

**CHPSO PATIENT SAFETY ORGANIZATION  
PARTICIPATING PROVIDER AGREEMENT**

This Agreement is between CHPSO Patient Safety Organization (CHPSO), a California nonprofit public benefit corporation, and \_\_\_\_\_ (PROVIDER); and is effective \_\_\_\_\_ (the “**Effective Date**”).

**BACKGROUND**

- A. CHPSO has been designated as a Patient Safety Organization pursuant to the federal Patient Safety and Quality Improvement Act of 2005 and its effectuating rules and regulations (the “**Act**”). Its purposes are to engage in:
1. Activities to improve patient safety and the quality of health care delivery.
  2. Collection and analysis of patient safety work product.
  3. Development and dissemination of information aimed at improving patient safety.
  4. Utilization of patient safety work product to encourage a culture of safety and to provide feedback and assistance toward minimizing patient risk.
  5. Other activities related to the operation of a patient safety evaluation system and to providing feedback to participants in a patient safety evaluation system.
- B. CHPSO is organized and operated to preserve confidentiality and security of patient safety work product, and to avail of all available protections of the Act.
- C. PROVIDER wishes to voluntarily participate in CHPSO’s data collection, reporting, and evaluation activities in an effort to improve the quality of care delivered at PROVIDER and in PROVIDER’s community, and ultimately improving the patient care delivery system in general.
- D. The underlying purpose and commitment of this Agreement is to conduct all such activities in a setting that is not intended to and does not ascribe blame or fault, but that promotes full and frank evaluation and discussion toward achieving the above-stated patient safety and healthcare quality improvement goals.

**SECTION 1.  
DEFINITIONS**

**1.1 PSO Regulatory Definitions**

The parties hereby adopt and incorporate by reference the definitions at 42 Code of Federal Regulations (“CFR”) Part 3 (the “**Regulations**”), § 3.20, a copy of which is appended as **Exhibit 1.1**. Without limiting the generality of the foregoing, the following terms are particularly relevant to this Agreement:

- Affiliated Provider
- Disclosure
- Identifiable Patient Safety Work Product
- Nonidentifiable Patient Safety Work Product
- Patient Safety Activities
- Patient Safety Evaluation System
- Patient Safety Work Product
- Provider
- Workforce

**1.2 Additional Definitions**

The following additional definitions shall apply to this Agreement:

- **Anonymized** – as defined in the Preamble to the Regulations (at 73 Federal Register, p. 70778) and specified in 42CFR3.206(b)(4)(iv), data from which provider-related direct identifiers listed in 42CFR3.206(b)(4)(iv)(A) and patient direct identifiers pursuant to the HIPAA Privacy Rule’s limited data set standard are removed.
- **Common Format** - shall mean the agreed-upon format for collecting and submitting data. Except as otherwise agreed by the parties, the Common Format shall be that adopted, from time to time, by the Agency for Healthcare Research and Quality (“AHRQ”).
- **De-Identified Data** – are data that do not contain unique identifying codes, except for codes that have not been derived from or do not relate to information about the individual and that cannot be translated so as to identify the individual, as further described in the HIPAA Privacy Rule.
- **Functional Reporting** - refers to an agreed-upon alternative means of “transferring” Patient Safety Work Product to CHPSO. A Functional Reporting arrangement may leave PSWP in the physical possession of PROVIDER, with CHPSO 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 (at 73 Federal Register, pp. 70740-70741).
- **HIPAA** – shall mean the Health Insurance Portability and Accountability Act of 1996.
- **HIPAA Privacy Rule** – shall mean the HIPAA Privacy regulations at 45 CFR Subpart E.
- **Limited Data Set (“LDS”)** – is information stripped of only the direct identifiers listed at section 164.514(e) of the HIPAA Privacy Rule.
- **Protected Health Information or PHI** – shall mean individually identifiable health information, as further described in the HIPAA Privacy Rule.

## **SECTION 2.**

### **GENERAL OVERVIEW**

#### **2.1 Overview of CHPSO’s Role**

CHPSO will develop a Patient Safety Evaluation System, in consultation with participating providers, including PROVIDER. CHPSO will develop specific data collection, monitoring, collaboration and evaluation activities, and offer them to participating providers. Each participating provider may select the level of participation it wishes to engage in.

