

**MISSOURI CENTER FOR PATIENT SAFETY  
PATIENT SAFETY ORGANIZATION PARTICIPANT AGREEMENT**

This MISSOURI CENTER FOR PATIENT SAFETY PATIENT SAFETY ORGANIZATION PARTICIPANT AGREEMENT (“Agreement”) is entered into this \_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_, by and between \_\_\_\_\_, (“Participant”), and the Missouri Center for Patient Safety Patient Safety Organization (“Center”), a Missouri non-profit corporation which is listed as a Patient Safety Organization under federal law.

**BACKGROUND**

WHEREAS, the Center has been designated as a Patient Safety Organization pursuant to the federal Patient Safety and Quality Improvement Act of 2005 (“Act”), and its implementing regulations, 42 CFR, Part 3 (“Final Rule”).

WHEREAS, pursuant to the Act, the Center’s purpose is to engage in the following activities:

- a. Efforts to improve patient safety and the quality of health care delivery.
- b. The collection and analysis of Patient Safety Work Product.
- c. The development and dissemination of information with respect to improving patient safety such as recommendations, protocols, or information regarding best practices.
- d. The utilization of Patient Safety Work Product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk.
- e. The maintenance of procedures to preserve confidentiality with respect to Patient Safety Work Product.
- f. The provision of appropriate security measures with respect to Patient Safety Work Product.

- g. The utilization of qualified staff.
- h. Activities related to the operation of a Patient Safety Evaluation System and to the provision of feedback to participants in a Patient Safety Evaluation System.

WHEREAS, the Center, provides directly or through contractors, patient safety improvement related services for its Participants, including a patient safety reporting system, patient safety analytics, and other Patient Safety Activities.

WHEREAS, the Center is organized and operated to preserve confidentiality and security of Patient Safety Work Product, pursuant to the Act, and to avail of all available protections of the Act.

WHEREAS, Participant is considered a “Provider” pursuant to the Final Rule, 42 CFR Part 3, §3.20, and

WHEREAS, Participant desires to voluntarily participate in the Center’s data collection, data analysis, reporting and evaluation activities in an effort to improve the quality of health care delivery and patient safety in Participant’s practice and the community.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual covenants and provisions contained herein below, the Parties agree as follows:

## **ARTICLE I**

### **DEFINITIONS**

#### **1.1 PSO Regulatory Definitions.**

The Parties hereby adopt and incorporate by reference the definitions at 42 CFR Part 3 (“Regulations”), §3.20, a copy of which is attached as **Exhibit A**. Without limiting the generality of the foregoing, the following terms are particularly relevant to this Agreement:

- a. Disclosure
- b. Identifiable Patient Safety Work Product
- c. Non-identifiable Patient Safety Work Product
- d. Patient Safety Activities
- e. Patient Safety Evaluation System
- f. Patient Safety Work Product
- g. Provider
- h. Workforce

**1.2 Additional Definitions.**

The following additional definitions shall apply to this Agreement:

a. Common Format shall mean the format for collecting and submitting data that is agreed upon by the Center and Participant, which may include the Common Formats as defined from time to time, by the Agency for Healthcare Research and Quality (AHRQ).

b. De-Identified Data shall mean data that does not contain unique identifying codes or information, except for codes that have not been derived from and do not relate to information about the individual, and cannot be translated so as to identify the individual, pursuant to the HIPAA Privacy Rule.

c. Functional Reporting shall mean an agreed upon alternative means of “transferring” Patient Safety Work Product (“PSWP”) to the Center whereby PSWP remains in Participant’s physical possession, with the Center having a right of access to the PSWP as needed to process and analyze the information, as further described in the Preamble to the Regulations (73 FR 70740-70741).

d. HIPAA shall mean the Health Insurance Portability and Accountability Act of 1996.

e. HIPAA Privacy Rule shall mean the HIPAA Privacy Regulations, 45 CFR Subpart E.

f. HIPAA Security Rule shall mean the HIPAA Security Regulations, 45 CFR Subpart C.

g. Limited Data Set shall mean Protected Health Information that excludes direct identifiers as described in the HIPAA Privacy Rule, 45 CFR § 164.514(e).

h. Participant shall mean a “Provider” under 42 CFR Part 3, § 3.20 who contracts with the Center to obtain PSO services in accordance with the terms and conditions of this Agreement.

i. Participant Workforce shall mean all physicians and other health care providers holding privileges with Participant, affiliated providers, employees, volunteers, trainees, contractors or other persons who perform work for or on behalf of Participant.

j. Participate or Participation shall mean participation by Participant in the Center data submission, reporting and evaluation process.

k. Protected Health Information shall mean individually identifiable health information, as further described in the HIPAA Privacy Rule.

l. PSO Workforce shall mean all employees, volunteers, trainees, contractors, or other persons who perform work for or on behalf of the Center, excluding Participants of the Center’s Board of Directors and the Center’s Advisory Panel.

## ARTICLE II

### GENERAL OVERVIEW

#### **2.1 Overview of the Center's Role.**

The Center will develop its own Patient Safety Evaluation System ("PSES"). It will develop specific data collection, monitoring, analysis, collaboration, reporting and evaluation systems for the purpose of conducting activities to improve patient safety and the quality of health care delivery and offer them to Participants. Participants may select the level of participation they wish to access, as further described in **Section 2.4** below.

#### **2.2 Overview of Participant's Role.**

Participant's participation is voluntary and nonexclusive. Participants will be given the opportunity to collaborate in the development of Patient Safety Activities, and on a general and/or a project-specific basis, to collect and submit data to the Center, to participate in evaluations, and to receive the results of such activities.

#### **2.3 Overview of Privileges and Confidentiality.**

The activities of the Center are structured to avail of the privileges and immunities afforded by the Act and the Regulations, as well as other applicable provisions of state and federal law, including but not limited to:

a. Privilege.

PSWP developed by Participant and/or maintained by the Center is privileged and shall not be subject to subpoena, discovery, disclosure or admitted into evidence, except as may be required or permitted by law pursuant to the Regulations § 3.204(b).

b. Confidentiality.

PSWP developed by Participant and/or maintained by the Center is confidential and will not be disclosed, except as may be required or permitted by law pursuant to the Regulations § 3.206(b).

**2.4 Participation Levels.**

Participation levels may be general and ongoing, or project specific. Participants may elect to participate in ongoing data collection, analytics, and reporting activities, or to participate in time-limited, event specific, or other defined activities that may be implemented from time to time during the term of this Agreement as set forth in **Exhibit B**, a copy of which is attached and incorporated herein.

a. Patient Safety Event Reports.

(1) Patient Safety Event Reports entail the reporting of healthcare events, including those defined by the Common Formats and other mutually agreed upon healthcare events to be reported by Participant to the PSO.

