Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
Seamless Care Models Group
7205 Windsor Blvd
Baltimore, MD 21244

DC Model
Implementation Period Participation Agreement
Global and Professional Options

Last Modified: September 1, 2020

Contents

PARTICIPATION AGREEMENT

This Participation Agreement ("**Agreement**") is between the CENTERS FOR MEDICARE & MEDICAID SERVICES ("**CMS**") and _____, a Direct Contracting Entity ("**DCE**").

CMS is the agency within the U.S. Department of Health and Human Services ("HHS") that is charged with administering the Medicare and Medicaid programs.

A Medicare DCE is an entity composed of health care providers operating under a common legal structure, which accepts financial accountability for the overall quality and cost of medical care furnished to Medicare fee-for-service ("**FFS**") Beneficiaries aligned to the entity.
CMS is implementing the Direct Contracting Model ("**Model**") under section 1115A of the Social Security Act ("**Act**"), which authorizes CMS, through its Center for Medicare and Medicaid Innovation, to test innovative payment and service delivery models that have the potential to reduce Medicare, Medicaid, or Children's Health Insurance Program expenditures while maintaining or improving the quality of beneficiaries' care.

The Model seeks to reduce Medicare FFS expenditures while improving the quality of care and health outcomes for Medicare FFS Beneficiaries through financial incentives, emphasis on beneficiary choice, strong monitoring to ensure that Beneficiaries maintain access to care, and an emphasis on care delivery for Beneficiaries with complex, chronic, and serious illness. The DCE has selected to participate in one of two Risk-Sharing Options offered under this Agreement: (1) a higher-risk option, under which the DCE assumes 100 percent risk for savings or losses and can select either Total Care Capitation Payment or Primary Care Capitation Payment as its DC Capitation Payment Mechanism ("**Global**"); or (2) a lower-risk option under which the DCE assumes 50 percent risk for savings or losses and must select Primary Care Capitation Payment as its DC Capitation Payment Mechanism ("**Professional**").

The DCE submitted an application to participate in the DC Model, and CMS has approved the DCE for participation in the Model.

This Agreement outlines the obligations and responsibilities of the parties during the Implementation Period, during which the DCE may engage in Marketing Activities, including Voluntary Alignment Activities; care coordination; quality improvement; and other activities as needed to prepare for participation in the Model during the Model Performance Period. The Implementation Period will be followed by a five-year Model Performance Period that will be governed by a separate agreement between CMS and the DCE.

The parties therefore agree as follows:

ARTICLE I Agreement Term

Section 1.01 This Agreement will become effective upon execution by both parties (the "**Effective Date**").

Section 1.02 The Implementation Period of this Agreement will begin on October 1, 2020 (the "**Start Date**"), and ends on March 31, 2021.

Section 1.03 This Agreement will automatically expire upon the conclusion of the Implementation Period. The DCE must sign a new agreement with CMS for the Model Performance Period in order to participate in the Model during the Model Performance Period. Any such agreement will authorize CMS to take remedial action against the DCE for non-compliance with the terms of this Agreement, regardless of when the non-compliance is discovered by CMS.

ARTICLE II Definitions

The parties agree that the following definitions apply for purposes of the Implementation Period:

"**Alignment Methodology**" means the methodology selected by the DCE pursuant to Section 8.02 that determines the frequency with which DC Beneficiaries are aligned to the DCE. The two Alignment Methodologies include Prospective Alignment and Prospective Plus Alignment.

"**Advanced Payment**" means a supplemental payment mechanism that may be selected by the DCE for the first Performance Year pursuant to Section 8.02 if the DCE also has selected the Primary Care Capitation Payment for that Performance Year. Under Advanced Payment, CMS will reduce the payment amount for FFS claims submitted by those DC Participant Providers and Preferred Providers who have opted to participate in Advanced Payment by a percentage determined by the DCE, with the exception of those FFS claims subject to Primary Care Capitation Payment, and make a prospective payment to the DCE equal to the aggregate amount of such payment reductions.

"**At Risk Beneficiary**" means a Beneficiary who—

A. Has a high risk score on the CMS-Hierarchical Condition Category (HCC) risk adjustment model;

B. Is considered high cost due to having two or more hospitalizations or emergency room visits each year;

C. Is dually eligible for Medicare and Medicaid;

D. Has a high utilization pattern;

E. Has one or more chronic conditions;

F. Has had a recent diagnosis that is expected to result in increased cost;

G. Is entitled to Medicaid because of disability;

H. Is diagnosed with a mental health or substance use disorder; or

I. Meets such other criteria as specified in writing by CMS.

"**Beneficiary**" means an individual who is enrolled in FFS Medicare.

"**Beneficiary Engagement Incentives**" means the incentives the DCE chooses to make available to DC Beneficiaries through DC Participant Providers and Preferred Providers in order to support high-value services and allow the DCE to more effectively manage the care of DC

Beneficiaries. The DCE may select one or more Beneficiary Engagement Incentives for the first Performance Year of the Model Performance Period pursuant to Section 8.02.

"**Benefit Enhancements**" means the enhanced benefits the DCE chooses to make available to DC Beneficiaries through DC Participant Providers and Preferred Providers in order to support high-value services and allow the DCE to more effectively manage the care of DC Beneficiaries. The DCE may select one or more Benefit Enhancements for the first Performance Year of the Model Performance Period pursuant to Section 8.02.

"**CCN**" means a CMS Certification Number.

"**Claims-Based Alignment**" means an analysis of certain Primary Care Qualified Evaluation & Management (PQEM) Services furnished by DC Professionals to Beneficiaries used to align Beneficiaries to the DCE.

"**Covered Services**" means the scope of health care benefits described in sections 1812 and 1832 of the Act for which payment is available under Part A or Part B of Title XVIII of the Act.

"**Days**" means calendar days unless otherwise specified.

"**DC Capitation Payment Mechanism**" means a payment mechanism that may be selected by the DCE for the first Performance Year of the Model Performance Period pursuant to Section 8.02, under which CMS will make periodic payments to the DCE during the Performance Year. The DC Capitation Payment Mechanisms available for selection include Primary Care Capitation Payment and Total Care Capitation Payment.

"**DCE Activities**" means activities related to promoting accountability for the quality, cost, and overall care for a population of DC Beneficiaries, including managing and coordinating care; encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery; or carrying out any other obligation or duty of the DCE under this Agreement. Examples of these activities include, but are not limited to, providing direct patient care in a manner that reduces costs and improves quality; promoting evidence-based medicine and patient engagement; coordinating care, such as through the use of telehealth, remote patient monitoring, and other enabling technologies; establishing and improving clinical and administrative systems for the DCE; evaluating health needs; communicating clinical knowledge and evidence-based medicine; and developing standards for Beneficiary access and communication, including Beneficiary access to medical records.

"**DC Beneficiary**" means a Beneficiary who is aligned to the DCE using the methodology set forth in Appendix B and who has not subsequently been excluded from the aligned population of the DCE.

"**DC Participant Provider**" means an individual or entity that satisfies the requirements of Section 4.01.A.

"**DC Participant Provider List**" means the list that identifies each DC Participant Provider that is approved by CMS for participation in the Model for the Implementation Period or for a Performance Year.

"**DC Professional**" means a DC Participant Provider who is any one of the following:

A. A physician (as defined in section 1861(r) of the Act); or

B. One of the following non-physician practitioners:

a. Physician assistant who satisfies the qualifications set forth at 42 CFR §410.74(a)(2)(i)-(ii);

b. Nurse practitioner who satisfies the qualifications set forth at 42 CFR §410.75(b);

c. Clinical nurse specialist who satisfies the qualifications set forth at 42 CFR §410.76(b);

d. Certified registered nurse anesthetist (as defined at 42 CFR §410.69(b));

e. Certified nurse midwife who satisfies the qualifications set forth at 42 CFR § 410.77(a);

f. Clinical psychologist (as defined at 42 CFR §410.71(d));

g. Clinical social worker (as defined at 42 CFR §410.73(a)); or

h. Registered dietician or nutritional professional (as defined at 42 CFR §410.314).

"**Electronic Voluntary Alignment**" means the process by which a Beneficiary may voluntarily align with the DCE by designating a DC Participant Provider as the Beneficiary's primary clinician on MyMedicare.gov. CMS uses the Beneficiary's Electronic Voluntary Alignment in performing Beneficiary alignment as described in Section 5.01 and Appendix C.

"**Implementation Period**" means the period of time described in Section 1.02 during which the DCE may engage in Marketing Activities, including Voluntary Alignment Activities; care coordination; quality improvement; and other activities as needed to prepare for participation in the Model during the Model Performance Period. "**Legacy TIN or CCN**" means a TIN or CCN that a DC Participant Provider or Preferred Provider previously used for billing Medicare Parts A and B services but no longer uses to bill for those services, and includes a "sunsetted" Legacy Tin or CCN (a TIN or CCN that is no longer used for billing for Medicare Parts A and B services by any Medicare-enrolled provider or supplier) or an "active" Legacy TIN or CCN (a TIN or CCN that may be in use by a Medicare-enrolled provider or supplier that is not a DC Participant Provider or Preferred Provider).

"**Marketing Activities**" means the distribution of Marketing Materials and other activities, including Voluntary Alignment Activities, conducted by or on behalf of the DCE or its DC Participant Providers or Preferred Providers, when used to educate, notify, or contact Beneficiaries regarding the DCE's participation in the Model.

"**Marketing Events**" means Marketing Activities that are events designed to educate Beneficiaries about the DCE's participation in the Model.

"**Marketing Materials**" means general audience materials such as brochures, advertisements, outreach events, letters to Beneficiaries, webpages published on a website, mailings, social media, or other materials sent by or on behalf of the DCE or its DC Participant Providers or Preferred Providers, when used to educate, notify, or contact Beneficiaries regarding the DCE's participation in the Model. Marketing Materials do not include communications that do not directly or indirectly reference the Model (for example, information about care coordination

generally would not be considered Marketing Materials); materials that cover Beneficiary-specific billing and claims issues; educational information on specific medical conditions; referrals for health care items and services; and any other materials that are excepted from the definition of "marketing" under the HIPAA Privacy Rule (45 CFR Part 160 & Part 164, subparts A & E).

"**Medically Necessary**" means reasonable and necessary as determined in accordance with section 1862(a) of the Act.

"**Model Performance Period**" means the period that begins on January 1 of the first Performance Year that begins after the conclusion of the Implementation Period and ends on December 31 of the final Performance Year.

"**NPI**" means a national provider identifier.

"**Originally Aligned Beneficiary**" means, for purposes of data and reports requested during the Implementation Period, a Beneficiary who is aligned to the DCE on the Start Date using the methodology set forth in Appendix B. For purposes of data and reports requested in advance of the first Performance Year, the term "Originally Aligned Beneficiary" means a Beneficiary who is aligned to the DCE at the start of the first Performance Year using the methodology set forth in Appendix B.

"**Other Monies Owed**" means a monetary amount owed by either CMS or the DCE that represents a reconciliation of payments made by CMS during a Performance Year that is neither Shared Savings nor Shared Losses.

"**Paper-Based Voluntary Alignment**" means the process by which a Beneficiary may voluntarily align with the DCE by using a Voluntary Alignment Form to designate a DC Participant Provider as their main doctor, main provider, and/or the main place they receive care. CMS uses the Beneficiary's Voluntary Alignment Form in performing Beneficiary alignment as described in Section 5.01, Appendix B, and Appendix C.

"Performance Year" means the 12-month period beginning on January 1 of each year during the Model Performance Period, except in the case of the first Performance Year, which will begin on April 1, 2021 and end on December 31, 2021.

"**Performance Year Benchmark**" means the target expenditure amount to which Medicare Part A and Part B expenditures for items and services furnished to DC Beneficiaries during a Performance Year are compared in order to calculate Shared Losses or Shared Savings, as determined by CMS.

"**Preferred Provider**" means an individual or entity that satisfies the requirements of Section 4.01.B.

"**Preferred Provider List**" means the list that identifies each Preferred Provider that is approved by CMS for participation in the Model for the Implementation Period or a Performance Year.

"**Primary Care Capitation Payment**" means a DC Capitation Payment Mechanism available for selection by the DCE pursuant to Section 8.02 that involves a per-Beneficiary-per month payment for enhanced primary care services furnished to DC Beneficiaries by those DC Participant Providers and Preferred Providers participating in the Primary Care Capitation

Payment arrangement with the DCE. If the DCE selects the Primary Care Capitation Payment Mechanism, CMS will reduce the payment amount for FFS claims for enhanced primary care services submitted by those DC Participant Providers and Preferred Providers participating in the Primary Care Capitation Payment arrangement with the DCE. If the DCE selects the Primary Care Capitation Payment Mechanism, the DCE may also select Advanced Payment pursuant to Section 8.02.

"Primary Care Qualified Evaluation & Management (PQEM) Services" means a Primary Care Service furnished by a Primary Care Specialist or a Selected Non-Primary Care Service as such terms are defined in Appendix B of this Agreement.

"Program Integrity Screening" means a review of an individual's or entity's program integrity history, which may include a review of the individual's or entity's history of exclusion or other sanctions imposed with respect to participation in Medicare, Medicaid, or CHIP; history of failure to pay Medicare debts in a timely manner; current or prior law enforcement investigations or administrative actions; affiliations with individuals or entities that have a history of program integrity issues; and other information pertaining to the trustworthiness of the individual or entity.

"**Prohibited Participant**" means an individual or entity that is: (1) a Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) supplier, (2) an ambulance supplier, (3) a drug or device manufacturer, or (4) excluded or otherwise prohibited from participation in Medicare or Medicaid.

"**Prospective Alignment**" refers to the Alignment Methodology in which Beneficiary alignment is performed only prospectively prior to the start of the Implementation Period or a Performance Year based on both Claims-Based Alignment and Voluntary Alignment.

"**Prospective Plus Alignment**" refers to the Alignment Methodology in which Beneficiary alignment is performed prospectively prior to the start of a Performance Year, based on both Claims-Based Alignment and Voluntary Alignment, and performed prospectively prior to the start of the second through fourth calendar quarters of a Performance Year, to align additional Beneficiaries based only on Voluntary Alignment.

"**Risk Sharing Option**" means either Professional or Global.

"**Risk Mitigation Option**" means a supplemental payment mechanism that includes stop loss that may be selected by the DCE for the first Performance Year pursuant to Section 8.02.

"**Shared Losses**" means the monetary amount owed to CMS by the DCE due to expenditures for Medicare Part A and Part B items and services furnished to DC Beneficiaries during a Performance Year in excess of the Performance Year Benchmark. The amount of Shared Losses is determined by CMS in accordance with the Risk Sharing Option and DC Capitation Payment Mechanism selected by the DCE.

"**Shared Savings**" means the monetary amount owed to the DCE by CMS due to expenditures for Medicare Part A and Part B items and services furnished to DC Beneficiaries during a Performance Year that are lower than the Performance Year Benchmark. The amount of Shared Savings is determined by CMS in accordance with the Risk Sharing Option and DC Capitation Payment Mechanism selected by the DCE.

"**TIN**" means a federal taxpayer identification number.

"**Total Care Capitation Payment**" means a DC Capitation Payment Mechanism available for selection by the DCE if the DCE is participating in Global that involves a per-Beneficiary-per month payment to the DCE for all items and services furnished to aligned Beneficiaries by DC Participant Providers and those Preferred Providers who have opted to participate in the Total Care Capitation Payment arrangement with the DCE. If the DCE selects the Total Care Capitation Payment Mechanism, CMS will reduce to $0 the payment amount for FFS claims submitted by the DCE's DC Participant Providers. Those Preferred Providers who have opted to participate in the Total Care Capitation Payment arrangement with the DCE will choose the percentage between 1-100% by which their FFS claims will be reduced.

"**Voluntary Alignment**" refers to both Paper-Based Voluntary Alignment and Electronic Voluntary Alignment.

"**Voluntary Alignment Activities**" means any Marketing Activities or other activities conducted by or on behalf of the DCE or its DC Participant Providers or Preferred Providers, when used for purposes of educating, notifying, or contacting Beneficiaries regarding Voluntary Alignment.

"**Voluntary Alignment Form**" has the meaning set forth in Appendix C.

Article III DCE Composition

Section 3.01 DCE Legal Entity

A. The DCE shall be a legal entity identified by a TIN formed under applicable state, federal, or tribal law, and authorized to undertake the activities required under this Agreement in each state in which it operates.

B. If the DCE was formed by two or more DC Participant Providers, the DCE shall be a legal entity separate from the legal entity of any of its DC Participant Providers or Preferred Providers.

C. If the DCE was formed by a single DC Participant Provider, the DCE's legal entity and governing body may be the same as that of the DC Participant Provider if the DCE satisfies the requirements of Section 3.02.

D. The DCE is not required to be a Medicare-enrolled provider or supplier.

Section 3.02 DCE Governance

A. <u>General</u>

1. The DCE shall maintain an identifiable governing body with sole and exclusive authority to execute the functions of the DCE and make final decisions on behalf of the DCE. The DCE shall have a governing body that satisfies the following criteria:

a. The governing body has responsibility for oversight and strategic direction of the DCE and is responsible for holding DCE management accountable for the DCE's activities;

b. The governing body is separate and unique to the DCE, except as permitted under Section 3.01.C;

c. The governing body has a transparent governing process;

d. When acting as a member of the governing body of the DCE, each governing body member has a fiduciary duty to the DCE, including the duty of loyalty, and shall act consistent with that fiduciary duty; and

e. The governing body shall receive regular reports from the designated compliance official of the DCE who satisfies the requirements of Section 11.01.

2. The DCE shall provide each member of the governing body with a copy of this Agreement and any amendments hereto.

B. Composition and Control of the Governing Body

1. The DCE governing body shall include at least one Beneficiary served by the DCE who:

a. Does not have a conflict of interest with the DCE;

b. Has no immediate family member with a conflict of interest with the DCE;

c. Is not a DC Participant Provider or Preferred Provider; and

d. Does not have a direct or indirect financial relationship with the DCE, a DC Participant Provider, or a Preferred Provider, except that such person may be reasonably compensated by the DCE for his or her duties as a member of the governing body of the DCE.