#### **2.2 Overview of Participating Providers’ Roles**

All participation is voluntary and nonexclusive. Participating providers will be offered the opportunity to collect and submit information to CHPSO, to participate in evaluations, and to receive the results of such activities. Decisions as to how to implement or integrate results in provider operations will be up to each participating provider. Participating providers may participate in other patient safety organizations.

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

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

##### **a) Privilege**

As provided by the Act, Patient Safety Work Product developed by PROVIDER and/or maintained by CHPSO is privileged and shall not be:

- (1) Subject to subpoena;
- (2) Subject to discovery;
- (3) Subject to Disclosure;
- (4) Admitted into evidence;

— provided, however, such information may be subject to Disclosure in certain criminal proceedings (as described at § 3.204(b)(1) of the Regulations), or to permit equitable relief (as described at § 3.204(b)(2) of the Regulations), or pursuant to provider authorizations (as described at § 3.204(b)(3) of the Regulations), or of Nonidentifiable Patient Safety Work Product (as described at § 3.204(b)(4) of the Regulations).

**b) Confidentiality**

Patient Safety Work Product is confidential, and CHPSO shall not disclose it, except as may be required or permitted by law pursuant to § 3.206(b) of the Regulations.

**2.4 Functional Reporting**

Upon mutual agreement as to the procedures and form thereof, PROVIDER may engage in Functional Reporting, which agreement shall be placed in writing and appended to this Agreement.

**SECTION 3.  
CHPSO RESPONSIBILITIES**

**3.1 Orientation**

CHPSO will conduct orientation and routine training, as necessary, to facilitate PROVIDER’s understanding of and effective participation in CHPSO’s Patient Safety Evaluation System and Patient Safety Activities.

**3.2 Common Format**

CHPSO will provide a Common Format for the collection and reporting of key information. At the outset of the Agreement, the Common Format will be the AHRQ Common Format. CHPSO may implement changes to the Common Format from time to time, as a result of changes in the AHRQ Common Format or as a result of other modifications developed in consultation with participating providers.

**3.3 Patient Safety Evaluation System**

CHPSO shall establish a CHPSO Patient Safety Evaluation System for the collection, management, and analysis of information received from and/or reported to participating providers, including PROVIDER.

**3.4 Patient Safety Work Product (“PSWP”)**

- a) CHPSO will collect and maintain reported information as Patient Safety Work Product. CHPSO shall maintain the confidentiality of Patient Safety Work Product. Without limiting the generality of the foregoing, CHPSO and PROVIDER shall, concurrently with the execution of this Agreement, enter into a Business Associate Addendum, attached as **Exhibit 3.4**, and shall maintain the confidentiality of PHI in accordance with all applicable laws pertaining to confidentiality of PHI and patient medical record information.
- b) Patient Safety Work Product reports that are circulated to other participating providers, PSOs, or are otherwise publicized will use Anonymized data, except as otherwise agreed, in writing, by PROVIDER. Use of patient identifiers in the reports will comply with the Anonymized data requirements or the terms of the Business Associate Addendum, whichever are more restrictive.
- c) As required by law and in accordance with the terms of the Business Associate Addendum, CHPSO will promptly notify PROVIDER of any breaches in confidentiality or security, and will take immediate remedial measures as appropriate to effectively address the breach.

**3.5 Patient Safety Activities**

CHPSO will assemble a knowledgeable Workforce, and in collaboration with its Workforce (which may consist of employees, volunteers, representatives of participating providers and other individuals as appropriate to the involved Patient Safety Activity), other Patient Safety Organizations and contractors, will develop and conduct Patient Safety Activities, including but not limited to data collection,

appropriate studies, evaluative activities, reports, and recommendations, including, where feasible, “best practices” recommendations; and will offer the results to participating providers, including PROVIDER, as appropriate to its level(s) of participation.