(a) Incidents – patient safety events that reached the patient, whether or not harm occurred;

(b) Near Misses – patient safety events that did not or could not reach the patient; and

(c) Unsafe Conditions – circumstances that increase the probability of a patient safety event.

(2) Patient Safety Event Reports and PSWP maintained within Participant's PSES should be completed and forwarded as soon as reasonably possible following

completion. Best efforts should be made to complete the reports within three years, or before termination of the contract, whichever comes first.

(3) Participant will engage in Functional Reporting, and grants the Center a right of access to PSWP as needed. PSWP that is functionally reported will be transferred to the Center upon the Center's written request to Participant's designated primary contact as identified in **Exhibit C**.

(4) PSWP that is not submitted to the Center by the mutually agreed upon schedule as defined in Section 2.4(2) or by the termination of this contract shall be deemed to be transferred to the Center by Functional Reporting as that term is described in the Preamble to the Regulations (73FR 70740-70741).

b. Specific Projects.

(1) Specific Projects entail participation in specially designed studies that may be time limited, event specific, or based on information generated by Patient Safety Event Reports, special reports from Participants, or other sources of information.

(a) Such projects may be national studies, regional studies, local studies, or Participant specific studies.

(b) Particulars of Specific Projects will be developed and communicated prior to Participant's commitment to participate in said project, and described in **Exhibit D**, which will be incorporated herein at the time **Exhibit D** is signed by both parties.

c. Other Patient Safety Activities.

(1) Other Patient Safety Activities entail participation in special teams assembled by the Center for the purpose of evaluating specific events or trends, developing recommendations, training, or monitoring.

(2) Participants may also request the Center to provide Participant specific assistance with evaluating events, developing corrective actions, training, monitoring, evaluating effects of interventions, and other mutually agreed upon patient safety related activities.

### **2.5 Participation Fees.**

The Center will assess each Participant's participation fees commensurate with their elected level of participation, according to the terms set forth in **Exhibit B**, a copy of which is attached and incorporated herein. Participant agrees that fees paid to the Center by Participant, or on behalf of Participant, are in consideration for provision of services identified in this agreement.

## **ARTICLE III**

### **THE CENTER RESPONSIBILITIES**

#### **3.1 Federally Listed PSO.**

The Center hereby represents and warrants that it is federally listed as a Patient Safety Organization by the Agency for Healthcare Research and Quality (AHRQ), pursuant to 42 USC 299b-24, and 42 CFR Part 3, Subpart B, § 3.102., as of the Effective Date of this Agreement. The Center further warrants that it will keep such listing in good standing during the term of this Agreement.

#### **3.2 Patient Safety Activities.**

Subject to Participant's submission of PSWP and other information to the Center, as provided in section 2 above, the Center will utilize the information submitted by Participant to perform Patient Safety Activities as set forth in **Exhibit B**, a copy of which is attached and incorporated herein. The Parties may elect to expand the scope of Services under this Agreement by mutual written modification.

### **3.3 Patient Safety Work Product.**

a. The Center will collect and maintain reported information as PSWP. The Center shall maintain the privilege and confidentiality of PSWP pursuant to 42 CFR Part 3.

b. The Center shall enter into a Business Associate Agreement with Participant, and shall maintain the confidentiality and security of Protected Health Information (PHI) in accordance with HIPAA.

c. Reports circulated to other Participants, PSOs, or otherwise reported will use a Limited Data Set and be de-identified as to patient and provider names, except as otherwise agreed in writing by Participants.

d. The Center will promptly notify Participant of any breaches in confidentiality or security, and will take immediate remedial measures as appropriate to effectively manage the breach.

### **3.4 Common Format.**

The Center will provide a Common Format for the collection and reporting of key information. Changes to the Common Format may be implemented by the Center from time to time, as a result of changes in the AHRQ Common Formats, other modifications as developed in consultation with Participants, or emerging information from patient safety resources.

### **3.5 Patient Safety Evaluation System.**

The Center shall establish a Patient Safety Evaluation System (“PSES”) for the collection, management and analysis of information received from and/or reported to Participants.

### **3.6 Contractors.**

The Center may retain contractors to perform certain services on its behalf, as permitted under the Final Rule. The Center will require that each contractor, and any subcontractor of a

contractor, abide by the confidentiality, security and privacy requirements imposed by federal and state law.

### **3.7 PSO Workforce.**

The Center will assemble a knowledgeable workforce and in collaboration with its workforce will develop and conduct Patient Safety Activities, including but not limited to, data collection, appropriate studies, evaluations, activities, reports and recommendations, including where feasible “best practices” recommendations and will offer results to Participants as appropriate to its level of Participation.

**3.8** The Center will keep confidential any PSWP or other information voluntarily submitted by Participant in accordance with the Act, Final Rule, applicable Missouri law and the HIPAA Privacy and Security Rules, and will require the Center’s Workforce to maintain such confidentiality. Individuals functioning as the Center’s Workforce acknowledge confidentiality requirements and will sign a Workforce Confidentiality Agreement, as set forth in **Exhibit E**, a copy of which is attached and incorporated herein.

## **ARTICLE IV**

### **PARTICIPANT RESPONSIBILITIES**

#### **4.1 Cooperation with the Center Requirements.**

Participant shall comply with the Center policies, created to provide a mechanism for Participants to report patient safety related information on a privileged and confidential basis, through the application of certain reporting standards and guidelines, including but not limited to, the Common Formats and Level of Participation negotiated between Participant and the Center, as described in **Exhibit B**. Further, Participant and Participant’s Workforce shall comply with

applicable requirements, policies, and procedures established by Participant's Patient Safety Evaluation System.

#### **4.2 Patient Safety Evaluation System.**

Participant shall develop a Patient Safety Evaluation System ("PSES") for collecting, maintaining and managing information:

- a. to meet federal statutory and regulatory requirements to maintain confidentiality;
- b. to review the appropriateness of submission of information to the Center; and
- c. to appropriately document information submitted to the Center. A

Participant's failure to abide by the requirements described in Sections 4.1 and 4.2 may result in the termination of a Participant's Participation.

#### **4.3 Patient Safety Work Product.**

Participant will be responsible to develop and maintain PSWP in accordance with the requirements of the Final Rule Part 3. Participant will develop a system for collecting, maintaining, and managing information, including but not limited to PSWP, reported to the Center. If PSWP is submitted to Participant's PSES, Participant documentation must include the date Participant's PSWP entered Participant's PSES.

a. Reported information will clearly delineate that information which is PSWP and that which is not PSWP. Participant understands and acknowledges that:

- (1) Information collected, maintained or developed separately, or that exists separately from Participant's PSES is not PSWP;
- (2) PSWP does not include a patient's original medical record, billing and discharge information, or any other original patient or provider information;

(3) PSWP assembled or developed by a Participant for reporting to the Center, and maintained in the Participant's PSES, may be reclassified by Participant as being or not being PSWP, up and until such time as the information is reported to the Center. Once the Participant PSES has reported PSWP to the Center it is not possible to reclassify the information.

