BOS Agreement # 16-049

COUNTY OF MENDOCINO
STANDARD SERVICES AGREEMENT

JUN 21 2016

This Agreement, dated as of _____, 2016, is by and between the COUNTY OF MENDOCINO, hereinafter referred to as the "COUNTY", and Redwood Quality Management Company, 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 mental health services for adults age 25 years and older; 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
Appendix B	Confidentiality of AOD Patient Records
Addendum A	Medi-Cal Data Privacy and Security Agreement

The term of this Agreement shall be from July 1, 2016 through June 30, 2017.

The compensation payable to CONTRACTOR hereunder shall not exceed Five Million, One Hundred Forty Three Thousand, One Hundred Three Dollars ($5,143,103) for the term of this Agreement.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

COUNTY OF MENDOCINO
HEALTH AND HUMAN SERVICES AGENCY:

By: _____
Jenine Miller, HHSA Assistant Director/
Behavioral Health Director

Date: 6/14/16

Budgeted: ☒ Yes ☐ No
Budget Unit: 4050
Line Item: 863280
Org/Object Code: MHAS75
Grant: ☐ Yes ☒ No
Grant No.:

COUNTY OF MENDOCINO

By: _____
DAN GJERDE, Chair
BOARD OF SUPERVISORS

Date: JUN 21 2016

ATTEST:
CARMEL J. ANGELO, Clerk of said Board

By: _____
Deputy
Date: JUN 21 2016

I hereby certify that according to the provisions of Government Code Section 25103, delivery of this document has been made.

CARMEL J. ANGELO, Clerk of said Board

By: _____
Deputy

Date: JUN 21 2016

CONTRACTOR/COMPANY NAME

By: _____
Signature
Printed Name: Camille Schraeder

Title: Executive Director

Date: 6-15-2016

NAME AND ADDRESS OF CONTRACTOR:

Redwood Quality Management Company
P.O. Box 422
Ukiah, CA 95482

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:
KATHARINE L. ELLIOTT, County Counsel

By: _____
Deputy

Date: 6-15-16

FISCAL REVIEW:

By: _____
Deputy CEO/Fiscal

Date 6/15/16

INSURANCE REVIEW:

By: _____
ALAN D. FLORA, Risk Manager

Date: 6/15/16

EXECUTIVE OFFICE REVIEW:
APPROVAL RECOMMENDED

By: _____
CARMEL J. ANGELO, Chief Executive Officer

Date: 6/15/16

Signatory Authority: $0-25,000 Department; $25,001- 50,000 Purchasing Agent; **$50,001+ Board of Supervisors**
Exception to Bid Process Required/Completed ☐ N/A (RFP #24-12)

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: CONTRACTOR shall indemnify, defend, and hold harmless the COUNTY, its officers, agents, and employees, from and against any and all claims, liabilities, and losses whatsoever including damages to property and injuries to, or death of persons, reasonable attorney's fees, expert fees and court costs occurring or resulting, or alleged to be occurring or resulting, to any and all persons, firms or corporations furnishing or supplying work, services, materials, or supplies in connections with the CONTRACTOR'S performance or its obligations under this AGREEMENT, and from any and all claims, liabilities, and losses occurring or resulting, or alleged to be occurring or resulting, to any person, firm, or corporation for damage, injury, or death arising out of or connected with the CONTRACTOR'S performance of its obligations under this AGREEMENT, unless such claims, liabilities, or losses arise 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.

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.

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 agrees to provide to a private, not-for-profit, successor and if there is none then 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.

CONTRACTOR shall pay all royalties and license fees which may be due for any patented or copyrighted materials, methods or systems selected by the CONTRACTOR and incorporated into the work as set forth in Exhibit "A", and shall defend, indemnify and hold the COUNTY harmless from any claims for infringement of patent or copyright arising out of such selection.

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 BHRS
1120 S. Dora Street
Ukiah, CA 95482
Attn: Jenine Miller

To CONTRACTOR:
Redwood Quality Management Company
P.O. Box 422
Ukiah, CA 95482
Attn: Camille Schraeder

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 and state laws pertaining to equal employment opportunity and that it shall not engage in any unlawful discrimination.

    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, disability, sex, sexual orientation, national origin, age, religion, Veteran's status, political affiliation, or any other non-merit factor.

    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 and display the same in a location that is reasonably conspicuous, as well as file copies of same with the County Executive Office.

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 prior written notice. 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 outlined in Exhibit "A" shall not exceed $5,143,103 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.

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. CONTRACTOR shall use subcontractors identified in Exhibit "A" and shall not substitute subcontractors without COUNTY's prior written approval.

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. PATENT AND COPYRIGHT INDEMNITY: CONTRACTOR represents that it knows of no allegations, claims, or threatened claims that the materials, services, hardware or software ("CONTRACTOR Products") provided to COUNTY under this Agreement infringe any patent, copyright or other proprietary right. CONTRACTOR shall defend, indemnify and hold harmless COUNTY of, from and against all losses, claims, damages, liabilities, costs expenses and amounts (collectively, "Losses") arising out of or in connection with an assertion that any CONTRACTOR Products or the use thereof, infringe any patent, copyright or other proprietary right of any third party.

a. COUNTY will: (1) notify CONTRACTOR promptly of such claim, suit or assertion; (2) permit CONTRACTOR to defend, compromise, or settle the claim; and, (3) provide, on a reasonable basis, information to enable CONTRACTOR to do so. CONTRACTOR shall not agree without COUNTY's prior written consent, to any settlement, which would require COUNTY to pay money or perform some affirmative act in order to continue using the CONTRACTOR Products.

b. If CONTRACTOR is obligated to defend COUNTY pursuant to this Section 32 and fails to do so after reasonable notice from COUNTY, COUNTY may defend itself and/or settle such proceeding, and CONTRACTOR shall pay to COUNTY any and all losses, damages and expenses (including attorney's fees and costs) incurred in relationship with COUNTY's defense and/or settlement of such proceeding.

c. 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.

d. Notwithstanding this Section 32, COUNTY retains the right and ability to defend itself, at its own expense, against any claims that CONTRACTOR Products infringe any patent, copyright, or other intellectual property right.

33. OTHER AGENCIES:

Other tax supported agencies within the State of California who have not contracted for their own requirements may desire to participate in this contract. The CONTRACTOR is requested to service these agencies and will be given the opportunity to accept or reject the additional requirements. If the CONTRACTOR elects to supply other agencies, orders will be placed directly by the agency and payments made directly by the agency.

[END OF GENERAL TERMS AND CONDITIONS]

EXHIBIT A - Adults
SCOPE OF WORK

CONTRACTOR agrees to arrange for the provision of the Mental Health Plan (MHP) Specialty Mental Health Services on behalf of the County of Mendocino to eligible Medi-Cal beneficiaries of Mendocino County within the Scope of Services defined in this contract.

1. Provision of Service

CONTRACTOR shall arrange and pay for all medically necessary covered Specialty Mental Health Services to beneficiaries over the age of 25, as defined for the purpose of this contract.

COUNTY shall provide and pay for the following mental health services to beneficiaries 25 years and older:

a. Medication Support Services
b. Access Line Coverage
c. Lanterman-Petris-Short Conservatorship oversight and placement
d. Mobile Outreach and Prevention Services (County Mobile Outreach teams to North County, South County, and Anderson Valley)
e. Probation Mental Health Services (AB109)
f. CalWorks Mental Health Services

CONTRACTOR shall ensure that all medically necessary covered Specialty Mental Health Services are sufficient in amount, duration, and scope to reasonably be expected to achieve the purpose for which the services are furnished.

All medically necessary covered Specialty Mental Health Services shall ensure:

a. The availability of services to address beneficiaries' emergency psychiatric conditions 24 hours a day, 7 days a week.
b. The availability of services to address beneficiaries' urgent conditions 24 hours a day, 7 days a week.
c. Timely access to routine services, as determined by the MHP to be required to meet beneficiaries' needs.

CONTRACTOR shall provide a beneficiary choice of the person/agency providing the services to the extent feasible.

2. Availability and Accessibility of Services

CONTRACTOR shall ensure the availability and accessibility of adequate numbers and types of subcontractors of medically necessary services. At a minimum, CONTRACTOR shall:

a. Maintain and monitor a network of appropriate providers that is supported by a subcontract with providers and that is sufficient to provide adequate access to all services covered under this contract. CONTRACTOR must

establish the network and monitor the network, taking into consideration all of the following:

i. Anticipated number of Medi-Cal eligible clients.
ii. Expected utilization of services.
iii. Expected number and type of subcontractors, including cultural competency of subcontractors.
iv. Number of subcontractors not accepting new beneficiaries.
v. Geographic location of subcontractors and their access to beneficiaries.
vi. Whether subcontractors are credentialed for the services being provided.

If CONTRACTOR determines that it is unable to arrange for access to all services covered under this contract, CONTRACTOR shall notify COUNTY in writing detailing the area and/or services CONTRACTOR is unable to fulfill under this contract. CONTRACTOR shall work with COUNTY to develop a plan for the provision of needed access and/or services to meet the MHP requirements set forth in this contract that CONTRACTOR has identified it cannot fulfill.

