

Centers for Medicare & Medicaid Services (CMS)

Center for Medicare and Medicaid Innovation

Seamless Care Models Group

7500 Security Blvd, Baltimore, MD 21244

Long-term Enhanced ACO Design (LEAD)

Model Implementation Period Participation Agreement

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LEAD MODEL IMPLEMENTATION PERIOD PARTICIPATION AGREEMENT

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

An **Accountable Care Organization (“ACO”)**.

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 ACO is an entity composed of health care providers operating under a common legal structure, which accepts financial accountability for the overall quality and cost of medical care furnished to **Medicare Fee-For-Service (“FFS”)** Beneficiaries aligned to the entity.

CMS is implementing the **Long-term Enhanced ACO Design Model** (hereinafter referred to as “**LEAD**” or “**Model**”) under **Section 1115A of the Social Security Act (“Act”)**, which authorizes CMS, through its **Center for Medicare and Medicaid Innovation (“Innovation Center” or “CMMI”)**, to test innovative payment and service delivery models that have the potential to reduce Medicare, Medicaid, or Children’s Health Insurance Program expenditures while maintaining or improving the quality of Beneficiaries’ care.

Built on lessons from prior ACO models and programs, including **ACO REACH, the Next Generation ACO Model**, and the **Medicare Shared Savings Program**, LEAD aims to accelerate the delivery of value-based care and increase savings to the Medicare Trust Fund by incentivizing providers to deliver preventive, coordinated care while empowering Medicare Beneficiaries to take greater control of their health. With a 10-year performance period, LEAD offers a predictable performance period without rebasing and a pathway toward sustainable long-term benchmarks and savings. LEAD also will focus on delivering coordinated care to High Needs Beneficiaries, including those dually eligible for Medicare and Medicaid and those who are homebound or home limited.

In anticipation of LEAD’s Agreement Performance Period (as defined in Article I, Section 1.03 below), CMS has established an optional Implementation Period (as defined in Article I, Section 1.02 below), September 15, 2026 through December 31, 2026, during which ACOs who have been accepted into LEAD (i.e., LEAD ACOs, as defined in Article II below) may prepare for the Agreement Performance Period, which begins on January 1, 2027. During the Implementation Period, LEAD ACOs may perform prospective Voluntary Alignment activities (as defined in Article II below), as an ACO’s alignment will establish the parameters of its alternative payment under LEAD. LEAD ACOs may also perform marketing, care coordination, and quality improvement activities during the Implementation Period.

This Implementation Agreement outlines the rights and obligations of the parties during the optional Implementation Period. The Implementation Period will be followed by an Agreement Performance Period that will be governed by a separate agreement between CMS and the ACO. Signing this Implementation Agreement does not obligate the undersigned ACO to participate in LEAD during the Agreement Performance Period. Conversely, choosing not to sign this

Implementation Agreement does not prevent an accepted applicant from participating in LEAD during the Agreement Performance Period.

The undersigned ACO submitted applied to participate in the Model, and CMS selected the ACO for participation in the Model. Therefore, the parties agree as follows:

ARTICLE I IMPLEMENTATION AGREEMENT TERMS

Section 1.01 Effective Date

The Implementation Agreement becomes effective when signed by the last party to sign it (as indicated by that party's dated signature) (the "**Effective Date**").

Section 1.02 Implementation Period

The performance period of this Implementation Agreement ("**Implementation Period**") begins on September 15, 2026 (the "**Start Date**") and ends at 11:59 PM ET on December 31, 2026, unless the Implementation Period or this Implementation Agreement is sooner terminated by either party in accordance with Article XIII, in which case the Implementation Period ends on the day specified in writing by CMS.

Section 1.03 Agreement Performance Period

"**Agreement Performance Period**" means, regardless of the duration of the Implementation Period, the period that begins on January 1, 2027, and ends on December 31, 2036, unless the Agreement Performance Period or the Agreement is sooner terminated by either party in accordance with Article XVIII. The Agreement Performance Period consists of the following 10 Performance Years:

1. **Performance Year 1** (Performance Year 2027): January 1, 2027 – December 31, 2027
2. **Performance Year 2** (Performance Year 2028): January 1, 2028 – December 31, 2028
3. **Performance Year 3** (Performance Year 2029): January 1, 2029 – December 31, 2029
4. **Performance Year 4** (Performance Year 2030): January 1, 2030 – December 31, 2030
5. **Performance Year 5** (Performance Year 2031): January 1, 2031 – December 31, 2031
6. **Performance Year 6** (Performance Year 2032): January 1, 2032 – December 31, 2032
7. **Performance Year 7** (Performance Year 2033): January 1, 2033 – December 31, 2033
8. **Performance Year 8** (Performance Year 2034): January 1, 2034 – December 31, 2034
9. **Performance Year 9** (Performance Year 2035): January 1, 2035 – December 31, 2035
10. **Performance Year 10** (Performance Year 2036): January 1, 2036 – December 31, 2036

Section 1.04 Expiration or Termination

This Implementation Agreement will automatically expire at the conclusion of the

Implementation Period, unless sooner terminated by either party. To participate in LEAD during the Agreement Performance Period, LEAD ACOs must sign a new agreement with CMS (**Model Participation Agreement**).

ARTICLE II DEFINITIONS

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

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

“Advanced Payment Option (APO)” is a LEAD payment alternative for non-primary care services provided by Preferred Providers and/or Participant Providers to ACO-aligned LEAD Beneficiaries, available to ACOs who have elected Primary Care Capitation Payment. The APO is based upon the aligned Beneficiaries’ historical Medicare Parts A and B costs and serves as an advance on expected FFS spending.

“At-Risk Beneficiary” means a Beneficiary who (1) has a high risk score on the CMS-Hierarchical Condition Category (HCC) risk adjustment model; (2) is considered high cost due to having two or more hospitalizations or emergency room visits each year; (3) is dually eligible for Medicare and Medicaid; (4) has a high utilization pattern; (5) has one or more chronic conditions; (6) has had a recent diagnosis that is expected to result in increased cost; (7) is entitled to Medicaid because of disability; (8) is diagnosed with a mental health or substance use disorder; or (9) meets such other criteria as specified in writing by CMS.

“Base Primary Care Capitation Amount” refers to one of two components of the Primary Care Capitation Payment. The Base Primary Care Capitation Amount for an ACO is the average primary care spending on Primary Care Capitation Payment-eligible services for aligned individuals, billed in a historical period by all Participant Providers with primary care specialties and Preferred Providers participating in the primary care capitation payment. The Base Primary Care Capitation Amount is included as a Performance Year expenditure in the calculation of Shared Savings and Shared Losses for the Performance Year.

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

“Beneficiary Alignment” means the process by which CMS identifies the Beneficiary population for which an ACO may be appropriately designated as exercising basic responsibility for that Beneficiary population’s care during a given benchmark or Performance Year.

“Beneficiary Engagement Incentives” are optional incentives that an ACO may choose to make

available to LEAD Beneficiaries through Participant TINs, Participant Providers, and Preferred Providers to encourage Beneficiary engagement in high-value care. ACOs may select one or more Beneficiary Engagement Incentives to make available to LEAD Beneficiaries pursuant to Section 8.02.D.

“**Benefit Enhancements**” are a variety of enhanced benefits that the ACO may choose to make available each Performance Year to LEAD Beneficiaries through Participant TINs, Participant Providers, and Preferred Providers to support high-value services and allow the ACO to more effectively manage the care of LEAD Beneficiaries. During the Implementation Period, the ACO may select one or more Benefit Enhancements for the ACO’s first Performance Year pursuant to Section 8.02.D.

“**Capitation Payment Mechanism**” means a payment mechanism that may be selected by the ACO for the ACO’s first Performance Year pursuant to Section 8.02.B, under which CMS will make periodic payments to the ACO during that Performance Year. The Capitation Payment Mechanisms available for selection include PCC Payment and TCC Payment.

“**CARA**” or “**CMS-Administered Risk Arrangements Initiative**” means the Innovation Center initiative and innovative payment mechanism that facilitates downstream **Episode-Based Risk Arrangements (EBRAs)** between ACOs that elect the Global Risk Option and their specialty care providers (i.e., Preferred Providers).

“**CCN**” means a CMS Certification Number.

“**Claims-based Alignment**” means an analysis of certain “**Primary Care Qualified Evaluation & Management (PQEM)**” services furnished to Beneficiaries by Participant Providers in LEAD ACOs, Federally Qualified Health Centers, Rural Health Centers, and Method II Critical Access Hospitals. Claims-based Alignment shall be used during the Agreement Performance Period to align Beneficiaries to LEAD ACOs as described in Section 5.06.

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

“**Days**” means calendar days unless otherwise specified.

“**Discount**” means a fixed percentage adjustment to an ACO’s historical expenditures. A Discount is used to determine the Performance Year Benchmark for ACOs participating in the Global Risk Option.

“**Dual Eligible**” means individuals who are entitled to or enrolled in Medicare Part A and/or Part B and are eligible for some form of Medicaid benefit.

“**Enhanced PCC**” or “**Enhanced Primary Care Capitation**” refers to one of two components of the Primary Care Capitation Payment. The Enhanced PCC Amount is intended to enable an ACO to make upfront investments in infrastructure, technology, tools, and resources to support increased access to primary care, provision of care, and care coordination. The maximum Enhanced PCC amount that an ACO is eligible to receive is the larger of (1) the difference between seven percent of the Performance Year Benchmark and the estimated Base Primary Care Capitation Amount, or (2) two percent of the Performance Year Benchmark. CMS will

recoup the Enhanced Primary Care Capitation Amount in full at the close of the relevant Performance Year.

“Enhanced PCC Percentage” means the percentage that will be multiplied by the Performance Year Benchmark to determine the Enhanced PCC Amount except as otherwise specified in the Model Participation Agreement, referenced in Section 1.04 of this Implementation Agreement.

“EBCM” or **“Episode-Based Cost Measures”** are used in the LEAD Model under CARA to assess the risk-adjusted cost to Medicare for items and services furnished under Medicare Parts A and B during a specific episode of care.

“EBRAs” or **“Episode-Based Risk Arrangements”** are the financial partnerships between LEAD ACOs and Preferred Providers centered around episodes of care where the Preferred Provider is accountable for the cost and quality of care delivered during specific clinical episodes for ACO-aligned Beneficiaries.

“Fee-for-Service (FFS)” is Medicare’s original payment model in which health care providers are reimbursed for each specific test, visit, or procedure they perform, rather than for the overall quality or outcome of care.

“Fee Reduction” refers to a reduction in Medicare FFS payments to all Participant TINs, Participant Providers and relevant Preferred Providers who, pursuant to a written agreement with either the ACO or the Participant TIN through which they bill Medicare, have agreed to receive such Fee Reduction for covered services furnished to LEAD Beneficiaries under the ACO’s selected Capitation Payment Mechanism.

“Financial Methodology” includes: (1) LEAD’s benchmarking methodology; (2) LEAD’s risk-sharing options, risk mitigation, and financial settlement; and (3) LEAD’s payment mechanisms and claims reductions.

“Financial Settlement” means the process during which CMS compares the ACO’s final Performance Year benchmark against the ACO’s Performance Year expenditures for LEAD Beneficiaries to determine the amount of Shared Savings or Shared Losses, calculates Other Monies Owed, and calculates the net amount owed by either CMS or the ACO for the Performance Year.

“High Needs Beneficiaries” are Beneficiaries with complex health care needs who meet the high needs eligibility criteria for the LEAD Model. Once a Beneficiary meets the High Needs eligibility criteria, the Beneficiary shall be considered High Needs as long as the Beneficiary is aligned to a LEAD ACO, as Beneficiaries in this population are unlikely to experience a radical improvement in health status. A High Needs Beneficiary:

1. Possesses one or more conditions that impair a Beneficiary’s mobility, as identified through Mobility Impairment ICD-10 Codes;
2. Exhibits frailty signs, evidenced by a claim for a hospital bed or transfer equipment for use in the home;
3. Meets a comprehensive definition of frailty as measured by a score of 0.35 or greater, as measured by the Claims-based Frailty Index developed by Doctor Dae Hyun Kim;

4. Has at least one significant chronic condition or other serious illness that is defined as having a hierarchical condition category risk score of 3.0 or greater for “**Aged and Disabled (A&D)**” Beneficiaries measured using either: (a) the 2024 CMS “**Hierarchical Condition Categories (HCC)**” Risk Adjustment Model (Version 28) or (b) the CMMI HCC Concurrent Risk Adjustment Model V1, which was used in ACO REACH;
5. Has a risk score of 0.35 or greater for “**End-Stage Renal Disease (ESRD)**” Beneficiaries measured using the 2023 CMS-HCC ESRD Risk Adjustment Model for the ESRD Beneficiaries;
6. Has a risk score between 2.0 and 3.0 for A&D Beneficiaries measured using the 2024 CMS- HCC Risk Adjustment Model (Version 28) or a risk score between 0.24 and 0.35 for ESRD Beneficiaries measured using the 2023 CMS-HCC ESRD Risk Adjustment Model for the ESRD Beneficiaries, and two or more unplanned hospital admissions in the previous 12 months;
7. Has qualified and received at least 45 Medicare-covered Days in a Skilled Nursing Facility within the past 12 months.

“**Hybrid Alignment**” is one of the two alignment processes used to (1) calculate the financial benchmarks for individual LEAD ACOs; and (2) determine which Beneficiaries are aligned to the ACO for monthly capitated payments.

Through Hybrid Alignment, LEAD ACOs are able to: (1) add new Participant TINs during biannual periods (i.e., mid-Performance Year) via Claims-based alignment; and (2) add Beneficiaries via Voluntary Alignment on a monthly basis.

“**Implementation Plan**” refers to a plan for implementing each Benefit Enhancement and each Beneficiary Engagement Incentive selected by the ACO, to be developed in accordance with the requirements in the Model Participation Agreement referenced in Section 1.04.

“**Implementation Period**” means the period, September 15, 2026 – December 31, 2026, described in Section 1.02 during which the ACO may engage in Voluntary Alignment Activities, including Marketing Activities; care coordination; quality improvement program development; and other activities as needed to prepare for participation in the Agreement Performance Period.

“**Key Executives**” means individuals who manage or have oversight responsibility for the organization, its finances, personnel, quality improvement, and compliance, including without limitation, a Chief Executive Officer (CEO), Chief Financial Officer (CFO), Chief Operations Officer (COO), Chief Informational Officer (CIO), medical director, compliance officer, or an individual responsible for maintenance and stewardship of clinical data.

“**LEAD ACO**” means an ACO that has applied to participate in the LEAD Model; been selected to participate by CMS; and that participates or intends to participate in LEAD during the Agreement Performance Period.

A. A LEAD ACO is also:

1. A legal entity identified by a Federal TIN and formed under applicable Federal, State, and/or Tribal law; and authorized to conduct business in

each State in which it operates, including:

- a. Performing ACO Activities required under this Implementation Agreement;
 - b. Receiving and distributing Shared Savings;
 - c. Repaying Shared Losses or Other Monies Owed to CMS;
 - d. Establishing, reporting, and ensuring Participant TIN, Participant Provider, and Preferred Provider compliance with health care quality criteria, including quality performance standards.
2. An organization, comprised of health care providers (i.e., Participant TINs, Participant Providers, and Preferred Providers), that has or intends to assume accountability for the cost and quality of aligned Beneficiaries' Medicare Parts A and B medical care via LEAD.
 3. An ACO that passed a CMS Program Integrity Screening with satisfactory results.
 4. Prohibited from participating in any other Medicare Shared Savings initiative or CMS Innovation Center model that prohibits simultaneous participation in LEAD; and
 5. A separate legal entity with a different TIN than the TINs of the Participant TINs that comprise it, if the ACO is comprised of at least two or more Participant TINs.
- B. If the ACO is comprised of a single Participant TIN, under which all the ACO's Participant Providers bill, that Participant TIN may be the ACO's TIN. The ACO and the Participant TIN are one legal entity. The ACO and the Participant TIN may share a governing body if the ACO satisfies the requirements of Section 3.02.
- C. The ACO is not required to be a Medicare-enrolled provider or supplier.

“LEAD Beneficiary” means a Medicare Beneficiary who has been aligned to a LEAD ACO for a given Performance Year as described in Article V of this Implementation Agreement.

“Legacy TIN or CCN” means a TIN or CCN that a Participant Provider or Preferred Provider previously used for billing Medicare Parts A and B services but no longer uses to bill for those services, and includes a “sunsetted” Legacy TIN or CCN (a TIN or CCN that is no longer used for billing for Medicare Parts A and B services by any Medicare-enrolled provider or supplier) or an “active” Legacy TIN or CCN (a TIN or CCN that may be in use by a Medicare-enrolled provider or supplier that is not a Participant Provider or Preferred Provider).