#### **4.4 Appointment of Participant's PSO Liaison.**

Participant will identify and make available a qualified Representative to communicate with the Center with respect to PSO services. The Representative may designate other individuals to interact with the Center with respect to specific Patient Safety Activities, and when doing so should inform the PSO of the scope of the Representative's authority and involvement within Participant's PSES. Participant will complete and submit to the Center the Primary Contact and System Administrator Contact Form as set forth in **Exhibit C**, a copy of which is attached and incorporated herein. The Representative may be changed at any time by Participant's written notice to the Center.

#### **4.5 Documentation.**

Participant will provide the Center with accurate and complete documentation, or other information necessary to perform the services commensurate with its Participation Level.

a. Participant will execute all agreements, documents, or forms reasonably requested by the Center to facilitate sharing of data and information between Participant and the Center, or to implement the Center's obligations under this Agreement.

b. Participant will provide the information reasonably requested by the Center to register for access to the Center's data system.

c. Participant will cooperate with reasonable follow up requests from the Center for information and clarification regarding reported information.

#### **4.6 Use and Protection of PSWP.**

Participant shall maintain the confidentiality of Participant's PSWP and shall not disclose PSWP, except as otherwise permitted by the Act or Regulations.

a. Participant may use Participant's PSWP internally in furtherance of Participant's own Patient Safety Activities. Participant shall be solely responsible for appropriately managing internal use of PSWP to maintain the Act's confidentiality and privilege protections.

b. Participant understands and agrees that it may not use PSWP to fulfill external reporting, regulatory, or accreditation obligations. To the extent information designated as PSWP is also required to meet external reporting or communications, Participant shall develop such systems as are necessary to maintain the integrity of the PSWP.

c. Except as otherwise permitted by the Act or the Regulations, Participant will not disclose other Provider's PSWP, nor use it in any manner other than Patient Safety Activities conducted as part of Participant's or the Center's PSES.

#### **4.7 Participant Workforce Confidentiality.**

Participant will keep confidential any PSWP or other information voluntarily submitted by Participant in accordance with the Act, Final Rule, applicable Missouri law and the HIPAA Privacy and Security Rules, and will require the Participant Workforce to maintain such confidentiality.

#### **4.8 Participant Participation in the Center.**

Participant may designate individuals to collaborate with the Center on Participant's behalf in the conduct of Center Patient Safety Activities, which may include assisting in study design, assimilating and evaluating anonymized or deidentified information, and information collected from other sources. Participant's Workforce acknowledge the confidentiality requirements and will sign a

Workforce Confidentiality Agreement, as set forth in **Exhibit E**, a copy of which is attached and incorporated herein.

#### **4.9 Implementation of the Center Recommendations.**

Participant has sole responsibility for its own decision-making with regard to Participation in the Center Patient Safety Activities, including, but not limited to determining which data to collect and submit to the Center and assessing the merits of and determining whether and how to implement or integrate the results and/or recommendations emanating from the Center Patient Safety Activities into their respective Participant Organization. Recommendations resulting from the Center Patient Safety Activities should not be construed as Standard of Care. The Center hereby disclaims any liability for any decisions made or actions taken by Participant, or results thereof, as a result of Participant's Participation in the Center's Patient Safety Activities. No representations or warranties, express or implied, made by any representative, agent or employee of the Center which are not specifically set forth herein shall be binding upon the Center.

#### **4.10 Notification of Participation in More than One PSO.**

In the event Participant participates in, and reports the same PSWP to more than one PSO, Participant will notify the Center and use best efforts to communicate and cooperate with all PSO recipients of Participant's PSWP, to avoid duplication of data that may be aggregated by cooperating PSOs.

### **ARTICLE V**

#### **REQUESTS/DEMANDS FOR CONFIDENTIAL INFORMATION**

##### **5.1 Confidentiality, Privilege and Security.**

Each Party will comply at all times with the applicable and ongoing privacy, confidentiality and security requirements of the Act, Final Rule, and applicable state and federal law. All records,

data, knowledge, information, analyses, or reports collected, reviewed or generated for or by the Center on behalf of Participant under this Agreement are confidential under federal law, will be used only for the purposes provided in this Agreement and shall be deemed privileged to the maximum extent provided by federal law.

## **5.2 HIPAA.**

Each Party will comply with all applicable provisions of the HIPAA Privacy and Security Rules. The Parties will comply with the terms of the Business Associate Agreement as set forth in **Exhibit F**, a copy of which is attached and incorporated herein.

## **5.3 Center Responsibilities**

a. In the event the Center receives a request, subpoena, or other attempt by an outside Party to access confidential Participant PSWP, the Center will promptly notify Participant and will assert all applicable privileges.

b. In the event that there is an applicable exception or disclosure permission that would require the Center to provide access to Participant's confidential PSWP, the Center will promptly notify Participant.

c. The Center will cooperate and coordinate with Participant regarding asserting applicable privileges for any disclosure requests, subpoenas or other attempts to access Participant PSWP, and in providing required information in the event of an applicable exception or disclosure permission, as described in Section 5.4 below.

## **5.4 Participant Responsibilities.**

a. In cases where Participant's PSWP is sought by litigants in cases where Participant or its Providers are a party, Participant or its Providers maintain primary responsibility for

defending PSWP privilege and confidentiality protections. The Center and its counsel will cooperate as necessary to protect Participant's PSWP.

b. In cases where Participant's PSWP is sought by agencies investigating Participant or its Providers, Participant or its Providers maintain primary responsibility for defending PSWP privilege and confidentiality protections. The Center and its counsel will cooperate as necessary to protect Participant's PSWP.

c. In cases where Participant's PSWP is sought by other litigants or interested parties, the Parties shall meet and confer as to appropriate allocation of responsibility and response.

