

ATTACHMENT V – Qualified Service Organization/Business Associate Agreement

THIS Agreement is made by and between the Office of Addiction Services and Supports (“Covered Entity”), and _____ (“Business Associate”).

WHEREAS, Business Associate provides, or intends to provide, certain services to Covered Entity through existing written agreement signed by Business Associate contemporaneously herewith, and, in connection with such services, may create, use or disclose for or on behalf of Covered Entity certain individually identifiable protected health information relating to individuals served by the Covered Entity (“PHI”) that is subject to protection under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as amended, including Subpart D of the Health Information Technology for Economic and Clinical Health Act (HITECH) of Title XIII, Division A of the American Recovery and Reinvestment Act of 2009, and related regulations, 45 CFR Parts 160 and 164 (the HIPAA Privacy and Security Rules); the Federal Confidentiality Law, 42 USC §§ 290dd-2 and underlying regulations 42 CFR Part 2 (“Part 2”) and

WHEREAS, by reason of such activities, the parties believe that Business Associate is a “business associate” of Covered Entity, as such term is defined in 45 CFR § 160.103; and

WHEREAS, Covered Entity and Business Associate wish to comply in all respects with the requirements of 42 CFR Part 2, HIPAA and HITECH, including requirements applicable to the relationship between a covered entity and its business associates;

NOW, THEREFORE, the parties agree as follows:

1. Definitions:

Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in 45 CFR §§160.103, 164.103, and 164.501.

- (a) “Breach” shall have the same meaning as the term “breach” in Section 13400 of the HITECH Act and guidance issued by the US Department of Health and Human Services and shall include the unauthorized acquisition, use, or disclosure of Protected Health Information that compromises the privacy or security of such information.
- (b) “Business Associate” shall mean the _____.
- (c) “Covered Entity” shall mean the Office of Addiction Services and Supports.
- (d) “Confidentiality Rule” shall mean the Federal Confidentiality regulation 42 CFR Part 2.
- (e) “Designated Record Set” shall have the same meaning as the term “designated record set” in 45 CFR 164.501.
- (f) “Disclose” or “Disclosure” shall have the same meaning as the terms “disclose” and “disclosure” in 42 CFR 2.11
- (g) “Individual” shall have the same meaning as the term “individual” in 45 CFR § 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR § 164.502(g).
- (h) “Privacy Rule” shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR § part 160 and part 164, subparts A and E.
- (i) “Protected Health Information” shall have the same meaning as the term “protected health information” in 45 CFR 160.103, limited to the information created or received by Business Associate from or on behalf of Covered Entity in connection with the Business Associate’s performance of this Agreement.

ATTACHMENT V – Qualified Service Organization/Business Associate Agreement

- (j) “Qualified Service Organization Agreement” shall have the same meaning as defined in 42 CFR § 2.12(c)(4).
- (k) “Required By Law” shall have the same meaning as the term “required by law” in 45 CFR § 164.103.
- (l) “Secretary” shall mean the Secretary of the Department of Health and Human Services or his or her designee.
- (m) “Security rule” shall mean the Security Standards for the Protection of Electronic Protected Health Information at 45 CFR Parts 160 and 164, subparts A and C.
- (n) “Unsecured Protected Health Information” shall mean Protected Health Information that is not secured through the use of a technology or methodology specified by the Secretary in guidance, or as otherwise defined in Section 13402(h) of the HITECH Act.

2. Obligations and Activities of Business Associate

- (a) Business Associate agrees to not use or further disclose Protected Health Information other than as Required by Law, or as otherwise permitted or as required by this Agreement.
- (b) Business Associate agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Agreement and to implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of any electronic Protected Health Information that it creates, receives, maintains, or transmits on behalf of Covered Entity pursuant to this Agreement in accordance with 42 CFR Part 2 (the Confidentiality Rule) and 45 CFR 164 (the HIPAA Security Rule). Business Associate agrees to fully comply with the responsibilities of Business Associates as set forth in Sections 13401 and 13404 of the HITECH Act.
- (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. Further, Business Associate agrees to report to Covered Entity any security incident, including a breach of Unsecured Protected Health Information as defined by the Security Rule, of which it becomes aware. In the event of such a breach:
 - (1) Business Associate shall promptly notify Covered Entity of the breach when it is discovered. A breach is considered discovered on the first day on which Business Associate knows or should have known of such breach. Such notification shall identify the Individuals, and their contact information, whose Unsecured Protected Health Information has, or is reasonably believed to have been, the subject of the breach. Business Associate shall provide additional information concerning such breach to Covered Entity as requested.
 - (2) Covered Entity or Business Associate, as determined by Covered Entity, shall promptly notify individuals about a breach of their Unsecured Protected Health Information as soon as possible but not later than 60 calendar days after discovery of the Breach, except where a law enforcement official determines that a notification would impede a criminal investigation or cause damage to national security. Notification shall be in a form and format prescribed by Covered Entity and shall meet the requirements of Section 13402 of the HITECH Act.
- (e) Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by Business Associate on behalf of Covered Entity, agrees to the same restrictions and conditions that

