

COLLABORATION AGREEMENT

BETWEEN

ONECARE VERMONT ACCOUNTABLE CARE ORGANIZATION, LLC (“ACO”)

AND

<xcd_contract_desc>

This Collaboration Agreement (the “Agreement”) is made as of the date it has been signed by OneCare Vermont Accountable Care Organization, LLC’s Chief Executive Officer, and indicated on the signature page of the agreement (the “Effective Date”), by and between **OneCare Vermont Accountable Care Organization, LLC (“ACO”)**, organized under the laws of the State of Vermont, and **<xcd_contract_desc>** (“Collaborator”), with the tax identification number (“TIN”) listed on the signature page hereto (collectively, the “Parties” and each, individually a “Party”).

WHEREAS, ACO is participating in the All Payer Model, including Medicare NextGeneration, Medicaid NextGeneration and Commercial NextGeneration Blue Cross programs and may participate in other value based payment arrangements (collectively, the “Programs”);

WHEREAS, Collaborator is an entity that provides for, arranges for or manages health care services and/or social support services in the ACO service area or otherwise supports the activities and goals of the ACO and desires to engage in functions or services with the ACO related to ACO activities;

WHEREAS, ACO and Collaborator are committed to improving the quality, cost and overall care of individuals attributed under the Programs and while Collaborator will not attribute individual lives to ACO, it desires to assist ACO to successfully meet its goals of better health, better healthcare, and reduced healthcare cost growth; and

WHEREAS, the sharing of de-identified data relating to quality and utilization is a necessary part of the Parties’ ability to meet the goals of this Agreement.

NOW, THEREFORE, the Parties agree as follows:

1.0 COLLABORATOR SERVICES

- 1.1 Collaborator shall support and assist ACO and ACO related activities which includes, but is not limited to: participating in Community Collaborative Committees; assisting ACO in a collaborative fashion to accomplish its triple aim; supporting and assisting with care coordination; supporting and assisting in the development, maintenance and implementation of the Clinical Model; supporting and assisting with applicable ACO case

management protocols and ACO Policies and Procedures; and supporting or assisting with other mutually defined goals.

- 1.2 Collaborator shall comply with all applicable laws, regulations and payment program requirements that are applicable to its services. This includes, but is not limited to, federal laws such as the False Claims Act, Anti-Kickback Laws, Civil Monetary Penalties Laws, HIPAA, Stark and anti-discrimination. The provisions of this Section 1.2 shall survive termination of this Agreement for any reason.
- 1.3 Collaborator shall hold confidential all confidential and proprietary information and all Data provided to or shared with it by ACO during the performance of this Agreement and will comply with the terms of the Business Associate Agreement attached hereto as **Exhibit 1**, the Data Use Agreement Addendum attached hereto as **Exhibit 2** (originally applicable to MSSP & VMSSP data, and now applicable to Medicare and Medicaid NextGen data as required in those program agreements), and ACO's Data Use Policies and Procedures. Collaborator may not disseminate or share any Data with any person or entity other than ACO employees; ACO Participants and/or ACO Affiliate Participants in the ACO Program from which the Data originated. The terms of this Section 1.3 shall survive termination of this Agreement for any reason.
- 1.4 Collaborator may not create or distribute any marketing or other materials that reference ACO, or Collaborator's participation in any ACO Program without ACO's express, written consent.
- 1.5 Collaborator acknowledges that CMS, DHHS, the Comptroller General, the federal government or its designees, DVHA or GCMCB have the right under various ACO Programs to monitor, investigate, audit, inspect or evaluate any books, contracts, records, documents or other evidence of services or functions related to ACO Programs. Collaborator agrees to cooperate and assist those parties and ACO in connection with any such activity, including allowing reasonable access to records and facilities to regulators with authority.
- 1.6 Collaborator agrees to maintain for ten (10) years from the final date of this Agreement all books, contracts, records, documents or other evidence of the performance of services or functions related to ACO activities. If there is a termination, dispute or allegation of fraud or similar fault against the Collaborator, Collaborator agrees to maintain such materials for an additional six (6) years (or sixteen (16) years total).

2.0 TERM & TERMINATION

- 2.1 The term of this Agreement shall commence on the Effective Date and shall continue in effect until one Party gives notice of intention to terminate no less than ninety (90) days before the effective date of termination.