2. The DCE governing body shall include at least one person with training or professional experience in advocating for the rights of consumers ("**Consumer Advocate**"), who may be the same person as the Beneficiary and who:

a. Does not have a conflict of interest with the DCE;

b. Has no immediate family member with a conflict of interest with the DCE;

c. Is not a DC Participant Provider or Preferred Provider; and

d. Does not have a direct or indirect financial relationship with the DCE, a DC Participant Provider, or a Preferred Provider, except that such person may be reasonably compensated by the DCE for his or her duties as a member of the governing body of the DCE.

3. The DCE governing body shall not include a Prohibited Participant, or an owner, employee or agent of a Prohibited Participant.

4. If Beneficiary and/or Consumer Advocate representation on the DCE governing body is prohibited by state law, the DCE shall notify CMS and request CMS approval of an alternative mechanism to ensure that its policies and procedures reflect consumer and patient perspectives. CMS shall use reasonable efforts to approve or deny the request within 30 days.

5. The governing body members may serve in similar or complementary roles or positions for DC Participant Providers or Preferred Providers.

6. At least 25 percent control of the DCE's governing body shall be held by DC Participant Providers or their designated representatives. The Beneficiary and Consumer Advocate required under this Section 3.02 shall not be included in either the numerator or the denominator when calculating the percent control. The DCE may seek an exception from the 25 percent control requirement by submitting a proposal to CMS describing the current composition of the DCE's governing body and how the DCE will involve DC Participant Providers in innovative ways in DCE governance. Any exception to the 25 percent control requirement will be at the sole discretion of CMS.

C. Conflict of Interest

The DCE shall have a conflict of interest policy that applies to members of the governing body and satisfies the following criteria:

1. Requires each member of the governing body to disclose relevant financial interests;

2. Provides a procedure to determine whether a conflict of interest exists and sets forth a process to address any conflicts that arise; and

3. Addresses remedial actions for members of the governing body that fail to comply with the policy.

Section 3.03 DCE Leadership and Management

A. The DCE's operations shall be managed by an executive, officer, manager, general partner, or similar party whose appointment and removal are under the control of the DCE's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve the efficiency of processes and outcomes.

B. Clinical management and oversight shall be managed by a senior-level medical director who is:

1. A DC Participant Provider;

2. Physically present on a regular basis at any clinic, office, or other location participating in the DCE; and

3. A board-certified physician and licensed in a state in which the DCE operates.

Section 3.04 DCE Financial Arrangements

A. The DCE shall not condition a DC Participant Provider's or Preferred Provider's participation in the Model, directly or indirectly, on referrals of items or services provided to Beneficiaries who are not aligned to the DCE.

B. The DCE shall not require that DC Beneficiaries be referred only to DC Participant Providers or Preferred Providers or to any other provider or supplier. This prohibition shall not apply to referrals made by employees or contractors who are operating within the scope of their employment or contractual arrangement with the employer or contracting entity, provided that the employees and contractors remain free to make referrals without restriction or limitation if a DC Beneficiary expresses a preference for a different provider or supplier, or the referral is not in the DC Beneficiary's best medical interests in the judgment of the referring party.

C. The DCE shall not condition the eligibility of an individual or entity to be a DC Participant Provider or Preferred Provider on the individual's or entity's offer or payment of cash or other remuneration to the DCE or any other individual or entity.

D. In establishing the terms of the arrangement described in Section 3.04.G, neither party gives or receives remuneration in return for or to induce business other than business covered by the terms of the arrangement.

E. The DCE shall not take any action to limit the ability of a DC Participant Provider or Preferred Provider to make decisions in the best interests of a Beneficiary, including the selection of devices, supplies and treatments used in the care of the Beneficiary, and shall impose this requirement on its DC Participant Providers, and Preferred Providers.

F. The DCE shall notify CMS within 15 days after becoming aware that any DC Participant Provider or Preferred Provider is under investigation or has been sanctioned by the government or any licensing authority (including, without limitation, the imposition of program exclusion, debarment, civil monetary penalties, corrective action plans, and revocation of Medicare billing privileges). If a DC Participant Provider or Preferred Provider is under investigation or has been sanctioned but not excluded from Medicare program participation, CMS may take any of the actions set forth in Section 13.01.

G. By the date specified in Section 3.04.H, below, the DCE shall have an arrangement with each of the individuals and entities that are approved by CMS to be DC Participant Providers or Preferred Providers that complies with the following criteria:

   1. The arrangement is in writing and the only parties to the arrangement are the DCE and the DC Participant Provider or Preferred Provider.

   2. The arrangement requires the DC Participant Provider or Preferred Provider to agree to participate in the Model during the Implementation

Period, to engage in DCE Activities, to comply with the applicable terms of the Model as set forth in this Agreement, and to comply with all applicable laws and regulations (including, but not limited to, those specified at Section 11.04). The DCE shall provide each DC Participant Provider and Preferred Provider with a copy of this Agreement and any amendments hereto.

3. The arrangement expressly sets forth the DC Participant Provider's or Preferred Provider's obligation to comply with the applicable terms of this Agreement, including any provisions regarding the following: participant exclusivity; Voluntary Alignment Activities; Marketing Activities; Beneficiary freedom of choice; participation in evaluation, shared learning, monitoring, and oversight activities; the DCE compliance plan; and audit and record retention requirements.

4. The arrangement requires the DC Participant Provider or Preferred Provider to update its Medicare enrollment information (including the addition and deletion of individuals that have reassigned to the DC Participant Provider or Preferred Provider their right to Medicare payment) on a timely basis in accordance with Medicare program requirements.

5. The arrangement requires the DC Participant Provider or Preferred Provider to notify the DCE of any changes to its Medicare enrollment information (including the addition and deletion of individuals that have reassigned to the DC Participant Provider or Preferred Provider their right to Medicare payment) within 30 days after the change.

6. The arrangement requires the DC Participant Provider or Preferred Provider to notify the DCE within seven days of becoming aware that it is under investigation or has been sanctioned by the government or any licensing authority (including, without limitation, the imposition of program exclusion, debarment, civil monetary penalties, corrective action plans, and revocation of Medicare billing privileges).

7. The arrangement permits the DCE to take remedial action against the DC Participant Provider or Preferred Provider (including the imposition of a corrective action plan, denial of any payments, and termination of the DCE's arrangement with the DC Participant Provider or Preferred Provider) to address noncompliance with the terms of this Agreement or program integrity issues identified by CMS.

8. The arrangement is for a term that ends no earlier than March 31, 2021, but permits early termination if CMS requires the DCE to remove the DC Participant Provider or Preferred Provider pursuant to Section 13.01.A.

9. The arrangement requires the DC Participant Provider or Preferred Provider to complete a close-out process upon termination or expiration of the arrangement that requires the DC Participant Provider to furnish all

data required by the DCE to participate in the Model and any data required by CMS to monitor or evaluate the Model.

10. If the arrangement involves the provision of electronic health records software to one or more DC Participant Providers or Preferred Providers, such software shall be interoperable (as defined in 42 C.F.R. § 411.351) or satisfy 42 C.F.R. § 411.357(w)(2) (related to interoperability) at the time it is provided to the recipient.

H. The DCE shall have fully executed written arrangements in place that meet the requirements set forth in Section 3.04.G by the following dates:

1. By the Start Date, in the case of arrangements with individuals and entities that were approved by CMS before the start of the Implementation Period to be DC Participant Providers and Preferred Providers during the Implementation Period.

2. By the date the DCE certifies its DC Participant Provider List and Proposed Preferred Provider List in accordance with Section 4.05, in the case of arrangements with individuals and entities approved by CMS to be DC Participant Providers and Preferred Providers effective on the first day of the first Performance Year of the Model Performance Period, if the DCE wishes to continue participation in the Model during the Model Performance Period.

I. The DCE shall maintain, in accordance with Section 12.02, records of all payments made or received pursuant to the arrangements described in Section 3.04.G.

J. CMS provides no opinion on the legality of any contractual or financial arrangement that the DCE, a DC Participant Provider, or a Preferred Provider has proposed, implemented, or documented. The receipt by CMS of any such documents in the course of the application process or otherwise shall not be construed as a waiver or modification of any applicable laws, rules, or regulations, and will not preclude CMS, HHS or its Office of Inspector General, a law enforcement agency, or any other federal or state agency from enforcing any and all applicable laws, rules, and regulations.

K. The DCE shall ensure that any DC Participant Provider or Preferred Provider that has been terminated pursuant to Sections 4.01.F or 13.01, or has been removed from the DC Participant Provider List or Preferred Provider List pursuant to Section 4.04.B, as applicable, does not engage in any Marketing Activities, including Voluntary Alignment Activities, after the effective date of such termination.

Article IV DC Participant Providers and Preferred Providers

Section 4.01 General

A. The DCE shall ensure that each DC Participant Provider:

1. Is a Medicare-enrolled provider (as defined at 42 CFR § 400.202) or supplier (as defined at 42 CFR § 400.202) as of August 14, 2020, or such other later date as may be specified by CMS;
2. Bills for items and services it furnishes to Beneficiaries under a Medicare billing number assigned to a TIN in accordance with applicable Medicare regulations;
3. Is not a Preferred Provider;
4. Is not a Prohibited Participant;
5. Has agreed to participate in the Model pursuant to a written arrangement with the DCE meeting the requirements of Section 3.04;
6. Is identified on the DC Participant Provider List in accordance with this Article IV.

B. The DCE shall ensure that each Preferred Provider:

1. Is a Medicare-enrolled provider (as defined at 42 CFR § 400.202) or supplier (as defined at 42 CFR § 400.202) as of August 14, 2020, or such other later date as may be specified by CMS;
2. Bills for items and services it furnishes to Beneficiaries under a Medicare billing number assigned to a TIN in accordance with applicable Medicare regulations;
3. Is not a DC Participant Provider;
4. Is not a Prohibited Participant;
5. Has agreed to participate in the Model pursuant to a written arrangement with the DCE meeting the requirements of Section 3.04; and
6. Is identified on the Preferred Provider List in accordance with this Article IV.

C. DC Participant Providers and Preferred Providers will be included on the DC Participant Provider List or Preferred Provider List only upon the prior written approval of CMS.

D. CMS shall maintain the DC Participant Provider List and Preferred Provider List in a manner that permits the DCE to review the lists.

E. The DCE shall maintain current and historical DC Participant Provider Lists and Preferred Provider Lists in accordance with Section 12.02.

F. CMS may periodically monitor the program integrity history of the DCE's DC Participant Providers or Preferred Providers. CMS may remove an individual or

entity from the DC Participant Provider List or Preferred Provider List or subject the DCE to additional monitoring pursuant to Section 13.01, on the basis of the results of a Program Integrity Screening or information obtained regarding an individual's or entity's history of program integrity issues, including but not limited to a DC Participant Provider's or Preferred Provider's licensure status and ongoing investigations by law enforcement, program integrity, or state licensure bodies. CMS shall notify the DCE if CMS chooses to remove an individual or entity from the DC Participant Provider List or Preferred Provider List, and such notice shall specify the effective date of removal.

Section 4.02 DC Participant Provider List for the Implementation Period

A. The parties acknowledge that the DCE submitted to CMS a proposed list of DC Participant Providers for the Implementation Period, identified by name, NPI, TIN, CCN (if applicable), or Legacy TIN or CCN (if applicable).

B. CMS states that it has reviewed the proposed list of DC Participant Providers for the Implementation Period and conducted a Program Integrity Screening on the proposed DC Participant Providers.

C. CMS states that it has submitted to the DCE a list of individuals and entities that it approved to be DC Participant Providers for the Implementation Period. The DCE states that it has reviewed this list and made any necessary corrections to it, including the addition of any individuals or entities to the proposed list of DC Participant Providers for the Implementation Period, identified by name, NPI, TIN, CCN (if applicable), or Legacy TIN or CCN (if applicable), or the removal of any individuals or entities that have not agreed to participate in the Model as of the Start Date pursuant to a written arrangement meeting the requirements of Section 3.04.G. CMS will review any individuals or entities added to the proposed list of DC Participant Providers for the Implementation Period and conduct a Program Integrity Screening on any added individuals or entities.

D. The DCE states that it has submitted to CMS, by a date specified by CMS, a final DC Participant Provider List for the Implementation Period that the DCE has certified is a true, accurate, and complete list identifying all of the DCE's DC Participant Providers approved by CMS to participate in the Implementation Period as of the Start Date pursuant to a fully executed written arrangement meeting the requirements of Section 3.04.G.

E. Any changes to the DC Participant Provider List to add or remove an individual or entity after the DCE certifies the final DC Participant Provider List for the Implementation Period described in Section 4.02.D will not affect Beneficiary alignment for the Implementation Period.

F. The DCE shall update the DC Participant Provider List for the Implementation Period in accordance with Section 4.04.

Section 4.03 Preferred Provider List for the Implementation Period

A. The parties acknowledge that the DCE submitted to CMS a proposed list of Preferred Providers for the Implementation Period, identified by name, NPI, TIN, CCN (if applicable), and Legacy TIN or CCN (if applicable).

B. CMS will review the proposed list of Preferred Providers for the Implementation Period and will conduct a Program Integrity Screening on the proposed Preferred Providers.

C. Before the Start Date, CMS will submit to the DCE a list of individuals and entities that it has approved to be Preferred Providers for the Implementation Period. The DCE shall review the list and make any necessary corrections to it, including the addition of any individuals or entities to the proposed list of Preferred Providers for the Implementation Period, identified by name, NPI, TIN, CCN (if applicable), or Legacy TIN or CCN (if applicable), or the removal of any individuals or entities that have not agreed to participate in the Model as of the Start Date pursuant to a written arrangement meeting the requirements of Section 3.04.G. CMS will review any individuals or entities added to the proposed list of Preferred Providers for the Implementation Period and conduct a Program Integrity Screening on any added individuals or entities.

D. Before the Start Date, or at such other time as may be specified by CMS, the DCE shall submit to CMS a final Preferred Provider List for the Implementation Period that the DCE has certified is a true, accurate, and complete list identifying all of the DCE's Preferred Providers approved by CMS to participate in the Implementation Period as of the Start Date pursuant to a fully executed written agreement meeting the requirements of Section 3.04.G.

E. The DCE shall update the Preferred Provider List for the Implementation Period in accordance with Section 4.04.

Section 4.04 Updating Lists during the Implementation Period

A. <u>Additions to a List</u>
The DCE may not make additions to its DC Participant Provider List or Preferred Provider List to take effect during the Implementation Period.

B. <u>Removals from a List</u>
In a form and manner specified by CMS, the DCE shall notify CMS no later than 30 days after an individual or entity has ceased to be a DC Participant Provider or Preferred Provider and shall include in the notice the date on which the individual or entity ceased to be a DC Participant Provider or Preferred Provider. The removal of the individual or entity from the DC Participant Provider List or Preferred Provider List will be effective on the date the individual or entity ceased to be a DC Participant Provider or Preferred Provider. An individual or entity ceases to be a DC Participant Provider when it no longer satisfies all of the requirements of Section 4.01.A(1)-(5). An individual or entity ceases to be a

Preferred Provider when it no longer satisfies all of the requirements of Section 4.01.B(1)-(5).

C. Updating Enrollment Information
The DCE shall ensure that all changes to enrollment information for DC Participant Providers and Preferred Providers, including changes to reassignment of the right to receive Medicare payment, are reported to CMS consistent with 42 CFR § 424.516.

Section 4.05 DC Participant Provider List and Preferred Provider List for the First Performance Year

A. Proposed DC Participant Provider List. If the DCE wishes to continue participation in the Model during the Model Performance Period, the DCE shall submit to CMS by a date and in a form and manner specified by CMS, a proposed list identifying each individual or entity that the DCE expects to participate in the Model as a DC Participant Provider effective at the start of the first Performance Year of the Model Performance Period ("**Proposed DC Participant Provider List**"). The Proposed DC Participant Provider List must:

1. Identify each individual or entity by name, NPI, TIN, CCN (if applicable), and Legacy TIN or CCN (if applicable);
2. Specify the Benefit Enhancements and Beneficiary Engagement Incentives, if any, in which each individual or entity has agreed to participate;
3. If the DCE has selected the Primary Care Capitation Payment as its DC Capitation Payment Mechanism for the first Performance Year pursuant to Section 8.02, identify the individuals and entities that will participate in the Primary Care Capitation Payment with the DCE, as well as any other information regarding those individuals and entities specified by CMS;
4. If the DCE has selected to participate in Advanced Payment for the first Performance Year pursuant to Section 8.02, identify which individuals and entities, if any, have opted to participate in Advanced Payment as well as any other information regarding those individuals and entities specified by CMS.

CMS will specify one or more submission deadlines to add the information specified in paragraphs (1) through (4) to the Proposed DC Participant Provider List. By a date specified by CMS, the DCE shall certify that the Proposed DC Participant Provider List is a true, accurate, and complete list of individuals and entities that have agreed to be DC Participant Providers, subject to CMS approval, at the start of the first Performance Year.

B. Proposed Preferred Provider List. If the DCE wishes to continue participation in the Model during the Model Performance Period, the DCE shall submit to CMS by a date and in a form and manner specified by CMS, a proposed list identifying each individual or entity that the DCE expects to participate in the Model as a

Preferred Provider effective at the start of the first Performance Year of the Model Performance Period ("**Proposed Preferred Provider List**"). The Proposed Preferred Provider List must:

1. Identify each individual or entity by name, NPI, TIN, CCN (if applicable), and Legacy TIN or CCN (if applicable);
2. Specify the Benefit Enhancements and Beneficiary Engagement Incentives, if any, in which each individual or entity has agreed to participate;
3. If the DCE has selected the Total Care Capitation Payment as its DC Capitation Payment Mechanism for the first Performance Year pursuant to Section 8.02, identify each individual or entity that will participate in the Total Care Capitation Payment with the DCE, as well as any other information regarding those individuals and entities specified by CMS;
4. If the DCE has selected the Primary Care Capitation Payment as its DC Capitation Payment Mechanism for the first Performance Year pursuant to Section 8.02, identify each individual or entity that will participate in Primary Care Capitation Payment with the DCE, as well as any other information regarding those individuals and entities specified by CMS.
5. If the DCE has selected to participate in Advanced Payment for the first Performance Year pursuant to Section 8.02, identify which individuals and entities, if any, will participate in Advanced Payment as well as any other information regarding those individuals and entities specified by CMS.

