

Centers for Medicare & Medicaid Services  
Center for Medicare & Medicaid Innovation  
Patient Care Models Group  
7500 Security Blvd.  
Baltimore, MD 21244

**Guiding an Improved Dementia Experience (GUIDE) Model  
Participation Agreement**

**Last Modified: March 27, 2024**



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## **PARTICIPATION AGREEMENT**

This Participation Agreement (“**Agreement**”) is between the Centers for Medicare & Medicaid Services (“**CMS**”) and

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(the “**Participant**”) [insert full legal name, including any d/b/a name].

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.

The Participant is a Medicare Part B-enrolled provider or supplier (excluding durable medical equipment and laboratory suppliers) that bills for Medicare Physician Fee Schedule services under a single Medicare Part B-enrolled Taxpayer Identification Number (“**TIN**”) and that has established, or intends to establish, an interdisciplinary Care Team to deliver GUIDE Care Delivery Services.

Under Section 1115A of the Social Security Act (“**the Act**”), the CMS Center for Medicare & Medicaid Innovation (“**Innovation Center**”) is authorized to test innovative payment and service delivery models to reduce Medicare, Medicaid, or Children’s Health Insurance Program expenditures while preserving or enhancing the quality of care provided to beneficiaries under those programs.

Through the Guiding an Improved Dementia Experience Model (“**GUIDE Model**” or “**Model**”), the Innovation Center will test whether providing an alternative payment methodology to deliver a broad package of care management and coordination, caregiver education and support, and GUIDE Respite Services to Medicare beneficiaries with dementia and their caregivers reduces expenditures while preserving or enhancing quality of care.

The Model offers two options for participation: 1) the Established Program Track; and 2) the New Program Track.

The Participant submitted an application to participate in the Model, and CMS approved the Participant for participation in either the Established Program Track or the New Program Track in accordance with this Agreement.

The parties therefore agree as follows:

### **Article 1. Agreement Term**

#### **Section 1.01 Effective Date**

This Agreement will become effective upon the last date of signature (the “**Effective Date**”).

#### **Section 1.02 Agreement Term**

The term of the Agreement begins on the Effective Date and expires two (2) years following the last day of the Agreement Performance Period (“**Agreement Term**”), unless sooner terminated by CMS in accordance with Section 16.03, in which case the Agreement Term ends on the effective date of termination.

#### **Section 1.03 Agreement Performance Period**

The performance period of this Agreement (“**Agreement Performance Period**”) begins on the

Start Date and ends at 11:59 PM ET on June 30, 2032, unless the Agreement Performance Period is sooner terminated by either party in accordance with Sections 16.03 or 16.04, or the Agreement is sooner terminated by CMS in accordance with Section 16.03, in which case the Agreement Performance Period ends on the effective date of termination. The Start Date will vary depending on the Participant's applicable program track.

#### **Section 1.04 Amended and Restated Agreements**

- A. Approximately 30 Days prior to Performance Year 2025 or any subsequent Performance Year, CMS may offer the Participant the opportunity to sign an amendment to this Agreement, which may be in the form of an amended and restated version of this Agreement.
- B. If the Participant fails to sign an amendment to this Agreement offered by CMS pursuant to Section 1.04(A) by a date specified by CMS, CMS may immediately or with advance notice terminate this Agreement pursuant to Section 16.03.

#### **Article 2. Definitions**

“Adult Day Center” means centers that provide care for older adults during the day, such as adult day care, adult medical day care, adult day services, adult day health centers.

“Beneficiary” means an individual who is enrolled in Medicare.

“Beneficiary Outreach Letter” means a letter mailed by CMS to an Eligible Beneficiary that includes (i) general information about the Model, (ii) a list of all GUIDE Model Participants who are accepting Eligible Beneficiaries as patients in the Eligible Beneficiary's zip-code area, and (iii) information on how the Eligible Beneficiary may voluntarily align with a GUIDE Model Participant to receive GUIDE Care Delivery Services, in the event the Eligible Beneficiary is interested in the GUIDE Model.

“Care Delivery Reporting” means the report submitted by the Participant to CMS detailing the GUIDE Care Delivery Services offered by the Participant and how the Participant has complied with Appendix C of this Agreement.

“Care Navigator” means an individual on the Participant's Care Team who has completed the Care Navigator Training and provides GUIDE Care Delivery Services to GUIDE Beneficiaries.

“Care Team” means the group of people, including but not limited to the Care Navigator and clinician with dementia proficiency, providing GUIDE Care Delivery Services to GUIDE Beneficiaries.

“Caregiver” means a relative, or an unpaid nonrelative, who assists the GUIDE Beneficiary with activities of daily living and/or instrumental activities of daily living. Depending on the GUIDE Beneficiary's need, the assistance may be episodic, daily, or occasional.

“CEHRT” stands for “Certified Electronic Health Record Technology” and means the health IT technology meeting the CEHRT definition required by the Quality Payment Program at 42 CFR 414.1305.

“Change in Control” means any of the following:

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 Participant representing more than 50% of the Participant's outstanding voting securities or rights to acquire such securities;

2. The acquisition of the Participant by any other individual or entity;
3. Any merger, division, dissolution, or expansion of the Participant.
4. Any sale, lease, exchange or other transfer (in one transaction or a series of transactions) of all or substantially all the assets of the Participant; or
5. The approval and completion of a plan of sale or liquidation of the Participant or an agreement for the sale or liquidation of the Participant.

“Community-Based Services and Supports” means services and supports delivered to individuals living in their personal home, assisted living facility, group home, or other community setting that create or maintain the individual's ability to safely live in the community.

“Comprehensive Assessment” means an assessment that complies with Section 1.1 of Appendix C.

“Data Dashboard” means the Expanded Data Feedback Reporting (eDFR) online portal through which CMS will share with the Participant aggregated sociodemographic data, line-level GUIDE Beneficiary claims data and payment and beneficiary alignment files.

“Days” means calendar days unless otherwise specified.

“DCMP” stands for “Dementia Care Management Payment” and means the monthly payment that the Participant may be eligible to receive as described in Section 9.02 for furnishing GUIDE Care Delivery Services, except for GUIDE Respite Services, to GUIDE Beneficiaries.

“Dementia Proficiency” means meeting at least one of the following criteria:

1. Having at least 25 percent of their patient panel (regardless of payer) at some time in the past 5 years comprised of adults with any cognitive impairment, including dementia; or
2. Having at least 25 percent of their patient panel (regardless of payer) at some time in the past 5 years comprised of adults aged 65 years old or older; or
3. Having a specialty designation of neurology, psychiatry, geriatrics, geriatric psychiatry, behavioral neurology, or geriatric neurology.

“Descriptive Materials and Activities” means general audience materials such as brochures, advertisements, outreach events, letters to Beneficiaries, web pages published on a website, mailings, social media, or other activities conducted by or on behalf of the Participant or its GUIDE Practitioners or Partner Organizations, when used to educate, notify, or contact Beneficiaries regarding the Model. Descriptive Materials and Activities does not include:

1. Communications that do not directly or indirectly reference the Model (for example, information about care coordination generally would not be considered Descriptive Materials and Activities);
2. Materials that cover Beneficiary-specific billing and claims issues;
3. Educational information on specific medical conditions;
4. Referrals for health care items and services; and

5. 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).

“Direct Care Worker” means an individual who provides home care services, including but not limited to certified nursing assistants, home health aides, personal care aides, caregivers, and companions.

“Director” means any person who is a member of the Partner Organization’s board of directors or governing body if a Partner Organization does not use the term board of directors.

“Eligible Beneficiary” means a Beneficiary that meets the requirements described in Section 5.01(A).

“Environmental Modification” means (i) an item purchased by the Participant and delivered to the GUIDE Beneficiary; or (ii) a physical modification to the residence that the GUIDE Beneficiary is residing in at the time that the Participant installs the physical modification regardless of whether the GUIDE Beneficiary owns the residence.

“Environmental Modification Beneficiary Engagement Incentive” means the environmental modifications that the Participant may choose to make available to GUIDE Beneficiaries in accordance with Appendix A.

“FFS” stands for fee-for-service.

“GAF” stands for “Geographic Adjustment Factor” and means a factor that is applied by Medicare Fee-for-Service Payment systems to reflect the cost of doing business in a geographic area. The Geographic Adjustment Factors include Area Wage Indices in the various prospective payment systems and Geographic Practice Cost Indices in the Physician Fee Schedule.

“GUIDE Beneficiary” means an Eligible Beneficiary who is voluntarily aligned to the Participant for the purposes of computing GUIDE Payments and evaluating quality performance.

“GUIDE Care Delivery Services” means the care activities and services as described in Appendix C.

“GUIDE Model Participant” means a Medicare Part B-enrolled provider or supplier that is participating in the GUIDE Model and is not the Participant.

“GUIDE Payment” means, collectively, the Dementia Care Management Payment (including the Performance Based Adjustment and Health Equity Adjustment), the GUIDE Respite Payment, and the Infrastructure Payment, or any combination thereof.

“GUIDE Payment Methodology Paper” means the paper published annually by CMS that describes in detail the methods used to calculate and send the GUIDE Payments to the Participant.

“GUIDE Practitioner” means an individual that (i) is a Medicare-enrolled physician or other non-physician practitioner identified by an individual NPI; (ii) bills under the TIN of the Participant; (iii) is not precluded by CMS from participation in the Model; and (iv) is identified by the Participant on the GUIDE Practitioner Roster.

“GUIDE Practitioner Roster” means the list that identifies each GUIDE Practitioner that is approved by CMS for participation in the Model that is updated from time to time in accordance with Sections 3.04(C) and (D).

- “GUIDE Respite Payment” means the payment described in Section 9.05 for furnishing GUIDE Respite Services to Eligible Respite GUIDE Beneficiaries.
- “GUIDE Respite Services” means temporary services provided to a GUIDE Beneficiary in their home, at an adult day center, or at a facility that can provide 24-hour care, for the purpose of giving the Caregiver a break from caring for the GUIDE Beneficiary.
- “HCPCS” stands for “Healthcare Common Procedural Coding System.”
- “HDR” stands for “Health Data Reporting” and means the online portal through which the Participant will submit the Patient Assessment and Alignment form and report quality measure data and sociodemographic data.
- “HEA” stands for “Health Equity Adjustment” and means an adjustment to a GUIDE Beneficiary’s DCMP based on the GUIDE Beneficiary’s health equity score.
- “Infrastructure Payment” means a one-time \$75,000 payment, adjusted by the GAF, that CMS may pay to the Participant, as described in Section 9.06.
- “Leadership Position” means all officers and directors of the Partner Organization if the Partner Organization is a corporation (whether for-profit or non-profit).
- “Long-Term Nursing Home Resident” means a Beneficiary whose nursing home stay is 4 months or longer and not covered under the Medicare skilled nursing facility benefit.
- “Medically Necessary” means reasonable and necessary as determined in accordance with section 1862(a) of the Social Security Act (“**the Act**”).
- “MEI” stands for “Medicare Economic Index” and means a measure of physician practice cost growth calculated by the CMS Office of the Actuary.
- “NPI” stands for “National Provider Identifier.”
- “Officer” means any person whose position is listed as being that of an officer in a Partner Organization’s “articles of incorporation” or “corporate bylaws,” or anyone who is appointed by the board of directors as an officer in accordance with a Partner Organization’s corporate bylaws.
- “Participant Activities” means activities, including but not limited to, the GUIDE Care Delivery Services, quality reporting requirements in accordance with Section 8.01 of this Agreement, and participation in learning activities in accordance with Section 12.02 of this Agreement, conducted under the Model.
- “Participant Reporting” means the periodic reporting that the Participant submits to CMS via Salesforce and the HDR in accordance with Article 11.
- “Partner Organization” means a legal entity that (i) is a provider, supplier, or organization, including both Medicare-enrolled and non-Medicare enrolled entities, that (ii) is not a GUIDE Practitioner; (iii) is not precluded from participation in the Model by CMS; (iv) has agreed to perform at least one of the GUIDE Care Delivery Services pursuant to a Partner Organization Arrangement; and (v) is identified on the Partner Organization Roster.
- “Partner Organization Arrangement” means a written arrangement between the Participant and Partner Organization that governs a Partner Organization’s participation in the Model.

“Partner Organization Roster” means the list that identifies each Partner Organization that is approved by CMS for participation in the Model and is updated from time to time in accordance with Sections 3.07(C) and (D).

“PBA” stands for “Performance Based Adjustment” and means an adjustment to the Participant’s DCMP based on the Participant’s performance on certain performance measures.

“PHI” stands for Protected Health Information.

“Pre-Implementation Period” means the period from July 1, 2024 to June 30, 2025 during the New Program Track.

“Program Integrity Screening” means a review of an individual’s or entity’s program integrity history and current status, which may include a review of the individual’s or entity’s eligibility, history of exclusion or other sanctions imposed with respect to participation in Medicare, Medicaid, or the Children’s Health Insurance Program (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.

“Proposed GUIDE Practitioner Roster” means the list that identifies each proposed GUIDE Practitioner and that is submitted by the Participant to CMS pursuant to Section 3.04.

“Proposed Partner Organization Roster” means the list that identifies each proposed Partner Organization and that is submitted by the Participant to CMS pursuant to Section 3.07.

“PY” stands for “Performance Year” and means the 12-month period beginning on July 1<sup>st</sup> of each year during the Model Performance Period for the Established Program Track and the Model Performance Period for the New Program Track.

“Salesforce” means the secure online website through which the Participant will submit its Care Delivery Reporting, report on its Health Equity Plan, and submit its GUIDE Practitioner Roster and Partner Organization Roster.

“Start Date” means the first day of the first Performance Year.

“TIN” stands for a federal “taxpayer identification number.”

“Voluntary Alignment” means the process by which an Eligible Beneficiary agrees to receive GUIDE Care Delivery Services from the Participant as evidenced by a GUIDE Practitioner submitting a Patient Assessment and Alignment form to CMS for the Eligible Beneficiary and billing HCPCS G-codes for the Eligible Beneficiary.

### **Article 3. General Requirements**

#### **Section 3.01 Participant Requirements**

- A. For the period beginning on the Effective Date and ending on the last Day of the Participant’s final Performance Year, the Participant shall:
1. Be a legal entity formed under applicable state, federal, or tribal law, and be authorized to conduct business in each state in which it operates for the purposes of carrying out the activities required by this Agreement; and

2. Be a Medicare Part B-enrolled provider or supplier (excluding Durable Medical Equipment and laboratory suppliers) identified by a single TIN.
- B. In addition to the requirements of Section 3.01(A), during the Agreement Performance Period, the Participant shall:
1. Use an electronic health record platform that meets CMS and Office of the National Coordinator for Health Information Technology (“**ONC**”) standards for Certified Electronic Health Record Technology (“**CEHRT**”), as such term is defined under 42 CFR § 414.1305, including any amendments thereto;
  2. Meet the requirements for the interdisciplinary Care Team, Care Navigator Training, and the GUIDE Care Delivery Services as described in Article 6; and
  3. Use a single TIN for billing all GUIDE Care Delivery Services furnished to GUIDE Beneficiaries by GUIDE Practitioners and/or Partner Organizations, if applicable, and for receiving all GUIDE Payments from CMS.
- C. The Participant shall provide written notice to CMS if the Participant fails to meet any requirements set forth in Sections 3.01(A) and (B). The Participant shall provide such written notice to CMS at least 30 Days before failing to satisfy any such requirements or within 5 Days of becoming aware that the Participant has failed to satisfy any such requirements.
- D. Information for Electronic Funds Transfer.
1. The Participant shall submit an Electronic Funds Transfer Authorization Agreement (Form CMS-588) to CMS in a manner and by a deadline specified by CMS.
  2. The Participant shall promptly update its Electronic Funds Transfer Authorization Agreement if there are account or bank changes, or any change to the Participant set forth in Section 3.02.
  3. If the Participant fails to submit or accurately complete the Electronic Funds Transfer Authorization Agreement, CMS will withhold GUIDE Payments owed to the Participant until the Participant has submitted and CMS has processed an Electronic Funds Transfer Authorization Agreement with the correct information.

### **Section 3.02 Changes to Participant**

- A. Notwithstanding the provisions in this Section 3.02, all applicable notification requirements in 42 C.F.R. § 424.516 continue to apply to the Participant during the Agreement Term.
1. Change of Participant Name. The Participant shall provide advance written notice to CMS of any change in its legal name. Such notice must be furnished at least 60 Days before the change in legal name becomes effective and must include a copy of any legal document effecting the name change, authenticated by the appropriate state official (if applicable). The parties shall execute an agreement reflecting the change of the Participant’s name. This obligation remains in effect until the later of the effective date of termination of this Agreement or when final payment by or to the Participant has been made under this Agreement.
  2. Change in Participant TIN. The Participant shall provide at least 90 Days’ advance written notice to CMS before the effective date of any change in the Participant’s TIN.

Such notice must be submitted in the form and manner specified by CMS. In response to a change in the Participant's TIN, CMS may terminate the Agreement or Agreement Performance Period, or take any other actions consistent with the terms of this Agreement. This obligation remains in effect until the later of the effective date of termination of this Agreement or when final payment by or to the Participant has been made under this Agreement.

3. Change in Control.

- i. The Participant shall provide written notice to CMS at least 90 Days before the effective date of any Change in Control. This obligation remains in effect until the later of the effective date of termination of this Agreement or when final payment by or to the Participant has been made under this Agreement.
- ii. Upon learning of a Change in Control, CMS may conduct a Program Integrity Screening and take other appropriate action to ensure compliance with the terms of the Model by the new controlling entity and may require the new controlling entity to execute a novation agreement with CMS or require the new controlling entity to execute a new agreement with CMS.
- iii. If the Participant undergoes a Change in Control that renders it ineligible for participation in the Model or creates a program integrity risk, CMS may take one or more of the following actions: terminate this Agreement; terminate the Agreement Performance Period; or immediately conduct Reconciliation.

4. Change in Primary Point of Contact. The Participant shall report to CMS through Salesforce any changes to the contact information for the Participant's primary point of contact no later than 15 Days following the change.

### **Section 3.03 Arrangements with GUIDE Practitioners**

- A. The Participant shall ensure that each GUIDE Practitioner has taken the following actions before furnishing services for which GUIDE Payments are made under this Agreement:
1. Agreed to accept assignment of all Medicare claims, as evidenced by the submission of a Medicare Participating Physician or Supplier Agreement (Form CMS-460) to CMS;
  2. Reassigned their right to receive Medicare payment under the Model to the Participant;
  3. Agreed to bill Medicare for services provided under the Model using the TIN of the Participant; and
  4. Agreed to comply with the applicable terms of this Agreement.

### **Section 3.04 GUIDE Practitioner Roster**

A. General.

1. The Participant shall identify all GUIDE Practitioners on a GUIDE Practitioner Roster.
2. GUIDE Practitioners identified on the GUIDE Practitioner Roster are limited to only those GUIDE Practitioners who received prior written approval by CMS.
3. The Participant shall retain all current and historical GUIDE Practitioner Rosters in accordance with Section 15.02.

4. In addition to the initial CMS approval, CMS may periodically screen and monitor the program integrity history of GUIDE Practitioners. CMS may remove an individual from the GUIDE Practitioner Roster or subject the Participant to additional monitoring pursuant to Article 14 based on the results of a Program Integrity Screening, including but not limited to issues with licensure status and ongoing investigations by law enforcement or state licensure bodies.
5. A GUIDE Practitioner's presence on the GUIDE Practitioner Roster does not imply or constitute a determination that the GUIDE Practitioner has no program integrity issues and does not preclude CMS or any other government authority from enforcing any and all applicable laws, rules, and regulations.

**B. GUIDE Practitioner Roster Requirements for Each Track.**

1. If the Participant is in the Established Program Track:
  - i. The Participant submitted to CMS a Proposed GUIDE Practitioner Roster as part of its application to participate in the Model.
  - ii. CMS reviewed the Proposed GUIDE Practitioner Roster, conducted a Program Integrity Screening of all individuals listed on the Proposed GUIDE Practitioner Roster, and issued to the Participant a list of individuals that CMS approved to be the GUIDE Practitioners on the Participant's GUIDE Practitioner Roster effective on the Start Date.
  - iii. The GUIDE Practitioner Roster must include the name, TIN and NPI for each individual that the Participant proposes to serve as a GUIDE Practitioner.
2. If the Participant is in the New Program Track:
  - i. The Participant shall submit to CMS a Proposed GUIDE Practitioner Roster in the manner and by the date specified by CMS in accordance with Section 4.03(B).
  - ii. CMS will review the Proposed GUIDE Practitioner Roster in accordance with Section 4.03(B).
  - iii. The Proposed GUIDE Practitioner Roster must include the name, TIN and NPI for each individual that the Participant proposes to serve as a GUIDE Practitioner.
3. The Participant must update its GUIDE Practitioner Roster on a timely basis in accordance with Sections 3.04(C) and (D).

**C. Additions to the GUIDE Practitioner Roster.**

1. The Participant may make additions to the GUIDE Practitioner Roster in a form and manner and by the date(s) specified by CMS.
2. If the Participant wishes to add an individual(s) to its GUIDE Practitioner Roster, the Participant shall submit to CMS, in a form and manner specified by CMS, the name, TIN, and individual NPI of each individual whom the Participant wishes to add to its GUIDE Practitioner Roster.
3. CMS will conduct a Program Integrity Screening of each individual identified by the Participant as a proposed GUIDE Practitioner.

4. CMS may not approve an individual(s) for the GUIDE Practitioner Roster based on the results of a Program Integrity Screening or on the basis that CMS determines an individual(s) is not a Medicare-enrolled physician or other non-physician practitioner.
5. CMS shall inform the Participant in writing whether the proposed GUIDE Practitioner has been added to the Participant's GUIDE Practitioner Roster following completion of the Program Integrity Screening.
6. A proposed GUIDE Practitioner is not permitted to perform or bill for any GUIDE Care Delivery Services under the Model until the Participant has received written notice from CMS that CMS added the individual to the Participant's GUIDE Practitioner Roster.

**D. Removals from the GUIDE Practitioner Roster.**

1. If an individual ceases to meet the requirements of clauses (i)-(iii) of the definition of GUIDE Practitioner, the Participant shall notify CMS, in a form and manner specified by CMS, within 15 Days of becoming aware that the GUIDE Practitioner ceases to meet the requirements of clauses (i)-(iii) of the definition of GUIDE Practitioner. The notice must include the date on which the individual ceases to meet such requirements.
2. If an individual on the GUIDE Practitioner Roster becomes ineligible to receive payment from Medicare, the Participant shall notify CMS, in a form and manner specified by CMS, within 15 Days of receiving notice of such ineligibility.
3. Except as set forth in Section 3.04(D)(4), the removal of the individual from the GUIDE Practitioner Roster will be effective on the date the individual ceases to meet the requirements of clauses (i)-(iii) of the definition of GUIDE Practitioner.
4. CMS will notify the Participant in writing if CMS removes an individual from the GUIDE Practitioner Roster in accordance with Section 3.04(A)(4) or for failure to comply with the terms of this Agreement, and such notice will specify the effective date of such removal.

