HIPAA BUSINESS ASSOCIATE ADDENDUM

The parties to this Business Associate Addendum ("Addendum") are the State of Michigan, acting by and through the Department of Management and Budget, on behalf of the Michigan Department of Community Health ("State") and Comprehensive NeuroScience, Inc, ("Contractor"). This Addendum supplements and is made a part of the existing contract(s) or agreement(s) between the parties including the following Contract(s): Behavioral Pharmacy Management Services Agreement ("Contract").

For purposes of this Addendum, the State is (check one):

- (X) Covered Entity ("CE")
- () Business Associate ("Associate")

and Contractor is (check one):

- () Covered Entity ("CE")
- (X) Business Associate ("Associate")

RECITALS

- A. Pursuant to the terms of the Contract, CE wishes to disclose certain information to Associate, some of which may constitute Protected Health Information ("PHI") (defined below). In consideration of the receipt of PHI, Associate agrees to protect the privacy and security of the information as set forth in this Addendum.
- B. CE and Associate intend to protect the privacy and provide for the security of PHI disclosed to Associate pursuant to the Contract in compliance with the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA") and regulations promulgated thereunder by the U.S. Department of Health and Human Services (the "HIPAA Regulations") and other applicable laws, as amended.
- C. As part of the HIPAA Regulations, the Privacy Rule and the Security Rule (defined below) requires CE to enter into a contract containing specific requirements with Associate prior to the disclosure of PHI, as set forth in, but not limited to, 45 CFR §§ 160.103, 164.502(e), 164.504(e), and 164.314 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:

Definitions.

- a. Except as otherwise defined herein, capitalized terms in this Addendum shall have the definitions set forth in the HIPAA Regulations at 45 CFR Parts 160, 162 and 164, as amended, including, but not limited to, subpart A, subpart C ("Security Rule") and subpart E ("Privacy Rule").
 - b. "Agreement" means both the Contract and this Addendum.
- c. "Contract" means the underlying written agreement or purchase order between the parties for the goods or services to which this Addendum is added.
- d. "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 CFR § 164.501.
- e. <u>"Protected Information"</u> shall mean PHI provided by CE to Associate or created or received by Associate on CE's behalf.

Obligations of Associate.

- a. Permitted Uses. Associate shall not use Protected Information except for the purpose of performing Associate's obligations under the Contract and as permitted under this Agreement. Further, Associate shall not use Protected Information in any manner that would constitute a violation of the HIPAA Regulations if so used by CE, except that Associate may use Protected Information: (i) for the proper management and administration of Associate; (ii) to carry out the legal responsibilities of Associate; or (iii) for Data Aggregation purposes for the Health Care Operations of CE. Additional provisions, if any, governing permitted uses of Protected Information are set forth in Attachment A to this Addendum.
- b. <u>Permitted Disclosures.</u> Associate shall not disclose Protected Information in any manner that would constitute a violation of the HIPAA Regulations if disclosed by CE, except that Associate may disclose Protected Information: (i) in a manner permitted pursuant to the Contract and this Addendum; (ii) for the proper management and administration of Associate; (iii) as required by law; (iv) for Data Aggregation purposes for the Health Care Operations of CE; or (v) to report violations of law to appropriate federal or state authorities, consistent with 45 CFR § 164.502(j)(1). To the extent that Associate discloses Protected Information to a third party, Associate must obtain, prior to making any such disclosure: (i) reasonable 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) an agreement to implement reasonable and appropriate safeguards to protect the Protected Information; and (iii) an agreement from such third party to immediately notify Associate of any breaches of confidentiality of the Protected Information or any Security Incident, to the extent it has obtained knowledge of such breach. Additional provisions, if any, governing permitted disclosures of Protected Information are set forth in Attachment A.

