

**COUNTY OF MENDOCINO
STANDARD SERVICES AGREEMENT**

This Agreement, dated as of _____, 2015, is by and between the COUNTY OF MENDOCINO, hereinafter referred to as the "COUNTY", and **FEI.com, Inc.**, 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 to provide support and maintenance services for Web-based Infrastructure for Treatment Services (WITS) software, reporting, and reporting system ("Services"); 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
- Appendix A Certification Regarding Debarment, Suspension, and other Responsibility Matters – lower tier covered transactions
- Appendix B Title 42 Confidentiality of Alcohol and Drug Abuse Patient Records
- Addendum A Medi-Cal Data Privacy and Security Agreement

The term of this Agreement shall be from July 1, 2015 through June 30, 2016.

The compensation payable to CONTRACTOR hereunder shall not exceed Sixty-Three Thousand, Three Hundred Dollars (\$63,300) 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: _____
STACEY CRYER, HHSA Director

Date: _____

Budgeted: Yes No

Budget Unit: 4012

Line Item: 86-2189

Org/Object: DDAdmin

Grant: Yes No

Grant No.:

COUNTY OF MENDOCINO

By: _____
CARRE BROWN, Chair
BOARD OF SUPERVISORS

Date: _____

ATTEST:

CARMEL J. ANGELO, Clerk of said Board

By: _____
Deputy

Date: _____

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: _____

INSURANCE REVIEW:

RISK MANAGER

By: _____
ALAN D. FLORA, Risk Manager

Date: _____

CONTRACTOR/COMPANY NAME

By: _____
Signature

Printed Name: _____

Title: _____

Date: _____

NAME AND ADDRESS OF CONTRACTOR:

FEI.Com, Inc.

7175 Columbia Gateway Dr., Ste A

Columbia, MD, 21046

Phone: (443) 270-5129

E-mail: kristyn.oreilly@feistysystems.com

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:

DOUGLAS L. LOSAK, Interim County Counsel

By: _____
Deputy

Date: _____

EXECUTIVE OFFICE REVIEW:

APPROVAL RECOMMENDED

By: _____
CARMEL J. ANGELO, Chief Executive Officer

Date: _____

FISCAL REVIEW:

By: _____
Deputy CEO/Fiscal

Date: _____

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

Exception to Bid Process Required/Completed 21-15

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: HHS Behavioral Health and Recovery Services
Substance Use Disorder Treatment
1120 South Dora St
Ukiah, CA 95482
Attn: Jenine Miller

To CONTRACTOR: FEI.Com, Inc.
7175 Columbia Gateway Dr., Ste A
Columbia, MD 21046
Attn: Kristin O'Reilly

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 listed in Exhibit A shall not exceed \$63,300 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
DEFINITION OF SERVICES

CONTRACTOR shall provide the following services:

Provide support and maintenance services for COUNTY'S version of the Web-based Infrastructure for Treatment Services ("MendoWITS") software system; support, maintenance of a MendoWITS Ad-hoc Reporting service/system; and various enhancements to the MendoWITS modules to comply with a request from COUNTY users and California Department of Alcohol and Drug Programs (ADP).

1. Support and Maintain the MendoWITS Software System.

The CONTRACTOR shall support and maintain the MendoWITS Software System by providing tier three (3) support which shall include:

- a. Unlimited telephone and e-mail support services to the MendoWITS Systems Administrator or other named single point of contact between the hours of 9:00 AM to 5:00 PM Pacific Standard Time (PST), Monday through Friday, except on County Holidays.
- b. Maintenance of the MendoWITS software which shall include, but not be limited to:
 - (1) Correcting any problem that has been reported by the COUNTY and does not meet agreed upon MendoWITS specification;
 - (2) Updating the MendoWITS system with all corrections and enhancements on a date and time agreed to by the COUNTY and the CONTRACTOR;
 - (3) Updating all data files affected by any correction and/or enhancement;
 - (4) Correcting any problem caused by business rule changes or minor adjustments to the MediCAL and CalOMS applications at the state level. "Minor" is defined as requiring fewer than 8 hours of development time. Estimates will be provided on a case by case basis, and those work items requiring more than 8 hours of development time will be handled through the "enhancement process" of time & cost estimation, review and approval.