“Letter of Intent” (“LOI”) refers to the letter to be drafted by the executive of a Participant TIN to state the Participant TIN's intention to participate in LEAD and in an ACO. LOIs must meet the requirements of Section 3.04.G.1-2.

“Marketing Activities” means the distribution of Marketing Materials and other activities

conducted by or on behalf of the ACO or its Participant TINs, Participant Providers or Preferred Providers, when used to educate, notify, or contact Beneficiaries regarding the ACO's participation in LEAD.

“Marketing Events” means Marketing Activities that are events designed to educate Beneficiaries about the ACO's participation in LEAD.

“Marketing Materials” means general audience materials such as brochures, advertisements, outreach events, letters to Beneficiaries, webpages published on a website, mailings, social media, or other materials sent by or on behalf of the ACO or its Participant TINs, Participant Providers or Preferred Providers, when used to educate, notify, or contact Beneficiaries regarding the ACO's participation in the Model. Marketing Materials do not include communications that do not directly or indirectly reference the Model (for example, information about care coordination generally would not be considered Marketing Materials); materials that cover Beneficiary-specific billing and claims issues; educational information on specific medical conditions; referrals for health care items and services; and any other communications or materials that are excepted from the definition of “marketing” under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (45 CFR Part 160 & Part 164, subparts A and E).

“Medically Necessary” means reasonable and necessary as determined in accordance with Section 1862(a) of the Act.

“MVA” or “Medicare.gov Voluntary Alignment” and means the process by which a Beneficiary may voluntarily align with the ACO by designating a Participant Provider as the Beneficiary's primary clinician on Medicare.gov or any successor site. CMS uses the Beneficiary's Medicare.gov Voluntary Alignment in performing Beneficiary Alignment as described in Section 5.02 and Appendix C.

“Newly Entering ACO” means an ACO that CMS selected to participate in the LEAD Model prior to the Effective Date that has: (1) no prior performance in a Medicare-sponsored ACO initiative (including ACO REACH and the Medicare Shared Savings Program); (2) has a total number of Participant TINs with less than 40 percent having participated in a Medicare ACO Initiative in the previous 5 years, and (3) has a total number of Participant Providers with fewer than 50 percent having participated in a Medicare ACO Initiative in the previous 5 years.

“Non-Primary Care Capitation (NPCC)” refers to the monthly prospective, population-based payment from CMS to an ACO for non-primary care services provided to ACO-aligned LEAD Beneficiaries by all Participant TINs, Participant Providers, and those Preferred Providers who have opted to participate in NPCC.

“Other Monies Owed” means a monetary amount owed by either party to the Model Participation Agreement that is owed to CMS or its designee by the LEAD ACO or vice versa that is neither Shared Savings nor Shared Losses.

“NPI” means a “National Provider Identifier.”

“Original Medicare” has the meaning given at 42 C.F.R. § 422.2 and refers to health insurance available under Medicare Part A and Part B through the traditional fee-for service payment

system.

“Participant Provider” means an individual or entity that satisfies the requirements of Section 4.01.B.

“Participant TIN” means an individual or entity that satisfies the requirements of Section 4.01.A.

“Participant TIN List” refers to the list of Participant TINs that participate in the ACO in a given Performance Year. After the ACO identifies and lists its Participant TINs, the Participant TIN List is submitted to CMS. CMS will automatically add all NPIs and CCNs associated with the Participant TINs on the list, generally Participant Providers who furnish primary care services and bill Medicare through the ACO’s Participant TINs.

“PCC Payment” or **“Primary Care Capitation Payment”** refers to the Capitation Payment Mechanism applicable to the Agreement Performance Period, available for selection by the ACO pursuant to Section 8.02.B.

“Performance-Based Risk” refers to an initiative implemented by CMS that requires an ACO to participate under a two-sided model during the Agreement Performance Period.

“Performance Year (PY)” means the 12-month period beginning on January 1 of each year during the Agreement Performance Period. If CMS and the ACO execute the Model Participation Agreement referenced in Section 1.04 allowing the ACO to participate in the Agreement Performance Period, the ACO’s first PY will begin on January 1, 2027.

“Performance Year Benchmark” or **“PY Benchmark”** refers to a risk-adjusted and trended prospective estimate of payments an ACO could expect to receive in exchange for the Medicare Part A and Part B items and services provided to the ACO’s aligned Beneficiary population in a specific PY, determined in accordance with LEAD’s Financial Methodology. At the conclusion of the PY, the PY Benchmark is compared to the actual cost of the Medicare Part A and Part B services provided to LEAD Beneficiaries to calculate Shared Losses or Shared Savings, as defined below.

“Person or Entity with an Ownership or Control Interest” refers to a person or entity that (1) has an ownership or control interest equal to 5 percent (5%) or more in the subject entity; (2) has an indirect ownership interest equal to 5 percent (5%) or more in the subject entity; (3) has a combination of direct and indirect ownership interests equal to 5 percent (5%) or more in the subject entity; or (4) has an ownership interest equal to 5 percent (5%) or more in any mortgage, deed of trust, note, or other obligation secured by a subject entity if that interest equals at least 5 percent (5%) of the value of the property or assets of the subject entity.

“Preferred Provider” means an individual or entity that satisfies the requirements of Section 4.01.C.

“Preferred Provider List” refers to the list that identifies each Preferred Provider that is approved by CMS for participation in the LEAD Model and specifies which Preferred Providers, if any, have agreed to participate in the ACO’s selected Capitation Payment Mechanism and designates the Benefit Enhancements and Beneficiary Engagement Incentives, and Healthy Living Flexibilities if any, in which each Preferred Provider participates, as updated from time to

time in accordance with the Model Participation Agreement.

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

“Primary Care Services” means all health care services and laboratory services customarily furnished by or through a Primary Care Specialist. CMS will provide the ACO with a list of codes that will be considered Primary Care Services for purposes of the ACO’s first PY prior to January 1, 2027.

“Primary Care Specialist” means either a:

- A. Physician who specializes in primary care or a physician who serves as the usual source of primary care for LEAD Beneficiaries who do not otherwise have a primary care relationship established via Voluntary or Claims-based Alignment. Primary care physicians’ specialties might include, but will not be limited to general practice, family medicine, internal medicine, obstetrics and gynecology, pediatric medicine, geriatric medicine, psychiatry. CMS will determine acceptable physician specialties based upon the National Plan & Provider Enumeration System (NPPES) and the Medicare Provider Enrollment, Chain, and Ownership System (PECOS). CMS will provide the ACO with a list of codes that will be considered Primary Care Services before the start of the Agreement Performance Period (January 1, 2027); or
- B. Non-Physician Practitioner such as a nurse practitioner, physician assistant, or clinical nurse specialist, that provides primary care services to LEAD Beneficiaries.

“Program Integrity Screening” means a review of an individual’s or entity’s current status and/or history, including, but not limited to, past or present eligibility status; exclusion or other sanctions imposed with respect to participation in Medicare, Medicaid, or the Children’s Health Insurance Program (CHIP); failure to pay Medicare debts in a timely manner; current or prior law administrative or law enforcement investigations and/or actions; organizational affiliation with individuals or entities with a documented history of program integrity issues; and other information pertaining to individual or organizational trustworthiness.

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

“Prospective Alignment” is one of two alignment processes used to: (1) calculate the financial benchmarks for individual LEAD ACOs; and (2) determine which Beneficiaries are aligned to the ACO for monthly capitated payments. Prospective alignment (unlike Hybrid Alignment) is performed only at the start of each PY.

“Risk Option” means either the Professional Risk Option or the Global Risk Option, chosen by the ACO at the time of LEAD application, used to determine preliminary benchmarks and financial guarantee estimates.

Under the lower risk **“Professional Risk Option”** an ACO assumes up to 50 percent risk for

savings or losses relative to its established PY benchmark and must select Primary Care Capitation Payment (PCC) as its Capitation Payment Mechanism. ACOs that elect the Professional Risk Option with PCC may also choose between NPCC or the APO. ACOs that elect the Professional Risk Option will be required to stay in that option for at least 4 Model PYs, after which time they would have the opportunity (but would not be required) to transition to the Global Risk Option.

Under the higher risk **“Global Risk Option”** an ACO assumes up to 100 percent risk for savings or losses relative to its established PY benchmark and can select either Total Care Capitation Payment or Primary Care Capitation Payment as its Capitation Payment Mechanism. If ACOs under the Global Risk Option elect PCC, they may also choose either NPCC or the APO. Newly Entering ACOs that elect the Global Risk Option for their first PY may switch to the Professional Risk Option for subsequent PYs, but only prior to the start of the pending PY during the period set by CMS for annual updates.

“Shared Losses” means any monetary amount the ACO owes to CMS due to expenditures for Medicare Parts A and B items and services furnished to LEAD Beneficiaries during a PY (inclusive of capitated payments under Total Care Capitation payment or Primary Care Capitation payment as well as FFS claims paid by CMS directly to Medicare providers and suppliers) in excess of the ACO’s final PY Benchmark for that PY. CMS determines Shared Losses in accordance with the ACO’s selected Risk Option and selected Capitation Payment Mechanism, pursuant to LEAD’s Financial Methodology, included in the Model Participation Agreement, referenced in Section 1.04 of this Implementation Agreement.

“Shared Savings” means the monetary amount the ACO owes to CMS due to expenditures for Medicare Parts A and B items and services furnished to LEAD Beneficiaries during a PY (inclusive of capitated payments under Total Care Capitation payment or PCC payment as well as FFS claims paid by CMS directly to Medicare providers and suppliers) that are lower than the ACO’s final PY Benchmark for that PY. CMS determines Shared Savings in accordance with the ACO’s selected Risk Option and selected Capitation Payment Mechanism.

“SVA” or “Signed Attestation-based Voluntary Alignment” and means the process by which a Beneficiary may voluntarily align with the ACO by using a Voluntary Alignment Form to designate a Participant TIN as their main provider and/or place they receive care. In addition to the Participant TIN, the Beneficiary may add his/her Participant Provider to the form as well. CMS will use the Beneficiary’s Voluntary Alignment Form in performing Beneficiary alignment for the ACO’s first PY as described in Appendix C.

“Start-up Arrangement” means an arrangement between the ACO and one or more Participant TINs, Participant Providers, or Preferred Providers for items, services, facilities, or goods (including non-medical items, services, facilities, or goods) that are used to create, develop, or operate the ACO.

“TIN” means a Federal Taxpayer Identification Number.

“TCC Fee Reduction” or “Total Care Capitation Payment Fee Reduction” means a full or partial reduction in Medicare FFS payments applied to all Participant TINs, Participant Providers, and those Preferred Providers who have agreed to receive such reduced payments for

Covered Services furnished to LEAD Beneficiaries to account for the monthly payments made by CMS to the ACO under TCC Payment.

“TCC Payment” or **“Total Care Capitation Payment”** is a LEAD Capitation Payment Mechanism, available to ACOs participating in the Global Risk Option and applied during the Agreement Performance Period. ACOs elect to receive TCC payment pursuant to Section 8.02.B of this Implementation Agreement.

For ACOs that elect TCC, TCC payment will cover all Medicare services provided to aligned Beneficiaries by all Participant TINs and by the Preferred Providers who have chosen to participate in TCC Payment. The ACO chooses the applicable percentage of fee reduction for its Preferred Providers, which means that Preferred Providers may receive some, all, or none of their payments through TCC payments.

“Voluntary Alignment” is the process whereby CMS aligns to an ACO those Beneficiaries who have designated a Participant TIN or Participant Provider as their primary clinician or main source of care. A Beneficiary who indicates that a Participant TIN or Provider/Supplier is his or her primary clinician or main source of care generally will be aligned to the ACO, even if the Beneficiary would not otherwise be aligned to the ACO based on Claims-based Alignment. Voluntary Alignment includes both MVA and SVA.

“Voluntary Alignment Activities” means any Marketing Activities or other activities conducted by, or on behalf of the ACO or its Participant TINs and/or Participant Providers, when used for purposes of educating, notifying, or contacting Beneficiaries regarding Voluntary Alignment.

“Voluntary Alignment Form” has the meaning set forth in Appendix C.

ARTICLE III ACO COMPOSITION AND FINANCIAL ARRANGEMENTS

Section 3.01 ACO Legal Entity

- A. The ACO shall be a legal entity identified by a TIN formed under applicable State, Federal, or Tribal law, and authorized to undertake the activities required under this Implementation Agreement in each state in which it operates.
- B. If the ACO was formed by two or more Participant TINs, the ACO shall be a legal entity separate from the legal entity of any of its Participant TINs.
- C. If the ACO was formed by a single Participant TIN, the ACO’s legal entity and governing body may be the same as that of the Participant TIN.
- D. The ACO is not required to be a Medicare-enrolled provider or supplier.

Section 3.02 ACO Governance

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

- a. The governing body has responsibility for oversight and strategic direction of the ACO and is responsible for holding ACO management accountable for the ACO's activities;
 - b. The governing body is separate and unique to the ACO, except as permitted under Section 3.01.C;
 - c. The governing body has a transparent governing process;
 - d. When acting as a member of the governing body of the ACO, each governing body member has a fiduciary duty to the ACO, including the duty of loyalty, and shall act consistent with that fiduciary duty;
 - e. The governing body shall receive regular reports from the designated compliance official of the ACO who satisfies the requirements of Section 11.01.
 - f. The governing body members may serve in similar or complementary roles or positions for Participant Providers or Preferred Providers, subject to Section 3.02.C.
 - 2. The ACO shall provide each member of the governing body with a copy of this Implementation Agreement and any amendments hereto.
 - 3. If CMS determines that the composition of the ACO's governing body, executive leadership, or parent organization compromises the ACO's ability to participate in the Model or to comply with the terms of the Agreement, CMS may take one or more of the remedial actions specified in Section 13.01.
 - 4. The ACO shall ensure that its governing body implements a process for documenting governing body composition, meetings and decisions, and shall retain such documentation in accordance with Article XII of this Agreement.
- B. Composition and Control of the Governing Body
- 1. At least 75 percent control of the ACO's governing body shall be held by individual Participant Providers, Preferred Providers, or their designated representatives.
 - a. For purposes of this requirement, a designated representative must be an individual employed by or under contract with the Participant Provider or Preferred Provider.
 - b. Any exception to the 75 percent control requirement will be at the sole discretion of CMS.
 - 2. The ACO's governing body shall not include a Prohibited Participant, or an owner, employee or agent of a Prohibited Participant.
 - 3. The ACO governing body shall also include either:
 - a. At least one or more Beneficiaries or Beneficiary's Caregivers, served by the ACO, or

- b. a Beneficiary and Consumer Advisory Committee.
- 4. In calculating governing body membership and control, the Beneficiary or Beneficiary's Caregiver must be considered and included in both the numerator and the denominator when calculating the percent control.

C. Beneficiary or Beneficiary's Caregiver.

- 1. The ACO governing body may include at least one or more Beneficiaries served by the ACO ("**Beneficiary Representative(s)**") who:
 - a. Does not have a conflict of interest with the ACO;
 - b. Has no immediate family member with a conflict of interest with the ACO;
 - c. Is not a Participant Provider or Preferred Provider;
 - d. Does not have a direct or indirect financial relationship with the ACO, a Participant TIN, a Participant Provider, or a Preferred Provider, except that such person may be reasonably compensated by the ACO for his or her duties as a member of the governing body of the ACO; and
 - e. Has voting rights on the ACO's governing body.
- 2. A Beneficiary's Caregiver may serve in the place of a Beneficiary being served by the ACO as long as the following requirements are met.
 - a. Does not have a conflict of interest with the ACO;
 - b. Has no immediate family member with a conflict of interest with the ACO;
 - c. Is not a Participant Provider or Preferred Provider;
 - d. Does not have a direct or indirect financial relationship with the ACO, a Participant TIN, a Participant Provider, or a Preferred Provider, except that such person may be reasonably compensated by the ACO for his or her duties as a member of the governing body of the ACO; and
 - e. Has voting rights on the ACO's governing body.

D. Beneficiary and Consumer Advisory Committee

If the ACO chooses to establish a Beneficiary and Consumer Advisory Committee to meet the requirement at Section 3.02.B.3, the following criteria must be met:

- 1. The Beneficiary and Consumer Advisory Committee must have a minimum of five members.
- 2. The Beneficiary and Consumer Advisory Committee must reflect a reasonably representative sample of the ACO's aligned beneficiaries, including geography and demographics.

3. The Beneficiary and Consumer Advisory Committee must meet at least twice per calendar year.
4. The Beneficiary and Consumer Advisory Committee must document its meetings.
5. The ACO must have a process through which the Beneficiary and Consumer Advisory Committee shall submit its ideas for consideration in the ACO's leadership and governance decision-making process.

