



## AGREEMENT

### PATIENT SAFETY ORGANIZATION (PSO) PARTICIPANT

This agreement, dated \_\_\_\_\_, reflects the PSO relationship between the **Center for Patient Safety (CPS)** and \_\_\_\_\_ (Organization).

#### I. BACKGROUND

1. The Organization desires to participate with a Patient Safety Organization (PSO) certified by the Agency for Healthcare Research and Quality (AHRQ) pursuant to the Patient Safety and Quality Improvement Act of 2005 (PSQIA) and its Final Rule. (These are described in Exhibit 1.)
2. CPS provides such services.
3. All of Organization's activities related to this agreement are undertaken voluntarily, and Organization can decide what data to report. The parties recognize that the value of the projects undertaken in relation to this agreement will depend on the quality and the quantity of data provided by Participants (including Organization) to CPS.

#### II. THE CENTER FOR PATIENT SAFETY AGREES:

1. It will maintain its certification as a listed PSO and will develop and implement policies and procedures to comply with AHRQ's requirements for listed PSOs, as specified in the relevant law described in Exhibit 1.
2. CPS will be a business associate of Organization, and the parties will enter into a Business Associate Agreement (BAA) that complies with the Health Insurance Portability and Accountability Act (HIPAA), the HIPAA privacy rule and the Health Information Technology for Economic and Clinical Health (HITECH) Act as they may apply. A proposed BAA is attached as Exhibit 3.
3. If CPS discloses any information that has been provided to it by any Participants, it will only share de-identified and/or aggregated information, as allowed by the PSQIA and the Final Rule.

#### III. FEE STRUCTURE:

1. Annual cost per year for a three (3) year period, to be billed in three (3) equal annual Installments, plus a one-time onboarding fee.

2. First payment is due upon contract execution.
3. Second payment is due 12-months thereafter and third payment is due another 12-months thereafter, continuing per agreement for successive 3-year periods. Center will invoice organization.
4. Organization's annual fee will be \_\_\_\_\_ plus a one-time onboarding fee the first year of \_\_\_\_\_.

**Invoice contact name and phone number:**

---

**Send invoice via email to:**

---

#### **IV. ORGANIZATION AGREES:**

1. It will submit data relevant to the program in which it is participating.
2. Organization will develop and implement policies that are compliant with the PSQIA, the Final Rule, and AHRQ's requirements to preserve the confidentiality of its work product and any confidential information provided to it by CPS. CPS will provide policy templates.
3. Organization will train its staff regarding the confidentiality of the work product protected under the PSQIA. Staff members who work with confidential information will sign a confidentiality agreement. CPS will provide training materials and a template agreement.
4. Organization will designate a contact person to interact with CPS on activities related to this agreement. If the designated contact person changes, Organization will notify CPS in writing of the change.
5. Organization will provide a list (using Exhibit 2) of any Affiliated Providers that will be included under this agreement.
6. If Organization works with more than one PSO, it will notify CPS, including the identity, of the other.
7. Feedback from CPS to Organization is advisory only, and any subsequent decisions made or actions undertaken are the responsibility of Organization.

#### **V. REQUESTS FOR PROTECTED INFORMATION**

1. If either party receives a request for protected information, it will notify the other party and will assert all relevant privileges under the PSQIA. The parties will communicate with each other regarding any decision to disclose potentially protected information.

2. The Organization will have primary responsibility for defending the privilege and confidentiality protections in cases where it or its affiliated providers are a party and/or are the subject of an investigation. In other cases, the parties will confer as to the appropriate responsibility. CPS will make resources and expertise available to support Organization's efforts under this paragraph.

#### **VI. INSURANCE AND INDEMNIFICATION**

1. Both parties and their relevant affiliates will maintain at least \$1 million per occurrence and \$1 million aggregate coverage for each of these: general, professional and D & O liability.
2. Each party shall be responsible for (and hold the other harmless from) any claims and expenses, including reasonable attorney's fees, that result from any liability arising from that party's acts or omissions.