CONTRACTOR shall comply with COUNTY requirements for timely access to services. CONTRACTOR shall:

a. Require all subcontractors to meet the COUNTY standards for timely access to care and services, taking into account the urgency of need for services.

b. Require all subcontractors to have hours of operations during which services are provided to Medi-Cal beneficiaries that are no less that the hours of operation during which the subcontractor offers services to non-Medi-Cal beneficiaries.

c. Establish mechanisms to ensure that subcontractors comply with timely access requirements.

d. Monitor subcontractors regularly to determine compliance with timely access requirements.

e. Take corrective action if a subcontractor fails to comply with timely access requirements.

f. Provide monthly timeliness access reports to COUNTY.

g. Notify COUNTY when a subcontractor is failing to comply with timely access requirements and provide COUNTY with corrective action provided to subcontractor. CONTRACTOR shall continue to work with subcontractor until subcontractor is in compliance with requirement or

subcontractor services have been terminated. CONTRACTOR shall keep COUNTY informed throughout the corrective action process.

3. Quality Assurance / Quality Improvement

A. Quality Management

CONTRACTOR shall adhere to COUNTY Quality Management program which defines the structure and operational processes, assigns responsibility to appropriate individuals, and adopts or establishes quantitative measures to assess performance and to identify and prioritize area(s) of improvement.

CONTRACTOR and COUNTY shall conduct performance monitoring activities throughout CONTRACTOR'S operations. These activities shall include, but are not be limited to, beneficiary system outcomes, utilization management, utilization review, subcontractor appeals, credentialing, and monitoring and resolution of beneficiary grievances.

CONTRACTOR, in coordination with COUNTY, shall ensure coordination of care with community health centers, law enforcement, county jail, acute care hospitals, Public Guardians, Substance Use Disorders Treatment, and any other identified entity by COUNTY. Memorandums of Understanding (MOU) shall be developed with each entity. COUNTRACTOR shall assess the effectiveness of each MOU and work with the entity to improve identified problematic areas. COUNTY shall be available to help resolve any issue that cannot be resolved between the parties. CONTRACTOR shall provide a copy of each MOU to COUNTY within 30 days of execution of the MOU.

CONTRACTOR shall track underutilization of services and overutilization of services. CONTRACTOR shall provide monthly reports to the COUNTY on the underutilization and overutilization of services.

CONTRACTOR shall prevent and eliminate barriers to effective care, including but not limited to non-discrimination against particular subcontractors that serve high-risk populations or specialize in conditions that require costly treatment.

CONTRACTOR shall resolve any identified service delivery problems and take effective action when improvement is required or desired. COUNTY shall be notified by CONTRACTOR of any service delivery problems and the steps being taken by CONTRACTOR to resolve the identified problem.

CONTRACTOR shall ensure that all subcontractors participate in the COUNTY and State required beneficiary/family satisfaction surveys. CONTRACTOR shall submit to COUNTY all surveys by the due date. CONTRACTOR shall work with COUNTY to use the data to identify trends and opportunities for improvement.

CONTRACTOR shall ensure that all subcontractors adhere to the COUNTY and MHP requirements with beneficiary grievances, appeals, fair hearings, and

change of subcontractor request. CONTRACTOR shall provide COUNTY original copies of beneficiary grievances, appeals, fair hearings, and change of subcontractor request. COUNTY shall work with CONTRACTOR and subcontractors, as appropriate, to resolve all beneficiary problem resolution matters. CONTRACTOR shall work with COUNTY to use the data to identify trends and opportunities for improvement.

CONTRACTOR shall establish processes to ensure that all subcontractors remain in compliance with COUNTY and MHP requirements. If a subcontractor is not in compliance CONTRACTOR will start the corrective action process. CONTRACTOR shall notify COUNTY of any subcontractor out of compliance and provide COUNTY with a copy of the corrective action provided to subcontractor. CONTRACTOR shall continue to work with subcontractor until subcontractor is in compliance with requirement or subcontractor services have been terminated. CONTRACTOR shall keep COUNTY informed throughout the corrective action process.

CONTRACTOR shall assure that all relevant cultural and linguistic standards of care are incorporated into service delivery.

a. CONTRACTOR and/or subcontractors shall have evidence of culture-specific programs or referrals to community-based, culturally-appropriate, and non-traditional mental health subcontractors.
b. CONTRACTOR and/or subcontractors shall have evidence of the availability, as appropriate, of alternatives and options that accommodate the individual preference of clients.

CONTRACTOR shall participate in the Department of Health Care Services reviews. In preparation for reviews, CONTRACTOR shall provide COUNTY all requested information and data to maintain in compliance. Information and data may be requested monthly to remain in compliance with set standards.

B. Quality Improvement

CONTRACTOR shall make continuous quality improvements to assure the appropriateness and effectiveness of Specialty Mental Health Services and meet the needs of the beneficiary. CONTRACTOR shall design and implement interventions for improving performance, and measure the effectiveness of interventions.

CONTRACTOR shall work with COUNTY to complete a minimum of two Performance Improvement Projects (PIP) each fiscal year, one clinical and one non-clinical. CONTRACTOR shall provide COUNTY will all required information and data to be in compliance with the PIP requirements. These PIPs measure performance using objective quality indicators and demonstrate planning for increasing or sustaining improvement.

CONTRACTOR shall assure that all identified issues are tracked over time and reported to the COUNTY.

CONTRTACTOR shall provide reports at COUNTY meetings, such as Quality Assurance/Quality Improvement, Behavioral Health Advisory Board, Utilization Management, and Quality Improvement Committee meetings.

CONTRACTOR shall participate in the Quality Improvement Committee meetings and provide reports as requested by the COUNTY and in relation to the goals set in the Quality Improvement Work Plan.

CONTRACTOR shall work with COUNTY annually to complete the Quality Improvement Work Plan and Quality Improvement Work Plan Summary. The Work Plan identifies key factors for quality improvement and utilization management. CONTRACTOR shall work with COUNTY toward agreed upon goals and provide COUNTY with requested information and data to complete the plans.

CONTRACTOR shall provide ongoing monitoring of the accessibility of services as evidenced by:

a. Timeliness of routine mental health appointments
b. Timeliness of services for urgent conditions
c. Access to after-hours care
d. Responsiveness of the crisis number

CONTRACTOR shall participate in the External Quality Review (EQR) annually. In preparation for the review, CONTRACTOR shall provide COUNTY will all requested information and data to complete the EQR requirements. EQR data shall be requested monthly by COUNTY to remain in compliance with set standards and goals. EQR focus areas are categorized as follows:

a. Service delivery capacity
b. Service delivery system and meaningful clinical issues
c. Service accessibility
d. Continuity of care and coordination of care
e. Beneficiary satisfaction

CONTRACTOR shall be responsible for the following:

a. Collaboration and coordination among clients, Mendocino County Behavioral Health and Recovery Services (BHRS), subcontractors, and CONTRACTOR;
b. Assessment of subcontractor competence and performance, including peer review, when appropriate;
c. Provision of sufficient resources and trainings to ensure compliance with regulations;
d. The requirement that subcontractors participate in QI activities;
e. Management of service delivery utilizing a comprehensive Electronic Health Record (EHR) to facilitate the collection, management, and analysis of data needed for monitoring, evaluation, and improvement;
f. All subcontractors follow the goals of the Quality Improvement Work Plan;
g. All subcontractors adhere to COUNTY and MHP requirements;

h. QI activities meet the requirements as specified by the State Department of Health Care Services (DHCS) and Specialty Mental Health Services requirements;
i. The provision of necessary resources to assure the delivery of culturally competent specialty mental health services; and,

C. Quality Improvement and Quality Management Committees

COUNTY shall be responsible for facilitation of a Quality Improvement/Quality Management (QI/QM) Committee. CONTRACTOR shall participate on the QI/QM committee and attend all meetings. QI/QM recommends policy decisions, implements specific review and evaluation activities, and ensures follow-up of QI processes.

CONTRACTOR may have their own internal quality improvement committee that they require their subcontractors to attend. COUNTY shall participate in any committee that CONTRACTOR requests COUNTY to be a member of. Agenda and meeting minutes shall be maintained by CONTRACTOR.

COUNTY shall facilitate a Quality Leadership Committee that shall provide oversight, approve policy and system changes, and review outcomes of PIPs. Summary reports shall be prepared for members with data and information concerning the QI functions measured. Identification and review of the performance of key indicators over time shall be intended to allow the leadership committee members to track success of improvement efforts and provide appropriate direction as needed. The Quality Leadership Committee shall provide oversight of the following:

a. Utilization Management (UM)
b. Subcontractor Relations
c. Client Services
d. Risk Management
e. Quality of Care

D. Utilization Management

CONTRACTOR shall be responsible for assuring that beneficiaries have appropriate access to specialty mental health services. CONTRACTOR shall assess the capacity of service delivery and accessibility of services to beneficiaries; this includes monitoring the number, type and geographic distribution of mental health services. This information shall be provided to COUNTY and reported at Utilization Management meetings.

