

BUSINESS ASSOCIATE ADDENDUM

This Addendum (“Addendum”) amends, supersedes or is hereby incorporated into any and all existing agreements entered into by and between _____ (hereinafter “Business Associate”) and Millers of Wyckoff, Inc. (hereinafter “Covered Entity”) effective _____ with an infinite term unless modified or terminated as described herein.

Covered Entity and Business Associate mutually agree to incorporate the terms of this Addendum to comply with the requirements of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and HIPAA’s implementing regulations, Title 45, Parts 160 and 164 of the Code of Federal Regulations (“Privacy Rule”), dealing with the confidentiality of health or health-related information. If any conflict exists between the terms of the original Agreement and this Addendum, the terms of this Addendum shall govern.

1. Definitions.

- a. Protected Health Information (PHI) means any information, whether oral or recorded in any form or medium, that: (i) relates to the past, present or future physical or mental condition of any individual; the provision of health care to an Individual; or the past, present or future payment of the provision of health care to an Individual; and (ii) identifies the Individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the Individual. PHI includes demographic information unless such information is de-identified according to the Privacy Rule.
 - b. Designated Record Set includes prescription records, billing records, insurance records and any other records used by or for the pharmacy to make health care decisions about a patient.
 - c. Individual means the person who is the subject of PHI, and shall include a person who qualifies under the Privacy Rule as a personal representative of the Individual.
 - d. Privacy Rule shall mean the Standards for Privacy of Individually Identifiable Health Information as set forth in the Health Insurance Portability and Accountability Act of 1996 (HIPAA).
 - e. Capitalized terms used in this Agreement, but not otherwise defined, shall have the same meaning as those terms in the Privacy Rule.
2. Prohibition on Unauthorized Use or Disclosure of PHI. Business Associate shall not use or disclose any PHI received from or on behalf of Covered Entity except as permitted or required by the Agreement or this Addendum, as required by law, or as otherwise authorized in writing by Covered Entity.
3. Use of PHI for Certain of Business Associate’s Operations. Business Associate may use and/or disclose PHI it creates for, or receives from, Covered Entity to the extent necessary for Business Associate’s proper management and administration (Business Associate’s proper management and administration does not include the use or disclosure of PHI by Business Associate for marketing purposes, or to support marketing.), or to carry out Business Associate’s legal responsibilities, only if:
- a. The disclosure is required by law; or
 - b. Business Associate obtains reasonable assurances, evidenced by written contract, from any person or organization to which Business Associate shall disclose such PHI that such person or organization shall:
 - (i) hold such PHI in confidence and use or further disclose it only for the purpose for which Business Associate disclosed it to the person or organization, or as required by law; and
 - (ii) notify Business Associate, who shall in turn promptly notify Covered Entity, of any instance which the person or organization becomes aware of when the confidentiality of such PHI was breached.
4. Safeguarding of PHI. Business Associate shall develop, implement, maintain, and use appropriate administrative, technical, and physical safeguards to prevent the improper use or disclosure of all PHI, in any form or media, received from or created or received by Business Associate on behalf of, Covered Entity. Business Associate shall document and keep these security measures current.