## ARTICLE VI

### INSURANCE AND INDEMNIFICATION

#### 6.1 Insurance.

a. The Center shall maintain the following minimum levels of insurance:

	<u>Per Occurrence/Aggregate</u>
General Liability	\$1,000,000/\$1,000,000
Professional Liability	\$1,000,000/\$1,000,000
D & O	\$1,000,000/\$1,000,000

b. Participant shall maintain the following minimum levels of insurance, either through insurance policy or self-funded arrangement:

	<u>Per Occurrence/Aggregate</u>
General Liability	\$1,000,000/\$1,000,000
Professional Liability	\$1,000,000/\$1,000,000
D & O	\$1,000,000/\$1,000,000

**6.2 Indemnification.**

a. Nothing in this Agreement is intended, nor shall it be construed to create any responsibility on the part of Participant for any liability, including but not limited to claims for damages, loss, cost or expense arising out of the gross negligence or intentional acts or omission of the Center or its officers, directors, employees, workforce, or agents. The Center shall defend, indemnify and hold harmless Participant, its officers, directors, employees, workforce, and agents from and against any and all claims, demands, liabilities, losses, damages, costs, and expenses, including reasonable attorney's fees, resulting in any manner, directly or indirectly, from any of the foregoing circumstances.

b. Nothing in this Agreement is intended, nor shall it be construed to create any responsibility on the part of the Center for any liability, including but not limited to claims for damages, loss, cost or expense arising out of the gross negligence or intentional acts or omission of Participant or its officers, directors, employees, workforce, or agents. Participant shall defend, indemnify and hold harmless the Center, its officers, directors, employees, workforce, and agents from and against any and all claims, demands, liabilities, losses, damages, costs, and expenses, including reasonable attorney's fees, resulting in any manner, directly or indirectly, from any of the foregoing circumstances.

**ARTICLE VII**

**TERM AND TERMINATION**

**7.1 Term.**

This Agreement takes effect on the Effective Date set forth below the signature line of this Agreement and shall continue in full force and effect for an initial term of three (3) years, unless terminated earlier, as provided in Section 7.2, 7.3 and 7.4 below. Upon completion of the initial

term, this Agreement will automatically renew for successive 3 year periods, unless either Party notifies the other of its intent not to renew the Agreement at least thirty (30) days prior to the end of the current term. All terms of this Agreement will remain in effect for each renewal term unless otherwise modified and agreed to by the Parties by written agreement at least thirty (30) days prior to the end of the current term.

#### **7.2 Termination Without Cause.**

This Agreement may be terminated by either Party at any time upon ninety (90) days advance written notice to the other Party.

#### **7.3 Termination for Cause.**

This Agreement shall terminate immediately and automatically if:

- a. The Center is delisted as a federally listed PSO by AHRQ and termination shall be effective as of the date of the Center's delisting as a PSO;
- b. Either Party is dissolved or otherwise loses its status as a corporate entity under State law;
- c. Either Party is insolvent determined by the filing of an involuntary petition against either Party seeking adjudication of bankruptcy or insolvency, or either Party commencing a voluntary proceeding seeking an adjudication of its bankruptcy or insolvency; or
- d. Either Party is deemed ineligible to participate in any federal healthcare programs, including Medicare or Medicaid.

#### **7.4 Termination for Breach of Contract.**

In the event either Party materially breaches this Agreement the non-breaching Party shall give written notice of breach, and the breaching Party shall have thirty (30) days to cure and

communicate in writing its cure to the non-breaching Party. Failure to cure or communicate said cure within this timeframe shall be grounds for immediate termination.

#### **7.5 Effect of Termination.**

Upon the effective date of termination of this Agreement, the obligations of the Parties shall cease immediately, except for those obligations which by their terms survive termination. The Parties acknowledge that this Agreement imposes certain duties on them which may continue after termination of the Agreement, such as those stated in Article V. After termination for any reason, the Parties will continue to fulfill those obligations which by their terms survive termination.

a. Upon termination of this Agreement, the Center will return or certify destruction of all identifiable PSWP submitted under this Agreement, unless disposition of said identifiable PSWP is otherwise agreed to in writing by the Parties.

b. If termination of this Agreement occurs due to the Center's delisting as a federally listed PSO, the Center shall comply with all requirements related to such termination as required by federal law and 42 CFR Part 3, § 3.108.

c. PSWP that is not submitted to the Center by the termination of this contract shall be deemed to be transferred to the Center by Functional Reporting as that term is described in the Preamble to the Regulations (73FR 70740-70741).

### **ARTICLE VIII**

#### **OWNERSHIP AND WORK PRODUCT RETENTION**

##### **8.1 Identifiable PSWP.**

Consistent with the Act, Final Rule and other applicable federal and state laws, and subject to Section 8.2 of this Agreement, Participant owns all identifiable PSWP and other identifiable information it submits to the Center.

## **8.2 Non-identifiable Information.**

Consistent with the Act, Final Rule and other applicable federal and state laws, and subject to Section 8.1 of this Agreement, the Center owns all aggregate, non-identifiable reports developed by the Center, as defined in 42 CFR Part 3, §§ 3.206, 3.208 and 3.212. The Center may use or disclose such non-identifiable information and aggregated data for any purpose. The Parties acknowledge that Non-identifiable PSWP that is disclosed by either Party is not privileged or confidential, pursuant to § 3.208.

## **8.3 Intellectual Property.**

The Center retains ownership of any preexisting intellectual property or proprietary materials provided to Participant as part of the services, subject to any usage rights as defined in this Agreement.

## **8.4 Data Use Obligations.**

Information reported by the Center that is in the form of a Limited Data Set shall be subject to the Data Use Obligations. The Center will comply with the terms of the Data Use Agreement as set forth in **Exhibit G**, a copy of which is attached and incorporated herein.

# **ARTICLE IX**

## **ADDITIONAL REPRESENTATIONS**

### **9.1 Affiliated Provider.**

If Participant is a parent organization to other Providers that meet the definition of Affiliated Provider under the Final Rule, Participant will provide the Center with a list of all Affiliated Providers that will receive services under this Agreement. The list will be set forth as **Exhibit H**, a copy of which is attached and incorporated herein. Participant will promptly notify the Center in writing of any change in Participant's Affiliated Providers.

**9.2 Authority.**

Each Party represents that it has full power and authority to enter into and fully perform this Agreement.

**ARTICLE X**

**MISCELLANEOUS**

**10.1 Relationship of Parties.**

Nothing in this Agreement shall constitute or be construed to be or to create a partnership, joint venture, agency or employment relationship between the Parties hereto. The relationship of the Parties under this Agreement is solely that of independent contractors.

**10.2 Limitation of Liability.**

In no event shall the Center be liable to Participant or any other entity for any special, consequential, incidental or indirect damages, however caused, on any theory of liability whether or not The Center has been advised of the possibility of such damages.

**10.3 APPLICABLE LAW.**

**THE VALIDITY OF THIS AGREEMENT AND OF ANY OF ITS TERMS AND PROVISIONS, AS WELL AS THE RIGHTS AND DUTIES OF THE PARTIES, SHALL BE INTERPRETED AND ENFORCED PURSUANT TO AND IN ACCORDANCE WITH THE LAWS OF THE STATE OF MISSOURI. THE EXCLUSIVE JURISDICTION AND VENUE FOR ALL SUITS, PROCEEDINGS, ACTIONS, OR DISPUTES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT SHALL BE IN COLE COUNTY, MISSOURI.**

**10.4 Publicity.**

After execution of this Agreement, the Center may indicate in its marketing materials and proposals to other prospective customers that the Center has been awarded this Agreement by

Participant, and Participant may identify the Center as its Patient Safety Organization. Notwithstanding the foregoing, The Center will not disclose any other information regarding Participant for publicity or marketing purposes, unless otherwise agreed to by Participant in writing.