- c. Appropriate Safeguards. Associate shall implement appropriate Security
 Measures as are necessary to protect against the use or disclosure of Protected Information other
 than as permitted by the Contract or this Addendum. Associate shall maintain a comprehensive
 written information privacy and security program that includes Security Measures that
 reasonably and appropriately protect the Confidentiality, Integrity, and Availability of Protected
 Information relative to the size and complexity of the Associate's operations and the nature and
 scope of its activities.
- d. Reporting of Improper Use or Disclosure. Associate shall report to CE in writing any use or disclosure of Protected Information, whether suspected or actual, other than as provided for by the Contract and this Addendum within ten (10) days of becoming aware of such use or disclosure. If the disclosure is a Major Disclosure, then the improper use or disclosure shall be reported within three (3) days. A Major Disclosure means any improper use or disclosure of over twenty-five percent (25%) of the Protected Information held by the Associate. CE and Associate will cooperate to mitigate the effects of any unauthorized use or disclosure and document the outcome.
- e. <u>Associate's Agents.</u> If Associate uses one or more subcontractors or agents to provide services under this Agreement, and such subcontractors or agents receive or have access to Protected Information, each subcontractor or agent shall sign an agreement with Associate containing substantially the same provisions as this Addendum and further identifying CE as a third party beneficiary of the agreement with such subcontractors or agents in the event of any violation of such subcontractor or agent agreement. Associate 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. Access to Protected Information. Associate shall make Protected Information maintained by Associate or its agents or subcontractors in Designated Record Sets available to CE for inspection and copying within ten (10) days of a request by CE to enable CE to fulfill its obligations to permit individual access to PHI under the Privacy Rule, including, but not limited to, 45 CFR § 164.524.
- g. Amendment of PHI. Within ten (10) days of receipt of a request from CE for an amendment of Protected Information or a record about an individual contained in a Designated Record Set, Associate or its agents or subcontractors shall make such Protected Information available to CE for amendment and incorporate any such amendment to enable CE to fulfill its obligations with respect to requests by individuals to amend their PHI under the Privacy Rule, including, but not limited to, 45 CFR § 164.526. If any individual requests an amendment of

Protected Information directly from Associate or its agents or subcontractors, Associate must notify CE in writing within ten (10) days of receipt of the request. Any denial of amendment of Protected Information maintained by Associate or its agents or subcontractors shall be the responsibility of CE.

- h. Accounting Rights. Within ten (10) days of notice by CE of a request for an accounting of disclosures of Protected Information, Associate 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 CFR § 164.528. As set forth in, and as limited by, 45 CFR § 164.528, Associate shall not provide an accounting to CE of disclosures made: (i) to carry out treatment, payment or health care operations, as set forth in 45 CFR § 164.506; (ii) to individuals of Protected Information about them as set forth in 45 CFR § 164.502; (iii) pursuant to an authorization as provided in 45 CFR § 164.508; (iv) to persons involved in the individual's care or other notification purposes as set forth in 45 CFR § 164.510; (v) for national security or intelligence purposes as set forth in 45 CFR § 164.512(k)(2); or (vi) to correctional institutions or law enforcement officials as set forth in 45 CFR § 164.512(k)(5). Associate agrees to implement a process that allows for an accounting to be collected and maintained by Associate and its agents or subcontractors for at least six (6) years prior to the request, but not before the compliance date of the Privacy Rule. At a minimum, such information shall include: (i) the date of disclosure; (ii) the name of the entity or person who received Protected Information and, if known, the address of the entity or person; (iii) a brief description of Protected Information disclosed; and (iv) a brief statement of purpose of the disclosure that reasonably informs the individual of the basis for the disclosure, or a copy of the individual's authorization, or a copy of the written request for disclosure. In the event that the request for an accounting is delivered directly to Associate or its agents or subcontractors, Associate shall within ten (10) days of the receipt of the request forward it to CE in writing. It shall be CE's responsibility to prepare and deliver any such accounting requested. Associate shall not disclose any Protected Information except as set forth in Section 2(b) of this Addendum.
- i. Governmental Access to Records. Associate shall make its internal practices, books and records relating to the use and disclosure of Protected Information available to the Secretary of the U.S. Department of Health and Human Services (the "Secretary"), in a time and manner designated by the Secretary, for purposes of determining CE's compliance with the HIPAA Regulations. Associate shall provide to CE a copy of any Protected Information that Associate provides to the Secretary concurrently with providing such Protected Information to the Secretary.
- j. <u>Minimum Necessary</u>. Associate (and its agents or subcontractors) shall only request, use and disclose the minimum amount of Protected Information necessary to accomplish the purpose of the request, use or disclosure, in accordance with the Minimum Necessary requirements of the Privacy Rule, including, but not limited to 45 CFR §§ 164.502(b) and 164.514(d).

