Long-term Enhanced ACO Design (LEAD) Model

Request for Applications

04/15/2026

The March 31, 2026 version of the Request for Applications (RFA) for the LEAD Model has been revised to clarify the following policies:

- **Pages 12, 80 and 135:** Updated to reflect the addition of physical therapists to the RISE coordinated care team, which will likely be comprised of occupational therapists, physical therapists, registered nurses, and handypersons.
- **Pages 19, 21, 31, 37 and 53**: If a beneficiary meets both High Needs eligibility criteria and has Age and Disability (A&D) as a reason for entitlement, they will be treated as High Needs for the purposes of determining risk adjustment, baseline benchmark, and trend. If a beneficiary meets both High Needs eligibility criteria and has End Stage Renal Disease (ESRD) as a reason for entitlement, they will be treated as ESRD for the purposes of risk adjustment, baseline benchmark, and trend. Both High Needs and ESRD beneficiary categories will count towards the 40% alignment threshold for an ACO to qualify for lower beneficiary alignment minimums.
- **Page 32**: The lookback period for the mid-year claims-based alignment update under Hybrid Alignment will be different than the lookback period used to run alignment before the beginning of the Performance Year. The lookback period for the initial alignment run is October 1 – September 30 prior to the Performance Year. The lookback period for the midyear update (applicable only to mid-year Participant TIN additions) is January 1 – December 31 prior to the Performance Year.
- **Page 55 and 56:** To calculate the regional efficiency adjustment, CMS will compare an ACO's historical baseline benchmark to average Medicare spending in the ACO's region in Base Year 3. CMS will calculate the difference separately for each beneficiary category, and then combine these amounts into a single, population-weighted adjustment.
- **Page 57 and 58**: Benchmark adjustments will be capped at 3% of risk-standardized USPCC for lower-spending ACOs that have participated in the Shared Savings Program within the previous two years. Higher-spending ACOs that have participated in the Shared Savings Program within the previous two years will have their benchmark adjustment (when relevant) capped at 5% of risk-standardized USPCC.
- **Page 64**: The footnotes on the benchmarking methodology graphic have been updated to:
    - Clarify that the risk score growth cap for High Needs beneficiaries will be between 3-8%,
    - Remove a phrase suggesting that the Regional Efficiency and Prior Savings Adjustments could be converted to capitated payments,
    - Correct the footnote in the Regional Efficiency adjustment box related to the cap.
- **Page 80**: Payment Example 2 has been updated to remove the double-counting of the regional efficiency adjustment in the calculation.
- **Page 90**: Remove erroneous references to REACH ACOs in the quality scoring graphic and add the Prevention and Quality Plan to the High Performer Pool criteria.
- **Page 103**: The Renewing ACO definition has been clarified to reflect that a Renewing ACO is defined as an ACO that meets any of the three criteria, rather than all of the criteria. In other

words, ACOs that do not meet all three criteria to be considered a Newly Entering ACO are considered Renewing ACOs.

Contents

I. Model Summary 8
II. Background 9
A. Purpose 9
B. Evidence Base 12
C. Statutory Authority 13
1. General Authority to Test Model 13
2. Waiver Authority 15
3. CMS- Sponsored Model Safe Harbor Authority 15
III. Scope and General Approach 15
A. Model Performance Period 15
B. Implementation Period 16
IV. Application Process 16
A. Application 16
B. Application Scoring 17
C. Withdrawal of Application 18
V. Application and Model Participation Requirements 18
A. Applicant Eligibility 19
B. Eligible Providers and Suppliers 19
C. Eligibility Requirements for ACOs Serving a High Proportion of High Needs Beneficiaries 21
VI. Participation Requirements 21
A. Participant TINs and Preferred Providers 22
B. Screening 23
C. ACO Structure and Governance 25
D. ACO Service Area 26
E. Use of Certified EHR Technology 27
F. Program Overlaps 28
G. Advanced APM Determination 30
VII. Model Design Elements 30
A. Beneficiary Eligibility 30
B. Beneficiary Alignment 31
1. Claims-Based Alignment 32

2. Voluntary Alignment 33
3. Frequency of Alignment Options 35
4. Beneficiary Alignment Hierarchies....36
5. Minimum Beneficiary Alignment Threshold 37
C. Beneficiary Engagement and Marketing....38
D. Medicare – Medicaid Integration Features and Partnership Agreements....40
E. Healthy Living Strategy 43
1. LEAD's Approach to Improving the Health of Medicare Beneficiaries 43
2. Benefit Enhancements for PY 2027 44
3. Patient Incentives 46
4. Benefit Enhancements and Beneficiary Engagement Incentives Under Consideration 51
VIII. Financial Methodology: Benchmarking Methodology 52
A. Calculating Historical Baseline Expenditures 55
B. ACO-Specific Benchmark Adjustments 57
C. Trending Benchmarks to the Performance Year....59
D. Risk Adjustment....61
E. Discount and Quality Withold 62
F. Retention Incentive 63
G. Regional Rate Book Transition....63
IX. Financial Methodology: Risk Sharing Options, Risk Mitigation, and Financial Settlement....65
A. Risk Sharing Options 65
B. Risk Corridors 65
C. Stop-Loss....66
D. Optional Provisional Financial Settlement and Final Financial Settlement 67
E. Financial Guarantee 68
F. Extended Repayment Option 70
G. Significant Anomalous, and Highly Suspect Billing Activity and Reopening Policies 70
X. Financial Methodology: LEAD Payment Mechanisms 71
A. Prospective Payments 71
1. Total Care Capitation 72
2. Primary Care Capitation Payment....73

3. Non-Primary Care Capitation (NPCC) 75
4. Advanced Payment Option (APO) 76
5. Administrative Add-On 77
B. LEAD Payment Examples 78
C. CMS Administered Risk Arrangements (CARA) Initiative 81
XI. Quality and Performance 83
A. Quality Measure Selection and Additional Reporting Requirements 83
B. Quality Performance and Impact on Performance Year Financial Benchmarks 89
C. Quality Measurement Scoring and Calculation of the Initial Quality Score 89
1. Continuous Improvement/Sustained Exceptional Performance (CI/SEP) 89
2. Additional Points for the Quality Score 90
3. Calculating the ACO's Total Quality Score and Final Quality Withhold Earnings 91
4. High Performers Pool (HPP) 91
D. Quality Monitoring 91
XII. Participant Monitoring, Auditing and Terminations 91
A. General Monitoring Activities 91
B. Remedial Actions for Noncompliance 92
C. Termination of Model Participation 93
XIII. Data Sharing and Reports 93
A. Data Sharing 93
B. Data Suppression and Beneficiary Data Sharing Opt Out 94
XIV. Evaluation 95
XV. Additional CMS Supports 96
A. Tech Enabler 96
B. Rapid Cycle Innovation Program 97
C. Learning System 97
Appendix A: Glossary of Key Terms 98
Appendix B: Application Questionnaire 105
ORGANIZATIONAL READINESS 112
REVENUE SOURCES AND PAYMENT ARRANGEMENTS 116
BENEFICIARY AND CAREGIVER EXPERIENCE 117

PREVENTATIVE CARE 118
DATA AND HEALTH INFORMATION TECHNICAL CAPABILITIES 118
Attestation and Signature 119
Appendix C. Specialty and HCPCS Codes Used for Beneficiary Alignment 120
Appendix D. HCPCS Codes Used to Calculate Primary Care Capitation Payment 130
Appendix E. CARA Initiative Details 135
E.1 CARA Overview and Objectives 135
E.2 Episode Types and Customization 135
E.3 Episode Risk Parameters and Negotiation Process 138
E.4 Payment Calculation and Benchmark Methodology 138
E.5 Implementation Timeline 139
E.6 Evaluation Framework 140
E.7 Eligibility and Requirements 140
E.8 Future Scalability 140
E.9 CARA Module Participation Instructions 140
E.9.1 CARA Module Access 140
E.9.2 Eligibility Verification 141
E.9.3 Attestation Requirements 141
E.9.4 Episode Selection Approach 142
E.9.5 Discount/Premium to Target Price 143
E.9.6 Quality Measure Selection 143
E.9.7 Performance Adjustment Selection 144
E.9.8 Episode Pricing and Financial Settlement Process 144
Appendix F: LEAD Benefit Enhancements Used in Previous ACO Models 146
3-Day Skilled Nursing Facility (SNF) Rule Waiver Benefit Enhancement 146
Telehealth Benefit Enhancement 146
Post-Discharge Home Visits Benefit Enhancement 147
Care Management Home Visits Benefit Enhancement 148
Home Health Homebound Waiver Benefit Enhancement 148
Concurrent Care for Beneficiaries that Elect the Medicare Hospice Benefit Enhancement 149
Nurse Practitioner (NP) and Physician Assistant (PA) Services Benefit Enhancement 150

I. Model Summary

This Request for Application (RFA) invites interested health care providers and Accountable Care Organizations (ACOs) to apply to participate in the Long-term Enhanced ACO Design (LEAD) Model, a new Center for Medicare and Medicaid Innovation (Innovation Center) ACO model. LEAD builds upon the Innovation Center's earlier accountable care work and uses improved benchmarking to appeal to a broader mix of health care providers, including those with specialized patient populations and those new to ACOs such as smaller, independent or rural-based practices. With a 10-year performance period — the longest CMS has ever tested — 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 (as defined in Section VII.A) and integrating care for dually eligible beneficiaries.

LEAD is designed to achieve the following goals:

1. Attract health care providers that have had limited participation in ACOs previously;
2. Encourage health care providers to deliver preventive care;
3. Empower beneficiaries to be more actively involved in their care; and
4. Support health care providers who serve High Needs and dually eligible beneficiaries to improve care and reduce costs.

Key Model Elements:

- **Scope and Duration:** LEAD will begin on January 1, 2027, and end on December 31, 2036. LEAD will be available nationally.
- **Model Participants:** Participants in the model will be ACOs, which will be comprised of Participant Tax Identification Numbers (Participant TINs), typically primary care practices composed of Participant Providers, and Preferred Providers, typically specialty care providers, serving Original Medicare beneficiaries.
- **Beneficiary Alignment:** Beneficiaries are aligned to an ACO based on an established primary care relationship with the Participant TINs in the ACO through claims-based and/or voluntary alignment.
- **Benchmark:** LEAD innovates on benchmarking methodologies from previous ACO initiatives with a focus on creating long-term, sustainable incentives and providing additional financial support for providers with high cost, complex care beneficiaries. In addition, the benchmark methodology is designed to attract a broad mix of health care providers including health care providers whose beneficiaries have higher costs of care compared to other beneficiaries in the same region.
- **Payment:** LEAD will feature Primary Care Capitation (PCC) and Total Care Capitation (TCC) payments to provide upfront cash flow for ACOs to make investments in their care programs and move providers towards value-based payment. LEAD will also have additional

prospective payment options for ACOs that want to establish downstream payment arrangements, including but not limited to, episode-based risk arrangements with specialty care providers participating in LEAD as Preferred Providers.

- **Quality:** The quality strategy for LEAD is designed to set achievable performance criteria for ACOs along with incentives that encourage care delivery transformations to improve quality of care delivered and reduce health care utilization. LEAD will feature the same claims-based and Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures included in the ACO REACH Model. To align with CMS's overall drive to electronic clinical quality measures (eCQMs), LEAD will phase in two new eCQMs during the model while offering incentives, reporting flexibility, and support to encourage implementation during the phase-in period.
- **Healthy Living Strategy:** LEAD's Healthy Living Strategy consists of various model features designed to promote healthy living and make Americans healthy again. For example, model participants will have access to several Benefit Enhancements, Beneficiary Engagement Incentives, and additional initiatives designed to promote preventive and coordinated care such as the Tech Enabler Initiative and the Prevention and Quality Plan. Model features that support healthy living include the ability to offer cost sharing support when beneficiaries access high-value care and incentives when beneficiaries adopt or maintain healthy lifestyle choices. Participants will also be required and supported in selecting and launching a prevention initiative among their aligned beneficiaries.
- **CMS-Administered Risk Arrangements (CARA):** LEAD features a new mechanism to facilitate downstream episode-based risk arrangements between ACOs and their specialty care providers, who are Preferred Providers (defined in Section V.B.), accountable for aligned beneficiaries initiating an episode in CARA.
- **Integrated Support for Complex Patient Populations:** Policies that support care for complex populations, including risk adjustment and benchmarking calibrated for High Needs beneficiaries (as defined in Section VII.A), will be integrated across all ACOs, increasing the incentive for all providers to develop specialized care models for these patients. LEAD ACOs that primarily serve High Needs beneficiaries will have additional supports and flexibilities, including lower beneficiary alignment minimums.

II. Background

A. Purpose

Building on lessons from prior ACO models and programs—including ACO REACH[1], the Next Generation ACO Model, and the Medicare Shared Savings Program (Shared Savings Program)—LEAD aims to enhance the quality of beneficiaries' care by accelerating the delivery of value-based care

[1] The ACO REACH Model was previously the Global Professional Direct Contracting Model.

and to increase savings to the Medicare Trust Fund by incentivizing health care providers to deliver preventive, coordinated care while empowering beneficiaries to take greater control of their health.

To do this, LEAD will test a few critical elements in ACO models, including:

1. Attracting health care providers into ACOs whose beneficiaries have higher Medicare costs compared to similar beneficiaries in the same geographic region and who, therefore, have the greatest opportunity to produce model savings ("higher-spending ACOs");
2. Maintaining consistent benchmarks without re-basing (resetting the benchmark base years to incorporate more recent historical expenditures) in order to avoid the 'ratchet effect' that penalizes ACOs that have successfully lowered costs;
3. Integrating policies that are tailored to High Needs and dually eligible beneficiaries so that all providers have an incentive to care for these populations;
4. Offering more support for ACOs to engage specialists through flexible payment and risk arrangement options; and
5. Creating incentives for beneficiaries to seek care from high-value health care providers and for ACOs to create linkages to community providers by allowing ACOs to offer a suite of innovative Benefit Enhancements and Beneficiary Engagement Incentives, with a focus on patient empowerment and healthy living.

LEAD begins to chart a course for what a more stable, long-term ACO incentive structure could look like by addressing the benchmarking challenges that have led to limited participation and savings in prior models. A central goal of LEAD is to bring in both higher- and lower-spending ACOs and create a pathway toward more stable, predictable benchmarks over time. Early in the model, benchmarks are structured to encourage participation by ACOs at different starting points, giving higher-spending ACOs an opportunity to participate without being penalized and giving lower-spending ACOs a benchmark that does not require them to continuously beat their previous performance. Over the ten-year model performance period, Medicare Parts A and B costs for both higher-spending and lower-spending ACOs should gradually start to converge, creating the foundation to transition away from benchmarks based on each individual ACO's historical performance.

CMS expects LEAD to create sustainable savings for both CMS and participating ACOs. In order to achieve this, CMS will apply a growth rate to LEAD benchmarks that are below the growth rate in Medicare expenditures that would occur in the absence of ACOs (to deliver savings to taxpayers) but, critically, above actually observed expenditure growth. This "wedge" - the opportunity between the benchmark that will be used to compensate ACOs and actual expenditures - represents the savings shared between CMS and ACOs. To ensure that these opportunities are durable, LEAD will not rebase benchmarks, making the model appealing to both higher-spending ACOs seeking room to improve and lower-spending ACOs seeking a longer runway to sustain and build on their success.

LEAD ACOs are accountable for and agree to take on financial risk for total Medicare Parts A and B spending for the ACO's aligned beneficiary population. LEAD will offer two distinct risk arrangements

designed to match organizational capacity and experience: a **Global Risk Option** that will provide full downside and upside risk based on Medicare total cost of care (TCOC) performance and a **Professional Risk Option** that will enable shared Medicare TCOC risk with CMS. The Global Risk Option will leverage ACO REACH features that were intended to mirror payment arrangements available in the private sector between private payers and capitated provider groups. While LEAD does not offer a separate participation option for health care providers new to ACOs that experience unique challenges with achieving the required alignment minimums to form an ACO and participate in LEAD, both the Global Risk and Professional Risk Options build off the ACO REACH New Entrant ACO experience to include beneficiary alignment minimums that can accommodate Newly Entering ACOs. Newly Entering ACOs are defined as: 1) the ACO entity does not have any prior performance in a Medicare ACO initiative[2], 2) Fewer than 40% of the ACO's Participant TINs have participated in a Medicare ACO Initiative in the past 5 years, and 3) Fewer than 50% of the ACO's Participant Providers have participated in a Medicare ACO Initiative in the past 5 years.

LEAD builds on lessons learned from the High Needs track of ACO REACH about how to support the providers who care for High Needs beneficiaries. Most importantly, LEAD allows health care providers that focus on caring for High Needs beneficiaries to align their entire attributable beneficiary population to an ACO. This is in contrast to the ACO REACH approach, where High Needs ACOs were a distinct participant type and could only align beneficiaries that met the High Needs criteria. As a result of this policy change, in LEAD, ACOs that focus on High Needs beneficiaries will have additional financial resources (via capitated payments) and flexibilities, allowing them to serve their patients more effectively and deliver a consistent care model across their entire population. At the same time, more accurate risk adjustment and benchmarking for High Needs beneficiaries will be integrated across all ACOs, creating an incentive for more providers to develop the capabilities to care for patients with complex needs.

LEAD also aims to support the integration of Medicare and Medicaid services for patients receiving Medicare benefits through Original Medicare. The goal is to create incentives for Medicare and Medicaid health care providers to coordinate care and improve outcomes for dually eligible beneficiaries in Original Medicare. During an initial planning phase from March 2026 through December 2027, CMS will identify two states that are interested in partnering to develop a framework for ACO-Medicaid partnership arrangements. This framework will help define how ACOs and state Medicaid agencies (SMAs) or Medicaid Managed Care Organizations (MCOs) can work together to share data and coordinate care to improve outcomes, including preventing avoidable hospitalizations and helping patients remain engaged in their communities. Pending successful completion of the planning period, ACOs in the selected states would have the opportunity to enter partnership arrangements with SMAs or MCOs, depending on whether the state operates a fee-for-service Medicaid program or delivers benefits primarily through managed care. These strategic partnerships would aim to unify accountability across payers and integrate care delivery, ultimately

[2] Includes participation in ACO REACH and the Shared Savings Program.

improving outcomes for this population while reducing care fragmentation and cost-shifting incentives that otherwise exist across Medicare and Medicaid programs.

LEAD will also deepen CMS's efforts to bring more specialists into accountable care models and give ACOs stronger tools for partnering with specialists. Specifically, LEAD ACOs will have access to the CMS-Administered Risk Arrangement (CARA) initiative, which facilitates downstream episode-based risk arrangements between ACOs and specialists. CARA includes a wide range of episode options including acute medical, procedural, and chronic condition episodes predicated on the Episode-Based Cost Measure (EBCM) methodology with slight modifications to align within a LEAD performance year. Additionally, CARA will include a falls prevention episode that delivers time-limited home-based interventions to promote functional safety at home. This episode centers on coordinated care delivery, likely comprising of occupational therapists (OTs), physical therapists (PTs), and registered nurses (RNs), as well as handypersons if needed, who collaborate on interventions that reduce fall risk and enable aging in place.

Finally, LEAD will include innovative flexibilities that allow ACOs to share savings with beneficiaries, for example through cost-sharing support for Part B services. This introduces an important market mechanism missing in previous ACO models that empowers beneficiaries and will stimulate consumer demand for ACOs to create value and, consequently, more savings. Other LEAD flexibilities, including certain programmatic waivers, are designed to facilitate access to high-value services and providers, with a particular focus on encouraging prevention and healthier lifestyles. In addition to these flexibilities, LEAD integrates other policies to support prevention interventions and empower beneficiaries as they navigate care—examples include requiring ACOs to develop a Prevention and Quality Plan and facilitating knowledge sharing and the adoption of innovative digital tools through a Tech Enabler Initiative.

Through LEAD's risk-based structures, LEAD will test whether aligned financial incentives, waivers, and flexibilities enable ACOs to meaningfully engage health care providers and patients in reducing Medicare total cost of care while preserving or enhancing the quality of care.

B. Evidence Base

ACOs have demonstrated an ability to drive savings, especially ACOs that are physician-led rather than hospital- or health system-led.[3] Innovation Center ACO models have consistently shown gross savings to Medicare, while net savings have been mixed. The Global and Professional Direct Contracting Model, which was later renamed the ACO REACH Model, has demonstrated reductions

[3] https://www.cbo.gov/publication/60213

in gross spending and improvements in quality across the first three Performance Years of model implementation.[4,5,6]

Despite these promising results related to gross savings and quality, there remains significant opportunity to expand ACOs in Medicare. Based on internal research, CMS has found that through 2022, the proportion of TINs with assignable beneficiaries participating in the Shared Savings Program or a CMS Innovation Center ACO was approximately 20%. As of June 2025, only 45% of Original Medicare beneficiaries were aligned to the Shared Savings Program or ACO REACH. Previous analyses of practices that did not participate in an ACO identified that non-participants exhibited higher per-beneficiary spend, underscoring the potential for heightened taxpayer savings from an ACO model that would attract new providers, a primary goal of LEAD.[7] By encouraging participation from health care providers that have not traditionally joined ACOs, LEAD will generate spillover effects from the delivery transformation that occurs across patient panels of participant practices, positively impacting both aligned and unaligned patients. To achieve this goal, LEAD builds upon many of the design components of ACO REACH, including strong financial incentives, coupled with tools to promote evidence-based prevention, patient empowerment, and choice and competition. For example, LEAD will include similar levels of financial risk to what is available in ACO REACH, and several innovative waivers and flexibilities that would attract greater participation, increase care coordination particularly for High Needs and dually eligible populations, and enable Medicare beneficiaries to live healthier lives. Building on lessons learned from ACO REACH and other ACO initiatives, LEAD will also incorporate innovations designed to attract and retain both lower- and higher-spending provider groups.

C. Statutory Authority

1. General Authority to Test Model

Section 1115A of the Social Security Act (the Act) (added by Section 3021 of the Affordable Care Act) (42 U.S.C. § 1315a) establishes the Innovation Center to test innovative payment and service delivery models that have the potential to lower Medicare, Medicaid, and Children's Health Insurance Program (CHIP) spending while maintaining or improving the quality of beneficiaries' care.

Financial and Payment Model Authorities

Section 1115A(b)(2) of the Act requires the Secretary to select models to be tested where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The

[4] https://www.cms.gov/priorities/innovation/data-and-reports/2023/gpdc-1st-ann-report
[5] https://www.cms.gov/priorities/innovation/data-and-reports/2024/gpdc-2nd-ann-report
[6] https://www.cms.gov/priorities/innovation/data-and-reports/2025/aco-reach-preview-py2023-evaluation
[7] McWilliams JM et al. Medicare Spending After 3 years of the Medicare Shared Savings Program. September 2018. N Engl J Med 2018;379:1139-1149. https://www.nejm.org/doi/full/10.1056/NEJMsa1803388

statute also provides a non-exhaustive list of examples of models that the Secretary may select to test.

LEAD seeks to improve quality of care and health outcomes for Medicare beneficiaries through alignment of financial incentives to promote effective and appropriate care, emphasis on patient choice, strong monitoring to ensure that beneficiaries maintain access to care, and emphasis on care delivery for complex, chronically and seriously ill populations. The two risk sharing options available under LEAD, combined with other model flexibilities, like the ability to offer Benefit Enhancements which broaden the set of covered services available to aligned beneficiaries, are expected to increase beneficiaries' access to innovative, affordable care while maintaining all Original Medicare benefits. LEAD also emphasizes voluntary alignment, thus empowering beneficiaries to choose the health care providers with whom they want to have a care relationship and enabling stability through stronger patient and provider relationships.

LEAD advances risk sharing options and builds upon lessons from CMS's previous ACO initiatives. It addresses stakeholders' concerns that the current approaches to benchmarking reduce long-term incentives to participate and generate meaningful savings. Further, LEAD includes financial incentives designed to attract organizations that responsibly manage complex, chronically and seriously ill patients, through refinements in our benchmarking methodology and risk adjustment. Through accountability for the Medicare total cost of care and the option for population-based payments, participating providers and suppliers will shift from Fee for Service (FFS) billing and gain the flexibility to adapt clinical delivery to meet beneficiaries' needs, such as longer visits for high-risk patients or continued care beyond a standard office visit. ACOs may also benefit from risk stratification of patients and tailoring care management strategies to match their patient population.

Building on the lessons learned from and experiences of previous ACO initiatives, LEAD is expected to reduce administrative burdens and empower primary care providers to spend more time caring for patients while reducing overall health care costs. For many patients, the primary care clinician is the first point of contact with the health care delivery system. Empirical evidence shows that strengthening primary care is associated with high quality of care, better outcomes, and lower costs within and across major population subgroups.[8] Despite this evidence, primary care spending accounts for a small portion of the Medicare total cost of care, and is even lower for patients with complex, chronic conditions.[9] CMS's experience with innovative models, programs and demonstrations to date has shown that when incentives for primary care clinicians are aligned to reward the provision of high-value care, the quality and cost effectiveness of patient care improves.

[8] National Academies of Sciences, Engineering, and Medicine. 2021. Implementing high-quality primary care: Rebuilding the foundation of health care. Washington, DC: The National Academies Press. https://doi.org/10.17226/25983.

[9] Millbank Memorial Fund. The Health of US Primary Care: 2024 Scorecard Report. https://www.graham-center.org/content/dam/rgc/documents/publications-reports/reports/2024-scorecard-final-report.pdf

2. Waiver Authority

Section 1115A(d)(1) of the Act authorizes the Secretary to waive such requirements of Title XVIII of the Act as may be necessary solely for purposes of carrying out the testing by the CMS Innovation Center of certain innovative payment and service delivery models, including LEAD. As such, CMS plans to utilize Title XVIII payment rule waivers to allow the LEAD Benefit Enhancements and Beneficiary Engagement Incentives found in section VII.E.

Any payment rule waivers would apply solely to LEAD and its associated initiatives (e.g., CARA and CARA's RISE to Age in Place episode as discussed in Appendix E) and could differ in scope or design from waivers granted for other programs or models, such as ACO REACH. Any such waivers granted would be contingent upon: 1) the ACO entering into a Performance Year Participation Agreement (PY PA) with CMS; 2) continued compliance with the terms and conditions of the PY PA, including the terms and conditions of the waivers as specified in the PY PA; 3) the ACO affirmatively selecting to participate in the Benefit Enhancement; 4) written agreements between the ACO and its Participant TINs and Preferred Providers outlining the financial relationships and health care activities subject to the waivers and the associated compliance requirements; and 5) CMS not making a determination that continued use of a payment rule waiver puts beneficiaries or program integrity at undue risk.

CARA will be available as a tool for specialist engagement to all Global Risk Option ACOs that elect to use it. Those ACOs would be required to execute an amendment to the PY PA—LEAD Participation Agreement CARA Amendment (LPACA). To operationalize CARA, CMS intends to provide model-specific waivers for LEAD that ACOs in CARA may use. More information on waivers can be found in Appendix F.

3. CMS- Sponsored Model Safe Harbor Authority

CMS may determine that the Anti-kickback Statute Safe Harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (42 CFR § 1001.952(ii)) is available to protect remuneration exchanged pursuant to certain financial arrangements (e.g., financial arrangements between ACOs, Participant TINs, Participant Providers, and Preferred Providers) or beneficiary incentives permitted under LEAD model participation documentation (e.g., In-Kind Items and Services, Beneficiary Engagement Incentives).