**10.5 No Third Party Beneficiaries.**

Nothing contained in this Agreement shall be construed to create in any person not a party to this Agreement any rights, duties or obligations.

**10.6 Dispute Resolution.**

The Parties agree that this Agreement is clear and fully enforceable as written. However, in the event of any dispute, controversy, or claim arising out of or in connection with, or relating to this Agreement or any breach or alleged breach hereof, the Parties shall first negotiate the matter between themselves in good faith. If direct negotiations do not resolve the matter, either Party may demand in writing that the disputed matter be submitted to non-binding mediation. After the delivery of the notice of mediation, the Parties shall select a mediator who will render a recommended resolution to the dispute. The Parties will share equally the cost of the mediator.

**10.7 No Waiver.**

The failure of either Party to either (a) require, at any time, the other Party's strict observance or performance of any provision of this Agreement, or (b) exercise any right or remedy as provided in this Agreement shall not impair any right or remedy of such Party or be construed as a waiver of, consent to, or relinquishment thereof. All waivers of and any required consents to any terms and conditions of this Agreement, or any waivers concerning any rights, powers, or remedies under this Agreement, by either Party, must be in writing and executed by a duly authorized representative of the granting Party to be effective. No waiver or consent granted by a Party with respect to one matter or incident shall be construed to operate as a waiver or consent by such Party with respect to the

same or any different or subsequent matter or incident. Every right and remedy afforded to the Parties under this Agreement may be exercised from time to time and at any time by a Party without limitation. All remedies, whether afforded under this Agreement, by applicable law, or otherwise shall be cumulative and not alternative.

**10.8 Severability.**

In the event any provision of this Agreement is held to be invalid, illegal, or unenforceable for any reason and in any respect, such invalidity, illegality, or unenforceability shall not affect the remainder of this Agreement, which shall be and remain in full force and effect, enforceable in accordance with its terms.

**10.9 Conformance to Law.**

It is the intent of the Parties to conform to applicable law. If it is determined that any provision of this Agreement, including any of the Exhibits, does not conform to applicable law, it will be deemed amended to the minimum degree necessary to fully comply with such law. As soon as possible, a formal amendment will be made to conform the language of the Agreement to the law.

**10.10 Force Majeure.**

Neither Party shall be liable or deemed to be in default for any delay or failure in performance under this Agreement or other interruption of service deemed to result, directly or indirectly, from acts of God, civil or military authority, acts of public enemy, war, accidents, fires, explosions, earthquakes, floods, failure of transportation, strikes or other work interruptions by either Party's employees, or any other similar cause beyond the reasonable control of either Party.

**10.11 Notice.**

Any notice, request, demand, instruction, communication or other document required, permitted, or desired to be given hereunder shall be in writing and, except as otherwise provided for

herein, shall be deemed effectively given: (a) on receipt if delivered personally or by commercial courier service or if sent by prepaid telex, telegram, by facsimile or by other instantaneous electronic transmission device, or (b) on the third day after deposit (unless a different date is shown on the return receipt) if sent postage prepaid registered or certified United States mail, return receipt requested, properly addressed to the authorized representative, or to such other address, and to the attention of such other person or officer as either Party may designate in writing.

**10.12 Headings.**

The subject headings of the articles and sections of this Agreement are solely for convenience and shall have no legal affect whatsoever in construing the provisions of this Agreement.

**10.13 Entire Agreement/Amendment.**

This Agreement, including the Exhibits which are deemed attached hereto and incorporated by reference, supersedes all previous contracts and constitutes the entire agreement existing between the Parties respecting the within subject matter, and neither Party shall be entitled to benefits other than those specified herein. As between the Parties, no oral statements or prior written material not specifically incorporated herein shall be of any force and effect. All prior representations or agreements between the Parties hereto, whether written or verbal, not expressly incorporated herein, are superseded. Except as specifically set forth in this Agreement and the Exhibits hereto, no changes in or additions to this Agreement shall be recognized or effective unless and until made in writing and signed by both Parties. This Agreement may be executed in two or more counterparts, each and all of which shall be deemed an original and all of which together shall constitute but one and the same instrument.

**10.14 Further Action.**

The Parties agree, without further consideration, to take all other steps, including executing further documents, which may be reasonably necessary to implement this Agreement after the effective date.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement effective as of the Effective Date.

**MISSOURI CENTER FOR PATIENT SAFETY  
PATIENT SAFETY ORGANIZATION**

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date Signed: \_\_\_\_\_

**PARTICIPANT**

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Date Signed: \_\_\_\_\_

## **EXHIBIT A**

### **PSO Regulatory Definitions as Provided in 42 CFR Part 3, § 3.20**

**Affiliated provider** means, with respect to a provider, a legally separate provider that is the parent organization of the provider is under common ownership, management, or control with the provider, or is owned, managed, or controlled by the provider.

**AHRQ** stands for the Agency for Healthcare Research and Quality in HHS.

**ALJ** stands for an Administrative Law Judge of HHS.

**Board** means the members of the HHS Departmental Appeals Board, in the Office of the Secretary, which issues decisions in panels of three.

**Bona fide contract** means:

- (1) A written contract between a provider and a PSO that is executed in good faith by officials authorized to execute such contract; or
- (2) A written agreement (such as a memorandum of understanding or equivalent recording of mutual commitments) between a Federal, State, local or Tribal provider and a Federal, State, local, or Tribal PSO that is executed in good faith by officials authorized to execute such agreement.

**Complainant** means a person who files a complaint with the Secretary pursuant to §3.306.

**Component organization** means an entity that:

- (1) Is a unit or division of a legal entity (including a corporation, partnership, or a Federal, State, local or Tribal agency or organization); or
- (2) Is owned, managed, or controlled by one or more legally separate parent organizations.

**Component PSO** means a PSO listed by the Secretary that is a component organization.

**Confidentiality provisions** means for purposes of Subparts C and D, any requirement or prohibition concerning confidentiality established by sections 921 and 922(b)-(d), (g) and (i) of the Public Health Service Act, 42 U.S.C. 299b-21, 299b-22(b)-(d), (g) and (i) and the provisions, at §§ 3.206 and 3.208, that implement the statutory prohibition on disclosure of identifiable patient safety work product.