- k. <u>Data Ownership</u>. Unless otherwise specified in the Contract, Associate acknowledges that Associate has no ownership rights with respect to the Protected Information. The CE retains all rights with respect to ownership of the Protected Information.
- Retention of Protected Information. Notwithstanding Section 5(d) of this
 Addendum, Associate and its subcontractors or agents shall retain all Protected Information
 throughout the term of the Contract and shall continue to maintain the information required
 under Section 2(h) of this Addendum for a period of six (6) years from the date of creation or the
 date when it last was in effect, whichever is later, or as required by law. This obligation shall
 survive the termination of the Contract.
- m. <u>Destruction of Protected Information</u>. Associate agrees to implement policies and procedures for the final disposition of electronic Protected Information and/or the hardware and equipment on which it is stored, including but not limited to, removal before re-use.
- n. Notification of Breach. During the term of the Contract or this Addendum, Associate shall notify CE within twenty-four (24) hours of any suspected or actual breach of security, intrusion, or unauthorized use or disclosure of PHI and/or any actual or suspected use or disclosure of data in violation of any applicable federal or state laws or regulations. Associate shall take (i) prompt corrective action to cure any such deficiencies and (ii) any action pertaining to such unauthorized disclosure required by applicable federal and state laws and regulations. CE and Associate will cooperate to mitigate the effects on any breach, Security Incident, intrusion, or unauthorized use and document the Security Incident and its outcome.
- CE, Associate and its agents or subcontractors shall allow CE 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 Associate has complied with this Addendum; provided, however, that: (i) Associate 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 Associate to which CE has access during the course of such inspection; and (iii) CE or Associate shall execute a nondisclosure agreement, if requested by Associate or CE. The fact that CE inspects, or fails to inspect, or has the right to inspect, Associate's facilities, systems, books, records, agreements, policies and procedures does not relieve Associate of its responsibility to comply with this Addendum, nor does CE's (i) failure to detect or (ii) detection, but failure to notify Associate or require Associate's remediation of any unsatisfactory practices, constitute acceptance of such practice or a waiver of CE's enforcement rights under this Agreement.
- p. <u>Safeguards During Transmission</u>. Associate shall be responsible for using Security Measures to reasonably and appropriately maintain and ensure the Confidentiality, Integrity, and Availability of Protected Information transmitted to CE pursuant to this Agreement, in accordance with the standards and requirements of the HIPAA Regulations, until such Protected Information is received by CE, and in accordance with any specifications set forth in Attachment A.

Obligations of CE.

