



BUSINESS ASSOCIATE AND QUALIFIED SERVICE ORGANIZATION AGREEMENT

This Business Associate and Qualified Service Organization Agreement (“BAQSOA” or “Agreement”) is made effective on the date of signature by and between (“Covered Entity”) and **FEi.com, Inc., dba FEI Systems** (“Business Associate”), collectively referred to as the “Parties.”

WHEREAS, Business Associate is providing services to Covered Entity for a data collection system for the Pennsylvania Department of Drug and Alcohol Programs (DDAP) to provide data to the federal government (“Services”) for or on behalf of Covered Entity;

WHEREAS, the relationship between Covered Entity and Business Associate is such that the Parties believe Business Associate is a “business associate” within the meaning of the HIPAA Privacy Rule;

WHEREAS, Covered Entity operates a federally assisted part 2 program in Pennsylvania that must comply with the Federal Confidentiality of Alcohol and Drug Abuse Patient Records law and regulations, 42 USC §290dd-2 and 42 CFR Part 2 (collectively, “Part 2”);

WHEREAS, Business Associate is also a Qualified Service Organization (QSO) under Part 2 and must agree to certain mandatory provisions regarding the use and disclosure of substance abuse treatment information; and

WHEREAS, the Parties desire to set forth the terms and conditions pursuant to which Protected Health Information, provided to Business Associate by Covered Entity (“Protected Health Information”), will be handled between themselves and third parties.

NOW THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. **DEFINITIONS.** Unless some other meaning is clearly indicated by the context, the following terms shall have the following meaning in this Agreement:
 - a. "Electronic Protected Health Information" shall have the same meaning as the term "electronic protected health information" in 45 C.F.R. § 160.103.
 - b. "HIPAA" means the Administrative Simplification Provisions, Sections 261 through 264, of the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, as modified and amended by the Health Information Technology for Economic and Clinical Health ("HITECH") Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009, Public law 111-5.
 - c. "Individual" shall have the same meaning as the term "individual" in 45 C.F.R. § 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 C.F.R. § 164.502(g).
 - d. "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Part 160 and Part 164.
 - e. "Protected Health Information" shall have the same meaning as the term "protected health information" in 45 C.F.R. § 160.103, limited to the information created or received by Business Associate from or on behalf of Covered Entity.



- f. "Qualified Service Organization" shall have the same meaning as the term "Qualified service organization" in 42 C.F.R. § 2.11
- g. "Required By Law" shall have the same meaning as the term "required by law" in 45 C.F.R. § 164.103.
- h. "Secretary" shall mean the Secretary of the United States Department of Health and Human Services or the person to whom the authority involved has been delegated.
- i. Unless otherwise defined in this Agreement, terms used herein shall have the same meaning as those terms have in the Privacy Rule.

2. **OBLIGATIONS OF BUSINESS ASSOCIATE.**

- a. Business Associate agrees to not use or disclose Protected Health Information other than as permitted or required by this Agreement or as Required By law.
- b. Business Associate agrees to use appropriate safeguards and comply, where applicable, with subpart C of 45 C.F.R. Part 164 with respect to electronic protected health information, to prevent use or disclosure of the Protected Health Information other than as provided for by this Agreement.
- c. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of Protected Health Information by Business Associate in violation of the requirements of this Agreement.
- d. Business Associate agrees to report to Covered Entity any use or disclosure of the Protected Health Information not provided for by this Agreement of which it becomes aware, including breaches of unsecured Protected Health Information as required by 45 C.F.R. 164.410.
- e. Business Associate agrees, in accordance with 45 C.F.R. 164.502(e)(1) and 164.308(b)(2), to ensure that any subcontractors that create, receive, maintain or transmit protected health information on behalf of Business Associate agree to the same restrictions and conditions that apply to Business Associate with respect to such information.
- f. Business Associate agrees to make available Protected Health Information as necessary to satisfy Covered Entity's obligations in accordance with 45 C.F.R. 164.524.
- g. Business Associate agrees to make available Protected Health Information for amendment so that Covered Entity can incorporate any amendments to Protected Health Information in accordance with 45 C.F.R. 164.526.
- h. Unless otherwise prohibited by law, Business Associate agrees to make internal practices, books, and records relating to the use and disclosure of Protected Health Information received from, or created or received by Business Associate on behalf of, Covered Entity available to the Secretary for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule.
- i. Business Associate agrees to make available the information required to provide an accounting of disclosures of Protected Health Information in accordance with 45 C.F.R. - 164.528.