CONTRACTOR shall evaluate medical necessity appropriateness and efficiency of services provided to beneficiaries. CONTRACTOR shall track utilization of data to show client outcomes and performance indicators over time. CONTRACTOR shall track patterns, trends, and outlier data and monitor post care outcomes to assess effectiveness of care and services.

CONTRACTOR shall participate in the COUNTY Utilization Management meetings and provide to COUNTY all request information and data for meeting.

E. Utilization Review

CONTRACTOR shall implement mechanisms to assure authorization decision standards are met. CONTRACTOR shall adhere to MHP requirements for processing request for initial and continuing authorizations of services. Authorization decisions shall be made within the timeframe set by Title 42, Code of Federal Regulations (C.F.R.) § 438.210(d).

CONTRACTOR shall have mechanisms in place to ensure consistent application of review criteria for authorization decisions, and shall consult with the requesting subcontractor when appropriate. CONTRACTOR shall authorize services based medically necessity criteria and each beneficiary's level of service needs. Any decisions to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested shall be made by a professional who has appropriate clinical expertise in treating the beneficiary's condition or disease.

CONTRACTOR shall issue Notices of Action (NOA), per the MHP requirements, within the timeframe set forth in 42 C.F.R. 438.404(c). A copy of every NOA sent shall be provided to COUNTY. NOAs shall be provided to the COUNTY monthly.

CONTRACTOR shall use COUNTY approved clinical documentation and forms. CONTRACTOR shall obtain approval from COUNTY Mental Health Director or designee before using a new clinical documentation or form that would be subject to review or audit by the State of California or Federal Government. Failure by CONTRACTOR to obtain COUNTY approval may result in the inability of CONTRACTOR to bill for services.

CONTRACTOR shall conduct clinical chart audits and billing code audits of subcontractors. CONTRACTOR shall ensure subcontractors undergo regularly scheduled chart reviews, as well as a minimum of two formal chart audits per calendar year. Audits may be conducted within the Electronic Health Record (EHR).

COUNTY shall conduct regular clinical chart and treatment authorization audits. COUNTY shall notify CONTRACTOR in writing the audit results. Corrective Action Plans shall be issued for any items found out of compliance during chart audits.

CONTRACTOR shall monitor the amount of time from initial request for services to first billable visit. This data shall be analyzed and findings reported on a monthly basis to the Mental Health Board and Quality Improvement Committee.

CONTRACTOR shall act as the Point of Authorization (POA) for mental health services for beneficiaries 25 years and older. At the same time, COUNTY shall

retain authority as the official POA for all mental health services and shall have the right to review, audit, and deny services based on MHP requirements. All denials shall be reviewed with CONTRACTOR. CONTRACTOR has the right to appeal decisions to the Mental Health Director or designee.

CONTRACTOR shall provide utilization review of the activities listed below. CONTRACTOR shall monitor and measure System Performance on a monthly basis, to include, not limited to the following:

a. Inpatient hospitalizations
b. Crisis services
c. Timely access to outpatient and psychiatric services
d. No shows
e. Client outcomes
f. Client satisfaction

4. Specialty Mental Health Services

A. Provide Cultural Competence

CONTRACTOR shall ensure subcontractors offer provide culturally competent services. CONTRACTOR shall coordinate with County to comply with annual cultural competency skills training for its staff and for the staff of each of the subcontractors. COUNTY shall develop and revise the Cultural Competency Plan in collaboration and coordination with CONTRACTOR and stakeholders. CONTRACTOR shall utilize industry experts to augment annual training for target populations in Mendocino County.

Areas of focus in the implementation of the cultural competence plan shall include, but not be limited to, elimination of the disparities in service delivery to special populations (Latino and Native American clients).

The CONTRACTOR and/or subcontractors shall submit to COUNTY copies of agendas, sign-in sheets, handouts, and flyers, for cultural competency training provided to CONTRACTOR staff and subcontractors staff as occurs.

B. Assure Consumer Rights

CONTRACTOR shall assure that the screening of a consumer for a treatment or service program shall not result in the consumer being deprived of any rights, privileges, or benefits which are guaranteed to individuals by state or federal law. CONTRACTOR shall assure that services are provided in a safe, sanitary, least restrictive and humane environment. All consumers shall have the right to be treated with dignity and respect by CONTRACTOR and all subcontractors. CONTRACTOR shall work with the Patient's Rights Advocate contracted by County to assure proper client interactions and interventions.

C. Maintain Client Records

CONTRACTOR and subcontractors shall maintain client records. CONTRACTOR shall identify a compliance officer that is responsible for maintaining the integrity of the clients' health care information. Records shall be organized in a systematic fashion and stored according to licensing/regulatory standards. Individual and aggregate records shall be accessible to clinicians, the Quality Management process, and Mendocino County BHRS. Records that are released to proper authorities, individuals, and others shall be released only with an appropriately signed Release of Information (ROI). CONTRACTOR and subcontractors shall comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations, state and federal laws, and other Mendocino County BHRS requirements for client confidentiality and record security.

D. Provide Access to Quality Care with a "no wrong door" access system

CONTRACTOR shall operate a "no wrong door" Access System to provide services for adults 25 years and older. No wrong door access means that community members in need of services can be presented at any contracted Mendocino County mental health service program and receive help or services. More importantly the client will be engaged and assisted to meet his/her needs.

The Access System's primary role shall be to receive all treatment requests for community mental health services made by clients, their families, county agencies, community subcontractors, or law enforcement.

CONTRACTOR's Access System shall determine eligibility for services and medical necessity. When Mendocino County adult residents 25 years and older access services they will be provided with "no wrong door" access to avoid delays or long waits for mental health service regardless of where they live within Mendocino County, without regard to their financial ability, and in compliance with Mendocino County MHP rules and regulations for services. If requested, Medi-Cal beneficiaries shall receive a screening and, if initial screening indicates, shall receive further assessment. A NOA shall be provided to all beneficiaries who, upon initial screening or assessment, do not meet medical necessity criteria. Initial intake screening, assessment, and plan development services shall be readily available in both English and Spanish. Additional resources shall be utilized to accommodate client and families need for services and documents to be provided in their native language. This same accommodation shall be made for those beneficiaries with disabilities.

The scope of the Access System shall include, but is not limited to:

a. Prompt access to screening, assessment, and triage. CONTRACTOR shall monitor and document the amount of time from initial request for services to first billable visit, client language, all service requests, and outcomes from initial contact through crisis line. This data shall be analyzed and findings reported on a monthly basis to the Mental Health Board and Quality Improvement Committee.

b. Client intakes and eligibility determinations.

c. Appropriate service referrals and authorizations within a Continuum of Care (CoC) appropriate to client's mental health needs

d. Care manager assignments

e. Transport coordination

f. Coordination with primary care and/or substance abuse needs

g. Offering hours of operation during which services are provided to Medi-Cal beneficiaries that are no less than the hours of operation offered to commercial beneficiaries or comparable to Medi-Cal fee-for-service, if the subcontractor serves Medi-Cal clients.

CONTRACTOR'S subcontractors shall provide assistance, linkage and referrals to clients accessing services at multiple entry points. These entry points may include Community Based Organizations, Federally Qualified Healthcare Centers (FQHC), Rural Health Clinics, several Indian Health Clinics, three Hospital Emergency Rooms, Redwood Coast Regional Center, community, and any mental health plan subcontractor.

a. Community Clinics within the system network may provide assessments, medication management, brief therapies, coordinated care management, and integration with substance abuse and primary health needs.

b. Hospital Emergency Rooms shall be the destination points for 5150 (5150 is a section of the California Welfare and Institution Code specifically, the Lanterman-Petris-Short Act or "LPS" which allows a qualified officer or professional to involuntary confine a person deemed to have a mental disorder that makes them a danger to him or herself, and/or others and/or gravely disabled. When used as a term, 5150 can informally refer to the person being confined or the declaration itself or as in "someone was 5150'd").

c. Mental Health Plan subcontractors shall provide mental health assessments and referrals; supportive care management services; substance abuse links; integration with primary care; crisis intervention and stabilization services; and emergency mental health services.

Clients shall be provided with required information pamphlets that include Client Rights, Privacy and Grievance Policy, and an EPSDT Membership Handbook.