The "enhancement process" involves the following steps:

 - i. COUNTY defines a need.
 - ii. COUNTY works with FEI.COM INC. staff to turn that need into a defined requirement for system change / improvement.
 - iii. CONTRACTOR provides quote for building defined requirement into the system. If this enhancement presents cost sharing opportunities with other

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- California Counties or other WITS customers, CONTRACTOR agrees to abide by the cost sharing guidelines agreed upon by the interested members.
- iv. COUNTY approves / rejects enhancement based on price quote.
 - v. If approved, CONTRACTOR builds the enhancement into the system, and places on Mendocino’s User Acceptance Site for review.
 - vi. Once COUNTY approves the enhancement as meeting their defined requirements, CONTRACTOR will bill Mendocino for the enhancement, and it will be scheduled to be moved to the Production environment.
- (5) Acknowledging the reported problem, providing an action plan for resolving the reported problem, and reporting the status and/or resolving the reported problem no later than the time limits specified in the Problem Level Matrix below. The start of the time limit begins when the problem is reported and received by the CONTRACTOR. All problems reported by the COUNTY must have a problem level specified by the COUNTY of critical (cannot continue working until problem resolved); moderately critical (can do work, but processes disrupted with loss of productivity); or non-critical (problem resolution can wait, but needs to be resolved as soon as possible). If no problem level is specified, the problem level shall be deemed to be non-critical; and

PROBLEM LEVEL MATRIX			
Problem Level	Acknowledge Problem (in hours)	Action Plan (in hours)	Status Reporting and/or Resolution (in days)
Critical	0.5	1.5	1.5
Moderately Critical	4.0	8.0	3.0
Non-Critical	24.0	48.0	7.0

- c. Providing, supporting, and maintaining a MendoWITS Training Site that shall be functionally identical to the MendoWITS Production Site and shall include, and not be limited to:
 - (1) Availability seven (7) days a week, 7:00 AM – 7:00 PM PST
 - (2) Updates to the latest version of the MendoWITS Production System software within forty-eight (48) hours after any updates are made to the MendoWITS Production System;
 - (3) Full database backup at least once a week; and

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- (4) Use PST when displaying date and time on all MendoWITS screens and reports, if applicable, and when date and time-stamping of all MendoWITS records that require date and time.
- d. In Fiscal Year 2015/2016, there is a one-time additional service of upgrading ICD-10/DSM-5.
- e. Providing and maintaining a MendoWITS Test Site that shall be used to test any correction and enhancement prior to updating the MendoWITS Production Site and MendoWITS Training Sites.
- f. WITS Production Server Maintenance window. Production site maintenance windows may cause the site to have limited availability from 9:00 am through noon EST when scheduled. CONTRACTOR will provide a 2 week notice for these maintenance windows that are almost always scheduled on a weekend.
2. MendoWITS Software System Network Infrastructure.

The CONTRACTOR shall support and maintain the MendoWITS software system by providing, maintaining, and supporting the hardware, software, and network infrastructure required to host the MendoWITS Production Site and be accessible over the internet. The MendoWITS Production Site shall:

 - a. Be a secure web site that is Health Information Portability and Accountability Act of 1996 (“HIPAA”) compliant;
 - b. Be accessible twenty-four (24) hours a day, seven (7) days a week to all MendoWITS users such that MendoWITS data may be entered and displayed;
 - c. Be accessible by all MendoWITS users a minimum of ninety-eight percent (98%) of each day, excluding the times required for data backups and planned system upgrades;
 - d. Use PST as the default date and time for date and time stamping data records and when displaying date and time on all MendoWITS screens and reports;
 - e. Have all MendoWITS database(s) backed up daily, at a minimum incrementally (with only updates made since the last backup), with a full database backup at least once a week. All backup times shall be agreed to by the COUNTY and the CONTRACTOR. The CONTRACTOR shall publish on MendoWITS Production system the backup schedule for the COUNTY;
3. MendoWITS Ad Hoc Reporting System.

The CONTRACTOR shall support the MendoWITS Ad Hoc Reporting System which shall include, but not limited to:

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- a. All hardware and system software (operating system and database software licenses) required to run the Ad Hoc Reporting System such that the Ad Hoc Reporting System shall not impede the performance to the MendoWITS Production system.
- b. Setting up the MendoWITS Ad Hoc Reporting System to be fully functional to the COUNTY and its contracted provider agencies. Setup shall include, but not limited to:
 - (1) Setting up the hardware and software for use by the Ad Hoc Reporting System.
 - (2) Analyzing the MendoWITS Production system data and working with the COUNTY to determine what data shall be included in the Ad Hoc Reporting System database.
 - (3) Designing the Ad Hoc Reporting System database.
 - (4) Developing the copy program to extract data from MendoWITS Production database and create the Ad Hoc Reporting System database. This program shall be run every night.
 - (5) Integrating Ad Hoc user accounts with the MendoWITS user accounts to ensure that only MendoWITS users can access the Ad Hoc Reporting System database and generate reports.
 - (6) Designing and developing a data dictionary for Ad Hoc users.
 - (7) Designing the system interface such that it is readable by MendoWITS users.
- c. Capability to generate, at a minimum, the following types of report:
 - (1) Table (columnar);
 - (2) Matrix; and
 - (3) Charts.
- d. Capability to export, at a minimum, data in the following formats:
 - (1) Microsoft Excel;
 - (2) Portable Document Format (“PDF”);
 - (3) Image;
 - (4) Extensible Markup Language (“XML”); and
 - (5) Comma Separated Values (“CSV”).
- e. Capability to:
 - (1) Filter data based on user defined criteria;
 - (2) Save reports created by users;
 - (3) Run saved reports; and
 - (4) Group and sort reports by user specified report data.
- f. Ability to restrict the data used in the Ad Hoc reports to only the data that is associated with the MendoWITS provider agency using the Ad Hoc Reporting System. A MendoWITS provider agency must not be allowed to access or report on any other MendoWITS provider agency data. The only exception shall be the Single County Authority (“SCA”)