**Section 3.05 Partner Organizations**

- A. If the Participant chooses to partner with one or more Partner Organizations, it shall enter into a Partner Organization Arrangement with each Partner Organization, pursuant to Section 3.06.
- B. The Participant must not condition a Partner Organization Arrangement, directly or indirectly, on referrals of items or services provided to Eligible Beneficiaries.
- C. The Participant shall not require, and shall ensure that its Partner Organizations, if any, do not require, that Eligible Beneficiaries be referred only to the Participant's GUIDE Practitioner(s), Partner Organization(s), or to any other provider or supplier. This prohibition does 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 an Eligible Beneficiary expresses a preference for a different provider or supplier, or the referral is not in the Eligible Beneficiary's best medical interests in the judgment of the referring party.
- D. The Participant shall not condition a Partner Organization's participation in the Model on the entity's offer or payment of cash or other remuneration to the Participant or any other



individual or entity.

- E. The Participant shall ensure that no party to the Partner Organization Arrangement gives or receives remuneration in return for, or to induce or reward, any Federal health care program referrals or other Federal health care program business generated outside of the Model.
- F. The compensation under the Partner Organization Arrangement must not encourage or induce either party or other providers or suppliers to furnish medically unnecessary items or services or reduce or limit Medically Necessary items or services furnished to any GUIDE Beneficiary.
- G. The Participant shall not take, and shall ensure that its Partner Organization(s) does not take, any action to limit the ability of a Partner Organization to make decisions in the best interests of a GUIDE Beneficiary, including the selection of devices, supplies, and treatments used in the care of the GUIDE Beneficiary.
- H. The Participant is responsible for ensuring that the services provided by a Partner Organization to GUIDE Beneficiaries are provided with the appropriate standard of care.
- I. The Participant shall notify CMS within 15 Days after becoming aware that any Partner Organization is under investigation or has been sanctioned by any local, state or federal government or any licensing authority (including, without limitation, the imposition of program exclusion, debarment, civil monetary penalties, corrective action plans, revocation of Medicare billing privileges, and inclusion on the CMS preclusion list as defined at 42 C.F.R. § 422.2). If a Partner Organization is under investigation or has been sanctioned CMS may take remedial action, or terminate the Agreement, in accordance with Article 16.
- J. The Participant shall ensure any Partner Organization that has been removed from the Partner Organization Roster pursuant to Section 3.07(D), as applicable, does not engage in any GUIDE Care Delivery Services following the effective date of such termination or removal from the Partner Organization Roster.
- K. The Participant shall provide each Partner Organization with a copy of this Agreement and any amendments hereto.

### **Section 3.06 Partner Organization Arrangements**

- A. If the Participant chooses to partner with a Partner Organization, the Participant shall have a Partner Organization Arrangement with each Partner Organization by the applicable date set forth in Section 3.06(B). Each Partner Organization Arrangement must comply with the criteria described in this Section 3.06(A):
  - 1. The Partner Organization Arrangement must be in writing;
  - 2. The Partner Organization Arrangement must be exclusively between the Participant and the Partner Organization;
  - 3. The Partner Organization Arrangement must require the Partner Organization to agree to participate in the Model and to engage in at least one of the GUIDE Care Delivery Services during the Agreement Performance Period;
  - 4. The Partner Organization Arrangement must require the Partner Organization to comply with the applicable terms of this Agreement, and expressly require compliance with any provisions regarding the following: performance of the GUIDE Care Delivery Services; Beneficiary notifications; Beneficiary freedom of choice; Telehealth Benefit

Enhancement; participation in evaluation, shared learning, monitoring, and oversight activities; and audit and record retention requirements;

5. The Partner Organization Arrangement must require the Partner Organization to comply with all applicable laws and regulations;
  6. The Partner Organization Arrangement must set forth the activities to be undertaken by the Partner Organization;
  7. The Partner Organization Arrangement must detail the nature of the remuneration to be exchanged between the Participant and Partner Organization;
  8. While the Partner Organization Arrangement must be executed by the applicable date specified in Section 3.06(B), the Partner Organization Arrangement must be effective prior to, or upon, CMS notifying the Participant that CMS has added the Partner Organization to the Participant's Partner Organization Roster.
  9. The Partner Organization Arrangement must require the Partner Organization to notify the Participant within 7 Days of becoming aware that the Partner Organization 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, revocation of Medicare billing privileges, and inclusion on the CMS preclusion list as defined at 42 C.F.R. § 422.2);
  10. The Partner Organization Arrangement must permit the Participant to take remedial action against the Partner Organization (including without limitation the imposition of a corrective action plan, denial of any payments, and termination of the Partner Organization Arrangement with the Partner Organization) to address noncompliance with the applicable terms of the Partner Organization Arrangement;
  11. The Partner Organization Arrangement must require the Partner Organization, upon termination or expiration of the Partner Organization Arrangement, to complete a close-out process in which the Partner Organization furnishes all data required by the Participant as detailed in the Partner Organization Arrangement and any data required by CMS to monitor or evaluate the Model to the Participant.
- B. The Participant must have a fully executed Partner Organization Arrangement in place that meets the requirements set forth in Section 3.06(A) by the following dates:
1. By the Start Date, in the case of Partner Organization Arrangements with entities that were approved by CMS before the Start Date to be Partner Organization(s).
  2. For Partner Organization Arrangements with entities approved by CMS to be Partner Organization(s) effective on a day after the Start Date, by the date the Participant requests CMS to add the entity to the Participant's Partner Organization Roster pursuant to Section 3.07(C).
- C. The Participant must maintain, in accordance with Section 15.02, records of all remuneration paid or received pursuant to the Partner Organization Arrangements described in Section 3.06(A).
- D. CMS provides no opinion on the legality of any contractual, financial, or other agreements or arrangements including any Partner Organization Arrangement, into which the Participant or a

Partner Organization may enter. The receipt by CMS of any such documents in the course of the application period or Agreement Term or otherwise will 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 other federal or state agency from enforcing any and all applicable laws, rules, and regulations.

E. Availability of Safe Harbor Protection for Partner Organization Arrangements.

1. CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 C.F.R. § 1001.952(ii)(1)) is available to protect a Partner Organization Arrangement reasonably related to the provision of GUIDE Care Delivery Services, provided that such Partner Organization Arrangement complies with:
  - i. Section 3.05(B)-(G) and 3.06(C) of this Agreement; and
  - ii. All safe harbor requirements set forth in 42 C.F.R. § 1001.952(ii)(1).

**Section 3.07 Partner Organization Roster**

A. General.

1. If the Participant chooses to partner with a Partner Organization, a Partner Organization will be included on the Participant's Partner Organization Roster upon the prior written approval of CMS.
2. The Participant must retain current and historical Partner Organization Rosters in accordance with Section 15.02.
3. In addition to the initial CMS approval, CMS may periodically screen and monitor the program integrity history of Partner Organizations. CMS may remove an entity from the Partner Organization Roster or subject the Participant to additional monitoring pursuant to Article 14, on the basis of the results of a Program Integrity Screening, including but not limited to a Partner Organization's licensure status or ongoing investigations by law enforcement or state licensure bodies.
4. A Partner Organization's presence on the Partner Organization Roster does not imply or constitute a determination that the Partner Organization has no program integrity issues and does not preclude CMS or any other government authority from enforcing any and all applicable laws, rules, and regulations.

B. Partner Organization Roster Requirements for Each Track.

1. If the Participant is in the Established Program Track and chooses to partner with a Partner Organization:
  - i. The Participant submitted to CMS a Proposed Partner Organization Roster as part of its application to participate in the Model, that states the following information for each proposed Partner Organization:
    - a. If the proposed Partner Organization is enrolled in Medicare: the name, Medicare-enrolled identifier, such as a TIN or NPI, and provider or supplier type; or
    - b. If the proposed Partner Organization is not enrolled in Medicare: the name, TIN,

address, state license number, if applicable, and the names, titles, dates of birth, and Social Security Numbers of individuals in leadership positions at the organization.

- ii. CMS reviewed the Proposed Partner Organization Roster, conducted a Program Integrity Screening of the entities listed on the Proposed Partner Organization Roster, and issued to the Participant a list of entities that CMS approved to be the Partner Organization(s) on the Participant's Partner Organization Roster effective on the Start Date.
2. If the Participant is in the New Program Track and chooses to partner with a Partner Organization:
  - i. The Participant shall submit to CMS a Proposed Partner Organization Roster in the manner and by the date specified by CMS in accordance with Section 4.03(B).
  - ii. CMS will review the Proposed Partner Organization Roster in accordance with Section 4.03(B).
  - iii. The Proposed Partner Organization Roster must state the following information for each proposed Partner Organization:
    - a. If the proposed Partner Organization is enrolled in Medicare: the name, Medicare-enrolled identifier, such as a TIN or NPI, and provider or supplier type; or
    - b. If the proposed Partner Organization is not enrolled in Medicare: the name, TIN, address, state license number, if applicable, and the names, titles, dates of birth, and Social Security Numbers of individuals in leadership positions at the organization.
3. The Participant will update its Partner Organization Roster on a timely basis, in accordance with Sections 3.07(C) and (D).

**C. Additions to the Partner Organization Roster.**

1. The Participant may make additions to the Partner Organization Roster in accordance with Section 3.07(C)(2) in a form and manner and by the date(s) specified by CMS.
2. If the Participant wants to add a Partner Organization to its Partner Organization Roster, the Participant must submit to CMS, in a form and manner specified by CMS, the following information for each proposed Partner Organization whom the Participant wants to add to its Partner Organization Roster:
  - i. If the proposed Partner Organization is enrolled in Medicare: the name, Medicare-enrolled identifier, such as a TIN or NPI, and provider or supplier type; or
  - ii. If the proposed Partner Organization is not enrolled in Medicare: the name, TIN, address, state license number, if applicable, and the names, titles, dates of birth, and Social Security Numbers of individuals in leadership positions at the organization.
3. CMS will conduct a Program Integrity Screening of each entity identified by the Participant as a proposed Partner Organization.

4. CMS may not approve a proposed Partner Organization for the Partner Organization Roster on the basis of the results of the Program Integrity Screening or in the event CMS determines a proposed Partner Organization does not satisfy the criteria in Section 3.05.
5. CMS shall inform the Participant in writing whether the proposed Partner Organization has been added to the Partner Organization Roster after completion of the Program Integrity Screening.
6. A proposed Partner Organization is not permitted to perform any services under the Model until the Participant has received written notice from CMS that CMS has added the proposed Partner Organization to the Participant's Partner Organization Roster.

**D. Removals from the Partner Organization Roster.**

1. If a Partner Organization ceases to meet the requirements of clauses (i)-(iv) of the definition of Partner Organization, the Participant shall notify CMS, in a form and manner specified by CMS, within 15 Days of becoming aware that the Partner Organization ceases to meet the requirements of clauses (i)-(iv) of the definition of Partner Organization. The notice must include the date on which the Partner Organization ceases to meet such requirements.
2. If a Medicare-enrolled Partner Organization becomes ineligible to receive payment from Medicare, the Participant shall notify CMS, in a form and manner specified by CMS, within 15 Days of receiving notice of such ineligibility.
3. Except as set forth in Section 3.07(D)(4), the removal of an entity from the Partner Organization Roster will be effective on the date the entity ceases to meet the requirements of clauses (i)-(iv) of the definition of Partner Organization.
4. CMS will notify the Participant if CMS removes a Partner Organization from the Partner Organization Roster in accordance with Section 3.07(A)(3) or for failure to comply with the terms of this Agreement, and such notice will specify the effective date of removal.

**Article 4. Model Performance Period and Pre-Implementation Period**

**Section 4.01 Model Performance Period for Established Program Track**

- A. If the Participant is in the Established Program Track, the Model Performance Period consists of the following eight Performance Years, unless CMS terminates or modifies the Model:
1. Performance Year 2024: July 1, 2024 – June 30, 2025
  2. Performance Year 2025: July 1, 2025 – June 30, 2026
  3. Performance Year 2026: July 1, 2026 – June 30, 2027
  4. Performance Year 2027: July 1, 2027 – June 30, 2028
  5. Performance Year 2028: July 1, 2028 – June 30, 2029
  6. Performance Year 2029: July 1, 2029 – June 30, 2030
  7. Performance Year 2030: July 1, 2030 – June 30, 2031
  8. Performance Year 2031: July 1, 2031 – June 30, 2032

## **Section 4.02 Model Performance Period for New Program Track**

A. If the Participant is in the New Program Track, the Model Performance Period consists of the following seven Performance Years, unless CMS terminates or modifies the Model:

1. Performance Year 2025: July 1, 2025 – June 30, 2026
2. Performance Year 2026: July 1, 2026 – June 30, 2027
3. Performance Year 2027: July 1, 2027 – June 30, 2028
4. Performance Year 2028: July 1, 2028 – June 30, 2029
5. Performance Year 2029: July 1, 2029 – June 30, 2030
6. Performance Year 2030: July 1, 2030 – June 30, 2031
7. Performance Year 2031: July 1, 2031 – June 30, 2032

## **Section 4.03 Requirements for Pre-Implementation Period for New Program Track**

A. General.

1. If the Participant is in the New Program Track, the Participant shall use the period from July 1, 2024 through June 30, 2025 (“**Pre-Implementation Period**”) for program development, including hiring and training staff, establishing program workflows and processes, developing networks, and building relationships with community-based organizations and respite providers, as applicable.
2. During the Pre-Implementation Period, CMS will provide to the Participant:
  - i. Information and assistance with onboarding onto the HDR and Data Dashboard;
  - ii. An opportunity to request data on the Participant’s Eligible Beneficiaries pursuant to Section 10.03(D)(3); and
  - iii. Access to learning activities as described in Article 12.

B. New Program Track Reporting Requirements.

1. The Participant shall submit to CMS a baseline Care Delivery Reporting, a Proposed GUIDE Practitioner Roster and, if applicable, a Proposed Partner Organization Roster, prior to May 1, 2025.
  - i. If the Participant submitted a Proposed GUIDE Practitioner Roster and/or a Proposed Partner Organization Roster as part of its application to the Model, the Participant must resubmit the Proposed GUIDE Practitioner Roster and/or Proposed Partner Organization Roster, or submit a revised or new Proposed GUIDE Practitioner Roster and/or Proposed Partner Organization Roster.
2. CMS will use the information submitted under Section 4.03(B)(1) to verify that the Participant will meet the requirements listed in Section 3.01(B) as of the Start Date.
3. CMS will review the Proposed GUIDE Practitioner Roster and Proposed Partner Organization Roster, if applicable, submitted under Section 4.03(B)(1) and conduct a Program Integrity Screening of the individuals or entities listed on the Proposed GUIDE

Practitioner Roster and Proposed Partner Organization Roster, respectively.

4. If, in advance of the Start Date, CMS determines that the Participant will meet the requirements listed in Section 3.01(B) as of the Start Date, CMS will:
  - i. Issue to the Participant a list of individuals that CMS approves to be the GUIDE Practitioners on the Participant's GUIDE Practitioner Roster effective on the Start Date; and
  - ii. If applicable, issue to the Participant a list of entities that CMS approves to be the Partner Organization(s) on the Participant's Partner Organization Roster effective on the Start Date.
5. If, in advance of the Start Date, CMS determines that the Participant will not meet the requirements listed in Section 3.01(B) as of the Start Date, CMS may terminate this Agreement in accordance with Section 16.03.

## **Article 5. Beneficiary Eligibility and Voluntary Alignment**

### **Section 5.01 Beneficiary Eligibility**

- A. To be considered a Beneficiary eligible for Voluntary Alignment in accordance with Section 5.02 (“**Eligible Beneficiary**”), the Beneficiary must meet the following criteria:
  1. Has mild, moderate, or severe dementia, as confirmed by a GUIDE Practitioner's attestation on a Patient Assessment and Alignment form that:
    - i. The Beneficiary meets the National Institute on Aging-Alzheimer's Association diagnostic guidelines for dementia based on the Beneficiary's Comprehensive Assessment;
    - ii. The Beneficiary meets the DSM-5 diagnostic guidelines for major neurocognitive disorder based on the Beneficiary's Comprehensive Assessment; or
    - iii. The GUIDE Practitioner received a written report of a documented dementia diagnosis for the Beneficiary from another Medicare-enrolled practitioner.
  2. Is enrolled in both Medicare Parts A and B,
  3. Has Medicare as their primary payer,
  4. Is not enrolled in Medicare Advantage or another Medicare health plan, including Special Needs Plans (SNPs) and the Program of All-Inclusive Care for the Elderly (PACE),
  5. Is not enrolled in Medicare hospice benefit,
  6. Is not a Long-Term Nursing Home Resident, and
  7. Is not aligned to another GUIDE Model Participant.

### **Section 5.02 Voluntary Alignment**

- A. CMS will align Eligible Beneficiaries to the Participant for purposes of receiving services under the Model via Voluntary Alignment in accordance with the provisions of this Section 5.02.

- B. The Participant must perform a Comprehensive Assessment of an Eligible Beneficiary in accordance with the requirements of Section 1 of Appendix C.
- C. During the Comprehensive Assessment, the Participant must administer screening tools that measure dementia stage and caregiver burden by either:
  - 1. Using the Zarit Burden Interview to measure caregiver burden and either the Clinical Dementia Rating (CDR) or the Functional Assessment Screening Tool (FAST) to measure dementia stage.
    - i. CMS may, in its sole discretion, modify the approved screening tools listed in Section 5.02(C)(1) and/or the criteria for the corresponding assessment tool scores outlined in Appendix F, Table 1 upon 30 Days written notice to the Participant.
  - 2. Receiving advance approval from CMS to use an alternative screening tool(s) by submitting to CMS, in a form and manner specified by CMS, the proposed tool(s), published evidence that the tool(s) is valid and reliable, and a crosswalk for how the tool(s) corresponds to the Model's tiering thresholds outlined in Appendix F, Table 1.
    - i. If the Participant submits to CMS an alternative screening tool, CMS will approve or reject the alternative screening tool(s) within 90 Days of CMS receiving the Participant's submission.
    - ii. The Participant may not submit scoring data on the Patient Assessment and Alignment form for a proposed alternative screening tool(s) until the Participant receives written approval to use the alternative scoring tool from CMS.
- D. After the Comprehensive Assessment, the Participant must submit the Patient Assessment and Alignment form and the individual responses from the Zarit Burden Interview, if applicable, to CMS in a form and manner specified by CMS.
- E. Upon receipt of a completed Patient Assessment and Alignment form from the Participant, CMS will analyze the Patient Assessment and Alignment form to confirm whether the Beneficiary is an Eligible Beneficiary.
  - 1. If CMS determines that the Beneficiary meets the criteria to be an Eligible Beneficiary, CMS will complete the following steps within 15 business days of CMS receiving a Patient Assessment and Alignment form from the Participant:
    - i. Align the Eligible Beneficiary to the Participant by adding the Eligible Beneficiary to the Participant's Beneficiary Alignment File, as referenced in Section 10.03(D)(1), at which time the Eligible Beneficiary becomes a GUIDE Beneficiary;
    - ii. Assign the GUIDE Beneficiary to one of five Model Tiers in accordance with the tiering criteria outlined in Appendix F, Table 1; and
    - iii. Notify the Participant of the GUIDE Beneficiary's Model Tier assignment and their alignment to the Participant in a form and manner specified by CMS.
  - 2. If CMS determines that the Beneficiary does not meet the criteria to be an Eligible Beneficiary, CMS will notify the Participant in a form and manner specified by CMS.



- F. If CMS determines that the Patient Assessment and Alignment form is incomplete, CMS, within 15 Days of the receipt of the form, will notify the Participant in writing of the information the Participant must provide to CMS to complete the Patient Assessment and Alignment form.

### **Section 5.03 Beneficiary Notifications**

- A. The Participant shall provide written notice to each GUIDE Beneficiary, using a form letter drafted in accordance with Section 5.03(B) (“**GUIDE Beneficiary Notification Letter**”) and approved by CMS pursuant to Sections 5.03(C) and (E).
- B. The Participant shall draft the form GUIDE Beneficiary Notification Letter required under Section 5.03(A) using a template letter provided by CMS.
1. The template letter from CMS will designate content that the Participant is not permitted to change when drafting its form GUIDE Beneficiary Notification Letter, as well as sections of the template letter in which the Participant may insert its original content.
  2. The GUIDE Beneficiary Notification Letter will state that the Participant is participating in the Model, the GUIDE Beneficiary is voluntarily aligned to the Participant, and any other information specified by CMS.
- C. By a date specified by CMS, the Participant shall submit the draft of its GUIDE Beneficiary Notification Letter, including any original content inserted by the Participant, to CMS for review. The GUIDE Beneficiary Notification Letter will be deemed approved within 15 Days following receipt by CMS, unless CMS provides a written notice of disapproval to the Participant on or before such date.
- D. The Participant shall use its approved GUIDE Beneficiary Notification Letter to provide written notice to each GUIDE Beneficiary either in-person, via postal mail, via email, via patient portal or other similar technology application within 45 Days of the Participant receiving notice from CMS that the GUIDE Beneficiary is voluntarily aligned to the Participant.
- E. CMS may issue written notice of disapproval of the Participant’s form GUIDE Beneficiary Notification Letter at any time, including after the form GUIDE Beneficiary Notification Letter has been deemed approved.

### **Section 5.04 Removal from Beneficiary Alignment File**

- A. CMS will remove a GUIDE Beneficiary from the Participant’s Beneficiary Alignment File effective on the first Day of the first month following one of the occurrences identified below:
1. The GUIDE Beneficiary’s death.
  2. The GUIDE Beneficiary is a Long-Term Nursing Home Resident.
  3. The GUIDE Beneficiary enrolls in the Medicare Hospice Benefit.
  4. The GUIDE Beneficiary enrolls in PACE.
  5. The GUIDE Beneficiary enrolls in a Medicare Advantage Plan.
  6. A GUIDE Practitioner attests in writing to CMS that the GUIDE Beneficiary no longer has mild, moderate, or severe dementia.

7. The GUIDE Beneficiary, or their legal representative, makes a request to the Participant to no longer receive services under the Model.
  8. The GUIDE Beneficiary moves out of the Participant's Zip-Code Based Service Area.
  9. The Participant does not file claims for the DCMP or the GUIDE Respite Payment for the GUIDE Beneficiary for a period of 8 months.
- B. If CMS removes a GUIDE Beneficiary from the Participant's Beneficiary Alignment File due to a reason listed in Sections 5.04(A)(7) and (9), CMS will continue to include the Beneficiary in the Participant's performance measure calculations through the end of the Performance Year in which CMS removed the Beneficiary from the Participant's Beneficiary Alignment File.

## **Article 6. GUIDE Care Delivery Approach**

### **Section 6.01 General**

- A. The Participant shall require and ensure that the Participant, its GUIDE Practitioners, and any Partner Organizations implement the GUIDE care delivery approach in accordance with the provisions of this Article 6.

### **Section 6.02 Interdisciplinary Care Team**

- A. The Participant shall maintain an interdisciplinary Care Team at all times during the Agreement Performance Period.
- B. The Participant's interdisciplinary Care Team shall include, at a minimum, a Care Navigator and a clinician with dementia proficiency who is eligible to bill Medicare Part B evaluation and management services (E/M).
- C. The Participant shall ensure that the Care Navigator is not artificial intelligence.
- D. If the clinician with dementia proficiency is not a physician, the Participant shall have a physician, who works at least part-time as a medical director for the Participant and oversees the quality of care of the Participant's dementia care program.

