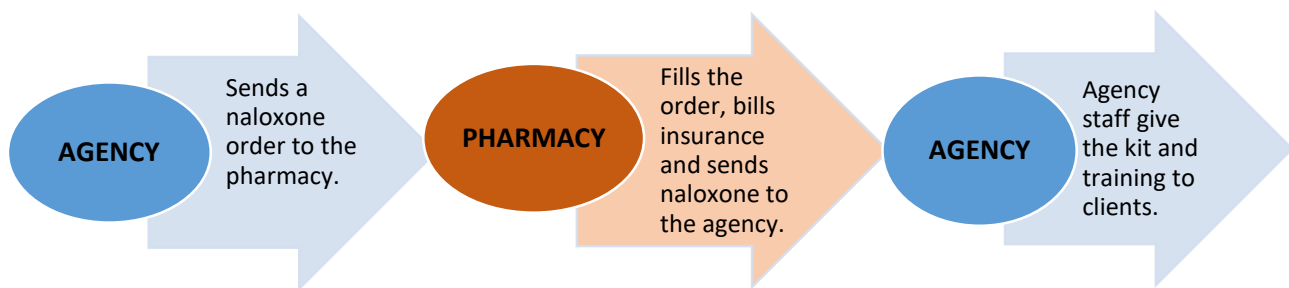


Using Pharmacies to Access Naloxone

A guide for community-based agencies

In Washington State, most retail chain pharmacies and many independent pharmacies have a *Collaborative Drug Therapy Agreement (CDTA)* with an authorized prescriber that permits the pharmacy to prescribe naloxone directly to individuals without seeing a medical provider. Medicaid, Medicaid-managed care organizations, and most private health insurance plans also cover naloxone with no or low co-pays. **This system provides an easy, low-cost way for community-based agencies to acquire naloxone for their clients.**

A community agency-pharmacy partnership works like this:



Partnership Success Story

Downtown Emergency Services Center (DESC) in King County serves people who are chronically homeless, many of whom are at high risk of opioid overdose. Using a HIPAA-compliant online portal, DESC case managers send orders for naloxone, along with client insurance information, to Kelley-Ross Pharmacy who then fills the order for naloxone under their CDTA, bills the insurance, and sends the naloxone back to DESC. Trained staff at DESC deliver the naloxone along with appropriate training to the clients. Kelley-Ross charges DESC a small administrative fee for the service.

Follow this checklist to set up your own pharmacy partnership for naloxone:

1. Develop and sign a business agreement with a local pharmacy.

- Find a local pharmacy with a naloxone CDTA (see a list here: <http://stopoverdose.org/section/find-naloxone-near-you/>).
- With the pharmacy manager, determine which naloxone product you want, procedures for ordering, delivery, payment and other administrative details.
- Identify potential costs (e.g., client co-pays, pharmacy administrative fees, delivery charges) and how your agency will cover these costs.
- Develop and co-sign a Business Associate Agreement that details how both parties will comply with these partnership details and all HIPAA requirements related to protected health information (see sample agreement below).

- Confirm the exact information the pharmacy needs to bill a client’s insurance, such as:

- First/last name
- Date of birth
- Social security number
- Address
- Drug allergies
- Insurance provider
- PPO (Coordinated Care, CHPW, Molina, Amerigroup or United Health)
- PPO Group and ID number
- ProviderOne and/or Medicaid ID number

- Identify a HIPAA-compliant way to submit client information and naloxone orders (e.g., online portal or fax).

A note about costs:

A program like this can be time-consuming for pharmacists, and insurance reimbursement may not always cover the full cost of the naloxone. To cover any financial loss, a pharmacy may charge an administrative fee, which organizations can pay as part of their agreement with the pharmacy.