3. **RESPONSIBILITY OF COVERED ENTITY.** With regard to the use and/or disclosure of Protected Health Information by Covered Entity, Covered Entity agrees to obtain any consent, authorization, or permission that may be required by the Privacy Rule, Part 2, or any other applicable federal, state, or local laws and/or regulations prior to furnishing such Protected Health Information to Business Associate.



4. **PERMITTED USES AND DISCLOSURES.**

- a. Except as otherwise limited in this Agreement or by other applicable law or agreement, if the Services arrangement permits, Business Associate may use or disclose Protected Health Information to perform functions, activities, or services for, or on behalf of, Covered Entity as specified in the Services provided that such use or disclosure:
 - i. would not violate the Privacy Rules if done by Covered Entity; or
 - ii. would not violate the minimum necessary policies and procedures of the Covered Entity.
 - b. Except as otherwise limited in this Agreement or by other applicable law or agreements, if the Services arrangement permits, Business Associate may disclose Protected Health Information for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate, provided that:
 - i. The disclosures are Required By Law; or
 - ii. Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and will be used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.
 - c. Except as otherwise limited in this Agreement or by other applicable law or agreements, if the Service arrangement permits, Business Associate may use Protected Health Information to provide data aggregation services to Covered Entity as permitted by 45 C.F.R. 164. 504(e)(2)(i)(B).
 - d. Business Associate agrees that when it uses, discloses, or request Protected Health Information, it will limit the use, disclosure, or request to the minimum necessary.
 - e. If Business Associate enters into a contract with any agent and/or subcontractor, the agent/subcontractor will agree to comply with 42 C.F.R. Part 2 and HIPAA, and if Business Associate learns of a pattern or practice by the agent/subcontractor that is a material breach of the contract with Business Associate, to take reasonable steps to cure the breach or terminate the contract, if feasible.
 - f. Notwithstanding the foregoing provisions, Business Associate may not use or disclose Protected Health Information if the use or disclosure would violate any conditions of the Services or other applicable law or agreements
5. **QUALIFIED SERVICE ORGANIZATION AGREEMENT.** Covered Entity and Business Associate hereby agree that this Agreement constitutes a Qualified Service Organization Agreement ("QSOA") as required by 42 CFR Part 2. Accordingly, information obtained by Business Associate relating to individuals who may have been diagnosed as needing, or who have received, substance use disorder treatment services shall be maintained and used only for the purposes intended under this Agreement and in conformity with all applicable provisions of 42 USC § 290dd-2 and the underlying federal regulations, 42 C.F.R. Part 2. This includes but is not limited to resisting any efforts in judicial proceedings to obtain access to the Protected Health Information, pursuant to 42 C.F.R. Part 2. Accordingly, except as otherwise limited in this Agreement, Business Associate may use or disclose Protected Health Information to perform functions, activities, or services for, or on behalf of, Covered Entity provided that such use or disclosure would not violate the Confidentiality or Privacy Rules if done by Covered Entity.