### **Section 6.03 Care Navigator Training**

- A. The Participant shall develop and administer an initial and annual training for the Care Navigators which covers the topics listed on Appendix B and complies with the requirements of this Section 6.03 ("**Care Navigator Training**") by the beginning of Performance Year 2024 if the Participant is in the Established Program Track.
- B. The Participant shall develop and administer Care Navigator Training by the beginning of Performance Year 2025 if the Participant is in the New Program Track.
- C. The Participant may use training programs that are available to the public or develop its own training of the required topics listed on Appendix B.
- D. The Participant must ensure that its initial Care Navigator Training is a minimum of 20 hours long, and includes the following:
  1. A minimum of 10 hours of didactic instruction, which may be a live (either virtual or in person) or a pre-recorded web-based training; and
  2. A minimum of 10 hours of experiential training, which must be live (either virtual or in

person).

- E. The Participant must assess its Care Navigators following the initial Care Navigator Training to ensure comprehension.
- F. Following the initial Care Navigator Training, each Care Navigator must take an additional 2 hours of training each Performance Year in accordance with the following:
  - 1. The annual training may be developed and offered by the Participant or be a continuing education training offered by a third party.
  - 2. The annual training may be on a topic chosen by the Participant or the Care Navigator.
  - 3. The Participant shall retain confirmation, in a form or manner that the Participant chooses, that its Care Navigator completed the annual training and retain such confirmation in accordance with Section 15.02.
- G. Except as provided for in Sections 6.03(G)(1) and (2), each Care Navigator must complete Care Navigator Training prior to providing any GUIDE Care Delivery Services.
  - 1. If the Participant's interdisciplinary Care Team includes an individual who took a training on one or more of the Care Navigator Training required topics listed on Appendix B in the five years prior to the Start Date, and the individual has continued to work for the Participant during this time, the individual is not required for purposes of satisfying Section 6.03(G) to retake the training on those topics that the individual has already received training.
  - 2. If the Participant is in the Established Program Track, the Participant shall ensure that any individuals, who were part of the interdisciplinary Care Team prior to the Participant signing this Agreement and who intend to serve as a Care Navigator after the Start Date, receive Care Navigator Training within 90 Days of the Start Date. The individual(s) may continue to work with GUIDE Beneficiaries while they complete the Care Navigator Training.

#### **Section 6.04 GUIDE Care Delivery Services and Reporting**

- A. The Participant shall furnish the GUIDE Care Delivery Services as described in Appendix C of this Agreement to GUIDE Beneficiaries and shall report on the GUIDE Care Delivery Services in accordance with Section 6.04(D).
- B. The Participant shall offer, and be able to provide, the GUIDE Care Delivery Services as outlined in Appendix C to its GUIDE Beneficiaries, as applicable and appropriate for each individual GUIDE Beneficiary's needs and preferences and as guided by the creation and maintenance of a person-centered care plan.
- C. The Participant may offer additional enhanced services outside of the GUIDE Care Delivery Services, such as the Environmental Modification Beneficiary Engagement Incentive described in Appendix A.
- D. Care Delivery Reporting.
  - 1. The Participant shall submit a Care Delivery Reporting to CMS through Salesforce at least once per Performance Year at the times specified in the Section 6.04(D)(2). The Care Delivery Reporting will include information regarding the Participant's

implementation of the GUIDE Care Delivery Services and the Health Equity Plan.

2. The Participant shall submit the Care Delivery Reporting to CMS by the following dates:
  - i. If the Participant is in the Established Program Track, the Participant shall submit its baseline Care Delivery Reporting by July 31, 2024.
  - ii. If the Participant is in the New Program Track, the Participant shall submit its baseline Care Delivery Reporting by May 1, 2025.
  - iii. Beginning in its second Performance Year, and for each subsequent Performance Year, the Participant shall submit its Care Delivery Reporting within 60 Days after the first day of the Performance Year.
  - iv. The Participant may request an extension for submitting its Care Delivery Reporting at a time and in a manner to be specified by CMS.
  - v. The Participant shall submit a final Care Delivery Reporting to CMS within 60 Days of any of the following events:
    - a. The last Day of the Agreement Performance Period;
    - b. Termination of the Agreement Performance Period by the Participant, in accordance with Section 16.04; or
    - c. Termination of the Agreement or Agreement Performance Period by CMS, in accordance with Section 16.03.

E. The Participant shall not include any PHI in its Care Delivery Reporting.

## **Article 7. Telehealth Benefit Enhancement**

### **Section 7.01 Background**

- A. If the waiver of geographic location requirements for telehealth services described in the Consolidated Appropriations Act, 2023 and in the CY 2024 PFS Final Rule (88 FR 78818, 78818 through 80047 (Nov. 16, 2023)) expires on December 31, 2024 and is not otherwise extended or changed by law or regulation, the Participant may select and implement the Telehealth Benefit Enhancement as described herein in order to provide Comprehensive Assessments via telehealth and deliver additional services under the GUIDE Care Delivery Services via telehealth.
- B. CMS will inform the Participant of any changes related to the waiver of the geographic location requirements for telehealth services, and the potential need for the Participant to select to implement the Telehealth Benefit Enhancement, via written guidance in advance of October 1, 2024.

### **Section 7.02 Selection of Telehealth Benefit Enhancement**

- A. If necessary and applicable, the Participant may select as described in this Section 7.02 to provide the Telehealth Benefit Enhancement as described in Appendix E.
- B. When initially selecting to use the Telehealth Benefit Enhancement, the Participant shall submit to CMS 60 Days in advance of the effective date of the Telehealth Benefit Enhancement that the Participant is selecting to offer the Telehealth Benefit Enhancement during that Performance Year.
- C. After a Participant has selected and implemented the Telehealth Benefit Enhancement for a Performance Year, the Participant must submit to CMS its selection to continue to use the

Telehealth Benefit Enhancement no later than 30 Days prior to the start of each subsequent Performance Year.

- D. The Participant's selections made as described in this Section 7.02 shall be deemed approved unless rejected in writing by CMS within 30 Days after submission.
- E. Appendix E will apply to the Agreement for a given Performance Year only if the Participant selected to provide the Telehealth Benefit Enhancement and that selection was not rejected by CMS pursuant to Section 7.02(D).

### **Section 7.03 Requirements to Terminate the Telehealth Benefit Enhancement**

- A. The Participant must obtain CMS consent before voluntarily terminating the Telehealth Benefit Enhancement effective during a Performance Year. The Participant shall provide at least 30 Days' advance written notice of such termination to CMS. If CMS consents to such termination, the effective date of such termination will be the date specified in the notice of termination or such other date specified by CMS.
- B. CMS will cease coverage of claims for a terminated Telehealth Benefit Enhancement 90 Days after the effective date of such termination, unless otherwise specified in Appendix E.
- C. If the Telehealth Benefit Enhancement will be terminated or otherwise cease to be in effect during a Performance Year pursuant to Section 7.03(A) or Article 16, the Participant shall provide written notices to its GUIDE Practitioners, Partner Organizations, and GUIDE Beneficiaries who are currently receiving items and services pursuant to the Telehealth Benefit Enhancement, within 30 Days after the effective date of termination or cessation of the Telehealth Benefit Enhancement. Such notification shall state that following a date that is 90 Days after the effective date of termination, services furnished under the Telehealth Benefit Enhancement will no longer be covered by Medicare and the GUIDE Beneficiary may be responsible for the payment of such services. Any notice to GUIDE Beneficiaries is subject to review and approval by CMS under Section 5.03(C).
- D. If the Participant selected to offer the Telehealth Benefit Enhancement for a Performance Year and does not select to offer the Telehealth Benefit Enhancement for the next Performance Year, the Participant shall notify all its GUIDE Practitioners, Partner Organizations, and GUIDE Beneficiaries who are currently receiving services pursuant to the Telehealth Benefit Enhancement, that the Telehealth Benefit Enhancement will not be offered during the next Performance Year. Such notices must be furnished no later than 30 Days prior to the start of the next Performance Year.
- E. If the Agreement is terminated by CMS, or the Agreement Performance Period is terminated by either CMS or the Participant prior to the end of a Performance Year, CMS will terminate the Participant's Telehealth Benefit Enhancement on the effective date of the termination.

## **Article 8. Performance Measures**

### **Section 8.01 Performance Measures and Reporting**

- A. On an annual basis, CMS shall publish a "**GUIDE Quality Measure Manual**", which will include information regarding the benchmark approach for each performance measure, the performance-based adjustment approach, reporting of the performance measures, and as needed, updates on the Model's quality strategy. CMS will publish the GUIDE Quality Measure Manual at least 30 Days before the start of the applicable Performance Year.

- B. CMS will assess measure performance using data reported by the Participant and identified in claims on an annual basis, in accordance with the GUIDE Performance Measure Set outlined in Appendix D.
- C. By a date specified by CMS, the Participant shall completely, timely, and accurately report via the HDR the following performance measures as set forth in Appendix D.
  - 1. Use of High-Risk Medications in Older Adults (MIPS #238, NQF #0022); and
  - 2. Quality of Life Outcome for People with Neurological Conditions (MIPS #AAN22).
- D. CMS or its designee(s) shall capture and analyze the following performance measures, based on claims, as set forth in Appendix D:
  - 1. Total Per Capita Cost (TPCC) (NQF #3575); and
  - 2. Rate of beneficiaries with a long-term nursing home stay ("**Long-Term Nursing Home Stay Measure**" or "**LTNH Measure**").
- E. The parties acknowledge that the Caregiver Burden Measure is not available as of the Effective Date of this Agreement. The Participant shall completely, timely, and accurately report via the HDR the Caregiver Burden Measure once CMS notifies and makes this measure available to the Participant.
- F. CMS may modify the performance measures identified in Appendix D, upon 30 Days written notice to the Participant prior to the beginning of a Performance Year.
- G. CMS may remove a performance measure from the GUIDE Performance Measure Set set forth in Appendix D upon written notice to the Participant at least 30 Days prior to the beginning of a Performance Year. If CMS removes a performance measure from the GUIDE Performance Measure Set set forth in Appendix D, CMS will not use that performance measure to evaluate the Participant and the Participant will not be accountable for performance on such performance measure, during the relevant Performance Year.

## **Section 8.02 Performance Benchmarks**

- A. CMS will determine the Participant's PBA by comparing the Participant's performance on the GUIDE Performance Measure Set in Appendix D to performance benchmarks outlined below in Sections 8.02(D) and (E) and further described in the GUIDE Quality Measure Manual.
  - 1. CMS will publish the performance benchmarks annually in the GUIDE Quality Measure Manual beginning with the GUIDE Quality Measure Manual that will be issued 30 Days prior to Performance Year 2026.
- B. CMS may update the performance benchmarks and will report any changes in the GUIDE Quality Measure Manual at least 30 Days prior to the beginning of the applicable Performance Year.
- C. For Performance Year 2024, there are no performance benchmarks for the Use of High-Risk Medications in Older Adults (MIPS #238, NQF #0022) and the Quality of Life Outcome for People with Neurological Conditions (MIPS #AAN22). CMS will calculate the PBA for Performance Year 2024 as set forth in Section 9.03(C)(1) and (2).
- D. For Performance Year 2024, CMS will calculate the performance benchmarks for Total Per

Capita Cost (TPCC) (NQF #3575) and LTNH Measure based on claims-based data from GUIDE Model Participants and non-GUIDE Model Participants from prior to the Agreement Performance Period.

- E. For Performance Year 2025, CMS will calculate the performance benchmarks as follows:
  - 1. Use of High-Risk Medications in Older Adults (MIPS #238, NQF #0022): Based on data from GUIDE Model Participants in the Established Program Track from Performance Year 2024.
  - 2. Quality of Life Outcome for People with Neurological Conditions (MIPS #AAN22): Based on data from GUIDE Model Participants in the Established Program Track from Performance Year 2024.
  - 3. Total Per Capita Cost (TPCC) (NQF #3575): A blend of claims-based data from GUIDE Model Participants and non-GUIDE Model Participants in Performance Year 2024.
  - 4. LTNH Measure: A blend of claims-based data from GUIDE Model Participants and non-GUIDE Model Participants in Performance Year 2024.
- F. For Performance Year 2026 and each subsequent Performance Year, CMS will inform the Participant of the performance benchmarks through the GUIDE Quality Measure Manual at least 30 Days prior to the beginning of the Performance Year in which CMS will use such benchmarks to determine the PBA.

## **Article 9. Payment**

### **Section 9.01 GUIDE Payment Overview**

- A. CMS will make GUIDE Payments to the Participant during the Agreement Performance Period in accordance with the terms of this Agreement.
- B. Additional details about the payment methodology are described in the GUIDE Payment Methodology Paper.
  - 1. CMS will publish an annual GUIDE Payment Methodology Paper for each Performance Year and will make it available to the Participant at least 30 Days prior to the start of each Performance Year.
- C. The Participant shall use its single TIN for billing all GUIDE Payments and for receiving all GUIDE Payments from CMS.
- D. The Participant must immediately and permanently stop billing GUIDE Payments for a GUIDE Beneficiary under any of the circumstances listed in Section 5.04(A).
- E. The Participant shall not bill a GUIDE Beneficiary or their Caregiver for providing GUIDE Respite Services or any other GUIDE Care Delivery Service as listed on Appendix C.
- F. The Participant shall not bill the GUIDE Beneficiary or their Caregiver for the difference in cost, whether by hourly rate or total cost (for example, if the total cost exceeds the Respite Cap) of providing GUIDE Respite Services or any other GUIDE Care Delivery Service listed on Appendix C.
- G. Unless otherwise specified in this Agreement, the Participant shall deliver, or contract with and pay a Partner Organization to deliver, the GUIDE Care Delivery Services as listed on

Appendix C. The Participant shall not utilize free, publicly available services to deliver GUIDE Care Delivery Services to GUIDE Beneficiaries.

- H. The Participant is solely responsible for paying Partner Organizations. The Participant shall pay to a Partner Organization:
- a. The full amount of the payment from CMS to the Participant for GUIDE Respite Services if the Partner Organization has furnished GUIDE Respite Services; or
  - b. The full amount that the Participant and Partner Organization negotiated as reimbursement to the Partner Organization in their Partner Organization Arrangement if the Partner Organization has furnished GUIDE Care Delivery Services other than GUIDE Respite Services.

## **Section 9.02 Dementia Care Management Payment**

### **A. General.**

1. CMS will pay to the Participant a DCMP, which will be calculated in accordance with Section 9.02(B), for each GUIDE Beneficiary for which the Participant bills the HCPCS codes G0519-G0528 associated with the GUIDE Beneficiary's assigned tier.

### **B. Amount of DCMP.**

1. For each DCMP claim submitted by the Participant, CMS will adjust the DCMP Base Payment Rate as listed in Appendix F, Table 2 by the following adjustments:
  - i. GAF;
  - ii. A Performance-Based Adjustment in accordance with Section 9.03; and
  - iii. A Health Equity Adjustment in accordance with Section 9.04.
2. CMS will annually update the DCMP Base Payment Rates by the MEI.
3. CMS may adjust the amounts for the DCMP Base Payment Rates as outlined in Appendix F, Table 2, upon advance notice to the Participant.
4. The DCMP shall not be subject to beneficiary cost sharing.

### **C. Participant Billing for the DCMP.**

1. The Participant must bill the correct HCPCS G-code for each GUIDE Beneficiary each month that the Participant provides a GUIDE Care Delivery Service, other than the GUIDE Respite Services, to the GUIDE Beneficiary.
  - i. The Participant is not permitted to bill a HCPCS G-code for any month that the Participant does not provide a GUIDE Care Delivery Service to the GUIDE Beneficiary.
2. The Participant must attach an eligible ICD-10 dementia diagnosis code to each claim for a DCMP.
  - i. CMS will not pay a DCMP to the Participant if the claim for the DCMP does not have an eligible ICD-10 dementia diagnosis code.
  - ii. CMS will include eligible ICD-10 dementia diagnosis codes in the Payment



Methodologies Paper each year.

- iii. CMS reserves the right to update the eligible diagnosis codes each year and may require the Participant to code severity of the GUIDE Beneficiary's dementia diagnosis.

**D. Duplicative Services.**

1. The Participant shall not bill CMS for any of the Physician Fee Schedule Services listed on Appendix F, Table 4 that the Participant, GUIDE Practitioner, or Partner Organization furnished to GUIDE Beneficiaries during the Agreement Performance Period.
2. If CMS makes a Medicare FFS payment to the Participant for one of the Physician Fee Schedule Services listed on Appendix F, Table 4 that the Participant, GUIDE Practitioner, or Partner Organization furnished to a GUIDE Beneficiary during the Agreement Performance Period, CMS will recoup the amount of the payment for that claim from a future Medicare payment to the Participant per Section 9.09.

**E. GUIDE Beneficiary Movement Between Tiers.**

1. The Participant may submit a Patient Assessment and Alignment form and the individual responses from the Zarit Burden Interview, if applicable, to CMS in accordance with Section 5.02(D) at most once every 180 Days.
2. Upon receipt of a completed Patient Assessment and Alignment form in accordance with Section 9.02(E)(1), CMS will assign the GUIDE Beneficiary to one of five Model Tiers in accordance with the tiering criteria outlined in Appendix F, Table 1.
3. If CMS assigns the GUIDE Beneficiary to a new tier, CMS will update the Beneficiary Alignment File with the new tier and the Participant may bill the HCPCS G-code associated with the new tier beginning on the month following CMS's assignment of the GUIDE Beneficiary to the new tier.

**Section 9.03 Performance-Based Adjustment (PBA)**

- A. CMS will determine the Participant's individual PBA ("**Individual PBA**") based on the Participant's performance on the GUIDE Performance Measure Set as compared to performance benchmarks established in accordance with Section 8.02.
- B. CMS will add together the Participant's Individual PBAs to determine the Participant's total PBA ("**Total PBA**").
- C. CMS will calculate the Individual PBAs for the Use of High-Risk Medications in Older Adults measure and the Quality of Life Outcome for People with Neurological Conditions measure as follows:
  1. For Performance Year 2024, if the Participant is in the Established Program Track and the Participant reports to CMS: (1) the Use of High-Risk Medications in Older Adults measure; and (2) the Quality of Life Outcome for People with Neurological Conditions measure for each GUIDE Beneficiary by a date and in a manner specified by CMS:
    - i. The Participant will receive a 1% Individual PBA for reporting the Use of High-Risk Medications in Older Adults measure; and

- ii. The Participant will receive a 2% Individual PBA for reporting the Quality of Life Outcome for People with Neurological Conditions measure.
- 2. For Performance Year 2024, if the Participant is in the Established Program Track and fails to report to CMS the Use of High Risk Medications in Older Adults measure or the Quality of Life Outcome for People with Neurological Conditions measure for each GUIDE Beneficiary in accordance with Section 9.03(C)(1), the Participant will receive a 0% Individual PBA for those measures that the Participant fails to report.
- 3. For Performance Year 2025, and all subsequent Performance Years, if the Participant:
  - i. Fails to meet by a date specified by CMS the performance benchmark referenced in Section 8.02(E) for the Quality of Life Outcome for People with Neurological Conditions measure, the Individual PBA for this performance measure is -1%.
  - ii. Meets by a date specified by CMS the performance benchmark referenced in Section 8.02(E) for the Quality of Life Outcome for People with Neurological Conditions measure, the Individual PBA for this performance measure is 0%.
  - iii. Passes by a date specified by CMS the performance benchmark referenced in Section 8.02(E) for the Quality of Life Outcome for People with Neurological Conditions measure, the Individual PBA for this performance measure is 1.5%.
  - iv. Exceeds by a date specified by CMS the performance benchmark referenced in Section 8.02(E) for the Quality of Life Outcome for People with Neurological Conditions measure, the Individual PBA for this performance measure is 3%.
- 4. For Performance Year 2025, and all subsequent Performance Years, if the Participant:
  - i. Fails to meet by a date specified by CMS the performance benchmark referenced in Section 8.02(E) for the Use of High-Risk Medications in Older Adults measure, the Individual PBA for this performance measure is -0.5%.
  - ii. Meets by a date specified by CMS the performance benchmark referenced in Section 8.02(E) for the Use of High-Risk Medications in Older Adults measure, the Individual PBA for this performance measure is 0%.
  - iii. Passes by a date specified by CMS the performance benchmark referenced in Section 8.02(E) for the Use of High-Risk Medications in Older Adults measure, the Individual PBA for this performance measure is 0.5%.
  - iv. Exceeds by a date specified by CMS the performance benchmark referenced in Section 8.02(E) for the Use of High-Risk Medications in Older Adults measure, the Individual PBA for this performance measure is 1%.

D. CMS will calculate the Individual PBAs for the Total Per Capita Cost and the Long-Term Nursing Home Stay Measure as follows:

- 1. For Performance Year 2024, and all subsequent Performance Years, if the Participant is in the Established Program Track, and if the Participant:
  - i. Does not meet the performance benchmarks referenced in Section 8.02(E) by a date specified by CMS for the Total Per Capita Cost or Long-Term Nursing Home Stay Measure, the Individual PBA for each performance measure that the Participant

does not meet is -0.5%.

- ii. Meets the performance benchmarks referenced in Section 8.02(E) by a date specified by CMS for the Total Per Capita Cost or Long-Term Nursing Home Stay Measure, the Individual PBA for each performance measure that the Participant meets is 1.5%.
  2. For Performance Year 2025, and all subsequent Performance Years, if the Participant is in the New Program Track, and if the Participant:
    - i. Does not meet the performance benchmarks referenced in Section 8.02(E) by a date specified by CMS for the Total Per Capita Cost or Long-Term Nursing Home Stay Measure, the Individual PBA for each performance measure that the Participant does not meet is -0.5%.
    - ii. Meets the performance benchmarks referenced in Section 8.02(E) by a date specified by CMS for the Total Per Capita Cost or Long-Term Nursing Home Stay Measure, the Individual PBA for each performance measure that the Participant meets is 1.5%.
- E. CMS may adjust the Individual PBAs as outlined in Section 9.03(C) and (D) upon advance notice to the Participant.
- F. Total PBA.
  1. Beginning in Performance Year 2025, and for each subsequent Performance Year, if the Participant is in the Established Program Track, CMS will calculate the Participant's Total PBA by adding together the Participant's Individual PBAs for each performance measure based on the Participant's performance in the prior Performance Year.
    - i. CMS will apply the Total PBA to the Participant's DCMP beginning six months after the end of a Performance Year.
    - ii. CMS will continue to apply that Total PBA to the Participant's DCMP for the next 12 months ("**PBA Year**"), as illustrated in Appendix F, Table 6.
  2. Beginning in Performance Year 2026, and for each subsequent Performance Year, if the Participant is in the New Program Track, CMS will calculate the Participant's Total PBA by adding together the Participant's Individual PBAs for each performance measure based on the Participant's performance in the prior Performance Year.
    - i. CMS will apply the Total PBA to the Participant's DCMP beginning six months after the end of a Performance Year.
    - ii. CMS will continue to apply that Total PBA to the Participant's DCMP for the next 12 months ("**PBA Year**"), as illustrated in Appendix F, Table 6.
  3. As a result of CMS phasing in measures over the Agreement Performance Period, the Total PBA that CMS can calculate will be no more than 6% and no lower than -1% for Performance Year 2024, and no more than 7% and no lower than -2.5% for Performance Year 2025.

#### **Section 9.04 Health Equity Adjustment**

- A. CMS will apply a Health Equity Adjustment (HEA) to the DCMP paid to the Participant for each GUIDE Beneficiary based on the GUIDE Beneficiary’s health equity score.
  1. If the Participant is in the Established Program Track, CMS will apply HEAs to the DCMPs paid to the Participant beginning the first month of Performance Year 2025.
  2. If the Participant is in the New Program Track, CMS will apply HEAs to the DCMP paid to the Participant beginning the first month of Performance Year 2026.
- B. CMS will calculate a health equity score for each GUIDE Beneficiary on an annual basis before the start of the Performance Year in which the HEA is applied to the DCMP.
- C. Each GUIDE Beneficiary’s health equity score will correspond to a HEA amount, as listed in Appendix F, Table 5.