## **SECTION 4.** **PROVIDER RESPONSIBILITIES**

### **4.1 Patient Safety Evaluation System**

PROVIDER (including all facilities listed in **Exhibit 4.1**) will develop a Provider Patient Safety Evaluation System for collecting, maintaining and managing information, including but not limited to Patient Safety Work Product reported to and PROVIDER’s interactions with CHPSO. PROVIDER must document the date PROVIDER’s Patient Safety Work Product enters its Patient Safety Evaluation System.

### **4.2 Appointment of PROVIDER/PSO Liaison Representative**

PROVIDER will appoint a primary and a secondary PROVIDER/PSO Liaison Representative (“Representative”) who will be the point of contact with respect to PROVIDER’s Patient Safety Activities. The Representative may designate other individuals to interact with respect to particular Patient Safety Activities, and when doing so should indicate any special instructions regarding confidentiality, authority, necessity to keep the Representative informed, and the like. At the outset of this Agreement, PROVIDER’s primary Representative is \_\_\_\_\_, secondary Representative is \_\_\_\_\_. PROVIDER may change the primary and/or secondary Representative at any time, by giving written notice to CHPSO.

### **4.3 Reporting**

- a) PROVIDER will use its best efforts to promptly provide data and information that are timely, accurate and complete with respect to the reported matters. Reported information will clearly delineate that information which is Patient Safety Work Product and that which is not Patient Safety Work Product. In this latter regard, PROVIDER acknowledges and understands that:
  - (i) Information that is collected, maintained or developed separately, or exists separately, from PROVIDER’s Patient Safety Evaluation System is **not** Patient Safety Work Product.
  - (ii) However, with respect to PSWP assembled or developed for reporting to CHPSO, up and until such time that the information has been reported to CHPSO, PROVIDER may reclassify information as being or not being Patient Safety Work Product. Once PSWP has been reported to CHPSO, it is not possible to reclassify the information.
- b) PROVIDER will cooperate, as appropriate, with reasonable follow-up requests from CHPSO for information and/or clarification regarding reported information.
- c) PROVIDER will notify CHPSO of intent to engage in Functional Reporting, determine the process for such reporting, and provide CHPSO with an agreement to be appended to this Agreement.
- d) CHPSO recommends that the PROVIDER submit all event fields collected within the PROVIDER event reporting system. However, the following fields should be submitted in order for patient safety events to be included in event analysis conducted by CHPSO:
  - (1) Event Number
  - (2) Event Type
  - (3) Date Event Occurred
  - (4) Event Severity (Incident or Near Miss)
  - (5) Event Description/Comments
  - (6) Age

- (7) Gender
- (8) Harm Level

#### **4.4 Use and Protection of PSWP**

- a) PROVIDER shall maintain the confidentiality of PROVIDER's PSWP, and shall not disclose PSWP, except as otherwise permitted by the Act.
- b) PROVIDER may use PROVIDER's PSWP internally and Disclose to Affiliated Providers in furtherance of Patient Safety Activities. PROVIDER shall be solely responsible for appropriately managing its internal uses of PSWP as necessary to maintain applicable protections of the Act. PROVIDER understands and agrees that it may not use PSWP to fulfill external reporting, regulatory, or accreditation obligations. To the extent events or circumstances that are designated as PSWP also require external reporting or communications, PROVIDER shall develop such systems as necessary to maintain the integrity of PSWP.
- c) Except as otherwise permitted by the Act or the Regulations, PROVIDER will not Disclose other providers' PSWP, nor use it in any manner other than Patient Safety Activities conducted as part of PROVIDER's or CHPSO's Patient Safety Evaluation System.
- d) Grant CHPSO the royalty-free, perpetual, irrevocable, worldwide, non-exclusive right and license to use, reproduce, modify, adapt, publish, create derivative works from, distribute, and display all non-identifiable PSWP, received from the PROVIDER.

#### **4.5 Implementation of CHPSO Recommendations**

PROVIDER shall be solely responsible for its own decision-making with respect to participating in CHPSO Patient Safety Activities, including but not limited to assessing the merits of and determining whether and how to implement the results and recommendations emanating from CHPSO Patient Safety Activities.