CMS will specify one or more submission deadlines to add the information specified in paragraphs (1) through (4) to the Proposed Preferred Provider List. By a date specified by CMS, the DCE shall certify that the Proposed Preferred Provider List is a true, accurate, and complete list of individuals and entities that have agreed to be Preferred Providers, subject to CMS approval, at the start of the first Performance Year.

C. DCE Notice to Proposed DC Participant Providers

By a date specified by CMS, the DCE shall furnish written notification to each individual or entity the DCE wishes to include on the Proposed DC Participant Provider List. Such notice shall:

1. State that the individual or entity and the TIN through which it bills Medicare will be identified on the Proposed DC Participant Provider List.
2. State that participation in the Model may preclude the individual or entity from participating in the Medicare Shared Savings Program, another Medicare DCE in the Model, the Next Generation ACO Model, the CEC Model, the Maryland Total Cost of Care Model, the Vermont All-Payer ACO Model, the Kidney Care Choices Model, the Primary Care First Model, and any other Medicare initiative that involves shared savings.

3. If the DCE has selected to participate in the Total Care Capitation Payment for the first Performance Year pursuant to Section 8.02, state that the individual's or entity's agreement to participate in the Total Care Capitation Payment pursuant to Section 4.05.E must apply for the full Performance Year and must be renewed annually prior to the start of each Performance Year in order for the individual or entity to participate as a DC Participant Provider for that Performance Year, and any other information regarding the individual or entity's participation in the Total Care Capitation Payment specified by CMS.

4. If the DCE has selected to participate in the Primary Care Capitation Payment pursuant to Section 8.02, state that the individual's or entity's agreement to participate in the Primary Care Capitation Payment pursuant to Section 4.05.E must apply for the full Performance Year and must be renewed annually prior to the start of each Performance Year in order for the individual or entity to participate in the Primary Care Capitation Payment for that Performance Year, and any other information regarding the individual or entity's participation in the Primary Care Capitation Payment specified by CMS.

5. If the DCE has selected to participate in Advanced Payment pursuant to Section 8.02, state that the individual's or entity's agreement to participate in Advanced Payment pursuant to Section 4.05.F must apply for the full Performance Year and must be renewed annually prior to the start of each Performance Year in order for the individual or entity to participate in Advanced Payment for that Performance Year.

D. DCE Notice to Proposed Preferred Providers

By a date specified by CMS, the DCE shall furnish written notification to each individual or entity the DCE wishes to include on the Proposed Preferred Provider List. Such notice shall:

1. State that the individual or entity and the TIN through which it bills Medicare will be identified on the Proposed Preferred Provider List.

2. State that the individual or entity may agree in accordance with the requirements of Section 4.05.E to participate in the DC Capitation Payment Mechanism selected by the DCE, and that the individual's or entity's agreement to participate in the DC Capitation Payment Mechanism must apply for the full Performance Year and must be renewed annually prior to the start of each Performance Year in order for the individual or entity to participate in the DC Capitation Payment Mechanism for that Performance Year, and any other information regarding the individual or entity's participation in the DC Capitation Payment Mechanism specified by CMS.

3. If the DCE has selected to participate in Advanced Payment pursuant to Section 8.02, state that the individual or entity may agree in accordance

with the requirements of Section 4.05.F to participate in Advanced Payment, and that the individual's or entity's agreement to participate in Advanced Payment must apply for the full Performance Year and must be renewed annually prior to the start of each Performance Year in order for the individual or entity to participate in Advanced Payment for that Performance Year.

E. Written Confirmation of Consent to Participate in a DC Capitation Payment Mechanism

1. ***DC Participant Providers.*** If the DCE has selected to participate in the Total Care Capitation Payment for the first Performance Year pursuant to Section 8.02, the DCE shall obtain written confirmation that every individual and entity listed on the Proposed DC Participant Provider List has consented to participate in the Total Care Capitation Payment with the DCE. If the DCE has selected to participate in the Primary Care Capitation Payment for the first Performance Year pursuant to Section 8.02, the DCE shall obtain written confirmation that each individual and entity that is listed on the Proposed DC Participant Provider List as participating in Primary Care Capitation Payment has consented to participate in the Primary Care Capitation Payment.

2. ***Preferred Providers.*** The DCE shall obtain written confirmation that each individual and entity that is listed on the Proposed Preferred Provider List as participating in the DCE's selected DC Capitation Payment Mechanism has consented to participate in the DCE's selected DC Capitation Payment Mechanism.

3. The written confirmation of consent required under this Section 4.05.E must be in the form of a completed Direct Contracting Model: DC Capitation Payment Mechanism Fee Reduction Agreement signed by an individual legally authorized to act for the entity through whose TIN the DC Participant Provider or Preferred Provider bills Medicare. CMS may provide to the DCE template language for the Direct Contracting Model: DC Capitation Payment Mechanism Fee Reduction Agreement. The DCE shall use any template language for the Direct Contracting Model: DC Capitation Payment Mechanism Fee Reduction Agreement provided by CMS. The Direct Contracting Model: DC Capitation Payment Mechanism Fee Reduction Agreement must specify the percentage by which each individual's or entity's FFS claims will be reduced by CMS.

3. As part of the written confirmation of consent, the individual legally authorized to act for the entity through whose TIN the DC Participant Provider or Preferred Provider bills Medicare must verify the accuracy of the list of DC Participant Providers and Preferred Providers billing under that TIN that have affirmatively consented to participate in the DCE's selected DC Capitation Payment Mechanism.

4. Consent to participate in the DCE's selected DC Capitation Payment Mechanism for the first Performance Year must be obtained prior to the start of the first Performance Year. Consent to participate in the DCE's selected DC Capitation Payment Mechanism must be voluntary and must not be contingent on or related to receipt of referrals from the DCE, its DC Participant Providers, or Preferred Providers.

F. Written Confirmation of Consent to Participate in Advanced Payment

1. If the DCE has selected to participate in Advanced Payment for the first Performance Year pursuant to Section 8.02, the DCE shall obtain written confirmation that each individual and entity that is listed on the Proposed DC Participant Provider List and the Proposed Preferred Provider List as having opted to participate in Advanced Payment has consented to participate in Advanced Payment.

2. Such written confirmation of consent must be in the form of a completed Direct Contracting Model: Advanced Payment Fee Reduction Agreement signed by an individual legally authorized to act for the entity through whose TIN the DC Participant Provider or Preferred Provider bills Medicare. Consent to participate in Advanced Payment must be voluntary and must not be contingent on or related to receipt of referrals from the DCE, its DC Participant Providers, or Preferred Providers. CMS may provide the DCE with template language for the Direct Contracting Model: Advanced Payment Fee Reduction Agreement. The DCE shall use any template language for the Direct Contracting Model: Advanced Payment Fee Reduction Agreement provided by CMS. The Direct Contract Model: Advanced Payment Fee Reduction Agreement must specify the percentage by which each individual's or entity's FFS claims will be reduced by CMS.

3. As part of the written confirmation of consent, the individual legally authorized to act for the entity through whose TIN the DC Participant Provider or Preferred Provider bills Medicare must verify the accuracy of the list of DC Participant Providers and Preferred Providers billing under that TIN that have affirmatively consented to participate in Advanced Payment.

4. Consent to participate in Advanced Payment for the first Performance Year must be obtained prior to the start of the first Performance Year.

G. DCE Notice to TINs

By a date specified by CMS, the DCE shall furnish written notification to the executive of any TIN through which an individual or entity on the Proposed DC Participant Provider List or Proposed Preferred Provider List bills Medicare. Such notification must:

1. Include a list identifying by name and NPI each individual or entity that will be identified on the DCE's Proposed DC Participant Provider List or Proposed Preferred Provider List as billing through the entity's TIN; and

2. Inform the executive of the TIN that a DC Participant Provider's participation in the DCE may preclude the entire TIN from participating in the Medicare Shared Savings Program and any other Medicare initiative that involves shared savings and identifies participants by an entire TIN.

3. Inform the executive of the TIN that a DC Participant Provider's participation in the DCE may preclude the TIN/NPI combination associated with that individual or entity from participating in the Kidney Care Choices Model, Next Generation ACO Model, CEC Model, Maryland Total Cost of Care Model, Vermont All-Payer ACO Model, Primary Care First Model, another Medicare DCE in the Model, and any other Medicare initiative that involves shared savings and identifies participants by a TIN/NPI combination.

H. Review, Certification, and Finalization of the DC Participant Provider List and Preferred Provider List for the first Performance Year

1. With respect to each individual and entity identified on the Proposed DC Participant Provider List and Proposed Preferred Provider List, CMS shall conduct a Program Integrity Screening.

2. CMS may reject any individual or entity on a Proposed DC Participant Provider List or a Proposed Preferred Provider List on the basis of the results of this Program Integrity Screening, history of program integrity issues, or:

   a. For any individual or entity on a Proposed DC Participant Provider List, if CMS determines that the individual or entity does not satisfy the criteria in paragraphs (1) through (5) of Section 4.01.A; or

   b. For any individual or entity on a Proposed Preferred Provider List, if CMS determines that the individual or entity does not satisfy the criteria in paragraphs (1) through (5) of Section 4.01.B.

3. CMS will provide the DCE with a list of individuals and entities that CMS has tentatively approved to be DC Participant Providers and Preferred Providers effective at the start of the First Performance Year, as well as the number of Beneficiaries aligned to the DCE for the Implementation Period.

4. In a manner and by a date specified by CMS, the DCE may propose to add individuals and entities to its Proposed DC Participant Provider List and its Proposed Preferred Provider List. CMS shall conduct a Program Integrity Screening for each individual or entity the DCE proposes to add to the Proposed DC Participant Provider List and Preferred Provider List,

and may reject any individual or entity proposed for inclusion on the basis of the criteria described in Section 4.05.H.2.

5. CMS will provide the DCE with lists of the individuals and entities that CMS has tentatively approved to be DC Participant Providers and Preferred Providers effective at the start of the first Performance Year, to include individuals and entities added to the Proposed DC Participant Provider List or Proposed Preferred Provider List pursuant to Section 4.05.H.4 that CMS has not rejected.

6. In a form and manner and by a date specified by CMS, the DCE shall, after a review of the lists of tentatively approved DC Participant Providers and Preferred Providers, confirm the accuracy of the revised Proposed DC Participant Provider List and of the revised Proposed Preferred Provider List with any necessary corrections, including the removal of any individuals or entities that have not agreed to participate in the Model pursuant to a written arrangement with the DCE meeting the requirements of Section 3.04.G, that fail to satisfy the requirements of Section 4.01.A (1)-(5) or Section 4.01.B(1)-(5), as applicable, or that are otherwise ineligible to participate in the Model as DC Participant Providers or Preferred Providers. If the DCE has selected to participate in the Total Care Capitation Payment pursuant to Section 8.02, the DCE shall remove any DC Participant Provider who has not agreed to participate in Total Care Capitation Payment with the DCE in accordance with Section 4.05.E from its Proposed DC Participant Provider List. The DCE shall certify that the revised DC Participant Provider list is a true, accurate, and complete list of the individuals and entities that have agreed to be DC Participant Providers and that the revised Preferred Provider list is a true, accurate and complete list of the individuals and entities that have agreed to be Preferred Providers effective at the start of the first Performance Year. The DCE may not add individuals or entities to the revised Proposed DC Participant Provider List or Preferred Provider List at this time.

7. CMS will remove from the DC Participant Provider List and Preferred Provider List: (1) any individuals and entities that bill under a TIN participating in the Medicare Shared Savings Program or any other Medicare initiative that involves shared savings and identifies participants by an entire TIN; and (2) any individuals and entities identified by a TIN/NPI combination participating in the Kidney Care Choices Model, Maryland Total Cost of Care Model, Next Generation ACO Model, CEC Model, Vermont All-Payer ACO Model, Primary Care First Model, another Medicare DCE in the Model, or any other Medicare initiative that involves shared savings and identifies participants by a TIN/NPI combination.

8. CMS will provide the DCE with a final DC Participant Provider List and a final Preferred Provider List, identifying all individuals and entities that CMS has approved to be DC Participant Providers and Preferred Providers

effective at the start of the first Performance Year (including information regarding participation in a DC Capitation Payment Mechanism with the DCE, Advanced Payments, Benefit Enhancements, and Beneficiary Engagement Incentives, as applicable, and any other information regarding these DC Participant Providers and Preferred Providers specified by CMS) effective at the start of the first Performance Year. The DCE shall update such lists in accordance with the terms of the agreement referenced in Section 1.03.

9. CMS will use the final DC Participant Provider List described in Section 4.05.H.8 to run Beneficiary alignment for purposes of calculating the DCE's Performance Year Benchmark for the first Performance Year of the Model Performance Period. Any individual or entity that is removed from or added to the DC Participant Provider List after CMS provides the DCE with the final DC Participant Provider List will not affect Beneficiary alignment for the first Performance Year.

Section 4.06 Non-Duplication and Exclusivity of Participation

A. CMS waives the non-duplication requirements under section 1899(b)(4)(A) of the Act and in the implementing regulations at 42 CFR § 425.114(a) and (b) regarding participation in a model tested under section 1115A of the Act that involves shared savings as they apply to the DCE, DC Participant Providers, and Preferred Providers for the duration of the Implementation Period, subject to the conditions and requirements set forth in Appendix A.

B. Consistent with the requirements set forth in Appendix A, the DCE, DC Participant Providers, and Preferred Providers may participate in the Independence at Home Medical Practice Demonstration Program under section 1866E of the Act, the Maryland Total Cost of Care Model, the Next Generation ACO Model, the CEC Model, the Vermont All-Payer ACO Model, or any other Medicare initiative that involves shared savings during the Implementation Period.

ARTICLE V Beneficiary Alignment, Beneficiary Engagement, and Beneficiary Protections

Section 5.01 Beneficiary Alignment

A. CMS shall, according to the methodology set forth in Appendix B and the precedence rules described in Section 5.01.D, use both Voluntary Alignment and Claims-Based Alignment to align Beneficiaries to the DCE for the Implementation Period and the first Performance Year of the Model Performance Period.

B. CMS will align Beneficiaries to the DCE for the Implementation Period to provide the DCE with an estimated count of Beneficiaries who will be aligned to the DCE for the first Performance Year and to determine the population of Beneficiaries whose data the DCE may request from CMS during the

Implementation Period for health care operations purposes, as set forth in Article VI, including any DCE Activities and Marketing Activities.

C. CMS will align Beneficiaries to the DCE prospectively, prior to the start of the Implementation Period or Performance Year, as applicable. If the DCE selects Prospective Plus Alignment as the DCE's Alignment Methodology for the first Performance Year pursuant to Section 8.02, CMS will also align Beneficiaries to the DCE prior to the start of the second through fourth calendar quarters of a Performance Year, using Voluntary Alignment, to take effect on a date specified by CMS. The implementation of Prospective Plus Alignment during the Model Performance Period will be governed by the agreement described in Section 1.03.

D. Precedence Rules

1. CMS shall establish precedence rules to govern the order in which Beneficiary alignment is conducted across Claims-Based Alignment, Paper-Based Voluntary Alignment, and Electronic Voluntary Alignment under the Model.

2. Under these precedence rules, the most recent valid designation of a DC Participant Provider as a Beneficiary's primary clinician, main doctor, main provider, and/or the main place they receive care (whether through Electronic Voluntary Alignment or Paper-Based Voluntary Alignment) will take precedence over any prior or invalid designations, and Voluntary Alignment will take precedence over Claims-Based Alignment. In addition, a Beneficiary, who has designated a provider or supplier that is not a DC Participant Provider as her or his primary clinician through Electronic Voluntary Alignment, will not be aligned to the DCE, if the designation is the most recent valid designation made by the Beneficiary.

3. The parties acknowledge that CMS notified the DCE of the precedence rules that apply to Beneficiary alignment for the Implementation Period. CMS will notify the DCE of the precedence rules that will apply to Beneficiary alignment for the first Performance Year of the Model Performance Period prior to the start of that Performance Year.

Section 5.02 Voluntary Alignment

A. Valid Designation

1. An Electronic Voluntary Alignment designation of a DC Participant Provider as a Beneficiary's primary clinician, main doctor, main provider, and/or the main place they receive care is valid for the Implementation Period, if either: (1) the designation was made no earlier than two years before the Start Date; or (2) the DC Participant Provider designated by the Beneficiary has submitted a claim for a PQEM Service furnished to the Beneficiary in the 24 months before the Start Date.

2. A designation of a DC Participant Provider as a Beneficiary's primary clinician, main doctor, main provider, and/or the main place they receive

care (whether through Electronic Voluntary Alignment or Paper-Based Voluntary Alignment) is valid for the first Performance Year of the Model Performance Period, if either: (1) the designation was made no earlier than two years before the start of the first Performance Year; or (2) the DC Participant Provider designated by the Beneficiary has submitted a claim for a PQEM Service furnished to the Beneficiary in the 24 months before the start of the first Performance Year.

B. Prospective Plus Alignment

The implementation of Prospective Plus Alignment during the Model Performance Period will be governed by the agreement described in Section 1.03.

C. Paper-Based Voluntary Alignment

Appendix C shall apply to this Agreement if the DCE selects to participate in Paper-Based Voluntary Alignment during the Implementation Period pursuant to Section 8.01.

D. Influencing or Attempting to Influence the Beneficiary

1. The DCE shall not, and shall require its DC Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to DCE Activities to not, directly or indirectly, commit any act or omission, nor adopt any policy, that coerces or otherwise influences a Beneficiary's decision to complete or not complete a Voluntary Alignment Form or a MyMedicare.gov designation, including but not limited to the following:
    a. Completing a Voluntary Alignment Form on behalf of the Beneficiary;
    b. Designating a primary clinician on MyMedicare.gov on behalf of the Beneficiary;
    c. Including the Voluntary Alignment Form and instructions with any other materials or forms, including but not limited to materials requiring the signature of the Beneficiary; and
    d. Withholding or threatening to withhold medical services or limiting or threatening to limit access to care.
2. The DCE may instruct its DC Participant Providers and Preferred Providers to answer questions from Beneficiaries regarding Voluntary Alignment, but must prohibit DC Participant Providers and Preferred Providers from completing a Voluntary Alignment Form or designating a clinician on MyMedicare.gov on behalf of the Beneficiary.
3. The DCE shall require its DC Participant Providers and Preferred Providers to instruct Beneficiaries to call the DCE for questions about how to make changes to a Voluntary Alignment Form or how to designate a primary clinician on MyMedicare.gov.