E. Conflict of Interest

1. The ACO shall have conflict of interest policy that applies to members of the governing body and satisfies the following criteria:
 - a. The governing body must have processes and procedures to determine whether a conflict of interest exists and to address any conflicts that arise; and
 - b. Applicable policy must include remedial actions for governing body members who fail to comply with the policy; and
 - c. Each member of the governing body must disclose relevant financial interests.

Section 3.03 ACO Leadership, Management, and Ownership

- A. The ACO's operations shall be managed by an executive, officer, manager, general partner, or similar party whose appointment and removal are under the control of the ACO's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve the efficiency of processes and outcomes.
- B. Clinical management and oversight shall be managed by a senior-level medical director who is:
 1. A Participant Provider, including nurse practitioners, physician assistants, and clinical nurse specialists;
 2. Physically present on a regular basis at any clinic, office, or other location participating in the ACO; and
 3. Licensed in a state in which the ACO operates.
- C. A LEAD ACO is considered to be owned by an individual or entity, if the individual or entity:
 1. Has an ownership interest equal to 5 percent or more in the subject entity;
 2. Has an indirect ownership interest equal to 5 percent or more in the subject entity;
 3. Has a combination of direct and indirect ownership interests equal to 5 percent or more in the subject entity; or

4. Has an ownership interest equal to 5 percent or more in any mortgage, deed of trust, note, or other obligation secured by a subject entity if that interest equals at least 5 percent of the value of the property or assets of the subject entity.

Section 3.04 ACO Financial Arrangements

- A. The ACO shall not condition a Participant TIN's or Preferred Provider's participation in the Model, and shall ensure that its Participant TINs or Preferred Providers do not condition a Participant Provider's participation in the Model, directly or indirectly, on referrals of items or services provided to Beneficiaries who are not aligned to the ACO.
- B. The ACO shall not require, and shall ensure that its Participant TINs, Participant Providers, and Preferred Providers do not require that LEAD Beneficiaries be referred only to Participant TINs, Participant Providers, or Preferred Providers or to any other provider or supplier. This prohibition shall not apply to referrals made by employees or contractors who are operating within the scope of their employment or contractual arrangement with the employer or contracting entity, provided that the employees and contractors remain free to make referrals without restriction or limitation if a LEAD Beneficiary expresses a preference for a different provider or supplier, or the referral is not in the LEAD Beneficiary's best medical interests in the judgment of the referring party.
- C. The ACO shall not require, and shall ensure that its Participant TINs, Participant Providers, and Preferred Providers do not condition the eligibility of an individual or entity to be a Participant TIN, Participant Provider, or Preferred Provider on the individual's or entity's offer or payment of cash or other remuneration to the ACO or any other individual or entity.
- D. The ACO shall ensure that no party to an ACO financial arrangement gives or receives remuneration in exchange for, or to induce or reward, any Federal health care program referrals or business generated outside of LEAD, and that any compensation paid will not induce any party to the arrangement or other providers or suppliers to furnish unnecessary items or services, or to reduce or limit Medically Necessary items or services to any Beneficiary.
- E. The ACO shall require, and shall ensure that its Participant TINs and Preferred Providers require its Participant TINs, Participant Providers, and Preferred Providers to make decisions in the best interests of Beneficiaries. Further, the ACO shall not take any action to limit the ability of a Participant TIN, Participant Provider, or Preferred Provider to make decisions in the best interests of a Beneficiary, including the selection of devices, supplies and treatments used in the care of the Beneficiary.
- F. The ACO shall notify CMS within 15 business Days after becoming aware that any Participant TIN, Participant Provider, or Preferred Provider is under investigation

or has been sanctioned by the government or any licensing authority (including, without limitation, the imposition of program exclusion, debarment, civil monetary penalties, corrective action plans, and revocation of Medicare billing privileges). If a Participant TIN, Participant Provider, or Preferred Provider is under investigation or has been sanctioned but not excluded from Medicare program participation, CMS may take any of the actions set forth in Article XIII of this Implementation Agreement.

G. Implementation Period Requirements for Participant TINs.

In a form and manner and by a date specified by CMS, the ACO shall have either a LOI or a written financial arrangement with each of the individuals and entities that are approved by CMS to be Participant TINs.

1. If the ACO requires its Participant TINs to submit an LOI, the LOI must be:

- a. Printed on the Participant TIN's corporate letterhead;
- b. Executed by an executive of the Participant TIN. The executive's name must be printed in the document and must accompany the executive's dated signature.

2. Further, the LOIs must include:

- a. The Participant TIN's practice name;
- b. The Participant TIN's address;
- c. The ACO's name and entity TIN;
- d. The Participant TIN's express intent to participate in LEAD during PY 2027;
- e. The Participant TIN's express intent to participate in LEAD as a part of the ACO;
- f. An affirmation from the executive of the Participant TIN that states that the executive has the authority to enter into the agreement with the ACO on behalf of the Participant TIN, its ownership, and its governing board;
- g. The title, phone number, and email of the executive of the Participant TIN and;
- h. An acknowledgement that participation in the Model will preclude the Participant TIN from participating in the Medicare Shared Savings Program, another ACO in the LEAD Model, the Kidney Care Choices Model, any other Medicare initiative that involves shared savings (except as otherwise specified by CMS), the Maryland Primary Care Program (MDPCP) and, in certain instances, the Primary Care AHEAD and Hospital Global Budget AHEAD Models.

- i. By signing the LOI or financial arrangement, the executive agrees that the Participant TIN will participate in the LEAD Model and agrees to provide written notice of LEAD participation to Participant Providers or Preferred Providers that bill Medicare via the Participant TIN and are participating in LEAD Capitation Payment Mechanisms by a date specified by CMS.
- 3. If the ACO requires its Participant TINs to establish written financial arrangements during the Implementation Period and in advance of the Agreement Performance Period, the arrangement must comply with the criteria described in paragraphs (a) through (k):
 - a. The arrangement is in writing and the only parties to the arrangement are the ACO and the Participant TIN.
 - b. The arrangement requires the Participant TIN to agree to participate in the Model during the Agreement Performance Period, to engage in ACO Activities, to comply with the applicable terms of the Model as set forth in this Implementation Agreement and/or the Model Participation Agreement, discussed in Section 1.04, and to comply with all applicable laws and regulations (including, but not limited to, those specified at Section 11.04).
 - c. The ACO shall provide each Participant TIN with a copy of the Implementation Agreement and/or the Model Participation Agreement and any amendments hereto.
 - d. The arrangement expressly sets forth the Participant TIN's obligation to comply with the applicable terms of Implementation Agreement and/or the Model Participation Agreement, referenced in Section 1.04, including any provisions regarding the following: participant exclusivity; quality measure reporting and continuous care improvement objectives; Voluntary Alignment Activities; Marketing Activities; Beneficiary freedom of choice; Benefit Enhancements and Beneficiary Engagement Incentives; participation in evaluation, shared learning, monitoring, and oversight activities; the ACO compliance plan; and audit and record retention requirements.
 - e. The arrangement requires the Participant TIN to update its Medicare enrollment information (including the addition and deletion of individuals that have reassigned to the Participant TIN their right to Medicare payment) on a timely basis in accordance with Medicare program requirements.
 - f. The arrangement requires the Participant TIN to notify the ACO of any changes to its Medicare enrollment information (including the addition and deletion of individuals that have reassigned to the

Participant TIN their right to Medicare payment) within 30 Days after the change.

- g. The arrangement requires the Participant TIN to notify the ACO within seven Days of becoming aware that it is under investigation or has been sanctioned by the government or any licensing authority (including, without limitation, the imposition of program exclusion, debarment, civil monetary penalties, corrective action plans, and revocation of Medicare billing privileges).
- h. The arrangement permits the ACO to take remedial action against the Participant TIN (including the imposition of a corrective action plan, denial of any payments, and termination of the ACO's arrangement with the Participant TIN or Participant TIN) to address noncompliance with the terms of the Agreement or program integrity issues identified by CMS.
- i. The arrangement is for a term of at least one Performance Year, but permits early termination if CMS requires the ACO to remove the Participant TIN pursuant to Section 13.01.D or the Model Participation Agreement.
- j. The arrangement requires the Participant TIN to complete a close-out process upon termination or expiration of the arrangement that requires the Participant TIN to furnish all data required by the ACO to participate in the Model and any data required by CMS to monitor or evaluate the Model.
- k. If the arrangement involves the provision of electronic health records software by the LEAD ACO to Participant TINs or Participant Providers, such software shall be interoperable (as defined in 42 CFR § 411.351) or satisfy 42 CFR § 411.357(w)(2) (related to interoperability) at the time it is provided to the recipient.

H. Participant TINs Required Notice to Participant Providers

- 1. In a form and manner and by a date specified by CMS, the ACO must require each Participant TIN to provide written notice to the Participant Providers that bill through the Participant TIN and will participate in LEAD's Capitation Payment Mechanisms.
 - a. As it relates to the Participant TIN's notice to Participant Providers who will participate in LEAD's payment mechanisms, the notice must contain specific information regarding the Capitation Payment Mechanism applicable to that Participant Provider, prospective capitation, and reduction of claims-based FFS payments, beginning January 1, 2027.

- i. If the ACO has elected to participate in Total Care Capitation (TCC), the notice must state that, during PY 2027, the ACO will receive monthly TCC as compensation for all Medicare Parts A and B services provided by the Participant TIN (i.e., the Participant Providers that bill Medicare via the Participant TIN) to ACO-aligned beneficiaries, and that the FFS claims for the care provided to the ACO-aligned beneficiaries will be reduced accordingly, beginning January 1, 2027.
 - ii. If the ACO has elected to participate in Primary Care Capitation (PCC), the notice must state that, during PY 2027, the ACO will receive monthly PCC as compensation for eligible primary care services provided by the Participant TIN (i.e., the Participant Providers that bill Medicare via the Participant TIN) to ACO-aligned beneficiaries, and that the FFS claims for the care provided to the ACO-aligned beneficiaries will be reduced accordingly, beginning January 1, 2027.
 - iii. If the ACO is participating in either Non-Primary Care Capitation (NPCC) or the Advanced Payment Option (APO), Participant Providers that bill NPCC or APO-eligible services may optionally elect to participate in NPCC or APO with a claims-reduction percentage of 1-100%, beginning January 1, 2027.
 - b. As it relates to the Participant TIN's notice to Participant Providers who will participate in LEAD's Capitation Payment Mechanisms, the notice must state that LEAD participation will preclude Participant Providers that bill Medicare via the Participant TIN from participating in the Medicare Shared Savings Program, another ACO in the LEAD Model, the Kidney Care Choices Model, any other Medicare initiative that involves shared savings (except as otherwise specified by CMS), the Maryland Primary Care Program (MDPCP) and, in certain instances, the Primary Care AHEAD and Hospital Global Budget AHEAD Models, if the individual seeks to participate in those models under the same TIN that is on the LEAD Participant TIN list.
2. The ACO will not require Participant TINs to provide notice to Participant Providers, if the Participant Provider will not participate in LEAD's Capitation Payment Mechanisms and either of the following requirements are met:
 - a. The individual Participant Provider is employed by, or under contract with the Participant TIN and has reassigned their Medicare

billing rights to the Participant TIN; or

- b. The Participant TIN has an existing or separate arrangement, formalized in a written agreement, with the individual Participant Provider, that reflects the individual Participant Provider's employment-related or contractual relationship with the Participant TIN.

I. ACOs Written Financial Arrangements with Participant TINs.

If the ACO chooses to participate in the Agreement Performance Period, the ACO shall have, by the start of the Agreement Performance Period (i.e., January 1, 2027), fully executed written arrangements that meet the requirements set forth in Sections 3.04.A-F and 3.04.G.3 with its Participant TINs.

J. ACOs Written Financial Arrangements with Preferred Providers.

If the ACO chooses to participate in the Agreement Performance Period, by January 1, 2027, the ACO shall have fully executed written arrangements with Preferred Providers that meet the requirements set forth in Sections 3.04.A-F and as follows:

1. The arrangement is in writing and the only parties to the arrangement are the ACO and the Preferred Provider.
2. The arrangement requires the Preferred Provider to agree to participate in the Model during the Agreement Performance Period and/or Agreement Performance Period, to engage in ACO Activities, to comply with the applicable terms of the Model as set forth in this Implementation Agreement and/or the Model Participation Agreement, referenced in Section 1.04, and to comply with all applicable laws and regulations (including, but not limited to, those specified at Section 11.04).
3. The ACO shall provide each Preferred Provider with a copy of the Implementation Agreement and/or the Model Participation Agreement and any amendments hereto.
4. The arrangement expressly sets forth the Preferred Provider's obligation to comply with the applicable terms of Implementation Agreement and/or the Model Participation Agreement, referenced in Section 1.04, including any provisions regarding the following: participant exclusivity; quality measure reporting and continuous care improvement objectives; Voluntary Alignment Activities; Marketing Activities; Beneficiary freedom of choice; Benefit Enhancements and Beneficiary Engagement Incentives; participation in evaluation, shared learning, monitoring, and oversight activities; the ACO compliance plan; and audit and record retention requirements.
5. The arrangement requires the Preferred Provider to update its Medicare enrollment information (including the addition and deletion of individuals that

have reassigned to the Preferred Provider their right to Medicare payment) on a timely basis in accordance with Medicare program requirements.

6. The arrangement requires the Preferred Provider to notify the ACO of any changes to its Medicare enrollment information (including the addition and deletion of individuals that have reassigned to the Preferred Provider their right to Medicare payment) within 30 Days after the change.
7. The arrangement requires the Preferred Provider to notify the ACO within seven Days of becoming aware that it is under investigation or has been sanctioned by the government or any licensing authority (including, without limitation, the imposition of program exclusion, debarment, civil monetary penalties, corrective action plans, and revocation of Medicare billing privileges).
8. The arrangement permits the ACO to take remedial action against the Preferred Provider (including the imposition of a corrective action plan, denial of any payments, and termination of the ACO's arrangement with the Preferred Provider) to address noncompliance with the terms of the Agreement or program integrity issues identified by CMS.
9. The arrangement is for a term of at least one Performance Year, but permits early termination if CMS requires the ACO to remove the Preferred Provider pursuant to Section 13.01.D of the Model Participation Agreement.
10. The arrangement requires the Preferred Provider to complete a close-out process upon termination or expiration of the arrangement that requires the Preferred Provider to furnish all data required by the ACO to participate in the Model and any data required by CMS to monitor or evaluate the Model.
11. If the arrangement involves the provision of electronic health records software by the LEAD ACO to Participant TINs, Participant Providers, or Preferred Providers, such software shall be interoperable (as defined in 42 CFR § 411.351) or satisfy 42 CFR § 411.357(w)(2) (related to interoperability) at the time it is provided to the recipient.
12. The ACO need not have an arrangement with the Preferred Provider that complies with the requirements of Section 3.04.J.1 through Section 3.04.J.11 with an individual approved by CMS to be a Preferred Provider if all the following requirements are met:
 - a. By the applicable date specified in Section 3.04.K, the ACO has an arrangement with an entity approved by CMS to be a Preferred Provider ("**Preferred Provider Contracting Entity**");
 - b. The arrangement between the ACO and the Preferred Provider Contracting Entity satisfies the requirements of Sections 3.04.G.1 through 3.04.G.16, identifies the individual Preferred Provider, and documents the individual Preferred Provider's agreement to comply

with the applicable terms of the arrangement between the ACO and the Preferred Provider Contracting Entity;

- c. The individual Preferred Provider is employed by, or under contract with, the Preferred Provider Contracting Entity and has reassigned his or her Medicare billing rights to the Preferred Provider Contracting Entity;
- d. The Preferred Provider Contracting Entity and the individual Preferred Provider enter into an arrangement that binds the individual Preferred Provider to the applicable terms of the arrangement between the ACO and the Preferred Provider Contracting Entity; and
- e. The arrangement between the ACO and the Preferred Provider Contracting Entity requires the Preferred Provider Contracting Entity to make available a copy of this Agreement and any amendments hereto to the individual Preferred Provider.

K. ACO Required Notice to Preferred Providers

- 1. In a form and manner and by a date specified by CMS, the ACO must provide written notice to each Preferred Provider on the ACO's Preferred Provider List, regardless of whether the Preferred Provider is participating in LEAD Capitation Payment Mechanisms.
- 2. Written notice to the Preferred Providers must state the following:
 - a. The ACO is participating in the LEAD Model and the TIN through which the individual Preferred Provider bills Medicare will be identified on the ACO's Proposed Preferred Provider List, as applicable.
 - b. The Preferred Provider's participation in the ACO may preclude the individual or entity from participating in the Hospital Global Budget AHEAD Model, if the Preferred Provider is enrolled in certain LEAD capitated payment arrangements.
 - c. If the ACO is participating in PCC Payment, Preferred Providers that bill PCC-eligible services may optionally elect to participate in PCC with a claims-reduction percentage of 1-100%, and that the agreement to participate in PCC Payment must be renewed annually prior to the start of each Performance Year.
 - d. If the ACO is participating in either Non-Primary Care Capitation (NPCC) or the Advanced Payment Option (APO), Preferred Providers that bill NPCC or APO-eligible services may optionally elect to participate in NPCC or APO with a claims-reduction percentage of 1-100%, and that the agreement to participate in NPCC or APO must be renewed annually prior to the start of each

Performance Year.