5. Subcontractors and Agents. If Business Associate provides any PHI which was received from, or created for, Covered Entity to a subcontractor or agent, then Business Associate shall require such subcontractor or agent to agree to the same restrictions and conditions as are imposed on Business Associate by this Addendum.
6. Maintenance of the Security of Electronic Information. Business Associate shall develop, implement, maintain and use appropriate administrative, technical and physical security measures to preserve the confidentiality, integrity and availability of all electronically maintained or transmitted Health Information received from, or on behalf of, Covered Entity which pertains to an Individual. Business Associate shall document and keep these security measures current and available for inspection, upon request. Business Associate's security measures must be consistent with HIPAA's Security regulations, Title 45, Part 142 of the Code of Federal Regulations ("Security Rule"), once these regulations are effective.
7. Compliance with Electronic Transactions and Code Set Standards. If Business Associate conducts any Standard Transaction for, or on behalf, of Covered Entity, Business Associate shall comply, and shall require any subcontractor or agent conducting such Standard Transaction to comply, with each applicable requirement of Title 45, Part 162 of the Code of Federal Regulation. Business Associate shall not enter into, or permit its subcontractors or agents to enter into, any Agreement in connection with the conduct of Standard Transactions for or on behalf of Covered Entity that:
 - a. changes the definition, Health Information condition, or use of a Health Information element or segment or in a Standard;
 - b. adds any Health Information elements or segments to the maximum defined Health Information Set;
 - c. uses any code or Health Information elements that are either marked "not used" in the Standard's Implementation Specification(s) or are not in the Standard's Implementation Specifications(s); or
 - d. changes the meaning or intent of the Standard's Implementations Specification(s).
8. Access to PHI. At the direction of Covered Entity, Business Associate agrees to provide access to any PHI held by Business Associate which Covered Entity has determined to be part of Covered Entity's Designated Record Set, in the time and manner designated by Covered Entity. This access will be provided to Covered Entity or, as directed by Covered Entity, to an Individual, in order to meet the requirements under the Privacy Rule.
9. Amendment or Correction to PHI. At the direction of Covered Entity, Business Associate agrees to amend or correct PHI held by Business Associate and which Covered Entity has determined to be part of Covered Entity's Designated Record Set, in the time and manner designated by Covered Entity.
10. Reporting of Unauthorized Disclosures or Misuse of PHI. Business Associate shall report to Covered Entity any use or disclosure of PHI not authorized by this Addendum or in writing by Covered Entity. Business Associate shall make the report to Covered Entity's Privacy Official not less than one (1) business day after Business Associate learns of such use or disclosure. Business Associate's report shall identify: (i) the nature of the unauthorized use or disclosure, (ii) the PHI used or disclosed, (iii) who made the unauthorized use or received the unauthorized disclosure, (iv) what Business Associate has done or shall do to mitigate any deleterious effect of the unauthorized use or disclosure, and (v) what corrective action Business Associate has taken or shall take to prevent future similar unauthorized use or disclosure. Business Associate shall provide such other information, including a written report, as reasonably requested by Covered Entity's Privacy Official.
11. Mitigating Effect of Unauthorized Disclosures or Misuse of PHI. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a misuse or unauthorized disclosure of PHI by Business Associate in violation of the requirements of this Addendum.
12. Tracking and Accounting of Disclosures. Business Associate must follow (a) and (b) below so the Covered Entity may meet its accounting obligations under the Privacy Rule.
 - a. Disclosure Tracking. Starting April 14, 2003, for each disclosure not excepted under subsection (b) below, Business Associate will record for each disclosure of PHI it makes to Covered Entity or a third party of PHI that Business Associate creates or receives for or from Covered Entity (i) the disclosure date, (ii) the name

and (if known) address of the person or entity to whom Business Associate made the disclosure, (iii) a brief description of the PHI disclosed, and (iv) a brief statement of the purpose of the disclosure. For repetitive disclosures which Business Associate makes to the same person or entity, including the Covered Entity, for a single purpose, Business Associate may provide (i) the disclosure information for the first of these repetitive disclosures, (ii) the frequency, periodicity or number of these repetitive disclosures, and (iii) the date of the last of these repetitive disclosures. Business Associate will make this log of disclosure information available to the Covered Entity within five (5) business days of the Covered Entity's request.

b. **Exceptions from Disclosure Tracking.** Business Associate need not record disclosure information or otherwise account for disclosures of PHI that meet one of the following conditions:

1. prior to April 14, 2003, the compliance date of the rules;
2. for purposes of treatment of the patient, such as disclosures made to dispense a prescription;
3. for payment activities, including billing, claims management, eligibility determinations, coordination of benefits, determination of cost-sharing amounts and adjudication of health benefit claims;
4. for internal (pharmacy specific) health care operations, including management and administrative activities, patient service, quality assessment and improvement, training programs, auditing, compliance, business planning and development and certain due diligence activities conducted in connection with the sale or transfer of assets;
5. to the individual who is the subject of the disclosed PHI
6. to individuals involved in the patient's care where the patient verbally agreed to the disclosure;
7. to authorized federal officials for the conduct of lawful intelligence, counter-intelligence, and certain other national security activities;
8. to a correctional institution or law enforcement official, upon a request by, and during such time as, the correctional institution or law enforcement official had lawful custody of the patient;
9. incident to a use or disclosure that is otherwise permitted by the privacy rules;
10. pursuant to a valid patient authorization; or
11. as part of a limited data set that was disclosed pursuant to a data use agreement for purposes of research, public health or health care operations.

c. **Disclosure Tracking Time Periods.** Business Associate must have available for Covered Entity the disclosure information required by this section for the six-year period preceding Covered Entity's request for the disclosure information (except Business Associate need have no disclosure information for disclosures occurring before April 14, 2003).

