

COE PHI InFocus Resource

Sample Provisions for Integrated QSOA/BAA to Disclose Protected Health Information with Contractors (HIPAA and Part 2 Compliant)



During the course of providing substance use disorder treatment, you may need to share protected health information with an outside entity for services like accounting or data processing. If your program is covered by HIPAA and 42 CFR Part 2 (Part 2), you may only share information if you enter a written contract that complies with both privacy laws: a HIPAA-compliant Business Associate Agreement (BAA) and a Part 2-compliant Qualified Service Organization Agreement (QSOA).

This resource provides sample provisions for an integrated QSOA/BAA, for use by Part 2 programs that are also HIPAA-covered entities.



Definitions

The following terms used in this Agreement shall have the same meaning as those terms in the HIPAA Rules, unless otherwise noted: Breach, Business Associate, Covered Entity, Data Aggregation, Designated Record Set, Disclosure, Individual, Minimum Necessary, Protected Health Information, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information, and Use.

The following terms used in this Agreement shall have the same meaning as those terms in Part 2, unless otherwise noted: Part 2 Program, Patient, Patient-Identifying Information, Qualified Service Organization.

- ✓ **BA/QSO.** BA/QSO shall mean a party meeting the definition of both a business associate and a qualified service organization; in reference to the party to this Agreement, BA/QSO shall mean [Insert name of BA/QSO].
- ✓ **Program.** Program shall mean a party meeting the definition of both a Covered Entity and a Part 2 Program; in reference to the party to this Agreement, Program shall mean [Insert name of program].
- ✓ **Program.** Program shall mean a party meeting the definition of both a Covered Entity and a Part 2 Program; in reference to the party to this Agreement, Program shall mean [Insert name of program].
- ✓ **Protected Information.** Protected Information shall mean protected health information, as that term is defined in 45 CFR § 160.103, and patient-identifying information, as that term is defined in 42 CFR § 2.11.
- ✓ **HIPAA Rules.** HIPAA Rules shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Parts 160 and 164.
- ✓ **Part 2.** Part 2 shall mean the Confidentiality of Substance Use Disorder Patient Records at 42 CFR Part 2.

Obligations and Activities of BA/QSO

BA/QSO acknowledges that in receiving, transmitting, transporting, storing, processing, or otherwise dealing with any information received from the Program identifying or otherwise relating to the patients in the Program, it is fully bound by the provisions of the HIPAA Rules and Part 2.

BA/QSO Agrees to:

- ✓ Not use or disclose protected information other than as permitted or required by the Agreement or as required by law.
- ✓ Resist any efforts to obtain access to patient-identifying information, including in judicial proceedings if necessary, unless permitted by Part 2.
- ✓ Use appropriate safeguards, comply with Subpart C of 45 CFR Part 164 with respect to electronic protected health information, and have formal policies and procedures in compliance with 42 CFR § 2.16, to prevent use or disclosure of protected information other than as provided for by the Agreement.
- ✓ Report to Program any use or disclosure of protected information not provided for by the Agreement of which it becomes aware, including breaches of unsecured protected health information as required by 45 CFR § 164.410, and any security incident of which it becomes aware.
- ✓ Make available protected health information in a designated record set to the [Choose one: Program / Individual] as necessary to satisfy Program's obligations to provide individuals access to their own protected health information (45 CFR § 164.524).
- ✓ Make any amendment to protected health information in a designated record set as directed or agreed to by the Program pursuant to 45 CFR § 164.526, or take other measures as necessary to satisfy Program's obligations to amend an individual's protected health information (45 CFR § 164.526).
- ✓ Maintain and make available the information necessary to provide an accounting of disclosures to the [Choose one: Program / Individual] as necessary to satisfy Program's obligations to provide an accounting of disclosures of protected health information (45 CFR § 164.528).
- ✓ Make its internal practices, books, and records relating to the use and disclosure of protected information available to the Secretary of Health and Human Services, for purposes of determining compliance with the HIPAA Rules.

Permitted Uses and Disclosures by BA/QSO

- ☑ BA/QSO may only use or disclose protected information to provide services to Program as set forth [Choose one: above / in the accompanying Service Agreement] and consistent with 42 CFR § 2.11.
- ☑ BA/QSO may only disclose protected information to Program, or to a contract agent of the BA/QSO for the purpose of providing the services described in this Agreement, or as otherwise permitted by law.
- ☑ If BA/QSO enters into a contract with an agent for the purpose of providing the services described in this Agreement, BA/QSO agrees that the contract agent will only use the protected information consistent with this Agreement and will only disclose protected information to BA/QSO or Program. If BA/QSO learns of a pattern or practice by the contract agent that is a material breach of the contract with the BA/QSO or a violation of this Agreement, BA/QSO agrees to take reasonable steps to cure the breach or terminate the contract.

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- ☑ BA/QSO agrees to make uses and disclosures and requests for protected information subject to the following minimum necessary requirements:
 - [Include specific minimum necessary provisions that are consistent with Program's minimum necessary policies and procedures]
- ☑ BA/QSO may not use or disclose protected information in a manner that would violate Subpart E of 45 CFR Part 164 if done by Program.



Term and Termination

- ☑ This Agreement shall be effective as of [Insert effective date] and shall terminate on [Insert termination date or event] or on the date Program terminates for cause, whichever is sooner.
- ☑ BA/QSO authorizes termination of this Agreement by Program, if Program, determines BA/QSO has violated a material term of the Agreement.
- ☑ Upon termination of this Agreement for any reason, BA/QSO shall return or destroy all protected information received from Program, or created or received by BA/QSO on behalf of Program. This provision shall apply to protected information that is in the possession of subcontractors or agents of BA/QSO. BA/QSO shall retain no copies of the protected information. If not feasible, BA/QSO shall extend the protections of the Agreement to the protected information and limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible.
- ☑ The obligations of BA/QSO shall survive the termination of this Agreement.



For More Information

Resources

This resource is one of many that are available within the Center of Excellence for Protected Health Information's resource library which can be found at coephi.org.

Request Technical Assistance

You can request brief, individualized technical assistance and join our mailing list for updates, including news about the publication of new resources and training opportunities, [here](#).



Disclaimer

Resources, training, technical assistance, and any other information provided through the Center of Excellence for Protected Health Information do not constitute legal advice. For legal advice, including legal advice on other applicable state and federal laws, please seek out local counsel.

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This resource only addresses concepts and requirements in HIPAA and Part 2; it does not address state law privacy requirements, state law contract requirements, nor does it include many provisions commonly required or included in a valid contract. This resource does not replace consultation with a lawyer or negotiation with the other party.