III. Scope and General Approach

A. Model Performance Period

The model will be implemented over ten Performance Years, from PY 2027-PY 2036 (collectively, the Model Performance Period or MPP).

CMS is committed to improving care for beneficiaries and thereby may modify or terminate LEAD if the model is not achieving its established goals and aims or as may be required under Section 1115A of the Act. This RFA is for ACOs to submit applications to begin participation in PY 2027. Throughout

this RFA and all other LEAD materials, CMS has chosen to use Performance Year-specific terminology (PY 2027 – PY 2036) rather than participant-specific terminology (e.g., a given participant's first Performance Year (PY1), second Performance Year (PY2), etc.) because all model policies apply equally to all model participants within a given year, regardless of when each participant began participation (unless otherwise specified). As such, all tables and other descriptions of policies that vary throughout the life of the model will be described in Performance Year-specific terms.

B. Implementation Period

The Innovation Center allows all applicants accepted under this RFA to participate in an optional Implementation Period prior to PY 2027 (herein referred to as the 'IP'). The IP will begin September 15, 2026, and run through December 31, 2026, and is intended to provide ACOs joining the model beginning in PY 2027 an opportunity to conduct voluntary alignment activities (described in Section VII.B.2) in preparation for meeting the applicable beneficiary alignment minimum at the start of PY 2027 (also described in Section VII.B.5). While lists of Participant TINs (described in Section VI.A) will be established for the IP for purposes of documenting which providers and suppliers will be conducting activities to support voluntary alignment during the IP, no beneficiaries will be aligned to the ACO for the IP itself, either through claims-based alignment or voluntary alignment (described in section VII.B); all beneficiaries aligned to the ACO via voluntary alignment activities conducted during the IP will have an effective date of alignment at the beginning of PY 2027. Moreover, ACOs participating in LEAD during the IP do not receive payments or take financial risk for their performance during the IP and no beneficiary-identifiable data will be shared with these ACOs for purposes of participation in the IP (described in Section XIII.A).

All accepted applicants under this RFA will have the opportunity, but not the obligation, to participate in the IP. Accepted applicants choosing to participate in the IP must sign an IP Participation Agreement (IP PA) governing their participation in the IP. Signing the IP PA does not obligate an accepted applicant to participate in the MPP beginning in PY 2027 and choosing not to sign the IP PA does not prevent an accepted applicant from participating in the MPP beginning in PY 2027. Regardless of whether they participate in the IP, all accepted applicants must sign a PY PA in order to participate in the MPP beginning in PY 2027.

IV. Application Process

All entities that want to participate in LEAD are required to submit an application.

A. Application

The LEAD application can be accessed at https://app.innovation.cms.gov/LEAD/IDMLogin.The application portal will be available beginning on March 31, 2026 and will close at 11:59 PM Eastern Time (E.T.) on May 17, 2026. All ACOs accepted under this RFA for participation beginning in PY 2027 will also have the opportunity to participate in the IP (but are not required to participate in

the IP), discussed in Section III.B. Please continue to check the website for updated timelines: https://innovation.cms.gov/innovation-models/LEAD.

Any questions that arise during the application process may be directed to the LEAD Model mailbox: LEAD@cms.hhs.gov with the subject "Application Question."

B. Application Scoring

CMS will assess applications in accordance with specific criteria in 5 key domains: (1) organizational readiness; (2) revenue sources and payment arrangements; (3) beneficiary and caregiver experience; (4) data and health information; and (5) preventive care. These domains and associated point scores are detailed in Appendix B of this RFA. In addition, applicants should demonstrate that their organizational structure promotes the goals of the model. Lastly, applicants with prior participation in a CMS program, demonstration or model will be asked to acknowledge that they have remained in good standing with CMS program requirements under the terms of such CMS programs, demonstrations or models.

As part of the LEAD Model application process, applicants will be asked questions regarding their proposed implementation of Benefit Enhancements, Beneficiary Engagement Incentives, risk sharing option, and prospective capitated payment. For applicants that expect that they will qualify for lower alignment minimums due to their high proportion of High Needs beneficiaries, the application will ask about the applicant's care model for High Needs beneficiaries. Acceptance into LEAD is not contingent upon an ACO implementing any particular Benefit Enhancement, Beneficiary Engagement Incentive, risk sharing option or prospective capitated payment. Rather, responses to these questions regarding proposed implementation of these approaches will help CMS assess interest in model design elements and assist CMS with planning and model implementation.

A panel of experts that may include Department of Health and Human Service (HHS) staff and HHS contractors will review completed applications from applicants, with an emphasis on expertise in provider payment policy, care improvement, and care coordination. Final selection for participation in the model will be based on an assessment of the five domains, as listed above, as well as assessments of program integrity risks and potential market effects. Depending on the volume of applications received, CMS may choose to limit the number of accepted applications. Further, CMS may choose to interview applicants during the application process in order to better understand applicant organizations and the individuals and entities the Applicant ACO expects will be Participant TINs and Preferred Providers.

Abbreviated Application for ACO REACH participants: ACOs that participated in the ACO REACH model in PY 2026 are eligible to submit an abbreviated application for LEAD using the same link as the LEAD application: **https://app.innovation.cms.gov/LEAD/IDMLogin**. This streamlined application process recognizes the substantial organizational infrastructure and care delivery capabilities that former ACO REACH participants have already demonstrated. The abbreviated application is designed to confirm and update critical information about the applicant organization's current structure and governance, including verifying key personnel and leadership roles, and to

allow applicants to select model participation options, e.g., Global or Professional Risk Option and participation in capitated payment mechanisms.

Eligibility to submit an abbreviated application does not guarantee acceptance into the LEAD Model. All applications, including abbreviated applications, will be evaluated to ensure that ACOs meet the model's standards for quality, financial stability, and operational capability. Organizations that did not maintain good standing in ACO REACH or that have significant outstanding compliance issues may be required to submit a full application or may be deemed ineligible for participation in the LEAD Model. CMS reserves the right to request additional information or documentation from any applicant during the review process.

C. Withdrawal of Application

Applicants seeking to withdraw a completed application must submit an electronic withdrawal request to CMS via email to the LEAD Model mailbox (LEAD@cms.hhs.gov) prior to signing either the IP PA, if applicable, or the PY PA. The request must be submitted as a PDF on the organization's letterhead and signed by an official authorized to act on behalf of the organization. It should include the applicant organization's legal name; organization's primary point of contact; full address of the organization; and a description of the reason for the withdrawal.

V. Application and Model Participation Requirements

This RFA opens the application period for PY 2027. CMS anticipates offering additional application windows for subsequent Performance Years as the model progresses. Consistent with Innovation Center practice, CMS will use early model experience to inform future cohorts, which may result in changes to model design, policies, or participation parameters. Interested ACOs are encouraged to consider applying to the initial cohort.

Letter of Interest: Organizations and ACOs that are interested in future cohorts but are not prepared to apply during this application window will have the opportunity to submit a Letter of Interest (LOI). CMS will use LOIs to gauge the level of interest in future application cycles and to inform planning for subsequent cohorts, including the timing and scope of future application windows. Organizations that submit an LOI will receive updates about the model's progress and will be notified when future application windows open, along with information about application support resources available to prospective applicants. CMS will release a standardized LOI form no later than April 20, 2026. Submission of an LOI will be non-binding and does not guarantee acceptance for future cohorts.

The following sections describe the requirements an ACO must meet to be eligible to participate in LEAD. LEAD is designed to attract a range of providers and suppliers operating under a common legal structure, with attention given to applicants with a clear plan to provide preventative, coordinated care for better health outcomes. LEAD is well-suited to various types of provider-led organizations, including primary care practices that care for beneficiaries with lower – and/or higher-spending levels that have yet to participate in an ACO model, specialists, and Non-Physician providers enrolled in

Medicare provider enrollment database, such as Critical Access Hospitals (CAHs), Federally Qualified Health Centers (FQHCs), and Rural Health Clinics (RHCs).

A. Applicant Eligibility

An ACO is eligible to participate in LEAD if CMS determines that all of the following criteria are met:

1. **Legal Entity:** An ACO must be a legal entity identified by a federal taxpayer identification number (TIN) formed under applicable state, federal, or tribal law, and authorized to conduct business in each state in which it operates.
2. **Beneficiary Minimum:** An ACO must have at least 5,000 Original Medicare beneficiaries aligned to their ACO in each Performance Year to be eligible for participation in LEAD. In addition, ACOs must have 3,000 claims-based aligned beneficiaries in at least one base year to be able to participate in LEAD. Under certain circumstances, ACOs may be able to participate at lower beneficiary alignment minimums, as described in Section VII.B.5. Lowered alignment minimums will be available to ACOs with a high proportion of beneficiaries in the High Needs and/or ESRD beneficiary categories. These exceptions are discussed in further detail in Section VII.B.5.
3. **Program integrity:** CMS has determined that a program integrity (PI) review of the ACO or any other relevant individuals or entities associated with the ACO has produced satisfactory results, meaning information found during the PI review does not warrant a denial of model participation for the ACO. See Section VI.B for more details.
4. **Participation in Other Shared Savings Initiatives:** An ACO does not have active participation in another Medicare initiative that involves Shared Savings or any other Innovation Center model where simultaneous participation is prohibited. The overlaps policy is outlined in detail in Section V.F.
5. **Ability to Repay:** The ACO must have the ability to repay Shared Losses and any Other Monies Owed for which it may be liable under LEAD, as demonstrated through the establishment of a financial guarantee for the model. See Section IX.E.

B. Eligible Providers and Suppliers

Medicare-enrolled Providers/Suppliers may participate in LEAD as part of a Participant TIN. To participate in LEAD, Participant TINs must form or join an ACO, and the ACO must apply and be accepted to LEAD. Eligible health care providers that may participate in LEAD as Participant Providers that are part of a Participant TIN include, but are not limited to:

- Physicians or other practitioners in group practice arrangements
- Networks of individual practices of physicians or other practitioners
- Hospitals employing physicians or other practitioners
- Federally Qualified Health Centers (FQHCs)
- Rural Health Clinics (RHCs)
- Critical Access Hospitals (CAHs)

LEAD will use a whole TIN approach to ACOs' participation in the model. This means that participation in a LEAD ACO will be managed at the TIN level and Medicare-enrolled Providers/Suppliers will participate in LEAD as Participant Providers if they bill under a Participant TIN. Through written agreements with the ACO, the Participant TINs will agree to participate in LEAD and comply with all LEAD requirements. Participant Providers will agree to participate with LEAD and comply with LEAD requirements via written agreements with their respective Participant TIN.[10]

Participant Provider eligibility for and participation in LEAD payment mechanisms will be based on a combination of factors, including the risk sharing option elected by the ACO and the provider specialty. This is discussed in more detail in Section X.A.

Model eligibility criteria for Participant TINs and Participant Providers are included below.

Participant TINs must meet the following eligibility criteria and are defined as follows:

- Identified as 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;
- Is not a Preferred Provider in the same ACO;
- Is not a Prohibited Participant (as defined in the Glossary at Appendix A); and
- Has agreed to participate in the model pursuant to a written arrangement with the ACO.

Participant Providers must meet the following eligibility criteria and are defined as follows:

- Is a Medicare-enrolled Provider or Supplier (as described in 42 C.F.R. § 400.202 and 42 C.F.R. § 424.502);
- Is not a Preferred Provider in the same ACO;
- Bills for items and services it furnishes to Original Medicare beneficiaries under a Medicare billing number assigned to a TIN in accordance with applicable Medicare regulations;
- Has a written agreement with the Participant TIN they are billing under;[11] and
- Is not a Prohibited Participant.

All ACOs participating in LEAD also have the option of entering into financial arrangements with Preferred Providers (defined in Appendix A), such as specialty providers and suppliers, who may share in financial risk with the ACO and access the incentives and flexibilities offered under the model but would not contribute to an ACO's beneficiary alignment or quality performance. For example, the ACO could share a portion of the ACO's Shared Savings or Shared Losses with the Preferred Provider on the condition that the Preferred Provider furnished covered services to aligned

[10] Participant TINs will not need to enter into a new written agreement with Participant Providers that are employed by (or under contract with) the Participant TIN and meet other criteria. The full exception will be detailed in the PY PA.

[11] Participant TINs will not need to enter into a new written agreement with Participant Providers that are employed by (or under contract with) the Participant TIN and meet other criteria. The full exception will be detailed in the PY PA.

beneficiaries, contributed to the ACO's Shared Savings or Shared Losses, and met all the requirements to share in the savings or losses as established in the financial arrangement. Participation as a Preferred Provider is at the TIN-NPI level.

Preferred Providers must meet the below eligibility criteria and are defined as follows:

- Medicare-enrolled Provider (as defined at 42 C.F.R. § 400.202) or Supplier (as defined in 42 C.F.R. § 400.202);
- Is identified on the ACO's Preferred Provider List by name, NPI, individual TIN, organizational TIN, Legacy TIN or CCN (if applicable), and CMS Certification Number (CCN) (if applicable);
- May not also be a Participant Provider in the same ACO;
- Bills for items and services it furnishes to Original Medicare beneficiaries under a Medicare billing number assigned to a TIN in accordance with applicable Medicare regulations;
- Is not a Prohibited Participant; and
- Has agreed to participate in the model pursuant to a written agreement with the ACO.

C. Eligibility Requirements for ACOs Serving a High Proportion of High Needs Beneficiaries

In LEAD, participating ACOs will be eligible for lower beneficiary alignment minimums if at least 40% of their total aligned beneficiary population are in the High Needs and/or ESRD beneficiary categories (see section VII.A for the High Needs eligibility criteria) and they have certain care delivery capabilities that are important for caring for seriously ill beneficiaries. The required care delivery capabilities are:

- 24-hour, 7-day-a-week access to a healthcare provider with access to a patients' electronic medical record;
- Providers with training in advanced care planning conversations; and
- The ability to deliver care in patients' homes.

Applicants will describe how they meet these care delivery requirements in their applications. CMS will determine whether an ACO meets the 40% High Needs and/or ESRD eligibility threshold prior to the start of each Performance Year.

VI. Participation Requirements

CMS will evaluate an ACO's application to determine whether the applicant ACO is eligible to participate in the model based on the eligibility criteria outlined in section V.A above. A LEAD ACO must adhere to the following participation requirements for the duration of its participation in the model:

1. **LEAD Eligibility Criteria:** A LEAD ACO must continue to meet the eligibility criteria outlined in section V.A;
2. **Participation Agreement:** A LEAD ACO must enter into a PY PA with CMS; and

3. **Required Reporting:** In the form and manner required by CMS for each Performance Year of the agreement period, a LEAD ACO may be required to submit information to CMS, including but not limited to public reporting of its performance in the model, information on any Health Insurance Portability and Accountability Act of 1996 (HIPAA) violations or data incidents or breaches involving CMS data files, any provider fraud within the ACO's provider lists (Participant TIN List and Preferred Provider List), any continued disclosure of a revocation of a provider, or other information.

CMS will monitor LEAD ACOs annually for changes that may cause the LEAD ACO to no longer meet the model eligibility or participation requirements and will take any appropriate action CMS deems necessary, including termination of the IP PA and/or PY PA.

A. Participant TINs and Preferred Providers

The ACO's Participant TIN List will identify all Participant TINs that comprise the ACO. NPIs and CCNs identified from the Participant TIN List will be used as the basis for beneficiary alignment. Each Participant Provider billing under a Participant TIN on the Participant TIN List will contribute to claims-based alignment for that Performance Year (see Section VII.B.1).

The ACO's Preferred Provider List will identify Preferred Providers that have a written agreement with the ACO to provide services to the ACO's aligned beneficiaries. LEAD will enable eligible ACOs to increase specialty provider accountability for quality and cost through the CARA initiative. Under the CARA initiative, CMS will enable downstream episode-based risk arrangements between ACOs and their Preferred Providers (also referred to throughout as specialists and health care provider organizations). Participation in the CARA initiative is exclusively available to Preferred Providers, ensuring that only specialists and health care provider organizations with established relationships with LEAD ACOs can engage in these episode-based risk arrangements. See Section X for more information on the CARA initiative.

Participant TINs and Preferred Providers who are included on the respective lists at the start of a Performance Year will be able (and in some cases required) to participate in the ACO's selected Capitation Payment Mechanism. All Participant TINs and Preferred Providers, regardless of when they are added to the Participant TIN List or Preferred Provider List, can participate in the ACO's selected Benefit Enhancements and Beneficiary Engagement Incentives. Table 1 summarizes the differences between Participant TINs and Preferred Providers.

Table 1: Summarizing the Differences Between LEAD Participant TINs and Preferred Providers:

Relationship to ACO	Participant TIN	Preferred Provider
Used for Alignment	Yes	No
Capitation	Mandatory	Optional
Quality Reporting	Yes	No

Relationship to ACO	Participant TIN	Preferred Provider
Access to Benefit Enhancements and Beneficiary Engagement Incentives	Optional	Optional
Eligible for Shared Savings	Yes	Yes
Whole TIN Participation	Yes	No
CARA Eligible[12]	No	Yes

Fee Reductions for Participant TINs and Preferred Providers: CMS will implement fee reductions for Participant Providers billing under Participant TINs and Preferred Providers who have enrolled in prospective payments. A Fee Reduction is a reduction in Medicare FFS payments to all Participant Providers and Preferred Providers enrolled in prospective payment mechanisms who, pursuant to a written agreement with the ACO, have agreed to receive such reduced Medicare FFS payment for covered services furnished to aligned beneficiaries under the ACO's selected prospective payment mechanism. To apply fee reductions, CMS will identify the TIN and CCN (if applicable) of each Participant TIN and the National Provider Identifier (NPI) of each Participant Provider and Preferred Provider enrolled in prospective payment mechanisms, because CMS's claims adjustment system understands each Participant Provider and Preferred Provider as a TIN/NPI combination.

An ACO may add Participant TINs and Preferred Providers under certain circumstances during the Performance Year, as specified in the PY PA.

LEAD also aims to prevent selection issues related to ACOs moving providers between different ACOs that are affiliated with the same convener (i.e., an organization that does not itself include Medicare-enrolled providers or suppliers but provides administrative and supportive services to facilitate the participation of Medicare-enrolled providers and suppliers in value-based care). In general, Participant TINs may not participate with a LEAD ACO affiliated with a particular convener if they have participated in a different LEAD ACO affiliated with that same convener within the past 3 Performance Years.

B. Screening

Applications will be screened to determine eligibility for further review. Screening will include the criteria for ACOs detailed in this RFA and applicable law and regulations, including 2 C.F.R Parts 180 and 376. In addition, CMS may deny selection of an otherwise qualified applicant on the basis of information found during a program integrity (PI) screening of the applicant or any other relevant individuals or entities associated with the applicant. The PI screening may include the following, without limitation, with respect to the Applicant ACO, persons with an ownership or control interest (as that term is defined in Appendix A) in the Applicant ACO, Key Executives (as that term is defined

[12] Participation is only applicable to ACOs who meet CARA eligibility requirements: 1. An ACO must sign the PY PA; and 2. An ACO must participate in the Global Risk Option.

in Appendix A), equity partners (e.g., private equity or venture capital), and individuals and entities that the Applicant ACO expects will be Participant TINs or Preferred Providers:

- Confirmation of current Medicare enrollment status and history of adverse enrollment actions;
- Identification of delinquent Medicare and Medicaid debt;
- Review of performance in, and compliance with the terms of, other CMS models, demonstration programs, and initiatives;
- Review of compliance with Medicare and Medicaid program requirements;
- Review of billing history and any administrative audits, investigations, or other activities conducted regarding suspicious billing or other potential program fraud and abuse; and
- Review of any administrative, civil, or criminal actions related to integrity or other factors relevant to participation in an initiative involving Federal funds.

To support the PI review, Applicant ACOs will be required to disclose the following with respect to the Applicant ACO, persons with an ownership or control interest in the Applicant ACO, Key Executives, equity partners, and individuals and entities the Applicant ACO expects to be Participant TINs and Preferred Providers: (i) any sanctions or corrective action plans imposed under Medicare, Medicaid, or state licensure authorities within the last three years (including corporate integrity agreements); (ii) any fraud investigations initiated, conducted, or resolved within the last three years; (iii) any outstanding debts owed to Federal healthcare programs, including any debts owed under an Innovation Center model or to any agency of the federal government; (iv) any awards of a CMS contract in the past five years, and, if applicable, the contract number and period of performance for such award; (v) whether any such individuals or entities are on a government suspension, debarment, or exclusion list relating to procurement and non-procurements; (vi) any instances of criminal convictions or filing of a criminal charge; (vii) any bankruptcy filings; and (viii) any additional information that CMS deems necessary to protect against fraud, waste, abuse, or similar action.

The Applicant ACO's application must include each Key Executive's Curriculum Vitae, containing their professional history and a list of organizations on whose governing body they serve. Applicant ACOs will additionally be required to disclose whether individuals and entities on their governing body or leadership team have any ownership or control interest in the Applicant ACO.

While CMS will not be collecting lists of Participant TINs or Preferred Providers as part of the application, if an Applicant ACO is selected for participation in the Model, CMS will require the ACO to submit a list of the ACO's proposed Participant TINs and proposed Preferred Providers prior to the start of the Performance Year. CMS will conduct a PI screening of the ACO's proposed Participant Providers and proposed Preferred Providers and may deny the Participant Provider's or Preferred Provider's participation in the model based on the results of a PI screening or other information obtained regarding an individual's or entity's history of program integrity issues.

C. ACO Structure and Governance

Structure of the Governing Body

LEAD ACOs must have an identifiable governing body with sole and exclusive authority to execute the functions and make final decisions on behalf of the ACO. The ACO governing body must be separate and unique to the ACO and must not be the same as the governing body of an entity participating in the ACO (unless all of the Providers/Suppliers that comprise the ACO bill under a single TIN, in which case the ACO's governing body may be the same as that of the Participant TIN).

Responsibilities of the Governing Body

- The governing body must have responsibility for oversight and strategic direction of the ACO and will be responsible for holding ACO management accountable for the ACO's activities.
- The governing body must have a transparent governing process.
- The ACO governing body's incorporating documents shall require that, when acting as a member of the governing body of the ACO, each governing body member shall have a fiduciary duty to the ACO, including the duty of loyalty, and shall act consistently with that fiduciary duty.
- The governing body must receive reports periodically from the designated compliance official of the ACO, who cannot serve as legal counsel to the ACO, and who must report directly to the governing body.

Composition and Control of the Governing Body

- At least 75 percent control, as apportioned through voting power, of the ACO's governing body shall be held by Participant Providers, Preferred Providers, or their designated representatives. The ACO may seek an exception from the 75 percent control requirement by submitting a proposal to CMS describing the current composition of the ACO's governing body and how the ACO will involve Participant Providers in innovative ways in ACO governance. Any exception to the 75 percent control requirement will be at the sole discretion of CMS.
- The ACO governing body shall not include a Prohibited Participant (as defined in the Glossary at Appendix A), or an owner, employee or agent of a Prohibited Participant.
- The governing body members may serve in similar or complementary roles or positions for a Participant TIN or Preferred Provider as the role or position that they serve for the ACO.

Conflict of Interest

The LEAD ACO governing body must have a conflict of interest policy that applies to members of the governing body. The conflict of interest policy must:

- Require each member of the governing body to disclose relevant interests that may present a potential conflict of interest;
- Provide a procedure to determine whether a conflict of interest exists and set forth a process to address any conflicts that arise; and

- Address remedial actions for members of the governing body who fail to comply with the policy.

ACO Leadership and Management

LEAD ACOs must have a leadership and management structure that meets the following criteria:

- The ACO's operations must be managed by an executive, officer, manager, general partner, or similar individual 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.
- Clinical management and oversight must 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.

Beneficiary Representation Requirements:

LEAD ACOs must engage beneficiaries in their governance process through one of the channels described below. ACOs have flexibility to choose the option that better meets the needs of the ACO's governance process.

- Beneficiary Representation on Governance Body:
    - At least one of the individuals serving on the governing body must be a Medicare beneficiary served by the ACO with voting rights. Caregivers may serve in the beneficiary's place if that is a more suitable fit for the governing body. In cases where beneficiary representation on the ACO governing body is prohibited by state law, the ACO shall opt for the second option to meet this requirement (Beneficiary and Consumer Advisory Committee).
- Beneficiary and Consumer Advisory Committee:
    - The ACO must establish an advisory committee that must reflect a reasonably representative sample of an ACO's aligned beneficiaries, reflecting their geography and demographics, with a minimum of 5 members.
    - The advisory committee must meet regularly (at least twice per year) and document its meetings.
    - The advisory committee must regularly (at least twice per year) submit its ideas for consideration in the ACO's leadership and governance decision-making process.

D. ACO Service Area

To be aligned to a LEAD ACO, a beneficiary must reside in a county in the ACO's service area. CMS will identify the ACO's service area for beneficiary alignment based on the list of the Participant TINs (described in more detail in Section A above) submitted by the ACO. The ACO's service area consists of the Core Service Area and the Extended Service Area. The Core Service Area includes the counties in which the ACO's Participants have physical office locations. The counties in which the ACO

operates its Core Service Area do not need to be contiguous. For example, the ACO could operate in multiple counties in the same state or more than one state. The Extended Service Area includes the counties contiguous to the Core Service Area to capture beneficiaries within a reasonable distance of the ACO's Core Service Area.

Applicants may propose an alternative approach to CMS to define the ACO's service area. Alternative approaches should document the ACO's capability to operate in the proposed service area, including the number of beneficiaries served in each proposed county, the number of years active in each proposed county, and the capacity for provision of face-to-face care and interaction with beneficiaries in each proposed county. For example, practices located in rural areas may propose an alternative service area given their beneficiaries may travel farther to access care. Similarly, home-based primary care practices or primary care provided in residential facilities may propose an alternative service area since the clinical model does not necessarily rely on a physical practice location.

Medicaid-based alignment will also take into account an ACO's service area—beneficiaries will be aligned to an ACO if they receive Medicaid benefits from an SMA or MCO that has entered into a partnership arrangement with the ACO, and they reside in the ACO's service area.

E. Use of Certified EHR Technology

LEAD ACOs shall ensure that Participant Providers that are eligible clinicians (as defined in 42 C.F.R. § 414.1305) and that use certified electronic health record technology (CEHRT) (as defined in paragraph (3) of CEHRT definition in 42 C.F.R. § 414.1305) to document and communicate clinical care to their patients or other health care providers use CEHRT in accordance with 42 C.F.R. § 414.1415(a)(1)(iii).

Under the terms of the IP PA and the PY PA, if an arrangement between an ACO and a Participant TIN or Preferred Provider involves the provision of electronic health records software to one or more Participant Providers or Preferred Providers, such software must be interoperable (as defined in 42 C.F.R. § 411.351) or must satisfy 42 C.F.R. § 411.357(w)(2) regarding interoperability at the time the software is provided to the recipient. Under § 411.357(w)(2), electronic health records software is deemed to be interoperable if, on the date it is provided to a physician, it is certified by a certifying body authorized by the National Coordinator for Health Information Technology to certification criteria identified in the then-applicable version of 45 CFR part 170.