3.0 GENERAL PROVISIONS

- 3.1 Amendments. This Agreement may be amended or modified in writing as mutually agreed upon by the Parties, or as provided in this Agreement. In addition, ACO may unilaterally modify any provision of this Agreement and its Exhibits, Attachments and Riders upon thirty (30) days prior written notice to Collaborator, or immediately upon receipt by Collaborator if such modification is made to comply with federal or state laws or other regulatory bodies.
- 3.2 Independent Contractor Relationship. None of the provisions of this Agreement between or among ACO, Collaborator, or Payors create a relationship other than that of independent entities contracting solely for the purposes of effecting the provisions of this Agreement.
- 3.3 No Third-Party Beneficiaries. Except as specifically provided herein by express language, no person or entity shall have any rights, claims, benefits, or powers under this Agreement, and this Agreement shall not be construed or interpreted to confer any rights, claims, benefits or powers upon any third party.
- 3.4 Notices. Notices and other communications required by this Agreement shall be deemed to have been properly given if mailed by first-class mail, postage prepaid, or hand delivered to the following address:
- OneCare Vermont Accountable Care Organization, LLC
356 Mountain View Drive, Suite 301
Colchester, VT 05446
Attn: Director of Contracting
- Collaborator
<send_full_address>
Attention: _____
- 3.5 Counterparts, Signatures. This Agreement may be executed in multiple counterparts, each of which shall be deemed an original, but all of which shall constitute one and the same instrument and shall be effective when OneCare Vermont has executed its counterpart. Any signature delivered by facsimile machine, or by .pdf, .tif, .gif, .peg or other similar attachment shall be treated in all manner and respects as an original executed counterpart and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person.
- 3.6 Applicable Law. This Agreement, together with all of the respective rights of the parties hereto, shall be governed by and construed and enforced in accordance with the laws of the State of Vermont.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by the duly authorized officers to be effective as of the Effective Date indicated above.

ONECARE VERMONT ACCOUNTABLE CARE ORGANIZATION, LLC

By: _____
Todd B. Moore
Chief Executive Officer

Effective Date: _____

<xcd_contract_desc>

By: _____
Authorized Signature

Print Name: _____

TIN: <xcd_tin>

Date: _____

EXHIBIT 1

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Addendum (the “Addendum”) is entered into by and between **OneCare Vermont Accountable Care Organization, LLC** (“ACO”) and Collaborator (“Business Associate”).

RECITALS

ACO and Business Associate are parties to this Collaboration Agreement (the “Agreement”) pursuant to which Business Associate provides certain services to ACO and, in connection with those services, ACO discloses to Business Associate certain Protected Health Information (“PHI”) that is subject to protection under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and Title XIII, The Health Information Technology for Economic and Clinical Health Act (“HITECH”), of the American Recovery and Reinvestment Act (“ARRA”).

The parties desire to comply with the requirements set forth in the Privacy and Security Regulations and HITECH concerning the privacy of PHI.

The purpose of this Addendum is to comply with the requirements of the Privacy Rule, the Security Rule, HITECH and, if applicable, 42 CFR Part 2 including but not limited to the Business Associate Requirements at 45 C.F.R. Section 164.504(e).

Therefore, in consideration of the mutual promises and covenants contained herein, the parties agree as follows:

SECTION I – DEFINITIONS

- 1.1 Definitions. Unless otherwise provided in this Agreement, capitalized terms shall have the same meaning as set forth in the HIPAA regulations, 45 C.F.R. Sections 160 and 164, and HITECH and its related regulations or under 42 CFR Section 2.11.

SECTION II – OBLIGATIONS OF BUSINESS ASSOCIATE

- 2.1 Use/Disclosure of PHI. In connection with its use and disclosure of PHI, Business Associate agrees that it shall use and/or disclose PHI only as permitted or required by this Addendum or as otherwise required by law.
- 2.2 Safeguards for Protection of PHI. Business Associate agrees to use reasonable and appropriate safeguards to prevent the use or disclosure of PHI other than as provided in this Addendum.
- 2.3 Compliance with HITECH Act and Regulations. Business Associate will comply with the requirements of HITECH, codified at 42 U.S.C. §§ 17921-17954, which are applicable to Business Associate, and will comply with all regulations issued by the Department of Health and Human Services to implement these referenced statutes, as of

the date by which Business Associate is required to comply with such referenced statutes and HHS regulations.

