CAROLINAS REHABILITATION PATIENT SAFETY ORGANIZATION

PARTICIPATING FACILITY AGREEMENT

This Agreement is between Carolinas Rehabilitation Patient Safety Organization (CR-PSO), a component organization of The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System, ("CHS") and _____(Participating Facility); and is effective the _____ day of _____, 2013.

BACKGROUND

A. CR-PSO has been designated as a Patient Safety Organization pursuant to the federal Patient Safety and Quality Improvement Act of 2005 and the rules and regulations promulgated there under, hereinafter referred to as the Act (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. CR-PSO 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. Participating Facility wishes to voluntarily participate in CR-PSO's data collection, reporting, quality benchmarking services and evaluation activities, through utilization of the EQUADR^{SM} database and other methodologies, in an effort to improve the quality of care delivered at Participating Facility and in Participating Facility's community, and ultimately improving the patient care delivery system in general.

D. The underlying purpose of this Agreement is to provide quality data benchmarking services to inpatient acute rehabilitation hospitals so that Participating Facilities can compare themselves to like facilities in order to drive performance and patient safety improvement initiatives for the ultimate purpose of achieving the above stated patient safety and healthcare quality improvement goals.

SECTION 1.
DEFINITIONS

1.1 PSO Regulatory Definitions

The following definitions shall apply to this Agreement, as such terms are defined at 42 Code of Federal Regulations ("CFR") Part 3 (the "Regulations"), § 3.20. To the extent terms are not defined herein, such terms are deemed to be defined in accordance with the CFR, as referenced above.

(a) **Affiliated Provider** – shall mean 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.

(b) **Disclosure** – shall mean the release, transfer, provision of access to, or divulging in any other manner of patient safety work product ("PSWP") by: (1) an entity or natural person holding the PSWP to another legally separate entity or natural person, other than a workforce member of, or a healthcare provider holding privileges with, the entity holding the PSWP; or (2) a component PSO to another entity or natural person outside the component PSO and within the legal entity of which the components PSO is a part.

(c) **Identifiable Patient Safety Work Product** – shall mean PSWP 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 define 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.

(d) **Non-identifiable Patient Safety Work Product** – shall mean PSWP that is not identifiable PSWP in accordance with the non-identification standards set forth at § 3.212 of the Regulations.

(e) **Patient Safety Activities** – shall mean 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 PSWP; (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 PSWP 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 PSWP; (6) the provision of appropriate security measures with respect to PSWP; (7) the utilization of qualified staff; and (8) activities related to the operation of a patient safety evaluation system ("PSES") and to the provision of feedback to participants in a PSES.

(f) **CR-PSO Patient Safety Evaluation System** – shall mean the collection, management, or analysis of information for reporting to or by a PSO.

(g) **Participating Facility Patient Safety Evaluation System** – shall mean a standardized process and secure procedure for collecting and communicating Patient Safety data at the Participating Facility, established in coordination with and guidance from CR-PSO.

(h) **Patient Safety Work Product** – shall mean any data, reports, records, memoranda, analyses, or written or oral statements (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 PSEP for reporting to a PSO, and such documentation includes the date the information entered the PSES; or (B) are developed by a PSO for the conduct of patient safety activities; or (ii) which indentify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a PSES.

(i) **Provider** – shall mean (1) an individual or entity licensed to provide health care services, including (i) hospital, nursing facility, comprehensive outpatient rehabilitation facility, etc.; or (ii) a physician, physician assistant, registered nurse, etc; (2) agencies, organizations and individuals that deliver health care, or as otherwise defined by § 3.20 of the Regulations; or (3) a parent organization of one or more entities described in § 3.20 of the Regulations.

(j) **Workforce** – shall mean employees, volunteers, trainees, contractors, or other persons which 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.

1.2 Additional Definitions

The following additional definitions shall apply to this Agreement:

(a) **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").

(b) **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.

(c) **Functional Reporting** - refers to an agreed-upon alternative means of "transferring" PSWP to CR-PSO. A Functional Reporting arrangement may leave PSWP in the physical possession of Participating Facility, with CR-PSO 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).

(d) **HIPAA –** shall mean the Health Insurance Portability and Accountability Act of 1996.

