

INSTRUCTIONS

All participating hospitals execute:

- Participating Hospital Agreement (page numbers 1-10)
- Business Associate Agreement (page numbers 14-22)

A PSO is, by definition, a HIPAA business associate of a participating hospital. Disclosure of patient information to a PSO is considered health care operations.

NOTE: For the participating hospital agreement, the following items need to be completed.

- Page 1: Name of hospital, effective date.
- Page 5: Hospital's Representative (primary point of contact for CHPSO)
- Page 9: Address at which hospital desires to receive any notices CHPSO sends regarding the contract.
- Page 10: Authorized signature (in blank on bottom left side)

For the business associate agreement, the following items need to be completed.

- Page 14: Name of hospital, effective date.
- Page 22: Addresses at which hospital desires to receive any notices CHPSO sends regarding the business associate agreement and handling of patient data.
- Page 22: Authorized signature, name, title, date (left hand side)

CALIFORNIA HOSPITAL PATIENT SAFETY ORGANIZATION

PARTICIPATING HOSPITAL AGREEMENT

This Agreement is between California Hospital Patient Safety Organization (CHPSO), a California nonprofit public benefit corporation, and _____ (Hospital); and is effective _____.

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. Hospital wishes to voluntarily participate in CHPSO's data collection, reporting, and evaluation activities in an effort to improve the quality of care delivered at Hospital and in Hospital's community, and ultimately improving the patient care delivery system in general.

D. The underlying purpose and commitment of this Agreement are 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:

- **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 (DID)** – 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 Hospital, 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 (PSES), in consultation with participating hospitals, including Hospital. CHPSO will develop specific data collection, monitoring, collaboration and evaluation activities, and offer them to participating hospitals. Each participating hospital may select the level of participation it wishes to engage in.

2.2 Overview of Participating Hospitals' Roles

All participation is voluntary and nonexclusive. Participating hospitals 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 hospital operations will be up to each participating hospital. Participating hospitals 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 Hospital 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 will not be Disclosed by CHPSO, 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, Hospital 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 Hospital'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. Changes to the Common Format may be implemented by CHPSO 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 hospitals.

3.3 Patient Safety Evaluation System (PSES)

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

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 shall enter into a Business Associate Agreement, 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 hospitals, PSOs, or are otherwise publicized will use a Limited Data Set, except as otherwise agreed, in writing, by Hospital.

(c) As required by law, CHPSO will promptly notify Hospital 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, contractors, volunteers, representatives of participating hospitals and other Patient Safety Organizations, and other individuals as appropriate to the involved Patient Safety Activity), 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 hospitals, including Hospital as appropriate to its level(s) of participation.

SECTION 4. HOSPITAL RESPONSIBILITIES

4.1 Patient Safety Evaluation System

Hospital will develop a Hospital Patient Safety Evaluation System for collecting, maintaining and managing information, including but not limited to Patient Safety Work Product reported to and Hospital’s interactions with CHPSO. Hospital documentation must document the date Hospital’s Patient Safety Work Product enters its Patient Safety Evaluation System.

4.2 Appointment of Hospital/PSO Liaison Representative

Hospital will appoint a Hospital/PSO Liaison Representative (Representative) who will be the primary point of contact with respect to Hospital’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, Hospital’s Representative is _____. The Representative may be changed at any time, by written notice to CHPSO.

4.3 Reporting

(a) Hospital 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, Hospital acknowledges and understands that:

(1) Information that is collected, maintained or developed separately, or exists separately, from Hospital’s Patient Safety Evaluation System is **not** Patient Safety Work Product.

(2) However, with respect to PSWP information maintained as part of Hospital's Patient Safety Evaluation System, up and until such time that the information has been reported to CHPSO, Hospital 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) Hospital will cooperate, as appropriate, with reasonable follow-up requests from CHPSO for information and/or clarification regarding reported information.

4.4 Use and Protection of PSWP

(a) Hospital shall maintain the confidentiality of Hospital's PSWP, and shall not Disclose PSWP, except as otherwise permitted by the Act.

(b) Hospital may use Hospital's PSWP internally and Disclose to Affiliated Providers in furtherance of Patient Safety Activities. Hospital shall be solely responsible for appropriately managing its internal uses of PSWP as necessary to maintain applicable protections of the Act. Hospital 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, Hospital shall develop such systems as necessary to maintain the integrity of PSWP.