#### **4.6 Independent Medical Judgment**

PROVIDER acknowledges that CHPSO is not intended and shall not be assumed to indicate any particular course of action with regard to the diagnosis or treatment of a medical condition. Any PSWP available via CHPSO is not a substitute for the professional judgment of clinical professionals in diagnosing and treating patients. Clinical professionals are responsible for determining the permissible and advisable uses of the PSWP in accordance with applicable laws and institutional rules. CHPSO shall not be deemed under any circumstance to be giving medical advice or providing medical or diagnostic services through CHPSO or the services provided hereunder. PROVIDER's clinical professionals are and remain solely responsible for making all medical, diagnostic or prescription decisions PROVIDER is solely responsible for complying with all laws, regulations, professional rules and licensing requirements applicable to its delivery of healthcare services.

#### **4.7 Notification of other Patient Safety Organization Participation**

In the event PROVIDER participates in and reports the same PSWP to other patient safety organizations, PROVIDER will notify CHPSO and use best efforts to communicate and cooperate with all PSO recipients of PROVIDER's PSWP, so they may take measures to avoid duplication of data that may be aggregated by cooperating PSOs.

**SECTION 5.**  
**RESPONDING TO REQUESTS/DEMANDS FOR INFORMATION**

**5.1 CHPSO's Obligations**

- a) In the event CHPSO receives a request, subpoena, or other attempt of an outside party or agency to access confidential PSWP provided by PROVIDER, CHPSO will assert all applicable privileges, and will promptly notify PROVIDER.
- b) In the event there is an applicable exception or Disclosure permission as defined in section 2.3(a) that would require CHPSO to provide access to PROVIDER's confidential PSWP, CHPSO will promptly notify PROVIDER.
- c) CHPSO will cooperate and coordinate with PROVIDER as described in Section 5.2.

**5.2 PROVIDER's Obligations**

- a) In cases where PROVIDER's PSWP is sought by litigants in cases where PROVIDER (or its staff) is/are parties, PROVIDER (or its staff) maintains primary responsibility for defending against attempts to access PROVIDER's PSWP. CHPSO and its counsel will cooperate as necessary to protect PROVIDER's PSWP.
- b) In cases where PROVIDER's PSWP is sought by agencies investigating PROVIDER or its staff, PROVIDER (or its staff) maintains primary responsibility for defending against attempts to access PROVIDER's PSWP. CHPSO and its counsel will use reasonable efforts to cooperate as necessary to protect PROVIDER's PSWP.
- c) In cases where PROVIDER's PSWP is sought by other litigants or interested parties, the parties shall meet and confer as to the appropriate allocation of responsibility and response.

**SECTION 6.**  
**INSURANCE AND INDEMNIFICATION**

**6.1 Insurance**

- a) CHPSO shall maintain the following minimum levels of insurance:
  - General liability           \$2,000,000 per occurrence  
  \$4,000,000 aggregate
  - Professional liability    \$2,000,000 per occurrence  
  \$2,000,000 aggregate
  - D&O                            \$3,000,000 per occurrence  
  \$3,000,000 aggregate
  - Cyber liability             \$2,000,000 per occurrence  
  \$2,000,000 aggregate
- b) PROVIDER shall maintain the following minimum levels of insurance or programs of self-insurance:
  - General liability           \$2,000,000 per occurrence  
  \$4,000,000 aggregate
  - Professional liability    \$2,000,000 per occurrence  
  \$2,000,000 aggregate
  - D&O                            \$3,000,000 per occurrence  
  \$3,000,000 aggregate
  - Cyber liability             \$2,000,000 per occurrence  
  \$2,000,000 aggregate

