Section 4.3 Implement

Business Associate and Other Agreements

This tool identifies the types of agreements that may be necessary for a community-based care coordination (CCC) program to have in place in order to provide access to or exchange data among participants in the program and with vendors.

Time needed: 2 hours to review tool

Suggested other tools: Community Resource Directory; Provider Resource Directory; Authorization Form Template

How to Use

1. Review the types of agreements that may be required for various uses and disclosures of health information within the CCC program.

2. Use the sample Business Associate Agreement from the U.S. Department of Health and Human Services (HHS) as a starting point for executing business associate agreements if any participating entity in the CCC program has not yet adopted such an agreement.

3. Use the links to examples of Medicare ACO forms to familiarize the CCC program with the Medicare personal health information sharing requirements.

4. Review the sample authorization form to create a HIPAA-compliant authorization form to fit the needs of any participating entity in the CCC program that has not yet adopted such a form.
## Request for Access to/Authorization for Use and Disclosure of Protected Health Information

**Patient Name:**

**Date of Birth:**

**Former Name:**

**Medical Record #:**

**Address:**

**City:**

**State:**

**Zip:**

**Day Phone:**

**Evening Phone:**

I hereby authorize [Insert name of organization] to disclose my protected health information as indicated below to:

- **Mail to:**
  - **Name:**
  - **Address:**
  - **City:**
  - **State:**
  - **Zip:**
  - **Fax:**

### INFORMATION TO BE RELEASED:

<table>
<thead>
<tr>
<th>Date</th>
<th>Information to Be Released</th>
</tr>
</thead>
<tbody>
<tr>
<td>DISCHARGE SUMMARY</td>
<td>I specifically authorize the release of information relating to:</td>
</tr>
<tr>
<td></td>
<td>- Substance abuse (including alcohol/drug abuse)</td>
</tr>
<tr>
<td></td>
<td>- Mental health or behavioral health</td>
</tr>
<tr>
<td></td>
<td>- HIV related information (AIDS related testing)</td>
</tr>
<tr>
<td></td>
<td>Signature of Patient or Personnel Representative</td>
</tr>
<tr>
<td></td>
<td>Date</td>
</tr>
</tbody>
</table>

### PURPOSE OF DISCLOSURE:

- Changing provider
- Consultation
- Insurance/Workers' Compensation
- School
- Research
- At request of individual
- Legal (specify):
- Other (specify):
- For personal access (specify):
- Copy
- Inspection
- Summary

### ACKNOWLEDGEMENT OF UNDERSTANDING:

- I understand the expiration date of this authorization is [ ] at end of research study [ ] not applicable for ongoing research
- I understand that I may revoke this authorization at any time by notifying the providing organization in writing, and it will be effective on the date notified except to the extent action has already been taken in reliance upon it.
- I understand that information used or disclosed pursuant to this authorization may be subject to re-disclosure by the recipient and no longer be protected by Federal privacy regulations.
- By authorizing this use or disclosure of information, there will be no conditions placed on my health care or payment for my health care.
- I understand that if I am being requested to authorize a use or disclosure that I will get a copy of this form after I sign it.
- I understand my request will be acted upon within 30 days. If I am not provided access or information cannot be supplied, I understand I will be notified, and have the right to request review of any denial of access other than those made in accordance with applicable law.
- I understand that I may be required to pay the cost of preparing and mailing copies, supervising my inspection, or preparing a summary except for uses and disclosures for the purpose of treatment, payment, and operations.

**Patient/Legal Representative Signature:**

**Date:**

**Relationship:**

**Records Received by:**

**Date:**

**ID Verified:**

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**For Office Use Only**

**Date Received:**

**Fee Collected:**

**Date Extension Requested:**

**Date Filed:**

We are unable to comply with your request because:

- [ ] The information you request was not created by [Name of Provider].
- [ ] Access is denied in accordance with applicable law.
- [ ] Access is denied because such access may be harmful to you or someone else. You may request review of denial by contacting our Information Privacy Official.
- [ ] Access to certain portions of the record must be denied; a summary or portions of the record is supplied instead.

Your request for review has been processed.

An independent licensed healthcare professional has [ ] confirmed the need to deny your request [ ] recommended provision of access, as supplied.

If you have any further questions or wish to file a complaint, please contact our Information Privacy Official. You may also request information about filing a complaint with the Secretary of Health and Human Services from our Information Privacy Official.