#### **VII. TERM AND TERMINATION**

1. This agreement begins on the effective date and will automatically renew for successive 3-year periods unless either party notifies the other of its intent not to review at least thirty (30) days prior to the end of the current term. CPS will notify Organization at least sixty (60) days before the end of the contract term about changes to fees. Organization agrees that fees paid to CPS, or on behalf of Organization, are in consideration for provision of services identified in this agreement.
2. CPS uses an outside vendor to support its PSO data system, and the PSO fee structure relies on the cost of that contract. If that contract changes in price, or if CPS needs to find a different provider of data services, it reserves the right to change its fees with 120 days' notice.
3. Either party may terminate the agreement on ninety (90) days written notice to the other party.
4. The agreement will terminate automatically on any of the following occurrences:
  - a. CPS is de-listed as a PSO by AHRQ. In that case, CPS will comply with all requirements of the PSQIA and the Final Rule regarding Organization's information.
  - b. Either Party is dissolved or loses its status as a corporate entity or is deemed insolvent.
5. Each party will bear the obligations outlined in the PSQIA and the Final Rule with respect to confidential information upon termination.

**VIII. OWNERSHIP AND WORK PRODUCT**

- 1. Organization owns all identifiable patient safety work product (PSWP) and other identifiable information it submits to CPS.
- 2. CPS owns all aggregate and non-identifiable information it has developed.

**IX. MISCELLANEOUS**

- 1. Any notice given by one party to the other shall be in writing. Unless sent by mail, it will be deemed given on receipt, but if mailed, on the third day after receipt or when actually delivered.
- 2. This agreement, together with Exhibits 1-3 continues the entire agreement between the parties. Any amendments shall be in writing.

**EFFECTIVE DATE:** \_\_\_\_\_

**CENTER FOR PATIENT SAFETY**

**PARTICIPANT**

\_\_\_\_\_  
SIGNATURE

\_\_\_\_\_  
SIGNATURE

Kathryn Wire  
PRINTED NAME

\_\_\_\_\_  
PRINTED NAME

Executive Director  
TITLE

\_\_\_\_\_  
TITLE

\_\_\_\_\_  
DATE SIGNED

\_\_\_\_\_  
ORGANIZATION

\_\_\_\_\_  
DATE SIGNED

## **EXHIBIT 1**

### **LEGAL REFERENCES**

The agreement between Organization and the Center for Patient Safety is based on the provisions of the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act, Pub. L 109-41). The Act amended Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) by inserting a new Part C, sections 921 through 926, which are codified at 42 U.S.C. 299b–21 through 299b–26.

The Agency for Healthcare Research and Quality issued the final Patient Safety Rule, which is codified at 42 CFR Part 3.

Both can be easily accessed in PDF form at <https://www.pso.ahrq.gov/legislation>.

**EXHIBIT 2**  
**AFFILIATED PROVIDERS**

The following entities are Affiliate Providers of Organization. An Affiliated Provider, as defined in the Final Rule, is a legally separate provider that is the parent organization of the provider or is under common ownership, management, or control with the provider, or is owned, managed, or controlled by the provider.

*For additional affiliated providers, please copy this form and include in the agreement.*

Name: _____
Mailing Address: _____
City: _____ State: _____ Zip Code: _____
Phone Number: _____ Fax Number: _____
Nature of Affiliation: _____
Name: _____
Mailing Address: _____
City: _____ State: _____ Zip Code: _____
Phone Number: _____ Fax Number: _____
Nature of Affiliation: _____
Name: _____
Mailing Address: _____
City: _____ State: _____ Zip Code: _____
Phone Number: _____ Fax Number: _____
Nature of Affiliation: _____

### EXHIBIT 3

#### HIPAA BUSINESS ASSOCIATE AGREEMENT

This HIPAA Business Associate Agreement (“BAA”) entered into on \_\_\_\_\_, between the Center for Patient Safety (“CPS”), and \_\_\_\_\_ (“Participant”), supplements and is made a part of the Participant Agreement.