(c) Except as otherwise permitted by the Act or the Regulations, Hospital will not Disclose other providers' PSWP, nor use it in any manner other than Patient Safety Activities conducted as part of Hospital's or CHPSO's Patient Safety Evaluation System.

4.5 Participation as Part of CHPSO's Workforce

Hospital may designate individuals to assist CHPSO in the conduct of CHPSO's Patient Safety Activities, which (depending on the project and Hospital's expressed participation commitments) may include assisting in study design as well as assimilating and evaluating Hospital-specific information, information collected from other participating hospitals and providers, and information collected from other sources. Hospital representatives who are functioning as CHPSO Workforce will be expected to acknowledge confidentiality and related responsibilities, and sign a Workforce Confidentiality Agreement.

4.6 Implementation of CHPSO Recommendations

Hospital 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.

4.7 Notification of other Patient Safety Organization Participation

In the event Hospital participates in and reports the same PSWP to other patient safety organizations, Hospital will notify CHPSO and use best efforts to

- D&O \$3,000,000 per occurrence
\$3,000,000 aggregate

(b) Hospital shall maintain the following minimum levels of insurance:

- General liability \$1,000,000 per occurrence
\$2,000,000 aggregate
- Professional liability \$1,000,000 per occurrence
\$1,000,000 aggregate
- D&O \$3,000,000 per occurrence
\$3,000,000 aggregate

6.2 Indemnification

(a) Nothing in this Agreement is intended, nor shall it be construed to create any responsibility on the part of Hospital 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 Hospital, 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 Hospital or its officers, directors, employees, staff members, independent contractors, or agents. Subject to the provisions of **Section 6.2(c)**, below, Hospital 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.
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 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.

8.2 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 Hospital:
California Hospital Patient Safety Organization 1215 K Street, Suite 800 Sacramento, CA 95814 Attn: Executive Director	

8.3 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.

8.4 Exhibits

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

8.5 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.

* * * * *

HOSPITAL

California Hospital Patient Safety
Organization (CHPSO)

By: _____

By: _____

Name: _____

Rory Jaffe, Executive Director
CHPSO

Title: _____

Date: _____

Date _____

EXHIBIT LIST

- 1.1** **Definitions Section of PSA Regulations**
- 3.6** **Business Associate Agreement**

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.

EXHIBIT 3.6
HIPAA BUSINESS ASSOCIATE AGREEMENT

This HIPAA Business Associate Agreement (“BA Amendment”) supplements and is made a part of the Participating Hospital Agreement, including supplements and amendments thereto (“Agreement”), entered into by and between the California Hospital Patient Safety Organization (“CHPSO”) and _____ (“HOSPITAL”) and is effective as of _____ (“Effective Date”).

RECITALS

- A. HOSPITAL and CHPSO desire to protect the privacy and provide for the security of Protected Health Information used by or disclosed to CHPSO in compliance with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, Public Law 111-5 (“HITECH Act”), and regulations promulgated thereunder by the U.S. Department of Health and Human Services, including 45 CFR Parts 160, 162 and 164) “” and other applicable state and federal laws and regulations (the “HIPAA Regulations”) . Further, 45 CFR Sections 164.308, 164.310, 164.312 and 164.316 apply to CHPSO in the same manner that such sections apply to HOSPITAL; and the additional requirements of the HITECH Act that relate to privacy and that apply to HOSPITAL also apply to CHPSO and are incorporated into this Agreement. The purpose of this BA Amendment is to satisfy certain standards and requirements of HIPAA, the HITECH Act and the HIPAA Regulations, including 45 CFR 164.504(e), as they may be amended from time to time.
- B. Pursuant to the terms of the Agreement, CHPSO provides services to HOSPITAL, or performs or assists in the performance of HOSPITAL activities or functions, which may involve the use or disclosure of Protected Health Information (as that term is defined herein) in the course of such service or assistance under this Agreement.
- C. In the course of carrying out the terms of the Agreement, HOSPITAL wishes to disclose to CHPSO certain information, some of which may constitute Protected Health Information.