Transitional CEHRT Pathway and Targeted Exceptions

LEAD will include a one-year CEHRT transitional pathway. During this period, ACOs may identify clinicians that require a temporary and targeted exception for CEHRT compliance for clinicians who have not been required to use CEHRT to date, provided those clinicians attest to a plan for achieving future CEHRT compliance. This pathway serves as an on ramp for ACOs and clinicians for whom achieving 100% CEHRT use may be operationally complex or where hardships may apply, while maintaining accountability for progress. Targeted exceptions may continue to be available beyond

the ACO's first Performance Year for specific clinicians or practice sites, subject to CMS discretion and determination that such exceptions are clinically appropriate.

CEHRT Exception for Advanced Custom Health IT Implementations

LEAD will include a three-year CEHRT deferral pathway for providers utilizing advanced, custom, or home-grown health IT systems. This pathway allows organizations with advanced health IT implementations to participate in LEAD while providing more time to adopt certified EHR technology, provided they can attest to meeting several technical capabilities in the first year of participation that would not be deferred under this policy. These technical capabilities will be specified in the PY PA but will likely include elements of existing certification criteria such as the 45 CFR 170.315(g)(10) API requirements for ensuring standards-based data sharing capabilities, technical capabilities focused on national, trusted data exchange (e.g., participation as a Participant or Sub-participant under a TEFCA-designated QHIN or equivalent TEFCA-aligned network), and quality measurement and reporting infrastructure sufficient to meet over time LEAD's eCQM and operational data submission requirements.

The eCQM requirements described elsewhere would not be subject to the three-year deferral and must be met according to the standard implementation timeline. Finally, and consistent with the HHS Health IT Alignment Program, all participants must attest to use of health IT that meets standards and implementation specifications adopted in 45 CFR part 170, Subpart B, if such standards and implementation specifications can support health IT activities and investments under LEAD. These standards are aligned with those required in the ONC Health IT Certification Program but also include additional or modular technical specifications for a wide range of use cases that support interoperable technology innovation. This requirement ensures that, where health IT is used, even if the participant is operating under the CEHRT deferral pathway, the technology adheres to nationally adopted interoperability standards and can reliably connect with the broader healthcare ecosystem.

F. Program Overlaps

Internal Model Overlaps

ACOs may not simultaneously participate in more than one LEAD risk sharing option (Professional Risk Option or Global Risk Option) during the model test. Applicant ACOs will submit their risk sharing option at the time applications are due. Please note, the risk sharing option elected in the application will be used when calculating financial guarantee estimates and Preliminary Benchmark Reports. Before signing the PY PA, the ACO may switch from the Global Risk Option to the Professional Risk Option but Renewing ACOs are prohibited from switching from the Global Risk Option to the Professional Risk Option after signing the PY PA. After signing the PY PA, Newly Entering ACOs may switch from the Global Risk Option to the Professional Risk Option after completing the Performance Year for which they signed a Global Risk Option PY PA. An ACO may only move from the Professional Risk Option to the Global Risk Option after participating in the Professional Risk Option for at least 4 years.

Medicare Shared Savings Program

LEAD ACOs and Participant TINs may not simultaneously participate in the Shared Savings Program. As a result, Participant TINs cannot participate simultaneously in LEAD and the ACO Primary Care FLEX Model. The determination of whether such an overlap exists will be made at the TIN level. During the IP, ACOs and their Participant TINs may participate in both the LEAD Model IP and the Shared Savings Program.

Other Medicare Initiatives Involving Shared Savings, Kidney Care Choices Model, and other Innovation Center Models

During the model's Performance Years, Participant TINs may not simultaneously participate in LEAD and another model tested or expanded under section 1115A of the Act that involves Shared Savings, or any other Medicare initiative that involves Shared Savings unless otherwise permitted by CMS. For example, Participant TINs may not participate in the Kidney Care Choices Model. CMS anticipates that Participant TINs will be prohibited from simultaneously participating in LEAD and AHEAD Hospital Global Budget and Geo AHEAD. Participant TINs will likely be permitted to simultaneously participate in LEAD and in the GUIDE, TEAM, ACCESS, ASM, and EOM Models, as well as Primary Care AHEAD in certain circumstances. Model overlap policies will be published and updated in annual LEAD methodology papers. CMS will issue guidance that assists ACOs and Participant TINs in determining how participation in certain demonstrations or models can be combined with participation in LEAD, and whether a beneficiary may be aligned to more than one initiative and, in such cases, whether there is any adjustment made to account for the potential overlap at Financial Settlement.

Participant TINs

Participant TINs will be identified by their billing TIN. In addition, NPIs that bill under the Participant TINs may participate in another model using a different TIN that is not being used for LEAD. ACOs should note that if an ACO creates a new TIN and includes the new TIN on its Participant TIN List, the newly created TIN will not have any billing history in the relevant look back period for claims-based alignment. Thus, the brand-new TIN will not contribute claims history to the beneficiary alignment process. The submission of Legacy TINs will only be permitted in the case of mergers or acquisitions and at CMS's sole discretion.

Preferred Providers

The overlap requirements described above generally do not apply to a LEAD ACO's Preferred Providers. Specifically, a Preferred Provider may serve in the following roles during both the IP and the MPP, provided all other applicable requirements are met: (1) Preferred Provider for one or more other ACOs participating in LEAD; (2) Participant TIN in another ACO participating in LEAD; (3) ACO Participant, provider or supplier and/or ACO professional in an ACO in the Shared Savings Program and/or (4) a role similar in function to a Participant TIN in another Medicare initiative that involves Shared Savings.

G. Advanced APM Determination

We expect LEAD to meet the criteria set forth at 42 C.F.R. § 414.1415 to be an Advanced Alternative Payment Model (APM) under the CMS Quality Payment Program (QPP). LEAD ACOs are considered Merit-based Incentive Payment System (MIPS) APMs under the criteria set forth at 42 CFR § 414.1367(b). Participants who are eligible clinicians and who do not attain QP status for a Performance Year are eligible to participate in the Alternative Payment Model Pathway (APP) and be scored as participants in a MIPS APM for that Performance Year according to 42 C.F.R. §§ 414.1317 or 414.1367.

VII. Model Design Elements

LEAD includes a number of key design elements that will test new features in payment and care delivery in Original Medicare. This section will focus on the following key design elements: beneficiary eligibility, alignment, engagement and marketing requirements, and Medicare-Medicaid integration features. In addition, this section describes LEAD's Healthy Living Strategy which includes Benefit Enhancements, Beneficiary Engagement Incentives, and other initiatives supporting a healthy lifestyle and access to high-value care.

A. Beneficiary Eligibility

Beneficiaries would be eligible for alignment to a LEAD ACO in a given month, if the beneficiary: (1) is enrolled in Medicare Parts A and B; (2) is not enrolled in Medicare Advantage or other Medicare managed care plan; (3) has Medicare as the primary payer; (4) is a resident of the United States; and (5) is a resident in a county included in the ACO's service area (defined in Section VI.D). If a beneficiary does not meet all of these eligibility criteria in a given month of a base year or Performance Year, the beneficiary would be excluded from expenditure calculations for that month and all subsequent months in the base year or Performance Year.

High Needs Eligibility Criteria: To be considered a High Needs beneficiary, beneficiaries must meet at least one of the following additional criteria:

1. Have one or more conditions that impair a beneficiary's mobility (as identified through Mobility Impairment ICD-10 Codes);
2. Exhibit signs of frailty, as evidenced by a claim submitted by a provider or supplier specifically for a hospital bed or transfer equipment for use in the home;
3. Meet a comprehensive definition of frailty, as measured by a score of 0.35 or greater on the Kim Claims-based Frailty Index,[13] which indicates a status of Moderate to Severely Frail;
4. Have at least one significant chronic condition or other serious illness that is defined as having a risk score of 3.0 or greater for Aged and Disabled (A&D) beneficiaries measured

[13] Kim DH, Schneeweiss S, Glynn RJ, Lipsitz LA, Rockwood K, Avorn J. Measuring Frailty in Medicare Data: Development and Validation of a Claims-Based Frailty Index. J Gerontol A Biol Sci Med Sci. 2018 Jun 14;73(7):980-987. doi: 10.1093/gerona/glx229. PMID: 29244057; PMCID: PMC6001883.

using either 1) the 2024 CMS-Hierarchical Condition Categories (HCC) Risk Adjustment Model (Version 28) (hereafter referred to as CMS HCC Prospective Risk Adjustment Model) or 2) the CMMI HCC Concurrent Risk Adjustment Model V1 (hereafter Concurrent Risk Adjustment Model V1), which was used in ACO REACH;

5. 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. A risk score between 2.0 and 3.0 for A&D beneficiaries measured using the CMS HCC Prospective Risk Adjustment Model or a risk score between 0.24 and 0.35 for ESRD beneficiaries measured using the 2023 CMS-HCC ESRD Risk Adjustment Model for ESRD beneficiaries, and two or more unplanned hospital admissions in the previous 12 months; or
7. Have qualified for and received at least 45 Medicare-covered days in a Skilled Nursing Facility within the past 12 months.

Once a beneficiary meets one or more of the High Needs eligibility criteria, the beneficiary will be considered High Needs for the duration of the model, as beneficiaries in this population are unlikely to experience a radical improvement in health status.

Dually Eligible Beneficiaries Eligibility Criteria: To be aligned to an ACO based on Medicaid affiliation, the beneficiary must also be a full benefit dually eligible beneficiary (not otherwise aligned to a different ACO or model) who receives Medicaid benefits through a SMA in a FFS program or Medicaid MCO that has entered into a partnership agreement with the LEAD ACO for the purposes of partnering under LEAD.

B. Beneficiary Alignment

Beneficiary alignment is used for two purposes in LEAD. First, CMS prospectively aligns beneficiaries to an ACO for each Performance Year. ACOs assume accountability for the Medicare total cost of care of beneficiaries aligned to their organization for the Performance Year, according to the risk sharing option selected by their organization (see Section IX.A). Second, CMS uses beneficiary alignment to determine an organization's historical baseline expenditures for purposes of calculating the Performance Year Benchmark. ACOs will be required to maintain a minimum number of aligned beneficiaries for each Performance Year; however, CMS will permit ACOs with a high proportion of High Needs and/or ESRD beneficiaries and Newly Entering ACOs to have lower minimum numbers of aligned beneficiaries, as discussed further in Section VII.B.5.

Mid-Year Participant TIN Additions

Unlike prior models, LEAD permits **mid-year updates to claims-based alignment** for newly participating TINs to reduce administrative errors and support onboarding of new Participant TINs. This policy aims to improve accuracy in alignment and encourage participation by smaller or emerging provider organizations. This is different from ACO REACH, where claims-based alignment was conducted on an annual basis and used claims from health care providers on the health care provider lists that ACOs submit to CMS during the participant management window prior to the

PY. ACOs that had errors on their health care provider lists, such as inaccurate health care provider identifiers, incorrect provider types, or mistakenly omitted health care providers, would have inaccurate claims-based alignment and did not have the opportunity to correct those errors during the Performance Year. To address this issue, and encourage new ACO participation, LEAD's claims-based alignment approach would allow ACOs one mid-year opportunity to add new ACO Participant TINs to their Participant TIN Lists and have the beneficiaries associated with these newly added TINs become aligned to the ACO if the ACO has selected Hybrid Alignment.

1. Claims-Based Alignment

LEAD ACOs will employ claims-based alignment for beneficiaries receiving the plurality of their **Primary Care Qualified Evaluation and Management (PQEM)** services from a Participant TIN. Claims-based alignment will be performed **prospectively** based on a one-year look-back period of qualifying evaluation-and-management claims. Mid-year updates (described above) will not be based on care provided during the Performance Year in which the mid-year update is conducted.

Lookback Period and Data Sources

CMS will use Medicare FFS claims data for Parts A and B services covering a one-year look-back period. For prospective alignment, the lookback period will end three months prior to the start of the Performance Year. For Hybrid Alignment, the lookback period will end the day prior to the start of the Performance Year. This look-back period ensures that beneficiaries' most recent care patterns are reflected in alignment determinations. CMS will identify all PQEM services during the look-back period. PQEM codes include professional and institutional E/M services, preventive-care visits, chronic-care management, and comparable HCPCS/CPT codes (as outlined in Appendix C). CMS will update the PQEM list annually to reflect changes in Medicare coverage policy and provider billing practices.

CMS expects to provide preliminary alignment estimates to ACOs when new Participant TINs are added to the Participant TIN list.

Claims-Based Alignment Algorithm

The claims-based alignment algorithm uses a two-stage process to determine which alignment-eligible Participant Providers furnished the plurality of PQEM services to each beneficiary during the look-back period.

Stage 1 – Primary-Care Specialist
If 10% or more of a beneficiary's PQEM allowable charges were billed by physicians or non-physician practitioners with a primary-care specialty (family medicine, internal medicine, geriatrics, general practice, nurse practitioner), alignment is based solely on these primary care providers.

Stage 2 – Selected Non-Primary-Care Specialist

If less than 10% of a beneficiary's PQEM allowable charges were billed by primary-care specialties, alignment will consider certain non-primary care providers that manage chronic or complex conditions (e.g., cardiology, nephrology, endocrinology, psychiatry, etc.).

The Primary Care and Specialty Non-Primary Care Specialist List is available in Appendix C.

Weighting and Plurality Determination
The beneficiary is aligned to a LEAD ACO if the Participant TIN that furnished the largest share of allowable charges incurred for PQEM services during the lookback period is participating in a LEAD ACO.

Specialist Treatment for FQHCs and RHCs
For Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs), all services are treated as primary-care services for alignment purposes to account for the comprehensive nature of care delivered in those settings.

2. Voluntary Alignment

Voluntary alignment provides beneficiaries with the opportunity to actively designate their main source of care and to choose the Participant TIN or Participant Provider accountable for the quality and cost of their services under LEAD. This approach reinforces the central principle of patient choice and strengthens longitudinal beneficiary–provider relationships, thereby improving care coordination and trust.

Under voluntary alignment, a beneficiary may elect to be aligned with a LEAD ACO by designating a provider or practice site as their *primary clinician* or *main source of care*. CMS will use the most recent valid attestation—electronic or signature-based—to prospectively align the beneficiary.

LEAD modernizes the voluntary alignment process first used in ACO REACH by enabling:

- Alignment to the Participant TIN, at the TIN level (not just individual clinicians);
- Home-based voluntary alignment for beneficiaries under care of home-based practices; and
- More frequent alignment updates with the Hybrid Alignment option.

Beneficiaries Eligible for Voluntary Alignment
To participate in voluntary alignment, beneficiaries must:

1. Be enrolled in both Medicare Parts A and B;
2. Not be enrolled in a Medicare Advantage plan, PACE organization, or Medicare Cost Plan;
3. Have Medicare as the primary payer; and
4. Reside in a county that falls within the ACO's approved service area.

Beneficiaries must also maintain an active relationship with the selected Participant TIN. A beneficiary whose designated provider is removed from the ACO's Participant TIN List may select a new provider or main source of care at any time through the processes described below.

Mechanisms for Voluntary Alignment
Beneficiaries can elect voluntary alignment through two channels:

A. Electronic Voluntary Alignment
Beneficiaries may use Medicare.gov to identify a "primary clinician." Electronic Voluntary Alignment (EVA) designations are transmitted directly to CMS.

B. Signature-Based Voluntary Alignment
Beneficiaries may complete a paper-based voluntary alignment form developed by CMS and distributed by LEAD ACOs participating in Signature-Based Voluntary Alignment (SVA). The form may be signed manually or electronically (for example, through a patient portal or secure e-signature tool). The form must clearly indicate: (1) the beneficiary's choice of Participant TIN or Participant Provider; (2) the effective Performance Year; and (3) confirmation that the beneficiary understands participation does not limit freedom to seek care from any Medicare-enrolled provider.

Resolution of Multiple Attestations
If a beneficiary seeks voluntary alignment through both electronic and signature-based means, the most recent valid attestation will take precedence, as determined by the date of the attestation. An attestation is considered valid if either the attestation was made within 2 calendar years prior to the start of the Performance Year (e.g., for a 1/1/2027 start in PY2027, the attestation was made no earlier than 1/1/2025) or the attestation was made more than 2 years prior to the start of the Performance Year, but the Participant TIN designated by the beneficiary has submitted a claim for a PQEM service furnished to the beneficiary within the last two calendar years.

Covered Services Check
To ensure that ACOs are providing services to beneficiaries aligned via voluntarily alignment, if at Final Financial Settlement CMS determines that a beneficiary did not have a single claim (of any type) during the Performance Year submitted by a Participant TIN or Preferred Provider (excluding labs or imaging services) in the ACO the beneficiary was aligned to via voluntary alignment and the beneficiary had at least one claim for PQEM Services during the Performance Year in the ACO's service area with a provider or supplier not in the ACO, the beneficiary will be retroactively removed from alignment to the ACO.

Effective Dates and Frequency of Updates
For ACOs participating in the standard Prospective Alignment option, Voluntary Alignment designations made during the year become effective on January 1 of the next Performance Year. ACOs electing the Hybrid Alignment option (see Section VII.B.3) may have beneficiaries added on a monthly basis following eligibility confirmation by CMS. In both cases, alignment remains prospective for financial and reporting purposes, and no retroactive payment adjustments will be made for services provided before the effective date of alignment.

Carryover of Signed Voluntary Alignment

CMS intends to incorporate valid voluntary alignment attestations established under the ACO REACH Model as participating ACOs transition into the LEAD Model. This approach is designed to promote continuity and recognize the relationships established between ACOs and beneficiaries through voluntary alignment. Specifically, if a beneficiary previously completed a voluntary alignment form under ACO REACH designating a participating provider as their primary source of care, and that provider participates in LEAD through the same ACO entity, CMS will treat that attestation as effective for purposes of alignment under LEAD.

As part of this transition, ACOs will be required to provide notice to beneficiaries whose voluntary alignment will be carried forward, including clear information about the model transition and instructions for opting out if the beneficiary does not wish to maintain voluntary alignment under LEAD.

CMS will issue forthcoming guidance outlining the operational parameters, beneficiary notification requirements, and any additional conditions associated with carrying voluntary alignment forward into LEAD.

Safeguards and Program Integrity

CMS will monitor voluntary alignment activity to identify potential misuse, such as selective targeting of low-risk beneficiaries or use of non-approved forms. CMS may conduct audits, which may include random sampling of beneficiary records, review of communication materials, and interviews with LEAD ACOs and Participant TINs. Violations of the PY PA may result in corrective action, suspension of voluntary alignment authority, or termination from LEAD. ACOs must fully cooperate with any CMS audits or other monitoring activities.

3. Frequency of Alignment Options

LEAD ACOs will have two choices for the frequency of prospective alignment of beneficiaries through voluntary and claims-based alignment: (1) Prospective Alignment; or (2) Hybrid Alignment. Both policies rely on establishing the ACO's aligned population prospectively. However, for those ACOs that select Hybrid Alignment, beneficiaries who voluntarily align to the ACO during the Performance Year would be added to the ACO's aligned beneficiary population on a monthly basis prior to the end of the Performance Year. The alignment frequencies are compared in Table 2 below.

- **Prospective Alignment**, like the methodology used in ACO REACH, will be conducted prior to the start of each Performance Year. Each new LEAD ACO will be given an opportunity to participate in an optional implementation period for voluntary alignment prior to the start of their first Performance Year in the model.
- **Hybrid Alignment** will allow LEAD ACOs to have voluntarily aligned beneficiaries added to their aligned beneficiary population on a monthly basis throughout the Performance Year,

plus an additional round of claims-based aligned beneficiaries to be added mid-Performance Year if the ACO adds new Participant TINs (see the claims-based alignment section above for more information). Hybrid Alignment will be used for two purposes: (1) calculating the financial benchmark; and (2) determining which beneficiaries are aligned to the ACO for monthly capitated payments.

To administer monthly voluntary alignment additions, prior to the start of each month, CMS will compile a list of beneficiaries who have voluntarily aligned through Medicare.gov and a list of beneficiaries who have completed a Signature-Based Voluntary Alignment form and meet all other beneficiary eligibility criteria. LEAD ACOs will be responsible for submitting updated Signature-based Voluntary Alignment information to CMS prior to the start of each month to allow for timely updates to these CMS lists. Only those beneficiaries who were not already aligned to another ACO, an organization participating in another Shared Savings initiative, or other model for which beneficiary overlap with LEAD is prohibited for the Performance Year would be aligned to the ACO mid-year under Hybrid Alignment. The Hybrid Alignment would also allow for an additional round of claims-based aligned beneficiaries to be added mid-Performance Year if the ACO adds new Participant TINs (see the claims-based alignment section above for more information.)

Allowing beneficiaries to be added throughout the Performance Year with partial-year payment eligibility balances flexibility and accuracy of payments and avoids the operational burden of reprocessing payments due to mid-year changes in a beneficiary's alignment.

Safeguards and Oversight

CMS will only permit inclusion of beneficiaries not aligned to other Shared Savings initiatives where overlaps are not permitted. LEAD ACOs must submit updated Participant TIN Lists before each biannual refresh and maintain documentation of beneficiary attestations. CMS reserves the right to audit Hybrid Alignment activity to ensure compliance with program integrity standards.

Table 2: Alignment Frequency Differences

Method	Claims-Based Alignment Frequency	Voluntary Alignment Frequency
Prospective	Once a year, prior to the PY. Drops due to loss of eligibility only.	Once a year, prior to the PY.
Hybrid	Twice a year, once prior to PY and once mid PY. Additions only to newly added TINs. Drops due to loss of eligibility only.	Monthly

4. Beneficiary Alignment Hierarchies

When a beneficiary qualifies for both voluntary and claims-based alignment to different ACOs, Voluntary Alignment takes precedence. If a beneficiary could be aligned to multiple initiatives that

prohibit overlap (e.g., Shared Savings Program or the KCC Model), CMS will apply the Innovation Center's cross-model governance rules to determine which model takes alignment precedence. We anticipate providing more specific information on alignment hierarchies in methodological papers ahead of the start of the model. For dual-eligible beneficiaries, Medicare alignment under LEAD will govern payment and reporting responsibility, while coordination with state Medicaid programs is encouraged to improve care integration. MCO enrollment-based alignment would be subordinate in alignment hierarchy to claims-based alignment and voluntary alignment.

5. Minimum Beneficiary Alignment Threshold

LEAD ACOs will maintain a minimum number of beneficiaries so that CMS can reliably calculate capitation payments (for both risk options) and financial benchmarks. Required minimums for Renewing ACOs not serving a high proportion of High Needs beneficiaries will be set at 5,000 aligned beneficiaries during the first Performance Year, with a required minimum of 3,000 claims-based aligned beneficiaries (*i.e.*, not inclusive of voluntarily aligned beneficiaries) in at least one of the base years (BY) to allow for accurate calculation of the benchmark. ACOs serving a high proportion of High Needs beneficiaries (those with at least 40% of the ACO's total alignment in the High Needs and/or ESRD beneficiary category) would have a lower alignment threshold recognizing that organizations focused predominantly on complex and High Needs beneficiaries tend to have smaller patient panels. LEAD will allow Newly Entering ACOs to participate at lower beneficiary alignment minimums and slowly grow to 5,000 by the end of the model (as outlined in Table 3 below).

CMS will offer LEAD ACOs that are falling within 10% below alignment minimums a two-time alignment buffer to allow them to continue participation in the model. If they do not meet minimums after utilizing their buffers, they will be terminated from the model. For ACOs that have a high proportion of High Needs eligible beneficiaries, a two-time buffer would be available to such ACOs that fall below the proportion of High Needs beneficiaries required to have a lowered alignment minimum (*i.e.,* the buffer would permit such ACOs would to have a lower aligned minimum if at least 30% of aligned beneficiaries met the High Needs eligibility criteria). If an ACO falls below 30% of their beneficiaries meeting the High Needs criteria, the ACO will be subject to the 5,000 claims-based aligned beneficiary minimum. ACOs would not be permitted to use both alignment buffers in consecutive PYs.

Table 3: Alignment Minimums

Performance Year	LEAD PY Alignment Minimum	LEAD Claims-Based Alignment Minimum in BY	LEAD PY Alignment Minimums for Newly Entering ACOs	Claims-Based Alignment Minimum in BY for Newly Entering ACOs	High Needs/ ESRD Eligible ACO PY Alignment Minimum	Claims-Based Alignment Minimum in BY for High Needs/ ESRD Eligible ACOs
1	5,000	3,000	1,000	600	800	500
2	5,000	3,000	2,000	1,200	1,000	625
3	5,000	3,000	3,000	1,800	1,200	750
4	5,000	3,000	4,000	2,400	1,400	825
5	5,000	3,000	5,000	3,000	1,600	1,000
6	5,000	3,000	5,000	3,000	1,600	1,000
7	5,000	3,000	5,000	3,000	1,600	1,000
8	5,000	3,000	5,000	3,000	1,600	1,000
9	5,000	3,000	5,000	3,000	1,600	1,000
10	5,000	3,000	5,000	3,000	1,600	1,000

C. Beneficiary Engagement and Marketing

LEAD ACOs will be required to adhere to a number of beneficiary protections, including, but not limited to, the following:

- 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 and regulations.
- 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 or Preferred Provider with an arrangement with the ACO. 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 original Medicare rules. 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 LEAD and that beneficiaries retain all Original Medicare benefits and rights. CMS will make available a template for such informational materials that the ACO and its Participant TIN will be required to use.

- 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.
- ACOs must submit all written materials that communicate the details of their Benefit Enhancements and Beneficiary Engagement Incentives (where applicable) to CMS for review and approval.

LEAD 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 LEAD, including that they are accurate and not misleading, are not discriminatory or used in a manner that is discriminatory, and make clear that alignment to an ACO does not remove or otherwise affect a beneficiary's freedom to choose a provider or supplier. Additional requirements concerning this review process will be provided in the IP PA and PY PA. ACOs are prohibited from conducting communication or marketing activities targeted to 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.

In order to allow for more robust outreach to beneficiaries regarding the ACO, CMS will permit LEAD 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 IP PA and PY PA, as applicable. For example, ACOs will be able to provide marketing materials and hold outreach events to the extent permitted by law. However, the IP PA and PY PA prohibit ACOs from engaging in marketing activities that are misleading to beneficiaries and from expressly stating or implying that alignment to the ACO removes or otherwise affects the beneficiary's freedom to choose a provider or supplier. ACOs will not be allowed to 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).

To reduce burden on REACH ACOs that wish to transition to LEAD, Applicant ACOs that participated in ACO REACH in Performance Year 2026 with previously approved voluntary alignment marketing materials may update the model name, Performance Year and ACO name, if applicable. However, applicant ACOs that: (1) did not previously participate in ACO REACH with a Performance Year 2026 voluntary alignment marketing materials; or (2) did participate in ACO REACH with a Performance Year 2026 voluntary alignment marketing materials but wish to change more than the model name, Performance Year and ACO name, if applicable, will need to submit voluntary alignment marketing materials to CMS for review, at a time requested by CMS, before sharing the marketing materials with beneficiaries.