**WHEREAS**, Participant desires to protect the privacy and security of Protected Health Information (“PHI”) Used or Disclosed by CPS in compliance with the Health Insurance Portability and Accountability of 1996 (“HIPAA”) and regulations promulgated thereunder by the U.S. Department of Health and Human Services (45 CFR Parts 160 and 164), as amended by the American Recovery and Reinvestment Act of 2009, Title XII “Health Information Technology for Economic and Clinical Health Act” (“HITECH”). The purpose of this BAA is to satisfy certain standards and requirements of HIPAA (hereinafter “HIPAA Rules”) as they may be amended from time to time.

**WHEREAS**, Participant and CPS have entered into a Participant Agreement under which Participant will voluntarily submit certain information to CPS and CPS will utilize the information to perform patient safety activities (“Services”) which involve the Use or Disclosure of PHI in the course of such services under this Participant Agreement.

In consideration of these mutual promises made below and the exchange of information under this BAA, the Parties agree as follows:

#### A. DEFINITIONS

In addition to the terms already defined in the Participant Agreement and this BAA, terms capitalized in this BAA shall have the same meaning as those terms defined in the HIPAA Rules unless the context requires otherwise. Any reference to PHI includes electronic PHI to the extent practicable.

1. “Breach.” As used in Section B.3 herein, the term “Breach” shall have the same meaning as the term “breach” in 45 CFR §164.402.
2. “Business Associate.” As used herein, the term “Business Associate” shall mean CPS.
3. “Covered Entity.” As used herein, the term “Covered Entity” shall mean Participant.
4. “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).
5. “Required By Law” shall have the same meaning as the term “required by law” in 45 CFR § 164.103.
6. “Secretary” shall mean the Secretary of the Department of Health and Human Services or his or her designee.

7. “Unsecured Protected Health Information.” As used herein, the term “Unsecured Protected Health Information” or “Unsecured PHI” shall have the same meaning as the term “unsecured protected health information” in 45 CFR §164.402.

## **B. RESPONSIBILITIES OF CPS**

### 1. Uses and Disclosures

CPS agrees not to Use and/or Disclose PHI received from Participant or created or received by CPS on behalf of Participant other than to perform the Services as permitted or required under the Participant Agreement or as Required by Law.

### 2. Safeguards

CPS agrees to use appropriate administrative, technical and physical safeguards to protect the confidentiality, integrity and availability of PHI it creates, receives, maintains or transmits on behalf of Participant as required by the HIPAA Rules and to prevent any Use or Disclosure of Participant’s PHI other than as permitted or required by the Participant Agreement or this BAA. By no later than February 17, 2010, CPS further agrees to implement policies and procedures to prevent, detect, contain and correct security violations related to PHI, and to comply with the following provisions of the HIPAA Security Rule: 45 CFR § 164.308 (administrative safeguards); §164.310 (physical safeguards); §164.312 (technical safeguards); and §164.316 (policies and procedures and documentation requirements).

### 3. Notification

CPS agrees to notify Participant of any Use or Disclosure of PHI not provided for by this BAA, within ten (10) days of CPS’ discovery of such Use or Disclosure, and to take reasonable steps to mitigate to the extent practicable any harmful effect of a breach of confidentiality or security in violation of this BAA.

a. In addition, in order to enable compliance with the breach notification requirements of HITECH, found at 45 CFR Part 164, Subpart D of the HIPAA Rules, CPS shall, following the discovery of a Breach of Unsecured PHI, notify Participant within ten (10) business days of discovery of such Breach. CPS agrees to exercise reasonable diligence to discover Breaches of Unsecured PHI. Such notice shall include the identification of each individual whose Unsecured PHI has been, or is reasonably believed by CPS to have been, accessed, acquired, or disclosed during such Breach, along with any other available information which Participant is required to include in notification to the individual under 45 CFR §164.404(c).

b. If CPS does not possess the identity of all such individuals within ten (10) business days of discovery of the Breach, CPS shall notify Participant with such information as is available by that deadline and supplement immediately as additional information becomes available.

### 4. Agents and Subcontractors

CPS agrees to ensure that any agent, including subcontractors to whom it provides PHI received from or created or received by CPS on behalf of Participant agrees to the same restrictions and confidentiality that apply to CPS with respect to such information.