4. CMS will provide the DCE with information on how a Beneficiary may designate a clinician on MyMedicare.gov as his or primary clinician for purposes of Electronic Voluntary Alignment. If the DCE chooses to share this information with Beneficiaries, the sharing of this information would be considered a Voluntary Alignment Activity, and the DCE shall submit to CMS, by a time and in a manner specified by CMS, a document describing the process the DCE in accordance with Section 5.04.I.

5. In addition to the actions available under Article XIII, failure to comply with the requirements of this Article V or, if the DCE has selected to participate in Paper-Based Voluntary Alignment, the requirements of Appendix C of this Agreement may result in retroactive reversal of any alignment of Beneficiaries to the DCE that occurred solely pursuant to Voluntary Alignment.

Section 5.03 Alignment Minimum

The DCE is not required to maintain a minimum number of aligned Beneficiaries during the Implementation Period. The applicable alignment minimum for the first Performance Year of the Model Performance Period and each subsequent Performance Year will be governed by the terms of the agreement described in Section 1.03.

Section 5.04 Marketing Activities and Marketing Materials

A. The DCE shall conduct, and shall require its DC Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to DCE Activities, to conduct Marketing Activities, including Voluntary Alignment Activities, only in accordance with this Article V and, if the DCE has selected to participate in Paper-Based Voluntary Alignment, Appendix C of this Agreement.

B. The DCE shall submit to CMS, in a form and manner and by a date specified by CMS, a plan for implementing the Marketing Activities described in this Agreement ("**Marketing Plan**"). CMS shall use reasonable efforts to approve or reject a Marketing Plan by the Start Date.

C. If CMS determines that the DCE's proposed Marketing Plan does not satisfy the applicable requirements of this Agreement, including the Appendices hereto, or is likely to result in program integrity concerns, CMS may reject (or require the amendment of) the DCE's Marketing Plan at any time, including after the Start Date. If CMS rejects the DCE's Marketing Plan, the DCE shall not, and shall require its DC Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to DCE Activities, not to, conduct Marketing Activities.

D. The DCE shall not conduct, and shall prohibit its DC Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to DCE Activities, from conducting Marketing Activities before the Start Date or such other date specified by CMS.

E. In conducting Marketing Activities, the DCE shall not, and shall require its DC Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to DCE Activities, not to, discriminate or selectively target Beneficiaries based on race, ethnicity, national origin, religion, gender, sex, age, mental or physical disability, health status, receipt of health care, claims experience, medical history, genetic information, evidence of insurability, geographic location, or income.

F. The DCE shall not and shall require DC Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to DCE Activities, to not conduct Marketing Activities outside the DCE Service Area, as defined in Section 5.04.G.

G. DCE Service Area

1. The DCE Service Area consists of the Core Service Area described in Section 5.04.G.2 and the Extended Service Area described in Section 5.04.G.3.

2. The Core Service Area includes the counties in which the DCE's DC Participant Providers have physical office locations. By a time and in a form and manner specified by CMS, the DCE shall submit to CMS a list of the counties in which the DCE's DC Participant Providers have physical office locations. CMS will use this information for purposes of defining the DCE's Core Service Area.

3. The Extended Service Area includes all counties adjacent to the Core Service Area unless the DCE requests an exception and such request is accepted by CMS. CMS will identify the counties adjacent to the counties in the DCE's Core Service Area for purposes of defining the DCE's Extended Service Area.

H. To ensure that Beneficiaries are not misinformed or mislead about the Model, CMS may develop and provide to the DCE template language for certain Marketing Materials. The DCE shall use any template language for Marketing Materials provided by CMS.

I. Marketing Materials and Marketing Activities Review

1. The DCE shall not, and shall require its DC Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to DCE Activities to not, use Marketing Materials or engage in Marketing Activities until such Marketing Materials and Marketing Activities are reviewed and approved by CMS.

2. Marketing Materials and Marketing Activities are deemed approved ten business days following their submission to CMS if:

a. The DCE certifies compliance with all applicable requirements under this Section 5.04 and, if the DCE has selected to participate

in Paper-Based Voluntary Alignment, Appendix C of this Agreement; and

b. CMS does not disapprove the Marketing Materials or Marketing Activities.

3. In addition to the actions available under Article XIII, if the DCE has falsely certified compliance with all applicable requirements under this Section 5.04 and, if applicable, Appendix C of this Agreement, this action may result in retroactive reversal of any alignment of Beneficiaries to the DCE that occurred solely pursuant to Voluntary Alignment.

4. CMS may review the Marketing Materials and Marketing Activities and issue written notice of disapproval of Marketing Materials and Marketing Activities at any time, including after the expiration of the initial ten business day review period.

5. The DCE shall promptly discontinue, and shall require its DC Participant Providers, Preferred Providers, or other individuals or entities performing functions or services related to DCE Activities to promptly discontinue, use of any Marketing Materials and Marketing Activities disapproved by CMS.

6. Any material changes to CMS-approved Marketing Materials and Marketing Activities must be submitted to CMS and approved by CMS, or deemed approved in accordance with Section 5.04.I.2, before use.

7. The DCE shall retain copies of all written and electronic Marketing Materials and appropriate records for all Marketing Activities in a manner consistent with Section 12.02.

J. In using Marketing Materials and conducting Marketing Activities, the DCE shall not, and shall require its DC Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to DCE Activities not to do any of the following:

1. Engage in activities that could mislead or confuse a Beneficiary regarding the Model, Medicare benefits, or the DCE; or

2. Claim the DCE is recommended or otherwise endorsed by CMS or that CMS recommends that the Beneficiary select a DC Participant Provider as his or her main doctor, main provider, and/or the main place the Beneficiary receives care; or

3. Expressly state or imply that selecting a DC Participant Provider as the Beneficiary's main doctor, main provider, and/or the main place the Beneficiary receives care removes a Beneficiary's freedom to choose to obtain health services from providers and suppliers who are not DC Participant Providers or Preferred Providers.

K. The DCE must translate Marketing Materials into any non-English language that is the primary language of at least 5 percent of the individuals in the DCE Service Area (as defined in Section 5.04.G).

L. Unsolicited Contacts

1. Except as otherwise specified in this Agreement, the DCE may use and may permit its DC Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to DCE Activities to conduct Marketing Activities through unsolicited direct contact with Beneficiaries using conventional mail and other print media or email, provided that the Beneficiaries are given an opportunity to opt-out of subsequent such contacts.

2. The DCE is prohibited and shall prohibit its DC Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to DCE Activities from using Marketing Materials or conducting Marketing Activities through the use of door-to-door solicitation, including leaving information such as a leaflet or flyer at a residence, approaching Beneficiaries in common areas, such as parking lots, hallways, lobbies, sidewalks, or using telephonic solicitation, including text messages and leaving voicemail messages. This restriction does not apply to solicitation in common areas of a health care setting, which is subject to the limitations of paragraphs 3 through 5 of this Section 5.04.L and, if the DCE has selected to participate in Paper-Based Voluntary Alignment, Appendix C.

3. The DCE may conduct and may permit DC Participant Providers, Preferred Providers, and other individuals and entities performing DCE Activities on behalf of the DCE to conduct Marketing Activities in common areas of a health care setting. Common areas of a health care setting include, but are not limited to, common entryways, vestibules, waiting rooms, hospital or nursing home cafeterias, and community, recreational, or conference rooms.

4. Except as provided in paragraph 5 of this Section 5.04.L, the DCE is prohibited and shall prohibit its DC Participant Providers, Preferred Providers, and other individuals and entities performing DCE Activities on behalf of the DCE from conducting Marketing Activities in restricted areas of a health care setting. Restricted areas of a health care setting include, but are not limited to, exam rooms, hospital patient rooms, treatment areas (where patients interact with a health care provider and his/her clinical team and receive treatment, including dialysis treatment facilities), and pharmacy counter areas (where patients interact with pharmacy providers and obtain medications).

5. The DCE may distribute and display Marketing Materials in all areas of the health care setting, including both common areas and restricted areas, except as otherwise specified in this Agreement.

M. Marketing Events

1. The DCE shall ensure that:

   a. Marketing Events do not involve health screenings or any other activity that is used, or could be perceived as being used, to avoid treating At-Risk Beneficiaries or to target certain Beneficiaries for services for the purpose of trying to affect the population of Beneficiaries aligned to the DCE for a subsequent Performance Year.

   b. Marketing Events do not require attendees to provide their contact information as a prerequisite for attending the Marketing Event and that any sign-in sheets used for purposes of the Marketing Event are clearly labeled as optional.

   c. Beneficiary contact information provided at a Marketing Event is used only for the purpose for which is was solicited. For example, Beneficiary contact information provided for a raffle or other drawing is used only for purposes of such raffle or drawing.

   d. Any Marketing Activities conducted and Marketing Materials distributed as part of the Marketing Event comply with the applicable requirements of this Section 5.04 and Section 5.08.

2. In conducting Marketing Events, the DCE may engage in activities including, but not limited to:

   a. Hosting the Marketing Event in a public venue;

   b. Answering Beneficiary-initiated questions regarding the DCE's participation in the Model; or

   c. Distributing the DCE's, a DC Participant Provider's, or a Preferred Provider's business cards and contact information to Beneficiaries.

Section 5.05 Beneficiary Notifications

A. In a form and manner and by one or more dates specified by CMS, the DCE shall provide written notice to all Beneficiaries who have been aligned to the DCE for the Implementation Period.

B. For purposes of the Beneficiary notification required under Section 5.05.A, the DCE shall use the template letter provided by CMS, in which CMS will designate letter content that the DCE shall not change, as well as places in which the DCE may insert its own original content.

C. In accordance with Section 5.04.I, the DCE shall obtain CMS approval of the final notification letter content, including any original content inserted by the DCE, prior to sending such letter to Beneficiaries.

Section 5.06 Availability of Services

A. The DCE shall require its DC Participant Providers and Preferred Providers to make Medically Necessary Covered Services available to Beneficiaries in accordance with applicable laws, regulations and guidance. Beneficiaries and their assignees retain their right to appeal claims determinations in accordance with 42 CFR Part 405, Subpart I.

B. The DCE shall not, and shall require its DC Participant Providers and Preferred Providers to not, take any action to avoid treating At-Risk Beneficiaries or to target certain Beneficiaries for services for the purpose of trying to affect the population of Beneficiaries aligned to the DCE for a subsequent Performance Year.

Section 5.07 Beneficiary Freedom of Choice

A. Consistent with Section 1802(a) of the Act, neither the DCE nor any DC Participant Provider, Preferred Provider, or other individuals or entities performing functions or services related to DCE Activities, shall commit any act or omission, nor adopt any policy, that inhibits Beneficiaries from exercising their freedom to obtain health services from providers and suppliers who are not DC Participant Providers or Preferred Providers. This prohibition shall not apply to referrals made by employees or contractors who are operating within the scope of their employment or contractual arrangement with the employer or contracting entity, provided that the employees and contractors remain free to make referrals without restriction or limitation if a Beneficiary expresses a preference for a different provider or supplier, or the referral is not in the Beneficiary's best medical interests in the judgment of the referring party.

B. Notwithstanding the requirements of Section 5.07.A, the DCE may communicate to Beneficiaries the benefits of receiving care with the DCE. All such communications shall be deemed Marketing Materials or Marketing Activities. To ensure that Beneficiaries are not misinformed or misled about the Model, CMS may provide the DCE with scripts, talking points or other materials explaining these benefits.

Section 5.08 Prohibition on Beneficiary Inducements

Except as otherwise permitted by applicable law, the DCE shall not, and shall require its DC Participant Providers, Preferred Providers, and other individuals or entities performing functions and services related to DCE Activities to not, provide gifts or other remuneration to Beneficiaries to induce them to receive items or services from the DCE, DC Participant Providers, or Preferred Providers, or to induce them to continue to receive items or services from the DCE, DC Participant Providers, or Preferred Providers.

Section 5.09 HIPAA Requirements

A. The DCE acknowledges that it is a covered entity or a business associate, as those terms are defined in 45 CFR § 160.103, of DC Participant Providers or Preferred Providers who are covered entities.

B. The DCE shall have all appropriate administrative, technical, and physical safeguards in place before the Start Date to protect the privacy and security of protected health information (PHI) in accordance with 45 CFR § 164.530(c).

C. The DCE shall maintain the privacy and security of all Model-related information that identifies individual Beneficiaries in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules and all relevant HIPAA Privacy and Security guidance applicable to the use and disclosure of PHI by covered entities and business associates, as well as other applicable federal and state laws and regulations.

ARTICLE VI Data Sharing and Reports

Section 6.01 General

A. Subject to the limitations discussed in this Agreement, and in accordance with applicable law, including HIPAA and the regulations in 42 CFR Part 2 regarding confidentiality of substance use disorder patient records, during the Implementation Period CMS will offer the DCE an opportunity to request certain Beneficiary-identifiable data, which are described in Section 6.02, using a data request form which CMS will provide and maintain (the "**HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet**").

B. Except for the data described in Section 6.02.C(a), the data provided to the DCE under the preceding paragraph will omit individually identifiable data for Beneficiaries who have opted out of data sharing with the DCE, as described in Section 6.04. The data provided to the DCE will also omit substance use disorder data for any Beneficiaries who have not opted into substance use disorder data sharing, as described in Section 6.05.

Section 6.02 Provision of Certain Claims Data and Beneficiary Reports

A. CMS believes that the health care operations work of the DCE (that is acting on its own behalf as a HIPAA covered entity (CE) or that is a business associate (BA) acting on behalf of its DC Participant Providers or Preferred Providers that are HIPAA CEs) would benefit from the receipt of certain beneficiary-identifiable claims data on Originally Aligned Beneficiaries and DC Beneficiaries. CMS will therefore offer to the DCE an opportunity to request specific Beneficiary-identifiable data by completing the HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet. 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.

B. In offering this Beneficiary-identifiable data, CMS does not represent that the DCE or any DC Participant Provider or Preferred Provider has met all applicable HIPAA requirements for requesting data under 45 CFR § 164.506(c)(4). The DCE and its DC Participant Providers and Preferred Providers should consult with their own counsel to make those determinations prior to requesting this data from CMS.

C. The Beneficiary-identifiable data available is the data described in HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet and this Agreement, including the following data:

a. ***Alignment Data***. This data will include a list of DC Beneficiaries, the Alignment Year a DC Beneficiary became an Alignment-Eligible Beneficiary (as such terms are defined in Appendix B of this Agreement), and a Part D coverage indicator. This data may also identify those Originally Aligned Beneficiaries who have been excluded from alignment.

b. ***Claims Data***. This data will include Parts A, B, and D claims data for DC Beneficiaries specified in the HIPAA-Covered Disclosure Request and Data Specification Worksheet.

c. ***Risk Adjustment Data***. This data will include DC Beneficiaries' risk scores.

D. The parties mutually agree that, except for data covered by Section 6.02.M below, CMS retains all ownership rights to the data files referred to in the HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet, and the DCE does not obtain any right, title, or interest in any of the data furnished by CMS.

E. The DCE represents, and in furnishing the data files specified in the HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet CMS relies upon such representation, that such data files will be used solely for the purposes described in this Agreement. The DCE 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 DCE further agrees not to sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement.

F. During the Implementation Period, the DCE intends to use the requested information for care management, care coordination, and quality improvement activities for DC Beneficiaries. Information derived from the CMS files specified in the HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet may be shared and used within the legal confines of the DCE and its DC Participant Providers and Preferred Providers in a manner consistent with Section 6.02.G to enable the DCE to improve care integration and be a patient-centered organization.

G. The DCE 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 the HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet to anyone who is not a HIPAA CE DC Participant Provider or Preferred Provider in a treatment relationship with the subject Beneficiary(ies); a HIPAA BA of such a CE DC Participant Provider or Preferred Provider; the DCE's BA, where the DCE is itself a HIPAA CE; the DCE's sub-BA, which is hired by the DCE to carry out work on behalf of the CE DC Participant Providers or Preferred Providers; or a non-participant HIPAA CE in a treatment relationship with the subject Beneficiary(ies). When using or disclosing PHI or personally identifiable information (PII), obtained from files specified in the HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet, the DCE must make "reasonable efforts to limit" the information to the "minimum necessary" to accomplish the intended purpose of the use, disclosure or request. The DCE 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 the HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet.

Subject to the limits specified above and elsewhere in this Agreement and applicable law, the DCE may link individually identifiable information specified in the HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet (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 DCE and its DC Participant Providers or Preferred Providers. The DCE 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).

H. The DCE shall 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/sites/whitehouse.gov/files/omb/circulars/A130/a130revised.pdf 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 DCE acknowledges that the use of unsecured telecommunications, including

the Internet, to transmit directly or indirectly individually identifiable information from the files specified in the HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet or any such derivative data files is strictly prohibited. Further, the DCE agrees that the data specified in the HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet must not be physically moved, transmitted or disclosed in any way from or by the site of the custodian indicated in the HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet other than as provided in this Agreement without written approval from CMS, unless such movement, transmission or disclosure is required by a law.

I. The DCE shall grant access to the data and/or the facility(ies) in which the data is maintained to the authorized representatives of CMS or Office of Inspector General of the Department of Health and Human Services (OIG) Authority , including at the site of the custodian indicated in the HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet, for the purpose of inspecting to confirm compliance with the terms of this Agreement.

J. The DCE agrees that any use of CMS data in the creation of any document concerning the purpose specified in this section and the HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet 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.

K. The DCE shall 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 DCE shall cooperate fully in any federal incident security process that results from such improper use or disclosure.

L. The parties mutually agree that the individual named in the HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet is designated as Custodian of the CMS data files on behalf of the DCE 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 DCE shall 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.

M. Data disclosed to the DCE pursuant to the HIPAA-Covered Disclosure Request Attestation and Data Specification Worksheet may be retained by the DCE until the expiration or termination of this Agreement. The DCE is permitted to retain any individually identifiable health information from such data files or derivative data files after the expiration or termination of the Agreement if the DCE 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 DCE provides such data in the course of carrying out the Model 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 DCE 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 expiration or termination of the Agreement, except as CMS shall authorize in writing or as otherwise required by law. Except for disclosures for treatment purposes, the DCE 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 expiration or termination of the Agreement.

