

EXHIBIT 3.4

BUSINESS ASSOCIATE ADDENDUM

This Business Associate Addendum (“*Addendum*”) supplements and is made a part of the services contract (“*Contract*”) by and between _____, which is a Covered Entity (defined below) (“*CE*”), and CHPSO Patient Safety Organization (“*CHPSO*”), which is a Business Associate (defined below), and is effective as of _____ (“*Effective Date*”).

- A. CE wishes to disclose certain information to CHPSO pursuant to the terms of the Contract, some of which may constitute Protected Health Information (“*PHI*” – defined below). CHPSO wishes to receive from and disclose to CE, certain PHI pursuant to the terms of the Contract.
- B. CE and CHPSO intend to protect the privacy and provide for the security of PHI disclosed to each other pursuant to the Contract in compliance with the Health Insurance Portability and Accountability Act of 1996, Public Law 104–191 (“*HIPAA*”), the Health Information Technology for Economic and Clinical Health Act, Public Law 111–005 (the “*HITECH Act*”), and regulations promulgated thereunder by the U.S. Department of Health and Human Services (the “*HIPAA Regulations*”); the Patient Safety and Quality Improvement Act of 2005, Public Law 109–41 (“*PSQIA*”), and regulations promulgated thereunder by the U.S. Department of Health and Human Services (the Patient Safety Rule); and other applicable laws.
- C. The HIPAA Regulations, the Privacy Rule and the Security Rule (defined below) require the parties to enter into a contract containing specific requirements prior to the disclosure of PHI, as set forth in, but not limited to, Title 45, Sections 164.314(a), 164.502(a) and (e) and 164.504(e) of the Code of Federal Regulations (“*C.F.R.*”) and contained in this Addendum.

In consideration of the mutual promises below and the exchange of information pursuant to this Addendum, the parties agree as follows:

1. Definitions

- a. ***Breach*** shall have the meaning given to such term under HIPAA, the HIPAA Regulations and the HITECH Act, and under applicable state law.
- b. ***Breach Notification Rule*** shall mean the HIPAA Regulation that is codified at 45 C.F.R. Parts 160 and 164, Subparts A and D.
- c. ***Business Associate*** shall have the meaning given to such term under the Privacy Rule, the Security Rule, and the HITECH Act, including, but not limited to, 42 U.S.C. Section 17938 and 45 C.F.R. Section 160.103.
- d. ***Covered Entity*** shall have the meaning given to such term under the Privacy Rule.
- e. ***Data Aggregation*** shall have the meaning given to such term under the Privacy Rule, including but not limited to, 45 C.F.R. Section 164.501.
- e. ***Designated Record Set*** shall have the meaning given to such term under the Privacy Rule, including, but not limited to, 45 C.F.R. Section 164.501.
- f. ***Electronic Protected Health Information*** means Protected Health Information that is maintained in or transmitted by electronic media.

- g. **Electronic Health Record** shall have the meaning given to such term in the HITECH Act, including, but not limited to, 42 U.S.C. Section 17921.
- h. **Health Care Operations** shall have the meaning given to such term under the Privacy Rule, including, but not limited to, 45 C.F.R. Section 164.501.
- i. **HITECH Compliance Date** shall mean the date for compliance set forth in the HITECH Act or the implementation regulations thereunder.
- j. **Minimum Necessary** shall have the meaning set forth in the HIPAA Regulations and guidance promulgated or issued, or may be further promulgated or issued, by the Secretary of HHS on what constitutes the minimum necessary for CHPSO to accomplish the purpose of the request, use or disclosure.
- k. **Privacy Rule** shall mean the HIPAA Regulation that is codified at 45 C.F.R. Parts 160 and 164, Subparts A and E.
- l. **Protected Health Information or PHI** means any information, whether oral or recorded in any form or medium: (i) 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 (ii) 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 the Privacy Rule, including, but not limited to, 45 C.F.R. Section 164.501. Protected Health Information includes Electronic Protected Health Information.
- m. **Protected Information** shall mean PHI provided by CE to CHPSO or created or received by CHPSO on CE's behalf.
- n. **Security Incident** shall have the meaning given to such term under the Security Rule, including, but not limited to, 45 C.F.R. Section 164.304.
- o. **Security Rule** shall mean the HIPAA Regulation that is codified at 45 C.F.R. Parts 160 and 164, Subparts A and C.
- p. **Subcontractor** shall mean a person/entity to whom CHPSO delegates a function, activity or service, other than in the capacity of a member of the workforce of CHPSO, pursuant to 45 C.F.R. Section 160.103.
- q. **Unsecured PHI** shall have the meaning given to such term under the HITECH Act and any guidance issued pursuant to such Act including, but not limited to, 42 U.S.C. Section 17932(h) and 45 C.F.R. Section 164.402.