E. Adult System of Care

Contractor shall arrange for an appropriate range of Specialty Mental Health Services (SMHS) that is adequate for the anticipated number of clients that will

be served by the MHP. CONTRACTOR shall provide oversight and regulation of the programs and services provided by subcontractors. SMHS means:

a. Rehabilitative Mental Health Services;
b. Mental Health Service;
c. Medication Support Services;
d. Crisis Intervention;
e. Crisis Stabilization;
f. Crisis Residential Treatment Services;
g. Psychiatric Health Facility Services;
h. Psychiatric Inpatient Hospital Services
i. Targeted Case Management
j. Psychologist Services
k. EPSDT Supplemental Specialty Mental Health Services; and
l. Psychiatric Nursing Facility Services

CONTRACTOR shall arrange for client advocacy, outreach services, coordinate local mental health and medical care, provide interagency information and communication, arrange or provide local service transports, as well as, discharge transportation from inpatient psychiatric hospitalizations, and maintain each client's care management record. Services shall include, but are not limited to:

a. Crisis Services
b. Access System
c. Prompt access to screening and assessment; client intakes and eligibility determinations
d. Appropriate client service referrals within a CoC appropriate to consumer's mental health needs
e. Care management
f. Transport coordination
g. Coordination with primary care and co-occurring needs
h. Crisis intervention and stabilization
i. Coordination with law enforcement
j. Emergency response to hospital emergency rooms
k. Obtaining 24-hour care service authorizations

Target Mental Health Population: The target population shall consist of Mendocino County Medi-Cal beneficiaries, 25 years and older, who meet medical necessity criteria for Mendocino County MHP reimbursement as defined in Title IX, Article 2, Section 1830.205 and 1830.210.

Mental Health Services: Services shall include a comprehensive array of services that address a beneficiary's mental health needs. Interventions shall be: individualized and designed to diminish impairments and prevent significant deterioration; culturally competent and appropriate services, which are sensitive and responsive to cultural and gender differences and special needs; and, delivered without regard to race, religion, national origin, gender, physical disability, or sexual orientation. Beneficiaries shall receive services in accordance with their level of medical necessity and the unique needs. Services shall be guided by an individualized client treatment plan, which shall be reviewed and revised annually.

Services shall be available in person, on the phone, and/or through telecommunication. Services shall be timely and accessible, and delivered by licensed/waivered staff, mental health professionals who are credentialed according to state requirements, and/or non-licensed subcontractors. Services shall be provided by or under the direction of mental health professionals functioning within the scope of their professional license and applicable state law. Transport services shall be available as needed.

Beneficiaries shall be linked to physical health care, dental services, benefits, employment, schools, training, transportation, and other non-mental health services as needed. Services shall also be coordinated with FQHC/Rural Health Clinic (RHC), Probation, and HHSA, as needed. Beneficiaries receiving mental health services shall be supported to receive health care at community health care organizations, and CONTRACTOR shall ensure that ROI promote integrated health care services. Beneficiaries shall be assisted with applying for and maintaining housing. Services shall be reviewed regularly to ensure client access to appropriate care for mental health and physical health needs.

Outpatient Services: CONTRACTOR shall provide outpatient services. Outpatient mental health services shall be provided to beneficiaries with a mental health diagnosis who meet medical necessity criteria for specialty mental health services. Outpatient services may be provided in the home, clinic, or community setting. Beneficiaries shall be actively involved throughout the assessment, treatment planning, and service delivery process. Services shall be beneficiary driven and culturally sensitive.

Specialty Mental Health Services: An array of specialty mental health services shall be available to Medi-Cal beneficiaries who meet medical necessity criteria. Services shall be aimed at ameliorating mental health symptoms, utilizing interventions that are designed to provide reduction of the client's mental disability, restoration, improvement and/or preservation of individual and community functioning. Specialty mental health services shall include Assessment, Plan Development, Collateral, Therapy, Rehabilitation, and Crisis Intervention. Specialty Mental Health services shall be delivered within the least restrictive and most normative environment that is clinically appropriate.

Targeted Case Management Services: Linkage services shall be provided to assist beneficiaries to receive appropriate services, arrange transportation to appointments and/or activities when needed, and help them perform activities of daily living. Targeted case management services are defined as services furnished to assist individuals in gaining access to needed medical, alcohol and drug treatment, social, educational and other services.

Mental Health Services Act (MHSA): The MHSA program shall continue to be planned, updated and administered by COUNTY. COUNTY expects that CONTRACTOR will be involved in the stakeholder's planning process and shall manage the implementation of the MHSA approved plan. CONTRACTOR shall integrate the MHSA programs into core programs in the System of Care by

organizing and contracting with subcontractors to initiate Full Service Partnerships (FSP) and by managing and monitoring other MHSA programs and services including prevention programs, innovation programs, care management, housing support programs, community services and supports, workforce education, and training.

Drop-in Centers: COUNTY believes in wellness and recovery. CONTRACTORS shall arrange for prevention and support programs through drop-in centers. Subcontractors shall operate three to five days per week, including some weekends, to serve the Severely Mentally Ill (SMI) population. Services at these sites shall include, but not limited to, client advocacy, assertive care management, illness prevention programs, peer-to-peer counseling, senior peer counseling, peer support programs, and transportation services.

FSP: CONTRACTOR shall authorize the FSP benefit for qualified SMI clients upon consultation and approval from COUNTY Behavioral Health Director or designee. This service shall respond to clients' needs and shall support their efforts toward wellness and recovery. Services may include treatment, wrap-around services, vocational training, and housing support.

Assisted Outpatient Treatment (AOT): CONTRACTOR shall arrange for subcontractors to provide AOT services. Subcontractors shall participate in the AOT Team meetings as requested by COUNTY and participate in the initial investigation of AOT referrals, providing known history on potential AOT clients. CONTRACTOR'S subcontractors shall accept referrals for Biopsychosocial Assessment and assess client, determine if client has a qualifying diagnosis that meets medical necessity for specialty mental health services, understanding that many AOT clients may be reluctant to participate in voluntary services and repeated and unique attempts to engage client in services may be necessary.

AOT requires subcontractor participation with the AOT Treatment team and beneficiary in developing an AOT treatment plan. Assigned Care Managers shall assist beneficiaries in overcoming barriers, meeting treatment plan goals and reducing functional impairments toward reducing risk to self or others and increasing ability to participate meaningfully in independent living. Subcontractor shall testify in court when required regarding AOT qualifications, assessment, diagnosis, risk of client, and any other pertinent information to beneficiary.

AOT also requires completing any documents necessary for the AOT petition requested by the COUNTY or required by the Courts, which includes the Declaration stating that there is reason to believe AOT criteria are met according to WIC Code 5346(b)(5)(B). CONTRACTOR shall ensure that all timelines outlined in regulation or ordered by the court proceedings are met. Family and natural supports shall be included as part of the beneficiary care. When successful treatment is sustained, CONTRACTOR shall facilitate transition of beneficiary to less restrictive treatment programs maintaining contact through a supported transition process.

COUNTY shall provide the following services for AOT:

a. Accept all referrals to Assisted Outpatient Treatment (AOT) services.
b. Investigate all referrals.
c. Outreach to client, build rapport, and attempt to obtain engagement in voluntary services.
d. Coordinate services with the AOT treatment team consisting of Administrative Service Organization (ASO) Clinician, Counsel, County Behavioral Health Director, and ASO Care Manager.
e. Assist with determining Treatment Plan Goals.
f. Support client and Care Manager in initial services needs such as financial, housing, and other imminent basic needs.
g. Make determination of need to file Declaration of AOT criteria with Court.
h. Notification of Counsel and Courts.
i. Tracking of all timelines and communication with treatment team around court processes and deadlines.
j. Complete documentation of non-compliance when necessary and communicate with Counsel.
k. Monitor and track transitions of client.
l. Report data to the State Department of Mental Health.

Forensic Services: CONTRACTOR shall establish a formal liaison with those agencies in the community that are primarily engaged with mental health care recipients who are actively connected to forensic, in order to be consistent with public safety and the needs of the individual. CONTRACTOR shall meet regularly in order to problem solve for concerns or specific clients, on an individual basis with the following offices, but not limited to the following:

a. Behavioral Health Court
b. Mendocino County Office of the Public Guardian
c. Mendocino County Jail and Sheriff
d. City Police Departments
e. California Forensics Medical Group (CFMG)
f. Office of the Public Defender
g. Mendocino County Probation Office
h. Mendocino County Superior Court

A representative of COUNTY shall be invited to participate in any interagency deliberation or meeting.

Transportation Service: CONTRACTOR shall arrange for transportation services. CONTRACTOR shall have subcontractors coordinate transportation for clients for admission to authorized services or placement sites, transfers between placement sites and discharges from placement sites back to the community. This service shall be provided through a coordinated effort by care managers with the local ambulance company, local care managers, and members of the subcontractor network and transportation contractors.

Behavioral Health Court: CONTRACTOR shall arrange for the provision of care management and outpatient services to participants of the Behavioral Health Court. In addition, CONTRACTOR shall arrange for subcontractors to collaborate and coordinate with the multi-agency Behavioral Health Court planning group.

Outcome Measurement Tools: CONTRACTOR shall require all in-county subcontractors to use the Adult Needs and Strengths Assessment (ANSA) outcome measurement tool. CONTRACTOR shall work with out-of-county subcontractors on using this outcome measurement tool. With the ANSA the frequency and intensity of services shall be correlated with outcome measure data. Outcome measure data shall be collected at regular intervals throughout treatment to ensure that services maintain the appropriate level of intensity, frequency, and duration.

All urgent care needs related to medication management, routine visits, emergent conditions, and nonemergency crisis situations shall be assessed, treated, referred to a local clinic, and discharged to home or family, unless they have a medical or psychiatric emergency or a supportive care or placement need.