Section 6.03 De-Identified Reports

During the Implementation Period, CMS may provide reports to the DCE, which will be de-identified in accordance with HIPAA requirements in 45 CFR § 164.514(b). These reports may include a summary of claims, alignment, risk adjustment, and historical experience data of Originally Aligned Beneficiaries. This aggregate information will not include individually identifiable health information and will incorporate de-identified data from Originally Aligned Beneficiaries who have opted out of data sharing.

Section 6.04 Beneficiary Rights to Opt Out of Data Sharing

A. The DCE shall provide 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 Beneficiary has elected to decline claims data sharing, CMS may still engage in certain limited data sharing for quality improvement purposes.

B. The DCE shall allow Beneficiaries to reverse a data sharing preference at any time by calling 1-800-MEDICARE.

C. 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 Medicare Shared Savings Program, the Pioneer ACO Model, or the Next Generation ACO Model.

D. The DCE may affirmatively contact a DC Beneficiary who has elected to decline claims data sharing no more than one time during the Implementation Period to provide information regarding data sharing. Such contact includes mailings, phone calls, electronic communications, or other methods of communicating with Beneficiaries outside of a clinical setting.

E. In the event that a DC Professional is terminated from the DCE for any reason, if that departing DC Professional is the sole DC Professional in the DCE to have submitted claims for a particular Beneficiary during the 12-month period prior to the effective date of the termination, CMS will administratively opt the Beneficiary out of all claims data-sharing under Section 6.02 within 30 days of the effective date of the termination, unless—

1. The Beneficiary affirmatively consents to continued data sharing of such claims with the DCE through an authorization that meets the requirements under 45 CFR § 164.508(b); or

2. The Beneficiary has become the patient of another DC Professional participating in the DCE.

F. Notwithstanding the foregoing, the DCE shall receive claims data regarding substance use disorder treatment only if the 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 6.05 of this Agreement.

Section 6.05 Beneficiary Substance Use Disorder Data Opt-In

A. The DCE may inform each DC Beneficiary, in compliance with applicable law:

1. That he or she may elect to allow the DCE to receive Beneficiary-identifiable data regarding his or her utilization of substance use disorder services;

2. Of the mechanism by which the Beneficiary can make this election; and

3. That 1-800-MEDICARE will answer any questions regarding sharing of data regarding utilization of substance use disorder services.

B. A Beneficiary may opt in to substance use disorder data sharing only by submitting a CMS-approved substance use disorder opt in form to the DCE. The DCE shall promptly send the opt-in form to CMS.

ARTICLE VII Care Improvement Objectives

Section 7.01 General

A. The DCE shall implement processes and protocols that relate to the following objectives for patient-centered care:

1. Promotion of evidence-based medicine, such as through the establishment and implementation of evidence-based guidelines at the organizational or

institutional level. An evidence-based approach would also regularly assess and update such guidelines.

2. Processes to ensure Beneficiary/caregiver engagement, and the use of shared decision making processes by DC Participant Providers that take into account Beneficiaries' unique needs, preferences, values, and priorities. Measures for promoting Beneficiary engagement include, but are not limited to, the use of decision support tools and shared decision making methods with which the Beneficiary can assess the merits of various treatment options in the context of his or her values and convictions. Beneficiary engagement also includes methods for fostering what might be termed "health literacy" in Beneficiaries and their families or caregivers.

3. Coordination of Beneficiaries' care and care transitions (e.g., sharing of electronic summary records across health care providers, telehealth, remote Beneficiary monitoring, and other enabling technologies).

4. Providing Beneficiaries access to their own medical records and to clinical knowledge so that they may make informed choices about their care.

5. Ensuring individualized care for Beneficiaries, such as through personalized care plans.

6. Routine assessment of Beneficiary and caregiver and/or family experience of care and seek to improve where possible.

7. Providing care that is integrated with the community resources Beneficiaries require.

B. The DCE shall require its DC Participant Providers to comply with and implement these designated processes and protocols, and shall institute remedial processes and penalties, as appropriate, for DC Participant Providers that fail to comply with or implement a required process or protocol.

Section 7.02 Outcomes-Based Contracts with Other Purchasers

A. CMS may require the DCE to report to CMS, in a manner and by a date determined by CMS, information regarding the scope of outcomes-based contracts held by the DCE and/or its DC Participant Providers with non-Medicare purchasers. For purposes of this provision, outcomes-based contracts mean contracts that evaluate patient experiences of care, include financial accountability (e.g., shared savings or financial risk) and/or quality performance standards.

B. Notwithstanding other sections of this Agreement, failure to comply with Section 7.02.A may result in CMS imposing appropriate remedial actions under Section 13.01 but shall not be cause for CMS to terminate this Agreement.

ARTICLE VIII DCE Selections and Approval

Section 8.01 DCE Selection for the Implementation Period

A. For the Implementation Period, in a form and manner and by a deadline specified by CMS, the DCE shall submit to CMS its decision with respect to participation in Paper-Based Voluntary Alignment.

B. The DCE's decision to participate in Paper-Based Voluntary Alignment for the Implementation Period refers to the DCE's decision to participate in Voluntary Alignment Activities specific to Paper-Based Voluntary Alignment in accordance with Appendix C during the Implementation Period for purposes of aligning Beneficiaries to the DCE for the first Performance Year.

Section 8.02 DCE Selections for the Model Performance Period

A. If the DCE wishes to continue participation in the Model during the Model Performance Period, by a time and in a form and manner specified by CMS, the DCE shall submit its selected Risk Sharing Option (Professional or Global) for the first two Performance Years of the Model Performance Period. This Risk Sharing Option selection may differ from the Risk Sharing Option selected by the DCE as part of its application to participate in the Model.

B. If the DCE wishes to continue participation in the Model during the Model Performance Period, by a time and in a form and manner specified by CMS, the DCE shall submit its selections for the following for the first Performance Year of the Model:

1. The DCE's selected DC Capitation Payment Mechanism. If the DCE has selected to participate in Global for the first two Performance Years of the Model Performance Period, the DCE may select either Total Care Capitation Payment or Primary Care Capitation Payment as its DC Capitation Payment Mechanism for the first Performance Year. If the DCE has selected to participate in Professional for the first two Performance Years of the Model Performance Period, the DCE may select only Primary Care Capitation Payment as its DCE Capitation Payment Mechanism for the first Performance Year;
2. If the DCE selects to participate in Primary Care Capitation Payment for the first Performance Year, whether the DCE selects to participate in Advanced Payment;
3. The DCE's decision whether to participate in the Risk Mitigation Option;
4. The Benefit Enhancements or Beneficiary Engagement Incentives, if any, that the DCE selects to offer with its DC Participant Providers and Preferred Providers; and
5. The DCE's selected Alignment Methodology (Prospective Alignment or Prospective Plus Alignment);

6. The DCE's decision with respect to participation in Paper-Based Voluntary Alignment. The DCE's decision to participate in Paper-Based Voluntary Alignment for the first Performance Year refers to the DCE's decision to participate in Voluntary Alignment Activities specific to Paper-Based Voluntary Alignment in accordance with Appendix C during the first Performance Year for purposes of aligning Beneficiaries to the DCE for the second Performance Year. If the DCE has selected Prospective Plus Alignment for the first Performance Year, the DCE's decision to participate in Voluntary Alignment Activities during the Performance Year also will be used for purposes of aligning Beneficiaries to the DCE for subsequent calendar quarters of the first Performance Year.

C. Benefit Enhancements and Beneficiary Engagement Incentives

1. The DCE may select to provide one or more Benefit Enhancements and may select to provide one or more Beneficiary Engagement Incentives for the first Performance Year. CMS will provide the DCE with information regarding the Benefit Enhancements and Beneficiary Engagement Incentives available for selection for the first Performance Year in advance of the deadline for making such selections.

2. The DCE shall submit to CMS, in a form and manner and by a date specified by CMS, a plan for implementing each Benefit Enhancement and each Beneficiary Engagement Incentive selected by the DCE pursuant to Section 8.02.B ("**Implementation Plan**").

3. If CMS determines that the DCE's proposed implementation of one or more Benefit Enhancements or Beneficiary Engagement Incentives is inconsistent with the terms of the agreement specified in Section 1.03 or likely to result in abuse, CMS may reject the DCE's selection to provide one or more Benefit Enhancements or Beneficiary Engagement Incentives or may reject (or require the amendment of) the DCE's Implementation Plan. If CMS rejects an Implementation Plan for a Benefit Enhancement or Beneficiary Engagement Incentive, the DCE shall not implement the Benefit Enhancement or Beneficiary Engagement Incentive for the first Performance Year.

ARTICLE IX Participation in Evaluation, Shared Learning Activities, and Site Visits

Section 9.01 Evaluation Requirement

A. General

1. The DCE shall participate and cooperate in any independent evaluation activities conducted by or on behalf of CMS aimed at assessing the impact of the Model on the goals of better health, better health care, and lower Medicare per capita costs for DC Beneficiaries. The DCE shall require its DC Participant Providers and Preferred Providers to participate and

cooperate in any such independent evaluation activities conducted by or on behalf of CMS.

2. The DCE shall ensure that it has written arrangements in place with any individuals and entities performing functions and services related to DCE Activities, that are necessary to ensure CMS or its designees can carry out evaluation activities.

B. Primary Data

In its evaluation activities, CMS may collect qualitative and quantitative data from the following sources:

1. Site visits;
2. Interviews with Beneficiaries and their caregivers;
3. Focus groups of Beneficiaries and their caregivers;
4. Interviews with DCE, DC Participant Provider, and Preferred Provider staff;
5. Focus groups with DCE, DC Participant Provider, and Preferred Provider staff;
6. Direct observation of Beneficiary interactions with DC Participant Provider and Preferred Provider staff, care management meetings among DC Participant Provider and Preferred Provider staff, and other activities related to the DCE's participation in the Model; and
7. Surveys.

C. Secondary Data

In its evaluation activities, CMS may use data or information submitted by the DCE as well as claims submitted to CMS for items and services furnished to Beneficiaries. This data may include, but is not limited to:

1. Survey data from Consumer Assessment of Healthcare Providers and Systems (CAHPS®)[1] surveys;
2. Clinical data such as lab values; and
3. Medical records.

Section 9.02 Shared Learning Activities

A. The DCE shall participate in CMS-sponsored learning activities designed to strengthen results and share learning that emerges from participation in the Model.

[1] CAHPS® is a registered trademark of the Agency for Healthcare Research and Quality.

B. The DCE shall participate in periodic conference calls, site visits, and virtual or in-person meetings, and actively share resources, tools and ideas as prescribed by CMS.

Section 9.03 Site Visits

A. The DCE shall cooperate and require its DC Participant Providers and Preferred Providers to cooperate in periodic site visits by or on behalf of CMS in order to facilitate evaluation, shared learning activities, or the fulfilment of the terms of this Agreement.

B. CMS shall schedule site visits to DC Participant Providers and Preferred Providers with the DCE no fewer than 15 days in advance. To the extent practicable, CMS will attempt to accommodate the DCE's request for particular dates in scheduling site visits. However, the DCE may not request a date that is more than 60 days after the date of the initial site visit notice from CMS.

C. The DCE shall ensure that personnel with the appropriate responsibilities and knowledge associated with the purpose of the site visit are available during site visits.

D. Notwithstanding the foregoing, CMS may perform unannounced site visits at the office of any DC Participant Provider or Preferred Provider at any time to investigate concerns about the health or safety of Beneficiaries or other program integrity issues.

E. Nothing in this Agreement shall be construed to limit or otherwise prevent CMS from performing site visits permitted by applicable law or regulations.

Section 9.04 Rights in Data and Intellectual Property

A. CMS may use any data obtained pursuant to the Model to evaluate the Model and to disseminate quantitative results and successful care management techniques, to other providers and suppliers and to the public. Data to be disseminated may include results of patient experience of care and quality of life surveys as well as measures based upon claims and medical records. The DCE will be permitted to comment on evaluation reports for factual accuracy but may not edit conclusions or control the dissemination of reports.

B. Notwithstanding any other provision in this Agreement, all proprietary trade secret information and technology of the DCE or its DC Participant Providers and Preferred Providers is and shall remain the sole property of the DCE, the DC Participant Provider, or Preferred Provider and, except as required by federal law, shall not be released by CMS without express written consent. The regulation at 48 CFR § 52.227-14, "Rights in Data-General" is hereby incorporated by reference into this Agreement. CMS does not acquire by license or otherwise, whether express or implied, any intellectual property right or other rights to the DCE's, DC Participant Providers', or Preferred Providers' proprietary information or technology.

C. The DCE acknowledges that it has submitted to CMS a form identifying specific examples of what it considers proprietary and confidential information currently maintained by the DCE that should not be publicly disclosed. The DCE must notify CMS of any updates to this form, which is attached as Appendix D.

ARTICLE X Public Reporting and Release of Information

Section 10.01 DCE Public Reporting and Transparency

The DCE shall report the following organizational information on a publicly accessible website maintained by the DCE.

A. Name and location of the DCE;

B. Primary contact information for the DCE;

C. Identification of all DC Participant Providers and Preferred Providers;

D. Identification of all joint ventures between or among the DCE and any of its DC Participant Providers and Preferred Providers;

E. Identification of the DCE's key clinical and administrative leaders and the name of any company by which they are employed; and

F. Identification of members of the DCE's governing body and the name of any entity by which they are employed.

CMS may publish some or all of this information on the CMS website.

Section 10.02 DCE Release of Information

A. The DCE, its DC Participant Providers, and its Preferred Providers shall obtain prior approval from CMS during the term of this Agreement and for 1 year thereafter for the publication or release of any press release, external report or statistical/analytical material that materially and substantially references the DCE's participation in the Model. External reports and statistical/analytical material may include, but are not limited to, papers, articles, professional publications, speeches, and testimony.

B. All external reports and statistical/analytical material that are subject to this Section 10.02 must include the following statement on the first page: "The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of CMS. The authors assume responsibility for the accuracy and completeness of the information contained in this document."

ARTICLE XI Compliance and Oversight

Section 11.01 DCE Compliance Plan

A. The DCE shall have a compliance plan that includes at least the following elements:

1. A designated compliance official or individual who is not legal counsel to the DCE and reports directly to the DCE's governing body;
2. Mechanisms for identifying and addressing compliance problems related to the DCE's operations and performance;
3. A method for employees or contractors of the DCE, its DC Participant Providers and Preferred Providers, and other individuals or entities performing functions or services related to DCE Activities to anonymously report suspected problems related to the DCE to the compliance official;
4. Compliance training for the DCE and its DC Participant Providers and Preferred Providers; and
5. A requirement for the DCE to report probable violations of law to an appropriate law enforcement agency.

B. The DCE's compliance plan must be in compliance with all applicable laws and regulations and be updated periodically to reflect changes in those laws and regulations.

Section 11.02 CMS Monitoring and Oversight Activities

A. CMS shall conduct monitoring activities to evaluate compliance by the DCE, its DC Participant Providers, and its Preferred Providers with the terms of this Agreement. Such monitoring activities may include, without limitation:

1. Claims analyses to identify fraudulent behavior or program integrity risks, such as inappropriate reductions in care (e.g., through claims-based utilization, inappropriate changes in case-mix or quality measures), efforts to manipulate risk scores or aligned populations, overutilization, and cost-shifting to other payers or populations; and
2. Documentation requests sent to the DCE, its DC Participant Providers, and/or its Preferred Providers, including surveys and questionnaires.

B. In conducting monitoring and oversight activities, CMS or its designees may use any relevant data or information including, without limitation, all Medicare claims submitted for items or services furnished to Beneficiaries.

Section 11.03 DCE Compliance with Monitoring and Oversight Activities

The DCE shall cooperate with, and the DCE shall require its DC Participant Providers, its Preferred Providers and other individuals and entities performing functions and services related to DCE Activities to cooperate with all CMS monitoring and oversight requests and activities.

Section 11.04 Compliance with Laws

A. <u>Agreement to Comply</u>

1. The DCE shall comply with, and shall require all DC Participant Providers, Preferred Providers, and other individuals or entities

performing functions or services related to DCE Activities to comply with the applicable terms of this Agreement and all applicable statutes regulations, and guidance, including without limitation: (a) federal criminal laws; (b) the False Claims Act (31 U.S.C. § 3729 et seq.); (c) the anti-kickback statute (42 U.S.C. § 1320a-7b(b)); (d) the civil monetary penalties law (42 U.S.C. § 1320a-7a); and (e) the physician self-referral law (42 U.S.C. § 1395nn).

2. This Agreement does not waive any obligation of the DCE or the DCE's DC Participant Providers or Preferred Providers to comply with the terms of any other CMS contract, agreement, model, or demonstration.

B. State Recognition

During the term of this Agreement, the DCE shall be in compliance with applicable state licensure requirements regarding risk-bearing entities in each state in which it operates unless it has provided a written attestation to CMS that it is exempt from such state laws. If the DCE is exempt from such laws, it shall submit a certification to CMS no later than 60 days after the Start Date or after the date on which it becomes exempt from any such laws.

C. Reservation of Rights

1. Nothing contained in this Agreement or in the application process for the Model is intended or can be construed as a waiver by the United States Department of Justice, the Internal Revenue Service, the Federal Trade Commission, OIG, or CMS of any right to institute any proceeding or action for violations of any statutes, rules or regulations administered by the government, or to prevent or limit the rights of the government to obtain relief under any other federal statutes or regulations, or on account of any violation of this Agreement or any other provision of law. This Agreement cannot be construed to bind any government agency except CMS and this Agreement binds CMS only to the extent provided herein.

2. The failure by CMS to require performance of any provision of this Agreement does not affect CMS's right to require performance at any time thereafter, nor does a waiver of any breach or default of this Agreement constitute a waiver of any subsequent breach or default or a waiver of the provision itself.

D. Office of Inspector General of the Department of Health and Human Services (OIG) Authority

None of the provisions of this Agreement limit or restrict the OIG's authority to audit, evaluate, investigate, or inspect the DCE, its DC Participant Providers, Preferred Providers or other individuals and entities performing functions or services related to DCE Activities.