To contact our Information Privacy Official, call or write to: [supply site name, address, and phone number and/or e-mail/web site].

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Section 4.3 Implement–Business Associate and Other Agreements - 2
Business Associate & Other Agreements for CCC Programs

Community-based care coordination (CCC) programs require a range of data uses and disclosures for various purposes and with various types of entities. As a result, these programs may need a number of agreements or contracts to be in place to ensure the privacy, confidentiality, and security of the data being exchanged. Some of these agreements are required by federal and/or state laws, and others may be required by policy of the organizations exchanging data.

In the context of HIPAA, the term “Use” refers to the sharing, employment, application, utilization, examination, or analysis of protected health information (PHI) within an entity that maintains such information. “Disclose” means the release, transfer, provision of access, or divulging in any manner of PHI outside the entity holding the information.

Business Associate Agreement

A business associate agreement (BAA), sometimes called business associate contract (BAC) is required by the Health Insurance Portability and Accountability Act (HIPAA) when exchanging protected health information (PHI) with any entity that is not a covered entity under HIPAA or when the exchange is with a covered entity for purposes other than treatment, payment, and operations. Protected health information is any health-related information that is individually identifiable. Covered entities include health plans, healthcare clearinghouses that may process claims and other HIPAA financial and administrative transactions, and providers (individuals or entities) who use any of the HIPAA financial and administrative transactions.

A business associate is a person or entity who is not a covered entity that performs work for a business associate in which access to or disclosure of PHI is provided. A covered entity may also be a business associate of another covered entity when the relationship is one in which services provided include access to PHI. Common business associates of a CCC program may include information technology vendors, transportation companies with whom you arrange transport for patients for clinic visits, attorneys, data analysis consultants, health information exchange organizations, billing companies, and many others.

In order to provide access to or exchange data with a business associate, a BAA is required to be in place. HHS provides a sample BAA on its web site, at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/contractprov.html. The sample BAA is also provided within this tool.

It is important to note that a BAA is different than (1) an authorization to disclose PHI, (2) other types of agreements frequently entered into, and (3) the notice of privacy practices.

1. An authorization to disclose is required by HIPAA when an individual wants PHI to be disclosed to another person or entity with whom the covered entity does not have a BAA and the disclosure is for purposes other than treatment, payment, and operations.

For example, if a patient were to ask a hospital to send a copy of his or her health record to the patient’s attorney, friend, accountant, etc., an authorization would be required. However, if the patient asks the hospital to send a copy of the health record to a provider in another location where the patient is moving or will be living temporarily and who will be providing continuing treatment for the patient, HIPAA does not require an authorization. HIPAA does permit such an authorization to be required – either by state law or by organizational policy.
a. Laws in the states in which the CCC program operates must be reviewed to determine which are more stringent in their requirements for authorization. If the program operates in several states, it may be easier to adopt a universal policy that reflects the most stringent state rather than to attempt to have different authorization policies for different states.

b. Some organizations have decided they will obtain authorizations for all disclosures simply as a matter of convenience. For example, in order to know that a patient is moving and another provider needs the patient’s health record, the hospital needs to know the name, address, and what information to send. It is easier to document this on a form, in which case the form may ask the patient to authorize the disclosure, perhaps for future reference that such a disclosure was requested by the patient. Although an authorization is not required by a provider to disclose PHI to the patient’s insurance company in order to have a claim paid, many providers have authorization forms that address other aspects of insurance, such as permission for assignment of benefits. These forms may also include an authorization for disclosure, although not necessary.

c. Most health information exchange (HIE) organizations address the need for an authorization by patients for exchange of their PHI. Note that this is different than the participants in the HIE organization requiring the HIE organization to have a BAA. The HIE organization, even if it is a provider or health plan, is acting as a vendor in supplying HIE services and therefore is a business associate. There are several approaches being taken by HIE organizations with respect to patient authorizations:

i. Some HIE organizations require that patients sign a one-time or annual authorization. This strategy is then often referred to as an “opt in” arrangement for patients to have their data shared by those entities participating in the HIE.

ii. A few HIE organizations require that patients sign an authorization for every disclosure of any kind made between the participating entities.