ATTACHMENT V – Qualified Service Organization/Business Associate Agreement

apply through this Agreement to Business Associate with respect to such information. Notwithstanding the preceding language of this subsection, Business Associate acknowledges that the Protected Health Information received from Covered Entity, or created by Business Associate is covered by 42 CFR Part 2 and therefore Business Associate is specifically prohibited from disclosing such information to agents or subcontractors without specific written consent of the subject individual.

- (f) Business Associate agrees to provide access, at the request of Covered Entity, and in the time and manner designated by Covered Entity, to Protected Health Information in a Designated Record Set, to Covered Entity or, as directed by Covered Entity, to an Individual in order to meet the requirements under 45 CFR § 164.524, if the Business Associate has Protected Health Information in a Designated Record Set.
- (g) Business Associate agrees to make any amendments to Protected Health Information in a Designated Record Set that the Covered Entity directs or agrees to pursuant to 45 CFR § 164.526 at the request of Covered Entity or an Individual, and in the time and manner designated by Covered Entity, if Business Associate has Protected Health Information in a Designated Record Set.
- (h) 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 Covered Entity, or at the request of the Covered Entity to the Secretary, in a time and manner designated by the Covered Entity or the Secretary, for purposes of the Secretary's determining Covered Entity's compliance with the Privacy Rule.
- (i) Business Associate agrees to document such disclosures of Protected Health Information and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR § 164.528.
- (j) Business Associate agrees to provide to Covered Entity or an Individual, in time and manner designated by Covered Entity, information collected in accordance with Section (2)(i) of this Agreement, to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR § 164.528.
- (k) Business Associate hereby acknowledges and agrees that Covered Entity has notified Business Associate that it is required to comply with the confidentiality, disclosure and re-disclosure requirements of Mental Hygiene Law Sections 32.17, 33.13 and 33.16 to the extent such requirements may be applicable.
- (l) Business Associate shall be directly responsible for full compliance with the relevant requirements of the Confidentiality, Privacy and the Security Rules to the same extent that Covered Entity is responsible for compliance with such Rules. Business Associate acknowledges that it is subject to civil and criminal penalties for violations of such provisions in the same manner as if Covered Entity violated such provisions.
- (m) Business Associate agrees to resist any efforts in judicial proceedings to obtain access to the Protected Health Information except as expressly provided for in the regulations governing the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2.

3. Permitted Uses and Disclosures by Business Associate

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

ATTACHMENT V – Qualified Service Organization/Business Associate Agreement

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 CFR 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.

- (a) Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.
- (b) Except as otherwise limited in this Agreement, Business Associate may disclose Protected Health Information for the proper management and administration of the Business Associate, provided that disclosures are required by law, or 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. Notwithstanding the preceding language of this subsection, Business Associate acknowledges that the Protected Health Information received from Covered Entity, or created by Business Associate is covered by 42 CFR Part 2 and therefore Business Associate is specifically prohibited from disclosing such information to agents or subcontractors without specific written consent of the subject individual.
- (c) Business Associate may use Protected Health Information to provide Data Aggregation services to Covered Entity as permitted by 45 CFR § 164.504(e)(2)(i)(B). Data aggregation includes the combining of protected information created or received by a business associate through its activities under this contract with other information gained from other sources.
- (d) Business Associate may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with New York State Mental Hygiene Law and 45 CFR § 164.502(j)(1) and 42 CFR § 2.12(c)(5)(ii).

4. Obligations of Covered Entity

- (a) Covered Entity shall notify Business Associate of any limitation(s) in the Notice of Privacy Practices Covered Entity produces in accordance with 45 CFR §164.520, to the extent that such limitation may affect Business Associate's use or disclosure of Protected Health Information.
- (b) Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by an Individual to use or disclose Protected Health Information, to the extent that such changes may affect Business Associate's permitted or required uses and disclosures.
- (c) Covered Entity shall notify Business Associate of any restriction to the use or disclosure of Protected Health Information that Covered Entity has agreed to in accordance with 45 CFR §164.522, to the extent that such restriction may affect Business Associate's use or disclosure of Protected Health Information.