### **Section 9.05 Payment for GUIDE Respite Services**

#### **A. General.**

1. CMS will pay the Participant for GUIDE Respite Services up to the Respite Cap described in Section 9.05(A)(3) if:
  - i. The Participant bills the HCPCS codes G0529-G0531 associated with the GUIDE Respite Services provided; and
  - ii. The Participant ensures that the GUIDE Respite Services are furnished, as described in Section 9 of Appendix C, by a qualifying GUIDE Respite Provider to an Eligible Respite GUIDE Beneficiary.
2. After the end of each month of a Performance Year, CMS will review and aggregate the Participant’s claims for GUIDE Respite Services and make one monthly payment to the Participant for all GUIDE Respite Services that the Participant billed in the preceding month.
3. CMS will pay the Participant for GUIDE Respite Services furnished to Eligible Respite GUIDE Beneficiaries up to an annual cap of \$2,500 per Eligible Respite GUIDE Beneficiary (“**Respite Cap**”).
4. If the Participant provides GUIDE Respite Services by contracting with an entity, the Participant is solely responsible for paying the contracted entity in accordance with a Partner Organization Arrangement and must comply with the requirements set forth in Section 3.06.
5. CMS will provide the Participant a monthly Payment File showing the amount of GUIDE Respite Services that the Participant has billed for each Eligible Respite GUIDE Beneficiary in the year to-date.
6. If an Eligible GUIDE Respite Beneficiary is dually eligible for Medicare and Medicaid, the Participant is not permitted to bill CMS under the GUIDE Model and bill Medicaid for the same unit of respite furnished to the Eligible GUIDE Respite Beneficiary.

#### **B. Amount of Payment for GUIDE Respite Services.**

1. CMS will pay the Participant in accordance with the following GUIDE Respite Payment Base Payment Rates:

- i. \$120 for the in-home respite G-Code for a 4-hour unit of service;
  - ii. \$78 for the adult day center respite G-code for an 8-hour unit of service; and
  - iii. \$260 for the facility-based respite G-code for a 24-hour unit of service.
2. CMS will geographically adjust the GUIDE Respite Payment Base Payment Rates and the Respite Cap by the GAF.
3. CMS will annually update the GUIDE Respite Payment Base Payment Rates by the amount of the Home Health Agency market basket less the productivity adjustment calculated by the CMS Office of the Actuary.
4. CMS may adjust the GUIDE Respite Payment Base Payment Rates as outlined in Section 9.05(B)(1) upon advance notice to the Participant.
5. The GUIDE Respite Payment is not subject to beneficiary cost sharing.

C. Eligible Respite GUIDE Beneficiaries.

1. To be eligible to receive GUIDE Respite Services (“**Eligible Respite GUIDE Beneficiary**”), the GUIDE Beneficiary must:
  - i. Have a Caregiver; and
  - ii. Be assigned to either the moderate complexity dyad tier or the high complexity dyad tier as outlined in Appendix F, Table 1.

D. Requirements for Respite Providers to Provide GUIDE Respite Services.

1. The entity (whether the Participant or the contracted entity) that is furnishing GUIDE Respite Services must be one of the following at all times while providing GUIDE Respite Services during the Agreement Performance Period:
  - i. A Medicare-certified facility that can provide 24-hour care;
  - ii. A Medicare-certified provider that provides in-home respite services;
  - iii. A Medicaid-certified adult day center;
  - iv. A Medicaid-certified facility that can provide 24-hour care;
  - v. A Medicaid-certified provider that provides in-home respite services; or
  - vi. A company or organization licensed or certified in the state in which the company or organization is providing services, to provide one of the following services:
    - a. respite care,
    - b. home care,
    - c. residential services,
    - d. adult day services, or
    - e. residential facility or group home (not a private residence).
2. The Participant shall ensure that all direct care workers that provide in-home GUIDE

Respite Services meet the following requirements prior to providing in-home GUIDE Respite Services:

- i. Are at least 18-years-old;
  - ii. Pass either a criminal history background check completed by a private agency or a background check of the type that may be required by the state in which the direct care worker is providing services to be licensed or certified as a direct care worker;
  - iii. Are licensed or certified as a direct care worker in the state in which they are providing services if such licensure or certification is a requirement to work as a direct care worker in said state; and
  - iv. Meet the training requirements to be a direct care worker, if any, of the state in which they are providing services.
3. If CMS or the Participant determines that the Participant, or a contracted entity furnishing GUIDE Respite Services, does not comply with Section 9.05(D), the Participant, or the contracted entity furnishing GUIDE Respite Services, shall immediately stop providing GUIDE Respite Services to GUIDE Beneficiaries. The Participant shall notify CMS in writing within 15 Days that the Participant, or the contracted entity furnishing GUIDE Respite Services, does not comply with Section 9.05(D) and the date that the Participant or the contracted entity fell out of compliance with Section 9.05(D).
  4. CMS will not pay, and the Participant may not bill, for GUIDE Respite Services that do not comply with Section 9.05(D).
  5. CMS will recoup payments for GUIDE Respite Services already distributed to the Participant, dating back to the date, as specified by CMS, on which CMS determined the Participant failed to comply with the terms of Section 9.05(D).

### **Section 9.06 Infrastructure Payment**

A. The following provisions of this Section 9.06 apply if:

1. CMS informed the Participant prior to the Start Date that the Participant qualifies to receive an Infrastructure Payment, and
2. The Participant agrees to receive an Infrastructure Payment from CMS by the deadline specified by CMS.

B. Permitted Uses of the Infrastructure Payment.

1. The Participant shall use the Infrastructure Payment for only the following purposes related to developing a dementia care program that complies with the requirements of the Model:
  - i. Hiring or training of members of its interdisciplinary Care Team or administrative staff;
  - ii. Developing dementia care program workflows, protocols, community partnerships, and educational or outreach materials;
  - iii. Community outreach and engagement related to its dementia care program; and

- iv. Electronic health record technology adaptations.
2. The Participant is not permitted to use the Infrastructure Payment for any expenses other than the purposes described in Section 9.06(B)(1).

C. Spend Plan.

1. The Participant must submit to CMS a document describing the purpose(s) listed under Section 9.06(B)(1) on which the Participant will spend the Infrastructure Payment, the approximate dollar amounts to be spent on each purpose, and such other information as may be specified by CMS in its notification to the Participant that the Participant qualifies to receive an Infrastructure Payment (“**Spend Plan**”).
2. The Participant must submit the Spend Plan to CMS, in a form and manner specified by CMS, within 60 Days of the date of CMS’s notification to the Participant that the Participant qualifies to receive an Infrastructure Payment.
3. CMS shall use reasonable efforts to approve or reject the Spend Plan, and communicate this decision to the Participant, within 45 Days of the date that the Participant submits the Spend Plan to CMS.
  - i. If CMS approves the Spend Plan, CMS will provide written notification to the Participant stating that CMS approves the Spend Plan and CMS will pay the Infrastructure Payment to the Participant via Electronic Funds Transfer before the end of the fourth quarter of calendar year 2024.
  - ii. If CMS rejects the Spend Plan because CMS determines that the Participant’s Spend Plan is inconsistent with the terms of the Agreement and/or likely to result in program integrity concerns:
    - a. CMS may require the Participant to revise and resubmit the Spend Plan in a manner and by the date(s) specified by CMS, and
    - b. CMS will not distribute the Infrastructure Payment to the Participant.

D. Spend Report.

1. The Participant must submit to CMS information on the Participant’s spending of the Infrastructure Payment, on an annual basis, in a form, manner and by a date specified by CMS (“**Spend Report**”).
2. The Spend Report shall include the following information:
  - i. How the Infrastructure Payment was spent,
  - ii. Any amounts of the Infrastructure Payment that remain unspent, and
  - iii. Such other information as may be requested by CMS.
3. CMS shall use reasonable efforts to approve or reject the Spend Report, and communicate this decision to the Participant, within 60 Days of the date that the Participant submits the Spend Report to CMS.
  - i. If CMS approves the Spend Report, CMS will provide written notification to the Participant stating that CMS approves the Spend Report.

- ii. If CMS rejects the Spend Report because CMS determines that the Participant's Spend Report is inconsistent with the terms of the Agreement and/or likely to result in program integrity concerns:
  - a. CMS may require the Participant to revise and resubmit the Spend Report in a manner and by the date(s) specified by CMS,
  - b. CMS may require the Participant to repay some or all of the Infrastructure Payment it received from CMS, and
  - c. The Participant shall not spend any remaining funds from the Infrastructure Payment until CMS approves a revised Spend Report.
- 4. This Section 9.06(D) does not preclude CMS from taking any remedial actions pursuant to Article 16 even after CMS approves a Spend Report.

**E. Repayment of Infrastructure Payment.**

- 1. The Participant shall repay to CMS a portion of, or the entire, Infrastructure Payment, whichever is specified by CMS, if the Participant uses the Infrastructure Payment for a purpose other than those purposes specified in Section 9.06(B)(1).
  - 2. The Participant must repay to CMS any portion of the Infrastructure Payment that remains unspent at the end of Performance Year 2025.
  - 3. If CMS terminates the Agreement or Agreement Performance Period pursuant to Section 16.03, or the Participant terminates the Agreement Performance Period pursuant to Section 16.04, before the start of Performance Year 2025, CMS may require the Participant to repay the entire Infrastructure Payment.
  - 4. If CMS terminates the Agreement or Agreement Performance Period pursuant to Section 16.03, or the Participant terminates the Agreement Performance Period pursuant to Section 16.04, during Performance Year 2025, CMS may require the Participant to repay half of the Infrastructure Payment.
  - 5. If CMS terminates the Agreement or Agreement Performance Period pursuant to Section 16.03, or the Participant terminates the Agreement Performance Period pursuant to Section 16.04, after the end of the second Performance Year, CMS will not require the Participant to repay the Infrastructure Payment.
- F. If the Participant receives the Infrastructure Payment, the Participant shall maintain, in accordance with Section 15.02 records regarding the Infrastructure Payment, including the Spend Report and all expenditures of the Infrastructure Payment.

**Section 9.07 Medicare Payment and CMS Monitoring**

CMS shall regularly monitor Medicare claims data, Beneficiary reported data, and any other available data to ensure that the Participant is treating Beneficiaries in an equitable manner and has not taken any action that threatens the health or safety of a Beneficiary or other patient.

**Section 9.08 Reconciliation and Settlement**

**A. Periodic DCMP Adjustments.**

- 1. If CMS determines that the amount of a DCMP made to the Participant by CMS during



that Performance Year has been calculated in error, CMS shall calculate the difference between the amount of the DCMP that was paid to the Participant in error and the amount of the DCMP that should have been paid to the Participant.

2. CMS will adjust the amount of a subsequent DCMP made by CMS to the Participant by the amount of the difference (“**DCMP Adjustment**”).
  - i. If the amount of the DCMP made to the Participant exceeds the correct DCMP amount as calculated by CMS, CMS shall make a DCMP Adjustment by subtracting the excess amount from a subsequent DCMP amount in the manner described in the GUIDE Payment Methodology Paper.
  - ii. If the amount of the DCMP made to the Participant is less than the correct DCMP amount as calculated by CMS, CMS will make a GUIDE Payment Adjustment by increasing the DCMP to the Participant during a subsequent month in the amount of the payment deficiency in the manner described in the GUIDE Payment Methodology Paper.

B. If the Participant is no longer receiving GUIDE Payments due to CMS terminating the Agreement or Agreement Performance Period pursuant to Section 16.03, the Participant terminating the Agreement Performance Period pursuant to Section 16.04, or because the Agreement Performance Period has ended, CMS shall collect from the Participant any amount owed to CMS.

C. Payments of Amounts Owed.

1. Upon expiration or termination of this Agreement, CMS will issue to the Participant a financial settlement report setting forth the type and amount of any GUIDE Payments that the Participant must repay to CMS, or that CMS must make to the Participant, in accordance with this Agreement (“**Final Financial Settlement Report**”).
2. If the Final Financial Settlement Report indicates that CMS owes the Participant additional payment, CMS will make such payment within 30 Days after the Final Financial Settlement Report is deemed final in accordance with Section 9.08(D).
3. If the Final Financial Settlement Report indicates that the Participant owes CMS repayment, CMS will issue the Participant a demand letter for any amounts determined to be owed to CMS. The Participant must pay CMS any final monies owed within 30 Days of the date of the demand letter. If CMS does not receive payment timely and in full, the remaining monies owed shall be considered a delinquent debt in accordance with Section 9.08(F).

D. Error Notice.

1. CMS shall deem any settlement report, including the Final Financial Settlement Report, final 30 Days after the date CMS issues the report to the Participant, unless the Participant submits to CMS written notice of an error in the mathematical calculations in the settlement report within 30 Days after CMS issues it to the Participant (“**Timely Error Notice**”).
2. Upon receipt of a Timely Error Notice, CMS shall review the calculations in question and any mathematical issues raised by the Participant in its written notice.

3. CMS shall issue to the Participant either a written determination that the settlement report is correct, or a revised settlement report. Such written determination that the settlement report is correct, or revised settlement report, is deemed final on the date it is issued by CMS.
4. Except as provided for in Section 9.08(E), there shall be no further administrative or judicial review of the settlement report, written determination, or revised settlement report.

E. Settlement Reopening.

1. If as a result of any inspection, evaluation, investigation, or audit conducted by CMS or HHS, it is determined that the amount due to the Participant from CMS or due to CMS from the Participant has been calculated in error, CMS may, for a period of six years following the expiration or termination of this Agreement, reopen any settlement report or revised settlement report to recalculate the monies owed, issue a revised settlement report, and make or demand payment of any monies owed to or by the Participant.
2. CMS may reopen and revise a settlement report at any time in the event of fraud or similar fault.
3. The parties shall pay any amounts determined to be owed as a result of a reopening under this Section 9.08(E).

F. Delinquent Debt.

1. If the Participant fails to pay amounts due to CMS in full and by the date specified in any demand letter, CMS will assess simple interest on the unpaid balance at the rate applicable to other Medicare debts under 42 C.F.R. § 405.378. Interest will be calculated in 30-day periods and will be assessed for each 30-day period that payment is not made in full.
2. If the Participant fails to pay amounts due to CMS in full and by the date specified in any demand letter, CMS shall recoup the unpaid balance from the Participant's present and future Medicare payments otherwise owed to the Participant in accordance with standard Medicare recoupment procedures and regulations. If CMS is unable to recoup the full amount via Medicare payments, CMS may use any applicable debt collection tools available and invoke all legal means necessary to collect the debt, including referral of the remaining monies owed to the U.S. Department of the Treasury.

**Section 9.09 Overlap with Other CMS Programs and Initiatives**

A. Participation in other Innovation Center Models.

1. The Participant may simultaneously participate in, and its GUIDE Beneficiaries may simultaneously be attributed to participants in, the Innovation Center models listed below, including, but not limited to:
  - i. Enhancing Oncology Model, ACO Realizing Equity, Access, and Community Health (ACO REACH) Model, Bundled Payments for Care Improvement (BPCI) Advanced Model, Comprehensive Care for Joint Replacement Model, ESRD Treatment Choices (ETC) Model, Making Care Primary (MCP), Comprehensive Kidney Care Choices Model, Maryland Total Cost of Care Model, Primary Care

First (PCF), and Vermont All Payer Model.

2. Payment.

- i. The Participant will be eligible for full GUIDE Payments only if the express purposes of the GUIDE Payments are not duplicative of other payments made in other Innovation Center models.
- ii. If the Participant is simultaneously participating in another Innovation Center Model(s), CMS may recoup, in full or in part, any DCMPs which were made to the Participant and deemed duplicative in purpose to other payments made in the other Innovation Center model(s) by CMS.

B. Participation in the Medicare Shared Savings Program (SSP).

1. The Participant may simultaneously participate as an ACO Participant in an ACO participating under any track in the SSP.
2. The Participant acknowledges that any beneficiary-identifiable GUIDE Payments to the Participant for GUIDE Beneficiaries who are also assigned under the SSP to the ACO in which the Participant is an ACO Participant may be treated as expenditures for purposes of financial calculations under the SSP.

C. CMS will publish, in a form and manner to be specified by CMS, a list in which CMS will specify the Innovation Center models, programs, initiatives, and demonstrations in which the Participant may simultaneously participate during the Agreement Performance Period. CMS may update the list unilaterally and without the consent of the Participant.

## **Article 10. CMS Data Sharing and Reports**

### **Section 10.01 General**

- A. Subject to the limitations discussed in this Agreement, and in accordance with applicable law, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the regulations in 42 C.F.R. Part 2, in advance of the Start Date, during the Agreement Performance Period, and any other time deemed necessary by CMS, CMS will offer the Participant an opportunity to request certain beneficiary-identifiable data and reports using the HIPAA – Covered Data Disclosure Request and Attestation Form (“DRA”) which CMS will provide and maintain throughout the term of this Agreement.
- B. CMS describes the Beneficiary-identifiable data available for request in Section 10.03 and in the DRA. CMS will not transmit any Beneficiary-identifiable data to the Participant before the Participant executes the DRA.
- C. The Participant shall update its DRA if the assertions therein become inaccurate over the course of the Agreement Performance Period through changes to the Participant’s information, data needs, or otherwise.
- D. To ensure periodic confirmation of continued accuracy, CMS will require the Participant to review and attest to the accuracy of the assertions in the Participant’s current DRA, at least annually, in a form and manner specified by CMS. On an annual basis, the Participant shall attest to the continued accuracy of the DRA, or submit a new or updated DRA, as applicable, as a condition of the Participant’s continued receipt of the data specified on the DRA.

- E. CMS will not include any Beneficiary-identifiable claims data regarding utilization of substance use disorder services in the data and reports CMS provides to the Participant.
- F. CMS will omit individually identifiable data for GUIDE Beneficiaries who have opted out of data sharing with the Participant, as described in Section 10.04, from the claims data described in Section 10.03.
- G. CMS may share practitioner-level and Participant-level data that identifies the Participant's performance with other GUIDE Model Participants for the purpose of improving other GUIDE Model Participants' quality outcomes and healthcare operations. This may include information gathered through Participant Reporting, quality scores, utilization scores, or other relevant data. Such data will not include individually identifiable health information, in accordance with the Model's policies and the HIPAA Privacy and Security Rule requirements, including those in 45 C.F.R. § 164.514(b), and will incorporate de-identified data from GUIDE Beneficiaries who have opted out of data sharing in accordance with Section 10.04.
- H. CMS may publish, on the CMS website, practitioner-level and Participant-level data that identifies the Participant's performance. This may include information gathered through Participant Reporting, quality scores, utilization scores, or other relevant data. Such data will not include individually identifiable health information, in accordance with the Model's policies and the HIPAA Privacy and Security Rule requirements, including those in 45 C.F.R. § 164.514(b), and will incorporate de-identified data from GUIDE Beneficiaries who have opted out of data sharing in accordance with Section 10.04.
- I. CMS may share practitioner-level data with each GUIDE Practitioner listed on the GUIDE Practitioner Roster that identifies the GUIDE Practitioner's performance, for the purposes of quality improvement, care coordination, and healthcare operations. This may include information gathered through Participant Reporting, quality scores, utilization scores, or other relevant data. Such data will not include individually identifiable health information, in accordance with this model's policies and the HIPAA Privacy and Security Rule requirements, including those in 45 C.F.R. § 164.514(b), and will incorporate de-identified data from GUIDE Beneficiaries who have opted out of data sharing in accordance with Section 10.04.

### **Section 10.02 De-Identified, Aggregated Data**

- A. CMS shall share the following types of de-identified, aggregated data with the Participant via the Data Dashboard:
  1. On a quarterly basis, CMS shall provide aggregated sociodemographic data, de-identified in accordance with the HIPAA requirements in 45 C.F.R. § 164.514(b), that describe the sociodemographic data submitted by the Participant to CMS.
  2. On an annual basis, CMS shall provide aggregated, quality data, de-identified in accordance with the HIPAA requirements in 45 C.F.R. § 164.514(b), that describe the quality data submitted by the Participant to CMS for the following measures: Use of High-Risk Medications in Older Adults (MIPS #238, NQF #0022) and Quality of Life Outcome for People with Neurological Conditions (MIPS #AAN22).
- B. The Data Dashboard will also show the Participant how it compares to other GUIDE Model Participants on important quality and utilization outcomes.