Medical needs shall be referred to a primary care clinic site within the System of Care network for assessment and treatment. Medical emergencies shall be referred to the appropriate emergency service or to the nearest hospital emergency room. Continued monitoring shall occur through an assigned care manager.

Psychiatric emergencies shall be assessed and referred to the appropriate level of the multi-tiered crisis service. Dispositions to crisis or 24-hour care services shall be based on medically necessary interventions centered on client safety and rapid stabilization of the crisis episode.

F. Crisis Services

CONTRACTOR shall arrange for multi-tiered crisis intervention and crisis response services to Mendocino County residents 25 years and older. Crisis services shall be available to all Mendocino County beneficiaries 25 years and older that are experiencing a mental health emergency and shall be accessible 24/7. Crisis services shall be accessible via the telephone, walk-in crisis centers, and mobile response to designated community locations.

The Crisis Service's goals are:

a. Provide emergency assessments, appropriate emergency services/referrals, and a safe environment. CONTRACTOR's Subcontractor shall maintain the response requirements.

b. Divert individuals from unnecessary presentations at local hospital emergency rooms.

c. Minimize the time involvement of emergency rooms and local law enforcement with each incident.

d. Reduce recidivism by linking client with appropriate resources and after care services.

e. Provide qualified professionals to respond to the local emergency rooms within 20 minutes in Ukiah and Fort Bragg and within 45 minutes or less to Willits to perform the assessment for a 5150 placement.

f. Coordinate with law enforcement and hospital emergency departments to provide quality mental health services.

Crisis services shall be available to those in need, regardless of ability to pay; however, funding streams shall be examined by CONTRACTOR in order to assist the indigent population with accessing mental health services, or to assist those with insurance in linking back to their care subcontractor network. Once crisis services are accessed, assessments at every level of care shall determine the beneficiary's need for additional services. In every case, particular care shall be given to provide a safe, secure, and confidential experience.

Individuals may be self-referred, family-referred, referred by law enforcement, Mendocino County agency referred, or referred by community-based mental health or medical professionals. Each individual shall be provided the least restrictive intervention possible. Assessments at every level of care shall determine the individual's need for additional services. CONTRACTOR shall assure that each crisis call is being responded to promptly; and, individuals who are determined to have a life-threatening or 5150 designation receive the highest priority.

Services by CONTRACTOR'S subcontractors may be provided over the phone or in person. All crisis contacts shall be logged and/or documented in the EHR, thus allowing the CONTRACTOR to monitor timeliness to access, appropriateness of intervention, and coordination of aftercare linkages, including, at times, access into mental health services. CONTRACTOR's subcontractor shall respond promptly and triage the crisis accordingly to the beneficiary's level of suicidal, homicidally, and/or grave disability. The subcontractor shall refer medical emergencies to the appropriate emergency service or to the nearest hospital emergency room.

CONTRACTOR shall ensure service provision meets the following levels of care:

a. Crisis Prevention and Outreach
b. Crisis Intervention
c. Inpatient Psychiatric Services
d. Supportive Aftercare Services
    i. Crisis Prevention & Outreach

CONTRACTOR shall work with subcontractors to ensure the provision of crisis prevention, outreach, and destigmatization services.

CONTRACTOR and subcontractors shall participate in education and awareness events held locally throughout the county.

CONTRACTOR shall arrange for crisis response to local community tragedies and disasters, as deemed necessary. CONTRACTOR shall provide subcontractors with assigned duties in emergency community efforts as per direction from the Behavioral Health Director.

CONTRACTOR and subcontractor shall have informational pamphlets, flyers, and cards located throughout the county to ensure that beneficiaries have access to crisis services as needs arise.

CONTRACTOR shall ensure appropriate networking to continue to expand local community supports and the development of a crisis continuum of care.

ii. Crisis Intervention

CONTRACTOR shall assure crisis services can be requested through self-referrals, as well as referrals from community mental health agencies/subcontractors, healthcare subcontractors, law enforcement, family members, friends, neighbors, landlords, or community members concerned about the welfare of an individual who appears to be in a mental health crisis. Referrals shall be accepted by CONTRACTOR through an advertised toll-free crisis phone number which shall operate 24 hours/day and 7 days/week.

CONTRACTOR shall ensure the operation of a minimum of two Crisis Centers to be located inland and on the coast, with walk-in availability for consumers in crisis.

CONTRACTOR's subcontractor shall have appropriately credentialed staff that is trained to manage the crisis intervention and to resolve problems and/or situations with the least restrictive crisis response.

Criteria used by CONTRACTOR in assessing situations shall, at minimum, include deterioration of the mental health status or an increase in mental illness symptoms, along with:

1. Acute emotional distress;
2. Thoughts of suicide or wanting to hurt oneself;
3. Thoughts of harm to others;
4. Physical aggression toward others;

5. Refusal of psychiatric or medical care because of impaired insight or judgment; and,
6. Grave disability.

CONTRACTOR'S subcontracted crisis staff shall, upon completion of the assessment, provide brief crisis interventions designed to de-escalate and resolve the crisis or diminish the symptoms. CONTRACTOR and subcontractors shall work to ensure that all parties involved in the initial crisis are content with the outcome of the initial assessment prior to determining a final disposition.

CONTRACTOR shall ensure appropriate referrals are made for the consumer to assist in the stabilization of functioning and reduce potential recidivism into the crisis continuum of care.

CONTRACTOR shall assist subcontractors as needed to facilitate access to community resources such as housing, food, transportation, eligibility workers, and other domains of daily functioning to assist in the development of appropriate safety networks.

CONTRACTOR shall ensure that crisis services are provided in the least restrictive setting.

CONTRACTOR shall ensure access to a psychiatrist 24/7 for available consultation on medication and psychiatric conditions, as well as, requests for second opinion when disagreements occur.

Crisis staff shall assess the need for inpatient psychiatric hospitalization and will work to complete the assessment, broker the bed, and arrange transportation should acute care be required.

CONTRACTOR shall monitor outcomes and indicators to look for trends and ways to prevent future inpatient psychiatric hospitalization.

Respite Care Services:
CONTRACTOR shall arrange for Respite Care Services. Respite Care Services offer safe, temporary relief for adults who are experiencing a nonthreatening but difficult crisis situation, and for their care-givers. Respite programs provide short-term and time-limited breaks for mentally ill adults in need of temporary housing relief, without which emotional distress and situational trauma might increase, precipitating a need for more intensive services. It also operates as a support to unpaid caregivers of adults with a mental health diagnosis in order to support and maintain the care-giving relationship. Respite Care may be provided at a licensed community care facility or through temporary housing in a shelter, transitional housing sites, or a local motel and is available 24

hours/day and 7 days/week. On occasion this service may be an alternative to costly higher levels of care, and avoids potential emergency room visits and law enforcement involvement. Respite care shall be accessed by referral and authorized by CONTRACTOR.

iii. Inpatient Psychiatric Services
CONTRACTOR shall provide voluntary and involuntary inpatient hospitalizations for adult clients 25 years of age or older when medical necessity has been determined. CONTRACTOR shall authorize placement, find a bed with a contracted psychiatric facility, and arrange for transportation. Examples of qualified inpatient subcontractors include St. Helena Hospital, Woodland Memorial Hospital, Aurora Behavioral Healthcare, Restpadd and Marin General Hospital. COUNTY expects length of stay to range from three to seven days. CONTRACTOR shall monitor inpatient care and coordinate linkage and treatment upon discharge.

iv. Supportive After Care Services
Following the initial crisis episode, CONTRACTOR shall ensure subcontractors timely follow-up is coordinated so as to assist in stabilization of the crisis and linkage for ongoing supports. When appropriate, the client's identified natural supports shall be involved in the planning and aftercare process.

Following an inpatient psychiatric stay, CONTRACTOR shall ensure that subcontractor provides a discharge exit interview the beneficiary and offer supportive aftercare services. This exit interview will happen within the first 72 hours of discharge and timeliness will be reported with utilization review reports.

CONTRACTOR shall ensure that all Mendocino County Beneficiaries are transported back to the county following an inpatient stay.

Supportive after care services shall be offered to all beneficiaries who meet medical necessity criteria. After care may include respite, peer support, linkage to primary care and/or substance abuse programs, psychiatric follow-up, medication monitoring, care management, case consultation, and possibly other psychiatric emergency services. Support and aftercare shall be provided by subcontractors, even if the crisis is deemed not to be a mental health emergency.

CONTRACTOR shall allow for post-crisis aftercare linkage and support services to be provided regardless of the beneficiary's insurance status or ability to pay.

CONTRACTOR shall ensure that aftercare services are mobile and provided in the community. The mobile aftercare model will assist crisis staff in evaluating client's environment, developing appropriate coping strategies, monitoring functioning in life domains, streamlining linkage referrals, and working to expand natural resources.

CONTRACTOR shall, to the extent possible, work with subcontractor to develop new resources in underserved areas so that referrals are made within the community of origin during crisis.

CONTRACTOR shall make supportive aftercare services available for up to 60 days post crisis to allow for stabilization and linkage to community supports.