- a. <u>Safeguards During Transmission</u>. CE shall be responsible for using Security Measures to reasonably and appropriately maintain and ensure the Confidentiality, Integrity, and Availability of Protected Information transmitted to Associate pursuant to this Agreement, in accordance with the standards and requirements of the HIPAA Regulations, until such Protected Information is received by Associate, and in accordance with any specifications set forth in Attachment A.
- b. Notice of Changes. CE shall provide Associate with a copy of its notice of privacy practices produced in accordance with 45 CFR § 164.520, as well as any subsequent changes or limitation(s) to such notice, to the extent such changes or limitations may effect Associate's use or disclosure of Protected Information. CE shall provide Associate with any changes in, or revocation of, permission to use or disclose Protected Information, to the extent it may affect Associate's permitted or required uses or disclosures. To the extent that it may affect Associate's permitted use or disclosure of Protected Information, CE shall notify Associate of any restriction on the use or disclosure of Protected Information that CE has agreed to in accordance with 45 CFR § 164.522.
- 4. <u>Term.</u> This Addendum shall continue in effect as to each Contract to which it applies until such Contract is terminated or is replaced with a new contract between the parties containing provisions meeting the requirements of the HIPAA Regulations, whichever first occurs. However, certain obligations will continue as specified in this Addendum.

Termination.

- a. <u>Material Breach</u>. In addition to any other provisions in the Contract regarding breach, a breach by Associate of any provision of this Addendum, as determined by CE, shall constitute a material breach of the Agreement and shall provide grounds for termination of the Contract by CE pursuant to the provisions of the Contract covering termination for cause. If the Contract contains no express provisions regarding termination for cause, the following shall apply to termination for breach of this Addendum, subject to 5.b.:
- (1) <u>Default</u>. If Associate refuses or fails to timely perform any of the provisions of this Addendum, CE may notify Associate in writing of the non-performance, and if not corrected within thirty (30) days, CE may immediately terminate the Agreement. Associate shall continue performance of the Agreement to the extent it is not terminated.
- (2) <u>Associate's Duties</u>. Notwithstanding termination of the Agreement, and subject to any directions from CE, Associate shall take timely, reasonable and necessary action to protect and preserve property in the possession of Associate in which CE has an interest.
- (3) <u>Compensation</u>. Payment for completed performance delivered and accepted by CE shall be at the Contract price.

- (4) Erroneous Termination for Default. If after such termination it is determined, for any reason, that Associate was not in default, or that Associate's action/inaction was excusable, such termination shall be treated as a termination for convenience, and the rights and obligations of the parties shall be the same as if the contract had been terminated for convenience, as described in this Addendum or in the Contract.
- b. Reasonable Steps to Cure Breach. If CE knows of a pattern of activity or practice of Associate that constitutes a material breach or violation of the Associate's obligations under the provisions of this Addendum or another arrangement and does not terminate this Agreement pursuant to Section 5(a), then CE shall take reasonable steps to cure such breach or end such violation, as applicable. If CE's efforts to cure such breach or end such violation are unsuccessful, CE shall either (i) terminate this Agreement, if feasible or (ii) if termination of this Agreement is not feasible, CE shall report Associate's breach or violation to the Secretary of the Department of Health and Human Services.
 - c. Reserved.
 - d. Effect of Termination.
- (1) Except as provided in paragraph (2) of this subsection, upon termination of this Agreement, for any reason, Associate shall return or destroy all Protected Information that Associate or its agents or subcontractors still maintain in any form, and shall retain no copies of such Protected Information. If Associate elects to destroy the Protected Information, Associate shall certify in writing to CE that such Protected Information has been destroyed.
- (2) If Associate believes that returning or destroying the Protected Information is not feasible, including but not limited to, a finding that record retention requirements provided by law make return or destruction infeasible, Associate shall promptly provide CE notice of the conditions making return or destruction infeasible. Upon mutual agreement of CE and Associate that return or destruction of Protected Information is infeasible, Associate shall continue to extend the protections of Sections 2(a), 2(b), 2(c), 2(d) and 2(e) of this Addendum to such information, and shall limit further use of such Protected Information to those purposes that make the return or destruction of such Protected Information infeasible.

Reserved.

- 7. No Waiver of Immunity. No term or condition of this Agreement shall be construed or interpreted as a waiver, express or implied, of any of the immunities, rights, benefits, protection, or other provisions of the Michigan Governmental Immunity Act, MCL 691.1401, et seq., the Federal Tort Claims Act, 28 U.S.C. 2671 et seq., or the common law, as applicable, as now in effect or hereafter amended.
- Reserved.