2. **Obligations of Business Associate**

- a. **Permitted Uses.** CHPSO may use Protected Information for the purpose of performing CHPSO's obligations under the Contract and as permitted under the Contract and Addendum, or as required by law. CHPSO may use Protected Information in a manner consistent with the role of a Patient Safety Organization, as defined in the PSQIA. Further, CHPSO shall not use Protected Information in any manner that would constitute a violation of the Privacy Rule or the HITECH Act if so used by CE. However, CHPSO may use

Protected Information (i) for the proper management and administration of CHPSO, (ii) to carry out the legal responsibilities of CHPSO, (iii) for Data Aggregation purposes for the Health Care Operations of CE, or (iv) for de-identification in accordance with 45 C.F.R. Section 164.514(a)-(c).

- b. **Permitted Disclosures.** CHPSO may disclose Protected Information for the purpose of performing CHPSO's obligations under the Contract and as permitted under the Contract and Addendum, or as required by law. CHPSO may disclose Protected Information in a manner consistent with the role of a Patient Safety Organization, as defined in the PSQIA, including sharing de-identified Protected Information with other providers who participate in CHPSO. CHPSO shall not disclose Protected Information in any manner that would constitute a violation of the Privacy Rule or the HITECH Act if so disclosed by CE. However, CHPSO may disclose Protected Information (i) for the proper management and administration of CHPSO; (ii) to carry out the legal responsibilities of CHPSO; (iii) as required by law; or (iv) for Data Aggregation purposes for the Health Care Operations of CE. If CHPSO discloses Protected Information to a third party, CHPSO must obtain, prior to making any such disclosure, (i) reasonable written assurances from such third party that such Protected Information will be held confidential as provided pursuant to this Addendum and only disclosed as required by law or for the purposes for which it was disclosed to such third party, and (ii) a written agreement from such third party to immediately notify CHPSO of any Breaches of confidentiality of the Protected Information, to the extent it has obtained knowledge of such Breach.
- c. **Prohibited Uses and Disclosures.** Notwithstanding any other provision in this Addendum, CHPSO shall comply with the following requirements: (i) CHPSO shall not use or disclose Protected Information for fundraising or marketing purposes, except as provided under the Contract and consistent with the requirements of 42 U.S.C. 17936 and the Privacy Rule; (ii) CHPSO shall not disclose Protected Information to a health plan for payment or health care operations purposes if the patient has requested this special restriction, and has paid out of pocket in full for the health care item or service to which the PHI solely relates, consistent with the requirements of 42 U.S.C. Section 17935(a) and the Privacy Rule; (iii) CHPSO shall not directly or indirectly receive remuneration in exchange for Protected Information, except with the prior written consent of CE and as permitted by the HITECH Act, 42 U.S.C. Section 17935(d)(2) and the Privacy Rule; however, this prohibition shall not affect payment by CE to CHPSO for services provided pursuant to the Contract.
- d. **Appropriate Safeguards.** CHPSO shall implement appropriate safeguards as are necessary to prevent the use or disclosure of Protected Information other than as permitted by the Contract or Addendum. CHPSO further agrees to use administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of Electronic PHI. CHPSO shall comply with Subpart C of Part 164 of the Security Rule. To the extent that CHPSO creates, maintains, receives or transmits Electronic PHI on behalf of the CE, CHPSO shall implement the safeguards required by this subsection 2.d with respect to Electronic PHI.
- e. **Business Associate's Subcontractors and Agents.** In accordance with 45 C.F.R. Sections 164.308(b)(2) and 164.502(e)(1)(ii), CHPSO shall ensure that any agents or Subcontractors that create, receive, maintain, or transmit PHI on behalf of CHPSO agree in writing to the same restrictions and conditions that apply to CHPSO with respect to such PHI. CHPSO

shall implement and maintain sanctions against agents and Subcontractors that violate such restrictions and conditions and shall mitigate the effects of any such violation.