COUNTY shall provide 5150 training to all of CONTRACTOR'S subcontractors who will be conducting 5150 assessments. All personnel conducting 5150 assessments shall be certified by the Behavioral Health Director. This training shall be conducted yearly to meet state requirements and all subcontractors need to be recertified yearly. Any subcontractor who does not attend the training or does not pass the training shall be unable to conduct 5150 assessments until the matter is rectified.

5. Administrative/Utilization Review Services

CONTRACTOR shall provide administrative and utilization review services. CONTRACTOR shall partner with COUNTY to coordinate and/or consolidate existing administrative functions where appropriate. COUNTY anticipates that COUNTY will retain certain functions including fiscal management, patient billing, and quality management; and perform oversight of the CONTRACTOR and the contract. CONTRACTOR shall provide the following administrative services to complete the mental health management structure for Mendocino County:

Administrative Services

a. Care management technology
b. Medi-Cal billing preparation
c. Compliance management
d. Program system/data reports
e. Subcontractor network development
f. Subcontractor contracting
g. Subcontractor management/relations
h. MHSA program/services management
i. Subcontractor fiscal planning and budget monitoring
j. Subcontractor coast reporting
k. Mendocino County BHRS/ASO functions, systems and committee integration
l. Mendocino County BHRS reporting/coordination/communication
m. Mendocino County BHRS interagency coordination/communication
n. Mendocino County Mental Health Board, NAMI stakeholder relations
o. Community relations

Utilization Review Services

a. Client eligibility verification
b. Medical necessity determination
c. Service authorization
d. Utilization management
e. Quality/outcome management
f. Compliance management
g. Clinician/agency credentialing
h. Chart Audits/Clinical Review

CONTRACTOR'S contracts with the network subcontractors shall be developed, negotiated and managed by the CONTRACTOR. A CONTRACTOR'S representative shall consult with Mendocino County Counsel regarding requirements and safeguards necessary for inclusion into each network subcontractor agreement. CONTRACTOR shall be responsible for contract management and shall be the point of contact between network subcontractors and COUNTY. CONTRACTOR shall maintain regular and routine communication with the Behavioral Health Director to report progress, solve problems, coordinate resources, provide information and maintain relationships.

6. Subcontracts

CONTRACTOR shall maintain and monitor a network of appropriate subcontractors that are supported by written contract. CONTRACTOR shall provide COUNTY with a copy of each subcontractor contract written, at least yearly. In all contracts, CONTRACTOR and subcontractor must comply with the requirements of 42 C.F.R. § 438.214. CONTRACTOR also shall ensure all subcontractors adhere to the COUNTY policies and procedures.

CONTRACTOR shall not discriminate in the selection, reimbursement, or indemnification of any subcontractor who is acting within the scope of his or her license or certification under applicable state law, solely on the basis of that license or certification. CONTRACTOR shall ensure that subcontractors adhere to the COUNTY policy and procedure for selection, retention, credentialing, and recredentialing of subcontractors.

CONTRACTOR shall give subcontractor or groups of subcontractors who apply to be contracted subcontractor, who CONTRACTOR decides not to contract with, written notice of the reason for a decision not to contract. A copy of notice shall be provided to COUNTY.

CONTRACTOR shall comply with California Code of Regulations (CCR) Title 9 § 1830.215 in the selection of subcontractors. Subcontractors shall maintain compliance with all MHP, State and Federal requirements. If a subcontractor does not maintain compliance CONTRACTOR shall issue a corrective action plan. COUNTY shall be notified when a subcontractor is failing to comply with

requirements. CONTRACTOR shall provide COUNTY with a copy of the corrective action plan provided to subcontractor. CONTRACTOR shall continue to work with subcontractor until subcontractor is in compliance with requirement or subcontractors services have been terminated. CONTRACTOR shall keep COUNTY informed throughout the corrective action process.

CONTRACTOR shall ensure that subcontractors only use licensed, registered, or waivered staff acting within their scope of practice for services which require a license, waiver, or registration.

CONTRACTOR shall ensure that all subcontractor sites meet the requirements for Medi-Cal certification. COUNTY shall certify all subcontractors and recertify every three years. COUNTY shall conduct annual site reviews to verify that all subcontractors are in compliance with Medi-Cal site certification requirements. Any subcontractor found out of compliance shall receive a corrective action plan from COUNTY. COUNTY shall provide to CONTRACTOR a copy of any corrective action plan issued to a subcontractor. Failure to comply with the corrective action plan may result in termination of subcontractors Medi-Cal certification.

CONTRACTOR shall assure that no subcontractor is on a list excluding them from billing Medi-Cal, such as:

a. Office of General Inspector General List of Excluded Individuals/Entities (LEIE).
b. DHCS Medi-Cal List of Suspended or Ineligible Subcontractors
c. Excluded Parties List System (EPLS)
d. Verification of licensure without restrictions
e. National plan and subcontractor Enumeration System (NPPES)

CONTRACTOR shall run monthly checks on the exclusion list sites, as directed by the COUNTY, and provide COUNTY monthly reports.

CONTRACTOR shall include in subcontractor contracts that following, but not limited to:

a) Anticipated number of Med-Cal eligible clients
b) The expected utilization of services
c) The number and types of subcontractors in terms of training, experience and specialization needed to meet expected utilization
d) The number of network subcontractors who are not accepting new clients
e) The geographic location of subcontractors and their accessibility to clients, considering distance, travel time, means of transportation ordinarily used by Medi-Cal recipients and physical access for disabled clients
f) Specific language stating the SUBCONTRACTOR is required to comply with all Federal, State & COUNTY requirements, regulations, and MHP policy and procedures for Specialty Mental Health Services. This includes notification to COUNTY in a timely manner according to code provisions of Special Incidences, and communicating in writing to COUNTY throughout the process with status updates and outcomes.

CONTRACTOR shall have a certification protocol for all subcontractors to ensure their capacity and capability for meeting the full requirements of the Mendocino County MHP. CONTRACTOR shall be responsible for financial and billing reconciliation, including cost reports, allowable costs, federal cost report compliance, etc. for all subcontractors.

CONTRACTOR shall ensure that all subcontractors use an EHR. The EHR allows subcontractor to enter client data, upload clinical documents, enter progress notes, and track outcome data. EHR also allows CONTRACTOR to access various reports, to assist in monitoring:

a. Subcontractor scheduling and productivity
b. Intensity and duration of services
c. Demographic data
d. Clinical data
e. Service utilization
f. Level of placement
g. High-cost beneficiaries

CONTRACTOR shall have a Medical Director (licensed psychiatrist) who will be available to provide medical consultation as needed. CONTRACTOR's Medical Director shall also assist with emergency expartes, as needed. CONTRACTOR'S Medical Director shall have particular focus on medication, assessment, consultation, inpatient denials, appeals, and assist with recommendations for further treatment.

CONTRACTOR shall be responsible for sending notification letters to clients, if a subcontractor terminates their contract with CONTRACTOR or CONTRACTOR terminates contract with COUNTY.

7. Monthly, Quarterly and Annually Reporting

CONTRACTOR shall provide monthly, quarterly, and annual reports. The CONTRACTOR shall fully cooperate with COUNTY BHRS and promptly provide all information pertaining to any aspect of the MHP when requested.

CONTRACTOR shall provide COUNTY with information and reports as required, including, but not limited to, the following information:

a. Annual Mental Health Plan and budget
b. Annual program report
c. Annual cost report - Cost report Template Excel forms for Contractor and all Subcontractors for current fiscal year with back up documentation (Invoices, Worksheets, Profit and Loss with Assets and Liabilities, Depreciation Schedule of Facilities and Equipment associated with this Contract.)
d. Monthly program report to Mendocino County Mental Health Advisory Board
e. Monthly and quarterly claim submissions; no more than one quarter in arrears
f. Quarterly CSS Demographic Reports for all CSS programs

g. Fiscal Year full Expenditure Detail Report by CSS Programs submit to BHRS (including receipts, invoices, vouchers, etc. to back up the expenditures that are entered in the Fiscal Report)
h. Fiscal Year full Expenditure Detail Report by PEI Programs submit to BHRS (including receipts, invoices, vouchers, etc. to back up the expenditures that are entered in the Fiscal Report)
i. PEI Quarterly Demographic Reports for all PEI programs
j. Maintain and submit to BHRS semiannual list of all Contractor and Subcontractor cultural and linguistic skills and training.
k. Report on utilization funds compared to Plan of Services as requested
l. Tracking Access/Crisis Log due by 10th of following month of occurrence
m. Access Log Monthly totals page, includes year to date information due by 10th of following month of occurrence
n. Outpatient timeliness to Authorization Report due by 10th of following month of occurrence
o. Outpatient TAR log (included hard copies of original TAR) due by 10th of following month of occurrence
p. Hospitalization Log including exit interview data done within seven (7) days of hospital exit, due by 10th of following month of occurrence
q. Hospital Report including charts/graphs, year to date which has admission average length of stay, readmission within 30 days data, due by 10th of following month of occurrence
r. Copies of Notice of Actions (NOA), due monthly
s. Quarterly Training Log
t. Annually Statements of disclosure of ownership, control, and relationship information, managing employees, including agents and managing agents from both Contractor and Subcontractor, as required in CRF, title 42, § 455.1012 and 455.104, and in the MHP Contract, Program Integrity Requirements.
u. Diagnosis/Periodic Update Form (DPU) as occurs
v. Monthly closing summary of all cases closed which includes the name of the client, date of birth, chart number and the effective close date
w. Any other data or costs reports, as requested
x. Mendocino County during the term of this agreement and with input from CONTRACTOR may develop reporting instruments to facilitate evaluation and monitoring. Upon implementation of these reporting instruments, CONTRACTOR shall comply with the established requirements.