(e) **HIPAA Privacy Rule** – shall mean the HIPAA Privacy regulations at 45 CFR Subpart E.

(f) **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 CR-PSO's Role

CR-PSO will establish a CR-PSO Patient Safety Evaluation System for the collection, management, and analysis of information received from and/or reported to participating facilities, including Participating Facility, as more specifically described in Section 3.3 below. Each Participating Facility may select the level of participation appropriate for that Participating Facility.

2.2 Overview of Participating Facility's Role

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

2.3 Overview of Privileges and Confidentiality

All PSO activities anticipated here under 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, PSWP developed by Participating Facility and/or maintained by CR-PSO 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 CR-PSO, 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, Participating Facility may engage in Functional Reporting, which agreement shall be placed in writing and appended to this Agreement as **Exhibit A.**

SECTION 3.
CR-PSO RESPONSIBILITIES

3.1 Orientation

CR-PSO will conduct orientation and routine training, as necessary, to facilitate Participating Facility's understanding of and effective participation in CR-PSO's PSES and Patient Safety Activities.

3.2 Common Format

CR-PSO will provide template for the collection and reporting of data from the Participating Facility, including specific definitions of data elements. CR-PSO will not generally use AHRQ Common Formats due to the specialized nature of rehabilitation data. Changes to the template and/or AHRQ Common Formats may be implemented from time to time as a result of changes in the AHRQ Common Formats or as a result of other modifications developed in consultation with Participating Facility. CR-PSO will be responsible for informing Participating Facility of such changes.

3.3 Patient Safety Evaluation System (PSES)

CR-PSO will establish and operate a CR-PSO Patient Safety Evaluation System (PSES). CR-PSO, in consultation with Participating Facility, will make recommendations for Participating Facility to develop and operate it's internal Participating Facility Patient Safety Evaluation System. CR-PSO will develop specific data collection, monitoring, collaboration and evaluation activities, utilizing the EQUADR^{SM} database as well as other methodologies and offer them to Participating Facility.

3.4 Patient Safety Work Product (PSWP)

(a) CR-PSO will collect and maintain reported information as PSWP. CR-PSO shall maintain the confidentiality of PSWP. Without limiting the generality of the foregoing, CR-PSO shall enter into a Business Associate Agreement, attached as **Exhibit B**, and shall maintain the confidentiality of PHI in accordance with all applicable laws pertaining to confidentiality of PHI and patient medical record information.

(b) PSWP reports that are circulated to other Participating Facilities, PSOs, or are otherwise publicized will utilize the Non-identifiable Patient Safety Work Product format, except as otherwise agreed, in writing, by Participating Facility.

(c) As required by law, CR-PSO will promptly notify Participating Facility 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

CR-PSO will assemble a knowledgeable workforce, and in collaboration with its workforce (which may consist of employees, contractors, volunteers, representatives of participating Participating Facilities and other Patient Safety Organizations, and other individuals as appropriate to the involved Patient Safety

Activity), will develop and conduct Patient Safety Activities, which may include, but will not be limited to, data collection, appropriate studies, evaluative activities, reports, and recommendations, including, where feasible, "best practices" recommendations; and will offer the results to participating Participating Facilities, including Participating Facility as appropriate to its level(s) of participation.

SECTION 4.
PARTICIPATING FACILITY RESPONSIBILITIES

4.1 Participating Facility Patient Safety Evaluation System

Participating Facility, in consultation with CR-PSO, will develop a Participating Facility Patient Safety Evaluation System for collecting, maintaining and managing information, including but not limited to Patient Safety Work Product reported to and Participating Facility's interactions with CR-PSO. Participating Facility documentation must document the date Participating Facility's Patient Safety Work Product enters its Patient Safety Evaluation System.

4.2 Appointment of Participating Facility/PSO Liaison Representative

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

4.3 Reporting

(a) Participating Facility 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, Participating Facility acknowledges and understands that:

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

(2) However, with respect to PSWP information maintained as part of Participating Facility's Patient Safety Evaluation System, up and

until such time that the information has be reported to CR-PSO, Participating Facility may reclassify information as being or not being Patient Safety Work Product. Once PSWP has been reported to CR-PSO, it is not possible to reclassify the information.