**Disclosure** means the release, transfer, provision of access to, or divulging in any other manner of patient safety work product by:

- (1) An entity or natural person holding the patient safety work product to another legally separate entity or natural person, other than a workforce member of, or a health care provider holding privileges with, the entity holding the patient safety work product; or
- (2) A component PSO to another entity or natural person outside the component PSO and within the legal entity of which the component PSO is a part.

**Entity** means any organization or organizational unit, regardless of whether the organization is

public, private, for-profit, or not-for-profit.

**Group health plan** means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income Security Act of 1974 (ERISA)) to the extent that the plan provides medical care (as defined in paragraph (2) of section 2791(a) of the Public Health Service Act, including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise.

**Health insurance issuer** means an insurance company, insurance service, or insurance organization (including a health maintenance organization, as defined in 42 U.S.C. 300gg-91(b)(3)) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance (within the meaning of 29 U.S.C. 1144(b)(2)). This term does not include a group health plan.

**Health maintenance organization** means:

- (1) A Federally qualified health maintenance organization (HMO) (as defined in 42 U.S.C. 300e(a));
- (2) An organization recognized under State law as a health maintenance organization; or
- (3) A similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

**HHS** stands for the United States Department of Health and Human Services.

**HIPAA Privacy Rule** means the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), at 45 CFR Part 160 and Subparts A and E of Part 164.

**Identifiable patient safety work product** means patient safety work product that:

- (1) Is presented in a form and manner that allows the identification of any provider that is a subject of the work product, or any providers that participate in, or are responsible for, activities that are a subject of the work product;
- (2) Constitutes individually identifiable health information as that term is defined in the HIPAA Privacy Rule at 45 CFR 160.103; or
- (3) Is presented in a form and manner that allows the identification of an individual who in good faith reported information directly to a PSO or to a provider with the intention of having the information reported to a PSO (“reporter”).

**Non-identifiable patient safety work product** means patient safety work product that is not identifiable patient safety work product in accordance with the non-identification standards set forth at § 3.212.

**OCR** stands for the Office for Civil Rights in HHS.

**Parent organization** means an organization that: owns a controlling interest or a majority interest in a component organization; has the authority to control or manage agenda setting,

project management, or day-to-day operations; or the authority to review and override decisions of a component organization. The component organization may be a provider.

**Patient Safety Act** means the Patient Safety and Quality Improvement Act of 2005 (Pub. L. 109-41), which 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.

**Patient safety activities** means the following activities carried out by or on behalf of a PSO or a provider:

- (1) Efforts to improve patient safety and the quality of health care delivery;
- (2) The collection and analysis of patient safety work product;
- (3) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;
- (4) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;
- (5) The maintenance of procedures to preserve confidentiality with respect to patient safety work product;
- (6) The provision of appropriate security measures with respect to patient safety work product;
- (7) The utilization of qualified staff; and
- (8) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

**Patient safety evaluation system** means the collection, management, or analysis of information for reporting to or by a PSO.

**Patient safety organization (PSO)** means a private or public entity or component thereof that is listed as a PSO by the Secretary in accordance with Subpart B. A health insurance issuer or a component organization of a health insurance issuer may not be a PSO. See also the exclusions in § 3.102 of this Part.

**Patient safety work product:**

- (1) Except as provided in paragraph (2) of this definition, patient safety work product means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements (or copies of any of this material)
  - (i) Which could improve patient safety, health care quality, or health care outcomes; and
  - (A) Which are assembled or developed by a provider for reporting to a PSO and are reported to a PSO, which includes information that is documented as within a patient safety evaluation system for reporting to a PSO, and such documentation includes the date the information entered the patient safety evaluation system; or
  - (B) Are developed by a PSO for the conduct of patient safety activities; or
  - (ii) Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.
- (2)(i) Patient safety work product does not include a patient's medical record, billing and discharge information, or any other original patient or provider information; nor does it include

information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered patient safety work product.

(ii) Patient safety work product assembled or developed by a provider for reporting to a PSO may be removed from a patient safety evaluation system and no longer considered patient safety work product if:

(A) The information has not yet been reported to a PSO; and

(B) The provider documents the act and date of removal of such information from the patient safety evaluation system.

(iii) Nothing in this part shall be construed to limit information that is not patient safety work product from being:

(A) Discovered or admitted in a criminal, civil or administrative proceeding;

(B) Reported to a Federal, State, local or Tribal governmental agency for public health or health oversight purposes; or

(C) Maintained as part of a provider's recordkeeping obligation under Federal, State, local or Tribal law.

**Person** means a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

**Provider** means:

(1) An individual or entity licensed or otherwise authorized under State law to provide health care services, including –

(i) A hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office (includes a group practice), long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or

(ii) A physician, physician assistant, registered nurse, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner;

(2) Agencies, organizations, and individuals within Federal, State, local, or Tribal governments that deliver health care, organizations engaged as contractors by the Federal, State, local, or Tribal governments to deliver health care, and individual health care practitioners employed or engaged as contractors by the Federal State, local, or tribal governments to deliver health care; or

(3) A parent organization of one or more entities described in paragraph (1)(i) of this definition or a Federal, State, local, or Tribal government unit that manages or controls one or more entities described in paragraphs (1)(i) or (2) of this definition.

**Research** has the same meaning as the term is defined in the HIPAA Privacy Rule at 45 CFR 164.501.

**Respondent** means a provider, PSO, or responsible person who is the subject of a complaint or a compliance review.

**Responsible person** means a person, other than a provider or a PSO, who has possession or custody of identifiable patient safety work product and is subject to the confidentiality provisions.

**Workforce** means employees, volunteers, trainees, contractors, or other persons whose conduct, in the performance of work for a provider, PSO or responsible person, is under the direct control of such provider, PSO or responsible person, whether or not they are paid by the provider, PSO or responsible person

**EXHIBIT B**  
**PSO Services, Participation Level and Fee Schedule**  
**Missouri Ambulatory Surgery Center Association Members**

Participant elects to utilize the PSO Services of the Missouri Center for Patient Safety as listed below:

\_\_\_\_\_ **Standard PSO Services**, including the following:

- ✓ Web-based data entry system, including initial training and support
- ✓ Guidelines for establishing a PSES and defining PSWP
- ✓ Federal-based legal protections for submitted PSWP
- ✓ Access to automated individual facility events data; quarterly de-identified data, aggregate root cause analysis review, and AHRQ Culture of Safety survey tool
- ✓ Participation in a state and national network of PSO-affiliated providers for discussion forums and peer-collaboration opportunities
- ✓ Safety and regulatory updates and key findings alerts
- ✓ Access to the Quantros™ Patient Safety Library, PSO Web meetings, Quantros™ Patient Safety Center Advisory Board, and CME/CE e-Learning Courses and credits
- ✓ Submission of facility data to the network of Patient Safety Databases (NPSD) as authorized

**The total annual fee for PSO Standard Services is \$2,500.** Participant agrees to pay the Center an annual fee of \$ 2,500 during the term of this Agreement in consideration for the provision of PSO Standard Services. An option for payment of the annual fee is available by checking this option below.