COUNTY reserves the right to add performance indicators to the submission packet by informing the CONTRACTOR of new indicator requirements by letter from the Behavioral Health Director. The CONTRACTOR agrees to submit all performance indicators to COUNTY within thirty (30) days of receipt of the letter from COUNTY.

CONTRACTOR shall provide COUNTY with a monthly "Operational" Cost Report using the most recent data, to be used to track against the interim rate for less future audit reconciliation variation, and an Official Annual Cost Report of Community Based Organizations that provide Medi-Cal services contracted with the Administrative Service Organization for services under the Mental Health Plan, in the

i. Full Service Partnership
j. Mandated Reporting
k. Documentation training and supervisory documentation review and compliance to regulations
l. Redwood Coast Regional Centers

9. Health Care Reform

CONTRACTOR shall collaborate with BHRS to participate, upon request, in the planning, coordination and implementation of the following Health Care Reform elements, including, not limited to:

a. Health systems service integration including, but not limited to, primary care and behavioral health (mental health and substance abuse) services
b. Establishment of the "Medical Home"
c. Medi-Cal Expansion
    i. Outreach and engagement to facilitate client enrollment and maintenance of benefits
d. Clinical and Fiscal Outcomes
    i. Monitor and measure the achievement of quality clinical and fiscal outcomes while reducing costs through the management and delivery of integrative care

10.MOU

CONTRACTOR shall develop and execute with COUNTY and other parties the following Memorandums of Understanding (MOU's):

a. COUNTY Substance Use Disorders Treatment
b. Justice System
c. Medical Hospitals
d. Community Health Centers
e. Law Enforcement
f. Public Guardians Office

CONTRACTOR shall include the following in all MOU's:

a. Defined roles and responsibilities of parties
b. Processes for follow-up and communication
c. Process for coordination of shared clients
d. Process for resolving disputes between parties

CONTRACTOR shall provide copies of all executed MOU's to COUNTY.

11.Compliance

The Mental Health Plan (MHP) oversees and is accountable for any functions and responsibilities that it delegates to any subcontractor and before any delegation evaluates the prospective subcontractor's ability to perform the activities to be delegated.

CONTRACTOR shall prepare a System Design Structure Report that describes the CONTRACTOR'S mental health delivery system, including all of the following:

a. Proposed goals and objectives for the delivery system;
b. Written description and/or outline of how the requirements specified in each section of the Scope of Work (Exhibit A) have been met; and for those requirements pending completion, a timeline for completion and the manner in which the requirements will me met;
c. Identification and description of the roles of all subcontracting subcontractors and other organizations providing services on behalf of or to CONTRACTOR;
d. Written description and flow chart for the referral and service delivery framework involving ASO and subcontracted subcontractors delivering mental health and any other services specified in the Scope of Work; and,
e. Written description of the CONTRACTOR'S mental health system interfaces, including services delivered to and by other systems, including community hospitals, community health centers and other health care subcontractors in the county, and the county jail and justice system.

The System Design Structure Report shall be due in a final form from CONTRACTOR no later than ninety (90) days from start date of this contract. The report shall be provided in written format and delivered to the Mental Health Director. BHRS, in its sole discretion, shall have the right to review and approve CONTRACTOR'S System Design Structure report and require modification of such report. If modifications are required, the Mental Health Director shall meet with CONTRACTOR to discuss the requested modifications. Following BHRS approval of CONTRACTOR'S System Design Structure Report, BHRS shall within ten (10) days provide written notice of approval to CONTRACTOR.

CONTRACTOR shall provide a compliance officer, in coordination with COUNTY, and meet all Federal and State requirements. CONTRACTOR shall assure that all subcontractors comply with MHP compliance plan and that there are tools and protocols in place for ongoing compliance review. All clinical documentation shall meet Medi-Cal (Title IX) standards and Early Periodic Screening, Diagnosis, and Treatment (EPSDT) requirements. Internal systems shall be employed to monitor strict compliance with all requirements to meet standards and regulations with service authorizations, service delivery, documentation, and billing.

CONTRACTOR'S program policies, procedures and protocols, as related to client services and as shown in Exhibit A shall be reviewed and revised to reflect the requirements set forth by the Mendocino County's MHP.

CONTRACTOR acknowledges, and understands all current requirement of the California State Department of Health Care Services (DHCS) for the provision of mental health services. Such requirements include the following agreements, but are not limited to:

a. County Mental Health Plan Performance Agreement
b. Medi-Cal Services Agreement
c. Managed Care Services Agreement
d. Mental Health Services Act Agreement

CONTRACTOR shall meet the standards of said agreements referenced above as well as all successor agreements between the COUNTY and DHCS during the term of this Agreement.

COUNTY shall operate a confidential phone line for calls regarding suspected fraud and compliance issues and shall respond to each call in a timely manner. All calls shall be recorded in a compliance log. CONTRACTOR shall post in all locations the compliance poster that includes the phone number.

All services that do not meet medically necessity are not sufficient to achieve the purpose for which the services are furnished, and shall be disallowed. All services disallowed are to be reimbursed by CONTRACTOR to COUNTY within 30-days for the notice of disallowance. Reimbursement for such disallowance shall include reimbursement of Medi-Cal and Base Match-able Allocation dollars.

In carrying out the Scope of Work contained in this Exhibit A, CONTRACTOR shall comply with all requirements to satisfaction of COUNTY, in the sole discretion of COUNTY. For any finding of CONTRACTOR'S non-compliance with the requirements contained in the Exhibit A, COUNTY shall within ten (10) working days of discovery of non-compliance notify CONTRACTOR of the requirement in writing and ask for a written response within five (5) working days. If the identified non-compliance issue has not been resolved through response from CONTRACTOR, then COUNTY shall request in writing CONTRACTOR submit a Corrective Action Plan to correct the area of non-compliance and shall define the timeframe and measurability for each item listed within such Corrective Action Plan. COUNTY shall respond within 60 days of receipt of CONTRACTOR'S Corrective Action Plan. Following such notification by COUNTY, should CONTRACTOR'S Corrective Action Plan and/or CONTRACTOR'S performance of such Plan fail to satisfy COUNTY that CONTRACTOR has complied with the requirements of this Exhibit A, COUNTY may withhold monthly payments for Administration/Utilization Review (UR) pending determination by COUNTY that CONTRACTOR'S Corrective Action Plan and/or performance meets COUNTY requirements. Should COUNTY determine that CONTRACTOR'S non-compliance has not been addressed to the satisfaction of COUNTY for a period of 60 days or more from the date of notice by COUNTY of the required Corrective Action Plan by CONTRACTOR, COUNTY may impose a penalty of five percent (5%) of the monthly amount otherwise payable to CONTRACTOR for Administration /UR for each month following the 60 day time period that CONTRACTOR'S non-compliance continues. Failure to meet compliance requirements may lead to termination of this contract by the County with a 30 day written notice, when non-complaint issues continue and the Corrective Action Plan has not been successfully completed within the allotted timeline.

12. Communication Plan

CONTRACTOR shall notify COUNTY of all communications with Media, including, but not limited to, press releases, interviews, articles, etc. CONTRACTOR shall not speak on behalf of COUNTY in any communications with Media but is encouraged to describe the services it provides and respond to questions about those services.

CONTRACTOR is also encouraged, where appropriate, to provide timely and factual responses to public concerns.

CONTRACTOR will collaborate with the COUNTY in the development of a specific communication plan, including an immediate short term plan announcing the award of the contract, interviews and feature stories about the transition of services, etc. and a long term plan including, but not limited to, periodic updates, feature stories, and special events.