- f. **Accounting of Disclosures.** Within thirty (30) days of notice by CE of a request for an accounting of disclosures of Protected Information, CHPSO and its agents or Subcontractors shall make available to CE the information required to provide an accounting of disclosures to enable CE to fulfill its obligations under the Privacy Rule, including, but not limited to, 45 C.F.R. Section 164.528, and its obligations under the HITECH Act, including but not limited to 42 U.S.C. Section 17935(c), as determined by CE. The provisions of this subsection 2.f shall survive the termination of this Addendum.
- g. **Governmental Access to Records.** CHPSO shall make its internal practices, books and records relating to the use and disclosure of Protected Information available to CE and to the Secretary of the U.S. Department of Health and Human Services (the “*Secretary*”) for purposes of determining CE’s and CHPSO’s compliance with the Privacy Rule. CHPSO shall, to the extent legally permissible, promptly notify CE of any requests from the Secretary for information relating to CE.
- h. **Minimum Necessary.** CHPSO (and its agents or Subcontractors) shall request, use and disclose only the minimum amount of Protected Information necessary to accomplish the purpose of the request, use or disclosure.
- i. **Notification of Possible Breach.** CHPSO shall, following the discovery of any Breach of Unsecured PHI, Security Incident, as defined in the Security Rule, and/or any actual or suspected access, use or disclosure of Protected Information not permitted by the Contract and Addendum or applicable law notify CE in writing of such Breach or disclosure without unreasonable delay and in no case later than three business days after discovery CHPSO shall take prompt corrective action and any action required by applicable state or federal laws and regulations relating to such disclosure. CHPSO agrees to pay the actual costs of CE to provide required notifications and any associated costs incurred by CE, such as credit monitoring for affected patients, and including any civil or criminal monetary penalties or fines levied by any federal or state authority having jurisdiction if CE reasonably determines that the nature of the Breach warrants such measures.
- j. **Breach Pattern or Practice by Business Associate’s Subcontractors and Agents.** Pursuant to 42 U.S.C. Section 17934(b), if CHPSO knows of a pattern of activity or practice of a Subcontractor or agent that constitutes a material breach or violation of the Subcontractor’s or agent’s obligations under the Contract or Addendum or other arrangement, CHPSO must take reasonable steps to cure the breach or end the violation. If the steps are unsuccessful, CHPSO must terminate the Contract or other arrangement if feasible, or if termination is not feasible, report the problem to the Secretary of DHHS.
- k. **Access to and Amendment of Protected Information.** To the extent CHPSO maintains a Designated Record Set on behalf of CE, CHPSO shall: (i) make available PHI in a designated record set to the CE as necessary to satisfy CE’s obligations under 45 CFR 164.524; and (ii) upon request from the CE or an individual for an amendment of PHI or a record about an individual contained in a Designated Record Set, CHPSO or its agents or Subcontractors shall make any amendments that CE directs or agrees to in accordance with the Privacy Rule

- l. **Delegation of Obligations.** To the extent CHPSO is delegated to carry out CE's obligations under the Privacy Rule, CHPSO shall comply with the requirements of the Privacy Rule that apply to CE in the performance of such delegated obligation.
- m. **Mitigation.** CHPSO agrees to mitigate, to the extent practicable, any harmful effect that is known to CHPSO of a use or disclosure of PHI in violation of this Addendum.
- n. **Audits, Inspection and Enforcement.** Within ten (10) days of a request by CE, CHPSO and its agents and subcontractors shall allow CE or its agents or subcontractors to conduct a reasonable inspection of the facilities, systems, books, records, agreements, policies and procedures relating to the use or disclosure of Protected Information pursuant to this Addendum for the purpose of determining whether CHPSO has complied with this Addendum or maintains adequate security safeguards; provided, however, that (i) CHPSO and CE shall mutually agree in advance upon the scope, timing and location of such an inspection, (ii) CE shall protect the confidentiality of all confidential and proprietary information of CHPSO to which CE has access during the course of such inspection; and (iii) CE shall execute a nondisclosure agreement, upon terms mutually agreed upon by the parties, if requested by CHPSO. The fact that CE inspects, or fails to inspect, or has the right to inspect, CHPSO's facilities, systems, books, records, agreements, policies and procedures does not relieve CHPSO of its responsibility to comply with this Addendum, nor does CE's (i) failure to detect or (ii) detection, but failure to notify CHPSO or require CHPSO's remediation of any unsatisfactory practices, constitute acceptance of such practice or a waiver of CE's enforcement rights under the Contract or Addendum. CHPSO shall notify CE within five (5) days of learning that CHPSO has become the subject of an audit, compliance review, or complaint investigation by the Office for Civil Rights or other state or federal government entity.