- 2.4 General Reporting. Business Associate shall report to ACO any use or disclosure of PHI which is not provided for by this Agreement of which Business Associate becomes aware.
- 2.5 Reporting of Breaches of Unsecured Protected Health Information. Business Associate will report in writing to ACO's Privacy Officer any breach of unsecured PHI, as defined in the breach notification regulations, within ten (10) business days of the date Business Associate learns of the incident giving rise to the breach. Business Associate will provide such information to ACO as required in the regulations. Business Associate will reimburse ACO for any reasonable expenses ACO incurs in notifying individuals of a breach caused by Business Associate or Business Associate's subcontractors or agents, and for reasonable expenses ACO incurs in mitigating harm to those Individuals. Business Associate also will defend, hold harmless and indemnify ACO and its employees, agents, officers, directors, members, contractors, and subsidiary and affiliate entities, from and against any claims, losses, damages, liabilities, costs, expenses, penalties or obligations (including attorneys' fees) which ACO may incur due to a breach caused by Business Associate or Business Associate's subcontractors or agents.
- 2.6 Mitigation. Business Associate shall make reasonable efforts to mitigate, to the greatest extent possible, any harmful effects arising from any improper use and/or disclosure of PHI.
- 2.7 Subcontractors. Business Associate shall ensure that any agents, including any subcontractor, to whom it provides PHI, shall agree to the same restrictions and conditions that apply to Business Associate with respect to PHI.
- 2.8 Access by Individuals. Business Associate shall allow individuals who are the subject of the PHI to inspect and copy their PHI in the possession of Business Associate if ACO does not also maintain such information.
- 2.9 Access by Department of Health and Human Services. Business Associate shall make its internal practices, books, and records relating to the use and disclosure of PHI available to the Secretary of the Department of Health and Human Services for purposes of determining ACO's compliance with the HIPAA privacy regulations.
- 2.10 Access by ACO. Upon reasonable notice, Business Associate shall make its internal practices, book, and records relating to the use and disclosure of PHI available to ACO for purposes of determining Business Associate's compliance with the terms of this Agreement and Business Associate's compliance with HIPAA and HITECH.
- 2.11 Accountings of Disclosures. If Business Associate discloses any PHI, Business Associate shall make available to ACO the information necessary for ACO to provide an accounting of disclosures to any individual who requests such an Accounting, or, in the

alternative, Business Associate shall provide an accounting of disclosures directly to the requesting individual, if requested by ACO.

- 2.12 Amendment of PHI. Business Associate agrees to make any amendment(s) to PHI in a designated record set that ACO directs or agrees to pursuant to ACO's obligations under the Privacy Rule.

SECTION III – PERMITTED USES AND DISCLOSURES

- 2.1 General. Except as otherwise limited in this Addendum, Business Associate may use or disclose PHI to perform functions, activities, or services for, or on behalf of, ACO as specified in the Agreement, provided that such use or disclosure would not violate the Privacy Rule if done by ACO.

SECTION IV – SECURITY

- 4.1 Compliance with Security Rule. Business Associate agrees to implement the Security Rule (security standards as set out in 45 C.F.R. parts 160, 162 and 164), Administrative, Physical and Technical Safeguards that reasonably and appropriately protect the Confidentiality, Integrity, and Availability of the electronic PHI that Business Associate creates, receives, maintains, or transmits on behalf of the Covered Entity.
- 4.2 Reporting. Business Associate agrees to report to Covered Entity any security incident of which it becomes aware.
- 4.3 Agents Compliance with Business Associate Addendum. Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides PHI received from, or created or received by, Business Associate on behalf of ACO agrees to the same restrictions and conditions that apply through this Addendum to Business Associate with respect to such information.
- 4.4 Agents Compliance with Security Rule. Business Associate will ensure that any agent, including a subcontractor, to whom it provides electronic PHI agrees to implement the Security Rule, Administrative, Physical and Technical Safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic PHI.
- 4.5 Records Availability. Business Associate agrees to make its policies, procedures, and documentation relating to the safeguards described herein available to the Secretary, for purposes of the Secretary determining ACO's compliance with the Security Rule.