- 9. <u>Disclaimer</u>. CE makes no warranty or representation that compliance by Associate with this Addendum, HIPAA or the HIPAA Regulations will be adequate or satisfactory for Associate's own purposes. Associate is solely responsible for all decisions made by Associate regarding the safeguarding of Protected Information.
- 10. <u>Certification</u>. To the extent that CE determines an examination is necessary in order to comply with CE's legal obligations pursuant to HIPAA relating to certification of its security practices, CE or its authorized agents or contractors, may, at CE's expense, examine Associate's facilities, systems, procedures and records as may be necessary for such agents or contractors to certify to CE the extent to which Associate's security safeguards comply with HIPAA, the HIPAA Regulations or this Addendum.

11. Amendment.

- 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 this Addendum may be required to provide for procedures 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 Privacy Rule, the Security Rule and other applicable laws relating to the security or privacy of Protected Information. The parties understand and agree that CE must receive satisfactory written assurance from Associate that Associate will adequately safeguard all Protected Information. Upon the request of either party, the other party agrees to promptly enter into negotiations concerning the terms of an amendment to this Addendum embodying written assurances consistent with the standards and requirements of HIPAA, the Privacy Rule, the Security Rule or other applicable laws. CE may terminate the Agreement upon thirty (30) days written notice in the event (i) Associate does not promptly enter into negotiations to amend this Agreement when requested by CE pursuant to this Section or (ii) Associate does not enter into an amendment to this Agreement providing assurances regarding the safeguarding of PHI that CE, in its sole discretion, deems sufficient to satisfy the standards and requirements of HIPAA, the HIPAA Regulations and other applicable laws.
- b. <u>Amendment of Attachment A</u>. Attachment A may be modified or amended by mutual agreement of the parties in writing from time to time without formal amendment of this Addendum.
- 12. Assistance in Litigation or Administrative Proceedings. Associate shall make itself, and any subcontractors, employees or agents assisting Associate in the performance of its obligations under this Agreement, available to CE, at no cost to CE, to testify as witnesses, or otherwise, in the event of litigation or administrative proceedings being commenced against CE, its directors, officers or employees, departments, agencies, or divisions based upon a claimed violation of HIPAA, the HIPAA Regulations or other laws relating to security and privacy of Protected Information, except where Associate or its subcontractor, employee or agent is a named adverse party.

- 13. No Third Party Beneficiaries. Nothing express or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person other than CE, Associate and their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever.
- 14. <u>Effect on Contract</u>. 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. This Addendum is incorporated into the Contract as if set forth in full therein. The parties expressly acknowledge and agree that sufficient mutual consideration exists to make this Addendum legally binding in accordance with its terms. Associate and CE expressly waives any claim or defense that this Addendum is not part of the Agreement between the parties under the Contract.
- 15. Interpretation and Order of Precedence. This Addendum is incorporated into and becomes part of each Contract identified herein. Together, this Addendum and each separate Contract constitute the "Agreement" of the parties with respect to their Business Associate relationship under HIPAA and the HIPAA Regulations. 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 and the HIPAA Regulations. The parties agree that any ambiguity in this Addendum shall be resolved in favor of a meaning that complies and is consistent with HIPAA and the HIPAA Regulations. This Addendum supercedes and replaces any previous separately executed HIPAA addendum between the parties. In the event of any conflict between the mandatory provisions of the HIPAA Regulations and the provisions of this Addendum, the HIPAA Regulations shall control. Where the provisions of this Addendum differ from those mandated by the HIPAA Regulations, but are nonetheless permitted by the HIPAA Regulations, the provisions of this Addendum shall control.
- 16. <u>Effective Date</u>. This Addendum is effective upon receipt of the last approval necessary and the affixing of the last signature required.
- 17. <u>Survival of Certain Contract Terms</u>. Notwithstanding anything herein to the contrary, Associate's obligations under Section 5(d) and record retention laws ("Effect of Termination") and Section 13 ("No Third Party Beneficiaries") shall survive termination of this Agreement and shall be enforceable by CE as provided herein in the event of such failure to perform or comply by the Associate.