E. Other Government Authority

None of the provisions of this Agreement limit or restrict any other government authority that is permitted by law to audit, evaluate, investigate, or inspect the DCE, its DC Participant Providers, Preferred Providers or other individuals and entities performing functions or services related to DCE Activities.

Section 11.05 Certification of Data and Information

A. With respect to data and information generated or submitted to CMS by the DCE, DC Participant Providers, Preferred Providers, or other individuals or entities performing functions or services related to DCE Activities, the DCE shall ensure that an individual with the authority to legally bind the individual or entity submitting such data or information certifies the accuracy, completeness, and truthfulness of that data and information to the best of his or her knowledge, information, and belief.

B. At the end of the Implementation Period, an individual with the legal authority to bind the DCE must certify to the best of his or her knowledge, information, and belief:

1. That the DCE, its DC Participant Providers, its Preferred Providers, and other individuals or entities performing functions or services related to DCE Activities are in compliance with Model requirements; and

2. The accuracy, completeness, and truthfulness of all data and information that are generated or submitted by the DCE, DC Participant Providers, Preferred Providers, or other individuals or entities performing functions or services related to DCE Activities.

ARTICLE XII Audits and Record Retention

Section 12.01 Right to Audit

The DCE agrees, and must require all of its DC Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to DCE Activities to agree, that the government (including CMS, HHS, and the Comptroller General or their designees) has the right to audit, inspect, investigate, and evaluate any books, contracts, records, documents and other evidence of the DCE and its DC Participant Providers, its Preferred Providers, and other individuals or entities performing functions or services related to DCE Activities that pertain to the following:

A. The DCE's compliance with the terms of this Agreement, including provisions that require the DCE to impose duties or requirements on DC Participant Providers or Preferred Providers; and

B. Whether DC Participant Providers and Preferred Providers complied with the duties and requirements imposed on them by the DCE pursuant to the terms of this Agreement; and

C. The quality of services performed under this Agreement.

Section 12.02 Maintenance of Records

The DCE shall maintain and shall give the government (including CMS, HHS, and the Comptroller General or their designees) access to, and shall require all DC Participant Providers, Preferred Providers, and other individuals and entities performing functions or services related to DCE Activities to maintain, and give the government access to, all books, contracts, records, documents, and other evidence (including data related to Medicare utilization and costs, quality performance measures, and financial arrangements) sufficient to enable the audit, evaluation, inspection, or investigation of the Model, including the subjects identified in Section 12.01. The DCE shall maintain, and shall require all DC Participant Providers, Preferred Providers, and individuals and entities performing functions or services related to DCE Activities to maintain, such books, contracts, records, documents, and other evidence for a period of 10 years from the expiration or termination of this Agreement or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless:

A. CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the DCE at least 30 calendar days before the normal disposition date; or

B. There has been a termination, dispute, or allegation of fraud or similar fault against the DCE, its DC Participant Providers, Preferred Providers, or other individuals or entities performing functions or services related to DCE Activities, in which case the records shall be maintained for an additional six years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

ARTICLE XIII Remedial Action and Termination

Section 13.01 Remedial Action

A. If CMS determines that any provision of this Agreement may have been violated, CMS may take one or more of the following actions:

1. Notify the DCE and, if appropriate, the DC Participant Provider, and/or Preferred Provider of the violation;
2. Require the DCE to provide additional information to CMS or its designees;
3. Conduct site visits, interview Beneficiaries, or take other actions to gather information;
4. Place the DCE on a monitoring and/or auditing plan developed by CMS;
5. Require the DCE to remove a DC Participant Provider or Preferred Provider from the DC Participant Provider List or Preferred Provider List and to terminate its arrangement, immediately or within a timeframe specified by CMS, with such DC Participant Provider or Preferred Provider with respect to this Model;

6. Require the DCE to terminate its relationship with any other individual or entity performing functions or services related to DCE Activities;

7. Request a corrective action plan (CAP) from the DCE that is acceptable to CMS, in which case, the following requirements apply:

   a. The DCE shall submit a CAP for CMS approval by a deadline established by CMS; and

   b. The CAP must address what actions the DCE will take (or will require any DC Participant Provider, Preferred Provider or other individual or entity performing functions or services related to DCE Activities to take) within a specified time period to ensure that all deficiencies will be corrected and that the DCE will be in compliance with the terms of this Agreement;

8. Prohibit the DCE from accessing any or all waivers of existing law made pursuant to section 1115A(d)(1) of the Act;

9. Discontinue the provision of data sharing and reports to the DCE under Article VI;

10. Prohibit the DCE from participating in Paper-Based Voluntary Alignment, Distributing Marketing Materials, or conducting Marketing Activities, including Voluntary Alignment Activities.

11. Retroactively reverse the alignment of Beneficiaries to the DCE that is based solely on Voluntary Alignment.

B. CMS may impose additional remedial actions or terminate this Agreement pursuant to Section 13.02 if CMS determines that remedial actions were insufficient to correct noncompliance with the terms of this Agreement.

C. CMS may require the DCE to remove a DC Participant Provider or Preferred Provider from the DCE's DC Participant Provider List or Preferred Provider List and to terminate its arrangement with the removed DC Participant Provider or Preferred Provider if CMS determines that the DC Participant Provider or Preferred Provider:

1. Has failed to comply with any Medicare program requirement, rule, or regulation;

2. Has failed to comply with the DCE's CAP, the monitoring and/or auditing plan developed by CMS for the DCE, or other remedial action imposed by CMS; or

3. Has taken any action that threatens the health or safety of a Beneficiary or other patient.

4. Is subject to sanctions or other actions of an accrediting organization or a federal, state or local government agency; or

5. Is subject to investigation or action by HHS (including OIG and CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the government has intervened, or similar action.

Section 13.02 Termination of Agreement by CMS

CMS may immediately or with advance notice terminate this Agreement if:

A. CMS determines that the Agency no longer has the funds to support the Model;

B. CMS modifies or terminates the Model pursuant to section 1115A(b)(3)(B) of the Act;

C. CMS determines that the DCE:

1. Has failed to comply with any term of this Agreement or any other Medicare program requirement, rule, or regulation;

2. Has failed to comply with a monitoring and/or auditing plan;

3. Has failed to submit, obtain approval for, implement or fully comply with the terms of a CAP;

4. Has failed to demonstrate improved performance following any remedial action;

5. Has taken any action that threatens the health or safety of a Beneficiary or other patient;

6. Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the Model;

7. Assigns or purports to assign any of the rights or obligations under this Agreement, voluntarily or involuntarily, whether by merger, consolidation, dissolution, operation of law, or any other manner, without the written consent of CMS.

8. Has significant program integrity risks, including but not limited to:

i. Is subject to sanctions or other actions of an accrediting organization or a federal, state or local government agency; or

ii. Is subject to investigation or action by HHS (including OIG and CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the government has intervened, or similar action;

D. CMS determines that one or more of the DCE's DC Participant Providers or Preferred Providers has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the Model; or

E. The state in which the DCE operates enters into an arrangement with CMS that is based on a statewide global or per-capita Medicare payment.

Section 13.03 Termination of Agreement by DCE

The DCE may terminate this Agreement upon advance written notice to CMS. Such notice must specify the effective date of the termination, which date may be no sooner than 30 days following the date of that notice.

Section 13.04 Notifications to DC Participant Providers, Preferred Providers, and Beneficiaries upon Termination

A. If this Agreement is terminated under Sections 13.02 or 13.03, the DCE shall provide written notice of the termination to all DC Participant Providers and Preferred Providers. The DCE shall also post a notice of the termination on its DCE website. The DCE shall deliver such written notice in a manner determined by CMS and no later than 30 days before the effective date of termination unless a later date is specified by CMS. The DCE shall include in such notices any content specified by CMS, including information regarding data destruction, Marketing Activities, in-kind incentives and services as described in Section 5.08.B.

B. The DCE shall provide written notice of the termination to DC Beneficiaries and may provide written notice of the termination to other Beneficiaries. The DCE shall deliver such notices in a manner specified by CMS and no later than 30 days before the effective date of termination unless a later date is specified by CMS. The DCE shall include in such notices any content specified by CMS. Any notice to Beneficiaries is subject to review and approval by CMS under Section 5.04 as Marketing Materials.

ARTICLE XIV Limitation on Review and Dispute Resolution

Section 14.01 Limitations on Review

There is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

A. The selection of organizations, sites, or participants to test models selected for testing or expansion under section 1115A of the Act, including the decision by CMS to terminate this Agreement or to require the termination of any individual's or entity's status as a DC Participant Provider or Preferred Provider;

B. The elements, parameters, scope, and duration of such models for testing or dissemination;

C. Determinations regarding budget neutrality under section 1115A(b)(3);

D. The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B);

E. Determinations about expansion of the duration and scope of a model under section 1115A(c), including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection (c); and

F. The alignment of Beneficiaries to the DCE by CMS.

Section 14.02 Dispute Resolution

A. Right to Reconsideration

The DCE may request reconsideration of a determination made by CMS pursuant to this Agreement only if such reconsideration is not precluded by section 1115A(d)(2) of the Act or this Agreement.

1. Such a request for reconsideration by the DCE must satisfy the following criteria:

   a. The request must be submitted to a designee of CMS ("**Reconsideration Official**") who—

      i. Is authorized to receive such requests; and

      ii. Did not participate in the determination that is the subject of the reconsideration request.

   b. The request must contain a detailed, written explanation of the basis for the dispute, including supporting documentation.

   c. The request must be made within 30 days of the date of the determination for which reconsideration is being requested via email to CMS at the address specified in Section 15.01 or such other address as may be specified by CMS.

2. Requests that do not meet the requirements of Section 14.02.A.1 will be denied by the Reconsideration Official.

3. Within 10 business days of receiving a request for reconsideration, the Reconsideration Official will send to the DCE and to CMS a written acknowledgement of receipt of the reconsideration request. Such an acknowledgement will set forth:

   a. The review procedures; and

   b. A schedule that permits each party to submit documentation in support of the party's position for consideration by the Reconsideration Official.

B. Standards for Reconsideration

1. The parties shall proceed diligently with the performance of this Agreement during the course of any dispute arising under the Agreement.

2. The reconsideration will consist of a review of documentation that is submitted timely and in accordance with the standards specified by the Reconsideration Official.

3. The burden of proof is on the DCE to demonstrate to the Reconsideration Official with clear and convincing evidence that the determination is inconsistent with the terms of the Agreement.

C. Reconsideration Determination

1. The reconsideration determination will be based only upon:

   a. Position papers and supporting documentation that are timely submitted to the Reconsideration Official and meet the standards for submission under Section 14.02.A.1; and

   b. Documents and data that were timely submitted to CMS in the required format before the agency made the determination that is the subject of the reconsideration request.

2. The Reconsideration Official will issue to CMS and to the DCE a written notification of the reconsideration determination. Absent unusual circumstances, such written notification will be issued within 60 days of receipt of timely filed position papers and supporting documentation.

3. Effect of the Reconsideration Determination

   a. The determination of the Reconsideration Official is final and binding.

   b. The reconsideration review process under this Agreement shall not be construed to negate, diminish, or otherwise alter the applicability of existing laws, rules, and regulations or determinations made by other government agencies.

ARTICLE XV Miscellaneous

Section 15.01 Agency Notifications and Submission of Reports

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this Agreement shall be submitted to the parties at the addresses set forth below.

CMS: Direct Contracting Model

Centers for Medicare & Medicaid Services

7500 Security Boulevard

Mailstop: WB-06-05

Baltimore, MD 21244

Email: DPC@cms.hhs.gov

DCE: _____

Address: _____

_____

_____

_____

Email: _____

_____

Section 15.02 Notice of Bankruptcy

If the DCE has filed a bankruptcy petition, whether voluntary or involuntary, the DCE must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment has been made by either CMS or the DCE under the terms of each model tested under section 1115A of the Act in which the DCE is participating or has participated and all administrative or judicial review proceedings relating to any payments under such models have been fully and finally resolved. The notice of bankruptcy must be sent by certified mail no later than 5 days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number), and a list of all models tested under section 1115A of the Act in which the DCE is participating or has participated. This list need not identify a model tested under section 1115A of the Act in which the DCE participated if final payment has been made under the terms of the model and all administrative or judicial review proceedings regarding model-specific payments between the DCE and CMS have been fully and finally resolved with respect to that model. The notice to CMS must be addressed to the CMS Office of Financial Management, Mailstop C3-01-24, 7500 Security Boulevard, Baltimore, Maryland 21244 or to such other address as may be specified on the CMS website for purposes of receiving such notices.

Section 15.03 Severability

In the event that any one or more of the provisions of this Agreement is, for any reason, held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Agreement, and this Agreement shall be construed as if such invalid, illegal or unenforceable provisions had never been included in the Agreement, unless the deletion of such provision or provisions would result in such a material change to the Agreement so as to cause continued participation under the terms of the Agreement to be unreasonable.

Section 15.04 Entire Agreement; Amendment

This Agreement, including all Appendices, constitutes the entire agreement between the parties. The parties may amend this Agreement or any Appendix hereto at any time by mutual written agreement; provided, however, that CMS may amend this Agreement or any Appendix hereto

without the consent of the DCE as specified in this Agreement or any Appendix hereto, or for good cause or as necessary to comply with applicable federal or state law, regulatory requirements, accreditation standards or licensing guidelines or rules. To the extent practicable, CMS shall provide the DCE with 30 Days advance written notice of any such unilateral amendment, which notice shall specify the amendment's effective date.

Section 15.05 Survival

Expiration or termination of this Agreement by any party shall not affect the rights and obligations of the parties accrued prior to the effective date of the expiration or termination of this Agreement, except as provided in this Agreement. The rights and duties under the following sections of this Agreement shall also survive termination of this Agreement and apply thereafter:

Article VI (Data Sharing and Reports);

Section 9.01 (Evaluation Requirement);

Section 9.04 (Rights in Data and Intellectual Property);

Section 10.02 (DCE Release of Information);

Section 11.03 (DCE Compliance with Monitoring and Oversight Activities);

Section 11.05 (Certification of Data and Information);

Article XII (Audits and Record Retention);

Section 13.04 (Notifications to DC Participant Providers, Preferred Providers, and Beneficiaries upon Termination);

Section 14.01 (Limitations on Review);

Section 15.05 (Survival);

Section 15.09 (Change in Control); and

Appendix B (Direct Contracting Model Beneficiary Alignment).

Section 15.06 Precedence

If any provision of this Agreement conflicts with a provision of any document incorporated herein by reference, the provision of this Agreement shall prevail.

Section 15.07 Change of DCE Name

The DCE will provide written notice to CMS at least 60 Days before any change in the DCE legal name becomes effective. The notice of legal name change shall be in a form and manner specified by CMS. Subsequent to the change in the DCE's name, the DCE shall forward to CMS a copy of the legal document effecting the name change, authenticated by the appropriate state official, and the parties shall execute an agreement reflecting a change in the DCE's name.

Section 15.08 Prohibition on Assignment

Except with the prior written consent of CMS, the DCE shall not transfer, including by merger (whether the DCE is the surviving or disappearing entity), consolidation, dissolution, or

otherwise: (1) any discretion granted it under this Agreement; (2) any right that it has to satisfy a condition under this Agreement; (3) any remedy that it has under this Agreement; or (4) any obligation imposed on it under this Agreement. The DCE shall provide CMS 90 Days advance written notice of any such proposed transfer. Any purported transfer in violation of this Section is voidable at the discretion of CMS.

Section 15.09 Change in Control

CMS may terminate this Agreement if the DCE undergoes a Change in Control. The DCE shall provide written notice to CMS at least 90 Days before the effective date of any change in control. The written notification must be furnished in a form and manner specified by CMS. For purposes of this paragraph, a "Change in Control" shall mean: (1) the acquisition by any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the DCE representing more than 50% of the DCE's outstanding voting securities or rights to acquire such securities; (2) the acquisition of the DCE by any individual or entity; (3) the sale, lease, exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the DCE; or (4) the approval and completion of a plan of liquidation of the DCE, or an agreement for the sale or liquidation of the DCE. If the DCE does not participate in the Model during the Model Performance Period, this obligation remains in effect until December 31, 2027.

Section 15.10 Certification

The executive signing this Agreement on behalf of the DCE ("**Alternative Payment Model (APM) Executive**") certifies to the best of his or her knowledge, information, and belief that the information submitted to CMS and contained in this Agreement (inclusive of appendices), is accurate, complete, and truthful, and that he or she is authorized by the DCE to execute this Agreement and to legally bind the DCE on whose behalf he or she is executing this Agreement to its terms and conditions.

Section 15.11 Execution in Counterpart

This Agreement and any amendments hereto may be executed in counterparts, each of which shall be deemed to be an original, but all of which, taken together, shall constitute one and the same agreement. This Agreement and any amendments hereto may be signed by autopen or electronic signature (e.g., DocuSign or similar electronic signature technology) and may be transmitted by electronic means. Copies of this Agreement and any amendments hereto that are so executed and delivered have the same force and effect as if executed with handwritten signatures and physically delivered.

[SIGNATURE PAGE FOLLOWS]

Each party is signing this Agreement on the date stated opposite that party's signature. If a party signs but fails to date a signature, the date that the other party receives the signing party's signature will be deemed to be the date that the signing party signed this Agreement.

DCE: _____

Date: _____ By: _____

_____

Name of authorized signatory

_____

APM Executive

CMS: _____

Date: _____ By: _____

_____

Name of Authorized Signatory

_____

CMS Executive

Appendix A: Implementation Period Non-Duplication Waiver and Participant Overlap

I. Waiver

CMS waives the non-duplication requirements under section 1899(b)(4)(A) of the Act and in the implementing regulations at 42 CFR § 425.114(a) and (b) as they apply to the DCE, DC Participant Providers, and Preferred Providers for the duration of the Implementation Period, subject to the requirements set forth in this Appendix A. This waiver is necessary to support the DCE's ability to prepare for participation in the Model during the Model Performance Period, while winding down the DCE's participation in the Medicare Shared Savings Program, as applicable, and to enable the DCE to enter into arrangements with Medicare-enrolled providers and suppliers to participate in the Model as DC Participant Providers and Preferred Providers, and thus enable the DCE to better care for its DC Beneficiaries in an environment where an increasing number of providers and suppliers are participating in ACOs and similar entities under the Medicare Shared Savings Program and in other Medicare shared savings initiatives.