AGREEMENTS

In consideration of the mutual promises made below and the exchange of information under this Business Associate Amendment, the parties agree as follows:

1. EFFECT OF AMENDMENT. This BA Amendment amends, supplements and is made a part of the Agreement, regardless of whether the Agreement shall have been entered into before or after the Effective Date of this BA Amendment. To the extent that the terms of the Agreement are inconsistent with the terms of this BA Amendment, the terms of this BA Amendment shall control.
2. DEFINITIONS
 - 2.1. "Information System" means an interconnected set of information resources under the same direct management control that shares common functionality. A system normally includes hardware, software, information, data, applications, communications, and people. "Information System" shall have the meaning given to such term under HIPAA and the HIPAA Regulations, including 45 CFR Section 164.304.
 - 2.2. "Protected Health Information" or "PHI" means any information, including Electronic PHI, whether oral or recorded in any form or medium: (i) that is created or received by a health care provider, health plan, employer, or health care clearinghouse, (ii) that relates to the past, present, or future physical or mental condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual, and (iii) that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual, and shall have the meaning given to such term under HIPAA, the HITECH Act and the HIPAA Regulations, including, but not limited to 45 CFR Section 160.103.
 - 2.3. "Electronic PHI" is PHI that is transmitted by or maintained in electronic media and shall have the meaning given to such term under HIPAA, the HITECH Act and the HIPAA Regulations, including 45 CFR Section 160.103.
 - 2.4. "Unsecured PHI" means PHI that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of a technology or methodology specified by the Secretary of Health and Human Services in the guidance issued under Section 13402(h)(2) of the HITECH Act, which may be found at 74 Fed. Reg. 19006 (Apr. 27, 2009).
 - 2.5. "Security Incident" means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an Information System, and shall have the meaning given to such term under HIPAA and the HIPAA Regulations, including 45 CFR Section 164.304.
 - 2.6. "Business Associate," is California Hospital Patient Safety Organization (CHPSO), which provides services, arranges, performs, or assists in the performance of a function or activity on behalf of HOSPITAL which involves the use or disclosure of PHI pursuant to the HIPAA Regulations, 45 C.F.R. part 160.103.

- 2.7. “Minimally Necessary” means when using or disclosing PHI, HOSPITAL and CHPSO shall make reasonable efforts to limit the quantity and type of PHI used or disclosed to the minimum necessary to accomplish the intended purpose of the use or disclosure, in accordance with 45 CFR 164.514(d)(1). HOSPITAL and CHPSO acknowledge that the phrase “minimally necessary” shall be interpreted in accordance with the HITECH Act and government guidance on the definition.
- 2.8. “Breach” means the acquisition, access, use, or disclosure of PHI in a manner not permitted under the HITECH Act which compromises the security or privacy of the PHI. BREACH does not include:
- (1) disclosure of PHI where CHPSO has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information; **OR**
- (2) any unintentional acquisition, access, or use of PHI by a Workforce member or person acting under the authority of CHPSO if:
- (a) such acquisition, access, or use was made in good faith and within the scope of authority; **AND**
- (b) such acquisition, access, or use does not result in further use or disclosure in a manner not permitted under the Privacy Rule; **OR**
- (3) any inadvertent disclosure by a person who is authorized to access PHI at CHPSO to another person authorized to access PHI at CHPSO; **AND** the information received as a result of such disclosure is not further used or disclosed in a manner not permitted under the HIPAA Regulations.
- 2.9. “Compromises the Security or Privacy of the PHI” means that the Breach poses a significant risk (to be determined by a documented risk assessment) of financial, reputational, or other harm to the individual. A use or disclosure of PHI that does not include: (i) the identifiers listed at 45 CFR 164.514(e)(2) pertaining to limited data sets, (ii) date of birth, and (iii) zip code, does not compromise the security or privacy of the PHI.
- 2.10. “Electronic Health Record” means an electronic record of health-related information on an individual that is created, gathered, managed, and/or consulted by authorized health care clinicians and staff.
- 2.11. “Workforce” means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for CHPSO, is under the direct control of CHPSO, whether or not they are paid by CHPSO.

3. RESPONSIBILITIES OF CHPSO

- 3.1. Permitted Uses and Disclosures. Except as otherwise provided in this BA Amendment, CHPSO may use and/or disclose PHI received by CHPSO in

its capacity as a Business Associate under this BA Amendment pursuant to the Agreement and this BA Amendment only as Minimally Necessary to perform its obligations under the Agreement and this BA Amendment or as required by law. Further, CHPSO may use and/or disclose PHI that CHPSO obtains or creates from or on behalf of HOSPITAL only if such use or disclosure is in compliance with each applicable requirement of 45 CFR 164.504(e). The additional requirements of Subtitle D of the HITECH Act that relate to privacy and that are made applicable with respect to HOSPITAL shall also be applicable to CHPSO and shall be and by this reference hereby are incorporated in this Agreement.