### **Section 10.03 Provision of Certain Beneficiary-Identifiable Data**

- A. Subject to the limitations discussed in this Agreement and in accordance with applicable law, including HIPAA, the Participant may request data from CMS. When such requests are for data and/or reports that contain individually identifiable health information, such requests will need to be made in writing, accompanied by certain attestations that document the legal disclosure basis/bases for the desired data/report, including for use in the HIPAA covered entity or business associate of a HIPAA covered entity's care coordination and quality improvement work (as described in the first and second paragraphs of the definition of "health care operations" under the HIPAA Privacy Rule at 45 C.F.R. 164.501).
- B. The Participant may request specific Beneficiary-identifiable data by completing the DRA form. All requests for Beneficiary-identifiable data shall be granted or denied at CMS' sole discretion based on CMS' available resources, the limitations in this Agreement, and applicable law.
- C. In offering the Participant an opportunity to request Beneficiary-identifiable data, CMS does not represent that the Participant or any GUIDE Practitioner has met all applicable HIPAA requirements for requesting data under 45 C.F.R. § 164.506(c)(4). The Participant and its GUIDE Practitioner(s), if applicable, should consult with its own legal counsel to make those determinations, prior to requesting any data from CMS.
- D. The Beneficiary-identifiable data available for request by completing the DRA form includes the following data and reports:
1. Beneficiary Alignment files: On a monthly basis, CMS shall provide to the Participant a list of the GUIDE Beneficiaries that are aligned to the Participant, each GUIDE Beneficiary's model tier assignment, the length of the GUIDE Beneficiary's alignment to the Participant, and other beneficiary-level data, such as GUIDE Beneficiary's Medicare Beneficiary Identifier, first name, last name, date of birth, and gender ("**Beneficiary Alignment File**").
  2. Payment files: On a monthly basis, CMS shall provide to the Participant a payment file. The payment file will include data on GUIDE Payment amounts for each GUIDE Beneficiary and aggregated across the Participant's total aligned beneficiary population ("**Payment Files**"). Such Payment Files will include the GUIDE Beneficiary's Medicare Beneficiary Identifier, first name, last name, date of birth, claim control number, service dates, performing NPI, TIN, claim line number, payment amount and the reason for any recoupment.
  3. Eligible Beneficiary List: Prior to the Participant's first Performance Year, the Participant may request a list that identifies any Eligible Beneficiaries ("**Eligible Beneficiary List**") who:
    - i. Have both a claims-based ICD-10 dementia diagnosis code as listed in Appendix F, Table 3 and have received Medicare services from the Participant, in the three-year historical look-back period beginning January 2021 and ending December 2023 if the Participant is in the Established Program Track and beginning January 2022 and ending December 2024 if the Participant is in the New Program Track;
    - ii. Are not voluntarily aligned to a GUIDE Model Participant for purposes of the GUIDE Model at the time CMS generates the list; and

- iii. Meet the eligibility requirements outlined in Section 5.01(A).
4. If CMS receives, in a form and manner specified by CMS, a properly executed DRA form from the Participant requesting an Eligible Beneficiary List, CMS will provide the Participant an Eligible Beneficiary List within 30 Days prior to the Start Date.
5. On a quarterly basis, CMS shall provide aggregated, quality data that describe the quality data calculated by CMS for the following measures: Total Per Capita Cost (TPCC) (NQF #3575) and LTNH measure.
6. Line-Level Beneficiary-Identifiable Claims Data: As specified in the DRA, these files will include:
  - i. Historical period and monthly Parts A, B, and D raw claims data files for GUIDE Beneficiaries that were voluntarily aligned to the Participant within all of the following data element categories: inpatient; outpatient carrier/Part B; physician; home health; skilled nursing facility; durable medical equipment; prescription drug event; and hospice records and data fields.
  - ii. Quarterly Parts A, B, and D raw claims data files that underlie the Feedback Reports and Dashboards. This data includes the underlying line-level Beneficiary-identifiable claims data used for the regular feedback reports and dashboards and the quarterly feedback reports and dashboards for GUIDE Beneficiaries.
- E. The aggregated data described in Section 10.03(D) shall incorporate de-identified data regarding GUIDE Beneficiaries who have opted out of data sharing. While aggregated, the data described in Section 10.03(D) may be identifiable due to the inclusion of cells that represent 10 or fewer GUIDE Beneficiaries; when this is the case, the data is subject to all requirements for Beneficiary-identifiable data under this Agreement and applicable law.
- F. The parties mutually agree that, except for data covered by Section 10.03(O) below, CMS retains all ownership rights to the data sources specified in Section 10.03(D) and requested via the DRA, and the Participant does not obtain any right, title, or interest in any of the data furnished by CMS.
- G. The Participant represents, and in furnishing the data files specified in Section 10.03(D) and requested via DRA form, CMS relies upon such representation, that such data files shall be used solely for care management, care coordination, quality improvement activities, and population-based activities relating to improving health or reducing health care costs for Eligible Beneficiaries and GUIDE Beneficiaries, and such other purposes described in this Agreement. The Participant 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 Participant further agrees not to sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement.
- H. Information derived from the CMS data specified in Section 10.03(D) and requested via the DRA form may be shared and used within the legal confines of the Participant and its GUIDE Practitioners and Partner Organizations in a manner consistent with Section 10.03(I) to enable the Participant to improve care integration and be a beneficiary-centered organization.
- I. The Participant may reuse original or derivative data without prior written authorization from CMS for clinical treatment, care management and coordination, quality improvement

activities, population-based activities relating to improving health or reducing health care costs, and healthcare provider incentive design and implementation, but shall not disseminate (unless required by law) any individually identifiable original or derived information from the data specified in Section 10.03(D) and requested via the DRA form to anyone who is not a HIPAA CE, a HIPAA BA, a GUIDE Practitioner or Partner Organization in a treatment relationship with the subject Eligible Beneficiary or GUIDE Beneficiary, or those GUIDE Practitioner's or Partner Organization's business associates. When using or disclosing PHI or personally identifiable information ("PII"), obtained from data specified in Section 10.03(D) and requested via the DRA form, the Participant must make "reasonable efforts to limit" the information to the "minimum necessary" to accomplish the intended purpose of the use, disclosure or request. The Participant shall further limit its disclosure of such information to the types of disclosures that CMS itself would be permitted to make under the "routine uses" in the applicable systems of records listed in the DRA form.

- J. Subject to the limits specified above and elsewhere in this Agreement and applicable law, the Participant may link individually identifiable data specified in Section 10.03(D) and requested via the DRA form (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 Participant and its GUIDE Practitioners or Partner Organizations. The Participant 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 C.F.R. § 164.514(b).
- K. The Participant 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://obamawhitehouse.archives.gov/sites/default/files/omb/assets/OMB/circulars/a130/a130\\_revised.pdf](https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/OMB/circulars/a130/a130_revised.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 Participant acknowledges that the use of unsecured telecommunications, including the Internet, to transmit directly or indirectly identifiable information from the files specified in Section 10.03(D) and requested via the DRA or any such derivative data files is strictly prohibited. Further, the Participant agrees that the data specified in Section 10.03(D) and requested via the DRA form must not be physically moved, transmitted or disclosed in any way from or by the site of the custodian or, if applicable, alternate data custodian indicated in the DRA form other than as provided in this Agreement without written approval from CMS, unless such movement, transmission or disclosure is required by a law.
- L. The Participant 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), including at the site of the custodian indicated in the DRA form, for the purpose of inspecting to confirm compliance with the terms of this Agreement.

- M. The Participant agrees that any use of CMS data in the creation of any document concerning the purpose specified in this section and the DRA form must adhere to CMS' current cell size suppression policy. The policy stipulates that no cell (e.g., admittances, discharges, patients, services) representing 10 or fewer GUIDE Beneficiaries may be displayed. Also, no percentages or other mathematical formulas may be used if they result in the display of a cell representing 10 or fewer GUIDE Beneficiaries. A cell that represents or uses percentages or other mathematical formulas to represent zero GUIDE Beneficiaries may be displayed.
- N. The Participant shall report within one hour following discovery of 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) 786-2580 or by email notification at [cms\\_it\\_service\\_desk@cms.hhs.gov](mailto:cms_it_service_desk@cms.hhs.gov). Furthermore, the Participant shall cooperate fully in any federal incident security process that results from such improper use or disclosure.
- O. The parties mutually agree that the individual named in the DRA form as the Participant's data custodian is designated as custodian of the CMS data files on behalf of the Participant and shall 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 data 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. In the event the data custodian named in the DRA form is unable to perform these functions for any reason, and the Participant has named an alternate data custodian in the DRA form, the parties mutually agree that the individual named in the DRA form as the alternate data custodian is designated as custodian of the CMS data files on behalf of the Participant and shall be responsible for performing these functions. The Participant shall ensure that any individual named in the DRA form as data custodian or alternate data custodian is either an employee of the Participant or an employee of a BA of the Participant that requires access to the requested data for the purposes for which the data is requested. The Participant shall notify CMS within 15 Days of any change of data custodian or alternate data custodian. The parties mutually agree that CMS may disapprove the appointment of a data custodian or may require the appointment of a new data custodian at any time.
- P. Data disclosed to the Participant pursuant to the DRA form may be retained by the Participant until 30 Days after the completion of the final settlement for the Agreement Performance Period, except as CMS shall authorize in writing or as otherwise required by law. The Participant is permitted to retain any individually identifiable health information from such data sources or derivative data after the expiration or termination of the Agreement if the Participant is a HIPAA CE, and the data has been incorporated into the subject GUIDE Beneficiaries' medical records that are part of a designated record set under HIPAA. Furthermore, any HIPAA CE to whom the Participant 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 GUIDE Beneficiaries' medical records that are part of a designated record set under HIPAA. The Participant shall destroy all other data and send written certification of the destruction of the data sources and/or any derivative data to CMS within 30 Days of completion of the final settlement for the Agreement Performance Period, except as CMS shall authorize in writing or as otherwise required by law. If the Participant terminates the Agreement Performance Period as specified by Section 16.04, the Participant shall destroy all other data and send written certification of the destruction of the



data sources and/or any derivative data to CMS within 30 Days of completion of Reconciliation following the effective date of termination. If the Participant terminates the Agreement Performance Period as specified by Section 16.04 with an effective date that is prior to the Start Date, the Participant shall destroy all data disclosed to the Participant pursuant to the DRA form, including any data that has been incorporated into the subject GUIDE Beneficiaries' medical records that are part of a designated record set under HIPAA, and send written certification of the destruction of the data sources and/or any derivative data to CMS within 30 Days of the effective date of termination. CMS may require the Participant to destroy all data and send written certification of the destruction of data files and/or any derivative data files to CMS at any time if CMS determines it necessary due to a program integrity concern. Except for disclosures for treatment purposes, the Participant 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 provision. These retention provisions survive the expiration or termination of the Agreement.

#### **Section 10.04 Beneficiary Rights to Opt Out of Data Sharing**

- A. The Participant shall provide GUIDE 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. The Participant shall direct GUIDE Beneficiaries to call 1-800-MEDICARE in order to modify their preferences regarding claims data sharing.
  1. The Participant shall further inform the GUIDE Beneficiary that even if a GUIDE Beneficiary has elected to decline claims data sharing, CMS may still engage in certain limited data sharing for care coordination and quality improvement activities for GUIDE Beneficiaries, and population-based activities relating to improving health or reducing health care costs.
  2. The Participant shall allow GUIDE Beneficiaries to reverse a claims data sharing preference at any time by calling 1-800-MEDICARE.
- B. The Participant shall provide GUIDE Beneficiaries who inquire about or wish to modify their preferences regarding sociodemographic data and/or health-related social needs (HRSN) data sharing for care coordination and quality improvement purposes with information about how to modify their data sharing preferences.
  1. The Participant shall allow GUIDE Beneficiaries to reverse a sociodemographic data and/or HRSN data sharing preference at any time by notifying the Participant or a GUIDE Practitioner.
  2. The Participant must report to CMS via Salesforce all GUIDE Beneficiaries who have opted out of sociodemographic data and/or HRSN data sharing by the date(s) specified by CMS.
- C. CMS shall maintain the data sharing preferences of GUIDE Beneficiaries who elect to decline claims, sociodemographic, and/or HRSN data sharing in the Model.
- D. The Participant may affirmatively contact a GUIDE Beneficiary who has declined claims data sharing or sociodemographic data sharing or HRSN data sharing no more than one time in a given Performance Year to provide information regarding data sharing. Such contact includes mailings, phone calls, electronic communications, or other methods of communicating with

GUIDE Beneficiaries outside of a clinical setting.

## **Article 11. Participant Reporting and Certification Requirements**

### **Section 11.01 Reporting Requirements**

- A. Pursuant to 42 C.F.R. § 403.1110(b), the Participant shall collect and report data described in this Section 11.01 to CMS for the Model's monitoring and evaluation purposes.
- B. The Participant shall complete all reporting required under this Agreement.
- C. Prior to each Performance Year, CMS will issue a list of data that the Participant must report to CMS and the specific dates by which the Participant must do so. The Participant shall submit the following reports in accordance with this Article 11 and the relevant Article or Section of each report.
  - 1. Beneficiary and Caregiver Assessment Data (Article 5)
  - 2. Sociodemographic Data (Article 12)
  - 3. Health-related Social Needs Data (Article 12)
  - 4. Data from Comprehensive Assessments (Article 12)
  - 5. Care Delivery Reporting (Article 6)
  - 6. Quality Data (Article 8)
- D. CMS may unilaterally amend reporting requirements or deadlines in accordance with this Agreement and shall issue any changes in writing no less than 30 Days in advance.
- E. The Participant may request a reporting deadline extension in a form, manner, and by a date specified by CMS. CMS reserves the right to reject an extension request for any reason.
- F. If CMS terminates this Agreement or Agreement Performance Period pursuant to Section 16.03, the Participant shall complete all reporting requirements and meet all reporting deadlines for the entire duration of the quarter in which this Agreement or Agreement Performance Period is terminated, even if such quarter ends after the effective date of termination. The Participant is not required to comply with reporting requirements beginning the quarter following the quarter that includes the effective date of termination, notwithstanding Section 16.03.
- G. The rights and obligations under this Section shall survive expiration of this Agreement and shall apply until all reporting requirements in accordance with this Article 11 and all Articles cited therein are complete.

### **Section 11.02 Certification of Data and Information**

The Participant shall certify that all data reported by the Participant as required in accordance with Section 11.01 with respect to that Performance Year is accurate, complete, and truthful to the best of the Participant's knowledge. The Participant shall certify that any GUIDE Practitioners, Partner Organizations, and any individuals or entities otherwise contracted to perform functions or services related to Participant Activities or furnish services to GUIDE Beneficiaries are in compliance with the terms of this Agreement. This certification shall be performed and documented in a form and manner to be determined by CMS.

## **Article 12. Participation in Evaluation, Learning Activities, and Site Visits**

### **Section 12.01 Participation in Evaluation**

#### **A. General.**

1. The Participant shall participate in and cooperate with any independent evaluation activities conducted by or on behalf of CMS aimed at assessing the impact of the Model on the goals improving quality of care and reducing expenditures for Eligible Beneficiaries.
2. The Participant shall ensure that its GUIDE Practitioners and its Partner Organizations participate and cooperate in any such independent evaluation activities conducted by or on behalf of CMS. Termination or expiration of the Agreement shall not affect the right of CMS to evaluate the Model.
3. The Participant shall ensure that it has written agreements or legal relationships with any individuals and entities performing functions and services related to GUIDE Care Delivery Services that are necessary to ensure that 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 with the Participant;
2. Interviews with GUIDE Beneficiaries and their Caregivers;
3. Focus groups of GUIDE Beneficiaries and their Caregivers;
4. Interviews with the Participant, its GUIDE Practitioners, and its Partner Organizations, if applicable;
5. Focus groups with the Participant, its GUIDE Practitioners, and its Partner Organizations;
6. Direct observation of GUIDE Beneficiary interactions with the GUIDE Practitioners and Partner Organizations and their staff, care management meetings among GUIDE Practitioners and Partner Organizations and their staff, and other activities related to the Participant's participation in the Model; and
7. Surveys.

#### **C. Secondary Data. In its evaluation activities, CMS may use data or information submitted by the Participant as well as claims submitted to CMS for items and services furnished to GUIDE Beneficiaries. These data may include, but are not limited to:**

1. Claims data;
2. Survey data from patient surveys;
3. Medical records; and
4. Quality data submitted on the HDR.

#### **D. Sociodemographic Data. Pursuant to 42 C.F.R. § 403.1110, CMS will use sociodemographic**

data submitted by the Participant for the purpose of monitoring and evaluating the Model.

1. The Participant shall collect Beneficiary-level sociodemographic data, including but not limited to race, ethnicity, preferred language, sex (assigned at birth), and disability status from GUIDE Beneficiaries that have not opted out of sharing such data pursuant to Section 10.04.
2. The Participant shall report the sociodemographic data through the HDR by the date(s) specified by CMS.

E. Health-Related Social Needs Data. Pursuant to 42 C.F.R. § 403.1110, CMS will use HRSN data submitted by the Participant for the purpose of monitoring and evaluating the Model.

1. The Participant shall collect HRSN data and annually report HRSN data that is aggregated across GUIDE Beneficiaries on the following domains: food insecurity, housing instability, transportation needs, social isolation, and safety.
2. The Participant shall report the HRSN data through annual Care Delivery Reporting by the date(s) specified by CMS.
3. The Participant may use the Accountable Health Communities (AHC) HRSN Screening tool, the Protocol for Responding to and Assessing Patient's Assets, Risks, and Experiences (PRAPARE®) tool, or a different HRSN screening tool to collect HRSN data, as long as the screening tool assesses the domains listed in Section 12.01(E)(1).

F. Data from the Comprehensive Assessments. Pursuant to 42 C.F.R. § 403.1110, CMS will use data from comprehensive assessments submitted by the Participant for the purpose of monitoring and evaluating the Model.

1. The Participant shall complete the Patient-Reported Outcomes Measurement Information System (PROMIS) Scale v1.2 – Global Health during the initial Comprehensive Assessment and submit the full questionnaire with individual responses to CMS in a manner and by the date(s) specified by CMS.
2. The Participant shall complete the Zarit Burden Interview, if applicable, during the initial and annual Comprehensive Assessments and submit the full questionnaire with individual responses to CMS in a manner and by the date(s) specified by CMS.

G. Reporting Requirements. CMS may add or modify evaluation-related reporting requirements during the Agreement Term. CMS will notify the Participant of any additions or modifications at least 30 Days prior to the start of the Performance Year in which such change would take effect.

### **Section 12.02 Participation in Learning Activities**

- A. The Participant shall participate in CMS-sponsored learning activities designed to drive improvement and foster innovations in care delivery through sharing best practices or new knowledge that emerges from participation in the Model.
- B. The Participant shall actively engage in a variety of learning events, learning communities, and sharing promising tools and ideas, as well as its lessons learned.
- C. The Participant shall participate in periodic assessments administered by the CMS GUIDE learning contractors. To the extent practicable, CMS will provide the Participant with at least

10 Days' advance notice of the distribution of any such assessments and shall affirmatively work to minimize any associated reporting burden.

- D. The Participant must designate at least one staff member to serve as point of contact to receive newsletters and communications from CMS related to the Model. The Participant shall identify this individual to CMS in a form and manner to be determined by CMS.

### **Section 12.03 Participation in Site Visits**

- A. The Participant shall cooperate and require its GUIDE Practitioners and Partner Organizations to cooperate in any site visits conducted by or on behalf of CMS.
- B. CMS or its designee(s) shall, to the extent practicable, schedule any site visits to the Participant, its GUIDE Practitioners, and Partner Organizations no fewer than 15 Days in advance. To the extent practicable, CMS shall attempt to accommodate the Participant's request for particular dates in scheduling site visits. However, the Participant may not request a date that is more than 60 Days after the date of the initial site visit notice from CMS.
- C. The Participant 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 or its designee(s) may perform unannounced site visits at any of the Participant's office locations 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 12.04 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 participants and to the public. Data to be disseminated may include results of beneficiary experience of care and quality of life surveys as well as measures based upon claims and other data sources. The Participant shall be permitted to comment on evaluation reports when the Participant has been specifically cited to ensure factual accuracy but may not edit conclusions or control the dissemination of reports.
- B. Notwithstanding any other provision in the Agreement, all proprietary trade secret information and technology of the Participant is and shall remain the sole property of the Participant, and, except as required by federal law, shall not be released by CMS without express written consent. The regulation at 48 C.F.R. § 52.227-14, "Rights in Data-General" is hereby incorporated by reference into the Agreement. CMS does not acquire by license or otherwise, whether express or implied, any intellectual property right or other rights to the Participant's proprietary information or technology.
- C. If the Participant maintains any information that should not be publicly disclosed because the Participant considers such information to be proprietary and confidential, the Participant acknowledges that it may submit to CMS a form, which will be provided by CMS, with specific examples of information the Participant considers to be proprietary and confidential. The Participant must notify CMS, in a form and manner to be specified by CMS, of any updates to this form. If the Participant does not submit such a form, the Participant shall be deemed to have confirmed that it has no information it considers proprietary and confidential.

## **Section 12.05 Participant Public Release of Information**

- A. Notwithstanding any other provision in the Agreement, the Participant, its GUIDE Practitioners, and its Partner Organizations shall obtain prior approval from CMS during the Agreement Term and for 6 months thereafter for the publication or release of any press release, external report or statistical/analytical material that materially and substantially references the Participant'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 12.05 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 13. Beneficiary Outreach, Engagement, and Protections**

### **Section 13.01 Beneficiary Outreach**

#### **A. Beneficiary Outreach Letters.**

1. The Participant shall provide to CMS and maintain, in a form and manner specified by CMS, a list of zip-codes for the areas that the Participant is willing to provide services to Eligible Beneficiaries ("**Zip-Code Based Service Area**").
2. CMS will use claims data to identify Eligible Beneficiaries who:
  - i. Currently live in the Participant's Zip-Code Based Service Area,
  - ii. Have a claims-based ICD-10 dementia diagnosis code as listed in Appendix F, Table 3 in a three-year historical look-back period that falls within the five years prior to the date that CMS mails the letters,
  - iii. Is not voluntarily aligned to a GUIDE Model Participant to receive services through the GUIDE Model, and
  - iv. Meets the eligibility requirements outlined in Section 5.01(A).
3. CMS will mail Beneficiary Outreach Letters to each Eligible Beneficiary described in Section 13.01(A)(2) on an annual basis starting in Performance Year 2024 through Performance Year 2030.
4. CMS may send additional Beneficiary Outreach Letters in future Performance Years.

#### **B. Participant Engagement with Beneficiaries.**

1. Subject to the prohibitions in Section 13.03, during the first Performance Year of the Model Performance Period, the Participant shall offer to all Eligible Beneficiaries to whom the Participant currently provides dementia care services the opportunity to voluntarily align to the Participant.
2. The Participant shall not discriminate or deny an Eligible Beneficiary the opportunity to voluntarily align to the Participant based on the Eligible Beneficiary's 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, or income.

3. The Participant may deny an Eligible Beneficiary the opportunity to voluntarily align to the Participant if the Eligible Beneficiary resides in a location that is outside of the Participant's Zip-Code Based Service Area.
4. The Participant shall notify CMS in a form and manner and by a date specified by CMS if the Participant is not able to accept new Eligible Beneficiaries into its dementia care program due to reaching capacity in the number of GUIDE Beneficiaries that the Participant is able to provide services.
5. The Participant shall accurately and timely respond to questions from Eligible Beneficiaries regarding Voluntary Alignment.

### **Section 13.02 Health Equity Plan**

- A. The Participant must report to CMS a plan to develop and implement strategies for outreach and engagement of Eligible Beneficiaries from historically underserved communities to the Model ("**Baseline Health Equity Plan**") by answering questions outlined in a section of the baseline Care Delivery Reporting and by the deadline specified in Section 6.04(D)(2).
- B. The Participant must report to CMS on an annual basis a plan ("**Health Equity Plan**") that:
  1. Identifies and addresses health disparities observed in its GUIDE Beneficiaries;
  2. Implements initiatives to measure and reduce these health disparities over the course of the Model;
  3. Identifies and selects evidence-based interventions for addressing health disparities and achieving equitable outcomes; and
  4. Describes how the Participant is setting goals and monitoring progress of goals and recruitment over time.
- C. The Participant must complete the Health Equity Plan by answering questions outlined in a section of the Care Delivery Reporting and by the deadline specified in Section 6.04(D)(2).
- D. CMS will review the Baseline Health Equity Plan and annual Health Equity Plans for compliance with Sections 13.02(A)-(B).
- E. CMS may, in a form and manner and by a date(s) specified by CMS, require the Participant to provide documentation, in addition to the information reported in the Care Delivery Reporting, related to the Participant's Health Equity Plan.
- F. If the Participant wishes to make a change(s) to its Health Equity Plan, it must submit to CMS an amendment to the Health Equity Plan in a form and manner and by the date(s) specified by CMS.
- G. The Participant must ensure that its Health Equity Plan complies with all applicable non-discrimination laws, including section 1557 of the Affordable Care Act, Title IX of the Education Amendments of 1972, Title VI of the Civil Rights Act of 1964, and Section 504 of the Rehabilitation Act.

- H. The Participant may not propose or use actions in its Health Equity Plan that selectively target beneficiaries based on race, ethnicity, national origin, disability, religion, or sex.
- I. The Participant is permitted to identify beneficiaries for health equity plan interventions based on other factors, including but not limited to medical history, health status, health needs, disability status, or income, provided the Participant and other individuals or entities performing functions or services related to the Health Equity Plan comply with all applicable non-discrimination laws and regulations.
- J. CMS may require the Participant to report data, in a form and manner and by a date specified by CMS, on its implementation of the Health Equity Plan pursuant to 42 CFR § 403.1110(b) for the purpose of monitoring and evaluating the Model.

