, these regulations impose restrictions upon the disclosure and use of alcohol and drug abuse patient records which are maintained in connection with the performance of any federally assisted alcohol and drug abuse program. The regulations specify:

(1) Definitions, applicability, and general restrictions in subpart B (definitions applicable to §2.34 only appear in that section);

(2) Disclosures which may be made with written patient consent and the form of the written consent in subpart C;

(3) Disclosures which may be made without written patient consent or an authorizing court order in subpart D; and

(4) Disclosures and uses of patient records which may be made with an authorizing court order and the procedures and criteria for the entry and scope of those orders in subpart E.

(b) *Effect.* (1) These regulations prohibit the disclosure and use of patient records unless certain circumstances exist. If any circumstances exists under which disclosure is permitted, that circumstance acts to remove the prohibition on disclosure but it does not compel disclosure. Thus, the regulations do not require disclosure under any circumstances.

(2) These regulations are not intended to direct the manner in which substantive functions such as research, treatment, and evaluation are carried out. They are intended to insure that an alcohol or drug abuse patient in a federally assisted alcohol or drug abuse program is not made more vulnerable by reason of the availability of his or her patient record than an individual who has an alcohol or drug problem and who does not seek treatment.

(3) Because there is a criminal penalty (a fine—see 42 U.S.C. 290ee–3(f), 42 U.S.C. 290dd–3(f) and 42 CFR 2.4) for violating the regulations, they are to be construed strictly in favor of the potential violator in the same manner as a criminal statute (see *M. Kraus & Brothers v. United States*, 327 U.S. 614, 621–22, 66 S. Ct. 705, 707–08 (1946)).

#### § 2.4 Criminal penalty for violation.

Under 42 U.S.C. 290ee–3(f) and 42 U.S.C. 290dd–3(f), any person who violates any provision of those statutes or these regulations shall be fined not more than \$500 in the case of a first offense, and not more than \$5,000 in the case of each subsequent offense.

#### § 2.5 Reports of violations.

(a) The report of any violation of these regulations may be directed to the United States Attorney for the judicial district in which the violation occurs.

(b) The report of any violation of these regulations by a methadone program may be directed to the Regional Offices of the Food and Drug Administration.

### Subpart B—General Provisions

#### § 2.11 Definitions.

For purposes of these regulations:

*Alcohol abuse* means the use of an alcoholic beverage which impairs the physical, mental, emotional, or social well-being of the user.

*Drug abuse* means the use of a psychoactive substance for other than medicinal purposes which impairs the physical, mental, emotional, or social well-being of the user.

*Diagnosis* means any reference to an individual's alcohol or drug abuse or to a condition which is identified as having been caused by that abuse which is made for the purpose of treatment or referral for treatment.

*Disclose or disclosure* means a communication of patient identifying information, the affirmative verification of another person's communication of patient identifying information, or the communication of any information from the record of a patient who has been identified.

*Informant* means an individual:

- (a) Who is a patient or employee of a program or who becomes a patient or employee of a program at the request of a law enforcement agency or official: and
- (b) Who at the request of a law enforcement agency or official observes one or more patients or employees of the program for the purpose of reporting the information obtained to the law enforcement agency or official.

*Patient* means any individual who has applied for or been given diagnosis or treatment for alcohol or drug abuse at a federally assisted program and includes any individual who, after arrest on a criminal charge, is identified as an alcohol or drug abuser in order to determine that individual's eligibility to participate in a program.

*Patient identifying information* means the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or by reference to other publicly available information. The term does not include a number assigned to a patient by a program, if that number does not consist of, or contain numbers (such as a social security, or driver's license number) which could be used to identify a patient with reasonable accuracy and speed from sources external to the program.

*Person* means an individual, partnership, corporation, Federal, State or local government agency, or any other legal entity.

*Program* means:

- (a) An individual or entity (other than a general medical care facility) who holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or
- (b) An identified unit within a general medical facility which holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or
- (c) Medical personnel or other staff in a general medical care facility whose primary function is the provision of alcohol or drug abuse diagnosis, treatment or referral for treatment and who are identified as such providers. (See §2.12(e)(1) for examples.)

*Program director* means:

- (a) In the case of a program which is an individual, that individual:
- (b) In the case of a program which is an organization, the individual designated as director, managing director, or otherwise vested with authority to act as chief executive of the organization.

*Qualified service organization* means a person which:

(a) Provides services to a program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, medical, accounting, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy, and

(b) Has entered into a written agreement with a program under which that person:

(1) Acknowledges that in receiving, storing, processing or otherwise dealing with any patient records from the programs, it is fully bound by these regulations; and

(2) If necessary, will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by these regulations.

*Records* means any information, whether recorded or not, relating to a patient received or acquired by a federally assisted alcohol or drug program.

*Third party payer* means a person who pays, or agrees to pay, for diagnosis or treatment furnished to a patient on the basis of a contractual relationship with the patient or a member of his family or on the basis of the patient's eligibility for Federal, State, or local governmental benefits.

*Treatment* means the management and care of a patient suffering from alcohol or drug abuse, a condition which is identified as having been caused by that abuse, or both, in order to reduce or eliminate the adverse effects upon the patient.

*Undercover agent* means an officer of any Federal, State, or local law enforcement agency who enrolls in or becomes an employee of a program for the purpose of investigating a suspected violation of law or who pursues that purpose after enrolling or becoming employed for other purposes.

[52 FR 21809, June 9, 1987, as amended by 60 FR 22297, May 5, 1995]

## § 2.12 Applicability.

(a) *General* —(1) *Restrictions on disclosure*. The restrictions on disclosure in these regulations apply to any information, whether or not recorded, which:

(i) Would identify a patient as an alcohol or drug abuser either directly, by reference to other publicly available information, or through verification of such an identification by another person; and

(ii) Is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972, or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (or if obtained before the pertinent date, is maintained by a federally assisted alcohol or drug abuse program after that date as part of an ongoing treatment episode which

extends past that date) for the purpose of treating alcohol or drug abuse, making a diagnosis for that treatment, or making a referral for that treatment.