iii. Other HIE organizations have chosen an opt-out approach, where patients are told they may choose to decline to share health information with other providers who are treating the patient. Patients who opt to decline to share their PHI may still be asked to sign an authorization for disclosure on a case-by-case basis.

iv. The opt out approach is an approach Medicare has taken in Medicare accountable care organizations (ACO). If the CCC program is a Medicare ACO, the program will be supplied templates that the program may customize for this purpose.

   a) The “Declining to Share Personal Health Information” form is required by the Medicare ACOs to provide to their patients. An example of one offered by the Partners ACO is available at: http://www.partners.org/Assets/Documents/For-Patients/ACO/Authorization_to_Opt_Out_of_Sharing_Personal_Health_Information.pdf

   b) Patients can also change their personal health information consent preferences.
An example from the Partners ACO is available at: http://www.partners.org/Assets/Documents/For-Patients/ACO/Consent_to_Change_Data_Sharing_Preference.pdf

c) There is also an “ACO Beneficiary Notification Letter” that introduces the Medicare ACO to patients and explains how health information will be used. This notification is similar to the HIPAA Notice of Privacy Practices (NPP), but does not substitute for the HIPAA NPP that any given provider participating in the Medicare ACO would be required to provide to their patients under HIPAA.

An example of the ACO Beneficiary Notification Letter from Partners ACO is available at: http://www.partners.org/Assets/Documents/For-Patients/ACO/ACO_Beneficiary_Notification_Letter_Website.pdf

CCC programs that participate in a Medicare ACO program are sent templates to create their own forms and notification letters. CCs should become familiar with the various forms adopted by the CCC program in order to respond to questions.

d. When an authorization is used, at a minimum it should conform to the requirements for authorization in HIPAA. A sample of such an authorization is provided at the end of this tool. It also includes the requirements of the Substance Abuse Confidentiality Regulations which are very commonly included in authorizations for disclosure.

2. Other types of agreements may be required by HIPAA for specialized types of disclosures or by covered entities for other purposes. These may or may not be combined with a BAA. These types of agreements are described in the next section of this tool.

3. A notice of privacy practices (NPP) is neither an agreement nor an authorization. The NPP is information about the types of uses and disclosures a covered entity may make and a description of the individual’s rights and the covered entity’s legal duties with respect to PHI. HIPAA requires that providers make a good faith effort to obtain a written acknowledgment of the receipt of the NPP. This acknowledgement only signifies that the patient received the NPP – it is not an authorization for disclosure of PHI or anything else, such as consent for treatment.

Data Use and Other Agreements

A data use agreement is required by HIPAA when a covered entity chooses to use or disclose a limited data set (i.e., PHI that excludes specified direct identifiers of the individual, relatives, employers, or household members of the individual). A limited data set, and therefore the need for a data use agreement, may be used only for the purposes of research, public health, or healthcare operations. For example, a limited data set may be provided in preparation to a research study in order for the researcher to determine if there are a sufficient number of cases to be studied that would produce valid research findings. A public health department may have disclosed to it a limited data set to study the characteristics of a recent outbreak of a certain disease. A limited data set may also be used for clinical quality improvement.

The Data Use and Reciprocal Services Agreement (DURSA) is a comprehensive, multi-party trust agreement that is entered into voluntarily by public and private organizations that desire to engage in electronic health information exchange (HIE) as part of the eHealth Exchange which is the national health information exchange. The DURSA establishes a variety of provisions for
such exchange of health information such as how patients will be identified, when updates to a patient’s health information previously exchanged will be made, and many others. The DURSA, or similar data use agreements, are very commonly used in private sector HIE organizations as well.

**Participation agreements** may also be drawn up within a CCC program to outline the roles and responsibilities of each of the participants in the CCC program. If the CCC program is an ACO or there are other financial arrangements made for providers and other participants in the CCC program, such arrangements may also be spelled out in a participation agreement. (See Provider Resource Directory and Community Resource Directory tools for examples of the contents of such agreements.)

**Sample Business Associate Agreement Provisions**

Outlined below are sample BAA provisions to help covered entities and business associates more easily comply with the business associate contract requirements. While these sample provisions are written for the purposes of the contract between a covered entity and its business associate, the language may be adapted for purposes of the contract between a business associate and subcontractor. Words or phrases contained in brackets are intended as either optional language or as instructions to the users of these sample provisions.