### **Section 13.03 Prohibition on Influencing or Attempting to Influence the Beneficiary**

- A. Neither the Participant nor its GUIDE Practitioners, Partner Organizations, or other individuals or entities performing functions or services on behalf of the Participant are permitted to commit any act or omission, or adopt any policy that coerces or otherwise influences a Beneficiary's or Eligible Beneficiary's decision to voluntarily align to the Model, including but not limited to the following:
  - 1. Offering gifts or other remuneration to the Beneficiary or Eligible Beneficiary;
  - 2. Marketing about the Environmental Modification Beneficiary Engagement Incentive (Section 13.05(B) and Appendix A), and
  - 3. Withholding or threatening to withhold medical services or limiting or threatening to limit access to care.
- B. CMS will remove a GUIDE Beneficiary from the Participant's GUIDE Beneficiary Alignment File if the Participant fails to comply with the requirements of this Section 13.03. CMS may also take remedial action, including termination of the Agreement or Agreement Performance Period as described in Section 16.03.

### **Section 13.04 Descriptive Materials and Activities**

- A. Descriptive Materials and Activities shall not 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, or income.
- B. The Participant is not permitted to use the logo, seal, identifying mark or symbol of HHS or CMS and shall ensure that those identifiers are not included in any Descriptive Materials and Activities.
- C. CMS may develop and provide to the Participant template language for certain Descriptive Materials and Activities. The Participant shall use, and shall require its GUIDE Practitioners and Partner Organizations to use, any template language for Descriptive Materials and Activities provided by CMS.
- D. The Participant, and its GUIDE Practitioners and Partner Organizations, as applicable, shall provide any Descriptive Materials and Activities to CMS upon request.



- E. CMS may review Descriptive Materials and Activities and issue written notice of approval or disapproval of Descriptive Materials and Activities at any time and in a form and manner specified by CMS.
- F. The Participant shall immediately discontinue, and shall require its GUIDE Practitioners and Partner Organizations to immediately discontinue, use of any Descriptive Materials and Activities disapproved by CMS.
- G. If CMS reviews and approves the Participant's Descriptive Materials and Activities in accordance with Section 13.04(E), any material change to such CMS-approved Descriptive Materials and Activities must be submitted to CMS and approved in a form and manner and by one or more dates specified by CMS before use of the revised version of the CMS-approved Descriptive Materials and Activities.
- H. The Participant shall retain copies of all current and historical written and electronic Descriptive Materials and Activities and appropriate records for all other Descriptive Materials and Activities provided to Eligible Beneficiaries and GUIDE Beneficiaries in accordance with Section 15.02.

### **Section 13.05 Beneficiary Engagement Incentives**

- A. Except as permitted by applicable law and Section 13.05(B), the Participant is not permitted, and shall ensure its GUIDE Practitioners and Partner Organizations do not provide gifts or other remuneration to Beneficiaries, Eligible Beneficiaries or GUIDE Beneficiaries to induce them to receive items or services from the Participant, its GUIDE Practitioners and Partner Organizations, or to induce GUIDE Beneficiaries to continue to receive items or services from the Participant, its GUIDE Practitioners and Partner Organizations.
- B. CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored Model Patient Incentives (42 CFR § 1001.952(ii)(2)) is available to protect in-kind environmental modifications by the Participant to GUIDE Beneficiaries that meets all safe harbor requirements set forth in 42 CFR § 1001.952(ii)(2) and the requirements of Appendix A.

### **Section 13.06 Availability of Services**

- A. The Participant shall make, and require its GUIDE Practitioners and Partner Organizations to make, Medically Necessary Covered Services available to GUIDE Beneficiaries in accordance with applicable laws, regulations and guidance.
- B. GUIDE Beneficiaries and their assignees retain their right to appeal claims determinations in accordance with 42 CFR § 405, Subpart I.
- C. The Participant, GUIDE Practitioners, and Partner Organizations shall not charge any Beneficiary, Eligible Beneficiary, or GUIDE Beneficiary a Retainer Fee or Concierge Fee.
- D. The Participant will not take any action to select or avoid treating certain Beneficiaries, Eligible Beneficiaries, or GUIDE Beneficiaries based on their diagnoses, care needs, income levels or other factors that would render the beneficiary an "at risk beneficiary" as defined at 42 CFR § 425.20.

### **Section 13.07 Beneficiary Freedom of Choice**

- A. Consistent with Section 1802(a) of the Act, neither the Participant nor the Participant's GUIDE

Practitioner(s) or Partner Organizations, shall commit any act or omission, or adopt any policy, that inhibits Beneficiaries, Eligible Beneficiaries or GUIDE Beneficiaries from exercising their freedom to obtain health services from any provider or supplier. This prohibition will 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, Eligible Beneficiary or GUIDE Beneficiary expresses a preference for a different practitioner or supplier, or the referral is not in their best medical interests in the judgment of the referring party.

- B. Notwithstanding the foregoing, the Participant may communicate to Beneficiaries, Eligible Beneficiaries or GUIDE Beneficiaries the benefits of receiving care under the Model with the Participant. All such communications shall be made in accordance with Section 13.07(A). CMS may provide the Participant with scripts, talking points, or other materials explaining these benefits.

### **Section 13.08 HIPAA Requirement**

- A. The Participant acknowledges that it is a HIPAA covered entity (CE) as defined in 45 C.F.R. § 160.103.
- B. The Participant shall have all appropriate administrative, technical, and physical safeguards in place before the Effective Date to protect the privacy and security of PHI in accordance with all applicable laws, including 45 C.F.R. § 160.530(c).
- C. The Participant shall maintain the privacy and security of all Model-related information that identifies individual GUIDE Beneficiaries in accordance with the HIPAA Privacy and Security Rules and all relevant HIPAA Privacy and Security guidance applicable to the use and disclosure of PHI by CEs and business associates (“BAs”), as well as other applicable federal, state, tribal, and local laws and regulations.

## **Article 14. Compliance and Oversight**

### **Section 14.01 CMS Monitoring and Oversight Activities**

- A. CMS will conduct monitoring activities to assess compliance by the Participant, its GUIDE Practitioners and its Partner Organizations with the terms of this Agreement. Such monitoring activities may include, but are not limited to:
  - 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 PBA, HEA, or alignment of GUIDE Beneficiaries, overutilization, and cost-shifting to other payers or populations;
  - 2. Review of the Care Delivery Reporting and any and all data submitted to CMS by the Participant via Salesforce and HDR;
  - 3. Review of utilization and quality data collected by CMS or reported to CMS by the Participant in accordance with Articles 8 and 11;
  - 4. Review of documents from the Participant, its GUIDE Practitioners, and its Partner Organizations, including documentation related to the Participant’s eligibility, surveys and questionnaires,

5. Review of Partner Organization Arrangements between GUIDE Practitioners and Partner Organizations;
  6. Interviews with the Participant's staff, GUIDE Practitioners and Partner Organizations;
  7. Interviews with GUIDE Beneficiaries and their Caregivers;
  8. Audits of any of the Participant's records and documentation, including but not limited to charts, medical records, and other data from the Participant, its GUIDE Practitioners, and its Partner Organizations; and
  9. Site visits to the Participant and its Partner Organizations.
- B. In conducting monitoring and oversight activities, CMS may use any relevant data or information including, without limitation, all Medicare claims submitted for items and/or services provided to GUIDE Beneficiaries.
- C. Nothing in this Agreement limits or prevents CMS from monitoring the Participant, its GUIDE Practitioners, and its Partner Organizations for compliance as permitted by applicable law and regulations.
- D. CMS may conduct monitoring activities pursuant to this Article 14 for up to two calendar years after the effective date of termination or expiration of this Agreement.

#### **Section 14.02 Compliance with Monitoring Activities**

- A. The Participant shall cooperate with, and the Participant shall require its GUIDE Practitioners and its Partner Organizations to cooperate with, all CMS monitoring and oversight requests and activities.
- B. The Participant shall ensure it has sufficient access to all records, data, and information necessary to comply with the monitoring activities described in this Agreement. As necessary, the Participant shall request this information from any GUIDE Practitioners and its Partner Organizations performing functions or providing services related to the Model.

#### **Section 14.03 Compliance with Laws**

- A. Agreement to Comply.
1. The Participant shall comply with, and shall require its GUIDE Practitioners and its Partner Organizations to comply with, the applicable terms of the 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 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 Participant, its GUIDE Practitioners and its Partner Organizations to comply with the terms of any other CMS contract, agreement, model, or demonstration.
- B. Reservation of Rights.
1. Nothing contained in this Agreement or in the application process for the Model constitutes a waiver by the United States Department of Justice, the Internal Revenue Service, the Federal Trade Commission, HHS Office of the Inspector General, 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 the Agreement or any other provision of law. This Agreement does not bind any government agency except CMS and the Agreement binds CMS only to the extent provided in this Agreement.

2. The failure by CMS to require performance of any provision of this Agreement does not affect CMS' right to require performance at any time thereafter, nor does a waiver of any breach or default of the Agreement constitute a waiver of any subsequent breach or default or a waiver of the provision itself.
- C. 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 Participant, its GUIDE Practitioners, and its Partner Organizations.
- D. 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 Participant, its GUIDE Practitioners, and its Partner Organizations.

## **Article 15. Audits and Record Retention**

### **Section 15.01 Right to Audit and Inspection**

- A. The Participant agrees, and must require all of its Partner Organizations to agree, that the government (including but not limited to 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 Participant, its GUIDE Practitioners, and its Partner Organizations that pertain to the following:
1. The Participant's compliance with the terms of this Agreement, including provisions that require the Participant to impose duties or requirements on its GUIDE Practitioners and its Partner Organizations;
  2. Whether the GUIDE Practitioners and Partner Organizations complied with the duties and requirements imposed on them by the Participant pursuant to the terms of this Agreement;
  3. The quality of services performed under this Agreement;
  4. Any activity by the Participant, its GUIDE Practitioners, and its Partner Organizations that may pose a potential risk of harm to Beneficiaries or a vulnerability to the integrity of the model test;
  5. The Participant's right to, and distribution of, the PBA;
  6. The ability of the Participant to repay amounts owed to CMS under this Agreement;
  7. The Participant's financial arrangements including Partner Organization Arrangements;
  8. Environmental Modification Beneficiary Engagement Incentive which may be provided by the Participant to Eligible Beneficiaries pursuant to Appendix A.

- B. The Participant must maintain and provide to CMS upon request a list of all Eligible Beneficiaries and GUIDE Beneficiaries to whom the Participant has submitted Patient Assessment and Alignment forms to CMS. CMS may monitor and audit the Participant's list of all Eligible Beneficiaries and GUIDE Beneficiaries to whom the Participant has submitted Patient Assessment and Alignment forms to CMS. This audit, including any surveys of Eligible Beneficiaries and GUIDE Beneficiaries by CMS, may take place during the Performance Year or at a later time, as determined by CMS.

### **Section 15.02 Maintenance of Records**

- A. The Participant shall maintain and shall give the government (including but not limited to CMS, HHS, and the Comptroller General or their designees) access to, and shall require all its GUIDE Practitioners and its Partner Organizations 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 15.01.
- B. The Participant shall maintain, and shall require all its GUIDE Practitioners and its Partner Organizations to maintain, such books, contracts, records, documents, and other evidence for a period of six years from the effective date of expiration or termination of this Agreement or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless:
  - 1. CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the Participant at least 30 Days before the effective date of expiration of the six-year period described above; or
  - 2. There has been a termination, dispute, or allegation of fraud or similar fault against the Participant, its GUIDE Practitioners or its Partner Organizations, 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 16. Remedial Action and Termination**

### **Section 16.01 Grounds for Remedial Action**

- A. CMS may take remedial action against the Participant if CMS determines that the Participant or any of its GUIDE Practitioners or Partner Organizations:
  - 1. Has failed to comply with any applicable term of the Agreement or any Medicare program requirement, rule, or regulation;
  - 2. Has failed to comply with the Participant's Corrective Action Plan (CAP), the monitoring or auditing plan, or both, developed by CMS for the Participant, or other remedial action imposed by CMS, if applicable;
  - 3. Has taken any action that threatens the health or safety of a Beneficiary, Eligible Beneficiary, GUIDE Beneficiary or other patient;
  - 4. Has failed to rectify deficiencies following any remedial action;
  - 5. Has undergone a Change in Control that renders it ineligible for participation in the

Model or presents a program integrity risk;

6. Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the Model or any requirement of the Medicare program; or
7. Poses 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, including but not limited to revocation of Medicare billing privileges, Medicare or Medicaid program exclusion, or debarment; or
  - ii. Is subject to investigation or action by HHS (including, but not limited to OIG and CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including but not limited to 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 16.02 Types of Remedial Action**

- A. If grounds for remedial action exist, CMS may take one or more of the following actions:
  1. Notify the Participant and, if appropriate, the GUIDE Practitioners and the Partner Organizations, of the violation;
  2. Require the Participant to provide additional information to CMS or its designees;
  3. Conduct site visits, interview Eligible Beneficiaries or GUIDE Beneficiaries, GUIDE Participants, and Partner Organizations or take other actions to gather information;
  4. Place the Participant on a monitoring and/or auditing plan developed by CMS;
  5. Require the Participant to remove a GUIDE Practitioner from the GUIDE Practitioner Roster, immediately or within a timeframe specified by CMS;
  6. Require the Participant to remove a Partner Organization from the Partner Organization Roster and to terminate the Partner Organization Arrangement, immediately or within a timeframe specified by CMS;
  7. Withhold GUIDE Payments until the Participant comes into compliance with this Agreement, at which point CMS shall resume making positive PBAs, if applicable, and shall distribute to the Participant all amounts withheld during the period of noncompliance;
  8. Suspend GUIDE Payments until the Participant comes into compliance with this Agreement, at which point CMS shall resume making positive PBAs, if applicable, but shall not distribute to the Participant any amounts suspended during the period of noncompliance;
  9. Recoup GUIDE Payments already distributed to the Participant, dating back to the date, as specified by CMS, on which CMS determined the Participant failed to comply with a term of this Agreement.

10. Require a CAP from the Participant that is acceptable to CMS. If CMS requires the Participant to prepare and submit a CAP to CMS, the following requirements apply:
    - i. The Participant shall submit a CAP to CMS for approval by a deadline established by CMS;
    - ii. The Participant shall address in the CAP what actions the Participant will take (or will require any GUIDE Practitioner or Partner Organization to take) within a specified time period to ensure that all deficiencies will be corrected and that the Participant will be in compliance with the terms of this Agreement; and
    - iii. If the Participant does not comply with the terms of the CAP within the specified period of time, CMS may take additional remedial actions or terminate the Agreement or Agreement Performance Period in accordance with Section 16.03.
  11. Prohibit the Participant from accessing any or all waivers of existing law made pursuant to section 1115A(d)(1) of the Act;
  12. Amend the Agreement without the consent of the Participant to deny the use of the Telehealth Benefit Enhancement by the Participant, its GUIDE Practitioners, or its Partner Organizations and to require the Participant to terminate any agreement effectuating such Telehealth Benefit Enhancement by a date specified by CMS;
  13. Prohibit the Participant from furnishing the Environmental Modification Beneficiary Engagement Incentive, and
  14. Discontinue data sharing and providing reports to the Participant under Article 10.
- B. CMS may impose additional remedial actions, including but not limited to, terminating the Agreement or Agreement Performance Period pursuant to Section 16.03, if CMS determines that the Participant's efforts to address noncompliance or other grounds for remedial action were insufficient.

### **Section 16.03 Termination by CMS**

- A. CMS may immediately, or with advance notice, terminate the Agreement or Agreement Performance Period if:
1. CMS determines that it no longer has the funds to support the Model;
  2. CMS modifies or terminates the Model pursuant to section 1115A(b)(3)(B) of the Act;
  3. CMS offers the Participant an amendment to this Agreement pursuant to Section 1.04, and the Participant does not sign such amendment by the date specified by CMS;
  4. CMS determines that the Participant fails to meet the requirements listed in Section 4.03(B)(2) by the Start Date;
  5. CMS determines that the entities and/or individuals that the Participant lists on its Proposed GUIDE Practitioner Roster and, if applicable, its Proposed Partner Organization Roster, fail program integrity screening;
  6. CMS determines that any grounds for remedial action exist;
  7. CMS determines that the Participant has failed to submit, obtain approval for, implement,

or fully comply with the terms of a CAP;

8. CMS determines that the Participant has failed to demonstrate improved performance following any remedial action imposed by CMS; or
9. The Participant 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.

#### **Section 16.04 Termination of the Agreement Performance Period by the Participant**

The Participant may terminate the Agreement Performance Period upon at least 180 Days prior written notice to CMS. Such notice must specify the effective date of the termination.

#### **Section 16.05 Financial Settlement Upon Termination**

If CMS terminates the Agreement, or the Agreement Performance Period is terminated by either party, CMS shall conduct financial settlement for the entire Agreement Performance Period.

#### **Section 16.06 Notifications to GUIDE Practitioners, Partner Organizations, and Beneficiaries Upon Termination**

- A. If the Agreement or Agreement Performance Period is terminated under Section 16.03 or Section 16.04, the Participant shall provide written notice of the termination to all of its GUIDE Practitioners and Partner Organizations. The Participant shall deliver such written notice no later than 30 Days before the effective date of termination unless a different date is specified by CMS. The Participant shall include in such notices any content specified by CMS, including but not limited to information regarding data retention and destruction, and the discontinuation of the Telehealth Benefit Enhancement and the Environmental Modification Beneficiary Engagement Incentive.
- B. The Participant shall provide written notice of the termination to GUIDE Beneficiaries. The Participant shall deliver such notices no later than 30 Days before the effective date of termination unless a different date is specified by CMS. The Participant shall include in such notices any content specified by CMS.

### **Article 17. Limitation on Review and Dispute Resolution**

#### **Section 17.01 Limitations on Review**

- A. There is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:
  1. 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 the Agreement or Agreement Performance Period or to require the termination of any individual's or entity's status as a GUIDE Practitioner or Partner Organization;
  2. The elements, parameters, scope, and duration of such models for testing or dissemination;
  3. Determinations regarding budget neutrality under section 1115A(b)(3) of the Act;
  4. The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B) of the Act;



5. Determinations about expansion of the duration and scope of a model under section 1115A(c) of the Act, including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection (c);
6. The selection of quality performance standards by CMS;
7. The assessment of the quality of care furnished by the Participant, its GUIDE Practitioners, or its Partner Organizations by CMS;
8. The methodology applied to calculate the PBA and HEA;
9. The methodology applied to calculate payment for GUIDE Respite Services; and
10. The methodology used to determine Beneficiary eligibility.

### **Section 17.02 Dispute Resolution**

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

1. Such a request for reconsideration by the Participant must satisfy the following criteria:
  - i. The request must be submitted to a designee of CMS (“**Reconsideration Official**”) who:
    - a. Is authorized to receive such requests;
    - b. Did not participate in the determination that is the subject of the reconsideration request; and
    - c. May be, but does not have to be, an Inferior Officer.
  - ii. The request must include a copy of the initial determination issued by CMS and contain a detailed, written explanation of the basis for the dispute, including supporting documentation;
  - iii. The request must be made within 30 Days of the date of the initial determination for which reconsideration is being requested; and
  - iv. The request must be delivered via email to CMS at InnovationModelsReconsideration@cms.hhs.gov or at such other address specified by CMS.
2. Requests that do not meet the requirements of Section 17.02(A)(1) shall be denied.
3. Within 15 Days of receiving a request for reconsideration, the parties will be sent a written acknowledgement of receipt of the reconsideration request. Such an acknowledgement will set forth:
  - i. The review procedures; and
  - ii. A briefing schedule that permits each party to submit written briefs, including any evidence or 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 shall 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 Participant 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 shall be based only upon:
  - i. Position papers and supporting documentation that are timely submitted to the Reconsideration Official and meet the standards for submission under Section 17.02(B)(2); and
  - ii. 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 Participant a written notification of the reconsideration determination (“**Reconsideration Determination**”). Absent unusual circumstances, the Reconsideration Determination will be issued within 60 Days of receipt of timely filed position papers and supporting documentation.
3. The Reconsideration Determination is final and binding 30 Days after its issuance, unless the Participant or CMS timely requests review of the Reconsideration Determination in accordance with Sections 17.02(D)(1) and (2).

D. CMS Administrator Review. The Participant or CMS may request CMS Administrator review of the Reconsideration Determination.

1. The request must be made via email to InnovationModelsReconsideration@cms.hhs.gov or such other address as specified by CMS within 30 Days after the date of the Reconsideration Determination.
2. The request must include a copy of the Reconsideration Determination and a detailed, written explanation of why the Participant or CMS disagrees with the Reconsideration Determination.
3. Within 30 business days after receiving a request for review, the CMS Administrator (or a delegate acting on behalf of the CMS Administrator) will send the parties a written acknowledgement of receipt of the request for review. Such an acknowledgement will set forth:
  - i. Whether the request for review is granted or denied; and
  - ii. If the request for review is granted, the review procedures and a schedule that permits each party to submit a brief in support of the party’s position for consideration by the CMS Administrator.
4. If the request for review is denied, the Reconsideration Determination is final and

binding as of the date the request for review is denied.

5. If the request for review is granted:

- i. The record for review shall consist of timely submitted briefs and the evidence contained in the record of the proceedings before the Reconsideration Official. The CMS Administrator shall not consider documentation submitted for review other than documents and data described in Sections 17.02(B)(2);
- ii. The CMS Administrator shall review the record and issue to CMS and to the Participant a written determination; and
- iii. The written determination of the CMS Administrator is final and binding.

E. Effect of Dispute Resolution. The dispute resolution 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 18. Miscellaneous**

**Section 18.01 Agency Notifications and Submission of Reports**

- A. For a notice or other communication required under this Agreement to be valid, it must be in writing.
- B. Unless otherwise specified in this Agreement or 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:** Guiding an Improved Dementia Experience Model  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Mailstop WB-06-05  
Baltimore, MD 21224  
Email: [GUIDEModelTeam@cms.hhs.gov](mailto:GUIDEModelTeam@cms.hhs.gov)

**Participant:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Section 18.02 Notice of Bankruptcy**

- A. If the Participant has filed a bankruptcy petition, whether voluntary or involuntary, the Participant 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 Participant under the terms of each model tested under section 1115A of the Act in which the Participant 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.

- B. 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 Participant is participating or has participated. This list need not identify a model tested under Section 1115A of the Act in which the Participant 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 Participant and CMS have been fully and finally resolved with respect to that model.
- C. The notice to CMS must be addressed to the CMS Office of Financial Management at 7500 Security Boulevard, Mailstop C3-01-24, Baltimore, MD 21244 or such other address as may be specified on the CMS website for purposes of receiving such notices.

### **Section 18.03 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 this Agreement, unless the deletion of such provision or provisions would result in such a material change to this Agreement so as to cause continued participation under the terms of this Agreement to be unreasonable.

### **Section 18.04 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 in writing without the consent of the Participant 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 Participant with 30 Days' advance written notice of any such unilateral amendment, which notice shall specify the amendment's effective date.

### **Section 18.05 Survival**

Expiration or termination of this Agreement by either 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 survive expiration or termination of this Agreement and apply thereafter:

1. Section 3.02 (Changes to Participant);
2. Section 9.08 (Reconciliation and Settlement);
3. Article 10 (CMS Data Sharing and Reports);

4. Article 11 (Participant Reporting and Certification Requirements);
5. Section 12.01 (Participation in Evaluation);
6. Section 12.04 (Rights in Data and Intellectual Property);
7. Section 12.05 (Participant Public Release of Information);
8. Article 14 (Compliance and Oversight);
9. Article 15 (Audits and Record Retention);
10. Section 16.05 (Financial Settlement Upon Termination);
11. Section 16.06 (Notifications to GUIDE Practitioners, Partner Organizations, and Beneficiaries upon Termination);
12. Section 17.01 (Limitations on Review);
13. Section 18.02 (Notice of Bankruptcy);
14. Section 18.05 (Survival); and
15. Section 18.07 (Prohibition on Assignment).