D. Medicare – Medicaid Integration Features and Partnership Agreements

LEAD will complement existing CMS programs that encourage states to provide Medicaid and Medicare benefits in an integrated way by providing a pathway for dually eligible beneficiaries enrolled in Original Medicare to access integrated care through an ACO participating in LEAD.

A recent Health Affairs article highlighted the importance of financial integration of insurance coverage and benefits between Medicare and Medicaid, noting that "Because Medicare and Medicaid are administered and funded separately, most dually eligible beneficiaries receive coverage through two distinct programs with separate budgets, which lack financial incentives to coordinate care."[14] The goal of Medicare-Medicaid integration in LEAD is to (1) expand access to integrated care for beneficiaries dually eligible for Medicare and Medicaid and (2) realign financial incentives towards increased accountability for this population and mitigate existing incentives for cost shifting across the two programs. Most efforts at integrating care between Medicare and Medicaid (often referred to as duals integration) have occurred through managed care and increasing focus on "aligned enrollment" under which a dually eligible beneficiary receives Medicare and Medicaid services through the same or affiliated managed care organizations. A continuing challenge however is that roughly 30% to 50% of dually eligible beneficiaries access Medicare benefits not through managed care but through Original Medicare – which is where ACO structures such as LEAD can play a critical role in facilitating integrated care. LEAD will test a new approach to incentivize better integration for these beneficiaries, who often have complex needs.

Specifically, pending successful completion of a planning period, LEAD will pilot a program for LEAD ACOs to partner with SMAs or MCOs (depending on whether beneficiaries receive Medicaid benefits through a Medicaid FFS program or MCO), for the ACO and SMA/MCO to share data, coordinate care, and potentially share in Medicare savings.[15]

Planning Period

During an initial planning phase from March 2026 through December 2027 (Planning Phase), CMS will identify two states ("DUAL states") that are interested in partnering to test the Medicare-Medicaid integration component of LEAD and work with selected states to develop the framework for partnership agreements between ACOs and SMAs or MCOs in those states. This framework will help define how ACOs and SMAs or MCOs can work together to share data and coordinate care to improve outcomes, including preventing avoidable hospitalizations and helping patients remain engaged in their communities. Pending successful completion of the Planning Phase, ACOs in the selected states would have the opportunity to enter partnership arrangements with SMAs or MCOs.

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[14] "The Case For Integrated ACOs For Dual-Eligible Beneficiaries", Health Affairs Forefront, July 14, 2025. DOI: 10.1377/forefront.20250709.353678

[15] In Medicaid managed care, there is no requirement to direct payment at the provider level, including a requirement to share savings at the provider level, or any expectation for the SMA to share savings directly with providers of the MCOs.

LEAD ACOs can indicate in their applications that they would be interested in a Medicaid partnership if that option were to become available in their state. CMS will provide more information about state selection as it becomes available.

State Selection

CMS will select DUAL states based on several criteria such as the following:

- **Markets with Large, High-Cost Dual Populations:** States with a significant concentration of high-cost dually eligible beneficiaries requiring coordinated care across multiple services, particularly those that are full-benefit dually eligible beneficiaries[16] with high long term services and supports (LTSS) utilization (recognizing that for dually eligible beneficiaries, LTSS is the main and highest cost service Medicaid is responsible for, and typically signifies the beneficiary qualifies for a nursing home level of care).
- **High-Cost Markets:** States with strong savings potential based on high regional Medicare costs or high rates of cost growth.
- **ACO Penetration:** States with a meaningful rate of ACO penetration, especially among full-benefit dually eligible beneficiaries.
- **Disposition Toward Integrated Care:** Historical state efforts to integrate care for dually eligible beneficiaries, including contracting with Medicare Advantage Dual Eligible Special Needs Plan (D-SNPs) through State Medicaid Agency Contract (SMAC) agreements or participation in the Financial Alignment Initiative (FAI), a previous duals integration demonstration offered by CMS.
- **Medicaid Data Quality:** Quality of Medicaid data is critical for supporting the data sharing element of this effort and for CMS to conduct the additional monitoring and evaluation required in states chosen for Medicaid partnerships under LEAD. CMS will assess completeness of enrollment, utilization and cost data in the Transformed Medicaid Statistical Information System (T-MSIS) Analytic Files.

Once CMS has identified DUAL states, it will notify LEAD ACOs and provide more information about next steps for establishing ACO-Medicaid partnerships in those states, pending successful completion of a planning phase.

Partnership Arrangements

During the Planning Phase, CMS and DUAL states will work together collaboratively to develop a framework for partnership arrangements to facilitate standardized partnership arrangements between ACOs and MCOs or SMAs. CMS would not be a party to the partnership agreements or subject to any associated risk sharing arrangements between the ACO and MCO, or the ACO and SMA.

[16] Full-benefit dually eligible beneficiaries receive full Medicaid benefits and Medicaid payment of Medicare premiums and, in many cases, cost sharing. This is in contrast to partial-benefit dually eligible beneficiaries, who do not receive full Medicaid benefits and may receive limited to no cost sharing.

The Medicaid entity (i.e., SMA or MCO for Medicaid FFS and managed care programs, respectively) would contract with the ACO directly as they would contract with other value-based provider entities. The focus of these agreements would be to align incentives such that Medicaid providers are more cognizant of and act on opportunities to avoid poor short-term outcomes, e.g., acute care crises.

While partnership arrangements will ultimately be subject to the framework developed by CMS and selected states, CMS expects that at a minimum, they will include the following domains:

- **Formal relationship:** Establish a formal relationship between the ACO and MCO or SMA (or their designee);
- **Roles and responsibilities:** Document each entity's roles and responsibilities with regard to dually eligible beneficiaries;
- **Strategies for care coordination and care improvement:** Articulate actions oriented towards integrated care and effective management of dually eligible beneficiaries that each party will take to better serve these beneficiaries. For example, define the scope of coordination activities (including development of an integrated care plan) that occurs when a Medicaid member is aligned to the ACO. Other examples of strategies include establishing processes to connect aligned beneficiaries to a primary care provider in the ACO, risk-stratifying and targeting care coordination resources toward aligned beneficiaries at risk of high Medicare spending, the potential return of long-stay nursing facility patients back to the community where appropriate, and entering into value-based purchasing arrangements with nursing facilities, consistent with Federal requirements, that factor in these facilities' hospitalization rates;
- **Bilateral risk sharing arrangements:** Define bilateral risk sharing arrangements that promote greater accountability for health care costs across Medicare and Medicaid for dually eligible beneficiaries. This could include arrangements where, for example, SMAs or MCOs share in ACO's savings, such as savings from reduced hospitalizations or avoided Skilled Nursing Facility (SNF) stays, that accrue from leveraging current Medicaid investments in home and community-based services; and
- **Data sharing:** Establish terms, conditions, and processes for improved data integration and sharing to support dually eligible beneficiaries, in compliance with all applicable laws and regulations and LEAD model policies.

Alignment

To support Medicare-Medicaid integration, CMS will use Medicaid enrollment-based alignment to align beneficiaries enrolled in participating SMAs or MCOs to those organizations' partner LEAD ACOs. Under Medicaid enrollment-based alignment, CMS will align eligible full-benefit dually eligible beneficiaries to an ACO when they meet all of the following criteria:

- They are enrolled for Medicaid benefits in the MCO or the State's Medicaid FFS program that serves as the ACO's partner, subject to a formal partnership agreement.

- They are enrolled in Original Medicare.
- They meet the requirements for alignment to LEAD.
- They reside in the ACO's service area.

Medicaid enrollment-based alignment will be subordinate in the alignment hierarchy to both claims-based and voluntary alignment methods. Any and all data sharing required to support this component of the model must be implemented in compliance with all applicable laws and regulations, including HIPAA Privacy and Security Rule requirements.

CMS continues to fully support integrated Medicare-Medicaid managed care. Beneficiaries who are already enrolled in integrated Medicare-Medicaid managed care options for a given Performance Year are not eligible for alignment to an ACO as part of a LEAD Model Medicaid-Medicare partnership agreement.

E. Healthy Living Strategy

1. LEAD's Approach to Improving the Health of Medicare Beneficiaries

LEAD seeks to improve the quality of care and health outcomes for all aligned Original Medicare beneficiaries. To achieve these goals, LEAD leverages the CMS Innovation Center's Strategy, which consists of three pillars: **promoting evidence-based prevention, empowering beneficiaries** to achieve their health goals, and **driving choice and competition**.[17] In addition to promoting these priorities, the model also advances the Center's foundational vision of protecting federal taxpayers' dollars.

To achieve the CMS Innovation Center's priorities, LEAD will incorporate several model features designed to promote a healthy lifestyle while empowering beneficiaries to take greater control of their health. These model features consist of Benefit Enhancements, Patient Incentives (including In-Kind Items and Services, Beneficiary Engagement Incentives), as well as other initiatives (e.g., The Tech Enabler Initiative) that ACOs can leverage and offer to their beneficiaries to facilitate beneficiaries' access to high-value, proactive, and coordinated care.

Key Elements of the Healthy Living Strategy in LEAD include:

1. The Prevention and Quality Plan Requirement
2. Tech Enabler Initiative
3. Benefit Enhancements
4. Patient Incentives

Each of these model features is discussed in greater detail below and will apply to all ACOs.

[17] https://www.cms.gov/priorities/innovation/about/cms-innovation-center-strategy-make-america-healthy-again

The Prevention and Quality Plan Requirement

Consistent with LEAD's goal to increase quality of care for all aligned Medicare beneficiaries by promoting evidence-based prevention, beginning PY2027, LEAD ACOs will be required to develop and implement a prevention intervention, which will be reported via a Prevention and Quality Plan (PQP). ACOs must develop or expand on at least one prevention intervention aimed at engaging beneficiaries and improving their health outcomes. The PQP intervention may be an enhancement or expansion of current activities or a new initiative. The purpose of a PQP requirement is for each ACO to understand the holistic needs of their beneficiaries and identify opportunities to promote preventive care over the course of the model lifecycle. Payment will be tied to the development and implementation of the prevention intervention and meeting established goals. For more information on the PQP, please see section XI.

Tech Enabler Initiative

The Tech Enabler Initiative is a CMS-led effort designed to facilitate ACOs' adoption of innovative tools that can guide beneficiaries toward high-value care (or health care services that are high in quality and cost-effective). Through this initiative, the CMS Innovation Center will work with provider organizations to identify high-value technology and artificial intelligence (AI) use cases, build out technology application requirements, and establish a channel for vendors to provide information on their technology applications specifically tailored to ACO participants. Through this data collection and exchange process, ACOs will receive the information and resources necessary to support future partnerships with technology vendors. More on the Tech Enabler initiative can be found in section XV.A.

2. Benefit Enhancements for PY 2027

LEAD ACOs will have the option to leverage several Medicare Benefit Enhancements designed to improve the health outcomes of Medicare beneficiaries while reducing the cost of care. These Benefit Enhancements will support improvements in health outcomes by facilitating access to high-value services and supporting beneficiaries' recovery in their homes. While LEAD leverages several Benefit Enhancements used in ACO REACH, LEAD also includes a new Benefit Enhancement.

Medical Nutrition Therapy Benefit Enhancement

Medical Nutrition Therapy (MNT) is an evidence-based, cost-effective lifestyle intervention associated with improvements in cholesterol, reductions in A1c, reductions in medication costs, and improvement in quality of life.[18] Given the impact of MNT services in improving health outcomes and quality of life for Medicare beneficiaries, LEAD intends to test the expansion of MNT services to further help beneficiaries with chronic conditions lead healthier lives.

[18] https://pmc.ncbi.nlm.nih.gov/articles/PMC10171906/

This Benefit Enhancement will offer the ability to expand the conditions for which beneficiaries may receive reimbursable MNT. This Benefit Enhancement extends MNT reimbursement beyond the current indications for diabetes, renal disease, or having undergone a kidney transplant in the last 36 months.[19] Under the proposed MNT Benefit Enhancement, MNT as defined in section 1861(vv)(1) of the Act would be extended to beneficiaries with Prediabetes and Hyperlipidemia—key conditions that increase risk of kidney and cardiometabolic diseases.

CMS would only make available the MNT Benefit Enhancement for ACOs participating in the Global Risk Option. As ACOs in the Global Risk Option assume full financial risk for their beneficiaries, they will be accountable for the beneficiary's Medicare total cost of care.

LEAD Benefit Enhancements Used in Previous ACO Models

Building on lessons learned from ACO REACH, LEAD will offer Benefit Enhancements used under ACO REACH while incorporating strategies that can further increase utilization and impact. Besides integrating strategies to increase the utilization and impact of Benefit Enhancements, LEAD will leverage additional data collection mechanisms to test the impact of Benefit Enhancements. For example, using rapid randomized controlled trials via the Rapid Innovation Cycle Program, there will be clearer evidence on how Benefit Enhancements support improvements in health outcomes. For a detailed description of LEAD Benefit Enhancements previously used in ACO REACH that will be offered under LEAD, please see Appendix F.

Table 4: LEAD Benefit Enhancements Previously Used in ACO REACH

Benefit Enhancements Used in ACO REACH	**Brief Description (See additional details in Appendix F)**
3-Day Skilled Nursing Facility (SNF) Rule Waiver Benefit Enhancement	Waives the 3-day inpatient stay requirement prior to SNF or swing-bed hospital admission
Care Management Home Visits Benefit Enhancement	Allows Care Management Home Visits by auxiliary personnel under general supervision
Post Discharge Home Visits Benefit Enhancement	Allows Post Discharge Home Visits by auxiliary personnel under general supervision
Home Health Homebound Waiver Benefit Enhancement	Allows home health services for beneficiaries with certain clinical risk factors that are not homebound

[19] As defined in section 1861(s)(2)(V) of the Act and 42 CFR § 410.130, MNT services, covered under Medicare Part B, are only available to beneficiaries with diabetes, kidney disease, or those who have undergone a kidney transplant in the last 36 months.

Benefit Enhancements Used in ACO REACH	Brief Description (See additional details in Appendix F)
3-Day Skilled Nursing Facility (SNF) Rule Waiver Benefit Enhancement	Waives the 3-day inpatient stay requirement prior to SNF or swing-bed hospital admission
Nurse Practitioner (NP) and Physician Assistant (PA) Services Benefit Enhancements	Allows NPs and PAs to certify and order six types of care for beneficiaries
Concurrent Care for Beneficiaries that Elect the Medicare Hospice Benefit Enhancement	Allows beneficiaries who have elected Medicare Hospice Benefit to concurrently receive hospice and curative care
Telehealth Benefit Enhancement	Allows beneficiaries to receive telehealth services from home; covers some asynchronous Telehealth services

3. Patient Incentives

CMS expects to make a determination that the Anti-kickback Statute Safe Harbor for CMS-sponsored Model patient incentives (42 C.F.R. § 1001.952(ii)(2)) is available to protect remuneration furnished in the LEAD Model in the form of patient incentives, such as in-kind items and services and other Beneficiary Engagement Incentives. These patient incentives are designed to support beneficiaries' health-related goals and pursuit of healthy behaviors. These incentives will also give ACOs better tools to attract beneficiaries and encourage beneficiaries to seek care from high-value providers, which in turn allows beneficiaries to drive improved performance and efficiency among providers. Patient incentives, such as Beneficiary Engagement Incentives, allow ACOs to promote use of specific high-value services that support improved health outcomes. Examples of Beneficiary Engagement Incentives that may be offered to LEAD beneficiaries include: Substance Access, Part B Cost Sharing Support, and Chronic Disease Prevention. Besides these Beneficiary Engagement Incentives, CMS is exploring additional opportunities for ACOs to share savings with aligned beneficiaries when they select high-value care services (for more information, please see the Benefit Enhancements and Beneficiary Engagement Incentives under consideration found in section VII.E.4).

In-Kind Items and Services

Consistent with the provisions of Section II.C., and subject to compliance with the PY PA and all applicable laws and regulations, LEAD ACOs and the ACO's Participant TINs, Participant Providers, and Preferred Providers, may be permitted to provide in-kind items or services to the ACO's aligned beneficiaries if the following conditions are satisfied:

- There is a direct connection between the items or services and the medical care of the beneficiary.

- The items or services are items that support prevention or management of a chronic condition or advance one or more goals of LEAD, including adherence to a treatment regime, adherence to a drug regime, adherence to a follow-up care plan, or management of a chronic disease or condition.
- The in-kind item or service is not a Medicare-covered item or service for the beneficiary on the date the in-kind item or service is furnished to that beneficiary. For purposes of this exception, an item or service that could be covered pursuant to a Benefit Enhancement is considered a Medicare-covered item or service, regardless of whether the ACO elects to implement such Benefit Enhancement for a given Performance Year.
- The in-kind item or service is not furnished in whole or in part to reward the beneficiary for designating or agreeing to designate through Voluntary Alignment a LEAD Participant Provider as his or her primary clinician, main doctor, main health care provider, or the main place where the beneficiary receives care.
- The items or services must not include cash or cash equivalents.
- The in-kind item or service is furnished to a beneficiary directly by the ACO, its Participant TIN or Participant Provider or Preferred Provider. It can also be furnished directly by other organizations with which the ACO, or its Participant TIN or Participant Provider or Preferred Provider, has a written agreement.

These items and services will be funded by the ACO or in coordination with their Participant TINs, Participant Providers, or Preferred Providers.

Beneficiary Engagement Incentives
Chronic Disease Prevention Beneficiary Engagement Incentive

Consistent with the provisions of Section II.C., and subject to compliance with the PY PA and all applicable laws and regulations, LEAD ACOs, their Participant TINs, Participant Providers, and Preferred Providers may be permitted to provide the Chronic Disease Prevention Beneficiary Engagement Incentive to the ACO's aligned beneficiaries in the form of healthy food products (value to not exceed $150). The Chronic Disease Prevention Beneficiary Engagement Incentive is designed to incentivize participation in evidence-based programs and healthy living activities that can help beneficiaries prevent or better manage their chronic conditions. Examples of efforts that can be incentivized include but are not limited to: participating in chronic disease self-management programs, completing tobacco cessation programs, consistent daily exercise, weight loss, and reduction in hemoglobin A1c level. Allowing ACOs and their Participant TINs, Participant Providers, and Preferred Providers to incentivize beneficiary participation in evidence-based programs focused on prevention and chronic disease management will promote beneficiary self-management and ultimately improve quality and reduce costs.

ACOs or their Participant TINs, Participant Providers, or Preferred Providers will have the flexibility to directly offer the Chronic Disease Prevention Beneficiary Engagement Incentive in the form of healthy food products or a restricted-spend card. If an ACO or their Participant TINs, Participant Providers, or Preferred Providers opts to reward their beneficiaries via a restricted-spend card, the allowable

purchases will be limited to healthy food products and will be restricted from being used for general purposes.

ACOs that elect to offer a Chronic Disease Prevention Beneficiary Engagement Incentive will be required to submit an Implementation Plan to CMS detailing how they will structure their incentive program. The Implementation Plan is subject to CMS approval. LEAD ACOs will be required to implement their Chronic Disease Prevention Beneficiary Engagement Incentive policies in accordance with the Implementation Plan approved by CMS. ACOs will be permitted to offer programs that address the needs of their aligned beneficiaries, as long as the program is consistent with an approved Implementation Plan and does not discriminate against any aligned beneficiary who will otherwise qualify for participation. ACOs that elect to offer a Chronic Disease Prevention Beneficiary Engagement Incentive will be required to maintain records of their reward program, including documentation of the amount, the type of healthy food products or restricted spend card offered, and the basis for beneficiary eligibility. Participating ACOs will be subject to monitoring and compliance activities in connection with this Beneficiary Engagement Incentive.

Part B Cost Sharing Support Beneficiary Engagement Incentive

Consistent with the provisions of Section II.C., and subject to compliance with the PY PA and all applicable laws and regulations, an ACO may be permitted to enter into a cost sharing support arrangement with its Participant TINs, Participant Providers, or Preferred Providers (the cost sharing support agreement). The cost sharing support arrangement will either take the form of an addendum or a freestanding, simplified provider agreement with one or more of these entities: Participant TINs, Participant Providers, and Preferred Providers. Pursuant to the cost sharing support agreement, the health care provider would not collect beneficiary cost sharing amounts (in whole or in part) from categories of aligned beneficiaries and for categories of Part B services (excluding durable medical equipment, prosthetics, orthotics, or supplies) identified by the ACO. Health care providers will continue collecting cost sharing amounts for durable medical equipment, prosthetics, orthotics, and supplies. Beneficiaries with supplemental insurance will not be eligible for this Beneficiary Engagement Incentive.

Pursuant to the terms of the cost sharing support agreement, ACOs could make payments to those Participant TINs, Participant Providers, or Preferred Providers to cover some or all of the amount of beneficiary cost sharing not collected. ACOs may also have the flexibility to establish a simplified Preferred Provider Agreement with high-value providers that want to participate in LEAD as Preferred Providers for the purposes of offering cost sharing support, in order to increase aligned beneficiaries' access to high-value providers. As an example, this simplified agreement will not have to include capitated payment arrangements.

Through this Beneficiary Engagement Incentive, LEAD offers an opportunity to share savings with aligned beneficiaries, support beneficiaries in accessing services from high-value providers, and reduce financial barriers to needed care, thus enabling adherence to treatment plans and contributing to improved health outcomes. In tandem with the utilization of this Beneficiary

Engagement Incentive, LEAD ACOs will be able to participate in the Tech Enabler initiative through which they can identify and use innovative tools that can facilitate beneficiaries' access to high-value health care providers providing high-value services, particularly medically necessary Medicare Part B items and services (e.g., care navigation tools that can identify high-value specialists, apps that connect beneficiaries to community health partners).

LEAD ACOs that wish to take advantage of this Beneficiary Engagement Incentive must submit an Implementation Plan to CMS that identifies the categories of beneficiaries who will be eligible for cost sharing support, the categories of eligible Part B services, and such other information as CMS may require. The ACO may specify in its Implementation Plan both primary care and specialty care Part B services that are eligible (unless excluded from eligibility under the PY PA) for cost sharing support so that beneficiaries with specialty needs may also be incentivized to obtain the care they need. ACOs may also specify in the Implementation Plan that it plans to use the Part B Cost Sharing Support Beneficiary Engagement Incentive to address financial barriers to accessing care. To the extent the ACO will not be covering the beneficiary's cost sharing in its entirety, the ACO will be required to specify in its Implementation Plan how it will determine the relative contributions of the ACO and the Participant TINs, Participant Providers, or Preferred Providers. Cost sharing support payments must come from the ACO and, if applicable, its Participant TINs, Participant Providers or Preferred Providers.

The Implementation Plan is subject to CMS approval. ACOs and their Participant TINs, Participant Providers, or Preferred Providers will be required to implement their cost sharing support policies in accordance with the Implementation Plan approved by CMS. Participating ACOs will be subject to monitoring and compliance activities in connection with the use of this Beneficiary Engagement Incentive.

Substance Access Beneficiary Engagement Incentive

Subject to compliance with all applicable laws and regulations, LEAD will offer the Substance Access Beneficiary Engagement Incentive to facilitate access to and use of Eligible Hemp Products as a complement to traditional treatments. Through this Beneficiary Engagement Incentive, LEAD ACOs will be able to recommend and provide an Eligible Hemp Product(s) to certain Medicare beneficiaries receiving care from Participant TINs, Participant Providers, or Preferred Providers.

Under this Beneficiary Engagement Incentive, "Eligible Hemp Products" means a product that meets the operative statutory definition of "hemp" and is comprised of the plant Cannabis sativa L. and any part of that plant, including seeds, derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol (THC) concentration of not more than 0.3 percent on a dry weight basis, as measured in the raw plant material or final product, and excludes any products containing more than 3 mg per serving of tetrohydrocannabinols (such as delta-8-tetrahyrdocannabinol, delta-10-tetrahyrdocannabinol, and tetrahydrocannabinolic acid) in an orally administered form, or containing cannabinoids not naturally produced or capable being of produced by or in the cannabis plant during its cultivation. Inhalable products that would

otherwise meet the requirements of the Eligible Hemp Products definition are not considered Eligible Hemp Products. An Eligible Hemp Product must meet the following quality and safety standards:

- Meet all state and local quality and safety laws, regulations and other mandated standards (these include state-level Medicaid policies on hemp-based products);
- Come from a legally compliant source and high-quality farm as those terms are defined and described in the 2018 Agriculture Improvement Act (Pub. L. No. 115-334; 21 C.F.R. Parts 1308 and 1312); and
- Has been tested by a third-party for:
    i. Potency with an accurate measurement of cannabidiol levels;
    ii. Contaminants, including but not limited to pesticides, heavy metals, and residual solvents, with a negative result; and
    iii. Microbials, including but not limited to pathogens such as E. coli, Salmonella, model, and yeast, with a negative result.

A "Substance Access Eligible Beneficiary" is a LEAD beneficiary for whom use is deemed appropriate by a Participant Provider or Preferred Provider and who meets the following criteria:

- Is 18 years or older;
- Does not exhibit signs of frailty, based on indicators such as a claim submitted by a health care provider or supplier for a hospital bed (e.g., specialized pressure-reducing mattresses and some bed safety equipment), or transfer equipment (e.g., patient lift mechanisms, safety equipment, and standing systems) for use in the home;
- Does not have a disqualifying medical conditions (see below); and
- With whom the physician has discussed the benefits and risks of taking an Eligible Hemp Product and for whom the physician has documented the discussion and shared decision-making and included such documentation in the Substance Access Eligible Beneficiary's medical record.

In addition, a Substance Access Eligible Beneficiary cannot have an active or past medical history of any of the following conditions:

- Substance abuse, including alcohol use disorder, cannabis use disorder, opioid use disorder, or tobacco use disorder;
- Active pulmonary conditions, including, but not limited to, chronic obstructive pulmonary disease, asthma, interstitial lung disease, or emphysema that limits activities and could present further risk with sedation;
- Serious mental illness, including schizophrenia, schizoaffective disorder, delusional disorder, bipolar disorder, severe anxiety disorder, major depressive disorder with suicidality, or active psychosis;
- Cognitive impairment or any form of dementia worsened by sedation;
- Severe cardiovascular disease, including serious or symptomatic arrhythmia;

- Severe liver disease with abnormality in liver function enzymes that could impact metabolism or risk drug interactions; or
- Severe kidney disease, including, but not limited to, chronic kidney disease stage 3 or higher, or any kidney disease with significantly reduced renal clearance.

In addition, a Substance Access Eligible Beneficiary cannot be pregnant or breastfeeding.

This Beneficiary Engagement Incentive will only be applicable in states where hemp is considered legal. If the model participant wants to offer the Beneficiary Engagement Incentive under the limited circumstances described above, state law on the legality of synthetic hemp-derived cannabinoids is a factor to be considered in what hemp-derived cannabinoid products can be recommended under the Beneficiary Engagement Incentive.

Each ACO will be required to provide additional information to CMS to enable the ACO's use of the optional Substance Access Beneficiary Engagement Incentive if it has elected to implement the Beneficiary Engagement Incentive. Each ACO would be required to submit an Implementation Plan. This Implementation Plan would be required to include, for example: (1) descriptions of the ACO's planned strategic use of the Substance Access Beneficiary Engagement Incentive (including the full legal Name of the Eligible Hemp Product, amount, frequency of distribution); (2) self-monitoring plans reflecting meaningful safeguards to prevent unintended consequences; and (3) other information required by CMS. As part of LEAD's monitoring and oversight strategy, CMS will incorporate a variety of program integrity safeguards to ensure that this Beneficiary Engagement Incentive does not result in program or patient abuse.

