

## QUALIFIED SERVICE ORGANIZATION/BUSINESS ASSOCIATE AGREEMENT

WHEREAS, the Ohio Department of Mental Health and Addiction Services (State Agency) will make available and/or transfer to Contractor confidential, Protected Information, as described below, in conjunction with [describe services] obtained pursuant to DAS Contract Number \_\_\_\_\_, and

WHEREAS, such information may be used or disclosed only in accordance with applicable federal regulations, including the confidentiality of substance use disorder patient records [ 42 CFR Part 2] and the privacy and security regulations [45 CFR Parts 160 and 164] issued pursuant to the Health Insurance Portability and Accountability Act [42 USC §§ 1320 - 1320d-8], as it has been amended, and the terms of this Agreement, or more stringent provisions of federal law or the law of the State of Ohio;

NOW THEREFORE, the parties agree as follows:

1. Protected Information includes both:

Patient Identifying Information ("PII") means the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient of a part 2 program can be determined with reasonable accuracy, either directly, or by reference to other information; and

Protected Health Information ("PHI") means individually identifiable information received from or on behalf of the State Agency and relating to the past, present or future physical or mental health or condition of an individual, provision of health care to an individual, or the past, present or future payment for health care provided to an individual, as more fully defined in 45 CFR § 160.103, and any amendments thereto.

Unsecured PHI is PHI that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals according to the technologies or methodologies specified by the Director of the U.S. Department of Health and Human Services.

2. Contractor agrees that it shall not receive, create, maintain, transmit, use, or disclose Protected Information except as follows:
  - a. To provide [identified services] and related functions;
  - b. Contractor agrees that it shall not receive, create, use or disclose PHI except if necessary for the proper management and administration of Contractor or to carry out legal responsibilities of Contractor. PHI may only be disclosed to another person/entity for such purposes if the disclosure is consistent with 42 CFR Part 2 with regard to PII, and if:
    - Disclosure is required by law as determined by State Agency.
    - Where Contractor obtains reasonable assurances from the person to whom disclosure is made that the PHI released will be held confidentially and only may be used or further disclosed as required by law or for the purposes of the disclosure; and person/entity agrees to notify Contractor of any breaches of confidentiality in a timely fashion and in writing. Reasonable assurances need to follow the same standards as section 6 below.
    - Prior to permitting any person or entity access to the Protected Information, Contractor notifies and receives written approval from the following, or a successor: [insert contact info]
  - c. Contractor acknowledges that in receiving, storing, processing, or otherwise dealing with any PII from or on behalf of State Agency:
    - Contractor is fully bound by the regulations at 42 CFR Part 2, including the prohibition on re-disclosure without appropriate authority; and
    - If necessary, Contractor will resist in judicial proceedings any efforts to obtain access to PII except as permitted by the regulations.
3. Contractor agrees that is shall not use or disclose PHI in a manner that would violate Subpart E of 45 CFR Part 164 if done by State Agency, except for the specific uses and disclosures enumerated in paragraph 2.b.