2. Develop your agency’s policies and procedures

- Determine which staff will identify clients who might be at risk for opioid overdose. These could be clients who are:
 - Using heroin and/or prescription opioids.
 - In treatment for opioid use disorder, including buprenorphine, methadone or naltrexone.
 - Prescribed opioids for chronic pain, especially those who are co-prescribed benzodiazepines.
 - Known to have overdosed in the past.
- Develop a form for a client to consent to have medication ordered on their behalf and billed to their insurance.
- Determine how you will:
 - Place and record orders.
 - Document receipt of the naloxone.
 - Store the naloxone until final hand-off to the client.
 - Train clients on overdose response and naloxone.
 - Handle “what if” scenarios (e.g., client refuses their naloxone or leaves/can’t be found).
- Designate a naloxone “point person” to oversee ordering, client training and troubleshooting with the pharmacy.

3. Train staff on the new procedures with refresher training on opioid overdose and naloxone as needed. See stopoverdose.org for easy-to-use training materials and videos for staff and clients.

4. Place a “test order” for 2-3 clients before offering naloxone agency-wide. This will help you and your partner pharmacy identify and fix any problems in ordering, billing or delivery.

For more information:

Center for Opioid Safety Education: <http://stopoverdose.org>

Kelley Ross Pharmacy: <https://www.kelley-ross.com/naloxone-program/faq-for-providers/>

Pharmacy Name.
BUSINESS ASSOCIATE AGREEMENT
(Standalone HITECH Compliant Version 12/29/2014)

This **Business Associate Agreement** ("BAA"), shall be effective on _____ 2016 (the "Effective Date"), by and _____ with an address at _____ on behalf of itself and all present and future affiliates ("Business Associate") and **Pharmacy Name** with an address at **Pharmacy Address** ("Covered Entity").

1. BACKGROUND AND PURPOSE

Business Associate will provide treatment and education services to Covered Entity's patients in their homes or such additional support services as agreed by the Parties ("Services") to Covered Entity that require Business Associate to create, receive, maintain, or transmit Protected Health Information ("PHI") on behalf of Covered Entity. This PHI is subject to federal privacy and security regulations issued pursuant to the Health Insurance Portability and Accountability Act ("HIPAA") and codified at 45 C.F.R. parts 160 through 164 ("Privacy Rule" and "Security Rule"). The parties intend for this BAA to comply with all applicable requirements of the Privacy Rule and Security Rule, including statutory amendments to HIPAA and all regulations issued under the Health Information Technology for Economic and Clinical Health Act ("HITECH").

2. RELATIONSHIP TO OTHER AGREEMENTS

This BAA governs Business Associate's creation, receipt, maintenance, or transmission of PHI. To the extent of any inconsistency between this BAA and any other agreement between the parties, this BAA will prevail. This BAA supersedes and replaces all prior business associate agreements or business associate addenda between the parties.

3. DEFINITIONS

Capitalized terms used but not defined in this BAA shall have the same meaning as set forth in the Privacy Rule and Security Rule.

4. PERMITTED USES AND DISCLOSURES

Except as otherwise limited by this BAA, Business Associate may:

4.1 Use and Disclose PHI to perform Services on behalf of Covered Entity, provided that such Use or Disclosure would not violate the Privacy Rule or Security Rule if done by Covered Entity. Business Associate shall not Use or further Disclose PHI other than as permitted or required by this BAA, or as required by law.

4.2 Use PHI for the proper management and administration of Business Associate or to carry out Business Associate's legal responsibilities.

4.3 Disclose PHI for the proper management and administration of Business Associate or to carry out Business Associate's legal responsibilities, if the Disclosure is required by law, or Business Associate obtains reasonable assurances from the person to whom the information is Disclosed that it shall be held confidentially and Used or further Disclosed only as required by law or for the purpose it was Disclosed, and the person notifies Business Associate of any instances it discovers where the confidentiality of the information has been breached.