3. Termination

- a. **Material Breach by CHPSO.** A breach by CHPSO of any provision of this Addendum, as determined by CE, shall constitute a material breach of the Contract and shall provide grounds for termination of the Contract, any provision in the Contract to the contrary notwithstanding, with or without an opportunity to cure the breach. If termination of the Contract is not feasible, CE will report the problem to the Secretary of DHHS. CHPSO shall ensure that it maintains for itself the termination rights in this Section in any agreement it enters into with a Subcontractor pursuant to section 2(e) hereof.
 - b. **Effect of Termination.** Upon termination of the Contract for any reason, CHPSO shall, at the option of CE, return or destroy all Protected Information that CHPSO or its agents or Subcontractors still maintain in any form, and shall retain no copies of such Protected Information. If return or destruction is not feasible, as determined by CE, CHPSO shall continue to extend the protections of Section 2 of this Addendum to such information, and limit further use of such PHI to those purposes that make the return or destruction of such PHI infeasible. If CE elects destruction of the PHI, CHPSO shall certify in writing to CE that such PHI has been destroyed in accordance with the Secretary's guidance regarding proper destruction of PHI.
4. **No Third-Party Beneficiaries.** Nothing express or implied in the Contract or Addendum is intended to confer, nor shall anything herein confer upon any person other than CE, CHPSO and their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever.

- 5. **Effect on Contract.** Except as specifically required to implement the purposes of this Addendum, or to the extent inconsistent with this Addendum, all other terms of the Contract shall remain in force and effect.
- 6. **Interpretation.** The provisions of this Addendum shall prevail over any provisions in the Contract that may conflict or appear inconsistent with any provision in this Addendum. This Addendum and the Contract shall be interpreted as broadly as necessary to implement and comply with HIPAA, the HITECH Act, the Privacy Rule and the Security Rule. The parties agree that any ambiguity in this Addendum shall be resolved in favor of a meaning that complies and is consistent with HIPAA, the HITECH Act, the Privacy Rule and the Security Rule. Except as specifically required to implement the purposes of this Addendum, or to the extent inconsistent with this Addendum, all other terms of the Contract shall remain in force and effect.
- 7. **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:

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

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

President/CEO
 Hospital Quality Institute
 1215 K St Ste 800
 Sacramento, CA 95814
 Fax: 916-554-2271

If to Covered Entity:

 Fax _____

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

 Fax _____

- 8. **Indemnification; Limitation of Liability.** To the extent permitted by law, CHPSO shall indemnify, defend and hold harmless CE from any and all liability, claim, lawsuit, injury, loss, expense or damage resulting from or relating to the acts or omissions of CHPSO or its agents and Subcontractors in connection with the representations, duties and obligations of CHPSO under this Addendum. Any limitation of liability contained in the Contract shall not apply to the indemnification requirement of this provision. To the extent permitted by law, CE shall indemnify, defend and hold harmless CHPSO from any and all liability, claim, lawsuit, injury, loss, expense or damage resulting from or relating to the acts or omissions of CE in connection with the representations, duties and obligations of CE under this Addendum. Any limitation of liability contained in the Contract shall not apply to the

indemnification requirement of this provision. This provision shall survive the termination of the Addendum.

9. Amendment to Comply with Law. The parties acknowledge that state and federal laws relating to data security and privacy are rapidly evolving and that amendment of the Contract or Addendum may be required to ensure compliance with such developments. The parties specifically agree to take such action as is necessary to implement the standards and requirements of HIPAA, the HIPAA Regulations, the HITECH Act, and other applicable state and federal laws and regulations relating to the security or confidentiality of PHI. The parties agree to negotiate in good faith an amendment to the Addendum to the extent that any final regulation or amendment to the final regulations promulgated by the Secretary requires an amendment to comply with the requirements of HIPAA.

10. Regulatory References. A reference in this Addendum to a section of regulations means the section as in effect or as amended, and for which compliance is required.

* * * * *

The parties to this Addendum have duly executed this Addendum as of the Addendum Effective Date.

Covered Entity

CHPSO Patient Safety Organization

By: _____

By: _____

Rory Jaffe, Executive Director
CHPSO

Name: _____

Title: _____

Date: _____

Date: _____