(2) *Restriction on use.* The restriction on use of information to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient (42 U.S.C. 290ee–3(c), 42 U.S.C. 290dd–3(c)) applies to any information, whether or not recorded which is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972, or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (or if obtained before the pertinent date, is maintained by a federally assisted alcohol or drug abuse program after that date as part of an ongoing treatment episode which extends past that date), for the purpose of treating alcohol or drug abuse, making a diagnosis for the treatment, or making a referral for the treatment.

(b) *Federal assistance.* An alcohol abuse or drug abuse program is considered to be federally assisted if:

(1) It is conducted in whole or in part, whether directly or by contract or otherwise by any department or agency of the United States (but see paragraphs (c)(1) and (c)(2) of this section relating to the Veterans' Administration and the Armed Forces);

(2) It is being carried out under a license, certification, registration, or other authorization granted by any department or agency of the United States including but not limited to:

(i) Certification of provider status under the Medicare program;

(ii) Authorization to conduct methadone maintenance treatment (see 21 CFR 291.505); or

(iii) Registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of alcohol or drug abuse;

(3) It is supported by funds provided by any department or agency of the United States by being:

(i) A recipient of Federal financial assistance in any form, including financial assistance which does not directly pay for the alcohol or drug abuse diagnosis, treatment, or referral activities; or

(ii) Conducted by a State or local government unit which, through general or special revenue sharing or other forms of assistance, receives Federal funds which could be (but are not necessarily) spent for the alcohol or drug abuse program; or

(4) It is assisted by the Internal Revenue Service of the Department of the Treasury through the allowance of income tax deductions for contributions to the program or through the granting of tax exempt status to the program.

(c) *Exceptions—* (1) *Veterans' Administration.* These regulations do not apply to information on alcohol and drug abuse patients maintained in connection with the Veterans' Administration provisions of hospital care, nursing home care, domiciliary care, and medical services under title 38, United States Code. Those records are governed by 38 U.S.C. 4132 and regulations issued under that authority by the Administrator of Veterans' Affairs.

(2) *Armed Forces.* These regulations apply to any information described in paragraph (a) of this section which was obtained by any component of the Armed Forces during a period when the patient was subject to the Uniform Code of Military Justice except:

- (i) Any interchange of that information within the Armed Forces; and
- (ii) Any interchange of that information between the Armed Forces and those components of the Veterans Administration furnishing health care to veterans.

(3) *Communication within a program or between a program and an entity having direct administrative control over that program.* The restrictions on disclosure in these regulations do not apply to communications of information between or among personnel having a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment of alcohol or drug abuse if the communications are

- (i) Within a program or
- (ii) Between a program and an entity that has direct administrative control over the program.

(4) *Qualified Service Organizations.* The restrictions on disclosure in these regulations do not apply to communications between a program and a qualified service organization of information needed by the organization to provide services to the program.

(5) *Crimes on program premises or against program personnel.* The restrictions on disclosure and use in these regulations do not apply to communications from program personnel to law enforcement officers which—

- (i) Are directly related to a patient's commission of a crime on the premises of the program or against program personnel or to a threat to commit such a crime; and
- (ii) Are limited to the circumstances of the incident, including the patient status of the individual committing or threatening to commit the crime, that individual's name and address, and that individual's last known whereabouts.

(6) *Reports of suspected child abuse and neglect.* The restrictions on disclosure and use in these regulations do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities. However, the restrictions continue to apply to the original alcohol or drug abuse patient records maintained by the program including their disclosure and use for civil or criminal proceedings which may arise out of the report of suspected child abuse and neglect.

(d) *Applicability to recipients of information—* (1) *Restriction on use of information.* The restriction on the use of any information subject to these regulations to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient applies to any person who obtains that information from a federally assisted alcohol or drug abuse program, regardless of the status of the person obtaining the information or of whether the information was obtained in accordance with these regulations. This restriction on use bars, among other things, the introduction of that information as evidence in a criminal proceeding and

any other use of the information to investigate or prosecute a patient with respect to a suspected crime. Information obtained by undercover agents or informants (see §2.17) or through patient access (see §2.23) is subject to the restriction on use.

(2) *Restrictions on disclosures — Third party payers, administrative entities, and others.* The restrictions on disclosure in these regulations apply to:

(i) Third party payers with regard to records disclosed to them by federally assisted alcohol or drug abuse programs;

(ii) Entities having direct administrative control over programs with regard to information communicated to them by the program under §2.12(c)(3); and

(iii) Persons who receive patient records directly from a federally assisted alcohol or drug abuse program and who are notified of the restrictions on redisclosure of the records in accordance with §2.32 of these regulations.

(e) *Explanation of applicability— (1) Coverage.* These regulations cover any information (including information on referral and intake) about alcohol and drug abuse patients obtained by a program (as the terms “patient” and “program” are defined in §2.11) if the program is federally assisted in any manner described in §2.12(b). Coverage includes, but is not limited to, those treatment or rehabilitation programs, employee assistance programs, programs within general hospitals, school-based programs, and private practitioners who hold themselves out as providing, and provide alcohol or drug abuse diagnosis, treatment, or referral for treatment. However, these regulations would not apply, for example, to emergency room personnel who refer a patient to the intensive care unit for an apparent overdose, unless the primary function of such personnel is the provision of alcohol or drug abuse diagnosis, treatment or referral and they are identified as providing such services or the emergency room has promoted itself to the community as a provider of such services.