5. OBLIGATIONS OF BUSINESS ASSOCIATE

5.1 No Property Interest. Notwithstanding anything to the contrary in any other agreement, Business Associate shall acquire no title or rights to the PHI, including any de-identified information.

5.2 Minimum Necessary. Business Associate shall Use or Disclose only the minimum amount of PHI necessary to accomplish the purposes of the Use or Disclosure.

5.3 Adequate Safeguards for PHI. Business Associate warrants that it shall implement and maintain appropriate safeguards to prevent the Use or Disclosure of PHI in any manner other than as permitted by this BAA.

5.4 Adequate Safeguards for EPHI. Business Associate shall implement and maintain administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of any electronic protected health information ("EPHI") it creates, receives, maintains, or transmits on behalf of Covered Entity. Business

Associate shall comply with the Security Rule, where applicable, with respect to EPHI to prevent the Use or Disclosure of EPHI other than as provided for by this BAA.

5.5 Incident Reporting. Business Associate shall report the incidents described in Sections 0-0 in writing to Covered Entity's Privacy Office within the timeframes specified in Section 5.5.3 and addressed to: Kelley-Ross & Associates, Inc., Attn: Privacy Officer, 2324 Eastlake Avenue East, Suite 400, Seattle, WA 98102.

5.5.1 Unauthorized Use or Disclosure. Business Associate shall report to Covered Entity within the time period specified in Section 0 each Use or Disclosure of PHI of which Business Associate becomes aware that is made by Business Associate, its employees, representatives, agents or Subcontractors that is not specifically permitted by this BAA.

5.5.2 Security Incident. Business Associate shall report to Covered Entity any Security Incident of which it becomes aware as follows: a) reports of successful unauthorized access shall be made within the timeframe specified in Section 0; and b) attempted but unsuccessful access to EPHI (where there is no unauthorized access, use or disclosure) may routinely occur and this BAA constitutes Business Associate's report to Covered Entity of such events and no further report is required under this BAA.

5.5.3 Breach of Unsecured PHI. Business Associate shall report to Covered Entity a Breach of Unsecured PHI without unreasonable delay, but not later than ten (10) days following Business Associate's Discovery of such Breach. The report shall include the identification of each individual whose Unsecured PHI has been or is reasonably believed to have been compromised and other information as requested by Covered Entity. Business Associate shall supplement its report(s) if the above information is not available at the time of the initial report, and Business Associate shall otherwise cooperate with Covered Entity's investigation and requests for information.

5.6 Availability/Audit of Records. Business Associate agrees to make its internal practices, books, and records available to the Secretary of the federal Department of Health and Human Services for purposes of determining compliance with the Privacy Rule and Security Rule. Business Associate further agrees to make such information available upon request to Covered Entity in a timely manner for Covered Entity to review Business Associate's (or its Subcontractor's or agent's) compliance with this BAA and/or the Privacy Rule and Security Rule.

5.7 Access to and Amendment of PHI. If the PHI in Business Associate's possession constitutes a Designated Record Set, Business Associate shall: a) make PHI available to Covered Entity to allow Covered Entity to comply with an individual's request to access or copy that PHI, and b) make PHI available to Covered Entity for the purpose of amendment and incorporating such amendments into the PHI. Business Associate shall provide such access and incorporate such amendments in a reasonable time and in the manner specified by Covered Entity.

5.8 Accounting of Disclosures. If the PHI in Business Associate's possession constitutes a Designated Record Set, Business Associate agrees to document Disclosures of PHI and information related to such Disclosures, and further, to provide such documentation to Covered Entity in a reasonable time and manner designated by Covered Entity, to permit Covered Entity to respond to a request by an individual for an Accounting of Disclosures.

5.9 Access Reports. If the Secretary issues future regulations requiring Covered Entity to respond to a request by an individual for a report of who has accessed EPHI about the individual, Business Associate agrees to document each access to the EPHI maintained or processed by Business Associate and to provide Covered Entity such documentation in a reasonable time and manner designated by Covered Entity.