Exhibit A – Page 5

and MendoWITS contracting agencies. The SCA agency must be able to access and run reports on all substance abuse data from all MendoWITS provider agencies. MendoWITS contracting agencies must be able to generate reports on only clients for which services were rendered and paid for by their contracts.

- g. Support is defined to be telephone support service which includes answering questions as it pertains to the use of the MendoWITS Ad Hoc Reporting System.
- h. Maintenance is defined to be the creating or updating of data views whenever there are new data elements added to or removed from the MendoWITS Production database. Maintenance also includes the support of the hardware and software that is used by the MendoWITS Ad Hoc Reporting System to ensure that it is performing optimally, including taking the necessary precautions for protecting the system from unauthorized access by external sources.

[END OF EXHIBIT A]



**EXHIBIT B
PAYMENT TERMS**

1. COUNTY will pay CONTRACTOR \$3,690 monthly upon receipt of invoice, as follows: WITS Hosting (\$1,080 per month), WITS Maintenance and Support (\$1,800 per month), and SSRS Report Hosting and Support services (\$810 per month).
2. This contract provides authority for COUNTY to pay CONTRACTOR a maximum amount of \$4,000 for authorized enhancements as described in Exhibit A, Sec. 1b.(4).
3. There is an additional fee of \$15,000 to upgrade ICD-10/DSM-5 in FY 2015/2016.

**Invoices will be submitted to:
HHS Behavioral Health and Recovery Services
SUDT Program
1120 S. Dora Street
Ukiah, CA 95482
Attn: Jenine Miller**

Payments under this agreement shall not exceed \$63,300 for the term of this agreement

[END OF PAYMENT TERMS]



EXHIBIT C

INSURANCE REQUIREMENTS

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

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: FEI.Com, Inc.

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.

Date
7175 Columbia Gateway Dr., Ste A, Columbia, MD 21046
Address of CONTRACTOR

CONTRACTOR Signature

Appendix A

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

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

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

- (2) Where the primary principal is unable to certify to any of the statements in this certification, such principal shall attach an explanation.

(Type Name)	FEI.Com, Inc. (Organization Name)
(Title)	7175 Columbia Gateway Dr. Ste A Columbia, MD 21046 (Organization Address)
(Signature)	(Date)

Appendix B

Title 42: Public Health

PART 2—CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

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

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

[§ 2.67 Orders authorizing the use of undercover agents and informants to criminally investigate employees or agents of a program.](#)

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

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

Subpart A—Introduction

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

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

§290ee–3. Confidentiality of patient records.

(a) *Disclosure authorization*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) between such components and the Armed Forces.

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

(f) Penalty for first and subsequent offenses

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

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

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

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

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

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

§290dd–3. Confidentiality of patient records

(a) Disclosure authorization

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) between such components and the Armed Forces.

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

(f) Penalty for first and subsequent offenses

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

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

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

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

§ 2.3 Purpose and effect.

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

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

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

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

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

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

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

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

§ 2.4 Criminal penalty for violation.

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

§ 2.5 Reports of violations.

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

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

Subpart B—General Provisions

§ 2.11 Definitions.

For purposes of these regulations:

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

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

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

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

Informant means an individual:

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

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

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

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

Program means:

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

Program director means:

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

Qualified service organization means a person which:

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

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

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

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

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

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

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

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

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

§ 2.12 Applicability.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 2.13 Confidentiality restrictions.

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

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

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

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

§ 2.14 Minor patients.

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

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

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

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

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

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

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

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

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

§ 2.15 Incompetent and deceased patients.

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

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

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

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

§ 2.16 Security for written records.

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

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

§ 2.17 Undercover agents and informants.

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

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

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

§ 2.18 Restrictions on the use of identification cards.