#### **Section 18.06 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 18.07 Prohibition on Assignment**

Except with the prior written consent of CMS, the Participant shall not transfer, including by merger (whether the Participant 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 Participant shall provide CMS 90 Days' advance written notice of any such proposed transfer. This obligation remains in effect until final payment by or to the Participant has been made under this Agreement. CMS may condition its consent to such transfer on full payment of any amounts owed by the Participant under this Agreement or owed to CMS by the proposed assignee. Any purported transfer in violation of this Section is voidable at the discretion of CMS.

#### **Section 18.08 Certification**

The Participant executive signing this Agreement certifies to the best of his or her knowledge, information, and belief that the information submitted to CMS is true, accurate, and complete, including that the Participant satisfies the requirements of Section 3.01 and that all GUIDE Practitioners satisfy the requirements of clauses (i)-(iii) of the definition of GUIDE Practitioner. The Participant executive signing this Agreement certifies to the best of his or her knowledge, information, and belief that he or she is authorized by the Participant to execute this Agreement and to legally bind the Participant to its terms and conditions.

#### **Section 18.09 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. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a “.pdf” format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or “.pdf” signature page were an original thereof. 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.

**Participant Name:**

\_\_\_\_\_



By: \_\_\_\_\_

Date: \_\_\_\_\_

\_\_\_\_\_  
Name of authorized signatory

\_\_\_\_\_  
Title of authorized signatory

**Participant ID:** \_\_\_\_\_

**CMS:**



By: \_\_\_\_\_

Date: \_\_\_\_\_

\_\_\_\_\_  
Name of authorized signatory

\_\_\_\_\_  
Title of authorized signatory

## **Appendices**

**Appendix A: Environmental Modification Beneficiary Engagement Incentive**

**Appendix B: Care Navigator Training Topics**

**Appendix C: GUIDE Care Delivery Services**

**Appendix D: GUIDE Performance Measure Set**

**Appendix E: Telehealth Benefit Enhancement**

**Appendix F: GUIDE Payment Tables**

**Appendix G: Medicare Waivers**



## **Appendix A: Environmental Modification Beneficiary Engagement Incentive**

- A. Consistent with the provisions of Section 13.05(B), and subject to compliance with all other applicable laws and regulations, the Participant may provide in-kind environmental modifications to GUIDE Beneficiaries if all the requirements of this Appendix A are satisfied:
1. The Participant reasonably determines that the environmental modification advances one or more of the following goals of the Model:
    - i. Improves quality of life for the GUIDE Beneficiary,
    - ii. Reduces burden and strain on the Caregiver, and
    - iii. Delays the GUIDE Beneficiary's move to a nursing home.
  2. The environmental modification shall have a reasonable connection to the GUIDE Beneficiary's health care.
  3. The environmental modification shall be furnished by the Participant (or by an agent of the Participant acting under the Participant's direction and control).
  4. The Participant shall arrange and pay a handy worker or home improvement contractor to install any physical modifications. The handy worker or home improvement contractor shall:
    - i. Be at least 18 years old;
    - ii. Have passed a background check;
    - iii. Obtain and maintain Commercial General Liability Insurance;
    - iv. Be licensed or certified in the state that the GUIDE Beneficiary is residing;  
and
    - v. Be bonded as may be legally required in the state that the GUIDE Beneficiary is residing.
  5. The total retail value of payments for environmental modifications made by the Participant on behalf of a GUIDE Beneficiary shall not exceed \$1,000 per year.
    - i. For example, the Participant may make five separate \$200 payments which totals \$1,000 on behalf of a GUIDE Beneficiary in a single year, or the Participant may make a payment of \$900 on behalf of a GUIDE Beneficiary in a single year. The Participant is not permitted to make five separate \$300 payments which totals \$1,500 in a single year or a payment of \$1,100 on behalf of the GUIDE Beneficiary in a single year, because these latter

examples exceed the annual \$1,000 monetary cap.

6. The in-kind environmental modification is not a Medicare-covered item or service, or a Medicaid-covered item or service (if the GUIDE Beneficiary is enrolled in Medicaid), for the GUIDE Beneficiary on the date that the in-kind environmental modification is furnished to the GUIDE Beneficiary.
  7. The cost of the environmental modification shall not be shifted to Medicare or another federal health care program.
- B. Environmental modifications under this Appendix A may include, but are not limited to, grab bars, flexible shower heads, safer flooring, signs, improved lighting, railing installation or other home modifications to prevent injury.
- C. The Participant shall maintain and make available to the Secretary, upon request, documentation of the following:
1. The nature of the environmental modification;
  2. The date the environmental modification was provided;
  3. The identity of the GUIDE Beneficiary to whom the environmental modification was provided;
  4. The retail value of the environmental modification; and
  5. Any other applicable materials and records sufficient to establish that the environmental modification was distributed in a manner consistent with the requirements of this Appendix A.
- D. The Participant shall maintain the records described in Paragraph C in accordance with Section 15.02.
- E. If the Participant wishes to offer the Environmental Modification Beneficiary Engagement Incentive during a Performance Year, it shall:
1. Timely submit to CMS its selection of the Environmental Modification Beneficiary Engagement Incentive in a form and manner and by one or more dates specified by CMS; and
  2. Timely submit to CMS an Environmental Modification Implementation Plan in accordance with Paragraph G.
- F. The Participant shall obtain CMS consent before voluntarily terminating an Environmental Modification Beneficiary Engagement Incentive effective during a Performance Year. The Participant shall provide at least 30 Days advance written notice of such termination to CMS. If CMS consents to such termination, the effective date of such termination will be the date

specified in the notice of termination or such other date specified by CMS.

G. The environmental modification(s) shall be provided to the GUIDE Beneficiary by the Participant in accordance with a CMS-approved Environmental Modification Implementation Plan, prepared in accordance with this Paragraph G.

1. If the Participant wishes to offer environmental modifications during a Performance Year, it shall develop an Environmental Modification Implementation Plan which the Participant shall apply uniformly and consistently. The Implementation Plan shall be submitted to CMS in a form and manner and by a deadline specified by CMS. The Implementation Plan shall include:

- i. An affirmative statement that the Participant elects to offer the Environmental Modification Beneficiary Engagement Incentive;
- ii. The conditions in accordance with this Appendix A under which the Participant elects to provide the Environmental Modification Beneficiary Engagement Incentive; and

iii. The procedures to be employed to meet the documentation requirements in accordance with Paragraph C.

2. The Environmental Modification Implementation Plan shall be reviewed and modified by the Participant, as necessary and at least annually. Any modification to the Environmental Modification Implementation Plan shall be submitted to CMS at least 30 Days before the modification becomes effective, unless a different deadline is specified by CMS.

3. CMS may reject an Environmental Modification Implementation Plan if it does not comply with the terms of this Appendix A. An Environmental Modification Implementation Plan is deemed approved if CMS has not rejected it within 30 Days after its submission to CMS. CMS may reject an Environmental Modification Implementation Plan after it has been deemed approved, but such rejection shall not be effective retroactively.

H. CMS may take remedial action, including the suspension or termination of the Participant's ability to offer the Environmental Modification Beneficiary Engagement Incentive, if CMS determines that:

1. The Participant has failed to comply with the requirements of this Appendix A; or
2. The Participant's implementation of the Environmental Modification Beneficiary Engagement Incentive might undermine the integrity of the Model.

I. If CMS terminates the Agreement or Agreement Performance Period, the Participant shall not provide the Environmental Modification Beneficiary Engagement Incentive to GUIDE Beneficiaries as of the effective date of termination as determined by CMS. The Participant

shall provide written notice of such termination to its GUIDE Beneficiaries who are currently receiving environmental modifications in a form and manner and by a date specified by CMS. The written notification shall state the effective date of termination and that the Environmental Modification Beneficiary Engagement Incentive will no longer be provided to the GUIDE Beneficiary.

## **Appendix B: Care Navigator Training Topics**

<b>Topic</b>	<b>Further Detail of Topic</b>
Background on Dementia	Overview of dementia as a medical condition; Progression of disease and balancing dementia with other co-morbidities
Overview of Assessments	Assessments available related to dementia; Recommendations for a successful assessment
Care Plan	What is a care plan; Including beneficiary in the development of plan
Person-Centered Planning	What person-centered planning means; How to incorporate into planning
Challenging Behaviors	Behavioral symptom management; Common behavioral changes due to dementia and how to address
Functional Needs	What are activities of daily living (ADLs) and instrumental activities of daily living (IADLs); Evaluation of ADLs and IADLs; Common changes in ADLs and IADLs due to dementia and how to address; Medication monitoring and maintaining a medication schedule
Advanced Care Planning	What is an advance medical directive and POLST form; How to assist beneficiary in advance care planning
Decision-Making Capacity	What is capacity for medical decision-making; What it means when a beneficiary does not have capacity for medical decision-making; supported decision-making
Safety	Considerations for safety at home, in public, and driving; elder abuse, neglect, and financial exploitation; access to weapons and dangerous substances
Communication	Communication strategies for persons with dementia and their caregivers
Coordination of medical care and community services	Communication with clinical providers; Supporting beneficiary in transitions between settings; Accessing community-based services and supports, including respite services; Working with case managers and other coordinators to address gaps and duplication in a beneficiary's community-based services and supports
Supporting a Caregiver	Caregiver strain and support (e.g.: peer-to-peer support, support group, 1:1 support); In-home caregiver training and importance of caregiver education
Diversity in Dementia	Treating dementia and communicating with diverse populations in a culturally competent way

**Appendix C: GUIDE Care Delivery Services**

Care Delivery Services	Care Delivery Services Description
<p align="center"><b>1</b></p> <p><b>Comprehensive Assessment</b></p>	<p><b>1.1 <u>Comprehensive Assessment:</u></b></p> <p><b>1.1.1</b> Participant shall deliver a Comprehensive Assessment of, and care planning for, the GUIDE Beneficiary in accordance with the requirements below.</p> <p><b>1.1.2 <u>Frequency:</u></b></p> <p><b>1.1.2.1</b> Participant shall perform a Comprehensive Assessment of the GUIDE Beneficiary. The Comprehensive Assessment will initiate the model intervention and serve as the initial model visit.</p> <p><b>1.1.2.2</b> Participant shall complete a new Comprehensive Assessment under the terms of this Section 1.1 for any GUIDE Beneficiaries that the Participant may have previously assessed as a patient prior to the GUIDE Beneficiary voluntarily aligning with the Participant for purposes of this Model.</p> <p><b>1.1.2.3</b> After the initial Comprehensive Assessment, Participant shall perform a Comprehensive Assessment of the GUIDE Beneficiary at least once every twelve months.</p> <p><b>1.1.2.4</b> The Participant has the discretion to re-assess the GUIDE Beneficiary more frequently; however, CMS will only accept data from reassessments once every one hundred and eighty (180) days.</p> <p><b>1.1.3 <u>Modality:</u></b></p> <p><b>1.1.3.1</b> An assessment may be performed via telehealth or in-person in the Care Team’s office or other outpatient home or domiciliary based on the preference of the GUIDE Beneficiary and/or Caregiver.</p> <p><b>1.1.3.2</b> The assessment shall be administered by appropriate members of the interdisciplinary Care Team according to their license and scope of practice.</p> <p><b>1.1.4 <u>Required Domains:</u></b></p> <p><b>1.1.4.1 <u>Clinical:</u></b></p> <p><b>1.1.4.1.1</b> Cognition-focused evaluation including a pertinent history and examination;</p> <p><b>1.1.4.1.2</b> Evaluation of medical decision-making of moderate or high complexity;</p> <p><b>1.1.4.1.3</b> Functional assessment (e.g., Basic and Instrumental Activities of Daily Living);</p>

- 1.1.4.1.4 Screening, or referral to screening, for hearing loss;
- 1.1.4.1.5 Use of standardized instruments for staging of dementia;
- 1.1.4.1.6 Medication reconciliation and review.

**1.1.4.2 Behavioral Health and Psychosocial Needs:**

- 1.1.4.2.1 Evaluation of GUIDE Beneficiary for behavioral health needs, including screening for depression, anxiety, substance use, and suicidal ideation;
- 1.1.4.2.2 Evaluation of safety, including, but not limited to, environmental, driving, wandering, fall risk, and abuse, neglect and exploitation.

**1.1.4.3 Health-Related Social Needs:**

- 1.1.4.3.1 Screening of GUIDE Beneficiary’s health-related social needs (HRSN) in accordance with the requirements detailed in Section 12.01(E) of this Agreement.

**1.1.4.4 Advance Care Planning:**

- 1.1.4.4.1 Development, revision, and/or review of an Advance Care Plan and a Physician Order for Life-Sustaining Treatment (POLST) if available and GUIDE Beneficiary wishes to complete.

**1.1.4.5 Coordination:**

- 1.1.4.5.1 Identification of GUIDE Beneficiary’s primary care provider, behavioral health provider, and specialty provider(s), if any, and coordination services to manage the GUIDE Beneficiary’s dementia and any co-occurring conditions.
- 1.1.4.5.2 Identification of any community-based services and supports, and home and community-based services that the GUIDE Beneficiary is receiving.

**1.2 Caregiver Assessment:** Participant shall deliver an assessment of the Caregiver in accordance with the requirements below.

- 1.2.1 Participant shall identify the Caregiver(s) and their ability and willingness to assume, or to continue to furnish, assistance.
- 1.2.2 Participant shall assess the Caregiver’s knowledge, needs, and social supports, and assess the Caregiver’s well-being, stress level, and other challenges.
- 1.2.3 If the GUIDE Beneficiary does not have a Caregiver, the Participant shall make a reasonable effort to help identify a Caregiver for the GUIDE Beneficiary.
  - 1.2.3.1 If the Participant and the GUIDE Beneficiary are not able to locate a Caregiver for the GUIDE Beneficiary, then Section 1.2: Caregiver

	<p>Assessment and Section 8: Caregiver Education and Support do not apply to that GUIDE Beneficiary, and instead the Participant shall make additional efforts and put safeguards into its care delivery to support the GUIDE Beneficiary continuing to reside in the community.</p> <p><b>1.3 Home Visit Assessment:</b></p> <p><b>1.3.1</b> For GUIDE Beneficiaries in the low complexity dyad tier or low complexity individual tier: Participant may, but is not required to, visit the GUIDE Beneficiary and, if applicable, his or her Caregiver in person at the current residence of the GUIDE Beneficiary. If the Participant does not visit the GUIDE Beneficiary in person, the visit may be performed remotely through electronic means. For GUIDE Beneficiaries in moderate or high complexity dyad tiers, or moderate to high complexity individual tier: Participant shall visit the GUIDE Beneficiary and, if available, his or her Caregiver at the current residence of the GUIDE Beneficiary. If the Caregiver or other members of the Care Team are not present, the Participant may facilitate participation of the Caregiver and other members of the Care Team by enabling such individuals to participate in the visit remotely through electronic means.</p> <p><b>1.3.2</b> The home visit with the GUIDE Beneficiary should occur within two months after the initial Comprehensive Assessment and can be performed by any member of the interdisciplinary Care Team.</p> <p><b>1.3.3</b> During the home visit, the Participant shall assess the following: i) safety of the home environment and the GUIDE Beneficiary’s ability to navigate and manage the home environment, ii) GUIDE Beneficiary’s function in activities of daily living, and iii) other environmental, social, and behavioral factors that might impact the function and needs of the GUIDE Beneficiary and their Caregiver.</p>
<p style="text-align: center;"><b>2</b></p> <p><b>Care Plan</b></p>	<p><b>2.1</b> Based on findings from the initial Comprehensive Assessment, including the HRSN screening, home visit, and guidance from the GUIDE Beneficiary and the Caregiver, the Participant shall develop elements of the person-centered care plan with recommendations for i) addressing the GUIDE Beneficiary’s goals, strengths, preferences and needs, ii) the required domains of the Comprehensive Assessment, iii) the coordination of community-based services and supports, including respite services if applicable, and a listing of recommended service providers and which individual or program is responsible for payment of each service provider, and iv) the Caregiver’s education and support services.</p> <p><b>2.2</b> The initial care plan and future revisions shall be led by the GUIDE Beneficiary. At the discretion of the GUIDE Beneficiary and as appropriate to the individual, the Participant may also incorporate input from the Caregiver. The Participant shall share the initial care plan and future revisions with the</p>



	<p>GUIDE Beneficiary and their Caregiver along with any relevant education, supports, and other resources, to carry out the goals of the plan.</p> <p><b>2.3</b> The Participant shall modify the written care plan as needed, or requested, to reflect the GUIDE Beneficiary’s changing circumstances, goals, preferences, and needs.</p> <p><b>2.4</b> The person-centered care plan shall be incorporated into the GUIDE Beneficiary’s electronic health record and shared with the GUIDE Beneficiary’s primary care provider (if the GUIDE Beneficiary’s primary care provider is not a member of the Participant’s Care Team) and any specialist or other provider in accordance with Section 5: Care Coordination and Transitional Care Management.</p>
<p style="text-align: center;"><b>3</b> <b>24/7 Access</b></p>	<p><b>3.1</b> Participant shall provide either (i) 24/7 access to an interdisciplinary Care Team member or (ii) maintain a 24/7 helpline that the GUIDE Beneficiary and/or their Caregiver may call to speak with either a member of the Care Team or a third party engaged by the Participant to provide communication with human support (e.g., not artificial intelligence) during off-duty hours. A third party engaged by the Participant to provide communication during off-duty hours shall share with the interdisciplinary Care Team information of any communication with a GUIDE Beneficiary and/or their Caregiver.</p> <p><b>3.2</b> If the Participant uses a 24/7 helpline, the 24/7 helpline shall be available to receive ad hoc one-on-one support calls from the Caregiver (see Section 8.2.4).</p>
<p style="text-align: center;"><b>4</b> <b>Ongoing Monitoring and Support</b></p>	<p><b>4.1</b> The Care Navigator shall be the primary point of contact for the GUIDE Beneficiary and their Caregiver.</p> <p><b>4.2</b> The Care Navigator shall provide ongoing contact with the GUIDE Beneficiary and/or Caregiver in order to revise and maintain the person-centered care plan as needed (see Section 2), identify unmet needs and coordinate clinical and community-based services and supports (see Section 6), monitor medication management and adherence (see Section 7), and provide caregiver education and support (see Section 8) as may be needed to support the GUIDE Beneficiary and their Caregiver.</p> <p><b>4.2.1</b> If the Care Navigator is a non-clinical professional, the Care Navigator should consult with the Care Team’s clinical team members for any medical or other issues that present with complexity.</p> <p><b>4.3 Frequency:</b> Participant shall maintain a minimum contact frequency with the GUIDE Beneficiary and/or their Caregiver. Minimum contact requirements vary by model tier, as follows:</p> <p><b>4.3.1</b> GUIDE Beneficiaries with a Caregiver</p> <ul style="list-style-type: none"> <li>○ Low complexity dyad tier: at least quarterly</li> <li>○ Moderate complexity dyad tier: at least once a month</li> <li>○ High complexity dyad tier: at least once a month</li> </ul>

	<p><b>4.3.2</b> GUIDE Beneficiaries without a Caregiver</p> <ul style="list-style-type: none"> <li>○ Low complexity individual tier: at least once a month</li> <li>○ Moderate to high complexity individual tier: at least twice a month</li> </ul> <p><b>4.4 Modality:</b> Participant may provide ongoing contact in-person (in-clinic or in-home), by phone, and/or by audio-visual modalities in accordance with the GUIDE Beneficiary’s and/or Caregiver’s preferences, as applicable. Short Messaging Service (SMS) may not be used to contact the GUIDE Beneficiary or Caregiver to meet the minimum contact frequency, but can be used, with the GUIDE Beneficiary’s and Caregiver’s consent, in other communications.</p>
<p style="text-align: center;"><b>5</b> <b>Care</b> <b>Coordination</b> <b>and</b> <b>Transitional</b> <b>Care</b> <b>Management</b></p>	<p><b>5.1</b> If the GUIDE Beneficiary’s primary care provider is not a member of the Participant’s Care Team, Participant shall coordinate with the GUIDE Beneficiary’s primary care provider and notify the GUIDE Beneficiary’s primary care provider that the GUIDE Beneficiary is participating in a dementia care management program and ensure that the primary care provider has access to the GUIDE Beneficiary’s care plan and any updated/revised care plans.</p> <p><b>5.2</b> Participant may refer the GUIDE Beneficiary to a specialist or other provider to address any physical or behavioral health (such as, mental health or substance use) co-occurring conditions of the GUIDE Beneficiary. Participant may notify the specialist or other provider that the GUIDE Beneficiary is participating in a dementia care management program and send the specialist or other provider the GUIDE Beneficiary’s person-centered care plan, and any updated/revised care plans, by electronic health record, fax, or mail. The Participant shall also notify the GUIDE Beneficiary’s primary care provider of the referral to a specialist and/or other provider. If the primary care provider is actively co-managing the GUIDE Beneficiary, the Participant should make this referral in consultation with the primary care provider. The Care Team must close the referral loop with the specialist by ensuring the Care Team receives documentation from the GUIDE Beneficiary’s visit and any changes to their care plan.</p> <p><b>5.3</b> If the Participant refers the GUIDE Beneficiary to a specialist or other provider, a member of the Care Team shall introduce the GUIDE Beneficiary to the new provider if requested by the GUIDE Beneficiary and/or their Caregiver so that the new provider is aware of the patient history and can share recommendations with the Care Team for incorporation into the care plan.</p> <p><b>5.4</b> Participant shall provide care coordination services, medication management/reconciliation, and support to the GUIDE Beneficiary in transitions between their personal residence and care settings, such as a hospital, emergency department, nursing facility, and/or hospice.</p> <p><b>5.5</b> Participant shall provide additional care coordination services needed to help manage the GUIDE Beneficiary’s dementia and co-occurring conditions, if any, across the care-continuum.</p>