5.10 Use of Subcontractors and Agents. Business Associate shall require each of its agents and Subcontractors that creates, receives, maintains or transmits PHI on behalf of Business Associate to execute a written agreement obligating the agent or Subcontractor to comply with terms that are substantially similar to the terms of this BAA and to agree to the restrictions and conditions substantially similar to those that apply to Business Associate with respect to the PHI. Before engaging a Subcontractor that operates outside the United States and that will create, receive, maintain or transmit Covered Entity's PHI, Business Associate will seek written approval from Covered Entity's Privacy Officer at the address in Section 0. Business Associate represents that all Covered Entity data, including PHI, shall remain on servers located within the United States at all times.

5.11 Violations by Subcontractors or Agents. Business Associate shall not be in compliance with the Privacy Rule and this BAA if Business Associate knew of a pattern of activity or practice of a Subcontractor or agent that constituted a material breach or violation of the Subcontractor's or agent's obligation under its written agreement with Business Associate, unless

Business Associate took reasonable steps to cure the breach or end the violation, and if such steps were unsuccessful, terminate the agreement, if feasible.

5.12 Mitigation and Cooperation. Business Associate agrees to mitigate any harmful effect that is known to Business Associate of a Use or Disclosure of PHI by Business Associate in violation of the requirements of this BAA, and to promptly communicate to Covered Entity any actions taken pursuant to this section. Business Associate further agrees to fully cooperate with Covered Entity regarding any such incident. Business Associate shall provide information requested by Covered Entity in a timely manner including but not limited to relevant electronic system log files within 72 hours of request; shall dedicate sufficient resources for investigation of an incident; and shall involve Business Associate's senior management in overseeing an investigation.

5.13 Practices, Policies and Procedures. Business Associate's privacy and security policies and practices shall meet current standards set by applicable state and federal law and industry standards for the protection of PHI including, without limitation, user authentication, data encryption of all mobile devices and data back-ups, logging and monitoring of system activity, internal privacy standards and a compliance plan, all designed to provide assurance that the requirements of this BAA are met.

5.14 Compliance with Covered Entity Obligations. To the extent Business Associate carries out Covered Entity's obligations under the Privacy Rule and Security Rule, Business Associate shall comply with the requirements of such rules that apply to Covered Entity in the performance of such obligations.

5.15 HITECH Compliance. Business Associate shall comply with the requirements of HITECH, codified at 42 U.S.C. §§ 17921–17954, which are applicable to business associates, and shall comply with all regulations issued by the Department of Health and Human Services to implement HITECH as of the date by which business associates are required to comply.

6. OBLIGATIONS OF COVERED ENTITY

Covered Entity shall inform Business Associate of any revocations, amendments or restrictions in the Use or Disclosure of PHI if such changes affect Business Associate's permitted or required Uses and Disclosures of PHI hereunder.

7. TERM AND TERMINATION

7.1 Term. The term of this Agreement shall commence on the Effective Date and shall terminate when all of the PHI in the possession of Business Associate or its Subcontractors or agents is returned, or, at the direction of Covered Entity, is destroyed in accordance with Section 0.

7.2 Termination. Should either party become aware of a breach of a material term of this BAA by the other party, the non-breaching party shall provide written notice of such breach in sufficient detail to enable the breaching party to understand the specific nature of the breach and an opportunity for the breaching party to cure. If the breaching party fails to cure the breach within a reasonable time period as specified by the non-breaching party in such notice, the non-breaching party shall be entitled to terminate the Services and this BAA. All provisions requiring continued performance shall survive termination or expiration of this BAA.

7.3 Disposition of PHI. Upon completion of the Services, Business Associate shall either return to Covered Entity (or if agreed to by Covered Entity, securely destroy) all PHI in the possession or control of Business Associate or its agents and Subcontractors. However, if Covered Entity determines that neither return nor destruction of PHI is feasible, Business Associate may retain PHI provided that Business Associate: a) continues to comply with the provisions of this BAA for as long as it retains PHI, and (b) limits further Uses and Disclosures of PHI to those purposes that make the return or destruction of PHI infeasible.