(2) *Federal assistance to program required.* If a patient's alcohol or drug abuse diagnosis, treatment, or referral for treatment is not provided by a program which is federally conducted, regulated or supported in a manner which constitutes Federal assistance under §2.12(b), that patient's record is not covered by these regulations. Thus, it is possible for an individual patient to benefit from Federal support and not be covered by the confidentiality regulations because the program in which the patient is enrolled is not federally assisted as defined in §2.12(b). For example, if a Federal court placed an individual in a private for-profit program and made a payment to the program on behalf of that individual, that patient's record would not be covered by these regulations unless the program itself received Federal assistance as defined by §2.12(b).

(3) *Information to which restrictions are applicable.* Whether a restriction is on use or disclosure affects the type of information which may be available. The restrictions on disclosure apply to any information which would identify a patient as an alcohol or drug abuser. The restriction on use of information to bring criminal charges against a patient for a crime applies to any information obtained by the program for the purpose of diagnosis, treatment, or referral for treatment of alcohol or drug abuse. (Note that restrictions on use and disclosure apply to recipients of information under §2.12(d).)

(4) *How type of diagnosis affects coverage.* These regulations cover any record of a diagnosis identifying a patient as an alcohol or drug abuser which is prepared in connection with the treatment or referral for treatment of alcohol or drug abuse. A diagnosis prepared for the purpose of treatment or referral for treatment but which is not so used is covered by these regulations. The following are not covered by these regulations:

(i) Diagnosis which is made solely for the purpose of providing evidence for use by law enforcement authorities; or

(ii) A diagnosis of drug overdose or alcohol intoxication which clearly shows that the individual involved is not an alcohol or drug abuser (e.g., involuntary ingestion of alcohol or drugs or reaction to a prescribed dosage of one or more drugs).

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987, as amended at 60 FR 22297, May 5, 1995]

#### § 2.13 Confidentiality restrictions.

(a) *General.* The patient records to which these regulations apply may be disclosed or used only as permitted by these regulations and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any Federal, State, or local authority. Any disclosure made under these regulations must be limited to that information which is necessary to carry out the purpose of the disclosure.

(b) *Unconditional compliance required.* The restrictions on disclosure and use in these regulations apply whether the holder of the information believes that the person seeking the information already has it, has other means of obtaining it, is a law enforcement or other official, has obtained a subpoena, or asserts any other justification for a disclosure or use which is not permitted by these regulations.

(c) *Acknowledging the presence of patients: Responding to requests.* (1) The presence of an identified patient in a facility or component of a facility which is publicly identified as a place where only alcohol or drug abuse diagnosis, treatment, or referral is provided may be acknowledged only if the patient's written consent is obtained in accordance with subpart C of these regulations or if an authorizing court order is entered in accordance with subpart E of these regulations. The regulations permit acknowledgement of the presence of an identified patient in a facility or part of a facility if the facility is not publicly identified as only an alcohol or drug abuse diagnosis, treatment or referral facility, and if the acknowledgement does not reveal that the patient is an alcohol or drug abuser.

(2) Any answer to a request for a disclosure of patient records which is not permissible under these regulations must be made in a way that will not affirmatively reveal that an identified individual has been, or is being diagnosed or treated for alcohol or drug abuse. An inquiring party may be given a copy of these regulations and advised that they restrict the disclosure of alcohol or drug abuse patient records, but may not be told affirmatively that the regulations restrict the disclosure of the records of an identified patient. The regulations do not restrict a disclosure that an identified individual is not and never has been a patient.

§ 2.14 Minor patients.

(a) *Definition of minor.* As used in these regulations the term “minor” means a person who has not attained the age of majority specified in the applicable State law, or if no age of majority is specified in the applicable State law, the age of eighteen years.

(b) *State law not requiring parental consent to treatment.* If a minor patient acting alone has the legal capacity under the applicable State law to apply for and obtain alcohol or drug abuse treatment, any written consent for disclosure authorized under subpart C of these regulations may be given only by the minor patient. This restriction includes, but is not limited to, any disclosure of patient identifying information to the parent or guardian of a minor patient for the purpose of obtaining financial reimbursement. These regulations do not prohibit a program from refusing to provide treatment until the minor patient consents to the disclosure necessary to obtain reimbursement, but refusal to provide treatment may be prohibited under a State or local law requiring the program to furnish the service irrespective of ability to pay.

(c) *State law requiring parental consent to treatment.* (1) Where State law requires consent of a parent, guardian, or other person for a minor to obtain alcohol or drug abuse treatment, any written consent for disclosure authorized under subpart C of these regulations must be given by both the minor and his or her parent, guardian, or other person authorized under State law to act in the minor's behalf.

(2) Where State law requires parental consent to treatment the fact of a minor's application for treatment may be communicated to the minor's parent, guardian, or other person authorized under State law to act in the minor's behalf only if:

(i) The minor has given written consent to the disclosure in accordance with subpart C of these regulations or

(ii) The minor lacks the capacity to make a rational choice regarding such consent as judged by the program director under paragraph (d) of this section.

(d) *Minor applicant for services lacks capacity for rational choice.* Facts relevant to reducing a threat to the life or physical well being of the applicant or any other individual may be disclosed to the parent, guardian, or other person authorized under State law to act in the minor's behalf if the program director judges that:

(1) A minor applicant for services lacks capacity because of extreme youth or mental or physical condition to make a rational decision on whether to consent to a disclosure under subpart C of these regulations to his or her parent, guardian, or other person authorized under State law to act in the minor's behalf, and

(2) The applicant's situation poses a substantial threat to the life or physical well being of the applicant or any other individual which may be reduced by communicating relevant facts to the minor's parent, guardian, or other person authorized under State law to act in the minor's behalf.

§ 2.15 Incompetent and deceased patients.

(a) *Incompetent patients other than minors* —(1) *Adjudication of incompetence*. In the case of a patient who has been adjudicated as lacking the capacity, for any reason other than insufficient age, to manage his or her own affairs, any consent which is required under these regulations may be given by the guardian or other person authorized under State law to act in the patient's behalf.