4. Benefit Enhancements and Beneficiary Engagement Incentives Under Consideration

For future PYs, CMS may consider other Benefit Enhancements and Beneficiary Engagement Incentives that foster beneficiaries' engagement in their own care. Benefit design flexibility, combined with a cost-saving payment approach, would encourage beneficiaries to seek appropriate, high-value services from high-value providers. Beneficiaries aligned to ACOs in the model would have the option to choose to participate in these Benefit Enhancements and Beneficiary Engagement Incentives and would not be required to participate. CMS welcomes feedback and suggestions from stakeholders on whether these or other Benefit Enhancements and Beneficiary Engagement Incentives would be useful to ACOs in improving health care quality and managing costs.

The following outlines at a high level a few benefit design flexibilities CMS may explore:

- **Part D Premium Buydown:** The Part D Premium Buydown incentive, which could be available in 2029, provides a mechanism through which ACOs could share savings earned with beneficiaries while reducing cost-related barriers to Part D drugs. CMS expects that this incentive would empower beneficiaries as consumers to drive meaningful behavior change and strengthen the model's ability to generate system-wide efficiencies as more beneficiaries choose to receive care from higher performing ACOs that can offer a Part D Premium Buydown. In addition, by removing cost-related barriers to Part D drugs (currently,

the average Medicare Part D stand-alone prescription drug plan premium is approximately $460 annually), this incentive could support medication adherence and improvements in health outcomes. To encourage participation and support early efforts to align beneficiaries, this incentive would be available for two years to both higher-spending ACOs and those meeting "High-value Care Champion ACO" criteria, defined as the top 30% of ACOs in terms of savings earned during the previous PY and satisfying a quality requirement. The quality requirement ensures beneficiaries' continued access to care, as captured via PQEM services provided during the PY to beneficiaries, with the threshold for each ACO calibrated based on the proportion of High Needs beneficiaries. In the ensuing years of the model, this incentive would be limited to only ACOs meeting the High-value Care Champion ACO criteria.

- **Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Flexibility:** DMEPOS are essential tools that enable beneficiaries to manage chronic conditions, recover from acute episodes, and maintain independence in their daily activities. However, administrative requirements currently create delays that can impede timely access to medically necessary equipment. High Needs beneficiaries, who use DMEPOS more than the general Medicare population, are particularly impacted by these requirements. CMS is exploring options to support improved access to DMEPOS in the model.
- **Annual Wellness Visit Flexibility**: Allowing Medicare beneficiaries to access their Annual Wellness Visit on a calendar year instead of once every twelve months. ACOs report that the 12-month requirement creates significant administrative burden related to tracking and reporting and may not be relevant in an accountable care context where ACOs are at risk for increased costs.
- **Other Substance Access Beneficiary Engagement Incentives:** Allowing ACOs to offer Beneficiary Engagement Incentives that facilitate access to other medically approved and beneficial substances that can improve health outcomes and quality of life for Medicare beneficiaries.
- **Beneficiary Savings Program**: Under a potential Beneficiary Savings Program, ACOs could offer beneficiaries direct (e.g., contributions to a health savings account) or indirect (e.g., reductions in premiums or co-pays) financial incentives to improve their health. CMS would identify a select number of high-value activities that would be eligible for this program such as lifestyle changes (e.g., physical activity goals) or resource utilization (e.g., selection of high-value providers or selection of lower cost but equally effective sites of care).

VIII. Financial Methodology: Benchmarking Methodology

The Financial methodology for LEAD includes: (1) the benchmarking methodology; (2) risk-sharing options, risk mitigation, and financial settlement; and (3) payment mechanisms and claims reductions. This section covers the benchmarking methodology.

The Performance Year Benchmark represents the ACO's expected Medicare Parts A and B expenditures for its aligned beneficiaries in a given Performance Year, which will be compared to the

actual Medicare Parts A and B expenditures for the ACO's aligned beneficiaries in the Performance Year. This comparison is used to calculate the ACO's Shared Savings or Shared Losses for the Performance Year – if the actual expenditures for the ACO's aligned beneficiaries are below the ACO's Performance Year Benchmark, it may be eligible for Shared Savings, but if the actual expenditures for the ACO's aligned beneficiaries are above its Performance Year Benchmark, it may be accountable for Shared Losses. The Performance Year Benchmark is also used to derive the monthly capitated payments paid to ACOs during the Performance Year (See Section X, LEAD Model Payment Mechanisms, for more information about capitated payments).

LEAD ACOs will have separate per-beneficiary per-month (PBPM) benchmarks for three beneficiary categories: Aged & Disabled (A&D), End-Stage Renal Disease (ESRD), and High Needs. Aligned beneficiaries will be included in the A&D and ESRD beneficiary categories based on the beneficiary's reason for entitlement to Medicare. Aligned beneficiaries will be included in the High Needs beneficiary category based on the High Needs eligibility criteria described in Section VII.A (if a beneficiary meets the High Needs criteria, the High Needs beneficiary category will take precedence over A&D for the purposes of determining risk adjustment methodology, baseline benchmarks, and trend factor, while ESRD will take precedence over High Needs. Benchmarks will also be calculated separately for beneficiaries who are voluntarily aligned versus claims-based aligned.

LEAD's benchmarking methodology builds upon the methodologies used for ACO REACH and the Shared Savings Program while featuring new policies that strengthen incentives for organizations to participate in the model and reduce unnecessary spending.

A core benchmarking challenge that LEAD endeavors to address is that the collective impact of ACOs on spending growth regionally and nationally lowers ACO benchmarks when benchmarks are trended based on concurrent rates of realized national and regional spending growth. This feedback mechanism, or collective ratchet effect, can prevent many participating providers from meaningfully sharing in the savings they generate, limiting the financial viability of (and thus participation in) Medicare ACO initiatives. LEAD includes two complementary approaches to allow total payments to rise above realized spending as ACOs collectively lower spending. These measures are designed to retain more participating ACOs that generate savings as participation expands.

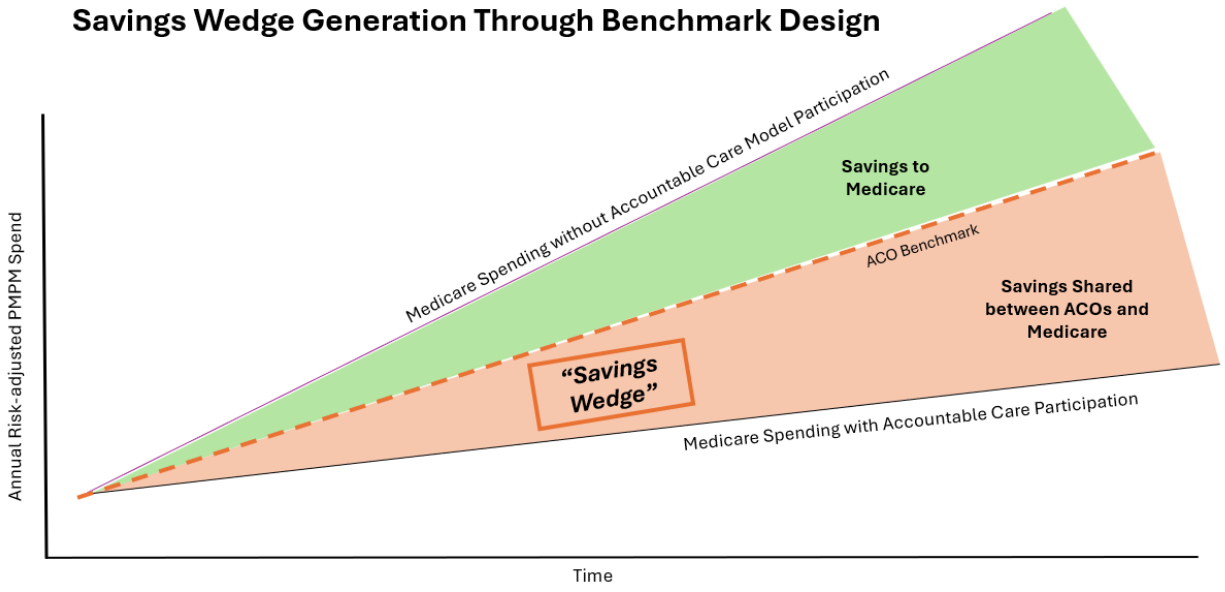
First, the positive regional efficiency adjustment available to lower-spending ACOs and the 1.5% administrative add-on capitation payment available to higher-spending ACOs directly elevate benchmarks above realized spending, making participation in LEAD sustainable for more providers even as ACOs' collective savings pull down benchmarks via the effect ACOs' collective savings have on the regional and national spending growth rates that serve as the primary basis for trending benchmarks. Second, the Accountable Care Prospective Trend (ACPT) allows benchmarks to rise above realized spending when ACOs collectively slow realized spending growth below expected spending growth (i.e., expected in the absence of ACO savings). Combined, these two measures allow up to a 3% difference between average benchmarks (inclusive of the add-on capitation payment) and average claims expenditures – a 3% savings "wedge" between the two – to form by year 5. For ACOs eligible for a regional efficiency adjustment, the permitted wedge will be more variable,

depending on an ACO's regional efficiency. In addition, LEAD ACOs have an opportunity to share in additional savings they generate by beating average realized national and regional spending trends (i.e., lowering spending by more than other ACOs or non-ACO providers).

Once participation in LEAD and other Medicare ACO initiatives expands and sufficient savings materialize, benchmarks can be converged to a common rate in a given region that reflects average spending plus a portion of the Medicare savings that ACOs have achieved. Incorporating prior savings into administratively set benchmarks ensures that ACOs can continue to generate sustainable savings. At the same time, as long as benchmarks are set below what spending would be in the absence of Medicare ACO initiatives ("counterfactual spending"), CMS will continue to generate savings as well.

Figure 1 illustrates this concept of a savings wedge between counterfactual spending (top line), LEAD ACO benchmarks (middle line), and actual spending (bottom line).

Figure 1. New Benchmarking Approach under LEAD and Generation of a Savings Wedge



Over the first half of the 10-year model performance period, CMS expects that the LEAD benchmarking methodology will result in PBPM expenditures converging across ACOs in a given region, as higher-spending ACOs reduce expenditures faster than lower-spending ACOs. As this convergence is achieved, CMS intends to begin phasing in a rate book-based benchmark that will ultimately replace historical expenditures-based benchmarks. This transition is discussed in Section VIII.G below.

Development of the Performance Year Benchmark, prior to the introduction of a regional rate book, will include five steps (described in more detail below):

1. Calculation of the ACO's historical baseline expenditures (Section VIII.A);
2. ACO-specific benchmark adjustments (Section VIII.B);
3. Trending the ACO's historical baseline expenditures forward (Section VIII.C);
4. Risk adjustment (Section VIII.D); and
5. Withholds for quality performance and the discount (Global Risk Option only) (Section VIII.E).

A. Calculating Historical Baseline Expenditures

CMS will determine the historical baseline Medicare expenditures for a LEAD ACO using a three-year historical baseline period comprising the three most recent calendar years – referred to as the "base years" – before an ACO's first Performance Year. For ACOs that join LEAD in the model's first Performance Year, PY 2027[20], the baseline period will be a fixed period of the following three base years: CY2024, CY2025, CY2026.

The baseline period will remain static for the duration of an ACO's participation in the model. However, historical baseline expenditures will be recalculated for each Performance Year based on that year's Participant TIN List. For example, the historical baseline expenditures used to calculate Performance Year 2027 benchmarks will be CY2024, CY2025, and CY2026 expenditures for providers on the PY 2027 Participant TIN List. The historical expenditures used to calculate Performance Year 2028 benchmarks will cover the same time period – CY2024-2026 – but using the providers on the PY 2028 Participant TIN List.

For all Newly Entering ACOs, the base years will be weighted as shown below to give additional weight to the more recent base years, in recognition that the population of beneficiaries that would have been aligned for more recent base years is likely more comparable to the population of aligned beneficiaries for the relevant Performance Year.

Table 6: Historical Base Year Weighting for Newly Entering ACOs

Base Year	Weight
Year 1	10%
Year 2	30%
Year 3	60%

For ACOs with prior experience in ACO REACH or the Shared Savings Program – referred to as Renewing ACOs – the base years will be weighted equally. The Shared Savings Program also weights the base years equally for ACOs beginning a second or subsequent Shared Savings Program agreement period. This policy is intended to mitigate the ratcheting effect of placing more weight on

[20] In PY 2027, an ACO's baseline expenditures may shift between the beginning of the PY and financial settlement due to claims processing timelines for expenditures accrued during CY2026.

more recent, typically lower cost, base years, when an ACO has successfully reduced spending over time:

Table 7: Historical Base Year Weighting for Renewing ACOs

Base Year	Weight
Year 1	33.33%
Year 2	33.33%
Year 3	33.33%

If CMS determines that an ACO does not have sufficient claims history to construct the historical baseline expenditures for any of the three base years, CMS will not use that base year in the calculation. For Renewing ACOs, if two base years are determined to have sufficient claims history, CMS will average the two base years, with equal weight. For all Newly Entering ACOs, if two base years are determined to have sufficient claims history, CMS will average the two base years with the more recent base year weighted two-thirds and the less recent base year weighted one-third. For all LEAD ACOs, if only one base year is determined to have sufficient claims history, CMS will weight that year at 100% for calculating the historical baseline expenditures.

CMS will also monitor whether individual Participant TINs have sufficient claims history. If CMS identifies a pattern of Participant TINs with zero claims history in the base years, it may consider additional policies to ensure that expenditures for these Participant TINs are accurately reflected in the ACO's Performance Year benchmark.

Calculating Historical Baseline Expenditures for Beneficiaries Aligned via Claims-Based Alignment

CMS will use different methodologies to calculate historical baseline expenditures for claims-aligned beneficiaries and voluntarily aligned beneficiaries.

For claims-aligned beneficiaries, historical baseline expenditures are constructed by taking the ACO's Participant TIN List for the current Performance Year and applying the claims-based alignment algorithm to those Participant TINs retrospectively for each historical base year. This identifies the beneficiaries who *would have been aligned* to the ACO in each base year had the current-year Participants TINs been participating during those years.

For example, for PY2027, CMS will determine which beneficiaries would have been aligned to providers on the PY2027 Participant TIN List in CY2024, CY2025, and CY2026 if the claims-based alignment rules were applied in those years. Historical expenditures for these beneficiaries form the basis of the benchmark and are then trended forward to the Performance Year. As a result, the base-year expenditure calculation may include beneficiaries who are not aligned to the ACO in the current Performance Year, but who would have been aligned to the ACO's current participants in one or more historical base year.

Calculating Historical Baseline Expenditures for Beneficiaries Aligned via Voluntary Alignment

Baseline benchmarks for voluntarily aligned beneficiaries are also calculated using historical Medicare expenditures in the base years. However, there is no way to determine which beneficiaries "would have been" voluntary aligned in the historical base years. Instead, an ACO's voluntary alignment benchmark will be based on historical spending in the base years for beneficiaries who are voluntarily aligned in the current Performance Year. If the voluntarily aligned population's historical expenditures differ by more than 10% from the claims-aligned population's historical expenditures, then the voluntarily aligned benchmark will be set such that it differs from the claims-aligned benchmark by no more than 10%.

This differs from ACO REACH, where newly voluntarily aligned beneficiaries initially received a regional rate only benchmark. Removing the regional rate only component minimizes the incentive for ACOs to seek to voluntarily align beneficiaries expected to spend below the regional average. LEAD's voluntary alignment benchmarking methodology likewise minimizes the incentive for health care provider groups to target beneficiaries thought to have higher expenditures in the base year that have regressed to the mean in the Performance Year.

B. ACO-Specific Benchmark Adjustments

After calculating an ACO's historical baseline expenditures, CMS will apply additional ACO-specific benchmark adjustments. Combined, these ACO-specific benchmark adjustments will be capped at either 3% (for lower-spending ACOs that were previously in the Shared Savings Program) or 5% (all other ACOs) of risk-standardized national average per capita spending (United States Per Capita Costs, or USPCC), meaning that the cap will be adjusted for each ACO's specific population risk.

Regional Efficiency Adjustment

ACOs in the Global Risk track with baseline spending that is lower than average Medicare FFS spending in their region ("lower-spending ACOs") will receive a positive regional efficiency adjustment to their benchmark. ACOs with higher-than-average Medicare FFS spending in their region will not receive a negative regional efficiency adjustment.

To calculate an ACO's regional efficiency adjustment, CMS will: 1) determine the ACO's historical baseline expenditures (BY1-BY3); 2) determine average Medicare FFS spending in the ACO's region in Base Year 3; 3) adjust for the proportions of beneficiaries that are A&D, High Needs and ESRD between the ACO's aligned population and the ACO's regional align-able population; and 4) determine the risk-adjusted difference between an ACO's historical base year expenditures and BY3 regional expenditures. The regional efficiency adjustment will be equal to 50% of the difference between the BY3 regional expenditures and the ACO's historical base year expenditures. This adjustment is subject to the cap on benchmark adjustments described above. If an ACO is eligible

to receive a regional efficiency adjustment and a prior savings adjustment, described below, the ACO will receive the higher of the regional adjustment or the prior savings adjustment amount, subject to the cap on benchmark adjustments described above.

Prior Savings Adjustment

Renewing ACOs in both the Professional and Global Risk Options will be eligible for a prior savings adjustment to their historical benchmark based on savings generated in the three calendar years immediately preceding the start of the LEAD performance period, similar to the methodology used in the Shared Savings Program as outlined in 42 CFR § 425.658.

CMS will calculate total per-capita savings or losses for each of the three prior Performance Years as the difference between the ACO's benchmark expenditures and actual performance-year expenditures, divided by aligned beneficiary months. This calculation reflects gross Medicare savings, not just the portion of savings the ACO retained. CMS then takes a simple average of the three annual per-capita values to determine eligibility for the prior savings adjustment. ACOs with a positive average are eligible for an adjustment; ACOs with an average that is zero or negative are not eligible.

For eligible ACOs, CMS applies a proration factor to account for changes in the size of the ACO's assigned beneficiary population between the historical benchmark period and the current Performance Year. This factor scales the adjustment when the benchmark population differs from the population that generated the prior savings, preventing savings earned on a smaller population from being fully applied to a substantially larger one. The proration factor is calculated as the ratio of beneficiary years in the current Performance Year to the average number of beneficiary years across the three historical base years. For example, if an ACO had an average of 10,000 beneficiary years in its benchmark period and grew to 20,000 beneficiary years in the current Performance Year, its proration factor would be 50%.

The final per-capita prior savings adjustment is 50% of the prorated average per-capita savings, subject to the risk-standardized caps (i.e., adjusted for each ACO's specific population risk) on benchmark adjustments described above. If an ACO is eligible to receive a prior savings adjustment and a regional efficiency adjustment, described above, the ACO will receive an adjustment to its benchmark equal to the higher of the regional adjustment and the prior savings adjustment amount.

Lower-spending, Renewing ACOs with more than 40% of Participant TINs that have participated in a Shared Savings Program ACO within the previous two years will have any benchmark adjustment capped at 3% of risk-standardized USPCC (i.e., the 3% cap amount will be adjusted for each ACO's specific population risk). This is intended to address potential short term selection issues associated with such ACOs switching to LEAD to access a greater share of savings (including under LEAD's Global Full Risk option) while at the same benefiting from LEAD's long-term savings incentives that eliminate future years' rebasing.

1.5% Administrative Add-On Capitation

Higher-spending ACOs—defined as ACOs with average beneficiary expenditures exceeding regional fee-for-service (FFS) expenditures in their operating area—may face greater challenges in achieving immediate spending reductions. To address this, LEAD will provide an additional incentive to higher-spending ACOs in the form of a capitated payment equal to 1.5% of the ACO's total benchmark (the "1.5% Administrative Add-On"). This capitated payment mechanism is described in more detail in Section X.A.F.

C. Trending Benchmarks to the Performance Year

To account for annual Medicare cost growth, CMS will trend an ACO's historical baseline expenditures plus any applicable benchmark adjustments forward to the current Performance Year using a three-way blended update factor.

Three-way Blended Update Factor

The three-way blended update factor is a weighted average of two components: (1) a two-way blend of national and regional growth rates, and (2) a fixed, prospectively set growth rate established at the start of the LEAD performance period, known as the Accountable Care Prospective Trend (ACPT). In accordance with the Shared Savings Program methodology outlined at 42 CFR § 425.652 and absent unforeseen circumstances, two-thirds of the update will reflect a two-way blend of the actual national and regional spending trends observed in each Performance Year. The remaining one-third—the administrative trend adjustment—will be set prospectively using the ACPT determined at the beginning of the ACO's Agreement Period, subject to a set of guardrails that limit how much the ACPT can influence the three-way blended update factor.

Calculating National and Regional Growth Rates

The national-regional blend is a weighted average of national and regional FFS growth rates calculated according to the methodology used in the Shared Savings Program as described at 42 CFR § 425.652. National growth rates are computed using CMS Office of the Actuary national Medicare expenditure data. Regional growth rates are computed using expenditures for the ACO's regional service area, as determined by CMS based on the ACO's aligned beneficiary population. The respective weights placed on the regional and national growth rates will depend on what share of eligible Medicare beneficiaries in the ACO's region are aligned to the ACO. The weight placed on regional growth rates will vary inversely to the proportion of eligible Medicare beneficiaries in the region that are aligned to the LEAD ACO: ACOs with a lower share of aligned eligible Medicare beneficiaries in the region will have more weight on the regional growth trend in their national-regional blend, while ACOs with a higher share of aligned eligible beneficiaries in the region will have more weight on the national growth trend.

This approach is designed to ensure that an ACO's trend is not overly influenced by its own impact on regional spending over time. For example, an ACO with a large regional presence—where its own performance could meaningfully affect regional spending—will rely more on national trends to avoid reinforcing its own impact on the benchmark.

Because each ACO will have a different national-regional blend based on its share of aligned eligible Medicare beneficiaries in the ACO's region, each ACO will have a unique three-way blended update factor. CMS will also make separate trend calculations for each LEAD beneficiary category (A&D, High Needs, and ESRD) for each ACO.

Calculating the Accountable Care Prospective Trend

For each Performance Year, CMS will incorporate the Accountable Care Prospective Trend (ACPT), a fixed projected growth rate determined at the beginning of the ACO's Agreement Period and calculated using one or more annualized growth rates based on national fee-for-service Medicare expenditures projected by the CMS Office of the Actuary. The methodology to construct the prospective external trend factor will align with the methodology to construct the ACPT under the Shared Savings Program.

ACPT Guardrail Policy

The goal of including the ACPT in the three-way blended update factor is to trend benchmarks in LEAD at a rate higher than actual, realized Medicare spending, but below what Medicare spending would be in the absence of ACOs. However, the ACPT is subject to potential forecasting errors, which makes it necessary to include a guardrail policy to prevent benchmarks based on ACPT from diverging too far from actual spending. The ACPT should be considered in context of the benchmark adjustments discussed in Section VIII.C, which also affects the relationship between benchmarks and realized spending.

In PY 2027, CMS will apply a guardrail that limits the three-way blended update factor to within +0.3/-0.2 percentage point of the two-way regional/national blended update factor, which represents realized Medicare spending growth. In other words, if the three-way blended update factor exceeds the two-way regional/national blend by more than 0.3 percentage points, it will be capped at the two-way regional/national blend plus 0.3 percentage points. Likewise, if the three-way blended update factor is more than 0.2 percentage points below the regional/national blend, it will be capped at the regional/national blend, minus 0.2 percentage points. In subsequent Performance Years, the upper bound of the guardrail may be widened by 0.3 percentage points per year (e.g., to +0.6 percentage points in PY2028 and +0.9 percentage points in PY2029, up to 1.5 percentage points in PY2031), while the lower bound may be widened by 0.2 percentage points per year (e.g., to -0.4 percentage points in 2029 and -0.6 percentage points in 2030, up to -1.0 percentage points in PY2031). However, this policy could be revised in the future to align with the Shared Savings Program. Table 8 illustrates how this guardrail policy is intended to work, barring any future changes.

Table 8: Illustrative ACPT Guardrail Policy

ACPT Guardrail Upper and Lower Bounds by Performance Year		
	Upper Bound	Lower Bound
PY1	+0.3%	-0.2%
PY2	+0.6%	-0.4%
PY3	+0.9%	-0.6%
PY4	+1.2%	-0.8%
PY5	+1.5%	-1.0%

D. Risk Adjustment

After applying the blended update factor according to process specified in Section VIII.C, CMS will further adjust benchmarks for the relative risk of an ACO's beneficiary population.

Risk Adjustment

CMMI HCC Prospective Risk Adjustment Model V1

Benchmarks for beneficiaries in the A&D beneficiary category will be risk adjusted using a modified version of the prospective 2024 CMS-Hierarchical Condition Categories (HCC) Risk Adjustment Model (Version 28) (the modified version is hereafter referred to as CMMI HCC Prospective Risk Adjustment Model V1). Specifically, the 2024 CMS- HCC Risk Adjustment Model will be recalibrated to reflect the removal of the High Needs population (described below). This will help avoid overpredicting the risk of non-High Needs beneficiaries. Benchmarks for beneficiaries in the ESRD beneficiary category will be risk adjusted using the 2023 ESRD CMS-HCC Risk Adjustment model.

CMMI HCC Concurrent Risk Adjustment Model

CMS will separately risk adjust benchmarks for beneficiaries in the High Needs beneficiary category using the CMMI HCC Concurrent Risk Adjustment Model V2 (hereafter referred to as the Concurrent Risk Adjustment Model V2). The Concurrent Risk Adjustment model V2 will be applied to all High Needs beneficiaries aligned to LEAD ACOs, regardless of whether the ACO they are aligned to is a High Needs ACO. The Concurrent Risk Adjustment Model V2 is a modified version of the CMMI HCC Concurrent Risk Adjustment Model V1, which was used in ACO REACH. It has been modified to reflect the 2024 CMS-HCC Prospective Risk Adjustment Model architecture (including updates made in Version 28) and recalibrated to improve risk score prediction by reflecting only the High Needs population.

Coding Intensity Mitigation Strategy

CMS will apply a 3% risk score growth cap for the A&D and ESRD populations using Base Year 3 as the static reference year, for both claims-aligned and voluntarily aligned beneficiaries. A risk score growth cap will also be applied to the High Needs population using Base Year 3 as the static reference year, for both claims-aligned and voluntarily aligned beneficiaries. For the High Needs population, the amount of the risk score growth cap will depend on the results of the concurrent risk adjustment model recalibration and the development of benchmark base rates specific to High Needs beneficiaries. Together, these updates are expected to improve benchmark and risk adjustment accuracy, which may reduce the need for a higher High Needs–specific cap. CMS anticipates that the High Needs risk score growth cap will fall between 3% and 8%. The final cap amount will be announced in financial methodology documents prior to the first Performance Year.