*Catch-all definition:*

The following terms used in this Agreement shall have the same meaning as those terms in the HIPAA Rules: Breach, Data Aggregation, Designated Record Set, Disclosure, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, Protected Health Information, Required By Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information, and Use.

*Specific definitions:*

a. Business Associate - “Business Associate” shall generally have the same meaning as the term “business associate” in 45 CFR 160.103, and in reference to the party to this agreement, shall mean [insert name of business associate].

b. Covered Entity - “Covered Entity” shall generally have the same meaning as the term “covered entity” in 45 CFR 160.103, and in reference to the party to this agreement, shall mean [insert name of business associate].


**Obligations and Activities of Business Associate**

Business Associate agrees to:

a. Not use or disclose protected health information other than as permitted or required by the Agreement or as required by law;

b. 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 protected health information other than as provided for by the Agreement;

c. Report to covered entity any use or disclosure of protected health information not provided for by the Agreement of which it becomes aware, including breaches of unsecured protected health information as required at 45 CFR 164.410, and any security incident of which it becomes aware;
[The parties may wish to add additional specificity regarding the breach notification obligations of the business associate, such as a stricter timeframe for the business associate to report a potential breach to the covered entity and/or whether the business associate will handle breach notifications to individuals, the HHS Office for Civil Rights (OCR), and potentially the media, on behalf of the covered entity.]

d. 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 business associate agree to the same restrictions, conditions, and requirements that apply to the business associate with respect to such information;

e. Make available protected health information in a designated record set to the [Choose either “covered entity” or “individual or the individual’s designee”] as necessary to satisfy covered entity’s obligations under 45 CFR 164.524; [The parties may wish to add additional specificity regarding how the business associate will respond to a request for access that the business associate receives directly from the individual (such as whether and in what time and manner a business associate is to provide the requested access or whether the business associate will forward the individual’s request to the covered entity to fulfill) and the timeframe for the business associate to provide the information to the covered entity.]

f. Make any amendment(s) to protected health information in a designated record set as directed or agreed to by the covered entity pursuant to 45 CFR 164.526, or take other measures as necessary to satisfy covered entity’s obligations under 45 CFR 164.526; [The parties may wish to add additional specificity regarding how the business associate will respond to a request for amendment that the business associate receives directly from the individual (such as whether and in what time and manner the business associate is to act on the request for amendment or whether the business associate will forward the individual’s request to the covered entity) and the timeframe for the business associate to incorporate any amendments to the information in the designated record set.]

g. Maintain and make available the information required to provide an accounting of disclosures to the [Choose either “covered entity” or “individual”] as necessary to satisfy covered entity’s obligations under 45 CFR 164.528; [The parties may wish to add additional specificity regarding how the business associate will respond to a request for an accounting of disclosures that the business associate receives directly from the individual (such as whether and in what time and manner the business associate is to provide the accounting of disclosures to the individual or whether the business associate will forward the request to the covered entity) and the timeframe for the business associate to provide information to the covered entity.]

h. To the extent the business associate is to carry out one or more of covered entity’s obligation(s) under Subpart E of 45 CFR Part 164, comply with the requirements
of Subpart E that apply to the covered entity in the performance of such obligation(s); and

i. Make its internal practices, books, and records available to the Secretary for purposes of determining compliance with the HIPAA Rules.

**Permitted Uses and Disclosures by Business Associate**

(a) Business associate may only use or disclose protected health information

[Option 1 – Provide a specific list of permissible purposes.]

[Option 2 – Reference an underlying service agreement, such as “as necessary to perform the services set forth in Service Agreement.”]

[In addition to other permissible purposes, the parties should specify whether the business associate 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 business associate will de-identify the information and the permitted uses and disclosures by the business associate of the de-identified information.]

(b) Business associate may use or disclose protected health information as required by law.

(c) Business associate agrees to make uses and disclosures and requests for protected health information

[Option 1] consistent with covered entity’s minimum necessary policies and procedures.

[Option 2] subject to the following minimum necessary requirements: [Include specific minimum necessary provisions that are consistent with the covered entity’s minimum necessary policies and procedures.]

(d) Business associate may not use or disclose protected health information in a manner that would violate Subpart E of 45 CFR Part 164 if done by covered entity [if the Agreement permits the business associate to use or disclose protected health information for its own management and administration and legal responsibilities or for data aggregation services as set forth in optional provisions (e), (f), or (g) below, then add “, except for the specific uses and disclosures set forth below.”]