(2) *No adjudication of incompetency*. For any period for which the program director determines that a patient, other than a minor or one who has been adjudicated incompetent, suffers from a medical condition that prevents knowing or effective action on his or her own behalf, the program director may exercise the right of the patient to consent to a disclosure under subpart C of these regulations for the sole purpose of obtaining payment for services from a third party payer.

(b) *Deceased patients* —(1) *Vital statistics*. These regulations do not restrict the disclosure of patient identifying information relating to the cause of death of a patient under laws requiring the collection of death or other vital statistics or permitting inquiry into the cause of death.

(2) *Consent by personal representative*. Any other disclosure of information identifying a deceased patient as an alcohol or drug abuser is subject to these regulations. If a written consent to the disclosure is required, that consent may be given by an executor, administrator, or other personal representative appointed under applicable State law. If there is no such appointment the consent may be given by the patient's spouse or, if none, by any responsible member of the patient's family.

§ 2.16 Security for written records.

(a) Written records which are subject to these regulations must be maintained in a secure room, locked file cabinet, safe or other similar container when not in use; and

(b) Each program shall adopt in writing procedures which regulate and control access to and use of written records which are subject to these regulations.

§ 2.17 Undercover agents and informants.

(a) *Restrictions on placement*. Except as specifically authorized by a court order granted under §2.67 of these regulations, no program may knowingly employ, or enroll as a patient, any undercover agent or informant.

(b) *Restriction on use of information*. No information obtained by an undercover agent or informant, whether or not that undercover agent or informant is placed in a program pursuant to an authorizing court order, may be used to criminally investigate or prosecute any patient.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§ 2.18 Restrictions on the use of identification cards.

No person may require any patient to carry on his or her person while away from the program premises any card or other object which would identify the patient as an alcohol or drug abuser. This section does not prohibit a person from requiring patients to use or carry cards or other identification objects on the premises of a program.

§ 2.19 Disposition of records by discontinued programs.

(a) *General.* If a program discontinues operations or is taken over or acquired by another program, it must purge patient identifying information from its records or destroy the records unless—

(1) The patient who is the subject of the records gives written consent (meeting the requirements of §2.31) to a transfer of the records to the acquiring program or to any other program designated in the consent (the manner of obtaining this consent must minimize the likelihood of a disclosure of patient identifying information to a third party); or

(2) There is a legal requirement that the records be kept for a period specified by law which does not expire until after the discontinuation or acquisition of the program.

(b) *Procedure where retention period required by law.* If paragraph (a)(2) of this section applies, the records must be:

(1) Sealed in envelopes or other containers labeled as follows: “Records of [insert name of program] required to be maintained under [insert citation to statute, regulation, court order or other legal authority requiring that records be kept] until a date not later than [insert appropriate date]”; and

(2) Held under the restrictions of these regulations by a responsible person who must, as soon as practicable after the end of the retention period specified on the label, destroy the records.

§ 2.20 Relationship to State laws.

The statutes authorizing these regulations (42 U.S.C. 290ee–3 and 42 U.S.C. 290dd–3) do not preempt the field of law which they cover to the exclusion of all State laws in that field. If a disclosure permitted under these regulations is prohibited under State law, neither these regulations nor the authorizing statutes may be construed to authorize any violation of that State law. However, no State law may either authorize or compel any disclosure prohibited by these regulations.

§ 2.21 Relationship to Federal statutes protecting research subjects against compulsory disclosure of their identity

(a) *Research privilege description.* There may be concurrent coverage of patient identifying information by these regulations and by administrative action taken under: Section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a) and the implementing regulations at 42 CFR part

2a); or section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c) and the implementing regulations at 21 CFR 1316.21). These “research privilege” statutes confer on the Secretary of Health and Human Services and on the Attorney General, respectively, the power to authorize researchers conducting certain types of research to withhold from all persons not connected with the research the names and other identifying information concerning individuals who are the subjects of the research.

(b) *Effect of concurrent coverage.* These regulations restrict the disclosure and use of information about patients, while administrative action taken under the research privilege statutes and implementing regulations protects a person engaged in applicable research from being compelled to disclose any identifying characteristics of the individuals who are the subjects of that research. The issuance under subpart E of these regulations of a court order authorizing a disclosure of information about a patient does not affect an exercise of authority under these research privilege statutes. However, the research privilege granted under 21 CFR 291.505(g) to treatment programs using methadone for maintenance treatment does not protect from compulsory disclosure any information which is permitted to be disclosed under those regulations. Thus, if a court order entered in accordance with subpart E of these regulations authorizes a methadone maintenance treatment program to disclose certain information about its patients, that program may not invoke the research privilege under 21 CFR 291.505(g) as a defense to a subpoena for that information.

#### § 2.22 Notice to patients of Federal confidentiality requirements.

(a) *Notice required.* At the time of admission or as soon thereafter as the patient is capable of rational communication, each program shall:

(1) Communicate to the patient that Federal law and regulations protect the confidentiality of alcohol and drug abuse patient records; and

(2) Give to the patient a summary in writing of the Federal law and regulations.

(b) *Required elements of written summary.* The written summary of the Federal law and regulations must include:

(1) A general description of the limited circumstances under which a program may acknowledge that an individual is present at a facility or disclose outside the program information identifying a patient as an alcohol or drug abuser.

(2) A statement that violation of the Federal law and regulations by a program is a crime and that suspected violations may be reported to appropriate authorities in accordance with these regulations.

(3) A statement that information related to a patient's commission of a crime on the premises of the program or against personnel of the program is not protected.

(4) A statement that reports of suspected child abuse and neglect made under State law to appropriate State or local authorities are not protected.

(5) A citation to the Federal law and regulations.