6. TERM AND TERMINATION.

- a. Term. This Agreement shall be effective as of the effective date stated above and shall terminate when the Services between the Parties terminates.
- b. Termination for Cause. Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity may, at its option:
 - i. Provide an opportunity for Business Associate to cure the breach or end the violation, and terminate this Agreement and services provided by Business Associate, to the extent permissible by law, if Business Associate does not cure the breach or end the violation with the time specified by Covered Entity;
 - ii. Immediately terminate this Agreement and services provided by Business Associate, to the extent permissible by law; or
 - iii. If neither termination nor cure is feasible, report the violation to the Secretary as provided in the Privacy Rule.
- c. Effect of Termination.
 - i. Except as provided in the Services arrangement or paragraph (ii) of this section or by other applicable law or agreements, upon termination of this Agreement and services provided by Business Associate, for any reason, Business Associate shall return or destroy all Protected Health Information received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the Protected Health Information.
 - ii. In the event that Business Associate determines that returning or destroying the Protected Health Information is not feasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction not feasible. Business Associate shall extend the protections of this Agreement to such Protected Health Information and limit further uses
and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such Protected Health Information.

7. GENERAL TERMS AND CONDITIONS.

- a. Once executed, this Agreement automatically and immediately becomes part of the Services.
- b. Except as provided in this Agreement, all terms and conditions of the Services shall remain in force and shall apply to this Agreement as if set forth fully herein.
- c. In the event of a conflict between this Agreement and the Services arrangement, the interpretation that is in accordance with the Privacy Rule and Part 2 shall prevail. In the event that a conflict still remains, the Services arrangement shall prevail so long as they are in accordance with the Privacy Rule and Part 2.
- d. A material breach of this Agreement by Business Associate shall be considered



sufficient basis for Covered Entity to terminate the Services for cause.

8. MISCELLANEOUS.

- a. Entire Agreement. This Agreement, and all attachments, schedules and exhibits hereto, constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and supersedes any prior or contemporaneous written or oral memoranda, negotiations, arrangements, contracts or understandings of any nature or kind between the Parties with respect to the subject matter hereof.
- b. Construction of Terms. The terms of this Agreement shall be construed in light of any interpretation and/or guidance on HIPAA, Part 2, the Privacy Regulation and/or the Security Regulation issued by HHS from time to time.
- c. Survival. Paragraphs 6(c), 8(b), 9, 10, and this 8(c), and any other provisions of this Agreement that by their terms are intended to survive, shall survive the termination of this Agreement.
- d. Counterparts and Copies. This Agreement may be executed in any number of counterparts. Properly processed photocopies, facsimiles, and/or scanned document images shall be deemed to be originals.
- e. Binding Agreement. This Agreement shall be binding upon the Parties and their successors and permitted assigns.

9. **LIMITATION OF LIABILITY.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INCIDENTAL, CONSEQUENTIAL, SPECIAL, OR PUNITIVE DAMAGES OF ANY KIND OR NATURE, WHETHER SUCH LIABILITY IS ASSERTED ON THE BASIS OF CONTRACT, TORT (INCLUDING NEGLIGENCE OR STRICT LIABILITY), OR OTHERWISE, EVEN IF THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGES.

10. **DEFINITIONS.** Regulatory citations in this Agreement are to the United States Code of Federal Regulations Title 45 and Title 42, as interpreted and amended from time to time by HHS, for so long as such regulations are in effect. Unless otherwise specified in this Agreement, all capitalized terms not otherwise defined shall have the meaning established for purposes of Title 42 and Title 45 parts 160 through 164 of the United States Code of Federal Regulations, as amended from time to time.

11. **SIGNATURE AUTHORITY.** Each person signing this Agreement represents and warrants that he or she is duly authorized and has legal capacity to execute and deliver this Agreement. Each party represents and warrants to the other that the execution and delivery of the Agreement and the performance of such party's obligations hereunder have been duly authorized and that the Agreement is a valid and legal agreement binding on such party and enforceable in accordance with its terms.

12. **COVERED ENTITY CONTACT.** For verification purposes, Business Associate requires Covered Entity to provide basic contact information, as set out below:

Contact Name: _____
Contact Email: _____
Facility License Number: _____



IN WITNESS WHEREOF, each of the undersigned has caused this Business Associate and Qualified Service Organization Agreement to be duly executed effective as of the Effective Date.

FEL.COM, INC. dba FEI Systems

COVERED ENTITY

Signature

Signature

Title and Printed Name

Title and Printed Name

Date

Date