\_\_\_\_\_ **I elect the following option for payment of the annual \$2,500 fee for Standard PSO Services.**

- Payment of ½ of the annual fee in the amount of \$1,250 shall be due within 30 days of the initial invoice for the contract year;
- Remaining annual fee in the amount of \$1,250 shall be due in August of the respective contract year.

**Optional PSO Services**

In addition to the Standard PSO services provided under this Agreement, Participant elects to participate in the following Optional PSO Services for an additional fee of \$\_\_\_\_\_ in consideration for the provision of identified service.

- \_\_\_\_\_ Technical assistance (one-site)
- \_\_\_\_\_ Technical assistance (remote)
- \_\_\_\_\_ Custom analytics and reporting, including AHRQ Culture of Safety Survey results and findings
- \_\_\_\_\_ Real-time root cause analysis review and recommendations

- \_\_\_\_\_ On-site risk assessment
- \_\_\_\_\_ IHI Trigger Audits
- \_\_\_\_\_ Claims analysis
- \_\_\_\_\_ Tracer methodology and procedural review of high risk areas
- \_\_\_\_\_ Special projects
- \_\_\_\_\_ Additional technical assistance and services on a project-specific basis as negotiated and mutually agreed upon between the parties to this agreement.  
(Describe here) \_\_\_\_\_

Participant agrees to pay the Center a total of \_\_\_\_\_ by \_\_\_\_\_, \_\_\_\_\_ in consideration for the provision of the identified optional services.

Should Participant desire changes to the optional services plan following the initial execution of this Agreement, an amended Exhibit B will be signed at that time.

**MISSOURI CENTER FOR PATIENT SAFETY  
PATIENT SAFETY ORGANIZATION**

By: \_\_\_\_\_  
 Name: \_\_\_\_\_  
 Title: \_\_\_\_\_  
 Date Signed: \_\_\_\_\_

**PARTICIPANT**

By: \_\_\_\_\_  
 Name: \_\_\_\_\_  
 Date Signed: \_\_\_\_\_

**EXHIBIT C**  
**Primary Contact and System Administrator Contact Form**

<b>Primary Contact for Organization:</b>		
Name: _____		
Job Title: _____		
Organization Name: _____		
Mailing Address: _____		
City: _____	State: _____	Zip Code: _____
E-Mail address: _____		
Phone number: _____	Fax number: _____	

**If this individual will serve as the Primary Contact for any other organizations affiliated with the Center, please list them below:**

1. \_\_\_\_\_
2. \_\_\_\_\_

**System Administrator:** Person with ability to submit data, run reports, and assigns user passwords. If this person is different than the Primary Contact, please complete the following information:

Name: _____		
Job Title: _____		
Organization Name: _____		
Mailing Address: _____		
City: _____	State: _____	Zip Code: _____
E-Mail address: _____		
Phone number: _____	Fax number: _____	

**EXHIBIT D**

**To be completed and signed at the time of agreement on Special Project descriptions per agreement provision 2.4 b. (b)**

**Project Description:**

**Project Procedure:**

**Additional Project Provisions as Agreed upon between Participant and Center.**

**MISSOURI CENTER FOR PATIENT SAFETY  
PATIENT SAFETY ORGANIZATION**

By: \_\_\_\_\_  
Name:  
Title:  
Date Signed: \_\_\_\_\_

**PARTICIPANT**

By: \_\_\_\_\_  
Name:  
Date Signed: \_\_\_\_\_

## **EXHIBIT E**

### **Workforce Confidentiality Agreement**

The Patient Safety and Quality Improvement Act of 2005 (the Act) and its implementing regulations, 42 CFR, Part 3 (“Final Rule”) provide for the assemblage of a “qualified workforce” of employees, volunteers, trainees, contractors, or other persons who perform work for or on behalf of the Provider or PSO.

Members of both Participant’s and the Center’s workforce are expected to be well trained and qualified to perform their responsibilities, and to understand and acknowledge their significant obligations, including but not limited to their obligations to maintain the confidentiality of Patient Safety Work Product (PSWP) as required by the Act, and of Protected Health Information (PHI), as required by the Health Insurance Portability and Accountability Act (HIPAA) and its regulations and other federal and state laws that were established to protect the confidentiality of medical and personal information, and provide, generally, that such information may not be disclosed except as permitted or required by law or unless authorized by the patient.

### **CONFIDENTIALITY STATEMENT**

As a member of the \_\_\_\_\_(Participant or Center) workforce, I understand that I may be working with confidential quality assurance, peer review, medical and other sensitive or private information. This information may include, but is not limited to, incident reports, medical reports, evaluation records, medical records, personnel information, ledgers, verbal discussion, and electronic communications including e-mail, and other information and data transmitted in written, verbal, electronic or other forms.

I understand and acknowledge that the Act and HIPAA require that I be trained on the requirements of the Act and HIPAA and the \_\_\_\_\_(Participant or Center) policies, procedures and guidelines relating to protection of confidential information, and I agree to obtain

all required training before I access, use or disclose any confidential information.

I acknowledge that it is my responsibility to respect the privacy and confidentiality of patient and other confidential information. I will not access, use or disclose patient or other confidential information unless I do so in the course and scope of fulfilling my duties as a member of the \_\_\_\_\_ (Participant or Center) workforce.

I understand that I am required to immediately report any information about unauthorized access, use or disclosure of confidential information. Initial reports go to \_\_\_\_\_ (Participant's PSES or the Center's Executive Director). An incident report will be forwarded to \_\_\_\_\_ (Participant's PSES or the Center's Executive Director).

I understand and acknowledge that, should I breach any provision of this agreement, I may be subject to civil or criminal liability and/or disciplinary action consistent with applicable federal and state law, employment policies, contracts and processes.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name

## **EXHIBIT F**

### **HIPAA BUSINESS ASSOCIATE AGREEMENT**

This HIPAA Business Associate Agreement (“BAA”) entered into this \_\_\_ day of \_\_\_\_\_, 2009, between the Missouri Center for Patient Safety Patient Safety Organization (“the Center”), and \_\_\_\_\_ (“Participant”), supplements and is made a part of the Participant Agreement including supplements and amendments.

**WHEREAS**, Participant desires to protect the privacy and security of Protected Health Information (“PHI”) Used or Disclosed by Center 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 Center have entered into a Participant Agreement under which Participant will voluntarily submit certain information to Center and Center 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 Center.
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 CENTER**

1. Uses and Disclosures.

Center agrees not to Use and/or Disclose PHI received from Participant or created or received by Center 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.