- 3.2. Management and Administration, Legal Responsibilities. CHPSO and its respective agents, employees and subcontractors are authorized to use or disclose PHI for CHPSO's own proper management and administration, and to fulfill any of CHPSO's legal responsibilities; provided, however, that the disclosures are required by law or CHPSO has received from any third party recipient of PHI written assurances that (i) the PHI will be held confidentially and used or further disclosed only as required by law or for the purposes for which it was disclosed to the third party, and (ii) the third party will notify CHPSO of any instances of which the third party becomes aware that the confidentiality of the PHI has been breached.
- 3.3. Data Aggregation. CHPSO may use PHI to provide data aggregation services relating to the health care operations of HOSPITAL. "Data aggregation" means the combining of HOSPITAL's PHI with the PHI received by CHPSO in its capacity as a Business Associate of another covered entity, to permit data analyses that relate to the health care operations of the respective covered entities.
- 3.4. Nondisclosure of PHI. CHPSO is not authorized and shall not use or further disclose HOSPITAL's PHI other than as permitted or required under the Agreement or this BA Amendment, or as required by law or regulation.
- 3.5. Prohibition on Marketing and Sale of Records. CHPSO agrees not to use or disclose PHI for marketing purposes without first receiving prior written approval from HOSPITAL and obtaining the necessary authorization from the subject of the PHI. Additionally, CHPSO shall not directly or indirectly receive remuneration in exchange for any PHI of an individual unless HOSPITAL or CHPSO obtained from the individual, in accordance with 45 CFR 164.508, a valid authorization that includes a specification of whether the PHI can be further exchanged for remuneration by the entity receiving PHI of that individual, except as otherwise allowed under the HITECH Act.
- 3.6. Safeguards. CHPSO shall develop, implement, maintain and use appropriate administrative, technical and physical safeguards (i) to protect the confidentiality, integrity and availability of HOSPITAL's Unsecured PHI and (ii) to prevent any unauthorized access to or use or disclosure of

HOSPITAL's Unsecured PHI other than as provided by the Agreement and this BA Amendment or required by law.

- 3.7. Notification of Security Incidents and Uses or Disclosures Not Permitted by this BA Amendment; Reports of Breach. CHPSO shall notify HOSPITAL in writing within ten (10) business days after CHPSO becomes aware of any Security Incident or discovers any use or disclosure of HOSPITAL's PHI not permitted by this BA Amendment. CHPSO shall notify HOSPITAL in writing immediately, but in no event more than ten (10) business days after CHPSO becomes aware of any Breach of Unsecured PHI. Upon request by HOSPITAL, CHPSO will (i) cooperate fully with any investigation of the improper use or disclosure or Breach of Unsecured PHI, (ii) "mitigate to the extent practicable any potential harm to the individuals impacted by the Breach; and (iii) fully assist HOSPITAL in complying with any notification procedures required by applicable state or federal law, including, without limitation, the HITECH Act. Notification of a Breach shall include, at a minimum, (i) the identification of each individual whose Protected Health Information has been, or is reasonably believed to have been, accessed, acquired, or disclosed during the Breach, (ii) the date of the Breach, if known, (iii) the scope of the Breach, and (iv) a description of CHPSO's response to the Breach. In addition, CHPSO agrees to implement reasonable systems to facilitate the discovery and prompt reporting of any Breach as required by this Section.
- 3.8. Individual's Request for Restrictions of PHI. CHPSO shall notify HOSPITAL in writing within ten (10) business days after receipt of any request by individuals or their representatives to restrict the use and disclosure of the PHI that CHPSO maintains for or on behalf of HOSPITAL. Upon written notice from HOSPITAL that it agrees to comply with the requested restrictions, CHPSO agrees to comply with any instructions to modify, delete or otherwise restrict the use and disclosure of PHI it maintains for or on behalf of HOSPITAL.
- 3.9. Individual's Request for Amendment of PHI. CHPSO shall inform HOSPITAL within ten (10) business days after receipt of any request by or on behalf of the subject of the PHI to amend the PHI that CHPSO maintains for or on behalf of HOSPITAL. CHPSO shall, within twenty (20) calendar days after receipt of a written request, make the subject's PHI available to HOSPITAL as may be required to fulfill HOSPITAL's obligations to amend PHI pursuant to HIPAA and the HIPAA Regulations, including, but not limited to, 45 CFR Section 164.526. CHPSO shall, as directed by HOSPITAL, incorporate any amendments to HOSPITAL's PHI into copies of such PHI maintained by CHPSO. This requirement to amend PHI shall apply only if the PHI in CHPSO's possession is part of HOSPITAL's designated record set.
- 3.10. Individual's Request for an Accounting of Disclosures of PHI. CHPSO shall, within twenty (20) calendar days after receipt of a written request, make available to HOSPITAL, and, if authorized in writing by HOSPITAL