[End of Exhibit A]

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EXHIBIT B - ADULTS
SERVICES PAYMENT TERMS

COUNTY shall pay CONTRACTOR a Base Match-able Allocation, administrative fee, and for specialty mental health services provided to all medically eligible clients as per the following instructions:

1. For the purposes of this Agreement, the term Base Match-able Allocation shall mean the projected amounts of 2011 Realignment and Mental Health Services Act (MHSA) in allocated funding received by Mendocino County from the State to provide the required match for Medi-Cal Specialty Mental Health services or to be spent on specified qualifying non-Medi-Cal, or non-Federal services. The COUNTY shall assign the CONTRACTOR a Base Match-able Allocation, effective only during the term of this Agreement and subject to increase, decrease, or no change upon sole discretion of COUNTY. All Base Match-able Allocation amounts shall be determined by COUNTY.
2. CONTRACTOR shall provide services with the Base Match-able Allocation as directed by the County Behavioral Health Director, and in compliance with the Mendocino County Mental Health Plan and the California Mental Health Services Act Plan. Funding sources shall include revenue from 2011 Realignment Behavioral Health Subaccount and Mental Health Services Act (MHSA), as described in Section 1 above.
3. COUNTY shall distribute the negotiated Administrative Service Organizational (ASO) Fee, funded with 1991 Realignment and Federal Financial Participation (FFP), and assign and distribute the Base Match-able Allocation amount of the designated funding sources, in regards to the Mental Health Plan and Mental Health Services Act Plan, in a disbursement schedule not to exceed:
    a. Administrative Fee shall be Seven Hundred Thousand Dollars ($700,000), with the stipulation that the Utilization Review (UR) percentage of the cost shall be equal to or in excess of 75% of the entire Administrative Fee. This Admin/UR fee is funded by 1991 Realignment and FFP.
    b. Base Match-Able Allocation shall be Two Million, Six Hundred Fifty Eight Thousand, One Hundred Three Dollars ($2,658,103) for Fiscal Year 2016-17.
    c. Contract maximum shall be Five Million, One Hundred Forty Three Thousand, One Hundred Three Dollars ($5,143,103). Such amount may be increased but such increase shall be dependent on the level of maximization of Federal revenue for all Certified Public Expenditure (CPE) of Medi-Cal match-able dollars over the projected FFP amount of One Million, Seven Hundred Eighty Five Thousand Dollars ($1,785,000).
    d. COUNTY shall generate the disbursement of FFP dollars to the CONTRACTOR.

e. The Base Match-able Allocation shall include payments for Sub-contracted Specialty Mental Health services and Mental Health Services Act (MHSA) prescribed services and shall follow the schedule set forth in Section 3.f.
f. Administrative Services Organization administrative services payments shall include the Administrative Fee / UR component and shall be distributed quarterly beginning in July, 2016 as scheduled:

- July 7, 2016
- October 13, 2016
- January 12, 2017
- April 13, 2017

Budget Amounts

	Quarterly	Annual	Total Annual
Base Match Allocation	$ 664,525.75	$2,658,103.00	$ 2,658,103.00
Administration 25%	$ 43,750.00	$ 175,000.00	$ 175,000.00
Utilization Review 75%	$ 131,250.00	$ 525,000.00	$ 525,000.00
Allocation Annualized			$ 3,358,103.00
Contract Maximum w/ FFP			$ 5,143,103.00

Distribution

	Quarterly	Annual	Total Annual
Administration 1991 Realignment and FFP	$ 175,000.00	$ 700,000.00	$ 700,000.00
2011 Realignment	$ 281,578.25	$1,126,313.00	$ 1,126,313.00
Mental Health Services Act			
MHSA PEI	$ 14,962.50	$ 59,850.00	$ 59,850.00
MHSA CSS	$ 367,985.00	$1,471,940.00	$ 1,471,940.00
Total MHSA	$ 382,947.50	$1,531,790.00	$ 1,531,790.00
Total Contract Maximum With FFP		$5,143,103.00	$ 5,143,103.00

4. CONTRACTOR shall submit Specialty Mental Health Medi-Cal Services Statement Packets to COUNTY as expeditiously as possible, and no later than sixty (60) days after the end of the month during which services were rendered (i.e. billing for services rendered in May would be due July 31). Claims submitted by CONTRACTOR in excess of one hundred eighty (180) days from date of service shall be reviewed with Behavioral Health Director and fiscal manager for justification regarding late submission. COUNTY is aware that some services may require a late submission. If CONTRACTOR and BHRS fiscal manager are unable to come to an agreement regarding late submission, Behavioral Health Director shall make the final determination if payment is to be remitted to CONTRACTOR. Behavioral Health Director shall meet with CONTRACTOR to allow CONTRACTOR to provide justification for late payment. If late submission is not approved, CONTRACTOR shall be responsible for payment to any subcontractors owed reimbursement for services subject to such late billing.
5. COUNTY shall submit billable services using the Specialty Mental Health Medi-Cal Services Statement Packet received from the CONTRACTOR to allow the COUNTY to draw down FFP dollars from the State for the CONTRACTOR for Short-Doyle Medi-Cal Eligible Services. COUNTY agrees to remit the FFP payment related to submitted and State approved claims by CONTRACTOR within sixty (60) days of receipt of approved claims by State.
6. CONTRACTOR shall work with COUNTY to develop a Plan of Services, in a COUNTY provided format, and submit by September 30 of calendar year 2016 for the Fiscal Year, to COUNTY including all phases of services, projected age groups, expected budgeted components and justification for all planned expenditures for approval by the County Behavioral Health Director, Health, and Human Services Agency Chief Financial Officer. The parties agree that all changes approved/assigned by the Behavioral Health Director shall take effect no later than 45 days from the approval date of such change.
7. Prior to CONTRACTOR making any changes in payment rates of any amount and/or changes of more than 5% to total budget amounts allocated to sub-contractors proportionate to the previous fiscal year, CONTRACTOR shall submit for approval to the Behavioral Health Director all such proposed changes.
8. CONTRACTOR shall comply with all Behavioral Health Director direction(s), policies, procedures, letters and notices of the County of Mendocino Mental Health Plan, Mental Health Services Act Plan, and California Department of Health Care Services and agrees to utilize the Base Match-able Allocation funds for client care services and exclude the use of funds for lobbying or other administrative activities not related to the delivery of services under the Mental Health plan.
9. CONTRACTOR shall provide COUNTY with a monthly "Operational" Cost Report using the most recent data, to be used to track against the interim rate for less future audit reconciliation variation, and an Official Annual Cost Report of Community Based Organizations that provide Medi-Cal services contracted with the Administrative Service Organization for services under the

Mental Health Plan, in the State approved format, for submission to the State of California, Department of Health Care Services.

10. COUNTY shall conduct quarterly reviews of CONTRACTOR'S interim rates with CONTRACTOR'S monthly "Operational" Cost Reports to maintain interim rates that align with COUNTY cost. COUNTY shall also review CONTRACTOR'S annual cost report to establish interim rates with CONTRACTOR. COUNTY shall consult with CONTRACTOR to determine possible adjustments and/or actions to be used for Cost Report reconciliation. CONTRACTOR shall provide COUNTY a copy of each contract negotiated with an outside provider within thirty (30) days of the contract completion.

11. The compensation payable to CONTRACTOR shall be dependent on CONTRACTOR satisfying all components of this Agreement and all direction from the Behavioral Health Director, the State/County Mental Health Plan, the Mental Health Services Act Plan, CFR 42 of Federal Regulations, California Title IX, Exhibit B and Exhibit A as directed within this contract.

As stated in the original agreement, the compensation payable to CONTRACTOR hereunder shall not exceed $5,143,103.00 for FY 20161-17, which shall be the first fiscal year of the Agreement term.

[END OF PAYMENT TERMS]

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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.

CONTRACTOR agrees to indemnify and hold harmless COUNTY, its elected or appointed officials, employees or volunteers against any claims, actions, or demands against them, or any of them, and against any damages, liabilities or expenses, including costs of defense and attorney's fees, for personal injury or death, or for the loss or damage to the property, or any or all of them, to the extent arising out of the performance of this Agreement by CONTRACTOR.

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 CONTRACTOR'S and subcontractors' employees.

CONTRACTOR shall furnish to COUNTY certificates of insurance with Automobile Liability/General Liability Endorsements evidencing at a minimum the following:

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.

[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 Quality Management Company

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.

6-15-2016
Date

CONTRACTOR Signature

P.O. Box 422, Ukiah, CA 95482
Address of CONTRACTOR

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.

Camille Schraeder	Redwood Quality Management Company
(Type Name)	(Organization Name)
	P.O. Box 422
Executive Director	Ukiah, CA 95482
(Title)	(Organization Address)
Camille Schraeder	6-15-2016
(Signature)	(Date)

Appendix B
Title 42: Public Health

PART 2—CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

Section Contents

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.

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.

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

§ 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 posttrial 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.

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, acitivities 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:

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:

A. 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 stored.

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.

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.

J. Ensure that all Contractor systems containing Medi-Cal PII provide an automatic timeout after no more than 20 minutes of inactivity.

K. 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.

L. 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.

M. Ensure that all Contractor systems containing Medi-Cal PII use role based access controls for all user authentication, enforcing the principle of least privilege.

N. 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.

O. 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.

VIII. Audit Controls

P. 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 cross cut 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:

A. Notify John Martire, Chief Welfare Investigator, at 467-5856.

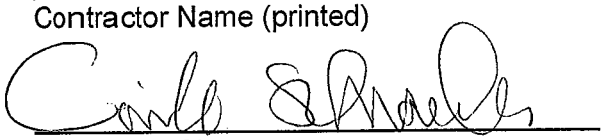
XI. Assessments and Reviews

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.

Camille Schraeder
Contractor Name (printed)



Contractor Signature

Executive Director
Contractor Title

Redwood Quality Management Company
Contractor's Agency Name

6-15-2016
Date