(b) Participating Facility will cooperate, as appropriate, with reasonable follow-up requests from CR-PSO for information and/or clarification regarding reported information.

4.4 Use and Protection of PSWP

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

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

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

4.5 Participation as Part of CR-PSO's Workforce

Participating Facility may designate individuals to assist CR-PSO in the conduct of CR-PSO's Patient Safety Activities, which (depending on the project and Participating Facility's expressed participation commitments) may include assisting in study design as well as assimilating and evaluating Participating Facility-specific information, information collected from other participating Participating Facilitys and providers, and information collected from other sources. Participating Facility representatives who are functioning as CR-PSO Workforce will be expected to acknowledge confidentiality and related responsibilities, and sign a Workforce Confidentiality Agreement, as set forth in **Exhibit 4.5.**

4.6 Implementation of CR-PSO Recommendations

Participating Facility shall be solely responsible for its own decision-making with respect to participating in CR-PSO 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 CR-PSO Patient Safety Activities.

4.7 Notification of other Patient Safety Organization Participation

In the event Participating Facility participates in and reports the same PSWP to other patient safety organizations, Participating Facility with notify CR-PSO and use best efforts to communicate and cooperate with all PSO recipients of Participating Facility'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 CR-PSO's Obligations

(a) In the event CR-PSO receives a request, subpoena, or other attempt of an outside party or agency to access confidential PSWP provided by Participating Facility, CR-PSO will assert all applicable privileges, and will promptly notify Participating Facility.

(b) In the event there is an applicable exception or disclosure permission that would require CR-PSO to provide access to Participating Facility's confidential PSWP, CR-PSO will promptly notify Participating Facility.

(c) CR-PSO will cooperate and coordinate with Participating Facility as described in **Section 5.2**.

5.2 Participating Facility's Obligations

(a) In cases where Participating Facility's PSWP is sought by litigants in cases where Participating Facility (or its providers) is/are parties, Participating Facility (or its providers) maintains primary responsibility for defending against attempts to access Participating Facility's PSWP. CR-PSO and its counsel will cooperate as necessary to protect Participating Facility's PSWP.

(b) In cases where Participating Facility's PSWP is sought by agencies investigating Participating Facility or its providers, Participating Facility (or its providers) maintains primary responsibility for defending against attempts to access Participating Facility's PSWP. CR-PSO and its counsel will cooperate as necessary to protect Participating Facility's PSWP.

(c) In cases where Participating Facility'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) CR-PSO 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

(b) Participating Facility 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 Participating Facility 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 CR-PSO or its officers, directors, employees, workforce members, or agents. Subject to the provisions of **Section 6.2(c)**, below, CR-PSO shall defend, indemnify, and hold harmless Participating Facility, 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 CR-PSO 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 Participating Facility or its officers, directors, employees, staff members, independent contractors, or agents. Subject to the provisions of **Section 6.2(c)**, below, Participating Facility shall defend, indemnify, and hold harmless CR-PSO, 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 CR-PSO is decertified as a Patient Safety Organization, termination shall be effective as of the date of CR-PSO'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 CR-PSO:
Carolinas Rehabilitation Patient Safety Organization / EQUADR
1100 Blythe Blvd
Charlotte, NC 28203
Attn: Administration

TO PARTICIPATING FACILITY:

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.

*** * * * ***

PARTICIPATING FACILITY	Carolinas Rehabilitation Patient Safety Organization (CR-PSO)
By:	By:
Name:	Name:
Title:	Title:
Date:	Date

EXHIBIT LIST

Exhibit A - Functional Reporting Agreement
Exhibit B - Business Associate Agreement
Exhibit C - Workforce Confidentiality Agreement

Exhibit A
Functional Reporting Agreement

In lieu of physically transmitting data or paper reports to CR-PSO, the following Functional Reporting arrangement shall be implemented:

EQUADR members may elect to have their healthcare associated infection data directly pulled out of the CDC/NHSN database_____
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_____
_____