4. Contractor agrees that it will not request, use or release more than the minimum amount of Protected Information necessary to accomplish the purpose of the use, disclosure or request.
5. Contractor shall comply with Subpart C of 45 CFR Part 164, and will establish and maintain appropriate safeguards to prevent any unauthorized use or disclosure of Protected Information, and implement administrative, physical, and technical safeguards that reasonably protect the confidentiality, integrity, and availability of electronic Protected Information that it creates, receives, maintains, or transmits on behalf of State Agency. Contractor will use all applicable appropriate safeguards under 42 CFR 2.16 and State of Ohio IT security policies, standards, and bulletins.
6. Contractor agrees that it shall immediately report to State Agency, in writing and within 72 hours of discovery, any unauthorized uses/disclosures of unsecured PHI and any security incident resulting in the loss or disclosure of PHI of which it becomes aware. Reports of unauthorized access, use or disclosure of unsecured PHI shall include identification of affected individuals whose PHI has been or is reasonably believed to have been accessed, used, disclosed, or lost. Contractor shall take all reasonable steps to mitigate the potentially harmful effects of such breach.
7. Contractor shall ensure that all of its subcontractors and agents are bound by the same restrictions and obligations contained herein, including but not limited to the obligation to implement reasonable and appropriate safeguards to protect the information, whenever PHI is made accessible to such subcontractors or agents. Notwithstanding the first sentence of this paragraph, Contractor acknowledges that some of the Protected Information received from or on behalf of State Agency is covered by 42 CFR Part 2 and therefore Contractor is prohibited from disclosing such information to agents or subcontractors unless the agent or subcontractor is a contract agent of Contractor, assisting Contractor in providing the services described herein, and the contract agent agrees that it may disclose the information only back to State Agency or Contractor. The contract agent is bound by the regulations at 42 CFR Part 2.
8. Contractor shall make all PHI and related information in a designated record set in its possession available as follows:
  - a. To the individual or his/her personal representative, and to State Agency, to the extent necessary to fulfill any obligation to allow access for inspection and copying in accordance with the provisions of 45 CFR § 164.524;
  - b. To the individual or his/her personal representative, and to State Agency, to the extent necessary to fulfill any obligation to account for disclosures of PHI in accordance with 45 CFR § 164.528;
  - c. To State Agency, as necessary to fulfill State Agency's obligation to amend PHI and related information in accordance with 45 CFR § 164.526, and shall, as directed by State Agency, incorporate any amendments or related statements into the information held by Contractor and any subcontractors or agents.
9. Contractor agrees to make its internal practices, books and records relating to the use or disclosure of information received from or on behalf of State Agency available to the U. S. Secretary of Health and Human Services, or the Secretary's designee, for purposes of determining compliance with the privacy regulations, and any amendments thereto.
10. Upon termination of the contractual relationship between State Agency and Contractor established pursuant to the DAS Contract, Contractor agrees, at the option of State Agency, to return or destroy all Protected Information created or received from or on behalf of State Agency. Contractor agrees that it will not retain any copies of Protected Information except as required by law. If return or destruction of all Protected Information, and all copies of Protected Information, is not feasible, Contractor agrees to extend the protections of this Agreement to such information for as long as it is maintained and to limit further uses and disclosures to those which make return or destruction infeasible.
11. The Protected Information and any related information created or received from or on behalf of State Agency is, and shall remain, the property of the State Agency. Contractor agrees that it acquires no title in or rights to the information, including any de-identified information.
12. Any non-compliance by Contractor with the terms of this Agreement or the HIPAA and 42 CFR Part 2 regulations shall be a breach of this Agreement if Contractor knew of the breach and failed to take immediate and reasonable steps to cure the non-compliance. Contractor agrees that State Agency has

the right to immediately terminate the underlying contract for [identified services], if State Agency determines that Contractor has violated a material term of this Agreement.

13. The obligations to safeguard the confidentiality and security of Protected Information imposed herein shall survive the termination of this Agreement.
14. Any ambiguities in this Agreement shall be resolved in favor of an interpretation that promotes compliance with 42 CFR Part 2, HIPAA and regulations promulgated thereunder. The parties agree that any modifications to those laws shall modify the obligations of the parties hereunder without the need for formal amendment of the Agreement. Any other amendments to this Agreement shall not be effective without the written agreement of both parties.

This Qualified Service Organization/Business Associate Agreement shall be effective as provided herein and shall govern the relationship between State Agency and Contractor for purposes of complying with 42 CFR Part 2 and HIPAA.

IN WITNESS WHEREOF, the Parties have signed this Agreement on the date indicated below.

\_\_\_\_\_  
(Contractor)

\_\_\_\_\_  
(State of Ohio Agency)

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Printed Name and Title)

\_\_\_\_\_  
(Printed Name and Title)

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Date)