SECTION V – TERM & TERMINATION

- 5.1 Term and Termination. This Addendum shall be effective as of effective date of the Agreement and shall terminate when all of the PHI provided by ACO to Business Associate, or created or received by Business Associate on behalf of ACO, is destroyed or returned to ACO. The parties acknowledge and agree that the terms and conditions

stipulated in this Agreement shall apply to any future written or oral agreements between ACO and Business Associate which require the disclosure of PHI, whether or not this Agreement is incorporated by reference into future agreements executed between the parties. This Agreement shall terminate in accordance with the termination provisions in the Agreement.

- 5.2 Effect of Termination. Upon termination of the Agreement, for any reason, Business Associate shall, if feasible, return or destroy all PHI that Business Associate still maintains in any form and shall not retain any copies of such PHI. If such return or destruction is not feasible, Business Associate shall extend the protections of this Agreement to the PHI and shall limit further uses and disclosures to those purposes that make the return or destruction of the PHI infeasible.

SECTION VI – MISCELLANEOUS

- 6.1 Amendment. This Addendum shall be deemed to amend automatically, by force of law and without further act of the parties, if necessary to bring the Agreement into compliance with any changes in HIPAA, HITECH or any related regulations that are made after the date of execution of this Agreement.
- 6.2 Interpretation. Any ambiguity in this Addendum shall be resolved in a manner that brings the Addendum into compliance with the then most current version of HIPAA and the HIPAA privacy regulations.
- 6.3 No Third Party Beneficiaries. Nothing express or implied in this Addendum is intended to confer, nor shall anything herein confer, upon any other person other than the parties and their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever.

EXHIBIT 2

DATA USE AGREEMENT

A. General

1. Subject to the limitations discussed in this Agreement, and in accordance with applicable law, in advance of the Start Date and at any other time deemed necessary by CMS, CMS will offer the ACO an opportunity to request certain data and reports, which are described in Sections VI.B, VI.C, and Appendix D of this Agreement.
2. The data and reports provided to the ACO under the preceding paragraph will omit individually identifiable data for Next Generation Beneficiaries who have opted out of data sharing with the ACO, as described in Section VI.D. of this Agreement. The data and reports provided to the ACO will also omit substance use disorder data for any Next Generation Beneficiaries who have not opted into substance use disorder data sharing, as described in Section VI.E. of this Agreement.

B. Provision of Certain Claims Data

1. CMS believes that the care coordination and quality improvement work of the ACO (that is acting on its own behalf as a HIPAA covered entity (“CE”) or who is a business associate (“BA”) acting on behalf of its Next Generation Participants or Preferred Providers that are HIPAA CEs) would benefit from the receipt of certain beneficiary-identifiable claims data on Next Generation Beneficiaries. CMS will therefore offer to the ACO an opportunity to request specific beneficiary-identifiable claims data by completing the HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet (Appendix D). All requests for beneficiary-identifiable claims data will be granted or denied at CMS’ sole discretion based on CMS’ available resources, the limitations in this Agreement, and applicable law.
2. In offering this beneficiary-identifiable claims data, CMS does not represent that the ACO or any Next Generation Participant or Preferred Provider has met all applicable HIPAA requirements for requesting data under 45 CFR § 164.506(c)(4). The ACO and its Next Generation Participants and Preferred Providers should consult with their own counsel to make those determinations prior to requesting this data from CMS.
3. The beneficiary-identifiable claims data available is the data described in Appendix D.
4. The parties mutually agree that, except for data covered by Section VI.B.13 below, CMS retains all ownership rights to the data files referred to in Appendix D, and the ACO does not obtain any right, title, or interest in any of the data furnished by CMS.
5. The ACO represents, and in furnishing the data files specified in Appendix D

CMS relies upon such representation, that such data files will be used solely for the purposes described in this Agreement. The ACO agrees not to disclose, use or reuse the data except as specified in this Agreement or except as CMS shall authorize in writing or as otherwise required by law. The ACO further agrees not to sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement.

