**Terms for a Business Associate Agreement[[1]](#footnote-1): Checklist**

**Specific definitions**

* “Business Associate” shall generally have the same meaning as the term “business associate” at 45 CFR §160.403, and in reference to the party to the agreement, shall mean [insert name of PCA-HCCN].
* “Covered Entity” shall generally have the same meaning as the term “covered entity” at 45 CFR §160.103, and in reference to the party to the agreement, shall mean [insert name of Health Center].
* “HIPAA Rules” shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.
* “Underlying Agreement” shall refer to the original agreement for services between the PCA-HCCN and the Health Center.

**Obligations and Activities of the Business Associate**

The PCA-HCCN (the Business Associate) agrees

* To not use and/or disclose protected health information unless permitted under the Business Associate Agreement or by law.
* To use appropriate safeguards, and comply with Subpart C of 45 CFR Part 164 with respect to electronic protected health information, to prevent unauthorized use or disclosure.
* Report to Health Center any unauthorized use or disclosure of protected health information, including breaches of unsecured protected health information (as required at 45 CFR §164.410) and any security incident, of which it becomes aware.
  + NOTE: The parties may wish to add additional specificity regarding the breach notification obligations of the PCA-HCCN, such as a specific timeframe for the PCA-HCCN to report a potential breach to the Health Center (which shall occur without unreasonable delay and in no case later than 60 calendar days after discovery of a breach) and/or whether the PCA-HCCN will handle breach notifications to individuals, HHS, and the media on behalf of the Health Center (both processes are permissible under the HIPAA Final Rule).
* In accordance with 45 CFR §164.502(e)(1)(ii) and §164.308(b)(2), if applicable, ensure that any subcontractors that create, receive, maintain, or transmit protected health information on behalf of the PCA-HCCN agree to the same restrictions, conditions, and requirements that apply to the PCA-HCCN with respect to such information.
* Make available protected health information in a designated record set to the Health Center as necessary to satisfy the Health Center’s obligations under 45 CFR §164.524.
  + NOTE: The parties may wish to add additional specificity regarding how the PCA-HCCN will respond to a request for access that the PCA-HCCN receives directly from the individual (such as whether and in what time and manner a PCA-HCCN is to provide the requested access or whether the PCA-HCCN will forward the individual’s request to the Health Center to fulfill) and the timeframe for the PCA-HCCN to provide the information to the Health Center.
* Upon request of the Health Center, to amend any protected patient information in a designated record set maintained by the PCA-HCCN as necessary to satisfy Health Center’s obligations under 45 CFR §164.526.
  + NOTE: The parties may wish to add additional specificity regarding how the PCA-HCCN will respond to a request for amendment that the PCA-HCCN receives directly from the individual (such as whether and in what time and manner the PCA-HCCN is to act on the request for amendment or whether the PCA-HCCN will forward the individual’s request to the Health Center) and the timeframe for the PCA-HCCN to incorporate any amendments to the information in the designated record set, which in no case shall be longer than 60 days after the receipt of the request by an individual.
* To make available to HHS the PCA-HCCN’s internal practices, books, and records for the purposes of determining compliance with the HIPAA Rules.
* To the extent the PCA-HCCN is to carry out one or more of Health Center’s obligation(s) under Subpart E of 45 CFR Part 164 (“*Privacy of Individually Identifiable Health Information*”), comply with the requirements of Subpart E that apply to the Health Center in the performance of such obligation(s).
* Upon notification by the Health Center that it has received a request for an accounting of disclosures, to provide to the Health Center (or to a patient or patient’s representative) information relating to disclosures.
  + NOTE: The parties may wish to add additional specificity regarding how the PCA-HCCN will respond to a request for an accounting of disclosures that the PCA-HCCN receives directly from the individual (such as whether and in what time and manner the PCA-HCCN is to provide the accounting of disclosures to the individual or whether the PCA-HCCN will forward the request to the Health Center) and the timeframe for the PCA-HCCN to provide information to the Health Center, which in no case shall be longer than 60 days after the receipt of the request by the individual.