AI-inferred risk adjustment

In 2028, LEAD will shadow test the use of risk scores generated from an AI-inferred risk adjustment model for the A&D population. In PY 2029, CMS will use a blend of AI-inferred risk scores and risk scores calculated using the CMMI HCC Prospective Risk Adjustment Model V1 weighted at 1/3rd and 2/3rd respectively. In PY 2030, CMS will use a blend of AI-inferred risk scores and risk scores calculated using the CMMI HCC Prospective Risk Adjustment Model V1 weighted at 2/3rd and 1/3rd respectively. In PY 2031 and every Performance Year thereafter, CMS will fully integrate the AI-inferred risk adjustment model and use 100% of AI-inferred risk scores for the A&D population. The application of these AI-inferred risk scores is subject to testing and validation. CMS may in the future also consider applying the AI-inferred risk adjustment model to High Needs beneficiaries, using a similarly weighted approach over the course of multiple PYs, subject to testing and validation.

E. Discount and Quality Withold

Similar to ACO REACH, LEAD's Global Risk Option applies a discount to the benchmark, representing the share of savings that CMS retains when an ACO generates shared savings. Specifically, the Performance Year benchmark is reduced by the discount rate during financial settlement, prior to calculating the ACO's Shared Savings or Shared Losses. Lower-spending ACOs will be subject to a 3.0% discount rate for all years that they participate in the Global Risk Option. Higher-spending ACOs will be subject to a 1.75% discount rate in the first year of the model if they participate in the Global Risk Option. In each subsequent year, participating higher-spending ACOs that elect the Global Risk Option will be subject to a discount rate that reflects the higher-spending ACO discount rate from the prior year grown by 0.25%, up to the maximum of 3.0% in the sixth year of the model. This ramp up period for the discount rate aims to give opportunity to higher spending ACOs to participate in full risk while also generating savings to CMS.

Table 9: Discount Rate Schedule

Type of ACO	Discount Rate Schedule
Lower-spending ACOs	3.0% static discount rate
Higher-spending ACOs	2027: 1.75% 2028: 2.0% 2029: 2.25% 2030: 2.5% 2031: 2.75% 2032-2036: 3.0%

A 3% quality withhold will be applied to all ACOs' Performance Year financial benchmark calculations. Individual ACOs will have the opportunity to "earn back" some or all the withhold based on their quality performance (see Section XII for more information about quality and performance measurement). During financial settlement, the Quality Withhold is applied after both the Discount (for ACOs in the Global Risk Option) and the Retention Incentive (discussed below).

F. Retention Incentive

To determine whether LEAD ACOs can succeed in improving quality and reducing costs over a longer time period, ACOs will be incentivized to participate in the model for a minimum of two Performance Years (e.g., PY 2027 and PY 2028 for ACOs starting LEAD participation in PY 2027). LEAD ACOs that terminate participation after one PY (by providing written notice to CMS on or before the Termination Without Liability date of the ACO's second PY) will have their PY benchmark reduced by 2% at Final Settlement for the ACO's first PY. LEAD ACOs that do not terminate participation on or before the Termination Without Liability Date of the ACO's second PY will "earn back" the retention incentive during Final Settlement for their first PY, meaning the 2% benchmark reduction will not be applied.

For ACOs that terminate participation after their first PY, the retention incentive is applied after the application of the Discount (for ACOs in the Global Risk Option) and before the Quality Withhold during Final Settlement.

G. Regional Rate Book Transition

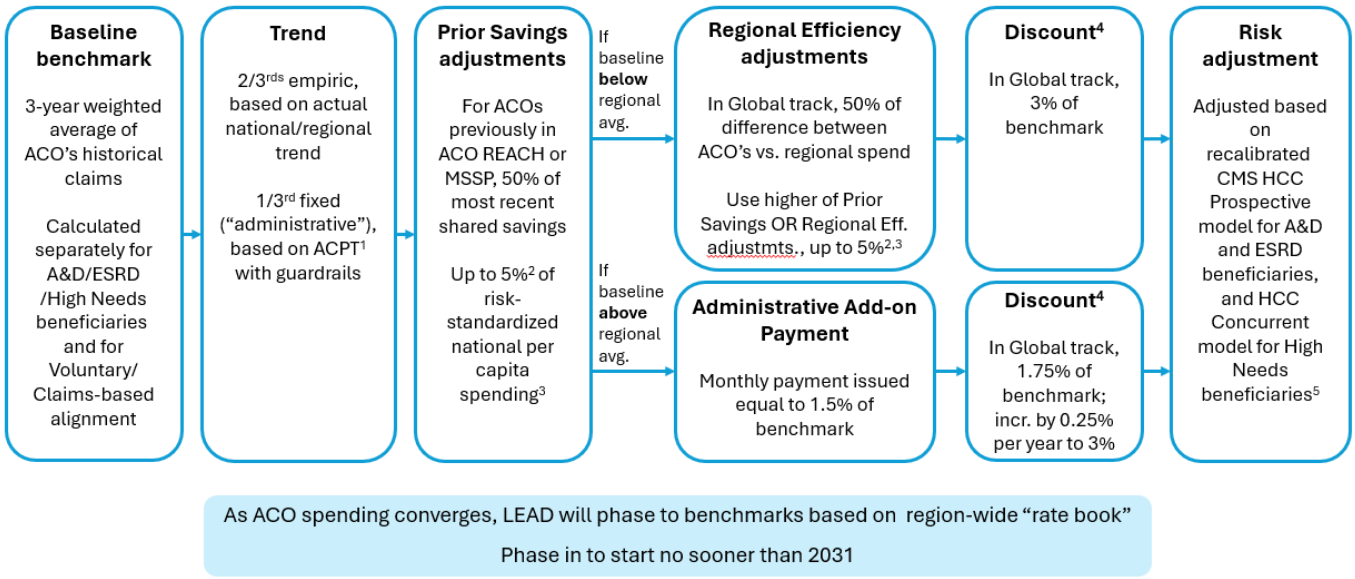
After the first 5 years of the model, CMS will gradually phase in a regional rate book-based benchmarking methodology as expenditures converge across ACOs in a given region. As the rate book methodology is phased in, the historical expenditures-based benchmarks will be gradually

phased out, with the goal of fully replacing the historical methodology by the end of the model performance period.

The timeline for initiating the phasing in of a LEAD-specific rate book in a given region will be based on a given region meeting a set of regional-level criteria, described below, as opposed to a specific Performance Year, but is expected to occur no sooner than the sixth year of the model performance period. The appropriateness of transition will be assessed at the regional level, with a focus on the level of convergence of ACO spending trends with regional rates.

CMS will determine when to initiate the transition in each region by considering three criteria: (1) the proportion of beneficiaries by region aligned to LEAD, Shared Savings Program or other accountable care models, (2) the amount of savings that ACOs have already generated (see Figure 1 above), and (3) the proportion of participating ACOs that are considered higher-spending ACOs. The proportion of the benchmark that is comprised of the regional rate will be higher in regions where the participation rate and convergence are higher, with the phase-in occurring more gradually in other regions.

Figure 2. LEAD Benchmarking Approach



1. ACPT: Accountable Care Prospective Trend.
2. Maximum adjustment is 3% for ACOs previously in the Shared Savings Program.
3. Specifically, the United States Per Capita Costs calculation, or USPCC.
4. 2% of benchmark will be withheld for the first year of participation and earned back by ACOs upon the completion of two full PYs.
5. Risk score growth is capped at 3% of Base Year 3 for A&D and ESRD beneficiaries and between 3-8% for High Needs beneficiaries.

IX. Financial Methodology: Risk Sharing Options, Risk Mitigation, and Financial Settlement

A. Risk Sharing Options

LEAD will offer two options for sharing risk between participating ACOs and CMS: the Professional Risk Option and the Global Risk Option. The risk option that a participating ACO selects will determine the portion of the savings or losses that will accrue to the ACO:

Professional Risk Option: ACOs that choose the Professional Risk Option would be eligible to receive up to 50% of total savings or be liable for up to 50% of total losses relative to their established Performance Year benchmark. ACOs that elect the Professional Risk Option will be required to stay in that option for at least 4 Performance Years, after which time they would have the opportunity (but would not be required) to transition the Global Risk Option.

Global Risk Option: ACOs that choose the Global Risk Option or move into the Global Risk Option after 4 years of participation in the Professional Risk Option would be eligible for up to 100% of savings, or liable for up to 100% of total losses, relative to their established performance benchmark. Only those ACOs participating in the Global Risk Option would be eligible to receive a positive regional efficiency adjustment. Newly Entering ACOs that elect the Global Risk Option for their first PY can switch to the Professional Risk Option if the ACO concludes it is not ready for Global Risk. Renewing ACOs cannot move from the Global Risk Option to the Professional Risk Option.

No Minimum Saving Rate or Minimum Loss Rate will apply to aggregate savings/losses for either the Global or Professional Risk Options, meaning that all ACOs will retain "first dollar" savings or be responsible for "first dollar" losses. However, ACOs participating in the Global Risk Option would also be subject to a discount, described in Section VIIE, that is directly applied against an ACO's benchmark as a first step in Shared Savings calculations. No discount will be applied to benchmarks for ACOs in the Professional Risk Option.

Under both risk sharing options, ACOs will be restricted from holding 100% of the ACO's total downside risk. Instead, ACOs will be required to assign and allocate at least 1% of the ACO's total downside risk (measured as a percentage of the ACO's benchmark) on average across its Participant Providers. The benchmark base used to determine 1% may be adjusted to account for any documented regulatory restrictions limiting a Participant's ability to accept downside risk.

B. Risk Corridors

The aggregate amount of savings or losses that ACOs in the Global or Professional Risk Options will be eligible to receive as Shared Savings or be liable for as Shared Losses will be constrained by a series of risk corridors. ACOs will receive a portion of Shared Savings, or be liable for a portion of Shared Losses, above each risk band, with the portion of gross savings/losses decreasing with each risk band.

Under the Professional Risk Option, for all savings and losses up to, and including, 10% of the Performance Year Benchmark, the ACO is responsible for 50% of the savings or losses and CMS is responsible for the remaining 50%. ACOs will be responsible for a progressively smaller portion of additional savings or losses as their savings or losses reach Risk Corridors 2, 3, and 4. Risk Corridors for the Global Risk Option operate in an analogous manner, but with different cutoff points for each risk band. ACOs in the Global Risk Option will be responsible for a higher portion of savings or losses in each risk band compared to ACOs in the Professional Risk Option.

The series of Shared Savings/Shared Losses caps are outlined below for the Professional (Table 9) and Global (Table 10) Risk Options:

Table 10: Risk Corridors for Professional Risk Option

Corridor	Corridor 1	Corridor 2	Corridor 3	Corridor 4
Percent of Benchmark	Up to 10%	10-15%	15-20%	More than 20%
Savings/Losses Rate	50%	35%	15%	5%

Table 11: Risk Corridors for Global Risk Option

Corridor	Corridor 1	Corridor 2	Corridor 3	Corridor 4
Percent of Benchmark	Up to 15%	15-35%	35-50%	More than 50%
Savings/Losses Rate	100%	50%	25%	10%

C. Stop-Loss

In LEAD, ACOs in both the Global and Professional Risk Options will be able to elect a stop-loss arrangement. The purpose of the stop-loss arrangement is to reduce the financial uncertainty associated with infrequent but high-cost expenditures for aligned beneficiaries. The stop-loss arrangement is an optional feature. ACOs that elect the stop-loss arrangement must make their selection prior to the start of each Performance Year. ACOs will have the opportunity to change their stop-loss preference prior to the start of each Performance Year.

The stop-loss arrangement in LEAD is designed to protect ACOs against exposure to high-cost beneficiaries whose healthcare spending exceeds their predicted spending by a certain amount (this amount—the magnitude of difference between actual and predicted spending above which stop-loss protection is triggered—is called the attachment point). This approach is known as "residual based reinsurance." For ACOs that elect the stop-loss arrangement, a PBPM stop-loss "charge" will

be applied to the ACO's Performance Year Benchmark. This charge is based on the percentage of expenditures above each of the ACO's attachment points, described below, in the baseline period.

Predicted spending for a beneficiary will be determined by the ACO's benchmark and the beneficiary's risk score, using either the CMMI Prospective Risk Adjustment Model V1 for A&D beneficiaries, 2023 CMS-HCC ESRD Risk Adjustment Model for ESRD beneficiaries, or the Concurrent Risk Adjustment Model V2 for High Needs beneficiaries.

CMS will calculate the model-wide stop-loss attachment points prospectively, prior to the start of each Performance Year, based on expenditure data derived from a national reference population of Original Medicare beneficiaries. These model-wide attachment points will be adjusted to the beneficiary level (generating an attachment point for each beneficiary) using beneficiary risk scores and the ACO's benchmark. The stop-loss payout is determined as the expenditure residual which surpasses the attachment point. Stop-loss payouts cover a share of expenditures once the attachment point is surpassed. This residual-based stop-loss effectively insures the ACO against outlier deviations from expected spending. A uniform multiplier budget neutrality adjustment may be applied at financial settlement to ensure that model-wide payouts equal model-wide charges.

D. Optional Provisional Financial Settlement and Final Financial Settlement

Financial Settlement is the process by which CMS determines an ACO's Shared Savings or Shared Losses by comparing the Performance Year Benchmark to actual Medicare expenditures (inclusive of Total Care Capitation Payment, Primary Care Capitation Payment, Non-Primary Care Capitation Payment, and Advanced Payment Option payment, as applicable, paid by CMS to the ACO, as well as FFS claims paid by CMS directly to Medicare providers and suppliers) for Medicare Part A and Part B items and services furnished to aligned LEAD beneficiaries.

Final Financial Settlement will be conducted for all LEAD ACOs after the Performance Year has ended and sufficient time has passed to allow for claims processing. The Final Financial Settlement process will be conducted in Q3 of the calendar year following the close of the Performance Year. This Final Financial Settlement will include claims run out through the end of Q1 of the calendar year following the Performance Year for expenditures incurred in the Performance Year and will be based on final risk scores for the Performance Year (calculated after the Performance Year has ended).

LEAD ACOs will also have the option to select Provisional Financial Settlement. This Provisional Financial Settlement will include ACO expenditures for the first six months of the Performance Year (through June 30) with six months of claims run out and will be calculated in Q1 of the following Performance Year. The purpose of the Provisional Financial Settlement is to provide ACOs with a timelier disbursement of provisional Shared Savings and to allow ACOs to more promptly repay provisional Shared Losses to CMS.

For purposes of calculating Shared Savings or Shared Losses as part of the Provisional Financial Settlement, CMS may make adjustments to account for anticipated differences between the ACO's expenditures in the Provisional Financial Settlement and those that will be included in the Final Financial Settlement, including the use of an Incurred But Not Reported (IBNR) estimate of Performance Year expenditures and a seasonal adjustment to account for anticipated seasonal fluctuations in expenditures throughout the Performance Year. Adjusted expenditures will then be compared to a Provisional Performance Year Benchmark; provisional insofar as several elements of the Performance Year Benchmark are not finalized until well after the end of the Performance Year. For example, the ACO's quality performance and final risk scores are components of the benchmark, which will not be available when CMS performs Provisional Financial Settlement. Consequently, CMS may use a default quality score (e.g., the average quality score from a prior year) and a preliminary risk score (e.g., estimated risk score provided in the ACO's Preliminary Benchmark Report before the start of the Performance Year) to calculate the Provisional Performance Year Benchmark. Final risk scores and the ACO's actual quality performance will be incorporated into the Performance Year Benchmark for the Final Financial Settlement.

Table 12 below summarizes the key differences between the Provisional Financial Settlement and the Final Financial Settlement, including timing, claims run-out periods, and the risk score information used.

Table 12: Provisional Financial Settlement and Final Financial Settlement

	Provisional Financial Settlement	**Final Financial Settlement**
Target Date for Financial Settlement	Quarter 1 of calendar year following the Performance Year	Quarter 3 of calendar year following the Performance Year
Claims Included in Financial Settlement	Performance year expenditures incurred through June 30th of the Performance Year	Performance year expenditures incurred through December 31st of the Performance Year
Claims Run-Out	Through December 31st of the Performance Year	Through March 31st of the calendar year following Performance Year
Risk Scores	Preliminary risk scores	Final risk scores

E. Financial Guarantee

LEAD ACOs must have the ability to repay all Shared Losses and Other Monies Owed, as that term is defined in Appendix A, for which it may be liable under this model and shall secure a financial guarantee to ensure CMS is able to recoup any Shared Losses and Other Monies Owed. ACOs who select the Global Risk Option and/or the Enhanced Primary Care Capitation will be required to maintain a larger financial guarantee.

Table 13 shows the required financial guarantee as a percentage of the LEAD ACO's per beneficiary Medicare Part A and B expenditures from the previous calendar year, applied to the expected aligned population for the upcoming Performance Year. The exact percentage will be based on the LEAD ACO's risk sharing option and capitation payment mechanism elections.

Financial guarantees cover Shared Losses as well as Other Monies Owed, including capitated payments. In the case of an ACO that elects Primary Care Capitation and opts to receive Enhanced Primary Care Capitation, as detailed further in Section X, the financial guarantee covers the requirement for the ACO to repay the Enhanced Primary Care Capitation amount to CMS during final settlement. ACOs that elect to receive Enhanced Primary Care Capitation may choose to secure two separate financial guarantees (one to cover Enhanced Primary Care Capitation and another to cover Shared Losses and the base Primary Care Capitation amount, as discussed in section X) or one combined financial guarantee based on the percentages displayed in Table 13. If an ACO elects Enhanced Primary Care Capitation and chooses to secure two separate financial guarantees, the two financial guarantees may be different mechanisms (e.g., Escrow for Shared Losses and Base PCC and Surety Bond for Enhanced Primary Care Capitation). ACOs that elect TCC must only secure one financial guarantee.

Table 13 Financial Guarantee Requirement by Risk Sharing Option and Capitation Payment Mechanism Election

	Shared Losses and Base Primary Care Capitation Payment Only	Enhanced Primary Care Capitation Only (optional)	Combined Shared Losses, Base Primary Care Capitation, and Enhanced Primary Care Capitation Payment (optional)	**Shared Losses and Total Care Capitation Payment**
Professional	2.0% of Previous Year's Part A & B Expenditures	1.5% of Previous Year's Part A & B Expenditures	3.5% of Previous Year's Part A & B Expenditures	N/A
Global	2.5% of Previous Year's Part A & B Expenditures	1.5% of Previous Year's Part A & B Expenditures	4.0% of Previous Year's Part A & B Expenditures	4.0% of Previous Year's Part A & B Expenditures

Previous year's Part A & B Expenditures in Table 13 above refers to the ACO's total Medicare Part A and B expenditures from the previous calendar year for the expected aligned population for the upcoming Performance Year.

This financial guarantee must be in one of the following three forms: 1) funds placed in escrow, 2) a line of credit, or 3) a surety bond. CMS will annually notify the ACO of the amount that must be funded by its financial guarantee for the relevant Performance Year. The ACO must submit documentation of

its compliance with the financial guarantee requirements by December 31st prior to the start of the Performance Year. If the ACO fails to submit such documentation, CMS will withhold monthly payments to the ACO under the ACO's selected capitation payment mechanism until the ACO has submitted the required documentation. LEAD ACOs that do not have an executed financial guarantee by the Termination Without Liability date may be terminated from participation in LEAD.

CMS will estimate an applicant ACO's financial guarantee amount based on beneficiary alignment estimates from providers on the Participant TIN List, due to CMS on August 5, 2026, risk sharing elections from ACOs' applications and other relevant data. CMS anticipates this information will be provided to ACOs in Q4 2026.

LEAD will have a mandatory draft period for financial guarantees, meaning LEAD ACOs will be required to submit draft financial guarantees for CMS to review. The due date for draft financial guarantees will be shared after ACOs are accepted into LEAD. The purpose of the draft is to correct any deficiencies in language ahead of the deadline. A template with the draft financial guarantee language will be made available to accepted ACOs by August 2026.

If CMS does not receive payment for Shared Losses and Other Monies Owed by the date the payment is due, CMS may pursue recovery under available debt collection authorities.

F. Extended Repayment Option

To support the participation of independent practices and ensure CMS's ability to recoup Shared Losses and payments, LEAD would include an Extended Repayment Option (ERO) that would allow ACOs that are continuing in the model and not terminating, to request, subject to CMS approval and satisfaction of ERO eligibility requirements, repayment of Shared Losses or Other Monies Owed to CMS over time. The ERO would be similar to the Extended Repayment Schedule that Medicare enrolled health care providers/suppliers are able to request.

G. Significant Anomalous, and Highly Suspect Billing Activity and Reopening Policies

CMS plans to implement significant, anomalous, and highly suspect (SAHS) billing activity and Reopening policies in LEAD similar to those currently present in ACO REACH and the Shared Savings Program. These policies are meant to protect ACOs that see significant expenditures that may be related to misuse, fraud, waste, or abuse.

SAHS billing is defined at 42 CFR § 425.672. The regulation stipulates that CMS, at its sole discretion, may determine that the billing of one or more specified HCPCS or CPT codes represents significant, anomalous, and highly suspect billing activity for a calendar year that warrants adjustment to calculations made under this part. For example, CMS may make a SAHS determination when a given HCPCS or CPT code that exhibits a level of billing that represents a significant claims increase either in volume or dollars (e.g., dollar volume significantly above prior year or claims volume beyond

expectations) with national or regional impact (e.g., not only impacting one or few ACOs) and represents a deviation from historical utilization trends that is unexpected and is not clearly attributable to reasonably explained changes in policy or the supply or demand for covered items or services. The billing level is significant and represents billing activity that would cause significantly inaccurate and inequitable payments and repayment obligations in LEAD if not addressed. When CMS determines that a SAHS billing activity has occurred, we will adjust LEAD ACOs' final financial settlement.

The Reopening policy will allow LEAD ACOs to submit a request in writing to have their final financial settlement reconsidered by CMS. Reopening could result in a reconsideration of a LEAD ACO's final settlement because of overpayments to Medicare providers or suppliers with significant individual ACO impact. More information about both policies will be made available in future guidance documents.

X. Financial Methodology: LEAD Payment Mechanisms

A. Prospective Payments

The goal of capitated payments is to give health care providers additional flexibility in how they deliver care and to reduce the volume-based incentives of fee-for-service payment. With capitated payments, health care providers get steady, predictable cash flow that is not tied to the number of services they provide. This flexibility frees health care providers to deliver care in innovative and flexible ways, such as non-face-to-face care management, telehealth, and electronic messaging, without worrying about foregone fee-for-service revenue.

Under LEAD, capitated payments replace Medicare fee-for-service payments for certain services provided by LEAD Participant Providers and enrolled Preferred Providers. Instead of paying the full amount on individual claims, CMS will reduce the claim payments for specific services delivered to aligned beneficiaries by Participant Providers and Preferred Providers enrolled in capitated payment mechanisms. Which services are subject to these payment reductions—and by how much—depends on the capitated payment option and reduction percentage selected by the ACO. LEAD Participant and Preferred Providers will continue to submit claims to CMS for all services furnished to aligned beneficiaries, even when those services are covered by a capitated payment.

Similar to ACO REACH and the ACO PC Flex Model, LEAD offers two main capitation payment mechanisms. All ACOs must select one of the following capitation payment mechanisms:

1. **Total Care Capitation Payment:** A per-beneficiary, per-month (PBPM) capitated payment for all services provided to aligned beneficiaries by all Participant TINs and those Preferred Providers who have opted to participate in TCC Payment. This capitation payment mechanism is only available to ACOs participating in Global Risk.

2. **Primary Care Capitation Payment:** A PBPM capitated payment for primary care services provided to aligned beneficiaries by all primary care specialists billing under Participant TINs and those Preferred Providers who have opted to participate in PCC Payment. Both Global Risk and Professional Risk ACOs may choose this capitation payment mechanism.

ACOs that elect PCC may also choose to participate in additional payment options to extend value-based arrangements beyond primary care. Specifically, ACOs may elect the Non-Primary Care Capitation (NPCC) or the Advanced Payment Option (APO) to support alternative payment arrangements for non-primary care providers. These options allow ACOs to incrementally expand capitation beyond primary care without adopting full Total Care Capitation.

Finally, higher-spending ACOs will receive an additional capitation, the 1.5% administrative add-on, to support care delivery investments aimed at improving quality and reducing cost. The rest of this section provides more detail on each of these capitated payment mechanisms.

1. Total Care Capitation

For ACOs that elect TCC, the TCC payment will cover all Medicare services provided to aligned beneficiaries by all Participant TINs and those Preferred Providers who have opted to participate in TCC Payment. Participant TINs in ACOs that elect TCC must participate in the TCC payment mechanism with a 100% fee reduction. This means that 100% of Medicare payments for services provided to aligned beneficiaries by Participant TINs will be paid through the TCC payments to the ACO; Participant TINs will not receive any claims-based payments for these services. Preferred Providers in ACOs that elect TCC can choose whether to participate in the TCC payment mechanism and the ACO will choose the amount of their fee reduction. This means that Preferred Providers can receive some, all, or none of their payments through TCC payments. Table 14 summarizes these policies.

Table 14: Total Care Capitation Payment

Provider Type	Requirements	Fee Reductions
Participant Providers in Participant TINs	Required to participate in TCC payment mechanism	100%
Preferred Providers	Optional to participate in TCC payment mechanism	1-100%, selected by ACO

TCC payment amounts are derived from the ACO's Performance Year benchmark, which represents the expected Medicare total cost of care for aligned beneficiaries. Because not all services for these beneficiaries will be furnished by health care providers participating in TCC, CMS will calculate the portion of the benchmark that is attributable to care delivered by TCC-participating providers.

CMS will base this calculation on historical spending patterns[21], including the share of total costs associated with non-LEAD ACO providers and any portion of Preferred Provider claims that are expected to remain payable under Medicare fee-for-service (for example, when a Preferred Provider elects less than a 100% claims offset). The remaining portion of the benchmark—representing services expected to be delivered by TCC-participating providers—equals the TCC payment, which is paid to the ACO in monthly installments over the Performance Year.

During the Performance Year, CMS will update capitation payment amounts on a quarterly basis to incorporate changes in beneficiary alignment, benchmark and risk score updates, and—if applicable—changes in the share of total spending provided by Participant TINs and Preferred Providers. Any remaining under or over-payments will be incorporated into final financial settlement.

2. Primary Care Capitation Payment

Primary Care Capitation (PCC) is a more targeted form of capitation than Total Care Capitation (TCC). Whereas TCC applies broadly to all services for all provider types that participate in the TCC, PCC applies only to primary care services furnished by primary care specialists (see Appendix D for the primary care services included in the PCC, and Appendix C for a list of provider types considered primary care specialists). Under PCC, CMS makes prospective monthly payments to the ACO for primary care services delivered to aligned beneficiaries, while services not covered by PCC continue to be paid through fee-for-service. PCC is mandatory for primary care providers in Participant TINs in LEAD ACOs that have elected the PCC (see Table 15). If a Participant TIN in an ACO that elects PCC includes non-primary care specialists, those non-primary specialists are not included in PCC and claims are not reduced; they may opt into NPCC or APO (discussed below) at the NPI level. This policy is intended to prevent specialists in Participant TINs from being impacted by capitated payments and claims reductions that are meant to be targeted to primary care.