CR-PSO

By_____

Participating Facility

By _____

Exhibit B
BUSINESS ASSOCIATE AGREEMENT

_____ ("Covered Entity") and The Charlotte Mecklenburg Hospital Authority, doing business as Carolinas HealthCare System or another business name, or by and through one of its wholly owned subsidiaries, including its physician network, Carolinas Physician Network, Inc. ("Business Associate") have entered into an agreement for services ("Services Agreement"), pursuant to which Business Associate may create, receive, maintain, or transmit individually identifiable health information, including electronic protected health information, as defined under the Health Insurance Portability and Accountability Act of 1996, and the regulations promulgated thereunder, as amended, including the Privacy, Security, Administrative, Enforcement, and Breach Notification Rules (collectively, "HIPAA") for, from, or on behalf of, Covered Entity (collectively, "Protected Health Information" or "PHI"). As such, the parties enter into this Business Associate Agreement ("BAA") and Business Associate will comply with its obligations, as well as the requirements and obligations of HIPAA. Any ambiguity in this BAA is to be interpreted to comply with HIPAA.

AGREEMENT

1. **Terms**. The terms used in this BAA shall have the same meaning as those set forth in the HIPAA, including, but not limited to, business associate, breach, breach of unsecured PHI, covered entity, data aggregation, designated record set, discovery, electronic PHI, individual, minimum necessary, Notice of Privacy Practices, Privacy Rule (Subpart E of 45 C.F.R. Part 164), protected health information, required by law, Secretary, security incident, Security Rule (Subpart C of 45 C.F.R. Part 164, subcontractor, and unsecured PHI.

2. **General Obligation**. Business Associate will comply with the applicable requirements of HIPAA, including the Privacy, Security, Enforcement, and Breach Notification Rules.

3. **Permitted and Prohibited Uses and Disclosures of PHI.**
a. Business Associate is permitted to use and disclose the PHI only as follows: (i) as set forth in this BAA; (ii) as required to perform its obligations under the Services Agreement (which may or may not include data aggregation relating to the health care operations of the Covered Entity); and, (iii) as required by law.
b. To the extent permitted by other state and federal confidentiality laws, Business Associate may use, and disclose to a third party, PHI received under this BAA as necessary for the proper management and administration of the Business Associate or as necessary to carry out the legal responsibilities of Business Associate if: (i) the disclosures are required by law; or, (ii) Business Associate has received written reasonable assurances from the receiving third party that (a) the PHI will be handled confidentially as required by HIPAA, (b) the PHI will only be used or further disclosed as required by law or in keeping with

the purposes for which it was disclosed, and (c) the third party will notify Business Associate promptly of any instances of which it is aware that the confidentiality of the PHI has been breached.
c. Except as set forth in this BAA or in the Services Agreement, Business Associate is prohibited from otherwise using or disclosing PHI. Business Associate is likewise prohibited from using or disclosing PHI in any manner that would violate HIPAA if done by the Covered Entity, including from any improper sale of PHI under 45 C.F.R. § 164.502.

4. **Minimum Necessary.** When using or disclosing PHI, or when requesting PHI from another covered entity or business associate, Business Associate will make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request. Should the amount of PHI needed by Business Associate change over the course of the Services Agreement, the parties will make the necessary adjustments.

5. **Safeguards**. Business Associate will implement and use appropriate safeguards, including comply with the applicable requirements of the Security Rule for electronic PHI, to prevent the use or disclosure of PHI in any manner other than as specifically permitted by this BAA or the Services Agreement.

6. **Business Associate Subcontractors**. Business Associate will ensure that any subcontractor who creates, receives, maintains, or transmits PHI, including electronic PHI, on behalf of the Business Associate agrees, in writing, to: (i) follow the same restrictions and requirements as those that apply to Business Associate under this BAA, including reporting of any security incident or breach of unsecured PHI; (ii) comply with the applicable requirements of the Privacy and Security Rules; and, (iii) implement reasonable and appropriate safeguards and security measures to protect the PHI, including electronic PHI. Business Associate agrees to disclose to subcontractors who create, receive, maintain, or transmit PHI on behalf of the Business Associate only that PHI which is necessary to perform the services required under the Services Agreement. Business Associate will monitor compliance by its subcontractors and, if necessary, terminate the arrangements as required under 45 C.F.R. § 164.504(e)(1)(iii).