(c) *Program options.* The program may devise its own notice or may use the sample notice in paragraph (d) to comply with the requirement to provide the patient with a summary in writing of the Federal law and regulations. In addition, the program may include in the written summary information concerning State law and any program policy not inconsistent with State and Federal law on the subject of confidentiality of alcohol and drug abuse patient records.

(d) *Sample notice.*

#### Confidentiality of Alcohol and Drug Abuse Patient Records

The confidentiality of alcohol and drug abuse patient records maintained by this program is protected by Federal law and regulations. Generally, the program may not say to a person outside the program that a patient attends the program, or disclose any information identifying a patient as an alcohol or drug abuser *Unless:*

(1) The patient consents in writing;

(2) The disclosure is allowed by a court order; or

(3) The disclosure is made to medical personnel in a medical emergency or to qualified personnel for research, audit, or program evaluation.

Violation of the Federal law and regulations by a program is a crime. Suspected violations may be reported to appropriate authorities in accordance with Federal regulations.

Federal law and regulations do not protect any information about a crime committed by a patient either at the program or against any person who works for the program or about any threat to commit such a crime.

Federal laws and regulations do not protect any information about suspected child abuse or neglect from being reported under State law to appropriate State or local authorities.

(See 42 U.S.C. 290dd-3 and 42 U.S.C. 290ee-3 for Federal laws and 42 CFR part 2 for Federal regulations.)

(Approved by the Office of Management and Budget under control number 0930-0099)

#### § 2.23 Patient access and restrictions on use.

(a) *Patient access not prohibited.* These regulations do not prohibit a program from giving a patient access to his or her own records, including the opportunity to inspect and copy any records that the program maintains about the patient. The program is not required to obtain a patient's written consent or other authorization under these regulations in order to provide such access to the patient.

(b) *Restriction on use of information.* Information obtained by patient access to his or her patient record is subject to the restriction on use of his information to initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation of the patient as provided for under §2.12(d)(1).

Subpart C—Disclosures With Patient's Consent

§ 2.31 Form of written consent.

(a) *Required elements.* A written consent to a disclosure under these regulations must include:

(1) The specific name or general designation of the program or person permitted to make the disclosure.

(2) The name or title of the individual or the name of the organization to which disclosure is to be made.

(3) The name of the patient.

(4) The purpose of the disclosure.

(5) How much and what kind of information is to be disclosed.

(6) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under §2.14; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign under §2.15 in lieu of the patient.

(7) The date on which the consent is signed.

(8) A statement that the consent is subject to revocation at any time except to the extent that the program or person which is to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third party payer.

(9) The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

(b) *Sample consent form.* The following form complies with paragraph (a) of this section, but other elements may be added.

1. I (name of patient) ☐ Request ☐ Authorize:

2. (name or general designation of program which is to make the disclosure)

\_\_\_\_\_

3. To disclose: (kind and amount of information to be disclosed)

\_\_\_\_\_

4. To: (name or title of the person or organization to which disclosure is to be made)

\_\_\_\_\_  
5. For (purpose of the disclosure)

\_\_\_\_\_  
6. Date (on which this consent is signed)

\_\_\_\_\_  
7. Signature of patient

\_\_\_\_\_  
8. Signature of parent or guardian (where required)

\_\_\_\_\_  
9. Signature of person authorized to sign in lieu of the patient (where required)

\_\_\_\_\_  
10. This consent is subject to revocation at any time except to the extent that the program which is to make the disclosure has already taken action in reliance on it. If not previously revoked, this consent will terminate upon: (specific date, event, or condition)

(c) *Expired, deficient, or false consent.* A disclosure may not be made on the basis of a consent which:

(1) Has expired;

(2) On its face substantially fails to conform to any of the requirements set forth in paragraph (a) of this section;

(3) Is known to have been revoked; or

(4) Is known, or through a reasonable effort could be known, by the person holding the records to be materially false.

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§ 2.32 Prohibition on redisclosure.

*Notice to accompany disclosure.* Each disclosure made with the patient's written consent must be accompanied by the following written statement:

This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

[52 FR 21809, June 9, 1987; 52 FR 41997, Nov. 2, 1987]

§ 2.33 Disclosures permitted with written consent.

If a patient consents to a disclosure of his or her records under §2.31, a program may disclose those records in accordance with that consent to any individual or organization named in the consent, except that disclosures to central registries and in connection with criminal justice referrals must meet the requirements of §§2.34 and 2.35, respectively.

§ 2.34 Disclosures to prevent multiple enrollments in detoxification and maintenance treatment programs

(a) *Definitions.* For purposes of this section:

*Central registry* means an organization which obtains from two or more member programs patient identifying information about individuals applying for maintenance treatment or detoxification treatment for the purpose of avoiding an individual's concurrent enrollment in more than one program.

*Detoxification treatment* means the dispensing of a narcotic drug in decreasing doses to an individual in order to reduce or eliminate adverse physiological or psychological effects incident to withdrawal from the sustained use of a narcotic drug.

*Maintenance treatment* means the dispensing of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

*Member program* means a detoxification treatment or maintenance treatment program which reports patient identifying information to a central registry and which is in the same State as that central registry or is not more than 125 miles from any border of the State in which the central registry is located.

(b) *Restrictions on disclosure.* A program may disclose patient records to a central registry or to any detoxification or maintenance treatment program not more than 200 miles away for the purpose of preventing the multiple enrollment of a patient only if:

(1) The disclosure is made when:

- (i) The patient is accepted for treatment;
- (ii) The type or dosage of the drug is changed; or
- (iii) The treatment is interrupted, resumed or terminated.

(2) The disclosure is limited to:

- (i) Patient identifying information;

(ii) Type and dosage of the drug; and

(iii) Relevant dates.