Center 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, Center 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.

Center agrees to notify Participant of any Use or Disclosure of PHI not provided for by this BAA, within ten (10) days of Center’s 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, Center shall, following the discovery of a Breach of Unsecured PHI, notify Participant within ten (10) business days of discovery of such Breach. Center 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 Center 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 Center does not possess the identity of all such individuals within ten (10) business days of discovery of the Breach, Center shall notify Participant with such information as is

available by that deadline and supplement immediately as additional information becomes available.

4. Agents and Subcontractors.

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

5. Regulatory Compliance.

Center 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 Center 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 CENTER**

1. Center Services.

Center may Use or Disclose PHI for the purpose of providing the Services described in the Participant Agreement.

2. Data Aggregation.

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

3. Center Management and Administration.

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

4. Disclosures for Center's Management and Administration.

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

a. The disclosure is Required by Law; or

b. Center 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 Center of any instances of which it is aware in which the confidentiality of the information has been breached.

5. Uses for Reporting Purposes.

Center 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 Center.

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

2. Impermissible Request by Participant.

Except as otherwise provided in this BAA, Participant will not request Center 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 Center, or created or received by Center 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, Center shall return or destroy all PHI received from Participant or created or received by Center on behalf of Participant. This provision shall apply to PHI that is in the possession of subcontractors or agents of Center.

b. In the event that the Parties agree in writing that returning or destroying the PHI is infeasible, Center 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 Center 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 Center 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.

**PARTICIPANT**

**MISSOURI CENTER FOR PATIENT  
SAFETY PATIENT SAFETY  
ORGANIZATION**

Signature: \_\_\_\_\_

Signature: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

## EXHIBIT G

### HIPAA DATA USE AGREEMENT FOR LIMITED DATA SET

This HIPAA Data Use Agreement for Limited Data Set (“DUA”) entered into this \_\_\_ day of \_\_\_\_\_, 20\_\_ between the Missouri Center for Patient Safety Patient Safety Organization (“Center”) and \_\_\_\_\_ (“Participant”) supplements and is made a part of the Participant Agreement including supplements and amendments.

**WHEREAS** Participant desires to protect the privacy and security of Protected Health Information (“PHI”) Used or Disclosed by Center 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). The purpose of this DUA is to satisfy certain standards and requirements of HIPAA (hereinafter “HIPAA Rules”) as they may be amended from time to time.

**WHEREAS** Participant and Center have entered into a Participant Agreement under which Participant will voluntarily submit certain information to Center and Center will utilize the information to perform patient safety activities (“Services”). In the performance of the Services on behalf of Participant, Center will create a Limited Data Set from Participant’s information as Participant’s Business Associate and Use and Disclose Participant’s information contained in the Limited Data Set as the intended recipient of the Limited Data Set.

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

#### A. **DEFINITIONS**

In addition to the terms already defined in the Participant Agreement, the Business Associate Agreement (“BAA”) attached to the Participant Agreement as **Exhibit F** and this DUA, the terms capitalized in this DUA 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.

#### B. **CREATION OF LIMITED DATA SET**

Center may create a Limited Data Set as described in 45 CFR § 164.514 from PHI received from Participant, or created or received by Center on behalf of Participant. Center may Use and Disclose Participant information contained in the Limited Data Set as the intended recipient of the Limited Data Set.

#### C. **PERMITTED USES AND DISCLOSURES OF LIMITED DATA SET**

1. Center may Use or Disclose the Limited Data Set for the purposes of providing Services under the Participant Agreement and as otherwise permitted under Section C of the BAA attached to the Participant Agreement as **Exhibit F** or as Required by Law.

2. Center agrees to use appropriate administrative, technical and physical safeguards to protect the confidentiality, integrity and availability of the Limited Data Set information as required by the HIPAA Rules and to prevent any Use or Disclosure other than as permitted by this DUA.

3. Center agrees to notify Participant of any Use or Disclosure of the Limited Data Set information not provided for by this DUA 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 DUA.

4. Center agrees to ensure that any agent, including subcontractors to whom it provides Limited Data Set information, agrees to the same restrictions and confidentiality that apply to Center with respect to such information.

5. Center will not use or further disclose the Limited Data Set information in a manner that would violate the HIPAA rules if done by Participant.

6. Center will not attempt to identify the Individuals to whom the Limited Data Set information pertains or attempt to contact such Individuals.

#### **D. TERM AND TERMINATION**

1. Term.

The Term of this DUA shall be effective as of the Effective Date of the Participant Agreement and shall terminate when all of the Limited Data Set information is destroyed or returned to Participant, or if it is infeasible to return or destroy the Limited Data Set information, 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 DUA 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 DUA 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 DUA for any reason, Center shall return or destroy the Limited Data Set information. This provision shall apply to any Limited Data Set information that is in the possession of subcontractors or agents of Center.

(b). In the event that the Parties agree in writing that returning or destroying the Limited Data Set information is infeasible, Center shall extend the protections of this DUA to the

Limited Data Set information and limit further Uses and Disclosures of the Limited Data Set information to those purposes that make the return or destruction infeasible, for so long as Center maintains the Limited Data Set information.

**E. MISCELLANEOUS**

1. Regulatory References.

A reference in this DUA 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 DUA 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 Center under Section D(3) of this DUA shall survive the termination of this DUA.

4. Interpretation.

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

5. Governing Law.

This DUA 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 Data Use Agreement for Limited Data Set to be duly executed in their respective names as of the date first above written.

**PARTICIPANT**

**MISSOURI CENTER FOR PATIENT  
SAFETY PATIENT SAFETY  
ORGANIZATION**

Signature: \_\_\_\_\_

Signature: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

**EXHIBIT H**  
**Affiliated Providers**

Participant identifies the following as Affiliated Providers, as defined in 42 CFR §3.20.

<b>Name:</b> _____
<b>Mailing Address:</b> _____
<b>City:</b> _____ <b>State:</b> _____ <b>Zip Code:</b> _____
<b>Phone Number:</b> _____ <b>Fax Number:</b> _____
<b>Nature of Affiliation:</b> _____

<b>Name:</b> _____
<b>Mailing Address:</b> _____
<b>City:</b> _____ <b>State:</b> _____ <b>Zip Code:</b> _____
<b>Phone Number:</b> _____ <b>Fax Number:</b> _____
<b>Nature of Affiliation:</b> _____

<b>Name:</b> _____
<b>Mailing Address:</b> _____
<b>City:</b> _____ <b>State:</b> _____ <b>Zip Code:</b> _____
<b>Phone Number:</b> _____ <b>Fax Number:</b> _____
<b>Nature of Affiliation:</b> _____

**If additional affiliated providers need to be listed, please copy this form and include in the agreement.**