7. **Reporting Breach/Security Incident.** Business Associate will promptly report to Covered Entity, both orally and in writing, any use or disclosure of PHI that is not permitted or required under this BAA, including any security incident or breach of unsecured PHI that Business Associate discovers. Business Associate will comply with the breach notification obligations set forth under 45 C.F.R. § 164.410 and will cooperate with the Covered Entity in investigating and addressing the breach. In the event Business Associate discovers that PHI has been stolen, is illegally compromised, or is otherwise in jeopardy of causing immediate harm to Covered Entity or the individual, Business Associate will

contact Covered Entity as soon as practicable after discovery, inform it of the situation, and cooperate in remediating the incident.

8. **Access by Individuals.** In accordance with 45 C.F.R. § 164.524 and within thirty (30) days of the request, Business Associate will make available to Covered Entity (or to the individual at Covered Entity's direction) an individual's PHI as maintained in a designated record set by Business Associate in the format requested, including provide an electronic copy of the PHI as requested, to the extent possible.

9. **Amendment of PHI.** In accordance with 45 C.F.R. § 164.526 and within forty-five (45) days of the request, Business Associate will make available to Covered Entity for amendment, and amend as requested, an individual's PHI as maintained by Business Associate in a designated record set in such manner as Covered Entity may from time to time request, or as otherwise required under 45 C.F.R. § 164.526.

10. **Accounting of Disclosures.** In accordance with 45 C.F.R. § 164.528 and within forty-five (45) days of the request, Business Associate will maintain and make available to Covered Entity an accounting of disclosures of PHI, including the date of the disclosure, the name and address of the recipient of the PHI, a brief description of the PHI disclosed, and the purpose of the disclosure.

11. **Privacy Obligations**. To the extent Business Associate is charged with carrying out the Covered Entity's obligations under the Privacy Rule, then Business Associate will comply with the requirements of the Privacy Rule that apply to the Covered Entity in the performance of such obligations.

12. **Covered Entity's Obligations.** To the extent such restrictions, changes or revocations affect Business Associate's use or disclosure of PHI, Covered Entity will notify the Business Associate of, and Business Associate will abide by: (i) any limitations in its Notice of Privacy Practices; (ii) any changes in, or revocation of, an individual's permission to use or disclose PHI; and, (iii) any restriction on the use or disclosure of PHI to which Covered Entity has agreed or by which it is required to abide. Without limiting Business Associate's ability to conduct data aggregation or to use PHI for the management, administration and legal responsibilities of Business Associate, Covered Entity will not request Business Associate to use or disclose PHI in any manner that would not be permissible under the Privacy Rule if done by the Covered Entity.

13. **Disclosures to United States Department of Health and Human Services.** Business Associate will make available to the Secretary its internal practices, books and records relating to the use and disclosure of PHI received from, or created or received by Business Associate on behalf of, Covered Entity, as well as the PHI itself, for purposes of determining Covered Entity's or the

Business Associate's compliance with the applicable sections of HIPAA, including the Privacy and Security Rules.

14. **Breach; Termination.** Without limiting any other rights or remedies of the parties, if one party determines that the other has in an act, omission, or pattern of activity or practice that constitutes a material breach or violation of Business Associate's obligations under the BAA, then such party will (i) provide the breaching party with written notice of the existence of a breach; and (ii) afford the breaching party an opportunity to cure such breach or violation upon reasonable terms and in a reasonable time period; *provided, however*, that if the breaching party is unable to successfully cure the breach or end the violation, then the non-breaching party may terminate this BAA and the Services Agreement (in whole or in part, as relevant) immediately by delivering written notice of termination to the breaching party.

15. **Procedure upon Termination.** Upon the termination or expiration of the Services Agreement for any reason, Business Associate will (i) return, or destroy in accordance with a process approved in advance by and acceptable to Covered Entity, all PHI that Business Associate received from, or created or received on behalf of Covered Entity, that Business Associate maintains in any form, including electronic PHI; and, (ii) not retain any copies of such PHI. If it is not feasible for Business Associate to return or destroy the PHI in accordance with the foregoing, then, for so long as it retains the PHI, Business Associate will: (i) continue to abide by this BAA and extend its protections to such PHI; (ii) continue to comply with HIPAA, including the Security Rule, as they relate to the PHI, including electronic PHI, to prevent unauthorized use or disclosure thereof; and, (iii) limit further use of the PHI to those purposes that make the return or destruction of the PHI infeasible.