(3) The disclosure is made with the patient's written consent meeting the requirements of §2.31, except that:

(i) The consent must list the name and address of each central registry and each known detoxification or maintenance treatment program to which a disclosure will be made; and

(ii) The consent may authorize a disclosure to any detoxification or maintenance treatment program established within 200 miles of the program after the consent is given without naming any such program.

(c) *Use of information limited to prevention of multiple enrollments.* A central registry and any detoxification or maintenance treatment program to which information is disclosed to prevent multiple enrollments may not redisclose or use patient identifying information for any purpose other than the prevention of multiple enrollments unless authorized by a court order under subpart E of these regulations.

(d) *Permitted disclosure by a central registry to prevent a multiple enrollment.* When a member program asks a central registry if an identified patient is enrolled in another member program and the registry determines that the patient is so enrolled, the registry may disclose—

(1) The name, address, and telephone number of the member program(s) in which the patient is already enrolled to the inquiring member program; and

(2) The name, address, and telephone number of the inquiring member program to the member program(s) in which the patient is already enrolled. The member programs may communicate as necessary to verify that no error has been made and to prevent or eliminate any multiple enrollment.

(e) *Permitted disclosure by a detoxification or maintenance treatment program to prevent a multiple enrollment.* A detoxification or maintenance treatment program which has received a disclosure under this section and has determined that the patient is already enrolled may communicate as necessary with the program making the disclosure to verify that no error has been made and to prevent or eliminate any multiple enrollment.

§ 2.35 Disclosures to elements of the criminal justice system which have referred patients.

(a) A program may disclose information about a patient to those persons within the criminal justice system which have made participation in the program a condition of the disposition of any criminal proceedings against the patient or of the patient's parole or other release from custody if:

(1) The disclosure is made only to those individuals within the criminal justice system who have a need for the information in connection with their duty to monitor the patient's progress (e.g., a

prosecuting attorney who is withholding charges against the patient, a court granting pretrial or post trial release, probation or parole officers responsible for supervision of the patient); and

(2) The patient has signed a written consent meeting the requirements of §2.31 (except paragraph (a)(8) which is inconsistent with the revocation provisions of paragraph (c) of this section) and the requirements of paragraphs (b) and (c) of this section.

(b) *Duration of consent.* The written consent must state the period during which it remains in effect. This period must be reasonable, taking into account:

(1) The anticipated length of the treatment;

(2) The type of criminal proceeding involved, the need for the information in connection with the final disposition of that proceeding, and when the final disposition will occur; and

(3) Such other factors as the program, the patient, and the person(s) who will receive the disclosure consider pertinent.

(c) *Revocation of consent.* The written consent must state that it is revocable upon the passage of a specified amount of time or the occurrence of a specified, ascertainable event. The time or occurrence upon which consent becomes revocable may be no later than the final disposition of the conditional release or other action in connection with which consent was given.

(d) *Restrictions on redisclosure and use.* A person who receives patient information under this section may redisclose and use it only to carry out that person's official duties with regard to the patient's conditional release or other action in connection with which the consent was given.

#### Subpart D—Disclosures Without Patient Consent

##### § 2.51 Medical emergencies.

(a) *General Rule.* Under the procedures required by paragraph (c) of this section, patient identifying information may be disclosed to medical personnel who have a need for information about a patient for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention.

(b) *Special Rule.* Patient identifying information may be disclosed to medical personnel of the Food and Drug Administration (FDA) who assert a reason to believe that the health of any individual may be threatened by an error in the manufacture, labeling, or sale of a product under FDA jurisdiction, and that the information will be used for the exclusive purpose of notifying patients or their physicians of potential dangers.

(c) *Procedures.* Immediately following disclosure, the program shall document the disclosure in the patient's records, setting forth in writing:

(1) The name of the medical personnel to whom disclosure was made and their affiliation with any health care facility;

- (2) The name of the individual making the disclosure;
- (3) The date and time of the disclosure; and
- (4) The nature of the emergency (or error, if the report was to FDA).

(Approved by the Office of Management and Budget under control number 0930-0099)

§ 2.52 Research activities

(a) Patient identifying information may be disclosed for the purpose of conducting scientific research if the program director makes a determination that the recipient of the patient identifying information:

- (1) Is qualified to conduct the research;
- (2) Has a research protocol under which the patient identifying information:
  - (i) Will be maintained in accordance with the security requirements of §2.16 of these regulations (or more stringent requirements); and
  - (ii) Will not be redisclosed except as permitted under paragraph (b) of this section; and
- (3) Has provided a satisfactory written statement that a group of three or more individuals who are independent of the research project has reviewed the protocol and determined that:
  - (i) The rights and welfare of patients will be adequately protected; and
  - (ii) The risks in disclosing patient identifying information are outweighed by the potential benefits of the research.

(b) A person conducting research may disclose patient identifying information obtained under paragraph (a) of this section only back to the program from which that information was obtained and may not identify any individual patient in any report of that research or otherwise disclose patient identities.

[52 FR 21809, June 9, 1987, as amended at 52 FR 41997, Nov. 2, 1987]

§ 2.53 Audit and evaluation activities

(a) *Records not copied or removed.* If patient records are not copied or removed, patient identifying information may be disclosed in the course of a review of records on program premises to any person who agrees in writing to comply with the limitations on redisclosure and use in paragraph (d) of this section and who:

- (1) Performs the audit or evaluation activity on behalf of:

(i) Any Federal, State, or local governmental agency which provides financial assistance to the program or is authorized by law to regulate its activities; or

(ii) Any private person which provides financial assistance to the program, which is a third party payer covering patients in the program, or which is a quality improvement organization performing a utilization or quality control review; or

(2) Is determined by the program director to be qualified to conduct the audit or evaluation activities.