II. DCE Overlap

A. Consistent with the waiver in Section I of this Appendix A, during the Implementation Period, the DCE and its DC Participant Providers and Preferred Providers may simultaneously participate in the Model and the Medicare Shared Savings Program. .

B. If otherwise eligible, the DCE and its DC Participant Providers and Preferred Providers may participate in other Medicare demonstrations, programs, or models during the Implementation Period, to the extent permitted under the terms of such demonstration, program, or model, including the Independence at Home Medical Practice Demonstration Program under section 1866E of the Act, the Maryland Total Cost of Care Model, Next Generation ACO Model, CEC Model, Vermont All-Payer ACO Model, or another Medicare initiative that involves shared savings.

C. If the DCE wishes to continue participation in the Model during the Model Performance Period, any requirements regarding overlapping participation during the Model Performance Period will be specified in the agreement described in Section 1.03 of this Agreement, including a requirement that the DCE and its DC Participant Providers may not simultaneously participate in the Model and the Medicare Shared Savings Program or any other initiative that involves shared savings for the duration of the Model Performance Period.

Appendix B: Direct Contracting Model Beneficiary Alignment

I. DC Beneficiary Alignment Procedures

A Beneficiary is aligned to the DCE for the Implementation Period or the first Performance Year of the Model Performance Period based on either Claims-Based Alignment or Voluntary Alignment in accordance with this Appendix B and the precedence rules described in Section 5.01 of this Agreement.

CMS will automatically run Electronic Voluntary Alignment for purposes of Beneficiary alignment for the Implementation Period and the first Performance Year. If the DCE selects to participate in Paper-Based Voluntary Alignment for the Implementation Period, CMS will use the Paper-Based Voluntary Alignment List submitted to CMS pursuant to Appendix C for purposes of Beneficiary Alignment for the first Performance Year.

Regardless of the Alignment Methodology selected by the DCE for the first Performance Year, CMS aligns Beneficiaries to the DCE prospectively, prior to the start of the Implementation Period or Performance Year, as applicable. The implementation of Prospective Plus Alignment during the Model Performance Period will be governed by the agreement described in Section 1.03 of this Agreement.

II. Claims-Based Alignment

A. Definitions

1. *Alignment Period*

The Implementation Period, the first Performance Year, and each Base Year are each associated with an Alignment Period that consists of two Alignment Years. The first Alignment Year for the Implementation Period and first Performance Year is the 12-month period ending 21 months prior to the start of the Implementation Period or the first Performance Year, as applicable. The second Alignment Year is the 12-month period ending 9 months prior to the start of the Implementation Period or the first Performance Year, as applicable.

Table A of this Appendix B specifies the Alignment Years for the Implementation Period (October 1, 2020 to March 31, 2021), for which there are no Base Years for any type of DCE. Table B of this Appendix B specifies the Alignment Years for the first Performance Year (April 1, 2021 to December 31, 2021) and, if the DCE is approved to participate in the Model as a Standard DCE (as such term is defined in the "Direct Contracting Model: Global and Professional Options Request for Applications," dated November 25, 2019), each of the relevant Base Years for the first Performance Year. If the DCE is approved by CMS to participate in the Model as a High Needs Population DCE or a New Entrant DCE (as such terms are defined in the "Direct Contracting Model: Global and

Professional Options Request for Applications," dated November 25, 2019), Base Years will not be used for the first Performance Year.

Table A Implementation Period (October 1, 2020 – March 31, 2021)

	Implementation Period			
Period Covered	October 1, 2020 — March 31, 2021			
Alignment Year 1	CY2018			
Alignment Year 2	CY2019			

Table B Performance Year One (CY2021)

	First Performance Year	Base Year 1	Base Year 2	Base Year 3
Period Covered	April 1, 2021-December 31, 2021	CY2017	CY2018	CY2019
Alignment Year 1	July 1, 2018-June 30, 2019	July 1, 2014-June 30, 2015	July 1, 2015-June 30, 2016	July 1, 2016-June 30, 2017
Alignment Year 2	July 1, 2019-June 30, 2020	July 1, 2015-June 30, 2016	July 1, 2016-June 30, 2017	July 1, 2017-June 30, 2018

2. *Alignable Beneficiary*

The population of "Alignable Beneficiaries" includes all Beneficiaries who had at least one PQEM Service that was paid by Medicare FFS during one of the two Alignment Years.

3. *Alignment Eligible Beneficiaries*

The population of Alignment Eligible Beneficiaries includes all Alignable Beneficiaries who meet all of the following criteria:

- Enrolled in Medicare Parts A and B;
- Not enrolled in Medicare Advantage or other Medicare managed care plan;

- Do not have Medicare as a secondary payer;
- Resident of the U.S.;
- Reside in a county that is included in the DCE Service Area (as defined in Section 5.04.G of this Agreement).

If the DCE is approved by CMS to participate in the Model as a High Needs Population DCE (as such term is defined in the "Direct Contracting Model: Global and Professional Options Request for Applications," dated November 25, 2019), a Beneficiary must also meet one [or more?] of the following conditions to be considered an Alignment Eligible Beneficiary for the Implementation Period:

- Have one or more conditions that impair the Beneficiary's mobility listed in Table C of this Appendix B;
- Have at least one significant chronic or other serious illness (defined as having a risk score of 3.0 or greater for Aged & Disabled beneficiaries or a risk score of 0.35 or greater for ESRD beneficiaries using the CMS Hierarchical Condition Category (CMS-HCC) methodologies);
- Have a CMS-HCC risk score between 2.0 and 3.0 for Aged & Disabled beneficiaries (or a risk score between 0.24 and 0.35 for ESRD beneficiaries) and two or more unplanned hospital admissions in the previous 12 months; or
- Exhibit signs of frailty, as evidenced by a claim submitted by a provider or supplier specifically for a hospital bed or transfer equipment for use in the home listed in Table D of this Appendix B.

If the DCE is approved by CMS to participate in the Model as a High Needs Population DCE and wishes to continue participation in the Model during the Model Performance Period, CMS will notify the DCE of any alternative or additional alignment eligibility criteria that may be required for the first Performance Year in advance of such Performance Year, which also will be specified in the agreement described in Section 1.03 of this Agreement.

4. *Base Years*

"Base Years" means "**Base Year One**," which is the calendar year that is four years prior to the first Performance Year; "**Base Year Two**," which is the calendar year that is three years prior to the first Performance Year; and "**Base Year Three**", which is the calendar year that is two years prior to the first Performance Year. The three months immediately following each Base Year will be used for claims runout for such Base Year.

5. *PQEM Services*

Primary Care Qualified Evaluation & Management (PQEM) Services means a Primary Care Service furnished by a Primary Care Specialist or a Selected Non-Primary Care Specialist.

6. *Primary Care Services*

Primary Care Services are those services identified by one of the Healthcare Common Procedure Coding System (HCPCS) codes listed in Table E of this Appendix B.

In the case of claims submitted by physicians and non-physician practitioners (NPPs), a Primary Care Service is identified by the HCPCS code appearing on the claim line.

In the case of claims submitted by a Federally Qualified Health Center (FQHC) (type of bill = 77x), a Primary Care Service is identified by the HCPCS code appearing on the line item claim for the service.

In the case of claims submitted by a Rural Health Clinic (RHC) (type of bill = 71x), a Primary Care Service is identified by the HCPCS code appearing on the line item claim for the service.

In the case of claims submitted by a Critical Access Hospital Method 2 (CAH2) (type of bill = 85x), a Primary Care Service is identified by the HCPCS code appearing on the line item claim (for revenue centers 096x, 097x, or 098x) for the service.

7. *Primary Care Specialist*

A Primary Care Specialist is a physician or NPP whose principal specialty is included in Table F of this Appendix B.

A physician or NPP's specialty is determined based on the CMS Specialty Code recorded on the claim. In the case of a claim submitted by an FQHC, RHC, or CAH2, the specialty code is determined based on the physician's or NPP's primary specialty as recorded in the National Plan & Provider Enumeration System (NPPES) or the Medicare Provider Enrollment, Chain, and Ownership System (PECOS).

8. *Selected Non-Primary Care Specialists*

A Selected Non-Primary Care Specialist is a physician or NPP whose principal specialty is included in Table G of this Appendix B.

A physician or NPP's specialty is determined based on the CMS Specialty Code recorded on the claim. In the case of a claim submitted by an FQHC, RHC, or CAH2, the specialty code is determined based on the physician's or NPP's primary specialty as recorded in the NPPES or PECOS.

B. Claims-Based Alignment Process

1. *General*

Claims-Alignment of a Beneficiary is determined by comparing:

a. The weighted allowable charges for all PQEM Services that the Beneficiary received from DC Participant Providers in each DCE (separately) participating in Direct Contracting; and

b. The weighted allowable charges for all PQEM Services that the Beneficiary received from each provider or supplier that is not a DC Participant Provider and identified by a Medicare-enrolled billing TIN.

2. *Weighted Allowable Charges*

The allowable charge on paid claims for services received during the two Alignment Years associated with the Implementation Period, Performance Year, or each Base Year will be used to determine the Medicare DCE, or other provider or supplier from which the Beneficiary received the plurality of PQEM Services.

a. The allowable charge for PQEM Services provided during the first (earlier) Alignment Year will be weighted by a factor of ⅓.

b. The allowable charge for PQEM Services provided during the second (later, or more recent) Alignment Year will be weighted by a factor of ⅔.

The allowable charge that is used in alignment will be obtained from claims for PQEM Services that are:

a. Incurred in each Alignment Year as determined by the date-of-service on the claim line-item; and,

b. Paid within 3 months following the end of the second Alignment Year as determined by the effective date of the claim.

3. *The Two-Stage Algorithm*

Alignment for the Implementation Period, Performance Year, or a Base Year uses a two-stage alignment algorithm.

a. *Alignment based on PQEM Services provided by Primary Care Specialists.* If 10% or more of the allowable charges incurred on PQEM Services received by a Beneficiary during the two Alignment Years are furnished by Primary Care Specialists, then Beneficiary alignment is based on the allowable charges incurred on PQEM Services furnished by Primary Care Specialists.

b. *Alignment based on Primary Care Services provided by Selected Non-Primary Care Specialists*. If less than 10% of the PQEM Services received by a Beneficiary during the two Alignment Years are furnished by Primary Care Specialists, then Beneficiary

alignment is based on the PQEM Services furnished by Selected Non-Primary Care Specialists.

4. *Tie-breaker Rules*

In the case of a tie in the dollar amount of the weighted allowed charges for PQEM Services, the Beneficiary will be aligned to the DCE if a DC Participant Provider has billed the most recent PQEM service for the Beneficiary in the Alignment Period.

5. *Alignment to the DCE*

Subject to the precedence rules described in Section 5.01 of this Agreement, CMS will align a Beneficiary to the DCE based on Claims-Based Alignment if CMS determines that: (1) the Beneficiary is an Alignable Beneficiary; (2) the Beneficiary is an Alignment Eligible Beneficiary; (3) the Beneficiary received the plurality of his or her PQEM Services during the two Alignment Years from the DCE's DC Participant Providers; and (4) the Beneficiary is not already aligned to a participant in the Medicare Shared Savings Program or other Medicare shared savings initiatives that takes precedence to the Model for purposes of Beneficiary alignment.

III. Voluntary Alignment

A. Paper-Based Voluntary Alignment

If the DCE selects to participate in Paper-Based Voluntary Alignment during the Implementation Period pursuant to Section 8.01 of this Agreement, subject to the precedence rules described in Section 5.01 of this Agreement, CMS will align a Beneficiary to the DCE for the first Performance Year based on Paper-Based Voluntary Alignment if the Beneficiary:

1. Is an Alignment-Eligible Beneficiary (as defined in Section II.A of this Appendix B); and
2. Has completed a Voluntary Alignment Form designating a DC Participant Provider as her or his main doctor, main provider, and/or the main place they receive care, provided that the designation is valid (determined in accordance with Section 5.02.A of this Agreement) and more recent than any other designation made by the Beneficiary.

CMS will align the Beneficiary to the DCE in accordance with this Section III.A regardless of whether the Beneficiary would be aligned to the DCE based on Claims-Based Alignment.

B. Electronic Voluntary Alignment

Subject to the precedence rules described in Section 5.01 of this Agreement, CMS will align a Beneficiary to the DCE for the Implementation Period or the first Performance Year, as applicable, based on Electronic Voluntary Alignment if the Beneficiary:

1. Is an Alignment-Eligible Beneficiary (as defined in Section II.A of this Appendix); and
2. Has designated a DC Participant Provider as her or his primary clinician through MyMedicare.gov, provided that the designation is valid (determined in accordance with Section 5.02.A of this Agreement) and more recent than any other designation made by the Beneficiary.

CMS will align the Beneficiary to the DCE in accordance with this Section III.B regardless of whether the Beneficiary would be aligned to the DCE based on Claims-Based Alignment.

C. Removal of Voluntarily Aligned Beneficiaries

A Beneficiary aligned to the DCE for the first Performance Year via Voluntary Alignment will be removed from alignment to the DCE for purposes of financial settlement for the Performance Year if: (1) none of the DCE's DC Participant Providers furnished any services to the Beneficiary during the Performance Year; and (2) a provider or supplier that is not a DC Participant Provider submitted a claim for services furnished to the Beneficiary during the Performance Year.

Table C. Mobility Impairment Codes for High Needs Population DCEs

The following diagnoses for mobility-related conditions are drawn from the list of Other Chronic or Potentially Disabling Conditions in the CMS Chronic Condition Data Warehouse. For a list of the ICD-10 codes associated with these diagnoses, please see the Condition Algorithms at: https://www.ccwdata.org/web/guest/condition-categories.

Cerebral Palsy

33371	Athetoid cerebral palsy
343	Infantile cerebral palsy
3430	Congenital diplegia
3431	Congenital hemiplegia
3432	Congenital quadriplegia
3433	Congenital monoplegia
3434	Infantile hemiplegia
3438	Other specified infantile cerebral palsy
3439	Infantile cerebral palsy unspecified

Cystic Fibrosis and Other Metabolic Developmental Disorders

243	Congenital hypothyroidism
2552	Congenital adrenal hyperplasia
2692	Unspecified vitamin deficiency
2701	Phenylketonuria (pku)
2702	Disturbance of aromatic amino-acid metabolism
2703	Disturbances of branched chain amino acid metabolism
2704	Disturbance of sulfur-bearing amino-acid metabolism
2706	Disorders of urea cycle metabolism
2707	Other disturbances of straight-chain amino-acid metabolism
2711	Galactosemia
2770	Cystic fibrosis
27700	Cystic fibrosis without mention of meconium ileus
27701	Cystic fibrosis with meconium ileus
27702	Cystic fibrosis with pulmonary manifestations
27703	Cystic fibrosis with gastrointestinal manifestations
27709	Cystic fibrosis with other manifestations
27781	Primary carnitine deficiency
27785	Disorders of fatty acid oxidation
2776	Other deficiencies of circulating enzymes (Biotinidase deficiency)

Mobility Impairments

3341	Hereditary spastic paraplegia
34200	Flaccid hemiplegia and hemiparesis affecting unspecified side
34201	Flaccid hemiplegia and hemiparesis affecting dominant side
34202	Flaccid hemiplegia and hemiparesis affecting non-dominant side
34210	Spastic hemiplegia and hemiparesis affecting unspecified side
34211	Spastic hemiplegia and hemiparesis affecting dominant side
34212	Spastic hemiplegia and hemiparesis affecting non-dominant side
34280	Other specified hemiplegia and hemiparesis affecting unspecified side
34281	Other specified hemiplegia and hemiparesis affecting dominant side

34282	Other specified hemiplegia and hemiparesis affecting non-dominant side
34290	Hemiplegia, unspecified, affecting unspecified side
34291	Hemiplegia, unspecified, affecting dominant side
34292	Hemiplegia, unspecified, affecting non-dominant side
344	Other paralytic syndromes
3440	Quadriplegia and quadraparesis
34400	Quadriplegia, unspecified
34401	Quadriplegia, C1-C4, complete
34402	Quadriplegia, C1-C4, incomplete
34403	Quadriplegia, C5-C7, complete
34404	Quadriplegia, C5-C7, incomplete
34409	Other quadriplegia
3441	Paraplegia
3442	Diplegia of upper limbs
3443	Monoplegia of lower limb
34430	Monoplegia of lower limb affecting unspecified side
34431	Monoplegia of lower limb affecting dominant side
34432	Monoplegia of lower limb affecting non-dominant side
3444	Monoplegia of upper limb
34440	Monoplegia of upper limb affecting unspecified side
34441	Monoplegia of upper limb affecting dominant side
34442	Monoplegia of upper limb affecting non-dominant side
3445	Unspecified monoplegia
3446	Cauda equina syndrome
34460	Cauda equina syndrome without mention of neurogenic bladder
34461	Cauda equina syndrome with neurogenic bladder
3448	Cauda equina syndrome with neurogenic bladder
34481	Locked-in state
34489	Other specified paralytic syndrome
3449	Paralysis, unspecified

43820	Late effects of cerebrovascular disease, hemiplegia affecting unspecified side
43821	Late effects of cerebrovascular disease, hemiplegia affecting dominant side
43822	Late effects of cerebrovascular disease, hemiplegia affecting non-dominant side
43830	Late effects of cerebrovascular disease, monoplegia of upper limb affecting unspecified side
43831	Late effects of cerebrovascular disease, monoplegia of upper limb affecting dominant side
43832	Late effects of cerebrovascular disease, monoplegia of upper limb affecting non-dominant side
43840	Late effects of cerebrovascular disease, monoplegia of lower limb affecting unspecified side
43841	Late effects of cerebrovascular disease, monoplegia of lower limb affecting dominant side
43842	Late effects of cerebrovascular disease, monoplegia of lower limb affecting non-dominant side
43850	Late effects of cerebrovascular disease, other paralytic syndrome affecting unspecified side
43851	Late effects of cerebrovascular disease, other paralytic syndrome affecting dominant side
43852	Late effects of cerebrovascular disease, other paralytic syndrome affecting non-dominant side
43853	Late effects of cerebrovascular disease, other paralytic syndrome, bilateral