## **6.2 Indemnification**

- a) Nothing in this Agreement is intended, nor shall it be construed to create any responsibility on the part of PROVIDER 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 omissions of CHPSO or its officers, directors, employees, Workforce members, or agents. Subject to the provisions of **Section 6.2(c)**, below, CHPSO shall defend, indemnify, and hold harmless PROVIDER, its officers, directors, employees, Workforce members and agents from and against any and all claims, demands, liabilities, losses, damages, costs, and expenses, including reasonable attorneys' 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 CHPSO 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 omissions of PROVIDER or its officers, directors, employees, staff members, independent contractors, or agents. Subject to the provisions of **Section 6.2(c)**, below, PROVIDER shall defend, indemnify, and hold harmless CHPSO, its officers, directors, employees, Workforce members and agents from and against any and all claims, demands, liabilities, losses, damages, costs and expenses, including reasonable attorneys' fees, resulting in any manner, directly or indirectly, from any of the foregoing circumstances.
- c) The provisions of **Sections 6.2(a)** and **6.2(b)** are intended to apply only to claims and liabilities that are not covered by or that exceed the policy limits of applicable insurance coverage and for which liability has not been otherwise allocated by agreement of the parties. This **Section 6.2** does not apply if the effect of such provision would be to negate insurance coverage that would otherwise be available but for these contractual indemnity provisions. Nothing contained in this **Section 6.2** is intended or should be construed to: (i) create any liability to or right of recovery or subrogation on the part of any insurance carrier or any other third party against either of the parties; or (ii) affect the allocation of responsibilities among insurance carriers or other persons who may have responsibility for satisfaction of all or any part of any claim made against either party.

## **SECTION 7. TERM AND TERMINATION**

### **7.1 Without Cause**

This Agreement may be terminated without cause upon 90 days written notice.

### **7.2 With Cause**

This Agreement may be terminated immediately or on shortened notice, for cause, as next provided.

- a) In the event CHPSO is decertified as a Patient Safety Organization, termination shall be effective as of the date of CHPSO's termination as a PSO.
- b) In the event of either party's material breach of this Agreement, the nonbreaching party shall give written notice of breach, and the breaching party shall have 30 days to cure and communicate, in writing, its cure to the nonbreaching party. Failure to cure or communicate cure within this timeframe shall be grounds for immediate termination.

## **SECTION 8. MISCELLANEOUS**

### **8.1 Fees**

Members of the California Hospital Association (CHA) may join at no charge. Non CHA Members/out of state facilities may contact CHPSO for custom pricing.

### **8.2 No Third Party Beneficiaries**

Nothing in this Agreement is intended, nor shall it be construed to create rights running to the benefit of third parties.

**8.3 Notices**

All notices required by this Agreement shall be in writing, and shall be deemed effective when personally delivered, when mailed by certified or registered mail return receipt requested, or when deposited with a comparably reliable postal delivery service (such as Federal Express), addressed to the other party as follows:

To CHPSO:	To PROVIDER:
CHPSO 1215 K Street, Suite 800 Sacramento, CA 95814 Attn: PSO Authorized Official	

**8.4 Force Majeure**

Neither party shall be liable nor deemed to be in default for any delay or failure in performance under this Agreement, or any interruption of service or employment deemed resulting, directly or indirectly, from acts of God, civil or military authority, acts of public enemy, war, accidents, fires, explosions, earthquakes, floods, failure of transportation, machinery or supplies, vandalism, strikes, or other work interruptions beyond the reasonable control of either party, including but not limited to interruptions caused by communications failures.

**8.5 Exhibits**

All referenced exhibits are deemed attached to this Agreement and incorporated herein by this reference.

**8.6 Entire Agreement, Modification**

This Agreement contains the entire agreement of the parties relating to this subject matter. The Agreement may only be modified in writing, signed by both parties, effective on the date set forth in such writing.

PROVIDER

CHPSO

By: \_\_\_\_\_

By: \_\_\_\_\_

Robert Imhoff, President, HQI

Name: \_\_\_\_\_

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

Date: \_\_\_\_\_

Date \_\_\_\_\_

**EXHIBIT LIST**

- 1.1 Definitions Section of PSA Regulations**
- 3.4 Business Associate Addendum**
- 4.1 Participating Healthcare Provider List**

## EXHIBIT 1.1

### Patient Safety Act Definitions

*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").

*Nonidentifiable patient safety work product* means patient safety work product that is not identifiable patient safety work product in accordance with the nonidentification standards set forth at § 3.212.

#### Subpart A—General Provisions

##### § 3.10 Purpose.

The purpose of this Part is to implement 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 adding sections 921 through 926, 42 U.S.C. 299b-21 through 299b-26.

##### § 3.20 Definitions.

As used in this Part, the terms listed alphabetically below have the meanings set forth as follows:

*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.

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.