- e. If the ACO is participating in Total Care Capitation (TCC) Preferred Providers may optionally elect to participate in TCC with a claims reduction percentage of 1-100% and that the agreement to participate
 - A. Finally, if the Preferred Provider is an entity (i.e., TIN) through which other individual Preferred Providers bill Medicare, the ACO's notification to the Preferred Provider entity must also require the Preferred Provider entity to provide written notice of LEAD participation to its individual Preferred Providers by October 15, 2026. The Preferred Provider entity's notice must include Items 1 – 5 (above).
- L. CMS provides no opinion on the legality of any contractual or financial arrangement that the ACO, a Participant TIN, a Participant Provider, or a Preferred Provider has proposed, implemented, or documented. The receipt by CMS of any such documents in the course of the application process or otherwise shall not be construed as a waiver or modification of any applicable laws, rules, or regulations, and shall not preclude CMS, HHS or its Office of Inspector General, a law enforcement agency, or any other federal or state agency from enforcing any and all applicable laws, rules, and regulations.
- M. Records Maintenance.

The ACO shall ensure that the Participant TINs and Preferred Providers maintain, in accordance with Section 12.02, records of all payments made or received pursuant to the arrangements described in Section 3.04.G.3.
- N. The ACO shall ensure that any Participant TIN, Participant Provider or Preferred Provider that has been terminated pursuant to Sections 3.04.F or 13.01, or has been removed from the Participant TIN List or Preferred Provider List, as applicable, pursuant to Section 4.04.B, as applicable, does not engage in any Marketing Activities, including Voluntary Alignment Activities, after the effective date of such termination.

Section 3.05 ACO Start-up Arrangements

- A. Start-up Arrangement Requirements. A Start-up Arrangement must comply with the following requirements:
 - 1. All parties enter into, and undertake, the Start-up Arrangement with the good faith intent to participate in PY 2027, pursuant to the Model Participation Agreement referenced in Section 1.04.
 - 2. In establishing the terms of the Start-up Arrangement, no party gives or receives remuneration in return for, or to induce the referral of, items or services furnished to Federal health care program Beneficiaries who are not

aligned to the ACO.

3. For Start-up Arrangements involving the exchange of information technology used predominantly to create, maintain, transmit, or receive electronic health records, such information technology is interoperable (as defined in 42 CFR § 411.351) or satisfies 42 CFR § 411.357(w)(2) (related to interoperability).
 4. The ACO's governing body has made a *bona fide* determination, consistent with each governing body member's fiduciary duty to the ACO, that the arrangement is reasonably related to the performance of ACO Activities and has authorized the arrangement.
 5. The Start-up Arrangement and its authorization by the governing body are documented. The documentation must be contemporaneous with the establishment of the arrangement, and the documentation of the authorization must be contemporaneous with the authorization. All such documentation must be retained by the ACO, Participant TIN, Participant Provider, and Preferred Provider, as applicable, for at least 10 years following completion of the arrangement and promptly made available to the Secretary upon request. The documentation must identify at least the following:
 - a. A description of the Start-up Arrangement, including all parties to the arrangement; the effective date of the arrangement; the purpose(s) of the arrangement; the items, services, facilities, and goods covered by the arrangement (including nonmedical items, services, facilities, or goods); evidence of the public disclosure of the arrangement; and the financial or economic terms of the arrangement.
 - b. The date and manner of the governing body's authorization of the Start-up Arrangement. The documentation of the authorization must include the basis for the bona fide determination by the ACO's governing body that the arrangement is reasonably related to the performance of ACO Activities during the Implementation Period.
 6. A description of the Start-up Arrangement is publicly disclosed and maintained on a public-facing website belonging to the ACO no later than 60 Days after the effective date of the Start-up Arrangement, through the earlier date of the effective date of expiration or termination of this Implementation Agreement.
- B. CMS provides no opinion on the legality of any Start-up Arrangement that the ACO, a Participant TIN, a Participant Provider, or a Preferred Provider has proposed, implemented, or documented. The receipt by CMS of any such documents in the course of the application process or otherwise shall not be construed as a waiver or modification of any applicable laws, rules, or regulations, and shall not preclude CMS, HHS or its Office of Inspector General, a law

enforcement agency, or any other federal or state agency from enforcing any and all applicable laws, rules, and regulations.

- C. Availability of Safe Harbor Protection for Start-up Arrangements. CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR § 1001.952(ii)(1)) is available to protect Start-up Arrangements reasonably related to the performance of ACO Activities, provided that such arrangements comply with:
1. Section 3.05.A.1-6, and
 2. All safe harbor requirements set forth in 42 CFR § 1001.952(ii)(1).

ARTICLE IV PARTICIPANT TINs, PARTICIPANT PROVIDERS, AND PREFERRED PROVIDERS

Section 4.01 General

- A. In LEAD, the LEAD ACO is comprised of one or more Participant TINs. Participant TINs must meet the following eligibility criteria and are defined as follows:
1. A Medicare-enrolled billing TIN through which one or more Medicare-enrolled Providers or Suppliers (as described in 42 C.F.R. § 400.202 and 42 C.F.R. § 424.502) bill Medicare for services furnished to Original Medicare Beneficiaries;
 2. Is not a Preferred Provider (as defined in this Implementation Agreement) in the same ACO;
 3. Is not a Participant TIN or Participant Provider in another LEAD ACO, and is not a participating TIN entity in the Medicare Shared Savings Program, the Kidney Care Choices Model, or any other Medicare initiative that involves shared savings;
 4. Is not a Prohibited Participant (as defined in this Implementation Agreement); and
 5. Has agreed to participate in LEAD pursuant to a written arrangement with the ACO, in accordance with Sections 3.04.A-F and 3.04.G.3 of this Agreement.
- B. The Participant TIN shall ensure that each of its Participant Providers:
1. Is a Medicare-enrolled provider (as defined at 42 CFR § 400.202) or supplier (as defined at 42 CFR § 400.202);
 2. Bills for items and services it furnishes to Beneficiaries under a Medicare billing number assigned to a TIN in accordance with applicable Medicare regulations;
 3. Has agreed to participate in the Model pursuant to a written arrangement that complies with the applicable requirements of Section 3.04.

- C. The Participant TIN shall ensure that each of its Participant Providers is not:
 - 1. A Preferred Provider in the same ACO.
 - 2. A Participant TIN or Participant Provider in another LEAD ACO, or billing Medicare via a TIN that participates in the Medicare Shared Savings Program, the Kidney Care Choices Model, or any other Medicare initiative that involves shared savings. The Participant Provider may only participate in another LEAD ACO, the Medicare Shared Savings Program, the Kidney Care Choices Model, or any other Medicare initiative that involves shared savings, if the Participant Provider bills Medicare via an alternate TIN.
 - 3. A Prohibited Participant;
- D. The ACO shall ensure that each Preferred Provider:
 - 1. Is a Medicare-enrolled provider (as defined at 42 CFR § 400.202) or supplier (as defined at 42 CFR § 400.202);
 - 2. Bills for items and services it furnishes to Beneficiaries under a Medicare billing number assigned to a TIN in accordance with applicable Medicare regulations;
 - 3. Has agreed to participate in the Model pursuant to a written arrangement that complies with the applicable requirements of Section 3.04; and
 - 4. Is identified on the Preferred Provider List in accordance with Section 4.04.
- E. Preferred Providers may participate in another ACO, the Medicare Shared Savings Program, the Kidney Care Choices Model, or any other Medicare initiative that involves shared savings, as long as the Medicare-enrolled billing TIN used is not the TIN of a LEAD Participant TIN or Participant Provider.
- F. The ACO shall ensure that each Preferred Provider is not a Prohibited Participant;
- G. Upon CMS' approval, Participant TINs, Participant Providers, and Preferred Providers will be included on either the Participant TIN List or the Preferred Provider List.
- H. CMS shall maintain the Participant TIN List and Preferred Provider List in a manner that permits the ACO to review the lists.
- I. The ACO shall maintain current and historical Participant TIN Lists and Preferred Provider Lists in accordance with Section 12.02.

Section 4.02 Program Integrity Monitoring

- A. CMS may periodically monitor the program integrity history of the ACO's Participant TINs, Participant Providers, and Preferred Providers.
- B. CMS may remove an individual or entity from the Participant TIN List or Preferred Provider List or subject the ACO to additional monitoring pursuant to Section 13.01, on the basis of the results of a Program Integrity Screening or information

obtained from any source regarding an individual's or entity's history of program integrity issues, including, but not limited to, a Participant TIN's, Participant Provider's or Preferred Provider's licensure status and ongoing investigations by law enforcement, program integrity, or state licensure bodies.

- C. CMS shall notify the ACO if CMS chooses to remove an individual or entity from the Participant TIN List or Preferred Provider List, and such notice shall specify the effective date of removal.
- A. **Section 4.03 Participant TIN List** The parties acknowledge that the ACO submitted to CMS a proposed list of Participant TINs, identified by name and TIN. Such proposed list was submitted in form and manner and by a date specified by CMS.
- B. CMS will automatically populate the individual Participant Provider NPIs and CCNs that are billing under each Participant TIN on to the ACO's Participant TIN List.
- C. Once populated, CMS will conduct a Program Integrity Screening on each individual or entity identified on the proposed list of Participant TINs, produce a revised proposed list of Participant TINs, and identify individuals and entities on the proposed list that did not qualify for Model participation or that required further action before they could be approved for Model participation.
- D. By a date specified by CMS, CMS will automatically review and make necessary corrections to the revised proposed list of Participant TINs, including removing any individuals or entities that have not agreed to participate in the Model as of the Start Date, in accordance with the requirements of Section 3.04.G. The ACO shall not add any individuals or entities to its revised proposed list of Participant TINs after the specified date.
- E. The ACO shall submit to CMS, by a date specified by CMS, a final Participant TIN List f that the ACO has certified is a true, accurate, and complete list identifying all of the individuals and entities that have agreed to participate in the LEAD Model Agreement Performance Period, pursuant to a fully executed LOI or written arrangement meeting the requirements of Section 3.04.G.
- F. CMS shall submit to the ACO a final Participant TIN List with all individuals and entities that it has approved to be Participant TINs for the Agreement Performance Period.
- G. The ACO shall update the Participant TIN List for the Implementation Period in accordance with Section 4.03.

Section 4.04 Preferred Provider List

- A. The parties acknowledge that the ACO submitted to CMS a proposed list of Preferred Providers identified by name, NPI, TIN, and CCN (if applicable). Such proposed list was submitted in form and manner and by a date specified by CMS.

- B. CMS shall conduct a Program Integrity Screening on each individual or entity identified on the proposed Preferred Provider List, identify individuals and entities on the proposed list that did not qualify for Model participation or that required further action before they could be approved for Model participation and shall produce a revised Preferred Provider List.
- C. By a date specified by CMS, the ACO shall review and make any necessary corrections to the revised Preferred Provider List, including the removal of any individuals or entities that have not agreed to participate in the Model as of the Implementation Period Start Date. The ACO shall not add any individuals or entities to its revised Preferred Provider List after the specified date.
- D. The ACO shall submit to CMS, by a date specified by CMS, a final Preferred Provider List that the ACO has certified is a true, accurate, and complete list identifying all the individuals and entities that have agreed to participate in the Implementation Period.
- E. CMS shall submit to the ACO a final Preferred Provider List with the individuals and entities that it has approved to be Preferred Providers.
- F. The ACO shall update the Preferred Provider List in accordance with Section 4.04.

Section 4.05 Participant TIN List and/or Preferred Provider List Updates during the Implementation Period

A. Additions Prohibited

The ACO may not make additions to its Participant TIN List or Preferred Provider List after the date specified by CMS, as discussed in Sections 4.03 and 4.04.

B. Removals from a List

1. General. In a form and manner specified by CMS, the ACO shall notify CMS no later than 30 Days before an individual or entity ceases to be a Participant TIN or Preferred Provider. The notice must include the date on which the individual or entity will cease to be a Participant TIN or Preferred Provider and the basis for removal (i.e., the applicable requirements of Section 4.01, as applicable, that the individual or entity no longer satisfies).
2. Except as specified in Section 4.05.B.3, the removal of the individual or entity from the Participant TIN List or Preferred Provider List will be effective on the last calendar day of the month in which the individual or entity ceases to be a Participant TIN or Preferred Provider.
3. **Loss of Eligibility for Medicare Payment.**
 - a. If an individual or entity on the Participant TIN List or Preferred Provider List becomes ineligible to receive payment from Medicare, the ACO shall notify CMS, in a

form and manner specified by CMS, within 15 Days of receiving notice of such ineligibility.

- b. The removal of the individual or entity from the Participant TIN List, or Preferred Provider List will be effective as of the date the individual or entity lost eligibility to receive payment from Medicare.

C. Updating Enrollment Information

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

Section 4.06 Participant TIN List and Preferred Provider List for the First PY

- A. Proposed Participant TIN List. If the ACO chooses to participate in the Agreement Performance Period, the ACO shall submit to CMS by a date and in a form and manner specified by CMS, a proposed list identifying each individual or entity that the ACO expects to participate in LEAD as a Participant TIN effective at the start of the Agreement Performance Period (“**Proposed Participant TIN List**”).
- B. The Proposed Participant TIN List must:
 - 1. Identify each entity by name, TIN;
 - 2. Specify the Benefit Enhancements and Beneficiary Engagement Incentives, if any, that each entity has selected to participate in;
 - 3. If the ACO has selected TCC Payment as its Capitation Payment Mechanism for the ACO’s first PY pursuant to Section 8.02.B, identify each individual or entity that has agreed to participate in TCC Payment with the ACO;
 - 4. If the ACO has selected PCC Payment as its Capitation Payment Mechanism for the ACO’s first PY pursuant to Section 8.02.B, identify the applicable PCC Fee Reduction for each individual or entity on the Proposed Participant TIN List;
 - 5. If the ACO has selected PCC Payment as its Capitation Payment Mechanism for the ACO’s first PY pursuant to Section 8.02.B and has selected NPCC or the APO, identify which individuals and entities on the Proposed Participant TIN List, if any, have agreed to participate in the NPCC or APO and the applicable NPCC or APO Fee Reduction for each such individual or entity.
- C. CMS shall specify one or more submission deadlines to add the information specified in paragraphs (a) through (e) to the Proposed Participant TIN List.

- D. By a date specified by CMS, the ACO shall certify that the Proposed Participant TIN List is a true, accurate, and complete list of individuals and entities that have agreed to be Participant TINs and Participant Providers, subject to CMS approval, at the start of the ACO's first PY.
- C. Proposed Preferred Provider List. If the ACO chooses to participate in the Agreement Performance Period, the ACO shall submit to CMS by a date and in a form and manner specified by CMS, a proposed list identifying each individual or entity that the ACO expects to participate in the Model as a Preferred Provider effective at the start of the ACO's first PY ("**Proposed Preferred Provider List**").
- D. The Proposed Preferred Provider List must:
 1. Identify each individual or entity by name, NPI, TIN, and CCN (if applicable);
 2. Specify the Benefit Enhancements and Beneficiary Engagement Incentives, if any, in which each individual or entity has agreed to participate;
 3. If the ACO has selected TCC Payment as its Capitation Payment Mechanism for the ACO's first PY pursuant to Section 8.02, identify each individual or entity that has agreed to participate in TCC Payment within the ACO, as well as the applicable TCC Fee Reduction for each such individual or entity;
 4. If the ACO has selected PCC Payment as its Capitation Payment Mechanism for the ACO's first PY pursuant to Section 8.02 and has selected NPCC, identify which individuals and entities on the Proposed Preferred Provider List, if any, have agreed to participate and the applicable NPCC Fee Reduction for each such individual or entity.
 5. If the ACO has selected PCC Payment as its Capitation Payment Mechanism for the ACO's first PY pursuant to Section 8.02 and has selected APO, identify which individuals and entities on the Proposed Preferred Provider List, if any, have agreed to participate and the applicable APO Fee Reduction for each such individual or entity.
 - a. CMS will specify one or more submission deadlines to add the information specified in paragraphs (a) through (e) to the Proposed Preferred Provider List.
 - b. By a date specified by CMS, the ACO shall certify that the Proposed Preferred Provider List is a true, accurate, and complete list of individuals and entities that have agreed to be Preferred Providers, subject to CMS approval, at the start of the ACO's first PY.
- E. Written Confirmation of Consent to Participate in a Capitation Payment Mechanism
 1. **Participant TINs**. By a date specified by CMS, the ACO shall obtain

written confirmation that each entity identified on the Proposed Participant TIN List has affirmatively consented to participate in the ACO's selected Capitation Payment Mechanism and the amount of the PCC Fee Reduction, NPCC or APO Fee Reduction, or TCC Fee Reduction, as applicable, agreed upon by each such individual or entity.