Multiple Sclerosis and Transverse Myelitis

340	Multiple sclerosis
341	Other demyelinating diseases of the central nervous system
3410	Neuromyelitis optica
3412	Acute (transverse) myelitis
34120	Acute (transverse) myelitis nos
34121	Acute (transverse) myelitis in conditions classified elsewhere
34122	Idiopathic transverse myelitis
3418	Other demyelinating diseases of the central nervous system
3419	Demyelinating diseases of central nervous system

Muscular Dystrophy

359	Muscular dystrophies and other myopathies
3590	Congenital hereditary muscular dystrophy
3591	Hereditary progressive muscular dystrophy

Spina Bifida and other Congenital Anomalies of the Nervous System

7400	Anencephalus
7401	Craniorachischisis
7402	Iniencephaly
741	Spina bifida
7410	Spina bifida with hydrocephalus
74100	Spina bifida unspecified region with hydrocephalus
74101	Spina bifida cervical region with hydrocephalus
74102	Spina bifida dorsal (thoracic) region with hydrocephalus
74103	Spina bifida lumbar region with hydrocephalus
7419	Spina bifida without mention of hydrocephalus
74190	Spina bifida unspecified region without hydrocephalus
74191	Spina bifida cervical region without hydrocephalus
74192	Spina bifida dorsal (thoracic) region without hydrocephalus
74193	Spina bifida lumbar region without hydrocephalus
7420	Encephalocele
7421	Microcephalus
7422	Congenital reduction deformities of brain
7423	Congenital hydrocephalus
7424	Other congenital anomalies of nervous system
7425	Other specified congenital anomalies of spinal cord
74251	Diastematomyelia
74253	Hydromyelia

74259	Other specified congenital anomalies of spinal cord
7428	Other specified congenital anomalies of nervous system
7429	Unspecified congenital anomaly of brain, spinal cord, and nervous system

Spinal Cord Injury

9072	Late effect of spinal cord injury
95200	C1-C4 level with unspecified spinal cord injury
95201	C1-C4 level with complete lesion of spinal cord
95202	C1-C4 level with anterior cord syndrome
95203	C1-C4 level with central cord syndrome
95204	C1-C4 level with other specified spinal cord injury
95205	C5-C7 level with unspecified spinal cord injury
95206	C5-C7 level with complete lesion of spinal cord
95207	C5-C7 level with anterior cord syndrome
95208	C5-C7 level with central cord syndrome
95209	C5-C7 level with other specified spinal cord injury
95210	T1-T6 level with unspecified spinal cord injury
95211	T1-T6 level with complete lesion of spinal cord
95212	T1-T6 level with anterior cord syndrome
95213	T1-T6 level with central cord syndrome
95214	T1-T6 level with other specified spinal cord injury
95215	T7-T12 level with unspecified spinal cord injury
95216	T7-T12 level with complete lesion of spinal cord
95217	T7-T12 level with anterior cord syndrome
95218	T7-T12 level with central cord syndrome
95219	T7-T12 level with other specified spinal cord injury
9522	Lumbar spinal cord injury without evidence of spinal bone injury
9523	Sacral spinal cord injury without evidence of spinal bone injury
9524	Cauda equina spinal cord injury without evidence of spinal bone injury
9528	Multiple sites of spinal cord injury without evidence of spinal bone injury

9529	Unspecified site of spinal cord injury without evidence of spinal bone injury

Table D. Frailty codes used to Determine Eligibility for Alignment to a High Needs DCE

Transfer equipment	
E0172	Seat lift mechanism placed over or on top of toilet, any type
E0621	Sling or seat, patient lift, canvas or nylon
E0625	Patient lift, bathroom or toilet, not otherwise classified
E0627	Seat lift mechanism, electric, any type
E0628	Separate seat lift mechanism for use with patient owned furniture-electric
E0629	Seat lift mechanism, non-electric, any type
E0630	Patient lift, hydraulic or mechanical, includes any seat, sling, strap(s) or pad(s)
E0635	Patient lift, electric with seat or sling
E0636	Multipositional patient support system, with integrated lift, patient accessible controls
E0637	Combination sit to stand frame/table system, any size including pediatric, with seat lift feature, with or without wheels
E0638	Standing frame/table system, one position (e.g., upright, supine or prone stander), any size including pediatric, with or without wheels
E0639	Patient lift, moveable from room to room with disassembly and reassembly, includes all components/accessories
E0640	Patient lift, fixed system, includes all components/accessories
E0641	Standing frame/table system, multi-position (e.g., three-way stander), any size including pediatric, with or without wheels
E0642	Standing frame/table system, mobile (dynamic stander), any size including pediatric
E0700	Safety equipment, device or accessory, any type
E0705	Transfer device, any type, each
E0710	Restraints, any type (body, chest, wrist or ankle)
E0910	Trapeze bars, a/k/a patient helper, attached to bed, with grab bar
E0911	Trapeze bar, heavy duty, for patient weight capacity greater than 250 pounds, attached to bed, with grab bar
E0912	Trapeze bar, heavy duty, for patient weight capacity greater than 250 pounds, free standing, complete with grab bar
E0940	Trapeze bar, free standing, complete with grab bar
E1035	Multi-positional patient transfer system, with integrated seat, operated by care giver, patient weight capacity up to and including 300 lbs
E1036	Multi-positional patient transfer system, extra-wide, with integrated seat, operated by caregiver, patient weight capacity greater than 300 lbs
Hospital Bed	
E0250	Hospital bed, fixed height, with any type side rails, with mattress
E0251	Hospital bed, fixed height, with any type side rails, without mattress
E0255	Hospital bed, variable height, hi-lo, with any type side rails, with mattress
E0256	Hospital bed, variable height, hi-lo, with any type side rails, without mattress
E0260	Hospital bed, semi-electric (head and foot adjustment), with any type side rails, with mattress
E0261	Hospital bed, semi-electric (head and foot adjustment), with any type side rails, without mattress

E0265	Hospital bed, total electric (head, foot and height adjustments), with any type side rails, with mattress
E0266	Hospital bed, total electric (head, foot and height adjustments), with any type side rails, without mattress
E0270	Hospital bed, institutional type includes: oscillating, circulating and stryker frame, with mattress
E0271	Mattress, innerspring
E0272	Mattress, foam rubber
E0273	Bed board
E0274	Over-bed table
E0277	Powered pressure-reducing air mattress
E0280	Bed cradle, any type
E0290	Hospital bed, fixed height, without side rails, with mattress
E0291	Hospital bed, fixed height, without side rails, without mattress
E0292	Hospital bed, variable height, hi-lo, without side rails, with mattress
E0293	Hospital bed, variable height, hi-lo, without side rails, without mattress
E0294	Hospital bed, semi-electric (head and foot adjustment), without side rails, with mattress
E0295	Hospital bed, semi-electric (head and foot adjustment), without side rails, without mattress
E0296	Hospital bed, total electric (head, foot and height adjustments), without side rails, with mattress
E0297	Hospital bed, total electric (head, foot and height adjustments), without side rails, without mattress
E0301	Hospital bed, heavy duty, extra wide, with weight capacity greater than 350 pounds, but less than or equal to 600 pounds, with any type side rails, without mattress
E0302	Hospital bed, extra heavy duty, extra wide, with weight capacity greater than 600 pounds, with any type side rails, without mattress
E0303	Hospital bed, heavy duty, extra wide, with weight capacity greater than 350 pounds, but less than or equal to 600 pounds, with any type side rails, with mattress
E0304	Hospital bed, extra heavy duty, extra wide, with weight capacity greater than 600 pounds, with any type side rails, with mattress
E0305	Bed side rails, half length
E0310	Bed side rails, full length
E0315	Bed accessory: board, table, or support device, any type
E0316	Safety enclosure frame/canopy for use with hospital bed, any type
E0370	Air pressure elevator for heel
E0371	Nonpowered advanced pressure reducing overlay for mattress, standard mattress length and width
E0372	Powered air overlay for mattress, standard mattress length and width
E0373	Nonpowered advanced pressure reducing mattress
E0462	Rocking bed with or without side rails

Table E: Evaluation & Management Services

Office or Other Outpatient Services	
99201	New Patient, brief
99202	New Patient, limited
99203	New Patient, moderate
99204	New Patient, comprehensive
99205	New Patient, extensive
99211	Established Patient, brief
99212	Established Patient, limited
99213	Established Patient, moderate
99214	Established Patient, comprehensive
99215	Established Patient, extensive
Domiciliary, Rest Home, or Custodial Care Services	
99324	New Patient, brief
99325	New Patient, limited
99326	New Patient, moderate
99327	New Patient, comprehensive
99328	New Patient, extensive
99334	Established Patient, brief
99335	Established Patient, moderate
99336	Established Patient, comprehensive
99337	Established Patient, extensive
Domiciliary, Rest Home, or Home Care Plan Oversight Services	
99339	Brief
99340	Comprehensive
Home Services	
99341	New Patient, brief
99342	New Patient, limited
99343	New Patient, moderate
99344	New Patient, comprehensive
99345	New Patient, extensive
99347	Established Patient, brief
99348	Established Patient, moderate
99349	Established Patient, comprehensive
99350	Established Patient, extensive
Prolonged care for outpatient visit	
99354	Prolonged visit, first hour
99355	Prolonged visit, add'l 30 mins
Telephone Visits – Audio Only	
99421	Online digital, Established Patient, 5–10 mins
99422	Online digital, Established Patient, 10–20 mins
99423	Online digital, Established Patient, 21+ mins
99441	Phone, Established Patient, 5–10 mins
99442	Phone, Established Patient, 10–20 mins

99443	Phone, Established Patient, 21+ mins
Chronic Care Management Services	
99490	Comprehensive care plan establishment/implementations/revision/monitoring
Transitional Care Management Services	
99495	Communication (14 days of discharge)
99496	Communication (7 days of discharge)
Advance Care Planning	
99497	ACP first 30 mins
99498	ACP add'l 30 mins
Wellness Visits	
G0402	Welcome to Medicare visit
G0438	Annual wellness visit
G0439	Annual wellness visit
Virtual check-ins	
G2010	Remote evaluation, Established Patient
G2012	Brief communication technology-based service, 5-10 mins of medical discussion

Table F. Specialty codes used to identify Primary Care Specialists

Code[1]	Specialty
1	General Practice
8	Family Medicine
11	Internal Medicine
37	Pediatric Medicine
38	Geriatric Medicine
50	Nurse Practitioner
89	Clinical nurse specialist
97	Physician Assistant

[1] The Medicare Specialty Code. A cross-walk between Medicare Specialty Codes and the Healthcare Provider Taxonomy is published on the CMS website at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/TaxonomyCrosswalk.pdf

TableG. Specialty codes used to identify Selected Non-Primary Care Specialists

Code[1]	Specialty
6	Cardiology
10	Gastroenterology
12	Osteopathic manipulative medicine
13	Neurology
16	Obstetrics/gynecology
17	Hospice and palliative care
23	Sports medicine
25	Physical medicine and rehabilitation
26	Psychiatry
27	Geriatric psychiatry
29	Pulmonology
39	Nephrology
44	Infectious disease
46	Endocrinology
66	Rheumatology
70	Multispecialty clinic or group practice

79	Addiction medicine
82	Hematology
83	Hematology/oncology
84	Preventative medicine
90	Medical oncology
98	Gynecological/oncology
86	Neuropsychiatry

[1] The Medicare Specialty Code. A cross-walk between Medicare Specialty Codes and the Healthcare Provider Taxonomy is published on the CMS website at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/TaxonomyCrosswalk.pdf

Appendix C: Paper-Based Voluntary Alignment

I. General

This Appendix C will apply only if the DCE selects participation in Paper-Based Voluntary Alignment pursuant to Article VIII of the Agreement.

II. Paper-Based Voluntary Alignment

A. The DCE may send a form (the "**Voluntary Alignment Form**") and a cover letter including instructions on how to complete the Voluntary Alignment Form ("**Letter**") electronically or by mail to a Beneficiary in a manner consistent with the requirements of Article V of this Agreement and this Appendix C.

B. CMS shall determine the content of the Voluntary Alignment Form and shall provide templates to the DCE for both the Voluntary Alignment Form and the Letter.

C. The DCE shall make no changes to the template Voluntary Alignment Form provided by CMS, with the exception of changes made solely for the insertion of the following information where indicated:

1. The name of the DC Participant Provider that the DCE believes may be the Beneficiary's main doctor, main provider, and/or the main place the Beneficiary receives care;
2. The logo of the DCE or DC Participant Provider; and
3. Instructions for how the Beneficiary can submit the Voluntary Alignment Form to the DCE.

D. The DCE shall make no changes to the template Letter where CMS has indicated content that the DCE cannot amend or remove. The DCE may otherwise make changes, subject to the DCE obtaining CMS approval of the final Letter content pursuant to Section 5.04.I of the Agreement, including:

1. Formatting for electronic distribution;
2. Inserting the name of the DC Participant Provider that the DCE believes may be the Beneficiary's main doctor, main provider, and/or the main place the Beneficiary received care;
3. Inserting the logo of the DCE or DC Participant Provider;
4. The addition of instructions for how the Beneficiary can submit the Voluntary Alignment Form to the DCE;
5. The insertion of information about unique care coordination and preventative services offered by the DCE; and
6. Inserting the DCE's contact information for answering Beneficiaries' questions.

E. The DCE shall submit to CMS, by a time and in a manner specified by CMS, a document describing how the DCE will conduct its Voluntary Alignment Activities specific to Paper-Based Voluntary Alignment in accordance with this Appendix C during the Implementation Period, including the criteria for determining which Beneficiaries will receive the Voluntary Alignment Form and Letter.

F. The DCE shall not, and shall require its DC Participant Providers and Preferred Providers not to send or distribute the Voluntary Alignment Form outside the DCE Service Area (as defined in Section 5.04.G of the Agreement). The DCE may provide the Voluntary Alignment Form at the point of care only in the offices of DC Participant Providers. The DCE shall notify CMS by a date specified by CMS if the DCE elects to provide the Voluntary Alignment Form at the point of care.

G. Form Requests

1. The DCE shall permit any Beneficiary who receives care from a DC Participant Provider to receive a Voluntary Alignment Form, upon request. The DCE shall permit the Beneficiary to request a Voluntary Alignment Form in person at the office of the DC Participant Provider or by calling the DCE.
2. The DCE shall permit any Beneficiary who has received a Voluntary Alignment Form to request another Voluntary Alignment Form that identifies a different DC Participant Provider as the Beneficiary's main doctor, main provider, and/or main place the Beneficiary receives care; or that identifies a physician or other individual or entity that is not a DC Participant Provider as the Beneficiary's main doctor, main provider, or main place the Beneficiary receives care; or otherwise reverses the Beneficiary's Paper-Based Voluntary Alignment. The DCE shall permit such requests to be made by calling the DCE.
3. The DCE shall permit the appointed representative of a Beneficiary who has received a Voluntary Alignment Form to complete and sign the Voluntary Alignment Form on behalf of the Beneficiary.

H. Maintenance of Records

In accordance with Section 12.02 of the Agreement, the DCE shall maintain and shall provide to the government upon request a list of all Beneficiaries to whom the DCE has sent the 'Voluntary Alignment Form and Letter, copies of all Voluntary Alignment Forms sent or otherwise furnished to Beneficiaries (including copies of the Letter sent with such forms), and, as applicable, original executed Voluntary Alignment Forms, envelopes in which Voluntary Alignment Forms were returned to the DCE, written documentation of any oral

communications with a Beneficiary or his or her appointed representative regarding the potential or actual reversal of a Voluntary Alignment Form, all electronic data and files associated with the distribution and submission of Voluntary Alignment Forms, and all other documents and records regarding the DCE's participation in Paper-Based Voluntary Alignment, including documents and records pertaining to Beneficiary communications.

III. Paper-Based Voluntary Alignment Process

A. The DCE shall submit to CMS a list ("**Paper-Based Voluntary Alignment List**") that contains the following:

1. The name, Medicare Beneficiary Identifier (MBI), and, to the extent required by CMS, any other identifying information of each Beneficiary who returned a valid Voluntary Alignment Form to the DCE identifying a DC Participant Provider as the Beneficiary's main doctor, main provider, and/or the main place the Beneficiary receives care. A Voluntary Alignment Form is valid only if it has been signed and dated by the Beneficiary or his or her appointed representative and was returned to the DCE on or before the date on which the DCE submits its Paper-Based Voluntary Alignment List to CMS. If a Beneficiary returns more than one valid Voluntary Alignment Form to the DCE, the DCE should include only the information from the latest submitted valid Voluntary Alignment Form. A Voluntary Alignment Form submitted to a DC Participant Provider is considered to have been returned to the DCE;
2. For each Beneficiary identified pursuant to Section III.A.1. of this Appendix C, the date on which the Beneficiary executed the Voluntary Alignment Form, and the identity of the DC Participant Provider that the Beneficiary has identified as his or her main doctor, main provider, and/or main place the Beneficiary receives care; and
3. A certification by an executive of the DCE made in accordance with Section 11.04 of the Agreement that, to the best of his or her knowledge, information, and belief, the information contained on the Paper-Based Voluntary Alignment List is true, accurate, and complete and identifies only those Beneficiaries who have submitted a valid Voluntary Alignment Form to the DCE.

B. The DCE shall submit the Paper-Based Voluntary Alignment List to CMS in advance of the first Performance Year by a date specified by CMS. CMS will use the Paper-Based Voluntary Alignment List to conduct alignment of Beneficiaries for the first Performance Year.

C. CMS will audit the DCE's Paper-Based Voluntary Alignment Lists for accuracy in accordance with Section 11.02 of the Agreement. This audit, including any surveys of Beneficiaries conducted pursuant to Section III.D of this Appendix C, may take place during the Implementation Period or at a later time, as determined by CMS.

D. CMS may survey Beneficiaries as a part of the audit process described in Section III.C of this Appendix C.

Appendix D: DCE Proprietary and Confidential Information

The following are specific examples, without limitation, of what the DCE considers proprietary and confidential information currently maintained by the DCE that should not be publicly disclosed:

1)

2)

3)

In accordance with Section 9.04 of the Agreement, this information shall remain the sole property of the DCE and, except as required by federal law, shall not be released by CMS without the express written consent of the DCE.