**Permitted Uses and Disclosures by PCA-HCCN**

Unless otherwise limited in the Business Associate Agreement, the PCA-HCCN may use or disclose protected health information for the following:

* To perform the functions, activities and/or services for, or on behalf of, the Health Center as specified in the Underlying Agreement.
  + NOTE: In addition to other permissible purposes, the parties should specify whether the PCA-HCCN is authorized to use protected health information to de-identify the information in accordance with 45 CFR 164.514(a)-(c). The parties also may wish to specify the manner in which the PCA-HCCN will de-identify the information and the permitted uses and disclosures by the PCA-HCCN of the de-identified information.]
* PCA-HCCN may use or disclose protected health information as required by law.
* PCA-HCCN agrees to make uses and disclosures and requests for protected health information consistent with Health Center’s “minimum necessary” policies and procedures.
* PCA-HCCN may not use or disclose protected health information in a manner that would violate Subpart E of 45 CFR Part 164 if done by Health Center except for the specific uses and disclosures set forth below.
* PCA-HCCN may *use* protected health information for the proper management and administration of the PCA-HCCN or to carry out the legal responsibilities of the PCA-HCCN.
* PCA-HCCN may *disclose* protected health information for the proper management and administration of PCA-HCCN or to carry out the legal responsibilities of the PCA-HCCN, provided the disclosures are required by law, or PCA-HCCN obtains reasonable assurances from the person to whom the information is disclosed that the information will remain confidential and used or further disclosed only as required by law or for the purposes for which it was disclosed to the person, and the person notifies PCA-HCCN of any instances of which it is aware in which the confidentiality of the information has been breached.
* PCA-HCCN may provide data aggregation services relating to the health care operations of the Health Center.

**Obligations of the Health Center**

The Health Center agrees, to the extent that the following may affect the PCA-HCCN:

* To notify the PCA-HCCN of any limitation(s) in the Health Center’s notice of privacy practices under 45 CFR §164.520.
* To notify the PCA-HCCN of any changes in, or revocation of, a patient’s authorization to use or disclose protected health information.
* To notify the PCA-HCCN of any restriction on the use or disclosure of protected health information as agreed to by the Health Center or required under 45 CFR §164.522.

**Term and Termination**

* The term of the Business Associate Agreement is effective as of the effective date, and shall terminate on the termination date or event or on the date Health Center terminates for cause or on the date in which PCA-HCCN no longer creates, receives, maintains, or transmits protected health information for Health Center, whichever is sooner.
* PCA-HCCN authorizes termination of the Business Associate Agreement by Health Center, if Health Center determines PCA-HCCN has violated a material term of the Business Associate Agreement and PCA-HCCN has not cured the breach or ended the violation within the time specified by Health Center.
* Upon termination of the Business Associate Agreement for any reason, PCA-HCCN, with respect to protected health information received from Health Center, or created, maintained, or received by PCA-HCCN on behalf of Health Center, shall:
  1. Retain only that protected health information that is necessary for PCA-HCCN to continue its proper management and administration or to carry out its legal responsibilities;
  2. Return to Health Center or destroy the remaining protected health information that the PCA-HCCN still maintains in any form;
  3. Continue to use appropriate safeguards and comply with Subpart C of 45 CFR Part 164 with respect to electronic protected health information to prevent use or disclosure of the protected health information, other than as provided for in the Business Associate Agreement, for as long as PCA-HCCN retains the protected health information;
  4. Not use or disclose the protected health information retained by PCA-HCCN other than for the purposes for which such protected health information was retained and subject to the same conditions set out in the paragraphs under above section, “Permitted Uses and Disclosures By PCA-HCCN”, which applied prior to termination; and
  5. Return to Health Center or destroy the protected health information retained by PCA-HCCN when it is no longer needed by PCA-HCCN for its proper management and administration or to carry out its legal responsibilities.
  + NOTE: The agreement also could provide that the PCA-HCCN will transmit the protected health information to another business associate of the Health Center at termination, and/or could add terms regarding PCA-HCCN’s obligations to obtain or ensure the destruction of protected health information created, received, or maintained by subcontractors.
* The obligations of PCA-HCCN shall survive the termination of the Business Associate Agreement.

1. The Authors of these materials include attorneys at the law firm of Feldesman Tucker Leifer Fidell LLP. The sample documents offer general guidance based on federal law and regulations and do not necessarily apply to all PCAs-HCCNs under all facts and circumstances. Further, these materials do not replace, and are not a substitute for, legal advice from qualified legal counsel. [↑](#footnote-ref-1)