5. Permissible Requests by Covered Entity

Covered Entity shall not request Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by Covered Entity. Covered Entity may permit Business Associate to use or disclose Protected Health Information for data aggregation or management and administrative activities of

ATTACHMENT V – Qualified Service Organization/Business Associate Agreement

Business Associate, if the agreement defining the parties' business relationship includes provisions for same.

6. Remedies in Event of Breach

- (a) Business Associate hereby agrees that any violation of this Agreement may cause irreparable harm to the Covered Entity. As such, in the event of breach of any provision of this Agreement, Covered Entity shall be entitled to enjoin and restrain Business Associate from any continued violation, and/or may seek specific performance, without bond, security or necessity of demonstrating actual damages.
- (b) Business Associate shall indemnify and hold Covered Entity harmless against all claims and costs resulting from acts and/or omissions of the Business Associate in connection with Business Associate's obligations under this Agreement, including but not limited to, reasonable attorneys' fees, expenses and costs. Business Associate shall be fully liable for the actions of its agents, employees, partners and subcontractors and shall fully indemnify and hold harmless Covered Entity from suits, actions, damages and costs of every name and description relating to breach notification required by 45 CFR Part 164 Subpart D, or State Technology Law Section 208, caused by any intentional act or negligence of Business Associate, its agents, employees, partners and subcontractors, without limitation; provided however, that Business Associate shall not indemnify for that portion of any claim, loss or damage arising hereunder due to the negligent act or failure to act of Covered Entity. The provisions of this Section 6 shall survive the expiration or termination of this Agreement.

7. Consideration

Business Associate acknowledges that the covenants and assurances it has made in the Agreement shall be relied upon by Covered Entity in choosing to continue or commence a business relationship with Business Associate.

8. Term and Termination

- (a) Term. The Term of this Agreement shall be effective as of the Effective Date of the Agreement defining the parties' business relationship and shall not terminate until all of the Protected Health Information provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity is destroyed or returned to Covered Entity or, if it is infeasible to return or destroy Protected Health Information, protections are extended to such information in accordance with the termination provisions in this Section.
- (b) Termination for Cause. Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity shall provide Business Associate with an opportunity to cure the breach and then terminate this Agreement and any other agreement between Covered Entity and Business Associate if Business Associate does not cure the breach within the time period specified by Covered Entity.
- (c) Effect of Termination.
 - (1) Except as provided in paragraph (2) of this Section, upon termination of this Agreement 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.
 - (2) In the event that Business Associate determines that returning or destroying the Protected Health Information is infeasible, Business Associate shall provide to Covered

ATTACHMENT V – Qualified Service Organization/Business Associate Agreement

Entity notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the parties that return, or destruction of Protected Health Information is infeasible, Business Associate shall extend the protection 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.

9. Miscellaneous.

- (a) Regulatory References. A reference in this Agreement to a Section in the Confidentiality or Privacy Rule means the section as in effect or as amended, and for which compliance is required.
- (b) Agreement. The parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Confidentiality or Privacy Rule and the Health Insurance Portability and Accountability Act, Public Law 104-191.
- (c) Survival. The respective rights and obligations of Business Associate under Section 6 of this Agreement shall survive the termination of this Agreement, as shall the rights of access and inspection of Covered Entity.
- (d) Interpretation. Any ambiguity in this Agreement shall be resolved in favor of a meaning that permits Covered Entity to comply with the Confidentiality and Privacy Rules.

10. Material Breach.

The parties acknowledge that in the event Covered Entity learns of a pattern or activity or practice of the Business Associate that constitutes violation of a material term of this Agreement, then the parties promptly shall take reasonable steps to cure the violation. If such steps are, in the judgment of Covered Entity, unsuccessful, ineffective or not feasible, then Covered Entity may terminate this Agreement upon written notice to the Business Associate, if feasible, and if not feasible, shall report the violation to the Secretary of HHS. Written notice may be transacted by certified or registered mail return receipt requested, facsimile transmission, personal delivery, expedited delivery service or via e-mail.

11. Law Governing Conflicts. This Agreement shall be enforced and construed in accordance with the laws of the State of New York. Jurisdiction of any litigation with respect to this Agreement shall be in New York, with venue in a court of competent jurisdiction in Albany County.

Covered Entity:

Business Associate:

By _____

By _____

Date: _____

Date: _____