6. The ACO intends to use the requested information as a tool to deliver seamless, coordinated care for Next Generation Beneficiaries to promote better care, better health, and lower growth in expenditures. Information derived from the CMS files specified in Appendix D may be shared and used within the legal confines of the ACO and its Next Generation Participants and Preferred Providers in a manner consistent with paragraph 7 below to enable the ACO to improve care integration and be a patient-centered organization.
7. The ACO may reuse original or derivative data without prior written authorization from CMS for clinical treatment, care management and coordination, quality improvement activities, and provider incentive design and implementation, but shall not disseminate individually identifiable original or derived information from the files specified in Appendix D to anyone who is not a HIPAA CE Next Generation Participant or Preferred Provider in a treatment relationship with the subject Next Generation Beneficiary(ies); a HIPAA BA of such a CE Next Generation Participant or Preferred Provider; the ACO's BA, where that ACO is itself a HIPAA CE; the ACO's sub-BA, which is hired by the ACO to carry out work on behalf of the CE Next Generation Participants or Preferred Providers; or a non-participant HIPAA CE in a treatment relationship with the subject Next Generation Beneficiary(ies). When using or disclosing PHI or personally identifiable information ("PII"), obtained from files specified in Appendix D, the ACO must make "reasonable efforts to limit" the information to the "minimum necessary" to accomplish the intended purpose of the use, disclosure or request. The ACO shall further limit its disclosure of such information to the types of disclosures that CMS itself would be permitted make under the "routine uses" in the applicable systems of records listed in Appendix D.

Subject to the limits specified above and elsewhere in this Agreement and applicable law, the ACO may link individually identifiable information specified in Appendix D (including directly or indirectly identifiable data) or derivative data to other sources of individually-identifiable health information, such as other medical records available to the ACO and its Next Generation Participants or Preferred Providers. The ACO may disseminate such data that has been linked to other sources of individually identifiable health information provided such data has been de-identified in accordance with HIPAA requirements in 45 CFR § 164.514(b).

8. The ACO agrees to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use or access to it. The safeguards shall provide a level and scope of security that

is not less than the level and scope of security requirements established for federal agencies by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix I--Responsibilities for Protecting and Managing Federal Information Resources (https://www.whitehouse.gov/omb/circulars_default) as well as Federal Information Processing Standard 200 entitled "Minimum Security Requirements for Federal Information and Information Systems" (<http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf>); and, NIST Special Publication 800-53 "Recommended Security Controls for Federal Information Systems" (<http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf>). The ACO acknowledges that the use of unsecured telecommunications, including the Internet, to transmit directly or indirectly identifiable information from the files specified in Appendix D or any such derivative data files is strictly prohibited. Further, the ACO agrees that the data specified in Appendix D must not be physically moved, transmitted or disclosed in any way from or by the site of the custodian indicated in Appendix D other than as provided in this Agreement without written approval from CMS, unless such movement, transmission or disclosure is required by a law.

9. The ACO agrees to grant access to the data and/or the facility(ies) in which the data is maintained to the authorized representatives of CMS or DHHS Office of the Inspector General, including at the site of the custodian indicated in Appendix D, for the purpose of inspecting to confirm compliance with the terms of this Agreement.
10. The ACO agrees that any use of CMS data in the creation of any document concerning the purpose specified in this section and Appendix D must adhere to CMS' current cell size suppression policy. This policy stipulates that no cell (e.g., admittances, discharges, patients, services) representing 10 or fewer beneficiaries may be displayed. Also, no use of percentages or other mathematical formulas may be used if they result in the display of a cell representing 10 or fewer beneficiaries.
11. The ACO agrees to report any breach of PHI or PII from or derived from the CMS data files, loss of these data or improper use or disclosure of such data to the CMS Action Desk by telephone at (410) 786-2850 or by email notification at cms_it_service_desk@cms.hhs.gov within one hour. Furthermore, the ACO agrees to cooperate fully in any federal incident security process that results from such improper use or disclosure.
12. The parties mutually agree that the individual named in Appendix D is designated as Custodian of the CMS data files on behalf of the ACO and will be responsible for the observance of all conditions of use and disclosure of such data and any derivative data files, and for the establishment and maintenance of security arrangements as specified in this Agreement to prevent unauthorized use or disclosure. Furthermore, such Custodian is responsible for contractually binding any downstream recipients of such data to the terms and conditions in this Agreement as a condition of receiving such data. The ACO agrees to notify CMS

within fifteen (15) days of any change of custodianship. The parties mutually agree that CMS may disapprove the appointment of a custodian or may require the appointment of a new custodian at any time.