8. GENERAL TERMS

8.1 Amendment. This BAA may be modified only through a written amendment signed by both parties, except that Covered Entity may unilaterally amend this BAA only to the extent necessary to comply with changes to HIPAA, the Privacy Rule, the Security Rule, or state privacy and security laws upon thirty (30) days written notice to Business Associate. Business Associate may object to the amendment upon thirty (30) days written notice to Covered Entity. Following such notice, the parties will negotiate in good faith appropriate amendment(s) to the BAA for up to thirty (30) days. If the parties are unable to reach agreement, the proposed amendment will not apply to Business Associate and Covered Entity may elect to terminate this BAA and the Services immediately upon written notice to Business Associate.

8.2 No Third Party Beneficiaries. There are no third party beneficiaries to this BAA.

8.3 Indemnification. Notwithstanding anything to contrary in any other agreement, Business Associate shall indemnify, defend and hold harmless Covered Entity from and against all claims, actions, damages, losses, liabilities, fines, penalties, and reasonable costs and expenses (including attorneys' fees) suffered by Covered Entity in connection with the following acts or omissions of Business Associate, its Subcontractors, or agents: a) a breach of this BAA; b) any negligent or wrongful acts or omissions in connection with this BAA; or c) a Breach of Unsecured PHI or a breach of the privacy or security of other personally identifiable information. Any limitation of liability provision or cap on damages in any other agreement between the parties shall not apply to Business Associate's obligations under this BAA.

8.4 Insurance. For as long as Business Associate has access to or is in possession of Covered Entity's PHI, Business Associate shall obtain and maintain professional liability Insurance with an aggregate limit of liability of not less than Two Million Dollars (\$2,000,000). Such insurance shall cover any and all errors, omissions or negligent acts in the delivery or performance of products, services and/or licensed programs to Covered Entity. Such professional liability insurance shall include coverage for claims and losses with respect to network risks (such as data breaches, unauthorized access/use, identity theft, invasion of privacy, damage/loss/theft of or to data, degradation, downtime, etc.). The professional liability insurance retroactive coverage date shall be no later than the effective date of this BAA. Business Associate shall continuously maintain such insurance or purchase an extended reporting period providing that claims first made and reported to the insurance company within two (2) years after termination of the agreement will be deemed to have been made during the policy period. A copy of such policy or a certificate evidencing the policy shall be provided to Covered Entity within fifteen (15) days upon written request.

8.5 Legal Compliance. The parties hereto shall comply with applicable laws and regulations governing their relationship, including the Privacy Rule, Security Rule, Washington Uniform Healthcare Information Act (RCW ch. 70.02), and any other federal or state laws or regulations governing the privacy, confidentiality or security of patient health information. Any ambiguity in this BAA shall be resolved to permit Covered Entity to comply with the above laws and regulations.

8.6 Independent Contractor. Business Associate and Covered Entity are independent contractors, and nothing in this BAA shall be deemed to create an agency, partnership, or joint venture between the parties. Neither party shall represent itself as the agent or legal representative of the other.

8.7 Successors. This agreement is binding upon, and inures to the benefit of, the parties, and their respective successors in interest by way of assignment, merger, acquisition, dissolution, operation of law or any other manner ("Successor"). Any Successor to Business Associate shall also be fully bound by the terms and obligations of this BAA as it applies to Business Associate, and Business Associate shall notify Successor of such obligations in advance of Successor assuming interests and obligations of Business Associate.

Agreed by the parties:

Pharmacy Name.

Business Associate

By: _____

By: _____

Print: _____

Print: _____

Title: _____

Title: _____

Date: _____

Date: _____

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