No person may require any patient to carry on his or her person while away from the program premises any card or other object which would identify the patient as an alcohol or drug abuser.

This section does not prohibit a person from requiring patients to use or carry cards or other identification objects on the premises of a program.

§ 2.19 Disposition of records by discontinued programs.

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

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

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

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

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

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

§ 2.20 Relationship to State laws.

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

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

(a) *Research privilege description.* There may be concurrent coverage of patient identifying information by these regulations and by administrative action taken under: Section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a) and the implementing regulations at 42 CFR part 2a); or section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c) and the implementing regulations at 21 CFR 1316.21). These “research privilege” statutes confer on the Secretary of Health and Human Services and on the Attorney General, respectively, the power to authorize researchers conducting certain types of research to withhold from all persons not connected with

the research the names and other identifying information concerning individuals who are the subjects of the research.

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

§ 2.22 Notice to patients of Federal confidentiality requirements.

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

- (1) Communicate to the patient that Federal law and regulations protect the confidentiality of alcohol and drug abuse patient records; and
- (2) Give to the patient a summary in writing of the Federal law and regulations.

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

- (1) A general description of the limited circumstances under which a program may acknowledge that an individual is present at a facility or disclose outside the program information identifying a patient as an alcohol or drug abuser.
- (2) A statement that violation of the Federal law and regulations by a program is a crime and that suspected violations may be reported to appropriate authorities in accordance with these regulations.
- (3) A statement that information related to a patient's commission of a crime on the premises of the program or against personnel of the program is not protected.
- (4) A statement that reports of suspected child abuse and neglect made under State law to appropriate State or local authorities are not protected.
- (5) A citation to the Federal law and regulations.

(c) *Program options.* The program may devise its own notice or may use the sample notice in paragraph (d) to comply with the requirement to provide the patient with a summary in writing of

the Federal law and regulations. In addition, the program may include in the written summary information concerning State law and any program policy not inconsistent with State and Federal law on the subject of confidentiality of alcohol and drug abuse patient records.

(d) *Sample notice.*

Confidentiality of Alcohol and Drug Abuse Patient Records

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

- (1) The patient consents in writing;
- (2) The disclosure is allowed by a court order; or
- (3) The disclosure is made to medical personnel in a medical emergency or to qualified personnel for research, audit, or program evaluation.

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

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

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

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

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

§ 2.23 Patient access and restrictions on use.

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

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

Subpart C—Disclosures With Patient's Consent

§ 2.31 Form of written consent.

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

- (1) The specific name or general designation of the program or person permitted to make the disclosure.
- (2) The name or title of the individual or the name of the organization to which disclosure is to be made.
- (3) The name of the patient.
- (4) The purpose of the disclosure.
- (5) How much and what kind of information is to be disclosed.
- (6) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under §2.14; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign under §2.15 in lieu of the patient.
- (7) The date on which the consent is signed.
- (8) A statement that the consent is subject to revocation at any time except to the extent that the program or person which is to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third party payer.
- (9) The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

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

1. I (name of patient) Request Authorize:

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

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

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

5. For (purpose of the disclosure)

6. Date (on which this consent is signed)

7. Signature of patient

8. Signature of parent or guardian (where required)

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

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

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

(1) Has expired;

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

(3) Is known to have been revoked; or

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

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§ 2.32 Prohibition on redisclosure.

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

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

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

§ 2.33 Disclosures permitted with written consent.

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

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

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

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

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

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

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

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

(1) The disclosure is made when:

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

(2) The disclosure is limited to:

- (i) Patient identifying information;
- (ii) Type and dosage of the drug; and
- (iii) Relevant dates.

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

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

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

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

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

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

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

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

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

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

(1) The disclosure is made only to those individuals within the criminal justice system who have a need for the information in connection with their duty to monitor the patient's progress (e.g., a prosecuting attorney who is withholding charges against the patient, a court granting pretrial or 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 party 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, activities or services directly related to the administration of the Medi-Cal program in accordance with Welfare and Institutions Code section 14100.2 and 42 Code of Federal Regulations section 431.300 et seq, or as required by law.

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

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

II. Employee Training and Discipline

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

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

III. Management Oversight and Monitoring

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

IV. Confidentiality Statement

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

V. Physical Security

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

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

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

VI. Computer Security Safeguards

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

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

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

VII. System Security Controls

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

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

VIII. Audit Controls

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

IX. Paper Document Controls

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

- A. Dispose of Medi-Cal PII in paper form through confidential means, such as 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 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.

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Signature Page

Contractor Name (printed)

Contractor Signature

Contractor Title

FEI.Com, Inc.

Contractor's Agency Name

Date