2. ***Preferred Providers.*** By a date specified by CMS, the ACO shall obtain written confirmation that each individual and entity that is identified on the Proposed Preferred Provider List as participating in the ACO's selected Capitation Payment Mechanisms has affirmatively consented to participate in the ACO's selected Capitation Payment Mechanisms and the amount of the TCC Fee Reduction or APO or NPCC Fee Reduction, as applicable, agreed upon by each such individual or entity.

Preferred Provider participation in ACO's selected Capitation Payment Mechanisms is optional. The ACO is required to obtain consent and relevant information regarding amount of the TCC Fee Reduction or APO or NPCC Fee Reduction from Preferred Providers that are participating in the ACO's selected Capitation Payment Mechanisms.

3. The written confirmation of consent required must be in the form of a completed LEAD Model Fee Reduction Agreement signed by either an individual legally authorized to act for the Participant TIN or Preferred Provider.
 - a. CMS may provide the ACO with a template or template language for its ACO LEAD Model Fee Reduction Agreements.
 - b. The ACO shall use any ACO LEAD Model Fee Reduction Agreement template language provided by CMS.
 - c. ACO LEAD Model Fee Reduction Agreements must specify the applicable Capitation Payment Mechanism and the applicable Fee Reduction percentage, as agreed upon by the individual or entity from among the applicable percentages specified by CMS.
4. As part of the written confirmation of consent, the individual legally authorized to act on behalf of the Participant TIN entity must verify the accuracy of the list of Participant Providers billing under that Participant TIN.
5. The individual legally authorized to act on behalf of the Participant TIN entity must verify that the individual Participant Providers listed have affirmatively consented to participate in the ACO's selected Capitation Payment Mechanism and the amount of the applicable Fee Reduction as agreed upon by each such individual or entity.

6. Consent to participate in the ACO's selected Capitation Payment Mechanism for the ACO's first PY must be obtained prior to the start of the ACO's first PY. Consent to participate in the ACO's selected Capitation Payment Mechanism must be voluntary and must not be contingent on or related to receipt of referrals from the ACO, its Participant Providers, or Preferred Providers.
- F. Review, Certification, and Finalization of the Participant TIN List, and Preferred Provider List for the first PY
1. With respect to each individual and entity identified on the Proposed Participant TIN List and Proposed Preferred Provider List, CMS shall conduct a Program Integrity Screening.
 2. CMS may reject any individual or entity on a Proposed Participant TIN List or a Proposed Preferred Provider List based on the results of this Program Integrity Screening, history of program integrity issues, or:
 - a. For any individual or entity on a Proposed Participant TIN List, if CMS determines that the individual or entity does not satisfy the applicable criteria in Section 4.01.A-C; or
 - b. For any individual or entity on a Proposed Preferred Provider List, if CMS determines that the individual or entity does not satisfy the criteria of Section 4.01.D.
 1. In a form and manner and by a date specified by CMS, CMS shall provide the ACO with a list of individuals and entities that CMS has tentatively approved to be Participant TINs, Participant Providers, and Preferred Providers effective at the start of the ACO's First PY.
 2. In a form and manner and by a date specified by CMS, the ACO may propose adding individuals and entities to its Proposed Participant TIN List and its Proposed Preferred Provider List. CMS shall conduct a Program Integrity Screening for each individual or entity the ACO proposes to add to the Proposed Participant TIN List and Proposed Preferred Provider List and may reject any individual or entity proposed for inclusion on the basis of the criteria described in Section 4.05.F.
 3. CMS shall provide the ACO with revised lists of the individuals and entities that CMS has tentatively approved to be Participant TINs and Preferred Providers effective at the start of the ACO's first PY, to include individuals and entities added to the Proposed Participant TIN List or Proposed Preferred Provider List pursuant to Section 4.05.F that CMS did not reject on the basis of criteria described in Section 4.05.F.
 4. In a form and manner and by a date specified by CMS, the ACO shall, after a review of the lists of tentatively approved Participant TINs and Preferred Providers, confirm the accuracy of the revised Proposed Participant TIN List

and of the revised Proposed Preferred Provider List and make any necessary corrections, including the removal of any individuals or entities that have not agreed to participate in the Model pursuant to a written arrangement or LOI meeting the requirements of Section 3.04.G, that have failed to satisfy the applicable requirements of Section 4.01. or that are otherwise ineligible to participate in the Model as a Participant TIN or Preferred Provider, as applicable.

5. The ACO shall remove any individuals or entities that are identified as a Participant TIN and have not agreed to participate in the ACO's selected Capitation Payment Mechanism with the ACO in accordance with Section 4.06.A from its Proposed Participant TIN List.
6. In form and manner and by one or more dates specified by CMS, the ACO shall certify:
 - a. That the revised Proposed Participant TIN List and the revised Proposed Preferred Provider List are true, accurate, and complete lists of individuals and entities that have agreed to be Participant TINs or Preferred Providers, as applicable, subject to CMS approval, during the ACO's first PY;
 - b. That each individual and entity identified on the revised Proposed Participant TIN List and the revised Proposed Preferred Provider List meets the applicable requirements Section 4.01, as applicable;
 - c. By the start of the Agreement Performance Period (January 1, 2027), each individual and entity identified on the revised Proposed Participant TIN List and the revised Proposed Preferred Provider List will have a fully executed written arrangement meeting the requirements of Sections 3.04.G.3 and 3.04.J.
 - d. That the revised Proposed Participant TIN List and the revised Proposed Preferred Provider List include true, accurate, and complete information regarding the following: participation in the ACO's selected Capitation Payment Mechanisms, the amount of applicable Fee Reduction, Benefit Enhancements, and Beneficiary Engagement Incentives, as applicable, effective at the start of the ACO's first Performance Year.
 - e. CMS shall remove from the Participant TIN List any individuals or entities that bill under a TIN participating in another LEAD ACO, the Medicare Shared Savings Program, the Kidney Care Choices Model, or any other Medicare initiative that involves shared savings.
7. CMS shall provide the ACO with a final Participant TIN List and a final Preferred Provider List, identifying all individuals and entities that CMS

has approved to be Participant TINs and Preferred Providers effective at the start of the ACO's first PY (including, as applicable, information regarding participation in the ACO's selected Capitation Payment Mechanism, the amount of the applicable Fee Reduction, Benefit Enhancements, and Beneficiary Engagement Incentives).

8. CMS shall use the final Participant TIN List to run Claims-Based Alignment for the ACO's first PY. Any individual or entity that is removed from or added to the Participant TIN List after CMS provides the ACO with the final Participant TIN List will not affect Claims-Based Beneficiary alignment for the ACO's first PY.
9. The ACO shall update such lists in accordance with the terms of the Model Participation Agreement, referenced in Section 1.04.

Section 4.07 Non-Duplication and Exclusivity of Participation

- A. CMS waives the non-duplication requirements under section 1899(b)(4)(A) of the Act and in the implementing regulations at 42 CFR § 425.114(a) and (b) regarding participation in a model tested under section 1115A of the Act that involves shared savings as they apply to the ACO, Participant TIN, Participant Providers, and Preferred Providers for the duration of the Implementation Period, subject to the conditions and requirements set forth in Appendix A.
- B. Consistent with the requirements set forth in Appendix A, the ACO, Participant TINs, Participant Providers, and Preferred Providers may participate in ACO REACH, the Medicare Shared Savings Program, the Kidney Care Choices Model, the Maryland AHEAD Hospital Global Budgets or Primary Care AHEAD, or any other Medicare initiative that involves shared savings during the Implementation Period.

ARTICLE V BENEFICIARY ALIGNMENT, BENEFICIARY ENGAGEMENT, AND BENEFICIARY PROTECTIONS

Section 5.01 Beneficiary Alignment

Prior to the PY, CMS shall align Beneficiaries for the ACO's PY via Claims-based Alignment, regardless of whether an ACO participates in the Implementation Period. However, ACOs participating in the Implementation Period can begin Voluntary Alignment activities before the beginning of the PY.

Prior to the PY, in a form and manner and by a date specified by CMS, CMS shall align Beneficiaries based upon the ACO's selected Alignment Methodology for the ACO's first PY (i.e., Prospective Alignment or Hybrid Alignment), using the methodology set forth in the Model Participation Agreement referenced in Section 1.04. ACOs participating in the Implementation Period can begin Voluntary Alignment activities before the beginning of the PY.

Section 5.02 Voluntary Alignment

A. Valid Designation

A designation by the Beneficiary of a Participant Provider and/or Participant TIN as a Beneficiary's primary clinician, main doctor, main provider, and/or the main place they receive care (whether through MVA or SVA) made during the Implementation Period will be valid for the ACO's first PY.

B. Prospective Alignment

Prospective Alignment will occur prior to and/or at the start of the Agreement Performance Period only and will be governed by the Model Participation Agreement referenced in Section 1.04.

C. Hybrid Alignment

Hybrid Alignment will occur during the Agreement Performance Period, during biannual periods (i.e., mid-Performance Year) via Claims-based Alignment and monthly via Voluntary Alignment. Hybrid Alignment will be governed by the Model Participation Agreement referenced in Section 1.04.

D. Medicare.gov Voluntary Alignment

Through MVA a Beneficiary may voluntarily align with the ACO by designating a Participant Provider as the Beneficiary's primary clinician on Medicare.gov or any successor site. CMS uses the Beneficiary's Medicare.gov Voluntary Alignment in performing Beneficiary Alignment as described in Section 5.02 and Appendix C.

E. Signed Attestation-based Voluntary Alignment

Through SVA a Beneficiary may voluntarily align with the ACO by using a Voluntary Alignment Form to designate a Participant TIN as their main provider and/or place they receive care. In addition to the Participant TIN, the Beneficiary may add a Participant Provider to the form as well. CMS' SVA processes and requirements for the Implementation Period are discussed in Appendix C and apply to this Implementation Agreement, pursuant to Section 8.01.

F. Voluntary Alignment Transferred from ACO REACH

CMS has permitted LEAD ACOs that participate(d) in ACO REACH in the PYs immediately preceding the Implementation Period to carry over Voluntary Alignment, pursuant to the requirements in Section 5.03.

G. Influencing or Attempting to Influence the Beneficiary

1. The ACO shall not, and shall require its Participant TINs, Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to ACO Activities or Marketing Activities to not, directly or indirectly, commit any act or omission, nor adopt any policy, that coerces or otherwise influences a Beneficiary's decision to complete or not complete a Voluntary Alignment Form or a Medicare.gov or any

successor site designation, including, but not limited to, the following:

- a. Completing a Voluntary Alignment Form on behalf of the Beneficiary;
 - b. Designating a primary clinician on Medicare.gov or any successor site on behalf of the Beneficiary;
 - c. Including the Voluntary Alignment Form and instructions with any other materials or forms, including, but not limited to, materials requiring the signature of the Beneficiary; and
 - d. Withholding or threatening to withhold medical services or limiting or threatening to limit access to care.
2. The ACO may instruct its Participant TINs, Participant Providers, and Preferred Providers to answer questions from Beneficiaries regarding Voluntary Alignment but must prohibit Participant TINs, Participant Providers, and Preferred Providers from completing a Voluntary Alignment Form or designating a clinician on Medicare.gov or any successor site on behalf of the Beneficiary.
 3. The ACO shall require its Participant TINs, Participant Providers and Preferred Providers to instruct Beneficiaries to call the ACO if they have questions about how to make changes to a Voluntary Alignment Form or how to designate a primary clinician on Medicare.gov or any successor site.
 4. CMS shall provide the ACO with information on how Beneficiaries may designate a clinician on Medicare.gov or any successor site as their primary clinician for purposes of MVA. If the ACO chooses to share this information with Beneficiaries, the sharing of this information would be considered a Voluntary Alignment Activity subject to the requirements of this Section 5.02.
 5. Failure to comply with the requirements of this Article V and, if the ACO has selected to participate in SVA, the requirements of Appendix C of this Implementation Agreement, may result in retroactive reversal of any alignment of Beneficiaries to the ACO that occurred solely pursuant to Voluntary Alignment, to include via Hybrid Alignment.

Section 5.03 Voluntary Alignment Transferred from ACO REACH

- A. LEAD ACOs that participate(d) in ACO REACH in PY 2026 were selected by CMS for participation in LEAD through a streamlined application process, through which the ACOs demonstrated that the ACO would generally be function as it did in ACO REACH, as it relates to TIN, ACO leadership, governing body, and providers.
- B. Thus, LEAD ACOs that participate(d) in ACO REACH in PY 2026 may carry over Signed ACO REACH Voluntary Alignment attestations for PY 2025 and PY 2026,

as long as:

1. The same TIN identified on the ACO REACH SVA Data Template for the given voluntary alignment attestation must be a Participant TIN with a LEAD ACO;
2. In a form and manner and by a date specified by CMS, the LEAD ACO notifies the corresponding ACO-aligned Beneficiaries that their Participant TINs and/or Participant Providers are no longer participating in ACO REACH and have moved to the LEAD Model.

Section 5.04 Claims-based Alignment

- A. Claims-based Alignment will be performed prior to the start of the Agreement Performance Period, after the Participant TIN List submitted by the ACO is finalized, as described in Section 4.06.
- B. The applicable alignment minimum for the ACO's first PY and each subsequent PY shall be governed by the terms of the Model Participation Agreement referenced in Section 1.04.

Section 5.05 Alignment Minimum

The applicable alignment minimum for the ACO's first PY and each subsequent PY shall be governed by the terms of the Model Participation Agreement referenced in Section 1.04.

Section 5.06 High Needs Beneficiaries

- A. PY Benchmarks are risk-adjusted for all LEAD ACOs to reflect ACO-aligned High Needs Beneficiaries (if applicable).
- B. Once a Beneficiary meets the High Needs eligibility criteria, the Beneficiary shall be considered High Needs for the remainder of the Agreement Performance Period.
- C. When 40 percent or greater of the ACO's aligned Beneficiaries are High Needs Beneficiaries, the ACO benefits from reduced alignment minimums as long as the ACO is able to provide the following care delivery capabilities:
 1. 24-hour, 7-Days-a-week access to a health care provider with access to a patients' electronic medical record;
 2. Health care providers with training in advanced care planning conversations; and
 3. The ability to deliver care in patients' homes.

Section 5.07 Availability of Services

- A. The ACO shall require its Participant TINs, Participant Providers, and Preferred Providers to make Medically Necessary Covered Services available to Beneficiaries in accordance with applicable laws, regulations and guidance. Beneficiaries and their assignees retain their right to appeal claims

determinations in accordance with 42 CFR Part 405, Subpart I.

- B. The ACO shall not, and shall require its Participant TINs, Participant Providers, and Preferred Providers to not, target Beneficiaries to favorably affect the aligned Beneficiary population of the ACO during the Implementation Period or during any PY of the Agreement Performance Period.
- C. The ACO, its Participant TINs, Participant Providers, and Preferred Providers shall not avoid or take any action to avoid treating At-Risk Beneficiaries.

Section 5.08 Beneficiary Freedom of Choice

- A. The ACO must permit its aligned Beneficiaries to maintain the freedom to choose their providers and suppliers, including the ability to select a primary clinician on Medicare.gov, even if the provider or supplier is not a Participant TIN, Participant Provider, or Preferred Provider with an arrangement with the ACO.
- B. The ACO is further required to notify its aligned Beneficiaries that they have the freedom to select their own primary clinician and to receive services from the providers and suppliers of their choice according to traditional Medicare rules.
- C. Consistent with Section 1802(a) of the Act, neither the ACO nor any Participant TIN, Participant Provider, Preferred Provider, or other individuals or entities performing functions or services related to ACO Activities or Marketing Activities, shall commit any act or omission, nor adopt any policy, that inhibits Beneficiaries from exercising their freedom to obtain health services from providers and suppliers who are not Participant TINs, Participant Providers, or Preferred Providers.
- D. The prohibition described in this section shall not apply to referrals made by employees or contractors who are operating within the scope of their employment or contractual arrangement with the employer or contracting entity, provided that the employees and contractors remain free to make referrals without restriction or limitation if a Beneficiary expresses a preference for a different provider or supplier, or the referral is not in the Beneficiary's best medical interests in the judgment of the referring party.
- E. Notwithstanding the requirements of Section 5.09, the ACO may communicate to Beneficiaries the benefits of receiving care with the ACO. All such communications shall be deemed Marketing Materials or Marketing Activities.
- F. To ensure that Beneficiaries are not misinformed or misled about the Model, CMS may provide the ACO with scripts, talking points or other materials explaining these benefits.