The PCC Payment consists of two components: a Base Primary Care Capitation amount and an Enhanced Primary Care Capitation amount. The Base PCC is intended to approximate the expected cost of primary care services furnished by participating primary care providers, while the Enhanced PCC provides additional upfront funding to support investments in primary care infrastructure, access, and care coordination. Together, these components make up the total PCC payment received by the ACO.

As with TCC, PCC payments are derived from the ACO's Performance Year benchmark. To calculate the Base PCC, CMS uses historical claims data to identify the portion of total spending attributable to primary care services furnished by primary care Participant TIN Providers and those Preferred Providers that elect to participate in PCC. This spending is adjusted based on the claims reduction levels elected by Participating Providers and expressed as a percentage of total historical

[21] For TCC, PCC, NPCC, and APO, the lookback period for calculating historical spending patterns will be the first nine months of the calendar year preceding the current performance year. For example, for PY2027, the lookback period will be January—September 2026.

expenditures. CMS then applies this percentage to the ACO's benchmark to determine the monthly Base PCC payment.

The Base PCC calculation includes a safeguard for Federally Qualified Health Centers (FQHCs) and Rural Health Centers (RHCs) to ensure ACOs are appropriately funded for beneficiaries aligned through these providers. This "FQHC/RHC True-up" is assessed at the ACO level for all beneficiaries aligned through FQHCs and RHCs. CMS compares base PCC payments to actual FFS fee reductions for these beneficiaries on a quarterly, year-to-date (YTD) basis, accounting for any prior adjustments in the Performance Year. If PCC payments are lower than the corresponding fee reductions, CMS will make an additional payment to cover the difference, applied in the following quarter. This adjustment can only increase payments, not reduce them. Adjustments will count toward ACOs' Performance Year Expenditures for the purpose of calculating Shared Savings/Losses.

The Enhanced PCC is calculated to provide ACOs with additional prospective funding beyond the Base PCC amount. Specifically, the Enhanced PCC equals the greater of (1) the difference between 7% of the ACO's Performance Year benchmark and the Base PCC amount, or (2) 2% of the Performance Year benchmark. Although paid prospectively, the Enhanced PCC is subtracted from Shared Savings/Shared Losses at final financial settlement and therefore functions as an advance payment rather than net new payments to the ACO.

Example. Consider an ACO with a prospective Performance Year benchmark of $1,000 per beneficiary per month. Based on historical Medicare claims, CMS determines that 3% of total spending is attributable to primary care services furnished by participating primary care providers. In this case, the Base PCC would equal $30 PBPM. 7% of the benchmark equals $70 PBPM, so the difference between 7% and the Base PCC is $40 PBPM. The ACO would receive an Enhanced PCC of $40 PBPM, for a total PCC payment of $70 PBPM.

Participation in PCC requires specified levels of fee-for-service claims reduction for primary care services, which vary by provider type and Performance Year, as summarized below.

Table 15. Primary Care Capitation

Type	**Payment Mechanism Participation Requirements**	**Claims Reduction Requirements**
Primary Care Specialist Participant Providers (Previous ACO REACH Participants*)	Mandatory participation in PCC payment mechanism	100%
Primary Care Specialist Participant Providers	Mandatory participation in PCC payment mechanism	PY2027: 1-100% PY2028: 5-100%

(New ACOs & previous Shared Savings Program Participants)		PY2029: 10-100% PY2030: 20-100% PY2031-2035: 100%
Preferred Providers	Optional participation	1-100%

** All Primary Care Specialists in a Participant TIN that participated in ACO REACH in 2026 will be required to select 100% PCC claims reduction*

As with TCC, CMS will update capitation payment amounts on a quarterly basis to incorporate changes in beneficiary alignment, benchmark and risk score updates, and—if applicable—changes in the share of total spending provided by Participant TINs and Preferred Providers. Any remaining under or over-payments will be incorporated into final financial settlement.

ACOs that elect PCC will also have two supplemental payment options to enable them to engage in innovative, value-based downstream arrangements with non-primary care providers: a Non-Primary Care Capitation (NPCC) and an Advanced Payment Option (APO), described below. Both the NPCC and APO allow ACOs to elect claims reduction percentages for non-primary care Participant and Preferred Providers, and to replace these claims reductions with upfront payments to the ACO, which the ACO can then use to fund alternative payment arrangements with these providers. The key difference is that the NPCC is a true prospective capitation, meaning the ACO is at risk for gains and losses on the capitation payment, while the APO is a pre-payment that is reconciled against actual fee-for-service spending. The APO was available in ACO REACH, while the NPCC is a new policy for LEAD. Specialist providers that elect NPCC or APO may not participate in a CARA arrangement, as doing so would interfere with CMS's ability to accurately administer CARA episodes.

3. Non-Primary Care Capitation (NPCC)

ACOs that elect PCC may also elect NPCC to extend capitation to non-primary care services. For example, an ACO could elect NPCC and enter into a sub-capitation arrangement with a cardiology group that provides a large share of specialty care to its aligned beneficiaries. Based on historical claims, CMS converts the portion of the ACO's benchmark attributable to cardiology services furnished by that group into a prospective monthly NPCC payment, which the ACO uses to make a fixed, downstream payment to the cardiology group. In exchange, the cardiology group accepts accountability for the cost and quality of cardiology care, aligning incentives away from Medicare fee-for-service and toward value-based care. Providers can currently participate in these types of sub-capitated arrangements under Medicare Advantage, and NPCC would bring this flexibility to Original Medicare.

Participation rules vary by risk track:

- **Global Risk ACOs** may have primary care specialists in a Participant TIN elect PCC + NPCC, or just PCC. Non-primary care providers in the Participant TIN can only elect NPCC or APO. Preferred providers may elect PCC + NPCC simultaneously, only PCC, or only NPCC.
- **Professional Risk ACOs** cannot have the same provider participating simultaneously in both PCC and NPCC or APO. Primary care specialists in Participating TINs can only elect PCC. Non-primary care specialists can only elect NPCC or APO. Preferred providers can elect PCC, NPCC, or APO.

Table 16: Payment Mechanism Participation Rules by Provider Type

	Global Risk Option			Professional Risk Option		
	Primary Care Specialist Participant Providers	**Non-PC Specialist Participant Providers**	**Preferred Providers**	**Primary Care Specialist Participant Providers**	**Non-PC Specialist Participant Providers**	**Preferred Providers**
PCC	Required	Non-eligible	Eligible	Required	Non-eligible	Eligible
NPCC	Eligible	Eligible	Eligible	Non-eligible	Eligible	Eligible
APO	Eligible	Eligible	Eligible	Non-eligible	Eligible	Eligible
PCC+NPCC	Eligible	Non-eligible	Eligible	Non-eligible	Non-eligible	Non-eligible
PCC+APO	Eligible	Non-eligible	Eligible	Eligible	Non-eligible	Eligible
TCC	Required if selected	Required if selected	Eligible	Non-eligible	Non-eligible	Non-eligible

ACOs will define the claims reduction percentage for NPCC-participating providers, ranging from 1 to 100%. CMS will continue to pay any remaining non-reduced portion of fee-for-service claims for services furnished by these providers.

The NPCC payment is calculated to reflect the estimated cost of care for non-primary care services delivered by NPCC-participating providers to aligned beneficiaries. CMS bases this calculation on historical claims for those services, following the same methodology used to determine PCC payments: historical spending is expressed as a percentage of the total benchmark, and this percentage is applied to the ACO's to determine the prospective monthly NPCC payment. Like TCC and PCC, NPCC is paid monthly, and capitation payments are included in the ACO's Medicare total cost of care for purposes of reconciliation.

4. Advanced Payment Option (APO)

As an alternative to the Non-Primary Care Capitation, ACOs that elect PCC may also elect the APO. Like the NPCC, the APO will also apply to non-primary care services provided to aligned beneficiaries by Participant and Preferred Providers who have opted into the APO arrangement and will be based on historical spending for aligned beneficiaries by APO participating providers. However, unlike NPCC, the APO will be reconciled against actual fee-for-service claims. In practice, this means the APO functions as an advance on expected fee-for-service spending rather than a fixed budget. If

actual claims exceed the prepaid amount, the difference is added to the ACO's Medicare total cost of care at reconciliation; if claims are lower, the ACO does not retain the savings, unlike under a true capitation arrangement. In effect, the APO may be attractive to ACOs seeking upfront cash flow with lower financial risk, while the NPCC is better suited to ACOs that want to fully shift non-primary care providers away from fee-for-service and capture savings from fixed, prospective payments.

Again, the ACO will define the percentage of claims reduction for Participant and Preferred Providers that participate in the APO arrangement, ranging from 1-100% (integer values only). CMS will continue to pay any remaining, non-reduced portion of FFS claim amounts to providers that participate.

Example. ACO A with a benchmark of $1200 PBPM elects NPCC, while ACO B with the same benchmark amount elects APO. In both ACOs, the Preferred Providers participating in these payment mechanisms elect 100% claims reduction for NPCC/APO, and the calculated amount paid prospectively for both payments is $20 PBPM. Throughout the year, the Preferred Providers in both ACOs submit claims for non-primary care services for aligned beneficiaries totaling $30 PBPM.

For ACO A, the total cost of care calculated at final settlement will include $20 PBPM in NPCC payments per beneficiary. The ACO will not receive payment for the additional $10 PBPM that were billed through claims (resulting in a lower total cost of care for the purposes of calculating Shared Savings/losses).

For ACO B, the total cost of care calculated in final settlement will include $20 in APO payments per beneficiary plus the additional $10 PBPM fee-for-service costs incurred throughout the year. During final settlement, CMS pays the ACO the additional $10 PBPM that were billed through claims (in addition to counting this extra spending toward the ACO's total cost of care).

5. Administrative Add-On

Higher-spending ACOs have historically been reluctant to join ACO models and make investments in enhanced care management, care coordination, home-based care, and other high-value services, because this results in higher Medicare spending (and thus fewer Shared Savings) in the short term. By providing a benchmark adjustment in a way that advances funds to support these activities, LEAD removes a key barrier to participation and successful care transformation.

Higher-spending ACOs will be eligible for an additional capitated payment equivalent to 1.5% of their benchmark. This payment is designed as an upfront benchmark adjustment to encourage higher-spending organizations to invest in primary care and other enhanced services that will ultimately enable them to reduce Medicare expenditures for LEAD-aligned beneficiaries over time.

The Administrative Add-on is paid on a monthly basis like LEAD's other capitated payments, but it is not included in Performance Year expenditures for the purposes of calculating an ACO's Shared Savings/Losses, nor is it subject to repayment.

Claims Payments Excluded from TCC Payment, PCC Payment, NPCC Payment and APO

Notwithstanding the above, certain services will be excluded from fee reductions under certain circumstances. These include, but are not limited to:

- Claims payments where Medicare is not the primary payer;
- Claims payments for providers enrolled in the Periodic Interim Payments (PiP) program or other Medicare programs or initiatives specified by CMS prior to the start of the Performance year or relevant subsequent quarter;
- Claims payments that represent a health professional shortage area (HPSA) payment. A HPSA payment will be based on the amount prior to the reduction;
- Claims payments to a home health agency for an episode period for which the home health agency has submitted a Request for Anticipated Payment (RAP);
- Claims payments for beneficiaries who elect to decline data sharing; and
- Claims payments for services related to the diagnosis and treatment of substance use disorder (SUD).

B. LEAD Payment Examples

The following examples are intended to illustrate how the LEAD payment methodologies described above translate into provider cash flows and total revenue under different participation scenarios. Each example applies the LEAD framework to a hypothetical ACO with distinct characteristics—such as size, baseline spending relative to the region, prior value-based experience, and risk option selection—to demonstrate how benchmarks, capitated payments, Shared Savings, and other model-specific adjustments interact in practice. These examples are illustrative only and rely on simplifying assumptions.

Payment Example #1: Independent physician practice ACO, new to value-based care

ACO Characteristics

1 practice, 12 primary care providers

6,000 Original Medicare beneficiaries, slightly sicker than average Medicare population (**1.1 average risk score**)

$3 million annual fee-for-service Medicare revenue (Higher spending per capita than regional peers)

Has not previously participated in the Shared Savings Program or ACO REACH

LEAD Options Selected

Professional Risk Option

Primary Care Capitation + Enhanced

50% fee reduction on primary care claims

Financial Calculations

Benchmark Calculation

($1,250 — ACO's historical risk-standardized per beneficiary per month spending in the base years) + (3% — Three-way blend update trend) X (1.1 — ACO's average beneficiary risk score) X (72,000 — Beneficiary Months (aligned beneficiaries x12))

= $102 Million Annual Benchmark

Monthly capitated payments

$127,463 /month	**Base Primary Care Capitation** *($3 million historical primary care revenue = 3% of benchmark, adjusted for 50% fee reduction)* $101,970,000 x 0.03 x 0.5 = $1,529,550/12 = $127,463
$339,900 /month	**Enhanced Primary Care Capitation** *(7% maximum PCC - 3% base PCC = 4% of benchmark)* $101,970,000 x 0.04 = $4,078,800/12 = $339,900
$127,463 /month	**1.5% Administrative Add-On** *(for high spending ACOs)* $101,970,000 x 0.015 = $1,529,550/12 = $127,463

$594,826 Total Monthly Upfront Payments

Shared Savings Calculation

($102 million — Annual benchmark) X (4.5% — ACO's gross savings rate) - (3% x (1-0.8) — ACO earns back 80% of the 3% quality withhold through performance) X (50% — ACO portion of shared savings)

= $2.0 Million Shared Savings

If ACO had selected the Global risk option, shared savings would be $2.2 million

Total Revenue Impact

Total Annual Practice Revenue under LEAD		***...compared to annual practice revenue under FFS***
$1.5 million	Fee-for service revenue	**$3 million**
$1.5 million	Base PCC Capitation	Fee-for service revenue
$0*	Enhanced PCC Capitation	
$1.5 million	Administrative Add-On	
$2.0 million	Shared Savings	
$6.5 million		

**Represented as $0 net new revenue because it is paid monthly, but must be re-paid at the end of the year*

Payment Example #2: Health-system-based ACO, experienced in value-based care

ACO Characteristics

Health system that owns **5 primary care practice sites, 10 multi-specialty practice sites,** and partners with (but does not have a financial stake in) preferred **home health, skilled nursing facility, and hospice providers**.

30,000 Original Medicare beneficiaries, average disease burden for Medicare population (**1.0 average risk score**)

Previously participated in **ACO REACH** (generated 3% lower spending per capita than regional peers)

LEAD Options Selected

Global Risk Option

Total Care Capitation

100% fee reduction for primary care and specialist providers, 60% fee reduction for post-acute care providers

Financial Calculations

Benchmark Calculation

($1,050 — ACO's historical per beneficiary per month spending in the base years, with 1.0 risk score) + ($16 — PBPM Regional Efficiency Adjustment**) + (3.5% — Three-way blend update trend) x (360,000 — Beneficiary Months (aligned beneficiaries x12))

= $397 Million Annual Benchmark

**Assumes regional average PBPM spending in the historical base years was $1,082, so the REA is ($1,082-$1,050)*0.5 = $16

Monthly capitated payments

$10.9 million /month

Total Care Capitation *(Benchmark minus historical spending for services provided by non-ACO providers, adjusted for fee reductions)**

$397,191,600*0.15*100% + $397,191,600*0.30*0.6 = $131,073,228/12 = $10,922,769

*This example assumes that spending by the ACO's primary care providers is 3% of benchmark (with 100% fee reduction), spending by the ACO's specialty providers is 12% of benchmark (with 100% fee reduction), and spending by the ACO's preferred post-acute providers is 30% of benchmark (with 60% fee reduction), for total participant and preferred provider spending under capitation of 30% of benchmark

Shared Savings Calculation

($397 million — Annual benchmark) x (7.5% — ACO's gross savings rate) - (3% x (1-0.9) — ACO earns back 85% of the 3% quality withhold through performance) - (3% — of benchmark: CMS discount)

= $16.7 Million Shared Savings

Total Revenue Impact

Total annual ACO Revenue under LEAD		*...compared to ACO revenue under FFS*	
$0*	Fee-for service revenue for health system-owned providers (primary and specialty care)	$60 million	Fee-for service revenue for health system-owned providers (primary and specialty care)
$48 million	Fee-for service revenue for non health system-owned providers (post-acute)	$119 million	Fee-for service revenue for non health system-owned providers (post-acute)
$131 million	Total Care Capitation		
$17 million	Shared Savings		
$195 million		**$179 million**	

*FFS revenue is $0 because primary care providers and specialists are receiving a 100% fee reduction

C. CMS Administered Risk Arrangements (CARA) Initiative

CARA is a voluntary initiative that enables ACOs to increase specialty provider accountability for quality and cost. Initially tested within LEAD among ACOs that maintain two-sided risk by electing the Global Risk Option, CARA facilitates more robust relationships with downstream specialty providers by reducing implementation barriers that currently prevent ACOs from establishing meaningful episode-based risk arrangements (EBRAs) with specialists. This approach addresses a critical gap where specialists drive significant healthcare costs but remain largely outside accountability frameworks.

CARA builds upon the existing shadow bundles data initiative, which provides data on nested episode bundles to ACOs participating in ACO REACH, the Shared Savings Program, and the Kidney Care Choice (KCC) Model. Shadow bundles data are episodic data and pricing information that ACOs had the opportunity to request from CMS pursuant to a HIPAA-Covered Data Disclosure Request Form for purposes described in the first and second paragraphs of the definition of "health care operations" under the HIPAA Privacy Rule at 45 C.F.R. § 164.501, and to facilitate setting up their own bundled payment arrangements or to help inform high-value referrals. Beginning in 2024, CMS packaged and priced acute care and procedural episodes using Bundled Payments for Care Improvements Advanced (BPCI Advanced) Model's specifications for ACOs, with the initiative expanding to include chronic condition episode-based cost measure (EBCMs) reporting in fall 2025.[22] In 2027, LEAD ACOs will have the opportunity to request reports similar to those provided in the shadow bundles data initiative to support identification of specialists and health care provider organizations for EBRAs. These reports will include data using the EBCM methodology.

CARA will offer acute medical and procedural EBCMs at baseline and will phase in chronic condition EBCMs early in the initiative. Additionally, CARA provides two participation options: Default Approach and Maximal Flexibility (or "Max Flex") Option. The Default Approach allows ACOs to select EBCMs that are predicated on the CMS constructed EBCM methodology with slight modifications to align within a LEAD performance year and does not allow ACOs to customize episode components. The Max Flex Option allows ACOs to select an existing EBCM and customize the episode by specifying modifications (e.g., specifying the episode trigger codes or episode length). Episode risk parameters, including episode selection and construction parameters, discounts/premiums to target prices, selection of quality measures for performance adjustment, and performance adjustment specifications, will be subject to CMS review and finalization through the CMS 4i platform to ensure clinical appropriateness and operational feasibility. CARA-related episode costs will be factored into the ACO's expenditures during LEAD's financial settlement and CMS will calculate payments, as permitted under the LEAD Participation Agreement CARA Amendment (LPACA) and EBRA, to determine the Preferred Providers performance in CARA. If a Preferred Provider's Medicare FFS payments are less than the target price the Preferred Provider may be eligible for a reconciliation payment or if the Preferred Provider's Medicare FFS payments are above the target price they may

[22] Centers for Medicare & Medicaid Services. (n.d.). *About cost measures *. U.S. Department of Health and Human Services. https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/about

owe a repayment. The incorporation of the CARA-related episode costs into the ACO benchmark and subsequent payment to, or repayment from, Preferred Providers based on the comparison of these Medicare FFS payments against the target price ensures that both ACOs and Preferred Providers are incentivized to negotiate appropriate target prices that are sufficiently competitive to generate specialist engagement while maintaining ACO benchmark integrity. As noted in Section X.A.C of this RFA, specialist providers that elect NPCC or APO may not participate in a CARA arrangement Further details on specifics related to the Default Approach and Max Flex Option are outlined in Appendix E, Section E.2 of this RFA.

In addition to the EBCMs, CMS will provide another CARA episode offering that focuses on falls prevention through time-limited home-based interventions designed to improve patients' functional safety in their home environment. The CMS falls prevention episode, called the Resilience and Independence in a Safe Environment (RISE) to Age in Place episode, directly supports LEAD's requirement for ACOs to develop PQPs by providing a structured intervention option that ACOs can select provided the RISE to Age in Place episode addresses beneficiaries' needs identified via their needs assessment. ACOs that choose to implement the RISE to Age in Place episode as their prevention intervention would satisfy the PQP requirement and would have to meet PQP milestones and other reporting requirements as defined by CMS. The RISE to Age in Place episode aims to increase activities of daily living (ADLs) and decrease acute events for Medicare beneficiaries by pairing an initial evaluation paid through FFS with a bundled payment to cover the cost of Medicare items and services provided by an interdisciplinary care team likely comprising of OTs, PTs and RNs who collaborate to deliver comprehensive fall prevention interventions including risk assessments, medication management, strength training, balance exercises and health care provider communication plans. When structural improvements up to $2,500 are warranted to a beneficiary's home, the RISE to Age in Place team, in partnership with the ACO may engage a handyperson to deliver targeted home modifications, subject to compliance with all applicable laws and regulations and the PY PA (See Section II.C. and Appendix E, Section 10.4 of this RFA). This offering exemplifies the type of community-based collaboration that LEAD envisions, where ACOs can partner with specialized health care providers to address upstream drivers of health through evidence-based prevention interventions tailored to their beneficiaries' specific needs. Unlike the EBCM episodes, the RISE to Age in Place episode would not have a target price. To pay for the RISE to Age in Place episode, CMS would establish Level II HCPCS (non-payable zeroed-out G-Codes) for RN and OT services billed through the IPC while ACOs would fund any handyperson services. Successful implementation of the RISE to Age in Place episode would yield a reduction in falls and corresponding reduction in expenditures. While not required, savings generated from the RISE episode may be shared between the ACO and the downstream RISE to Age in Place entity, pursuant to sharing terms outlined in their negotiated agreement.

CARA facilitates the EBRAs between ACOs and Preferred Providers on 4i. CMS will collect attestations from ACOs participating in CARA via 4i that provide confirmation that an EBRA has been established with a Preferred Provider. The agreements themselves will not be collected.

CARA's modular design enables potential scaling to other TCOC contexts based on demonstrated success and market uptake within LEAD. Before broader implementation across the CMS portfolio, CARA's success would be measured based on evaluation of the effectiveness of ACO and specialist partnerships. Uptake of CARA could also potentially inform future bundled-payment episode policies by illuminating characteristics of episodes selected by ACOs and their Preferred Providers as part of their EBRAs.

XI. Quality and Performance

The LEAD quality strategy is designed to provide ACOs achievable performance criteria and incentives that encourage practice transformations necessary to reduce utilization and improve patients' quality of care. The model will use five existing quality measures used in ACO REACH and phase in two new quality measures that align with the LEAD's prevention-focused approach and beneficiary-centered care goals. The measure selection process prioritizes clinical impact, actionability, and alignment with LEAD's theory of action and CMS and CMS Innovation Center strategic priorities while building upon established measurement infrastructure to reduce administrative burden.

LEAD's financial incentives for quality improvement are also modeled closely off ACO REACH and include incentives for continuing and sustaining quality improvement as well as the opportunity for bonus payments to support ACO-led prevention efforts.

A. Quality Measure Selection and Additional Reporting Requirements

As discussed in detail below, five of LEAD's quality measures will be retained from ACO REACH and there will be two new quality measures. Measures carried over from ACO REACH will be scored by performance from the start of the model, with established quality benchmarks, providing continuity for ACOs that previously participated in ACO REACH and adding minimal burden to new entrants because these measures are all administratively calculated. The two new measures are eCQMs. For the purposes of LEAD, the goal of including these new measures is to use data derived from medical records for assessing quality. In recognition of variation in ACO readiness to report these two new quality measures, LEAD will implement a phased approach to measure reporting, with flexibility and support for a range of electronic submission options at the outset, aiming for long-term alignment with the direction of the CMS digital quality strategy. LEAD plans to focus quality reporting to Medicare beneficiaries aligned to the ACOs participating in the model.

The two new measures will be optional for PYs 1 and 2. They will be measured on a pay-for-reporting basis for PY 3 and PY 4 and would transition to pay-for-performance beginning in PY 5 through PY 10 Making the two new measures optional for the first 2 years before transitioning to pay-for-reporting would afford ACOs time to acclimate to the collection and reporting of data derived from electronic medical records.

The five quality measures retained from ACO REACH and included in LEAD are:

- **Risk-Standardized All-Condition Readmission:** claims-based measure that measures how many hospital stays result in a readmission within 30 days after patient discharge. This measure will be adjusted to address feedback that very small differences in performance have produced outsized impacts on the measure's quality score.
- **All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions:** claims-based measure that measures unplanned hospital admissions among beneficiaries who are 66 years of age or older with multiple chronic conditions.
- **Days at Home for Patients with Complex, Chronic Conditions:** claims-based measure that measures the number of days that adults with complex, chronic disease spend at home or in community settings—not in acute and post-acute care settings.
- **Timely Follow-Up After Acute Exacerbations of Chronic Conditions:** claims-based measure that is defined as the percentage of acute events related to one of six chronic conditions where follow-up care was received within the time frame recommended by clinical practice guidelines in a non- emergency outpatient setting. Acute events are those that require either an emergency department visit or hospitalization. The six chronic conditions include hypertension, asthma, heart failure, coronary artery disease, chronic obstructive pulmonary disease, and diabetes.
- **CAHPS Survey:** patient-reported measure that will use the ACO CAHPS Survey and derive CAHPS Summary Survey Measures for scoring, which would then be combined into a single CAHPS Composite Score. The LEAD CAHPS Survey will also have questions about patient/caregiver experience with care delivered by a LEAD ACO. LEAD ACOs must contract with a CMS-approved CAHPS Survey vendor for each reporting year to administer the CAHPS Survey.

The two new measures requiring data derived from electronic medical records included in LEAD are:

- **Controlling High Blood Pressure:** directly links to cardiovascular health outcomes, addressing a leading cause of morbidity and mortality among Medicare beneficiaries. Improved blood pressure control reduces the risk of heart attack, stroke, and other cardiovascular complications, leading to better health outcomes and reduced healthcare utilization.
- **Diabetes: Glycemic Status Assessment Greater Than 9%:** addresses chronic disease management and prevention of complications such as diabetic retinopathy, nephropathy, and neuropathy, which significantly impact beneficiary quality of life and healthcare costs. This measure is intended to reflect the quality of services provided for patients with diabetes.

CMS reserves the right to amend this measure set or redesign existing measures as they evolve and new measures become available over the course of the model. Additionally, specifications for the quality measure set and scoring principles will be reviewed annually and may be subject to revision each Performance Year.