(b) *Copying or removal of records.* Records containing patient identifying information may be copied or removed from program premises by any person who:

(1) Agrees in writing to:

(i) Maintain the patient identifying information in accordance with the security requirements provided in §2.16 of these regulations (or more stringent requirements);

(ii) Destroy all the patient identifying information upon completion of the audit or evaluation; and

(iii) Comply with the limitations on disclosure and use in paragraph (d) of this section; and

(2) Performs the audit or evaluation activity on behalf of:

(i) Any Federal, State, or local governmental agency which provides financial assistance to the program or is authorized by law to regulate its activities; or

(ii) Any private person which provides financial assistance to the program, which is a third part payer covering patients in the program, or which is a quality improvement organization performing a utilization or quality control review.

(c) *Medicare or Medicaid audit or evaluation.* (1) For purposes of Medicare or Medicaid audit or evaluation under this section, audit or evaluation includes a civil or administrative investigation of the program by any Federal, State, or local agency responsible for oversight of the Medicare or Medicaid program and includes administrative enforcement, against the program by the agency, of any remedy authorized by law to be imposed as a result of the findings of the investigation.

(2) Consistent with the definition of program in §2.11, program includes an employee of, or provider of medical services under, the program when the employee or provider is the subject of a civil investigation or administrative remedy, as those terms are used in paragraph (c)(1) of this section.

(3) If a disclosure to a person is authorized under this section for a Medicare or Medicaid audit or evaluation, including a civil investigation or administrative remedy, as those terms are used in paragraph (c)(1) of this section, then a quality improvement organization which obtains the

information under paragraph (a) or (b) may disclose the information to that person but only for purposes of Medicare or Medicaid audit or evaluation.

(4) The provisions of this paragraph do not authorize the agency, the program, or any other person to disclose or use patient identifying information obtained during the audit or evaluation for any purposes other than those necessary to complete the Medicare or Medicaid audit or evaluation activity as specified in this paragraph.

(d) *Limitations on disclosure and use.* Except as provided in paragraph (c) of this section, patient identifying information disclosed under this section may be disclosed only back to the program from which it was obtained and used only to carry out an audit or evaluation purpose or to investigate or prosecute criminal or other activities, as authorized by a court order entered under §2.66 of these regulations.

#### Subpart E—Court Orders Authorizing Disclosure and Use

##### § 2.61 Legal effect of order

(a) *Effect.* An order of a court of competent jurisdiction entered under this subpart is a unique kind of court order. Its only purpose is to authorize a disclosure or use of patient information which would otherwise be prohibited by 42 U.S.C. 290ee-3, 42 U.S.C. 290dd-3 and these regulations. Such an order does not compel disclosure. A subpoena or a similar legal mandate must be issued in order to compel disclosure. This mandate may be entered at the same time as and accompany an authorizing court order entered under these regulations.

(b) *Examples.* (1) A person holding records subject to these regulations receives a subpoena for those records: a response to the subpoena is not permitted under the regulations unless an authorizing court order is entered. The person may not disclose the records in response to the subpoena unless a court of competent jurisdiction enters an authorizing order under these regulations.

(2) An authorizing court order is entered under these regulations, but the person authorized does not want to make the disclosure. If there is no subpoena or other compulsory process or a subpoena for the records has expired or been quashed, that person may refuse to make the disclosure. Upon the entry of a valid subpoena or other compulsory process the person authorized to disclose must disclose, unless there is a valid legal defense to the process other than the confidentiality restrictions of these regulations.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§ 2.62 Order not applicable to records disclosed without consent to researchers, auditors and evaluators.

A court order under these regulations may not authorize qualified personnel, who have received patient identifying information without consent for the purpose of conducting research, audit or evaluation, to disclose that information or use it to conduct any criminal investigation or prosecution of a patient. However, a court order under §2.66 may authorize disclosure and use of records to investigate or prosecute qualified personnel holding the records.

§ 2.63 Confidential communications.

(a) A court order under these regulations may authorize disclosure of confidential communications made by a patient to a program in the course of diagnosis, treatment, or referral for treatment only if:

- (1) The disclosure is necessary to protect against an existing threat to life or of serious bodily injury, including circumstances which constitute suspected child abuse and neglect and verbal threats against third parties;
- (2) The disclosure is necessary in connection with investigation or prosecution of an extremely serious crime, such as one which directly threatens loss of life or serious bodily injury, including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect; or
- (3) The disclosure is in connection with litigation or an administrative proceeding in which the patient offers testimony or other evidence pertaining to the content of the confidential communications.

(b) [Reserved]

§ 2.64 Procedures and criteria for orders authorizing disclosures for noncriminal purposes

(a) *Application.* An order authorizing the disclosure of patient records for purposes other than criminal investigation or prosecution may be applied for by any person having a legally recognized interest in the disclosure which is sought. The application may be filed separately or as part of a pending civil action in which it appears that the patient records are needed to provide evidence. An application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the patient is the applicant or has given a written consent (meeting the requirements of these regulations) to disclosure or the court has ordered the record of the proceeding sealed from public scrutiny.

(b) *Notice.* The patient and the person holding the records from whom disclosure is sought must be given:

- (1) Adequate notice in a manner which will not disclose patient identifying information to other persons; and
- (2) An opportunity to file a written response to the application, or to appear in person, for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order.

(c) *Review of evidence: Conduct of hearing.* Any oral argument, review of evidence, or hearing on the application must be held in the judge's chambers or in some manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceeding, the patient, or the person holding the record, unless the patient requests an open hearing in a

manner which meets the written consent requirements of these regulations. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria for entry of order.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find that:

- (1) Other ways of obtaining the information are not available or would not be effective; and
- (2) The public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services.

(e) *Content of order.* An order authorizing a disclosure must:

- (1) Limit disclosure to those parts of the patient's record which are essential to fulfill the objective of the order;
- (2) Limit disclosure to those persons whose need for information is the basis for the order; and
- (3) Include such other measures as are necessary to limit disclosure for the protection of the patient, the physician-patient relationship and the treatment services; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

§ 2.65 Procedures and criteria for orders authorizing disclosure and use of records to criminally investigate or prosecute patients.