<p style="text-align: center;"><b>6</b></p> <p style="text-align: center;"><b>Referral and Coordination of Services and Supports</b></p>	<p><b>6.1</b> Participant shall i) refer and connect GUIDE Beneficiaries and their Caregivers to community-based services and supports that address the common needs of persons with dementia and their caregivers (e.g., home-delivered meals, adult day centers, personal care, environmental modifications, contractors, food banks), and/or ii) enter into a written agreement with a local Area Agency on Aging or a Tribal Aging Program (funded through Title VI of the Older Americans Act) requiring that the local Area Agency on Aging or Tribal Aging Program assists GUIDE Beneficiaries and their Caregivers with coordinating community-based services and supports.</p> <p><b>6.2</b> If the GUIDE Beneficiary is eligible for and receiving home- and community-based services (HCBS) through a state Medicaid program, the Participant shall contact and attempt to coordinate the delivery of community-based services and supports and HCBS with the GUIDE Beneficiary’s waiver/HCBS program case manager. Coordination between the Participant and the GUIDE Beneficiary’s waiver/HCBS program case manager shall include sharing information about the GUIDE Model and reviewing the services that the GUIDE Beneficiary receives through both the GUIDE Model and Medicaid for the purpose of understanding gaps or duplication in the GUIDE Beneficiary’s care.</p> <p><b>6.3</b> Participant shall join or maintain a community referral inventory system that includes resources for the health-related social needs screened as part of the Comprehensive Assessment (see Section 1.1.4.3), and the Care Navigator shall refer and connect the GUIDE Beneficiary and their Caregiver to resources relevant to their needs.</p> <p><b>6.4</b> Participant shall maintain, or have access to, an inventory of community-based resources for services and supports that address the common needs of persons with dementia and their Caregivers (e.g., home-delivered meals, adult day centers, personal care, environmental modification, contractors, food banks) and as appropriate, share these resources with the GUIDE Beneficiary and their Caregiver.</p>
<p style="text-align: center;"><b>7</b></p> <p style="text-align: center;"><b>Medication Management and Reconciliation</b></p>	<p><b>7.1</b> A clinician with prescribing authority shall review and reconcile the medications that GUIDE Beneficiary is taking at the time of the initial Comprehensive Assessment, at any additional future assessments, and then periodically as requested by other members of the Care Team, the GUIDE Beneficiary or the Caregiver, as appropriate. Medication review would customarily include, as part of this element, a review of prescription drugs, over-the-counter medications, supplements, natural treatments, and/or any other substances the GUIDE Beneficiary might be using for any purpose.</p> <p><b>7.2</b> If clinically advisable for the GUIDE Beneficiary, Participant’s advanced practice nurse, physician assistant, or physician shall consider prescribing medications that are beneficial for the GUIDE Beneficiary.</p> <p><b>7.3</b> If clinically advisable for the GUIDE Beneficiary, Participant’s advanced practice nurse, physician assistant, or physician shall de-prescribe any</p>

	<p>medications that are inappropriate for the GUIDE Beneficiary to continue taking.</p> <p><b>7.4</b> Participant shall share recommended changes to the GUIDE Beneficiary’s medications with the GUIDE Beneficiary’s primary care provider and other medical specialists, as applicable, and confirm that the relevant medical provider, either the primary care provider or the medical specialist, agrees to the proposed change to the GUIDE Beneficiary’s medications prior to the GUIDE Beneficiary changing their medications.</p> <p><b>7.5</b> Participant’s Care Navigator shall provide information on supports to help the GUIDE Beneficiary maintain the correct medication schedule, such as pill reminders, pill boxes, and/or software applications.</p>
<p style="text-align: center;"><b>8</b></p> <p style="text-align: center;"><b>Caregiver Education and Support</b></p>	<p><b>8.1</b> In order to provide education and support to the Caregiver of a GUIDE Beneficiary, Participant shall administer a caregiver support program, which is based on the caregiver assessment referred to in Section 1.2 and is responsive to ongoing Caregiver needs.</p> <p><b>8.2</b> The caregiver support program shall offer the following services:</p> <p><b>8.2.1</b> Caregiver skills training: Participant shall provide the Caregiver with the option to receive training to help the GUIDE Beneficiary continue to live as safely and comfortably as possible in the community. The training shall include the following topics: emergency services, safety in the home, assistance with activities of daily living (ADL) and instrumental ADLs, responding to and managing the GUIDE Beneficiary’s behavioral and psychosocial symptoms, identifying and obtaining help across the care continuum, working with health care and other community-based providers, recreation, social and leisure activities, making plans for the future, and caregiver self-care and stress management.</p> <p><b>8.2.2</b> Dementia diagnosis information: If GUIDE Beneficiary and/or Caregiver wish to receive further information regarding the GUIDE Beneficiary’s dementia diagnosis, Participant shall speak with and provide written educational materials to the Caregiver regarding the GUIDE Beneficiary’s dementia diagnosis. These materials may include, but are not limited to, information on dementia, common behavioral changes, functional status, and resources available publicly and through the Participant. These materials should be comprehensible to a lay person and in the primary language spoken by the GUIDE Beneficiary and the Caregiver.</p> <p><b>8.2.3</b> Support group services: Participant shall provide the Caregiver with the option to participate in a group setting where a facilitator trained in dementia and caregiving shall work with caregivers on self-care, home safety, caregiver skills, personal care, and managing challenging behaviors.</p> <p><b>8.2.4</b> Ad hoc one-on-one support calls: Participant shall be available for one-on-one support calls with the Caregiver to address issues in furnishing care and</p>

support to the GUIDE Beneficiary as the issues arise. For example, these calls may focus on the Caregiver's needs and goals by coaching caregivers on stress management, self-care and well-being behaviors, and how to identify and address behavioral challenges and functional status of the GUIDE Beneficiary, and support safety of the Caregiver, and the GUIDE Beneficiary. The calls may be initiated by the GUIDE Beneficiary, the Caregiver, or the Participant. The Participant's requirement to maintain minimum contact with the GUIDE Beneficiary in accordance with Section 4.3 may be used to satisfy this requirement for one-on-one support calls.

**8.3 Modality:** All services may be provided virtually or in-person. In addition, Participant shall deliver the services listed under Section 8.2 as follows:

**8.3.1 Caregiver skills training:** Must be provided by either a member of the Care Team or through a contracted vendor or community organization that is reimbursed by the Participant; may be provided in a one-on-one setting or group format.

**8.3.2 Dementia diagnosis information at program entry:** Must be provided directly by a member of the Care Team in a one-on-one setting.

**8.3.3 Support group services:** May be provided directly by a member of the Care Team, through a contracted vendor or community organization that is reimbursed by the Participant, or through referral to a community organization that offers support group services to the community free of charge. GUIDE Beneficiaries and Caregivers may decline to participate in support groups or change their mind about participation at any time.

**8.3.4 Ad hoc one-on-one support calls:** Must be provided directly by a member of the Care Team.

**8.4** In addition to the required services listed above, the Participant should consider whether to provide the following optional services:

**8.4.1 Peer-to-peer support:** Experienced caregivers, whose caregiving experience has come to an end, would provide practical information, and support and mentoring to the Caregiver.

**8.4.2 Resources or referrals for self-care and well-being instruction (e.g., group walks, meditation classes):** Specialized services centered around caregiver stress and health management. Services could include, but are not limited to, mindfulness and relaxation techniques, cognitive behavioral therapy, musical and arts classes, and exercise classes.

**8.4.3 Assist with education on the role of the caregiver:** Information on the traditional responsibilities of a caregiver for a person living with dementia and the resources available to them through the Participant.

**8.4.4 Accessing community-based resources:** Coaching the Caregiver on how to access community-based resources relevant to their caregiving role, such as transportation, nutrition support, homemaker/yard services. This service is in

	<p>addition to the referral support provided under Section 6 Referral and Coordination of Services and Supports.</p> <p><b>8.4.5</b> Psychological counseling referral: The Caregiver may work with a specialist on developing new behaviors or strategies to help address caregiving demands, identifying areas for improvement for the beneficiary-caregiver dyad, or assistance in addressing depression, anxiety, and suicidal ideation in the Caregiver and/or the GUIDE Beneficiary.</p>
<p style="text-align: center;"><b>9</b></p> <p style="text-align: center;"><b>Respite</b></p>	<p><b>9.1</b> Participant shall provide GUIDE Respite Services to Eligible Respite GUIDE Beneficiaries who choose to receive GUIDE Respite Services. GUIDE Respite Services are furnished based on the Eligible Respite GUIDE Beneficiary’s qualifying status. Participants and Eligible Respite GUIDE Beneficiaries shall decide how much GUIDE Respite Services the Eligible Respite GUIDE Beneficiary will receive taking into consideration the Eligible Respite GUIDE Beneficiary’s need for GUIDE Respite Services and the Respite Cap.</p> <p><b>9.2</b> Participant shall provide in-home GUIDE Respite Services directly or contract with at least one provider of in-home respite services. The contract must specify how the Participant will reimburse the respite provider for Respite Services rendered to Eligible Respite GUIDE Beneficiaries.</p> <p><b>9.3</b> Participant may also contract with adult day centers or facilities that can provide 24-hour care to deliver GUIDE Respite Services in these settings to Eligible Respite GUIDE Beneficiaries.</p>

## Appendix D: GUIDE Performance Measure Set

CMS will use the following performance measures for monitoring, evaluating the overall quality of care in the Model, and evaluating the Participant’s performance during the Agreement Performance Period. The Participant shall report on all measures identified as “Participant Reported” in the Data Source column of the table below.

<b>PBA Domain</b>	<b>Measure Name</b>	<b>Data Source</b>	<b>Level of Reporting</b>	<b>Type of Reporting by Participant</b>	<b>Reporting Frequency</b>
Care Coordination and Management	Use of High-Risk Medications in Older Adults MIPS #238, NQF #0022	Participant Reported	Beneficiary-level	Participant reported to CMS	Annually
Beneficiary Quality of Life	Quality of Life Outcome for People with Neurological Conditions MIPS #AAN22	Participant Reported	Beneficiary-level	Survey conducted by Participant and reported to CMS	Annually
Caregiver Support	Caregiver Burden Measure*	Participant Reported	Beneficiary-level	Survey conducted by Participant and reported to CMS	Annually
Utilization	Total Per Capita Cost (TPCC) NQF #3575	Claims-based	Practice-level	None. Calculated by CMS using Administrative Data	Annually
Utilization	Rate of beneficiaries entering a long-term nursing home stay (“LTNH measure”)	Claims-based	Beneficiary-level	None. Calculated by CMS using Administrative Data	Annually

\* The Caregiver Burden Measure is not available as of the Effective Date of this Agreement. CMS is researching the development of a measure for this purpose and will use a survey-based tool to capture the burden and strain caregivers encounter in their caregiving role. The measure development process could take several years.

## **Appendix E: Telehealth Benefit Enhancement**

Appendix E shall apply to this Agreement for any Performance Year in which the Participant selected in accordance with Article 7 the Telehealth Benefit Enhancement and for which CMS has not rejected the Participant's selection of the Telehealth Benefit Enhancement in accordance with Section 7.02(D).

### **A. Election of the Telehealth Benefit Enhancement.**

1. If the Participant wishes to offer the Telehealth Benefit Enhancement during a Performance Year, the Participant shall:
  - i. Timely submit to CMS its selection of the Telehealth Benefit Enhancement in accordance with Section 7.02; and
  - ii. Timely submit a true, accurate, and complete list of the GUIDE Practitioners that have agreed to participate in the Telehealth Benefit Enhancement.

### **B. Waiver.**

1. CMS waives the following requirements with respect to otherwise covered telehealth services furnished by an Eligible Telehealth Provider (as that term is defined in Paragraph C) to a GUIDE Beneficiary in accordance with the terms and conditions set forth in this Appendix:
  - i. Waiver of Originating Site Requirements. CMS waives the requirements in Section 1834(m)(4)(C) of the Social Security Act (“Act”) and 42 CFR § 410.78(b)(3)–(4) with respect to telehealth services furnished in accordance with this Appendix.
  - ii. Waiver of Originating Site Requirement in the Eligible Telehealth Individual Provision. CMS waives the requirement in Section 1834(m)(4)(B) of the Act that telehealth services be “furnished at an originating site” when the services are furnished in accordance with this Appendix.
  - iii. Waiver of Originating Site Facility Fee Provision. CMS waives the requirement in Section 1834(m)(2)(B) of the Act and 42 CFR § 414.65(b) with respect to telehealth services furnished to a GUIDE Beneficiary at his or her home when furnished in accordance with this Appendix.
2. The waivers described in this Section B of this Appendix are collectively referred to as the “**Telehealth Benefit Enhancement**”.

### **C. Eligible Telehealth Providers.**

1. For purposes of this Telehealth Benefit Enhancement, an “Eligible Telehealth Provider” is an individual who is:
  - i. A physician or non-physician practitioner listed at 42 CFR § 410.78(b)(2) who is a GUIDE Practitioner; and
  - ii. Authorized under relevant Medicare rules and applicable state law to bill for telehealth services; and
  - iii. Designated on the Election of Telehealth Benefit Enhancement as participating in the Telehealth Benefit Enhancement; and
  - iv. Approved by CMS according to the criteria described in this Appendix.
2. CMS's review and approval of a GUIDE Practitioner to provide services in accordance with the Telehealth Benefit Enhancement under this Appendix includes consideration of the program integrity history of the GUIDE Practitioner and any other factors that CMS determines may affect the qualifications of the GUIDE Practitioner to provide telehealth services under the terms of the Telehealth Benefit Enhancement.



**D. GUIDE Beneficiary Eligibility Requirements.**

1. In order for telehealth services to be eligible for reimbursement under the Telehealth Benefit Enhancement, the telehealth services must be furnished by an Eligible Telehealth Provider to a GUIDE Beneficiary that is located at an originating site that is either:
  - i. One of the sites listed in section 1834(m)(4)(C)(ii) of the Act; or
  - ii. The GUIDE Beneficiary's home or place of residence.
2. In the event that technical issues with telecommunications equipment required for telehealth services cause an inability to appropriately furnish such telehealth services, the Eligible Telehealth Provider shall not submit a claim for such telehealth services.
3. All telehealth services must be furnished in accordance with all other applicable state and Federal laws and all other Medicare coverage and payment criteria, including the remaining requirements of Section 1834(m) of the Act and 42 CFR §§ 410.78 and 414.65.
4. An Eligible Telehealth Provider shall not furnish telehealth services in lieu of in person services or encourage, coerce, or otherwise influence a GUIDE Beneficiary to seek or receive telehealth services in lieu of in person services when the Eligible Telehealth Provider knows or should know in person services are Medically Necessary.

**E. Responsibility for Denied Claims.**

1. If a claim for any telehealth services furnished by an Eligible Telehealth Provider under the Telehealth Benefit Enhancement is denied as a result of a CMS error and the Eligible Telehealth Provider did not know, and could not reasonably have been expected to know, as determined by CMS, that the claim would be denied, payment shall, notwithstanding such denial, be made by CMS for such telehealth services under the terms of the Telehealth Benefit Enhancement as though the coverage denial had not occurred.
2. If a claim for any telehealth services furnished by an Eligible Telehealth Provider is denied for any reason other than a CMS error and the Eligible Telehealth Provider did not know, and could not reasonably have been expected to know, as determined by CMS, that payment would not be made for such items or services under Part A or Part B of Title XVIII of the Act:
  - i. CMS shall, notwithstanding such denial, pay for such telehealth services under the terms of the Telehealth Benefit Enhancement as though the coverage denial had not occurred, but CMS will recoup these payments from the Participant. The Participant shall owe CMS the amount of any such payments, payable as other monies owed for that Performance Year;
  - ii. The Participant shall ensure that the Eligible Telehealth Provider that provided the telehealth services does not charge the GUIDE Beneficiary for the expenses incurred for such services; and
  - iii. The Participant shall ensure that the Eligible Telehealth Provider that provided the telehealth services returns to the GUIDE Beneficiary any monies collected from the GUIDE Beneficiary related to such services.
3. If a claim for any telehealth services furnished by an Eligible Telehealth Provider is denied and the Eligible Telehealth Provider knew, or reasonably could be expected to have known, as determined by CMS, that payment would not be made for such items or services under Part A or Part B of Title XVIII of the Act:
  - i. CMS shall not make payment to the Participant for such services;
  - ii. The Participant shall ensure that the Eligible Telehealth Provider that provided the telehealth services does not charge the GUIDE Beneficiary for the expenses incurred for such services; and
  - iii. The Participant shall ensure that the Eligible Telehealth Provider that provided the telehealth services returns to the GUIDE Beneficiary any monies collected from the GUIDE Beneficiary

related to such services.

4. If a GUIDE Practitioner that is not an Eligible Telehealth Provider submits claims for telehealth services for which CMS only would have made payment if the GUIDE Practitioner was an Eligible Telehealth Provider participating in this Telehealth Benefit Enhancement at the time of service:
  - i. CMS shall not make payment to the Participant for such services;
  - ii. The Participant shall ensure that the GUIDE Practitioner that provided the telehealth services does not charge the GUIDE Beneficiary for the expenses incurred for such services; and
  - iii. The Participant shall ensure that the Participant that provided the telehealth services returns to the GUIDE Beneficiary any monies collected from the GUIDE Beneficiary related to such services.

F. Compliance and Enforcement.

1. CMS may reject the Participant's designation of a GUIDE Practitioner as an Eligible Telehealth Provider at any time if the GUIDE Practitioner's participation in this Telehealth Benefit Enhancement might compromise the integrity of the Model.
2. The Participant shall have appropriate procedures in place to ensure that GUIDE Practitioners have access to the most up-to-date information regarding GUIDE Beneficiary alignment to the Participant.
3. In accordance with Article 16 of this Agreement, CMS may terminate or suspend one or more of the waivers under Paragraph B or take other remedial action if the Participant or any of its GUIDE Practitioners fail to comply with the terms and conditions of the Telehealth Benefit Enhancement.

## Appendix F: GUIDE Payment Tables

**Table 1: Model Tiers**

<b>Beneficiary Type</b>	<b>Tier</b>	<b>Criteria</b>	<b>Corresponding Assessment Tool Scores</b>
<b>Beneficiaries with a caregiver</b>	Low complexity dyad tier	Mild dementia	CDR= 1, FAST= 4
	Moderate complexity dyad tier	Moderate or severe dementia <i>AND</i> Low to moderate caregiver strain	CDR= 2-3, FAST= 5-7 <i>AND</i> ZBI= 0-60
	High complexity dyad tier	Moderate or severe dementia <i>AND</i> High caregiver strain	CDR= 2-3, FAST= 5-7 <i>AND</i> ZBI= 61-88
<b>Beneficiaries without a caregiver</b>	Low complexity individual tier	Mild dementia	CDR= 1, FAST= 4
	Moderate to high complexity individual tier	Moderate or severe dementia	CDR= 2-3, FAST= 5-7

**Table 2: Dementia Care Management Payment (DCMP) Base Payment Rates**

<b>Timeframe</b>	<b>Monthly payment rates for beneficiaries with caregiver</b>			<b>Monthly payment rates for beneficiaries without caregiver</b>	
	<b>Low complexity dyad tier</b>	<b>Moderate complexity dyad tier</b>	<b>High complexity dyad tier</b>	<b>Low complexity individual tier</b>	<b>Moderate to high complexity individual tier</b>
<b>First 6 months</b> (New Patient Payment Rate)	\$150	\$275	\$360	\$230	\$390
<b>After first 6 months</b> (Established Patient Payment Rate)	\$65	\$120	\$220	\$120	\$215

**Table 3: ICD-10 Dementia Diagnosis Codes**

<b>Codes:</b>
F01.xx*
F02.xx*
F03.xx*
F10.27
F10.97
F13.27
F13.97
F18.97
F19.17
F19.27
F19.97
G30.0
G30.1
G30.8
G30.9
G31.1
G31.2
G31.01
G31.09
G31.83
Eligible code list may change over time to reflect updates to ICD-10 codes. * “xx” represents any combination of numbers or letters as relevant to these ICD-10 Codes.

**Table 4: Medicare Physician Fee Schedule Services Included Under the DCMP**

<b>Service Type</b>	<b>HCPCS Codes</b>
Advance care planning	99497, 99498
Welcome to Medicare and Annual Wellness Visits	G0402, G0438, G0439
Home Health Care Plan Oversight	G0181
Hospice Care Plan Oversight	G0182
Cognitive Assessment and Planning	99483
Technology-based check-in services	G2012, G2252
Transitional Care Management	99495-99496
Chronic Care Management	99487, 99489-99491, 99437, 99439, G0506
Principal Care Management	99424–99427
Administration of patient-focused health risk assessment (HRA)	96160
Administration of caregiver-focused HRA	96161
Depression screening	G0444
Group Caregiver Behavior Management/Modification Training Services	96202, 96203
Caregiver Training Services under a Therapy Plan of Care established by a PT, OT, SLP	97550, 97551, 97552
Community Health Integration Services	G0019, G0022
Principal Illness Navigation Services	G0023, G0024, G0140, G0146
Administration of a Standardized, Evidence-based Social Determinants of Health Risk Assessment	G0136

**Table 5. Equity Score Percentiles and Associated Health Equity Adjustment Amounts**

<b>Equity Score Percentile</b>	<b>Health Equity Adjustment to DCMP</b>
≥80 <sup>th</sup> percentile of equity scores	<b>+\$15</b>
51 <sup>st</sup> -79 <sup>th</sup> percentile of equity scores	<b>\$0</b>
0-50 <sup>th</sup> percentile of equity scores	<b>-\$6</b>

**Table 6: Timing of Performance Year and Corresponding Performance-Based Adjustment**

Calendar Year	2025	2026	2027	2028	2029	2030	2031	2032
<b>Established Program Track</b>	<b>PY 1</b> 7/2024 – 6/2025	<b>PY 2</b> 7/2025 – 6/2026	<b>PY 3</b> 7/2026 – 6/2027	<b>PY 4</b> 7/2027 – 6/2028	<b>PY 5</b> 7/2028 – 6/2029	<b>PY 6</b> 7/2029 – 6/2030	<b>PY 7</b> 7/2030 – 6/2031	<b>PY 8</b> 7/2031 – 6/2032
			<b>PBA 1</b> 1/2026- 12/2026	<b>PBA 2</b> 1/2027- 12/2027	<b>PBA 3</b> 1/2028- 12/2028	<b>PBA 4</b> 1/2029- 12/2029	<b>PBA 5</b> 1/2030- 12/2030	<b>PBA 6</b> 1/2031- 12/2031
<b>New Program Track</b>	Pre- Implement- ation Year	<b>PY 1</b> 7/2025 – 6/2026	<b>PY 2</b> 7/2026 – 6/2027	<b>PY 3</b> 7/2027 – 6/2028	<b>PY 4</b> 7/2028 – 6/2029	<b>PY 5</b> 7/2029 – 6/2030	<b>PY 6</b> 7/2030 – 6/2031	<b>PY 7</b> 7/2031 – 6/2032
				<b>PBA 1</b> 1/2027- 12/2027	<b>PBA 2</b> 1/2028- 12/2028	<b>PBA 3</b> 1/2029- 12/2029	<b>PBA 4</b> 1/2030- 12/2030	<b>PBA 5</b> 1/2031- 12/2031

## **Appendix G: Medicare Waivers**

- A. **Beneficiary Cost Sharing.** In accordance with Section 1115A(d)(1) of the Act, CMS finds that it is necessary for purposes of testing the GUIDE Model to waive the requirements for beneficiary cost-sharing under Section 1833(a)(1)(N) and Section 1833(b) of the Act to the extent otherwise applicable for purposes of the DCMP and GUIDE Respite Payment. The Participant shall not subject GUIDE Beneficiaries to any cost-sharing for the DCMP or GUIDE Respite Payment.
- B. **Physician Fee Schedule.**
1. Section 1848(a)(1) of the Act requires that payment amounts for physicians' services be determined under the Physician Fee Schedule (PFS).
  2. Section 1833(a)(1)(O)(i) through (ii) of the Act specifies certain payment adjustments with respect to services described in Section 1861(s)(2)(K) of the Act relating to services furnished by physician assistants, nurse practitioners, or clinical nurse specialists.
  3. In accordance with Section 1115A of the Act, CMS finds that it is necessary for purposes of testing the GUIDE Model to waive the requirements under Section 1848(a)(1) of the Act, and Section 1833(a)(1)(O)(i) through (ii) of the Act, in order to allow the DCMPs and PBAs to be made as set forth in this Agreement.
- C. At any time and for any reason, CMS may withdraw or amend one or more waivers described herein. CMS will use its best efforts to provide the Participant with 30 Days' advance written notice of any changes to a waiver and the notice shall specify the effective date of such changes.