Section 5.09 Marketing Activities and Marketing Materials

- A. The ACO shall conduct, and shall require its Participant TINs, Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to ACO Activities or Marketing Activities to conduct,

Marketing Activities including Voluntary Alignment Activities, only in accordance with this Article V and, if the ACO has selected to participate in SVA (as opposed to MVA), Appendix C of this Implementation Agreement.

- B. The ACO shall submit to CMS, in a form and manner and by a date specified by CMS, a plan for implementing the Marketing Activities described in this Implementation Agreement (“Marketing Plan”). CMS shall make reasonable efforts to approve or reject a Marketing Plan within 10 business days of submission.
- C. If CMS determines that the ACO’s proposed Marketing Plan, including any amendments described in Section 5.09.D below, does not satisfy the applicable requirements of the Implementation Agreement, including Appendix C, or is likely to result in program integrity concerns, CMS may reject (or require the amendment of) the ACO’s Marketing Plan at any time, including after the Implementation Period Start Date.
 - 1. If CMS rejects the ACO’s Marketing Plan, the ACO shall not, and shall require its Participant TINs, Participant Providers, Preferred Providers, and/or other individuals or entities performing functions or services related to ACO Activities or Marketing Activities not to conduct Marketing Activities.
 - 2. If CMS rejects any material changes to the ACO’s Marketing Plan described in an amendment described in Section 5.09.D, the ACO shall not, and shall require its Participant TINs, Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to ACO Activities or Marketing Activities not to, conduct Marketing Activities outside the scope of the Marketing Plan.
- D. If the ACO chooses to make any material changes to the ACO’s Marketing Plan, the ACO shall submit to CMS, in the form and manner specified by CMS, an amendment to the Marketing Plan describing the material changes the ACO proposes to make to the ACO’s Marketing Plan. An amendment to the ACO’s Marketing Plan shall be deemed approved within 10 business days after submission, unless rejected in writing by CMS.
- E. In conducting Marketing Activities, the ACO shall not, and shall require its Participant TINs, Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to ACO Activities or Marketing Activities not to, discriminate or selectively target Beneficiaries based on race, ethnicity, national origin, religion, gender, sex, age, mental or physical disability, health status, receipt of health care, claims experience, medical history, genetic information, evidence of insurability, geographic location, or income.
- F. In conducting Marketing Activities, the ACO shall not, and shall require its Participant TINs, Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to ACO Activities or Marketing Activities not to conduct communication or Marketing Activities targeted to Beneficiaries enrolled in Medicare Advantage or any other Medicare managed care

plan.

- G. The ACO shall not, and shall require Participant TINs, Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to ACO Activities or Marketing Activities to not, conduct Marketing Activities outside the ACO Service Area, as defined in Section 5.09.Q.
- H. Additionally, all Participant TINs will be required to prominently display informational materials in settings where Beneficiaries receive primary care services notifying aligned Beneficiaries that the Participant TIN is participating in the LEAD Model, and that Beneficiaries retain all Original Medicare benefits and rights.
- I. ACOs must inform Beneficiaries who have been aligned to the ACO what that means for the Beneficiary in terms of the care that they will receive and how to opt-out of CMS sharing certain data about them with the ACO.
- J. ACOs must communicate the details of their Benefit Enhancements (where applicable) to their aligned Beneficiaries, and CMS must approve such written materials prior to use.
- K. ACOs are required to submit any Marketing Materials and Marketing Activities to CMS for review to ensure that the materials comply with the requirements of the LEAD Model, including that they are not:
 - 1. Inaccurate, misleading, or discriminatory
 - 2. Used in a manner that is discriminatory, and
 - 3. Clear that alignment to an ACO does not remove or otherwise affect a Beneficiary's freedom to choose a provider or supplier.
- L. ACOs are prohibited from conducting communication or Marketing Activities targeted towards individuals aligned to their ACOs for the purpose of recruitment into Medicare managed care products. Similarly, ACOs are prohibited from conducting communication or Marketing Activities targeted to individuals enrolled in Medicare managed care.
- M. To allow for more robust outreach to Beneficiaries regarding the ACO, CMS shall permit ACOs to proactively communicate with Beneficiaries regarding Voluntary Alignment, provided such communications comply with all applicable laws and regulations and with the requirements of the Implementation Agreement and Model Participation Agreement, as applicable. For example, ACOs will be able to provide Marketing Materials and hold outreach events to the extent permitted by law.
- N. The LEAD ACO may not engage in misleading Marketing Activities and is prohibited from expressly stating or implying that alignment to the ACO removes or otherwise affects their freedom to choose a provider or supplier.
- O. ACOs shall not, and shall require its Participant TINs, Participant Providers, Preferred Providers, and other individuals or entities performing functions or

services related to ACO Activities or Marketing Activities to not, engage in certain activities that may be intrusive to Beneficiaries or to discriminate against Beneficiaries (such as based on the anticipated costs of a Beneficiary's care).

- P. If the LEAD ACO (1) did not participate in ACO REACH during PY 2026; or (2) did participate in ACO REACH during the 2026 PY, but wishes to change its 2026 voluntary alignment Marketing Materials beyond simply the model name, PY, and ACO name, if applicable, the LEAD ACO must submit voluntary alignment Marketing Materials, at a time requested by CMS, before sharing with Beneficiaries.
- Q. ACO Service Area
1. Except as described in Section 5.09.Q.4, the ACO Service Area consists of the Core Service Area described in Sections 5.09.Q.1 and 5.09.Q.2 and the Extended Service Area described in Section 5.09.Q.3.
 2. The Core Service Area includes the counties in which the ACO's Participant Providers have physical office locations. By the time and in the form and manner specified by CMS, the ACO shall submit to CMS a list of the counties in which the ACO's Participant Providers have physical office locations. CMS shall use this information for purposes of defining the ACO's Core Service Area.
 3. The Extended Service Area includes all counties adjacent to the Core Service Area. CMS shall identify the counties adjacent to the counties in the ACO's Core Service Area for purposes of defining the ACO's Extended Service Area.
 4. If CMS determines that the ACO's clinical care model does not rely on physical practice locations, such as if the ACO is located in a Rural Area or is a home-based care provider that does not have a physical office location where it sees patients, and the ACO proposes an alternative service area definition which CMS approves, the ACO's Service Area shall be the alternative service area so approved by CMS.
- R. To ensure that Beneficiaries are not misinformed or misled about the Model, CMS may develop and provide ACO template language for certain Marketing Materials. The ACO shall use any template language for Marketing Materials provided by CMS.
- S. Marketing Materials and Marketing Activities Review
1. The ACO shall not, and shall require its Participant TINs, Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to ACO Activities to not, use Marketing Materials or engage in Marketing Activities until such Marketing Materials and Marketing Activities are reviewed and approved by CMS, or deemed approved in accordance with Section 5.09.
- T. Marketing Materials and Marketing Activities are deemed approved 10 business

days following their submission to CMS if:

1. The ACO certifies compliance with all applicable requirements under this Section 5.09;
 - a. The ACO has selected to participate in SVA (see Appendix C of this Implementation Agreement); and
 - b. CMS does not disapprove of the Marketing Materials or Marketing Activities.
2. In addition to the actions available under Article XIII, if the ACO has falsely certified compliance with all applicable requirements under this Section 5.09 and, if applicable, Appendix C of this Implementation Agreement, CMS may retroactively reverse any alignment of Beneficiaries to the ACO that occurred solely pursuant to Voluntary Alignment, including via Hybrid Alignment.

U. CMS may review the Marketing Materials and Marketing Activities and issue written notices of disapproval of Marketing Materials and Marketing Activities at any time, including after the expiration of the initial 10 business day review period.

1. The ACO shall promptly discontinue, and shall require its Participant TINs, Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to ACO Activities to promptly discontinue, use of any Marketing Materials and Marketing Activities disapproved by CMS.
2. Any material changes to CMS-approved Marketing Materials and Marketing Activities must be submitted to CMS and approved by CMS or deemed approved in accordance with this Section 5.09.U, before use.
3. The ACO shall retain copies of all written and electronic Marketing Materials and appropriate records for all Marketing Activities in a manner consistent with Section 12.02.

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

1. Engage in activities that could mislead or confuse a Beneficiary regarding the Model, another model currently tested or under development by CMS under the authority of Section 1115A of the Act, the Medicare Shared Savings Program, Medicare benefits, or the ACO; or
2. Claim the ACO is recommended or otherwise endorsed by CMS or that CMS recommends that the Beneficiary select a Participant TIN or Participant Provider as their main doctor, main provider, and/or the main place the Beneficiary receives care; or

3. Expressly state or imply that selecting a Participant TIN or Participant Provider as the Beneficiary's main doctor, main provider, and/or the main place the Beneficiary receives care removes a Beneficiary's freedom to choose to obtain health services from providers and suppliers who are not Participant Providers or Preferred Providers.
- W. The ACO must translate Marketing Materials into any non-English language that is the primary language of at least 5 percent of the individuals in the ACO Service Area as defined in Section 5.09.Q.
- X. Unsolicited Contacts
1. Except as otherwise specified in this Implementation Agreement, the ACO may conduct, and may permit its Participant TINs, Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to ACO Activities or Marketing Activities to conduct, Marketing Activities through unsolicited direct contact with Beneficiaries using conventional mail and other print media or email, provided that the Beneficiaries are given an opportunity to opt-out of subsequent unsolicited contacts.
 2. The ACO is prohibited from using, and shall prohibit its Participant TINs, Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to ACO Activities or Marketing Activities from using, Marketing Materials or conducting Marketing Activities through the use of door-to-door solicitation, including leaving information such as a leaflet or flyer at a residence, approaching Beneficiaries in common areas, such as parking lots, hallways, lobbies, sidewalks, or using telephonic solicitation, including text messages and leaving voicemail messages.
 3. This restriction does not apply to solicitation in common areas of a health care setting, which is subject to the limitations of paragraphs 4 through 7 of this Section 5.09.X and, if the ACO has selected to participate in SVA pursuant to Section 8.01 and applicable requirements in Appendix C.
 4. The ACO may conduct, and may permit Participant TINs, Participant Providers, Preferred Providers, and other individuals and entities performing ACO Activities or Marketing Activities on behalf of the ACO to conduct Marketing Activities in common areas of a health care setting. Common areas of a health care setting include, but are not limited to, common entryways, vestibules, waiting rooms, hospital or nursing home cafeterias, and community, recreational, or conference rooms.
 5. Except as provided in paragraph 5 of this Section 5.09.V, the ACO is prohibited, and shall prohibit its Participant TINs, Participant Providers, Preferred Providers, and other individuals and entities performing ACO Activities or Marketing Activities on behalf of the ACO, from conducting Marketing Activities in restricted areas of a health care setting. Restricted areas of a health

care setting include, but are not limited to, exam rooms, hospital patient rooms, treatment areas (where patients interact with a health care provider and his/her clinical team and receive treatment, including dialysis treatment facilities), and pharmacy counter areas (where patients interact with pharmacy providers and obtain medications).

6. However, for Beneficiaries who are receiving all their clinical care at home or in an institutional setting,
 - a. The ACO may conduct, and may permit Participant TINs, Participant Providers, Preferred Providers, and other individuals and entities performing ACO Activities, to conduct Marketing Activities on behalf of the ACO in these settings. CMS shall not consider the home or institutional setting to be the exam room for SVA purposes.
 - b. The SVA form must include an option for the Beneficiary to decline Marketing Activities such as SVA at their home or their institutional setting (i.e., the place of clinical care).
 - c. CMS requires that SVA forms be completed either at the beginning or end of the second visit.
7. The ACO may distribute and display Marketing Materials in all areas of the health care setting, including both common areas and restricted areas, except as otherwise specified in this Implementation Agreement.

Y. Marketing Events

1. The ACO shall ensure that:
 - a. Marketing Events do not involve health screenings or any other activity that is used, or could be perceived as being used, to avoid treating At-Risk Beneficiaries or to target certain Beneficiaries for services for the purpose of trying to affect the population of Beneficiaries aligned to the ACO for the ACO's first PY or a subsequent PY.
 - b. Marketing Events do not require attendees to provide their contact information as a prerequisite for attending the Marketing Event and that any sign-in sheets used for purposes of the Marketing Event are clearly labeled as optional.
 - c. Beneficiary contact information provided at a Marketing Event is used only for the purpose for which it was solicited. For example, Beneficiary contact information provided for a raffle or other drawing must be used only for purposes of such raffle or drawing.
 - d. Any Marketing Activities conducted, and Marketing Materials distributed as part of the Marketing Event comply with the applicable requirements of this Section 5.09.

2. In conducting Marketing Events, the ACO may engage in activities including, but not limited to:
 - a. Hosting the Marketing Event in a public venue;
 - b. Answering Beneficiary-initiated questions regarding the ACO's participation in the Model; or
 - c. Distributing the ACO's, the Participant TIN's, a Participant Provider's, or a Preferred Provider's business cards and contact information to Beneficiaries.

Section 5.10 [Reserved]

Section 5.11 Prohibition on Beneficiary Inducements

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

Section 5.12 HIPAA Requirements

- A. The ACO acknowledges that it is a covered entity or a business associate, as those terms are defined in 45 CFR § 160.103, of Participant TINs, Participant Providers or Preferred Providers who are covered entities.
- B. The ACO shall have all appropriate administrative, technical, and physical safeguards in place before the Implementation Period Start Date to protect the privacy and security of protected health information (PHI) in accordance with 45 CFR § 164.530(c).
- C. The ACO shall maintain the privacy and security of all Model-related information that identifies individual 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 covered entities and business associates, as well as other applicable federal and state laws and regulations.

ARTICLE VI DATA SHARING AND REPORTS

Section 6.01 General

CMS is not offering the ACO an opportunity to request any Beneficiary-identifiable data from CMS in connection with its LEAD participation during the Implementation Period under the

terms of this Implementation Agreement. Any Beneficiary-identifiable data sharing for purposes of the ACO's first PY shall be governed by the terms of the Model Participation Agreement referenced in Section 1.04 of this Implementation Agreement.

Section 6.02 De-Identified Reports

During the Implementation Period, CMS may provide reports to the ACO, which shall include aggregated data that is de-identified in accordance with HIPAA requirements in 45 CFR § 164.514(b). This aggregate information shall not include individually identifiable health information.

ARTICLE VII

[Reserved]

ARTICLE VIII ACO SELECTIONS AND APPROVAL

Section 8.01 ACO Selection for the Implementation Period

- A. For the Implementation Period, in a form and manner and by a deadline specified by CMS, the ACO shall submit to CMS its decision with respect to participation in SVA (as opposed to MVA).
- B. The ACO's decision to participate in SVA for the Implementation Period refers to the ACO's decision to participate in Voluntary Alignment Activities specific to SVA in accordance with Appendix C during the Implementation Period for purposes of aligning Beneficiaries to the ACO for the ACO's first PY.

Section 8.02 ACO Selections for the Agreement Performance Period

- A. Risk Option Selection
 - 1. If the ACO chooses to participate in the Agreement Performance Period, by a time and in the form and manner specified by CMS, the ACO shall submit its selected Risk Option (Professional or Global) for the ACO's first PY.
 - 2. The Risk Option selected during the Implementation Period may differ from the Risk Option selected by the ACO as part of its application to participate in the Model.
 - 3. If the ACO selects Professional as its Risk Option for the ACO's first PY, the ACO may select to change its Risk Option to Global for the ACO's second PY or any subsequent PY pursuant to the Model Participation Agreement referenced in Section 1.04 of this Implementation Agreement.
 - 4. If the ACO selects Global as its Risk Option for the ACO's first PY, the ACO's selection of Global as its Risk Option shall remain in effect for the duration of the ACO's participation in the Agreement Performance Period.
- B. Capitation Payment Mechanism Selection
 - 1. If the ACO chooses to participate in the Agreement Performance Period, by a time and in a form and manner specified by CMS, the ACO shall submit its selections for Capitation Payment Mechanism for the Agreement Performance Period.
 - 2. If the ACO has selected to participate in the Global Risk Option for the ACO's first PY, the ACO may select either TCC Payment or PCC Payment as its Capitation Payment Mechanism for its first PY.
 - 3. If the ACO has selected to participate in the Professional Risk Option for the ACO's first PY, the ACO may select only PCC Payment as its ACO Capitation Payment Mechanism for its first PY.
 - 4. PCC Payment
 - a. If the ACO selects PCC Payment, CMS shall make a prospective

monthly payment to the ACO for PCC Eligible Services furnished to ACO-aligned LEAD Beneficiaries by the eligible Primary Care Specialists (i.e., Participant Providers and Preferred Providers) participating in PCC Payment during the Agreement Performance Period.