or if the request is made directly to CHPSO by the subject of the PHI, to the subject of the PHI, such information maintained by CHPSO or its agents as may be required to fulfill HOSPITAL's obligations to provide an accounting for disclosures of HOSPITAL's PHI pursuant to HIPAA, the HITECH Act and the HIPAA regulations, including, but not limited to, 45 CFR Section 164.528. CHPSO shall maintain such information necessary to account for disclosures and any written accounting that is provided to the subject of the PHI for at least six (6) years following the date of the accountable disclosure or three (3) years for disclosures related to an Electronic Health Record, starting with the date specified by HHS.

- 3.11. Access to PHI by the Individual. If HOSPITAL determines that a designated record set is held solely by CHPSO or if CHPSO is acting on behalf of HOSPITAL to provide access to or a copy of the designated record set, CHPSO shall, within five (5) calendar days after receipt of a written request, make available to HOSPITAL, and, if authorized in writing by HOSPITAL, to the subject of the PHI, such information as may be required to fulfill HOSPITAL's obligations to provide access to or provide a copy of the designated record set of HOSPITAL's PHI pursuant to HIPAA, the HITECH Act and the HIPAA regulations, including, but not limited to, 45 CFR Section 164.524. Additionally, effective as of the date specified by HHS, if the PHI is held in an Electronic Health Record, then the Individual shall have a right to obtain from CHPSO a copy of such information in an electronic format.
- 3.12. Regulatory Compliance. CHPSO shall make (i) its internal practices, books and records relating to the use and disclosure of PHI and (ii) policies, procedures and documentation relating to the safeguarding of Electronic PHI received from HOSPITAL (or created or received by CHPSO on behalf of HOSPITAL) available to any state or federal agency, including the U.S. Department of Health and Human Services, for purposes of determining HOSPITAL's compliance with HIPAA, the HITECH Act and the HIPAA Regulations.
- 3.13. Inspection of Records. Within thirty (30) calendar days after a written request, CHPSO shall make available to HOSPITAL during normal business hours all records, books, agreements, policies and procedures relating to the use and/or disclosure of HOSPITAL's PHI for purposes of enabling HOSPITAL to determine CHPSO's compliance with the terms of this BA Amendment.
- 3.14. Examination by Company. HOSPITAL and its authorized agents or contractors, may examine CHPSO's facilities, systems, procedures, and records as may be necessary to determine the extent to which CHPSO's security safeguards comply with HIPAA, the HITECH Act, the HIPAA Regulations, or this BA Amendment.
- 3.15. Compliance with Law. In connection with all matters related to this BA Amendment, CHPSO shall comply with all applicable federal and state

laws and regulations, including but not limited to HIPAA, the HITECH Act and the HIPAA Regulations, 45 CFR Parts 160, 162 and 164, as they may be amended from time to time.