(e) [Optional] 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.

(f) [Optional] Business associate may disclose protected health information for the proper management and administration of business associate or to carry out the legal responsibilities of the business associate, provided the disclosures are required by law, or business associate 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 business associate of any instances of which it is aware in which the confidentiality of the information has been breached.
(g) [Optional] Business associate may provide data aggregation services relating to the health care operations of the covered entity.

Provisions for Covered Entity to Inform Business Associate of Privacy Practices and Restrictions

(a) [Optional] Covered entity shall notify business associate of any limitation(s) in the notice of privacy practices of covered entity under 45 CFR 164.520, to the extent that such limitation may affect business associate’s use or disclosure of protected health information.

(b) [Optional] Covered entity shall notify business associate of any changes in, or revocation of, the permission by an individual to use or disclose his or her protected health information, to the extent that such changes may affect business associate’s use or disclosure of protected health information.

(c) [Optional] Covered entity shall notify business associate of any restriction on the use or disclosure of protected health information that covered entity has agreed to or is required to abide by under 45 CFR 164.522, to the extent that such restriction may affect business associate’s use or disclosure of protected health information.

Permissible Requests by Covered Entity

[Optional] Covered entity shall not request business associate to use or disclose protected health information in any manner that would not be permissible under Subpart E of 45 CFR Part 164 if done by covered entity. [Include an exception if the business associate will use or disclose protected health information for, and the agreement includes provisions for, data aggregation or management and administration and legal responsibilities of the business associate.]

Term and Termination

- **Term** - The Term of this Agreement shall be effective as of [Insert effective date], and shall terminate on [Insert termination date or event] or on the date covered entity terminates for cause as authorized in paragraph (b) of this Section, whichever is sooner.

- **Termination for Cause** - Business associate authorizes termination of this Agreement by covered entity, if covered entity determines business associate has violated a material term of the Agreement [and business associate has not cured the breach or ended the violation within the time specified by covered entity]. [Bracketed language may be added if the covered entity wishes to provide the business associate with an opportunity to cure a violation or breach of the contract before termination for cause.]

- **Obligations of Business Associate Upon Termination**

  [Option 1 – if the business associate is to return or destroy all protected health information upon termination of the agreement]

  Upon termination of this Agreement for any reason, business associate shall return to covered entity [or, if agreed to by covered entity, destroy] all protected health information received from covered entity, or created, maintained, or received by business associate on behalf of covered entity, that the business associate still maintains in any form. Business associate shall retain no copies of the protected health information.
[Option 2—if the agreement authorizes the business associate to use or disclose protected health information for its own management and administration or to carry out its legal responsibilities and the business associate needs to retain protected health information for such purposes after termination of the agreement]

Upon termination of this Agreement for any reason, business associate, with respect to protected health information received from covered entity, or created, maintained, or received by business associate on behalf of covered entity, shall:

1. Retain only that protected health information which is necessary for business associate to continue its proper management and administration or to carry out its legal responsibilities;

2. Return to covered entity [or, if agreed to by covered entity, destroy] the remaining protected health information that the business associate 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 this Section, for as long as business associate retains the protected health information;

4. Not use or disclose the protected health information retained by business associate other than for the purposes for which such protected health information was retained and subject to the same conditions set out at [insert section number related to paragraphs (e) and (f) above under “Permitted Uses and Disclosures By Business Associate”] which applied prior to termination; and

5. Return to covered entity [or, if agreed to by covered entity, destroy] the protected health information retained by business associate when it is no longer needed by business associate for its proper management and administration or to carry out its legal responsibilities.

[The agreement also could provide that the business associate will transmit the protected health information to another business associate of the covered entity at termination, and/or could add terms regarding a business associate’s obligations to obtain or ensure the destruction of protected health information created, received, or maintained by subcontractors.]

- Survival - The obligations of business associate under this Section shall survive the termination of this Agreement.
**Miscellaneous [Optional]**

*Regulatory References*

- A reference in this Agreement to a section in the HIPAA Rules means the section as in effect or as amended.

*Amendment*

- The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for compliance with the requirements of the HIPAA Rules and any other applicable law.

*Interpretation*

- Any ambiguity in this Agreement shall be interpreted to permit compliance with the HIPAA Rules.
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