18. Representatives and Notice.

- a. <u>Representatives</u>. For the purpose of this Agreement, the individuals identified in the Contract shall be the representatives of the respective parties. If no representatives are identified in the Contract, the individuals listed below are hereby designated as the parties' respective representatives for purposes of this Agreement. Either party may from time to time designate in writing new or substitute representatives.
- b. <u>Notices</u>. All required notices shall be in writing and shall be hand delivered or given by certified or registered mail to the representatives at the addresses set forth below.

Covered Entity Representative:

Name: Janet Olszewski

Title: Director

Department and Division: Michigan Department of Community Health

Address: 320 S. Walnut Lansing, MI 48913

Business Associate Representative:

Name: Richard Surles, Ph.D. Title: Senior Vice President

Department and Division: Comprehensive NeuroScience, Inc.

Address: 2 Tree Farm Road

Suite B-210

Pennington, NJ 08534

Any notice given to a party under this Addendum shall be deemed effective, if addressed to such party, upon: (i) delivery, if hand delivered; or (ii) the third (3rd) Business Day after being sent by certified or registered mail.

IN WITNESS WHEREOF, the parties hereto have duly executed this Addendum as of the Addendum Effective Date.

Associate

Covered Entity

Comprehensive NeuroScience, Inc

Michigan Department of Community Health

Print Name: Richard C. Surles

Print Name:

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Title: Senior Vice President

Title: Chief

Michigan Model BA Addendum Rev. 2/25/2003 10

ATTACHMENT A

This Attachment sets forth additional terms to the HIPAA Business Associate Addendated, between Michigan Department of Community Health and Comprehensive NeuroScience, Inc. ("Addendum") and is effective as of (to "Attachment Effective Date"). This Attachment applies to the specific contracts listed below covered by the Addendum. This Attachment may be amended from time to time as provided Section 11(b) of the Addendum.	ne v
1. <u>Specific Contract Covered</u> . This Attachment applies to the following specific contractovered by the Addendum: <u>Behavioral Pharmacy Management Services Agreement</u>	ct
2. <u>Additional Permitted Uses</u> . In addition to those purposes set forth in Section 2(a) of Addendum, Associate may use Protected Information as follows:	the
3. Additional Permitted Disclosures. In addition to those purposes set forth in Section 2 of the Addendum, Associate may disclose Protected Information as follows:	?(b)
4. Subcontractor(s). The parties acknowledge that the following subcontractors or ager Associate shall receive Protected Information in the course of assisting Associate in the performance of its obligations under the Contract and the Addendum: Statement Outsourcing, LLC.	its of
5. Receipt. Associate's receipt of Protected Information pursuant to the Contract and Addendum shall be deemed to occur as follows, and Associate's obligations under the Addendum shall commence with respect to such PHI upon such receipt:	
6. Additional Restrictions on Use of Data. CE is a Business Associate of certain other Covered Entities and, pursuant to such obligations of CE, Associate shall comply with the following restrictions on the use and disclosure of Protected Information:	

7. <u>Additional Terms</u> . [This section may include specifications for disclosure format, method of transmission, use of an intermediary, use of digital signatures or PKI, authentication additional security of privacy specifications, de-identification or re-identification of data and other additional terms.]		
Associate	Covered Entity	
Comprehensive NeuroScience, Inc	Michigan Department of Community Health	
By: July And	By:	
Print Name: Richard C. Surles	Print Name:	
Title: Senior Vice President	Title:	
Date:	Date:	

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