### 5. Regulatory Compliance



CPS agrees to make its internal practices, books and records, including policies and procedures, relating to the Use and Disclosure of PHI received from or created or received by CPS on behalf of Participant available to Participant or the Secretary in a time and manner designated by Participant or Secretary for the purpose of the Secretary determining Participant's compliance with the HIPAA Rules.

### **C. PERMITTED USES AND DISCLOSURES OF PHI BY CPS**

#### **1. CPS Services**

CPS may use or disclose PHI for the purpose of providing the Services described in the Participant Agreement.

#### **2. Data Aggregation**

CPS may use PHI to perform Data Aggregation services to Participant, as defined by 45 CFR § 164.501.

#### **3. CPS Management and Administration**

CPS may use PHI for the proper management and administration of CPS or to carry out CPS' own legal responsibilities.

#### **4. Disclosures for CPS' Management and Administration**

CPS may disclose PHI for the proper management and administration of CPS, provided:

- a. The disclosure is Required by Law; or
- b. CPS obtains reasonable assurances from the person or entity to whom the information is Disclosed that it will be held confidentially and Used or further Disclosed only as Required by Law or for the purpose for which it was Disclosed to the person or entity, and the person or entity notifies CPS of any instances of which it is aware in which the confidentiality of the information has been breached.

#### **5. Uses for Reporting Purposes**

CPS may Use PHI to report violations of law to appropriate federal and state authorities, consistent with the HIPAA Rules.

### **D. RESPONSIBILITIES OF PARTICIPANT**

#### **1. Notice to CPS**

Participant agrees to notify CPS of any limitations in its Notice of Privacy Practices to the extent that such limitations affect CPS Use and Disclosure of PHI.

#### **2. Impermissible Request by Participant**

Except as otherwise provided in this BAA, Participant will not request CPS to Use or Disclose PHI in any manner that would not be permissible under the HIPAA Rules if done by Participant.

### **E. TERM AND TERMINATION**

#### **1. Term**

The Term of this BAA shall be effective as of the Effective Date of the Participant Agreement and shall terminate when all of the PHI provided by Participant to CPS, or created or received by CPS on behalf of Participant, is destroyed or returned to Participant, or if it is infeasible to return or destroy PHI, protections are extended to such information in accordance with termination provisions in this section.

2. Termination for Cause

Upon either Party's knowledge of a material breach of this BAA by the other, the Parties shall either:

a. Provide an opportunity to the breaching Party to cure the breach or end the violation within 30 days after written notice by the non-breaching Party; or

b. Immediately terminate this BAA if a material term has been breached and cure is not possible and report the violation to the Secretary.

3. Effect of Termination

a. Unless otherwise agreed by the Parties in writing, upon termination of this BAA for any reason, CPS shall return or destroy all PHI received from Participant or created or received by CPS on behalf of Participant. This provision shall apply to PHI that is in the possession of subcontractors or agents of CPS.

b. In the event that the Parties agree in writing that returning or destroying the PHI is infeasible, CPS shall extend the protections of this BAA to such PHI and limit further Uses and Disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as CPS maintains such PHI.

**F. MISCELLANEOUS**

1. Regulatory References

A reference in this BAA to a section in the HIPAA Rules means the section as in effect or as amended and for which compliance is required.

2. Amendment

The Parties agree to take such action as is necessary to amend this BAA from time to time as is necessary to comply with the requirements of the HIPAA Rules as may be amended.

3. Survival

The respective rights and obligations of CPS under Section E (3) of this BAA shall survive the termination of this BAA.

4. Interpretation

Any ambiguity in this BAA shall be resolved in favor of permitting the Parties to comply with the HIPAA Rules as may be amended.

5. Governing Law.

This BAA and the rights and obligations of the Parties hereunder shall in all respects be governed by, and construed in accordance with, the laws of the State of Missouri including all matters of construction, validity and performance.

The Parties have caused this Business Associate Agreement to be duly executed in their respective names as of the date first above written.

**CENTER FOR PATIENT SAFETY**

**PARTICIPANT**

\_\_\_\_\_  
SIGNATURE

Kathryn Wire

PRINTED NAME

Executive Director

TITLE

\_\_\_\_\_  
SIGNATURE

\_\_\_\_\_  
PRINTED NAME

\_\_\_\_\_  
TITLE