- b. The PCC Payment amount will be equal to a percentage of the risk adjusted, trended, and regionally adjusted (if applicable) benchmark, where the exact percentage is determined based on the sum of the Base Primary Care Capitation Amount and the Enhanced PCC amount.
- c. If the ACO selects to participate in PCC Payment for its first PY, the ACO must also select whether it will participate in NPCC and/or the APO by a time and in a form and manner specified by CMS.

C. Alignment Method Selection

- 1. The ACO must select the Alignment Methodology (Prospective Alignment or Hybrid Alignment) that will apply to the ACO's first PY by a time and in a manner specified by CMS.

D. Benefit Enhancements and Beneficiary Engagement Incentives

- 1. Benefit Enhancements and Beneficiary Engagement Incentives are optional and may be selected by the ACO during the Implementation Period for the upcoming PY.
- 2. The ACO may select to provide one or more Benefit Enhancements and/or Beneficiary Engagement Incentives for the ACO's first PY. CMS shall provide the ACO with information regarding the Benefit Enhancements and Beneficiary Engagement Incentives available for selection for the first PY and the procedures for submitting selections in advance of the applicable deadline.
- 3. The ACO shall submit to CMS, in a form and manner and by a date specified by CMS, a plan (i.e., Implementation Plan) for implementing each Benefit Enhancement and each Beneficiary Engagement Incentive selected by the ACO.

Section 8.03 ACO Selection and Acceptance

- A. The ACO's selections regarding SVA alignment, made as described in Section 8.01, shall be deemed approved unless rejected in writing by CMS within 30 Days c after submission.
- B. If CMS determines that the ACO's proposed implementation of one or more Benefit Enhancements or Beneficiary Engagement Incentives is inconsistent with the terms of this Implementation Agreement or the Model Participation Agreement

referenced in Section 1.04, or likely to result in abuse or program integrity concerns, CMS may reject the ACO's selection to provide one or more Benefit Enhancements or Beneficiary Engagement Incentives or may reject (or require the amendment of) the ACO's Implementation Plan.

- C. If CMS rejects an Implementation Plan for a Benefit Enhancement or Beneficiary Engagement Incentive, the ACO shall not implement the Benefit Enhancement or Beneficiary Engagement Incentive for the ACO's first PY.
- D. CMS is not precluded from taking any remedial actions described in Section 13.01 after the ACO's selections have been deemed approved.

ARTICLE IX RIGHTS IN DATA AND INTELLECTUAL PROPERTY

Section 9.01 Rights in Data and Intellectual Property

- A. Notwithstanding any other provision in the Agreement, all proprietary trade secret information and technology of the ACO or its Participant TINs, Participant Providers and Preferred Providers is and shall remain the sole property of the ACO, the Participant TIN, the Participant Provider, or Preferred Provider and, except as required by federal law, shall not be released by CMS without express written consent. The regulation at 48 CFR § 52.227-14, "Rights in Data-General" is hereby incorporated by reference into the Agreement. CMS does not acquire by license or otherwise, whether express or implied, any intellectual property right or other rights to the ACO's, Participant TINs, Participant Providers', or Preferred Providers' proprietary information or technology.
- B. If the ACO maintains any information that should not be publicly disclosed because the ACO considers such information to be proprietary and confidential, the ACO acknowledges that it has submitted to CMS a form, using either the template attached as Appendix EE, or a form substantially the same as Appendix EE, identifying specific examples of information the ACO considers to be proprietary and confidential. CMS will deem any information received from the ACO solely to evaluate an ERO Request to be included on this form. The ACO must notify CMS, in a form and manner to be specified by CMS, of any updates to this form. If the ACO does not submit such a form, it will be deemed to be confirmed that the ACO has no information it considers proprietary and confidential.

ARTICLE X PUBLIC REPORTING AND RELEASE OF INFORMATION

Section 10.01 ACO Public Reporting and Transparency

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

- A. Name and location of the ACO;
- B. Primary contact information for the ACO;

- C. Identification of all Participant TINs, and Preferred Providers;
- D. Identification of all joint ventures between or among the ACO and any of its Participant TINs and Preferred Providers;
- E. Identification of the ACO's key clinical and administrative leaders and the name of any company by which they are employed; and
- F. Identification of members of the ACO's governing body and the name of any entity by which they are employed.
- G. Financial Performance information (SL/SS/QPP, etc.) in the LEAD Model for all years of Participation.

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

Section 10.02 ACO Release of Information

- A. The ACO, its Participant TINs, Participant Providers, and Preferred Providers shall obtain prior approval from CMS during the term of this Implementation Agreement and for 1 year thereafter for the publication or release of any press release, external report or statistical/analytical material that materially and substantially references the ACO's participation in the Model. External reports and statistical/analytical material may include, but are not limited to, papers, articles, professional publications, speeches, and testimony.
- B. All external reports and statistical/analytical material that are subject to this Section 10.02 must include the following statement on the first page: "The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of CMS. The authors assume responsibility for the accuracy and completeness of the information contained in this document."

ARTICLE XI COMPLIANCE AND OVERSIGHT

Section 11.01 ACO Compliance Plan

- A. The ACO shall have a compliance plan that includes at least the following elements:
 - 1. A designated compliance official or individual who is not legal counsel to the ACO and reports directly to the ACO's governing body;
 - 2. Description of the ACO Governance requirements articulated in Section 3.02 of this Implementation Agreement, including (a) the purpose, functions, and processes of the governing body and/or Beneficiary and Consumer Advisory Committee; (b) the required make-up of the Beneficiary and Consumer Advisory Committee; and (c) applicable conflict of interest requirements and policy.
 - 3. Mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance;

4. A method for employees or contractors of the ACO, its Participant TINs, Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to ACO Activities or Marketing Activities to anonymously report suspected problems related to the ACO to the compliance official;
 5. Compliance training for the ACO, its Participant TINs, Participant Providers, and Preferred Providers; and
 6. A requirement for the ACO to report probable violations of law to an appropriate law enforcement agency.
- B. The ACO's compliance plan must be aligned and in compliance with all applicable laws and regulations and must be updated periodically to reflect changes in those laws and regulations.

Section 11.02 CMS Monitoring and Oversight Activities

- A. CMS shall conduct monitoring activities to evaluate compliance by the ACO, its Participant TINs, Participant Providers, and its Preferred Providers with the terms of this Implementation Agreement. Such monitoring activities may include, without limitation:
1. Claims analyses to identify fraudulent behavior or program integrity risks, such as inappropriate reductions in care (e.g., through claims-based utilization, inappropriate changes in case-mix or quality measures), efforts to manipulate risk scores or aligned populations, overutilization, and cost-shifting to other payers or populations.
 2. Documentation requests sent to the ACO, its Participant TINs, Participant Providers, and/or its Preferred Providers, including surveys and questionnaires.
 3. Interviews with any individual or entity participating in ACO Activities or Marketing Activities, including, but not limited to, members of the ACO leadership and management, the ACO's Participant TINs, Participant Providers, and Preferred Providers.
 4. Interviews with Beneficiaries and their caregivers.
 5. Audits of charts, medical records, Implementation Plans, and other data from the ACO, its Participant TINs, Participant Providers, and its Preferred Providers.
 6. Site visits to the ACO, Participant TINs, Participant Providers, and Preferred Providers; and
 7. Documentation requests sent to the ACO, Participant TINs, Participant Providers, and/or Preferred Providers, including surveys and questionnaires.

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

Section 11.03 ACO Compliance with Monitoring and Oversight Activities

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

Section 11.04 Compliance with Laws

A. Agreement to Comply

1. The ACO shall comply with, and shall require its Participant TINs, Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to ACO Activities or Marketing Activities to comply with, the applicable terms of this Implementation Agreement and all applicable statutes, regulations, and guidance, including without limitation: (a) federal criminal laws; (b) the False Claims Act (31 U.S.C. § 3729 et seq.); (c) the anti-kickback statute (42 U.S.C. § 1320a-7b(b)); (d) the civil monetary penalties law (42 U.S.C. § 1320a-7a); (e) the physician self-referral law (42 U.S.C. § 1395nn); and (f) State laws, as applicable.
2. This Implementation Agreement does not waive any obligation of the ACO or the ACO's Participant TINs, Participant Providers, or Preferred Providers to comply with the terms of any other CMS contract, agreement, model, or demonstration.
3. In addition to meeting any other overpayment or fraud reporting obligations of all applicable statutes, regulations, and guidance, the ACO shall notify CMS in the form and manner described by CMS no later than 60 Days after the date on which the ACO identified credible evidence to substantiate fraud, and having a reasonable suspicion or belief that a Medicare-enrolled provider or supplier submitted fraudulent claims for Covered Services rendered to a LEAD Beneficiary.

B. State Recognition

During the term of this Implementation Agreement, the ACO shall be in compliance with applicable state licensure requirements regarding risk-bearing entities in each state in which it operates.

C. Reservation of Rights

1. Nothing contained in this Implementation Agreement or in the application process for the Model is intended or can be construed as a waiver by the United States Department of Justice, the Internal Revenue Service, the

Federal Trade Commission, Office of Inspector General of the Department of Health and Human Services (OIG), or CMS of any right to institute any proceeding or action for violations of any statutes, rules or regulations administered by the government, or to prevent or limit the rights of the government to obtain relief under any other federal statutes or regulations, or on account of any violation of this Implementation Agreement or any other provision of law. This Implementation Agreement cannot be construed to bind any government agency except CMS, and this Implementation Agreement binds CMS only to the extent provided herein.

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

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

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

E. Other Government Authority

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

Section 11.05 Certification of Data and Information

- A. With respect to data and information generated or submitted to CMS by the ACO, its Participant TINs, Participant Providers, Preferred Providers, or other individuals or entities performing functions or services related to ACO Activities or Marketing Activities, the ACO shall ensure that an individual with the authority to legally bind the individual or entity submitting such data or information certifies the accuracy, completeness, and truthfulness of that data and information to the best of the individual's knowledge, information, and belief.
- B. At the end of the Implementation Period, an individual with the legal authority to bind the ACO must certify to the best of the individual's knowledge, information, and belief:

1. That the ACO, its Participant TINs, Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to ACO Activities or Marketing Activities are in compliance with Model requirements; and
2. The accuracy, completeness, and truthfulness of all data and information that are generated or submitted by the ACO, its Participant TINs, Participant Providers, Preferred Providers, or other individuals or entities performing functions or services related to ACO Activities or Marketing Activities.

ARTICLE XII AUDITS AND RECORD RETENTION

Section 12.01 Right to Audit

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

- A. The ACO's compliance with the terms of this Implementation Agreement, including provisions that require the ACO to impose duties or requirements on Participant TINs, Participant Providers, or Preferred Providers;
- B. Whether Participant TINs, Participant Providers, and Preferred Providers complied with the duties and requirements imposed on them by the ACO pursuant to the terms of this Implementation Agreement;
- C. The ACO's compliance with applicable laws, regulations, and Medicare program requirements; and
- D. Any activity by the ACO, a Participant TIN, Participant Provider, or a Preferred Provider that may pose a potential risk of harm to Beneficiaries or a vulnerability to the integrity of the model test.

Section 12.02 Maintenance of Records

- A. The ACO shall maintain and shall give the government (including CMS, HHS, and the Comptroller General or their designees) access to, and shall require all Participant TINs, Participant Providers, Preferred Providers, and other individuals and entities performing functions or services related to ACO Activities or Marketing Activities to maintain, and give the government access to, all books, contracts, records, documents, and other evidence (including data related to Medicare utilization and costs, quality performance

measures, and financial arrangements) sufficient to enable the audit, evaluation, inspection, or investigation of the Model, including the subjects identified in Section 12.01.

- B. The ACO shall maintain, and shall require all Participant TINs, Participant Providers, Preferred Providers, and individuals and entities performing functions or services related to ACO Activities or Market Activities to maintain, such books, contracts, records, documents, and other evidence for a period of 10 years from the expiration or termination of this Implementation 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 ACO at least 30 Days before the normal disposition date; or
 2. There has been a termination, dispute, or allegation of fraud or similar fault against the ACO, its Participant TINs, Participant Providers, Preferred Providers, or other individuals or entities performing functions or services related to ACO Activities or Marketing Activities, in which case the records shall be maintained for an additional six years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

ARTICLE XIII REMEDIAL ACTION AND TERMINATION

Section 13.01 Remedial Action

- A. CMS may immediately or with advance notice terminate this Implementation Agreement at any point for non-compliance with its terms or as required by Section 1115A(b)(3)(B) of the Act.
- B. If CMS determines that any provision of this Implementation Agreement may have been violated, CMS may take one or more of the following actions:
1. Notify the ACO and, if appropriate, the Participant TIN, Participant Provider, and/or Preferred Provider of the violation;
 2. Require the ACO to provide additional information to CMS or its designees;
 3. Conduct site visits, interview Beneficiaries, or take other actions to gather information;
 4. Place the ACO on a monitoring and/or auditing plan developed by CMS;
 5. Require the ACO to remove a Participant TIN, Participant Provider, or Preferred Provider from the Participant TIN List, or Preferred Provider List and to terminate any arrangements, immediately or within a timeframe specified by CMS, with such Participant TIN, Participant Provider or Preferred Provider with respect to this Model;

6. Require the ACO to terminate its relationship with any other individual or entity performing functions or services related to ACO Activities or Marketing Activities;
 7. Request a corrective action plan (“CAP”) from the ACO that is acceptable to CMS, in which case, the following requirements apply:
 - a. The ACO shall submit a CAP for CMS approval by a deadline established by CMS; and
 - b. The CAP must address what actions the ACO will take (or will require any Participant TIN, Participant Provider, Preferred Provider, or other individual or entity performing functions or services related to ACO Activities or Marketing Activities to take) within a specified time period to ensure that all deficiencies will be corrected, and that the ACO will be in compliance with the terms of this Implementation Agreement;
 8. Prohibit the ACO from accessing any or all waivers of existing law made pursuant to Section 1115A(d)(1) of the Act;
 9. Discontinue the provision of reports to the ACO under Article VI of this Implementation Agreement;
 10. Prohibit the ACO from participating in SVA, distributing Marketing Materials, or conducting Marketing Activities, including Voluntary Alignment Activities.
 11. Require the ACO to suspend or terminate a Start-up Arrangement.
- C. CMS may impose additional remedial actions or terminate this Implementation Agreement pursuant to Section 13.02 if CMS determines that remedial actions were insufficient to correct noncompliance with the terms of this Implementation Agreement.
- D. CMS may require the ACO to remove a Participant TIN, Participant Provider, or Preferred Provider from the ACO’s Participant TIN List, or Preferred Provider List and to terminate any arrangements with the removed Participant TIN, Participant Provider, or Preferred Provider with respect to this Model if CMS determines that the Participant TIN, Participant Provider, or Preferred Provider:
1. Has failed to comply with any Medicare program requirement, rule, or regulation;
 2. Has failed to comply with the ACO’s CAP, the monitoring and/or auditing plan developed by CMS for the ACO, or other remedial action imposed by CMS;
 3. Has taken any action that threatens the health or safety of a Beneficiary or other patient;

4. Is subject to sanctions or other actions of an accrediting organization or a federal, state, or local government agency; or
 5. Is subject to investigation or action by HHS (including OIG and CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the government has intervened, or similar action.
- E. The Model Participation Agreement shall authorize CMS to take remedial action against the ACO for non-compliance with the terms of this Implementation Agreement, regardless of when CMS discovers the non-compliance.

Section 13.02 Termination of Implementation Agreement by CMS

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

- A. CMS determines that the Agency no longer has the funds to support the Model;
- B. CMS modifies or terminates the Model pursuant to Section 1115A(b)(3)(B) of the Act;
- C. CMS determines that the ACO:
 1. Has failed to comply with any term of this Implementation Agreement or any other Medicare program requirement, rule, or regulation;
 2. Has failed to comply with a monitoring and/or auditing plan;
 3. Has failed to submit, obtain approval for, implement or fully comply with the terms of a CAP;
 4. Has failed to demonstrate improved performance following any remedial action;
 5. Has taken any action that threatens the health or safety of a Beneficiary or other patient;
 6. Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the Model;
 7. Assigns or purports to assign any of the rights or obligations under this Implementation Agreement, voluntarily or involuntarily, whether by merger, consolidation, dissolution, operation of law, or any other manner, without the written consent of CMS.
 8. Poses significant program integrity risks, including, but not limited to:
 - a. Is subject to sanctions or other actions of an accrediting organization or a federal, state, or local government agency; or
 - b. Is subject to investigation or action by HHS (including OIG and

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

- D. CMS determines that one or more of the Participant TINs, Participant Providers, or Preferred Providers has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the Model; or
- E. The state in which the ACO operates enters an arrangement with CMS that is based on a statewide global or per-capita Medicare payment.