4. CHPSO'S AGENTS. CHPSO will only provide HOSPITAL's PHI to agents or subcontractors for the purposes of carrying out this Agreement. CHPSO shall ensure that the requirements of this BA Amendment are incorporated into each agreement with any agent or subcontractor to whom CHPSO discloses PHI, and that each such agent and/or subcontractor shall agree in writing to be bound to the same terms and conditions that apply to CHPSO with respect to PHI. In addition, CHPSO shall ensure that any agent or subcontractor to whom CHPSO discloses PHI agrees with CHPSO in writing to implement reasonable and appropriate safeguards to protect the PHI.
5. TERMINATION
 - 5.1. Material Breach. Without limiting the rights of the parties under this BA Amendment or the Agreement, and in accordance with 45 CFR 164.504(e)(1)(ii), as amended by the HITECH Act, which makes such provision applicable to HOSPITAL and CHPSO equally, if HOSPITAL or CHPSO (the "Breaching Party") breaches a material term of this BA Amendment, the other party (the "Terminating Party") may provide the Breaching Party an opportunity to cure the breach within thirty (30) days. If such cure is not possible within thirty (30) days, the Terminating Party may terminate the Agreement immediately thereafter.
 - 5.2. Notice to Secretary. If the Terminating Party knows of a pattern of activity or practice of the Breaching Party that constitutes a material breach or violation of the Breaching Party's obligation under this BA Amendment, if the breach or violation continues, and if termination of this BA Amendment or the Agreement is not feasible, the Terminating Party is required by HIPAA regulations to report the problem to the Secretary of Health and Human Services.
 - 5.3. Effect of Termination - Return or Destruction of PHI held by CHPSO or CHPSO's Agents. Except as otherwise provided at Section 5.4, upon termination, expiration or other conclusion of the Agreement for any reason, CHPSO shall return or, at the option of HOSPITAL, destroy all PHI received from HOSPITAL, or created and received by CHPSO on behalf of HOSPITAL in connection with the Agreement, that CHPSO or its Agents still maintains in any form, and shall retain no copies of such PHI. Not less than thirty (30) calendar days after the termination of the Agreement, CHPSO shall both complete such return or destruction and certify in writing to HOSPITAL that such return or destruction has been completed.
 - 5.4. Return or Destruction Not Feasible. If CHPSO represents to HOSPITAL that return or destruction of HOSPITAL's PHI is not feasible, CHPSO must provide HOSPITAL with a written statement of the reason that return or

destruction by CHPSO or its Agents is not feasible. If HOSPITAL determines that return or destruction is not feasible, this BA Amendment shall remain in full force and effect and CHPSO and its Agents continue to extend indefinitely the protection of this BA Amendment to such information and limit further uses and disclosures to those purposes that make the return or destruction of the PHI infeasible.

6. CHANGES TO THIS BA AMENDMENT

- 6.1. Compliance with Law. The parties acknowledge that state and federal laws relating to electronic data security and privacy are rapidly evolving and that changes to this BA Amendment may be required to ensure compliance with such developments. The parties specifically agree to take such action as may be necessary to implement the standards and requirements of HIPAA, the HITECH Act, the HIPAA Regulations and other applicable state and federal laws relating to the security or confidentiality of PHI.
- 6.2. Negotiations. In the event of a change in or interpretation of any state or federal law, statute, or regulation which materially affects the rights or obligations of either party under the Agreement or this BA Amendment, the parties agree to negotiate immediately in good faith any necessary or appropriate revisions to the Agreement or to this BA Amendment. If the parties are unable to reach an agreement concerning such revisions within the earlier of sixty (60) calendar days after the date of notice seeking negotiations or the effective date of a change in law or regulation, then either party may immediately terminate the Agreement upon written notice to the other.

7. MISCELLANEOUS PROVISIONS

- 7.1. No Third Party Beneficiaries. Nothing express or implied in this BA Amendment is intended to confer, nor shall anything herein confer, any rights, remedies, obligations or liabilities whatsoever upon any person or entity other than HOSPITAL, CHPSO and their respective successors or assigns.
- 7.2. Notices. Any notices to be given to either party shall be made via U.S. Mail or express courier to the address given below and/or via facsimile to the facsimile telephone numbers listed below.

If to CHPSO:

With a copy (which shall not constitute notice) to:

Executive Director
CHPSO
1215 K St Ste 800
Sacramento, CA 95814
Fax: 916-554-2299

President
California Hospital Association
1215 K St Ste 800
Sacramento, CA 95814
Fax: 916-443-7401

If to HOSPITAL:

With a copy (which shall not constitute notice) to:

Fax _____

Fax _____

Each party may change its address and that of its representative for notice by giving notice in the manner provided above.

* * * * *

[Name of HOSPITAL]

California Hospital Patient Safety
Organization (CHPSO)

By: _____

By: _____
Rory Jaffe, Executive Director
CHPSO

Name: _____

Title: _____

Date: _____

Date: _____