13. **Accounting to Covered Entity and to Government Agencies.** Business Associate shall make its internal practices, books, and records relating to the use and disclosure of PHI received from or on behalf of, or created for, Covered Entity available to Covered Entity, or at the request of Covered Entity, to the Secretary of the Department of Health and Human Services (HHS) or his/her designee, in a time and manner designated by Covered Entity or the Secretary or his/her designee, for the purpose of determining Covered Entity's compliance with the Privacy Rule. Business Associate shall promptly notify Covered Entity of Communications with HHS regarding PHI provided by or created by Covered Entity and shall provide Covered Entity with copies of any information Business Associate has made available to HHS under this provision.

14. **Terms and Termination.**

- a. This Addendum shall take effect immediately upon the signing of this document by both parties involved
- b. In addition to the rights of the parties established by the underlying Agreement, if Covered Entity reasonably determines in good faith that Business Associate has materially breached any of its obligations under this Addendum, Covered Entity, in its sole discretion, shall have the right to:
 - (i) exercise any of its rights to reports, access and inspection under this Addendum; and/or

- (ii) require Business Associate to submit to a plan of monitoring and reporting, as Covered Entity may determine necessary to maintain compliance with this Addendum; and/or
- (iii) provide Business Associate with a 10 business day period to cure the breach; or
- (iv) terminate the Agreement immediately.

- c. Before exercising any of these options, Covered Entity shall provide written notice to Business Associate describing the violation and the action it intends to take.
- d. If neither termination or cure are feasible, Covered Entity shall report the violation to HHS.

15. Return or Destruction of PHI. Upon termination, cancellation, expiration or other conclusion of the Agreement, Business Associate shall:

- a. Return to Covered Entity or, if return is not feasible, destroy all PHI and Health Information in whatever form or medium Business Associate received from or created on behalf of Covered Entity. This provision shall also apply to all PHI that is in the possession of subcontractors or agents of Business Associate. In such case, Business Associate shall retain no copies of such information, including any compilations derived from and allowing identification of PHI. Business Associate shall complete such return or destruction as promptly as possible, but not less than thirty (30) days after the effective date of the conclusion of this Agreement. Within such thirty (30) Day period, Business Associate shall certify on oath in writing to Covered Entity that such return or destruction has been completed.
- b. If Business Associate believes the return or destruction of PHI or Health Information is not feasible, Business Associate shall provide written notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the Parties that return or destruction is not feasible, Business Associate shall extend the protections of this Addendum to PHI and Health Information received from or created on behalf of Covered Entity, and limit further uses and disclosures of such PHI, for so long as Business Associate maintains the PHI.

16. Miscellaneous.

- a. Automatic Amendment. Upon the effective date of any amendment to the regulations promulgated by HHS with regard to PHI, this Addendum shall automatically amend so the obligations imposed on Business Associate remain in compliance with such regulations.
- b. Interpretation. Any ambiguity in this Addendum shall be resolved in favor of a meaning that permits Covered Entity to comply with the Privacy Rule.
- c. Indemnification. Business Associate shall defend and hold Covered Entity harmless from all claims, liabilities, damages or judgments involving a third party, including Covered Entity's costs and attorney fees, which arise as a result of Business Associate's failure to meet any of its obligations under this Addendum.

IN WITNESS WHEREOF, each of the undersigned has caused this Addendum to be duly executed in its name and on its behalf.

COVERED ENTITY

BUSINESS ASSOCIATE

By: _____

By: _____

David M. Miller, R.Ph. Privacy Officer
 Millers of Wyckoff
 678 Wyckoff Avenue Wyckoff, NJ 07481

Printed: _____

Title: _____

Date: _____

Date: _____