(a) *Application.* An order authorizing the disclosure or use of patient records to criminally investigate or prosecute a patient may be applied for by the person holding the records or by any person conducting investigative or prosecutorial activities with respect to the enforcement of criminal laws. The application may be filed separately, as part of an application for a subpoena or other compulsory process, or in a pending criminal action. An application must use a fictitious name such as John Doe, to refer to any patient and may not contain or otherwise disclose patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny.

(b) *Notice and hearing.* Unless an order under §2.66 is sought with an order under this section, the person holding the records must be given:

- (1) Adequate notice (in a manner which will not disclose patient identifying information to third parties) of an application by a person performing a law enforcement function;
- (2) An opportunity to appear and be heard for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order; and
- (3) An opportunity to be represented by counsel independent of counsel for an applicant who is a person performing a law enforcement function.

(c) *Review of evidence: Conduct of hearings.* Any oral argument, review of evidence, or hearing on the application shall be held in the judge's chambers or in some other manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceedings, the patient, or the person holding the records. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria.* A court may authorize the disclosure and use of patient records for the purpose of conducting a criminal investigation or prosecution of a patient only if the court finds that all of the following criteria are met:

(1) The crime involved is extremely serious, such as one which causes or directly threatens loss of life or serious bodily injury including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, and child abuse and neglect.

(2) There is a reasonable likelihood that the records will disclose information of substantial value in the investigation or prosecution.

(3) Other ways of obtaining the information are not available or would not be effective.

(4) The potential injury to the patient, to the physician-patient relationship and to the ability of the program to provide services to other patients is outweighed by the public interest and the need for the disclosure.

(5) If the applicant is a person performing a law enforcement function that:

(i) The person holding the records has been afforded the opportunity to be represented by independent counsel; and

(ii) Any person holding the records which is an entity within Federal, State, or local government has in fact been represented by counsel independent of the applicant.

(e) *Content of order.* Any order authorizing a disclosure or use of patient records under this section must:

(1) Limit disclosure and use to those parts of the patient's record which are essential to fulfill the objective of the order;

(2) Limit disclosure to those law enforcement and prosecutorial officials who are responsible for, or are conducting, the investigation or prosecution, and limit their use of the records to investigation and prosecution of extremely serious crime or suspected crime specified in the application; and

(3) Include such other measures as are necessary to limit disclosure and use to the fulfillment of only that public interest and need found by the court.

[52 FR 21809, June 9, 1987; 52 FR 42061, Nov. 2, 1987]

§ 2.66 Procedures and criteria for orders authorizing disclosure and use of records to investigate or prosecute a program or the person holding the records.

(a) *Application.* (1) An order authorizing the disclosure or use of patient records to criminally or administratively investigate or prosecute a program or the person holding the records (or employees or agents of that program or person) may be applied for by any administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency having jurisdiction over the program's or person's activities.

(2) The application may be filed separately or as part of a pending civil or criminal action against a program or the person holding the records (or agents or employees of the program or person) in which it appears that the patient records are needed to provide material evidence. The application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny or the patient has given a written consent (meeting the requirements of §2.31 of these regulations) to that disclosure.

(b) *Notice not required.* An application under this section may, in the discretion of the court, be granted without notice. Although no express notice is required to the program, to the person holding the records, or to any patient whose records are to be disclosed, upon implementation of an order so granted any of the above persons must be afforded an opportunity to seek revocation or amendment of that order, limited to the presentation of evidence on the statutory and regulatory criteria for the issuance of the court order.

(c) *Requirements for order.* An order under this section must be entered in accordance with, and comply with the requirements of, paragraphs (d) and (e) of §2.64 of these regulations.

(d) *Limitations on disclosure and use of patient identifying information:* (1) An order entered under this section must require the deletion of patient identifying information from any documents made available to the public.

(2) No information obtained under this section may be used to conduct any investigation or prosecution of a patient, or be used as the basis for an application for an order under §2.65 of these regulations.

§ 2.67 Orders authorizing the use of undercover agents and informants to criminally investigate employees or agents of a program.

(a) *Application.* A court order authorizing the placement of an undercover agent or informant in a program as an employee or patient may be applied for by any law enforcement or prosecutorial agency which has reason to believe that employees or agents of the program are engaged in criminal misconduct.

(b) *Notice.* The program director must be given adequate notice of the application and an opportunity to appear and be heard (for the limited purpose of providing evidence on the statutory and regulatory criteria for the issuance of the court order), unless the application asserts a belief that:

(1) The program director is involved in the criminal activities to be investigated by the undercover agent or informant; or

(2) The program director will intentionally or unintentionally disclose the proposed placement of an undercover agent or informant to the employees or agents who are suspected of criminal activities.

(c) *Criteria.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find:

(1) There is reason to believe that an employee or agent of the program is engaged in criminal activity;

(2) Other ways of obtaining evidence of this criminal activity are not available or would not be effective; and

(3) The public interest and need for the placement of an undercover agent or informant in the program outweigh the potential injury to patients of the program, physician-patient relationships and the treatment services.

(d) *Content of order.* An order authorizing the placement of an undercover agent or informant in a program must:

(1) Specifically authorize the placement of an undercover agent or an informant;

(2) Limit the total period of the placement to six months;

(3) Prohibit the undercover agent or informant from disclosing any patient identifying information obtained from the placement except as necessary to criminally investigate or prosecute employees or agents of the program; and

(4) Include any other measures which are appropriate to limit any potential disruption of the program by the placement and any potential for a real or apparent breach of patient confidentiality; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

(e) *Limitation on use of information.* No information obtained by an undercover agent or informant placed under this section may be used to criminally investigate or prosecute any patient or as the basis for an application for an order under §2.65 of these regulations.