Section 13.03 Termination of Implementation Agreement by ACO

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

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

- A. If this Implementation Agreement or the Implementation Period is terminated under Sections 13.01, 13.02 or 13.03, the ACO shall post a notice of the termination on its ACO website and provide written notice of the termination to all Participant TINs, Participant Providers, and Preferred Providers. The ACO shall deliver such written notice no later than 30 Days before the effective date of termination unless a later date is specified by CMS. The ACO shall include in such notices any content specified by CMS, including information regarding Marketing Activities.

The ACO may provide written notice of the termination to Beneficiaries aligned to the terminated ACO. Any notice to Beneficiaries is subject to review and approval by CMS under Section 5.09 as Marketing Materials.

ARTICLE XIV LIMITATION ON REVIEW AND DISPUTE RESOLUTION

Section 14.01 Limitations on Review

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

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

- B. The elements, parameters, scope, and duration of such models for testing or dissemination;
- C. Determinations regarding budget neutrality under Section 1115A(b)(3);
- D. The termination or modification of the design and implementation of a model under Section 1115A(b)(3)(B); and
- E. Beneficiaries Alignment to the ACO by CMS.

Section 14.02 Dispute Resolution

A. Right to Reconsideration

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

1. Such a request for reconsideration by the ACO must satisfy the following criteria:
 - a. The request must be submitted to a designee of CMS (“**Reconsideration Official**”) who—
 - i. Is authorized to receive such requests;
 - ii. Did not participate in the determination that is the subject of the reconsideration request; and
 - iii. May be, but does not have to be, an inferior officer.
 - b. The request must contain a detailed, written explanation of the basis for the dispute, including supporting documentation.
 - c. The request must be made within 30 Days of the date of the determination for which reconsideration is requested via email to CMS at the address specified in Section 15.01 or such other address as may be specified by CMS.
2. Requests that do not meet the requirements of Section 14.02.A.1 shall be denied by the Reconsideration Official.
3. Within 10 business days of receiving a request for reconsideration, the Reconsideration Official shall send to the ACO and to CMS a written acknowledgement of receipt of the reconsideration request. Such an acknowledgement shall state:
 - a. The review procedures; and
 - b. A schedule that permits each party to submit documentation in support of the party’s position for consideration by the Reconsideration Official.

B. Standards for Reconsideration

1. The parties shall proceed diligently with the performance of this Implementation Agreement during the course of any dispute arising under the Implementation 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 ACO to demonstrate to the Reconsideration Official with clear and convincing evidence that the determination is inconsistent with the terms of the Implementation Agreement.

C. Reconsideration Determination

1. The reconsideration determination shall be based only upon:
 - a. Position papers and supporting documentation that are timely submitted to the Reconsideration Official and meet the standards for submission under Section 14.02.A.1 and the Reconsideration Official's written acknowledgement under Section 14.01.A.3; and
 - b. Documents and data that were timely submitted to CMS in the required format before the agency made the determination that is the subject of the reconsideration request.
2. The Reconsideration Official shall issue to CMS and to the ACO a written notification of the reconsideration determination. Absent unusual circumstances, such written notification shall be issued within 60 calendar days of receipt of timely filed position papers and supporting documentation.
3. Effect of Reconsideration Determination
 - a. The determination of the Reconsideration Official is final and binding.
 - b. The reconsideration review process under this Implementation Agreement shall not be construed to negate, diminish, or otherwise alter the applicability of existing laws, rules, and regulations or determinations made by other government agencies.

ARTICLE XV MISCELLANEOUS

Section 15.01 Notifications and Submission of Reports

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

CMS/LEAD Model

Centers for Medicare & Medicaid Services

7500 Security Boulevard

Mailstop: WB-06-05 Baltimore, MD 21244

Email: LEAD@cms.hhs.gov

ACO _____

Address: _____

Email: _____

Section 15.02 Notice of Bankruptcy

If the ACO has filed a bankruptcy petition, whether voluntary or involuntary, the ACO 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 ACO under the terms of each model tested under Section 1115A of the Act in which the ACO is participating or has participated and all administrative or judicial review proceedings relating to any payments under such models have been fully and finally resolved.

The notice of bankruptcy must be sent by certified mail no later than five calendar 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 ACO is participating or has participated. This list need not identify a model tested under Section 1115A of the Act in which the ACO 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 ACO and CMS have been fully and finally resolved with respect to that model.

The notice to CMS must be addressed to the CMS Office of Financial Management, Mailstop C3-01-24, 7500 Security Boulevard, Baltimore, Maryland 21244 or to such other address as may be specified on the CMS website for purposes of receiving such notices. This obligation remains in effect after the expiration or termination of this Implementation Agreement.

Section 15.03 Severability

In the event that any one or more of the provisions of this Implementation 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 Implementation Agreement, and this Implementation Agreement shall be construed as if such invalid, illegal or unenforceable provisions had never been included in the Implementation Agreement, unless the deletion of such provision or provisions would result in such a material change to the Implementation Agreement so as to cause continued participation under the terms of the Implementation Agreement to be unreasonable.

Section 15.04 Entire Agreement; Amendment

This Implementation Agreement, including all Appendices, constitutes the entire agreement between the parties for the Implementation Period of the Model. The parties may amend this Implementation Agreement or any Appendix hereto at any time by mutual written agreement; provided, however, that CMS may amend this Implementation Agreement or any Appendix hereto without the consent of the ACO as specified in this Implementation 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 ACO with 30 calendar days advance written notice of any such unilateral amendment, which notice shall specify the amendment's effective date.

Section 15.05 Survival

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

Section 3.05	(Start-up Arrangements);
Section 9.01	(Evaluation Requirement);
Section 9.01	(Rights in Data and Intellectual Property);
Section 10.02	(ACO Release of Information);
Section 11.03	(ACO Compliance with Monitoring and Oversight Activities);
Section 11.05	(Certification of Data and Information);
Article XII	(Audits and Record Retention);

Section 13.04	(Notifications to Participant TINs, Participant Providers, Preferred Providers, and Beneficiaries upon Termination);
Section 14.01	(Limitations on Review);
Section 15.02	(Notice of Bankruptcy);
Section 15.05	(Survival);
Section 15.08	(Prohibition on Assignment); and
Section 15.09	(Change in Control).

Section 15.06 Precedence

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

Section 15.07 Change of ACO Name

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

Section 15.08 Prohibition on Assignment

Except with the prior written consent of CMS, the ACO shall not transfer, including by merger (whether the ACO is the surviving or disappearing entity), consolidation, dissolution, or otherwise: (1) any discretion granted it under this Implementation Agreement; (2) any right that it has to satisfy a condition under this Implementation Agreement; (3) any remedy that it has under this Implementation Agreement; or (4) any obligation imposed on it under this Implementation Agreement. The ACO shall provide CMS with a 90-day (i.e., calendar days) advance written notice of any such proposed transfer. This obligation remains in effect after the expiration or termination of this Implementation Agreement. Any purported transfer in violation of this Section is voidable at the discretion of CMS.

Section 15.09 Change in Control

CMS may terminate this Implementation Agreement if the ACO undergoes a Change in Control. The ACO shall provide written notice to CMS at least 90 calendar days before the effective date of any Change in Control. The written notification must be furnished in a form and manner specified by CMS. For purposes of this paragraph, a "Change in Control" shall mean: (1) the acquisition by any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the ACO representing more than 50% of the ACO's outstanding

voting securities or rights to acquire such securities; (2) the acquisition of the ACO by any individual or entity; (3) the sale, lease, exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the ACO; or (4) the approval and completion of a plan of liquidation of the ACO, or an agreement for the sale or liquidation of the ACO. If the ACO does not participate in the Agreement Performance Period, this obligation remains in effect until December 31, 2028.

Section 15.10 Change in TIN

The ACO shall provide CMS at least 60 calendar days' advance written notice of any change in the ACO's TIN by completing and submitting the change of TIN form provided by CMS. In response to a change in the ACO's TIN, CMS may terminate the Implementation Agreement or take any other actions consistent with the terms of the Implementation Agreement.

Section 15.11 Certification

The executive signing this Implementation Agreement on behalf of the ACO certifies to the best of their knowledge, information, and belief that the information submitted to CMS and contained in this Implementation Agreement (inclusive of appendices), is accurate, complete, and truthful, and that he or she is authorized by the ACO to execute the Implementation Agreement and to legally bind the ACO on whose behalf he or she is executing the Implementation Agreement to its terms and conditions.

Section 15.12 Execution in Counterpart

This Implementation Agreement and any amendments hereto may be executed in counterparts, each of which shall be deemed to be original, but all of which, taken together, shall constitute one and the same agreement. This Implementation 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 Implementation 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 the 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 the Agreement.

ACO: _____

Date: _____ By: _____

Name of authorized signatory and
APM Executive

CMS:

Date: _____ By: _____

Name of authorized signatory and
CMS Executive

APPENDIX A: IMPLEMENTATION PERIOD NON-DUPLICATION WAIVER AND PARTICIPANT OVERLAP

I. Waiver

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

II. ACO Overlap

- A. Consistent with the waiver in Section I of this Appendix A, during the Implementation Period, the ACO and its Participant Providers and Preferred Providers may simultaneously participate in the Model and the Medicare Shared Savings Program.
- B. If otherwise eligible, the ACO and its Participant Providers and Preferred Providers may participate in other Medicare demonstrations, programs, or models during the Implementation Period, to the extent permitted under the terms of such demonstration, program, or model, including the ACO REACH, the Medicare Shared Savings Program, the Kidney Care Choices Model, the Maryland AHEAD Hospital Global Budgets or Primary Care AHEAD, or any other Medicare initiative that involves shared savings, the ACCESS (Advancing Chronic Care with Effective, Scalable Solutions) Model, the EOM (Enhancing Oncology Model), the TEAM (Transforming Episode Accountability Model), and the ASM (Ambulatory Specialty Model).
- C. If the ACO chooses to participate in the Agreement Performance Period, any requirements regarding overlapping participation during the Agreement Performance Period shall be specified in the Model Participation Agreement referenced in Section 1.04 of this Implementation Agreement, including a requirement that the ACO and its Participant Providers may not simultaneously participate in another LEAD ACO in the Model, the Medicare Shared Savings Program, the Kidney Care Choices Model, the Maryland AHEAD Hospital Global Budgets or Primary Care AHEAD, or any other Medicare initiative that involves shared savings for the remaining duration of the Agreement Performance Period.

APPENDIX B: [RESERVED]

APPENDIX C: SIGNED ATTESTATION-BASED VOLUNTARY ALIGNMENT

I. General

This Appendix applies to SVA performed during the Implementation Period, pursuant to Section 8.01 of the Implementation Agreement.

II. SVA

- A. The ACO may send a form (the “**Voluntary Alignment Form**”) and a cover letter including instructions on how to complete the Voluntary Alignment Form (“**Letter**”) electronically or by mail to a Beneficiary in a manner consistent with the requirements of Article V of the Implementation Agreement and this Appendix.
- B. CMS shall determine the content of the Voluntary Alignment Form and shall provide templates to the ACO for both the Voluntary Alignment Form and the Letter.
- C. The ACO shall make no changes to the template Voluntary Alignment Form provided by CMS, with the exception of changes made solely for the insertion of the following information where indicated:
 - 1. The name of the Participant TIN that the ACO believes may be the Beneficiary’s usual source of care. If the ACO wishes, the name of a Participant Provider may also be added to the form.
 - 2. The logo of the ACO or Participant Provider and/or Participant TIN; and
 - 3. Instructions for how the Beneficiary can submit the Voluntary Alignment Form to the ACO.
- D. The ACO shall make no changes to the template Letter where CMS has indicated content that the ACO cannot amend or remove. The ACO may otherwise make changes, subject to the ACO obtaining CMS approval of the final Letter content pursuant to Section 5.09.R of the Implementation Agreement, including:
 - 1. Formatting for electronic distribution;
 - 2. Inserting the name of the Participant TIN that the ACO believes may be the Beneficiary’s usual source of care. If the ACO wishes, the name of a Participant Provider may also be added to the form.
 - 3. Inserting the logo of the ACO or Participant Provider;
 - 4. The addition of instructions for how the Beneficiary can submit the Voluntary Alignment Form to the ACO;
 - 5. The insertion of information about unique care coordination and

preventative services offered by the ACO; and

6. Inserting the ACO's contact information for answering Beneficiaries' questions.
- E. The ACO shall submit to CMS, by a time and in a form and manner specified by CMS, a document describing how the ACO will conduct its Voluntary Alignment Activities specific to SVA in accordance with this Appendix during the Implementation Period, including the criteria for determining which Beneficiaries will receive the Voluntary Alignment Form and Letter.
- F. The ACO shall not, and shall require its Participant TINs, Participant Providers and Preferred Providers not to, send or distribute the Voluntary Alignment Form outside the ACO Service Area (as defined in Section 5.09.Q of the Implementation Agreement). The ACO may provide the Voluntary Alignment Form at the point of care only in the offices of Participant TINs and/or Participant Providers. The ACO shall notify CMS by a date specified by CMS if the ACO elects to provide the Voluntary Alignment Form at the point of care.
- G. Form Requests
 1. The ACO shall permit any Beneficiary who receives care from a Participant TIN or Participant Provider to receive a Voluntary Alignment Form, upon request. The ACO shall permit the Beneficiary to request a Voluntary Alignment Form in person at the office of the Participant TIN or Participant Provider or by calling the ACO.
 2. The ACO shall permit any Beneficiary who has received a Voluntary Alignment Form to request another Voluntary Alignment Form that identifies:
 - a. Beneficiary's usual source of care by Participant TIN and, if the ACO wishes, by Participant Provider in addition to Participant TIN; or
 - b. A physician or other individual or entity that is not a Participant TIN or Participant Provider as the Beneficiary's usual source of care; or
 - c. Otherwise reverses the Beneficiary's SVA.The ACO shall permit such requests to be made by calling the ACO.
 3. The ACO shall permit the appointed representative of a Beneficiary who has received a Voluntary Alignment Form to complete and sign the Voluntary Alignment Form on behalf of the Beneficiary.
- H. Maintenance of Records. In accordance with Section 12.02 of the Implementation Agreement, the ACO shall maintain and shall provide to the government upon request a list of all Beneficiaries to whom the ACO has sent the Voluntary Alignment Form and Letter, copies of all Voluntary Alignment Forms sent or otherwise furnished to Beneficiaries (including copies of the

Letter sent with such forms), and, as applicable, original executed Voluntary Alignment Forms, envelopes in which Voluntary Alignment Forms were returned to the ACO, written documentation of any oral communications with a Beneficiary or the Beneficiary's appointed representative regarding the potential or actual reversal of a Voluntary Alignment Form, all electronic data and files associated with the distribution and submission of Voluntary Alignment Forms, and all other documents and records regarding the ACO's participation in SVA, including documents and records pertaining to Beneficiary communications.

III.SVA Process

- A. The ACO shall submit to CMS a list ("**SVA List**") that contains the following:
 - 1. The name, Medicare Beneficiary Identifier (MBI), and, to the extent required by CMS, any other identifying information of each Beneficiary who returned a valid Voluntary Alignment Form to the ACO identifying a Participant TIN as the Beneficiary's usual source of care. A Voluntary Alignment Form is valid only if it has been signed and dated by the Beneficiary or the Beneficiary's appointed representative and is returned to the ACO on or before the date on which the ACO submits its SVA List to CMS. If a Beneficiary returns more than one valid Voluntary Alignment Form to the ACO, the ACO should include only the information from the latest submitted valid Voluntary Alignment Form. A Voluntary Alignment Form submitted to a Participant TIN or Participant Provider is considered to have been returned to the ACO;
 - 2. For each Beneficiary identified pursuant to Section III.A.1 of this Appendix, the date on which the Beneficiary executed the Voluntary Alignment Form;
 - 3. For each Beneficiary identified pursuant to Section III.A.1 of this Appendix, the identity of the Participant TIN that the Beneficiary has identified as their usual source of care; and
 - 4. A certification by an executive of the ACO made in accordance with Section 11.05 of the Implementation Agreement that, to the best of the executive's knowledge, information, and belief, the information contained on the SVA List is true, accurate, and complete and identifies only those Beneficiaries who have submitted a valid Voluntary Alignment Form to the ACO.
- B. The ACO shall submit the SVA List to CMS in advance of the ACO's first PY in a form and manner and by one or more dates specified by CMS. CMS shall use the SVA List to conduct alignment of Beneficiaries for the ACO's first PY.
- C. CMS may monitor and/or audit the ACO's SVA Lists for accuracy in accordance with Section 12.01 of the Implementation Agreement. This audit, including any surveys of Beneficiaries conducted pursuant to Section III.D of

this Appendix, may take place during the Implementation Period or at a later time, as determined by CMS.

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

APPENDIX D: ACO PROPRIETARY AND CONFIDENTIAL INFORMATION

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

- A.
- B.
- C.

In accordance with Section 9.01 of the Implementation Agreement, this information shall remain the sole property of the ACO and, except as required by federal law, shall not be released by CMS without the express written consent of the ACO.