13. Data disclosed to the ACO pursuant to Appendix D may be retained by the ACO until the conclusion or termination of this Agreement. The ACO is permitted to retain any individually identifiable health information from such data files or derivative data files after the conclusion or termination of the Agreement if the ACO is a HIPAA CE, and the data has been incorporated into the subject Beneficiaries' medical records that are part of a designated record set under HIPAA. Furthermore, any HIPAA CE to whom the ACO provides such data in the course of carrying out the Model initiative may also retain such data if the recipient entity is a HIPAA CE or BA and the data is incorporated into the subject Beneficiaries' medical records that are part of a designated record set under HIPAA. The ACO shall destroy all other data and send written certification of the destruction of the data files and/or any derivative data files to CMS within 30 days following the conclusion or termination of the Agreement. Except for disclosures for treatment purposes, the ACO shall bind any downstream recipients to these terms and conditions as a condition of disclosing such data to downstream entities and permitting them to retain such records under this paragraph. These retention provisions survive the conclusion or termination of the Agreement.

C. De-Identified Reports

CMS will provide the following reports to the ACO, which will be de-identified in accordance with HIPAA requirements in 45 CFR § 164.514(b):

1. [Monthly Financial Reports](#)

These reports will include monthly and year-to-date information on total Medicare expenditures and expenditures for selected categories of services for Next Generation Beneficiaries. This aggregate information will not include individually identifiable health information and will incorporate de-identified data from Next Generation Beneficiaries who have opted out of data sharing.

2. [Quarterly Benchmark Reports](#)

CMS will provide quarterly benchmark reports ("BRs") to the ACO to monitor ACO financial performance throughout the year. The BRs will not contain individually identifiable data. The design and data source used to generate the BRs is also used for the final year-end settlement report, as described in Section XIV.C. In the event that data contained in the BRs conflicts with data provided from any other source, the data in the BRs will control with respect to settlement under Section XIV.B of the Agreement.

D. Beneficiary Rights to Opt Out of Data Sharing

1. The ACO shall provide Next Generation Beneficiaries who inquire about or wish to modify their preferences regarding claims data sharing for care coordination and quality improvement purposes with information about how to modify their data sharing preferences via 1-800-MEDICARE. Such communications shall note that, even if a Next Generation Beneficiary has elected to decline claims data sharing, CMS may still engage in certain limited data sharing for quality improvement purposes.
2. The ACO shall allow Next Generation Beneficiaries to reverse a data sharing preference at any time by calling 1-800-MEDICARE.
3. CMS will maintain the data sharing preferences of Beneficiaries who elect to decline data sharing in this Model or who have previously declined data sharing under the MSSP or the Pioneer ACO Model.
4. The ACO may affirmatively contact a Next Generation Beneficiary who has elected to decline claims data sharing no more than one time in the Performance Year to provide information regarding data sharing. Such contact includes mailings, phone calls, electronic communications, or other methods of communicating with Next Generation Beneficiaries outside of a clinical setting.
5. In the event that a Next Generation Professional is terminated from the ACO for any reason, if that departing Next Generation Professional is the sole Next Generation Professional in the ACO to have submitted claims for a particular Next Generation Beneficiary during the 12-month period prior to the effective date of the termination, CMS will administratively opt the Next Generation Beneficiary out of all claims data-sharing under this Section VI within 30 days of the effective date of the termination, unless—
 - (a) The Next Generation Beneficiary affirmatively consents to continued data sharing of such claims with the ACO through an authorization that meets the requirements under 45 CFR § 164.508(b); or
 - (b) The Next Generation Beneficiary has become the patient of another Next Generation Professional participating in the ACO.
6. Notwithstanding the foregoing, an ACO shall receive claims data regarding substance use disorder treatment only if the Next Generation Beneficiary has not elected to decline data sharing or otherwise been opted out of data sharing and has also submitted a CMS-approved form pursuant to Section VI.E of this Agreement.

E. Beneficiary Substance Use Disorder Data Opt-In

1. The ACO may inform each newly-aligned Next Generation Beneficiary, in compliance with applicable law:
 - (a) That he or she may elect to allow the ACO to receive beneficiary-identifiable data regarding his or her utilization of substance use disorder services;
 - (b) Of the mechanism by which the Next Generation Beneficiary can make

this election; and

- (c) That 1-800-Medicare will answer any questions regarding sharing of data regarding utilization of substance use disorder services.
- 2. A Next Generation Beneficiary may opt in to substance use disorder data sharing only by submitting a CMS-approved substance use disorder opt in form to the ACO. The ACO shall promptly send the opt-in form to CMS