16. **Independent Contractor**. Notwithstanding any other designations in the Services Agreement or otherwise, Business Associate is an independent contractor to Covered Entity for purposes of HIPAA, and nothing in this BAA is intended to create any other relationship between the parties.

17. **Amendment**. This BAA is intended to comply with the requirements of HIPAA. If the applicable laws and regulations should be amended, then the parties will amend this BAA accordingly, provided that if the change in law or regulations causes any paragraph or provision of this BAA to be invalid, incomplete, void, in any manner unlawful, or subjects either party to penalty, then the BAA will be deemed to be amended by operation of law, regardless of whether the parties document such changes in the law by written amendment.

18. **Survival**. The rights and obligations of this BAA will survive the termination of the services agreement and this BAA as required to continue to protect any PHI that is required to be maintained, created, received or transmitted by Business Associate or its subcontractors after termination for whatever reason.

19. **Scope**. This BAA applies to any and all Services Agreements entered into by the parties, whether in effect now or in the future. This BAA also amends and restates any existing business associate agreements that the parties may have in existence between them.

20. **Miscellaneous**. Neither party may assign its rights or obligations under this BAA without mutual agreement. Any illegal or unenforceable provisions in this BAA are severed without affecting the remaining provisions. Remedies under this BAA and any other provisions of the Services Agreement will be cumulative, and failure to exercise any remedy will not constitute a waiver. If this BAA is attached to the Services Agreement and is not executed below, it is deemed executed by incorporation.

IN WITNESS WHEREOF the authorized representatives of the parties sign below in acknowledgement of their agreement to the foregoing.

COVERED ENTITY:	**BUSINESS ASSOCIATE:**
_____	Carolinas Rehabilitation Patient Safety Organization
_____	_____
By: _____	By: _____
Title: _____	Title: _____
Date: _____	Date: _____

Exhibit C
Workforce Confidentiality Agreement

The Patient Safety and Quality Improvement Act of 2005 (PSQIA) and its regulations govern the conduct of Carolinas Rehabilitation Patient Safety Organization (CR-PSO) operations and activities. Included among these activities is the assemblage of a "workforce" of employees, volunteers, trainees, contractors, and other persons who perform work for or on behalf of CR-PSO. Members of CR-PSO's workforce are expected to be well-trained in their responsibilities, and to understand and acknowledge their significant obligations, including but not limited to their obligations to maintain the confidentiality of Patient Safety Work Product, as required by the PSQIA, and of Protected Health Information, as required by the Health Insurance Portability and Accountability Act (HIPAA) and its regulations and other federal and state laws and regulations were established to protect the confidentiality of medical and personal information, and provide, generally, that such information may not be disclosed except as permitted or required by law or unless authorized by the patient. Accordingly, all members of the CR-PSO workforce are required to agree to and sign this confidentiality statement.

CONFIDENTIALITY STATEMENT

As a member of the CR-PSO workforce, I understand that I may be working with confidential quality assurance, peer review, medical and other sensitive or private information. This information may include, but is not limited to, incident reports and data, evaluation records, medical records, personnel information, ledgers, verbal discussions, and electronic communications including e-mail. I understand and acknowledge that PSQIA and HIPAA require that I be trained on the requirements of PSQIA, HIPAA and the CR-PSO policies, procedures and guidelines relating to protection of confidential information, and I agree to obtain all required training before I access, use or disclose any confidential information. I acknowledge that it is my responsibility to respect the privacy and confidentiality of patient and other confidential information. I will not access, use or disclose patient or other confidential information unless I do so in the course and scope of fulfilling my duties as a member of the CR-PSO workforce. I understand that I am required to immediately report any information about unauthorized access, use or disclosure of confidential information. Initial reports go to the CR-PSO Executive Director. If electronic media is involved, an incident report will be forwarded to The CR-PSO Executive Director. I understand and acknowledge that, should I breach any provision of this agreement, I may be subject to civil or criminal liability and/or disciplinary action consistent with applicable CR-PSO policies, contracts and processes. For more information on CR-PSO PSQIA and/or HIPAA-related policies, procedures and guidelines please contact the CR-PSO Executive Director.

_____ _____

Signature Printed Name Date