Table 17: Summary of LEAD Quality Measures

Measure	Source	Method of Data Submission	Domain	Pay for Performance/ Pay for Reporting
Risk-Standardized All-Condition Readmission	ACO REACH	Claims	Care Coordination/ Patient Safety	Pay for Performance
All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions	ACO REACH	Claims	Care Coordination/ Patient Safety	Pay for Performance
Days at Home for Patients with Complex, Chronic Conditions	ACO REACH	Claims	Care Coordination/ Patient Safety	Pay for Performance
Timely Follow-Up After Acute Exacerbations of Chronic Conditions	ACO REACH	Claims	Care Coordination/ Patient Safety	Pay for Performance
CAHPS Survey	ACO REACH	Patient-Reported	Patient/Caregiver Experience	Pay for Performance
Diabetes: Glycemic Status Assessment Greater Than 9%	New	eCQM	Prevention and Management of Chronic Diseases	PY 1-2 Optional PY 3-4 Pay for Reporting PY 5-10 Pay for Performance
Controlling High Blood Pressure	New	eCQM	Prevention and Management of Chronic Diseases	PY 1-2 Optional PY 3-4 Pay for Reporting PY 5-10 Pay for Performance

Prevention and Quality Plan Requirement

Starting in PY 2027, CMS will require all LEAD ACOs to develop a prevention intervention to be reported via the Prevention and Quality Plan (PQP). The PQP would outline the prevention intervention each ACO intends to implement to actively drive care delivery transformation in preventive care. CMS defines preventive care on a spectrum from preventing chronic disease (primary prevention), to diagnosing chronic disease early and intervening early before clinically significant events occur (secondary prevention) to improving the quality of life of individuals with an existing chronic disease and preventing complications (tertiary prevention). To support the

development and implementation of ACOs' prevention interventions, CMS will tie additional quality points to meeting specific and actionable goals identified by ACOs representing progress on prevention interventions (this is referred to as the Prevention and Quality Plan Reporting Adjustment as further described below). Payment will be tied to the development of the plan and meeting the established goals.

CMS expects LEAD ACOs to design new, or expand existing, preventive care delivery interventions that align with LEAD's goals of improving beneficiaries' wellbeing and health outcomes. CMS recognizes that ACOs participating in ACO REACH and other value-based arrangements are likely to have existing care delivery programs in place to drive their performance that could be enhanced or expanded in a way that reflects both the needs of their aligned beneficiaries and the intent of the PQP. The goal of the PQP is to support the implementation and success of the chosen preventive care delivery intervention and to understand the success and obstacles LEAD ACOs face in engaging Medicare beneficiaries. The PQP ensures LEAD ACOs have the flexibility to decide how to invest their dollars in upstream, proactive interventions and achieve personalized, clinically meaningful goals.

Prevention and Quality Plan Timeline and Tracks

CMS expects LEAD ACOs to develop their PQP via a phased approach, thus allowing ACOs time to develop or expand upon a robust and data-driven prevention intervention. Key phases of the PQP development and implementation include:

a) Phase I (Goal Setting and Design of Prevention Intervention);
b) Phase II (Launch Prevention Intervention); and
c) Phase III (Implementation of Prevention Intervention).

Phases I and II will occur in PY 1 and PY 2 of the LEAD ACO's model participation, respectively. Phase III will occur in subsequent PYs.

During Phase I of the PQP, LEAD ACOs will be expected to identify their prevention goals and design their prevention interventions. Prior to designing a prevention intervention, ACOs are expected to conduct a needs assessment to understand their beneficiaries' needs and opportunities to advance prevention. As LEAD ACOs design their new or expanded prevention interventions, ACOs are expected to address the core needs of their beneficiaries. For example, if an ACO primarily serves High Needs beneficiaries, this ACO is expected to design an intervention that addresses the needs of their High Needs beneficiaries. If an ACO serves beneficiaries with a high prevalence of behavioral health conditions, the ACO is expected to design its prevention intervention in ways that address the behavioral health needs of its beneficiaries. If an ACO serves beneficiaries with multiple needs, the ACO retains flexibility around how they design their prevention intervention to meet their beneficiaries' core needs.

During this phase, ACOs must also identify and report specific measures they will use to track the impact of their prevention intervention. ACOs are also encouraged to identify and establish partnerships with community-based organizations or other local organizations to inform the

development of their prevention intervention and/or support the implementation of their prevention intervention.

During Phase II of the PQP, LEAD ACOs are expected to start launching their prevention and must have a fully established prevention intervention by the end of this phase. As part of their prevention intervention, LEAD ACOs must actively engage their beneficiaries and identify lessons learned and goals for future Performance Years. During this phase, ACOs will start reporting data on how they are engaging their beneficiaries, challenges they are experiencing, and strategies to increase beneficiary engagement and improve health outcomes.

The PQP is intentionally flexible to reflect the anticipated range of participant types and variation in aligned populations' needs; LEAD ACOs will decide how to design their preventive care delivery intervention. To support ACOs, CMS has developed several thematic prevention areas centered on core chronic conditions that ACOs can consider when designing their interventions. The thematic areas are optional but recommended tracks that ACOs can leverage to inform the design of their prevention intervention. Participants doing work outside these tracks may be asked to explain these choices with data-informed and evidence-based rationale. These tracks include:

1. **Cardiovascular Disease / Hypertension / Cardiometabolic-Kidney Disease / Tobacco Cessation** – Cardiovascular disease is the leading cause of death for Medicare recipients and smoking is the leading cause of preventable death.[23] Reducing the risk of cardiovascular morbidity and mortality as well as progression of related kidney disease is a powerful way to enhance quality of life and prevent downstream healthcare costs. Prevention in this track could focus broadly on risk reduction or more narrowly on critical areas of prevention such as smoking cessation or hypertension control.
2. **Prevention out of home placement/Fall Prevention** – Falls are the leading cause of injury and injury-related deaths for older adults.[24] Prevention and early diagnosis and treatment of falls is a powerful way to improve quality of life and reduce future health spending and allow Medicare beneficiaries to remain in their home and community living situation.
3. **Nutrition Services** to mitigate chronic disease and frailty – Food can have a positive outcome on health across numerous chronic conditions.[25] Access to healthy food and nutrition counseling is a powerful tool to reduce spending on diet-sensitive chronic conditions and avoid frailty in older adults.

During Phase III of the PQP, CMS expects LEAD ACOs to implement their prevention interventions and submit annual reports capturing the status and progress of their prevention interventions, including achieving milestones for beneficiary engagement with the intervention and progress on prevention measures identified by the ACO during Phase II.

Prevention and Quality Plan Data Submission Process

[23] https://www.cdc.gov/heart-disease/data-research/facts-stats/index.html
[24] https://www.cdc.gov/falls/about/index.html
[25] https://jamanetwork.com/journals/jama/article-abstract/2841539

To assist LEAD ACOs in developing a PQP, CMS will develop and provide a standardized, user-friendly form that ACOs can complete and update on an annual basis. Using these forms, LEAD ACOs will submit PQP data to CMS, in a form and manner by a date specified by CMS. In advance of a submission deadline, CMS will provide the LEAD ACO with a list of components that the ACO must include in these annual submissions to CMS and the requirements regarding the content and use of the PQP data will be described in the PY PA.

Prevention and Quality Plan Reporting Adjustment

In the initial years of the model, additional quality points will be tied to developing a PQP and launching or expanding a prevention intervention. After launching or expanding a prevention in the early years of the model, LEAD ACOs will continue to earn additional points on their quality score for submitting participant-level data on their intervention and achieving progress on their prevention goals in subsequent years. ACOs will be able to earn up to 5 additional percentage points in PY 1 and PY 2 and up to 10 additional percentage points per PY thereafter upon meeting PQP-related goals. These points will be added after the ACO's Initial Quality Score and CI/SEP multiplier is applied to determine the ACO's Total Quality Score and final Quality Withhold Earn Back. CMS plans to publish additional details regarding the PQP Reporting Adjustment including what qualifies as 'successful reporting'. The ACO Total Quality Scores will not exceed 100% and there will be no downward adjustment for non-submission.

Resources and Flexibilities to Support ACOs' Prevention Interventions

LEAD includes numerous flexibilities that ACOs can leverage to develop and implement their PQP—some of these flexibilities include Benefit Enhancements and Beneficiary Engagement Incentives. Examples of prevention-focused Benefit Enhancements and Beneficiary Engagement Incentives include: the Chronic Disease Prevention Beneficiary Engagement Incentive which encourages beneficiaries' participation in evidence-based programs focused on prevention and healthy living activities and the Medical Nutrition Therapy (MNT) Benefit Enhancement which expands Medicare coverage of MNT from diabetes, chronic kidney disease, and post kidney transplant to include to Medicare beneficiaries diagnosed with Pre-diabetes and Hyperlipidemia (more information on Benefit Enhancements and Beneficiary Engagement Incentives can be found in Section VII.E.).

In addition to Benefit Enhancements and Beneficiary Engagement Incentives, LEAD ACOs may be able to leverage technology-supported care through the Advancing Chronic Care with Effective Scalable Solutions (ACCESS) Model, which includes four tracks: early cardio-kidney-metabolic, cardio-kidney-metabolic, musculoskeletal, and behavioral health. Eligible LEAD ACOs can also use the RISE to Age in Place episode that is part of the voluntary CARA program focused on supporting falls prevention, and partner with local community-based organizations to address upstream preventive care interventions, including nutritional services and physical activity. CMS will continue to explore opportunities to support ACOs as they develop and implement their prevention interventions.

B. Quality Performance and Impact on Performance Year Financial Benchmarks

LEAD will incentivize providers to improve quality performance and maintain high standards of care through a framework based largely on the ACO REACH quality scoring and payment system. LEAD will apply a withhold to all ACOs' Performance Year financial benchmark calculations and give individual ACOs the opportunity to "earn back" some or all the withhold based on their quality performance.

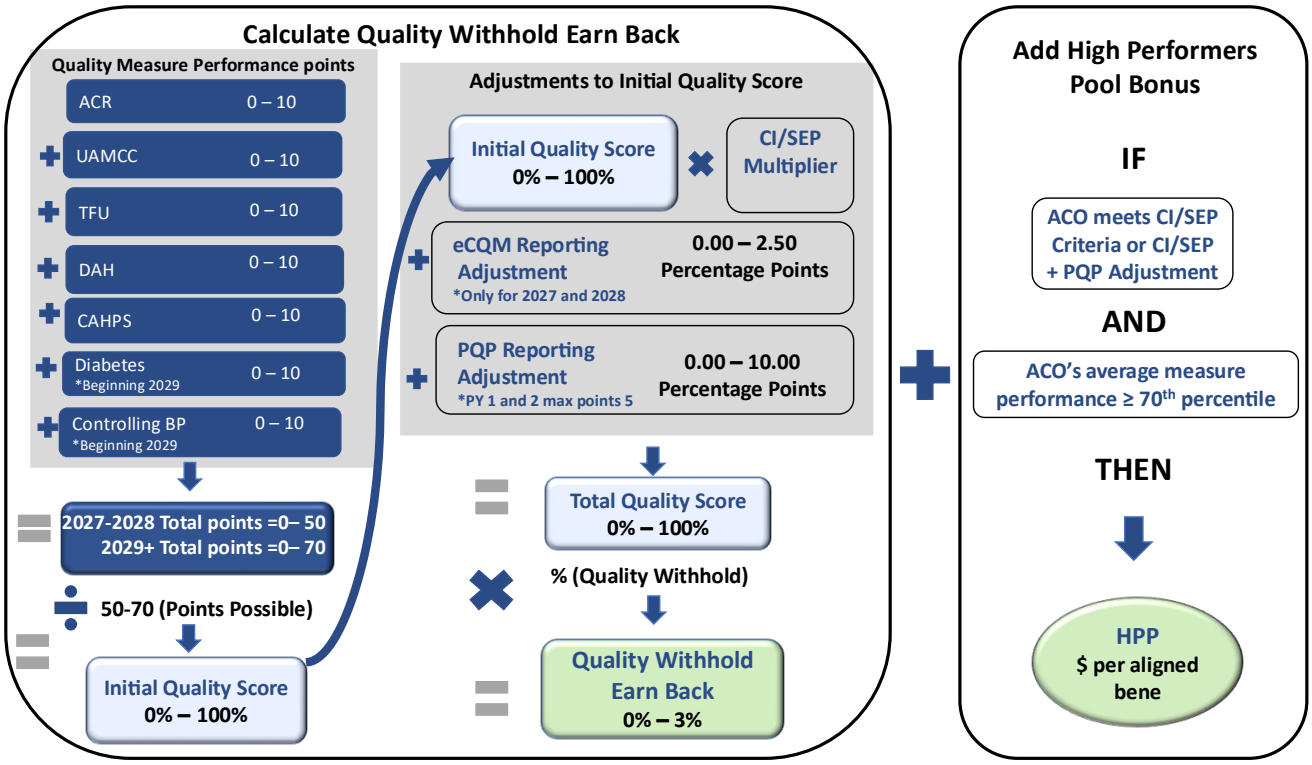
C. Quality Measurement Scoring and Calculation of the Initial Quality Score

Like REACH ACOs, LEAD ACOs will be able to earn up to 10 Quality Measure Points for each required quality measure, totaling 50 maximum Quality Measure Points available to be earned in PY1-PY2 and 70 maximum Quality Measure Points in PY3 once the two eCQMs are required. For pay-for-performance measures, CMS will perform additional analysis to finalize how points will be awarded for each measure based on clinical impact, distribution, benchmark distribution and alignment with LEAD goals. The quality measurement approach will recognize that some ACOs serve more complex patient populations, including those that serve a high proportion of high needs beneficiaries. Beginning in PY 2029, for each pay-for-reporting eCQM, ACOs will be awarded the full 10 points for each measure that is adequately reported as defined by CMS in future guidance and zero (0) points for measures that are not adequately reported. The Initial Quality Score is equal to the percentage of possible points (50 or 70) earned by the LEAD ACO.

1. Continuous Improvement/Sustained Exceptional Performance (CI/SEP)

LEAD will also use a CI/SEP criterion to encourage ACOs to deliver high-quality, high-value care by tying a portion of an ACO's financial performance to quality improvement and maintenance. We will implement a graduated approach to incorporating the CI/SEP criteria into quality scoring, rather than using a binary determination. Instead of applying a single threshold to decide whether LEAD ACOs receive full or partial credit, the number of measures for which an ACO meets CI/SEP criteria will influence the adjustment applied to their Initial Quality Score. For each LEAD ACO and each included measure, improvement and decline will be assessed in way that is similar to the approach in ACO REACH, with the addition of statistical noise to distinguish significant decline and improvement. CMS will provide methodological details on the CI/SEP criteria in a follow-up Quality Measurement Methodology paper. The methodology will recognize that ACOs achieving high quality performance scores may have less room to show improvement. Accordingly, when establishing these continuous improvement targets, CMS will establish targets that still incentivize higher performing ACOs to continue to improve. ACOs' quality performance on each measure would continue to be assessed for each Performance Year and serve as the baseline for the ACOs' ongoing quality improvement activities in future Performance Years. ACOs that meet or exceed predefined CI/SEP criteria could earn back all or a portion of their quality withhold based on their quality performance scores. Those that do not meet the CI/SEP criteria could earn back a portion of their quality withhold based on their quality performance scores. When assessing whether an ACO meets the CI/SEP criteria, CMS will use as a placeholder the most recent Total Quality Score an ACO has achieved for purposes of Final Financial Settlement for a past Performance Year. Once the

quality scores from the prior Performance Year are finalized as part of the Final Financial Settlement for the prior Performance Year, the quality benchmark for the Performance Year will be updated with the more recent placeholder score.



2. Additional Points for the Quality Score

To advance the CMS Innovation Center's goal of advancing evidence-based prevention, LEAD's quality measure set includes two new measures that require data derived from electronic medical records—Controlling High Blood Pressure and Diabetes: Glycemic Status Assessment Greater Than 9% for patients with diabetes—to direct LEAD ACOs' focus on preventing disease progression for two prevalent chronic conditions among Medicare beneficiaries. To support the collection and reporting of these measures, LEAD ACOs will have the opportunity to earn 2.5 additional percentage points to the Initial Quality Score per measure if they report these measures during PY 1 and PY 2 of model implementation. Over the course of LEAD's implementation, LEAD ACOs will be required to report these measures on a pay-for-reporting basis during PYs 3 and 4 and would transition to pay-for-performance during PY 5 through PY 10.

In addition, LEAD ACOs will be required to report their prevention intervention via the PQP. ACOs will earn 5 additional percentage points to the Initial Quality Score in PY 1 and PY 2; thereafter, ACOs would earn 10 percentage points per PY to the Initial Quality Score for PQP reporting. These points will be added after the ACO's Initial Quality Score and CI/SEP multiplier is applied to determine the ACO's Total Quality Score and final Quality Withhold Earn Back. As previously stated, points earned

when submitting the PQP materials will constitute the "PQP Reporting Adjustment" which will be used to calculate the final Quality Withhold Earn Back.

3. Calculating the ACO's Total Quality Score and Final Quality Withhold Earnings

A LEAD ACO's Total Quality Score is the sum of their Initial Quality Score divided by 100 to create a percentage figure then multiplied by their CI/SEP factor plus any additional points earned through the PQP reporting or optional measure reporting; this figure will not be allowed to exceed 100 total percentage points. The amount of the quality withhold that an ACO earns back would be calculated by multiplying the ACO's Total Quality Score by their 3% withhold from their financial Performance Year Benchmark.

4. High Performers Pool (HPP)

LEAD will further incentivize high performance and continuous improvement on LEAD's quality measure set through a High Performer's Pool (HPP). LEAD ACOs will qualify for a bonus from the HPP if they: Meet criteria to receive CI/SEP score of at least 1 or receive both a CI/SEP score of 0 and the full PQP Reporting Adjustment, and have an average percentile rank of 70% or more across the measures.

The HPP will be funded from the amount of the quality withholds not earned back by LEAD ACOs with 50% of the remaining, unearned withhold amount contributing to the HPP. For example, an ACO that earns back 2.85% of its 3% Performance Year Benchmark withhold contributes 50% of the remaining 0.15% of its Performance Year Benchmark withhold (that is, the remainder of its quality withhold) to the HPP. To account for potential variation in the size of organizations that may qualify to receive an HPP Bonus, the funds from the HPP will be distributed to ACOs proportionally, based on each qualifying ACO's overall number of beneficiary alignment-months in the Performance Year relative to the overall number of beneficiary alignment-months for all ACOs that qualify for this bonus. The highest performing ACOs may earn a net quality performance payment above their 3% Performance Year Benchmark withhold because of their high-quality performance and HPP Bonus.

D. Quality Monitoring

To ensure quality measures are reported accurately and completely, CMS may conduct data validation audits of ACO quality data. These audits may involve ad hoc or scheduled desk reviews, focused audits, or full audits. These efforts would be in addition to the overall program monitoring and oversight strategy described in Section XII.

XII. Participant Monitoring, Auditing and Terminations

A. General Monitoring Activities

Model Participants will be required to comply with rigorous safeguards that will be specified in the IP PA and the PY PA and must cooperate with CMS monitoring activities. Under the terms of the IP PA and the PY PA, LEAD ACOs will be required to have a compliance plan with at least the following attributes:

- Designated compliance officer, who is not legal counsel to the ACO and who reports directly to the ACO's governing body;
- Mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance;
- Compliance training for the ACO and its Participant Providers and Preferred Providers;
- A method for employees or contractors of the ACO, Participant TINs, Participant Providers, Preferred Providers, and other individuals or entities performing functions or services related to ACO activities to anonymously report suspected problems related to the ACO to the compliance officer; and
- A requirement for the ACO to report probable violations of law immediately to an appropriate law enforcement agency. The ACO's compliance plan must be updated, as necessary, to reflect changes in laws and regulations.

B. Remedial Actions for Noncompliance

Noncompliance with the terms of the IP PA and the PY PA will trigger appropriate actions based on the nature of the noncompliance, degree of severity, and the LEAD ACO's compliance record while in the model. If CMS determines that any provision of the PY PA may have been violated, CMS may take one or more of the following actions (note: only a subset of the following remedial actions would be relevant and, therefore, available to address violations of the terms of the IP PA):

- Notify the LEAD ACO and, if appropriate, the Participant TIN, Participant Provider, or Preferred Provider of the violation;
- Require the ACO to provide additional information to CMS or its designees;
- Conduct on-site visits, interview beneficiaries, or take other actions to gather information;
- Place the ACO on a monitoring and/or auditing plan developed by CMS;
- Require the ACO to remove Participant TINs or Preferred Providers from the Participant TIN List or Preferred Provider List and to terminate its arrangement, immediately or within a timeframe specified by CMS, with such Participant TIN or Preferred Provider, with respect to this model;
- Require the ACO to terminate its relationship with any individual or entity performing functions or services related to ACO activities or Marketing Activities;
- Prohibit the ACO from distributing Shared Savings to a Participant TIN or Preferred Provider;
- Request a corrective action plan (CAP) from the ACO that is acceptable to CMS, by a deadline established by CMS;
- Amend the PY PA without the consent of the ACO to deny, terminate, or amend the use of any Capitation Payment Mechanism or the APO by the ACO, Participant TINs, or Preferred Providers;
- Amend the PY PA without the consent of the ACO to deny, terminate, or amend the use of Enhanced PCC by the ACO, in which case, CMS will calculate PCC Payment without the Enhanced PCC;

- Prohibit the ACO from accessing any or all waivers of existing law made pursuant to section 1115A(d)(1) of the Act;
- Amend the PY PA without the consent of the ACO to deny the use of one or more Benefit Enhancements by the ACO or any Participant TIN or Preferred Provider and to require that the ACO terminate any agreements effectuating such Benefit Enhancements by a date determined by CMS;
- Prohibit the ACO, a Participant TIN or a Preferred Provider from furnishing any in-kind remuneration or from implementing one or more Beneficiary Engagement Incentives;
- Discontinue the provision of data sharing and reports to the ACO;
- Prohibit the ACO from participating in Paper-Based Voluntary Alignment, distributing Marketing Materials, or conducting Marketing Activities, including Voluntary Alignment Activities; and
- Retroactively reverse the alignment of Beneficiaries to the ACO that is based solely on Voluntary Alignment, to include Hybrid Alignment.

C. Termination of Model Participation

At any time, CMS may immediately or with advance notice terminate an ACO's IP PA or PY PA for non-compliance with the terms and conditions of the relevant agreement, or as otherwise specified in the IP PA or PY PA or required by section 1115A(b)(3)(B) of the Act.

An ACO may give CMS notice of termination at any time, with an effective date of termination at least 30 days after notice is given. Starting in the ACO's second Performance Year, the Termination Without Liability (TWL) deadline is the later of either: (1) February 28 of the Performance Year; or (2) 30 days after CMS distributes the Performance Year Benchmark Report for the Performance Year to the ACO, however, the TWL date will be no later than August 31 of a Performance Year even if it has not been 30 days since the Performance Year Benchmark Report for Performance Year has been distributed to the ACO. ACOs that provide notice of termination prior to the TWL date for a Performance Year with an effective termination date of no greater than 30 days after the TWL deadline will not be held financially liable for that Performance Year, meaning the ACO will not earn Shared Savings or owe Shared Losses for that year. There will be no TWL in an ACO's first Performance Year of participation. As discussed in Section VIII.F, ACOs that terminate participation on or before the TWL in their second PY will also be subject to the Retention Incentive.

XIII. Data Sharing and Reports

A. Data Sharing

The exchange of timely, appropriate and useful data continues to be a top priority for CMS. LEAD will build upon the data sharing strategies and data reports established in earlier Shared Savings initiatives and other Innovation Center models.

LEAD ACOs will have the opportunity to request several types of Medicare data related to beneficiaries aligned to the LEAD ACO to develop and implement care coordination and quality improvement activities. For the MPP, ACOs may request certain CMS data for clinical treatment, care management and coordination, quality improvement activities, population-based activities relating to improving health or reducing health care costs, and provider incentive design and implementation. The data may be used only in a manner consistent with the terms of the applicable CMS agreements and forms, including the PY PA and HIPAA-Covered Data Disclosure Request Form. All requests for data will be granted or denied at CMS's sole discretion based on CMS's available resources and technological capabilities, the limitations in applicable CMS agreements, and applicable law.

During each Performance Year, CMS will offer ACOs an opportunity to request certain beneficiary-identifiable data and reports.[26] The data that the ACO may request includes but is not limited to:

- Alignment reports describing the beneficiaries aligned to the ACO.
- Risk score reports that provide individual risk scores for each aligned beneficiary.
- Claim and Claim Line Feed (CCLF) files for services furnished by Medicare-enrolled providers and suppliers to aligned beneficiaries during the Performance Year. CMS will additionally permit ACOs to request historical CCLF files, which will capture a 36-month historical look-back of claims for newly aligned beneficiaries.
- Fee Reduction Files, including claim-level data, to assist the ACOs in implementing Capitation Payment Mechanisms and, if applicable, the Advanced Payment Option to support population-based activities to improve health care quality and outcomes.

CMS will also periodically provide aggregate reports that do not include beneficiary identifiable data. As with the beneficiary-identifiable reports described above, the reports below will be provided at CMS's sole discretion based on CMS's available resources and technological capabilities, the limitations in applicable CMS agreements, and applicable law. These aggregate, de-identified reports may include:

- Utilization and Expenditure data.
- Benchmark and other financial reports.
- Quality reports.

B. Data Suppression and Beneficiary Data Sharing Opt Out

ACOs will be required to provide aligned beneficiaries who inquire about or wish to modify their preferences regarding claims data sharing for care coordination and quality improvement purposes with information about how to modify their data sharing preferences and opt out of certain CMS data sharing with the ACO.

Reports containing individually identifiable data will not include beneficiaries who opt out of data sharing with the ACO. Moreover, LEAD will honor the data sharing opt-out decisions by beneficiaries

[26] Note: individually identifiable beneficiary data that CMS shares with ACOs for health care operations may not be used for marketing of non-ACO products or other purposes not specified in the PY PA.

who were previously given that choice while an aligned beneficiary in another Medicare Shared Savings initiative. Data sharing will be offered for all aligned beneficiaries who were either: (1) not previously aligned to any ACO; or (2) previously aligned to the ACO REACH Model ACO or another ACO and did not opt out of data sharing. A beneficiary who has opted out of data sharing remains aligned to the ACO. Aggregate reports will incorporate de-identified data from aligned beneficiaries who have opted out of data sharing. The data and reports provided to the ACO will also omit individually identifiable substance use disorder data for all beneficiaries. Aggregate reports will incorporate de-identified substance use disorder data.

Under the terms of the PY PA, if a Participant Provider is terminated from the ACO and an aligned beneficiary solely had a care relationship with that terminated Participant Provider and no other Participant Provider in the prior twelve months, CMS will suppress that beneficiary's identifiable data and not include it as part of the data sharing with the ACO. If another Participant Provider in the ACO establishes a care relationship with the beneficiary whose data is suppressed, data sharing of the beneficiary's identifiable data will be resumed with the applicable ACO.

Participant Providers and Preferred Providers will submit claims to the relevant Medicare Administrative Contractor (MAC) for services delivered to all aligned beneficiaries, including those who have opted out of CMS data sharing with the ACO or whose claims data are otherwise suppressed. These claims remain necessary for a number of purposes including claims-based alignment, risk adjustment, cost sharing, stop-loss, monitoring, and model evaluation. Additionally, services furnished to beneficiaries who have opted out of data sharing with the ACO or whose claims data are otherwise suppressed will still be included in the determination of the Performance Year expenditures that will be compared against the ACO's Performance Year Benchmark in the Financial Settlement process. However, claims for services furnished to a beneficiary who has opted out of claims data sharing with the ACO and claims for the diagnosis and treatment of a substance use disorder will not be subject to the ACO's selected Capitation Payment Mechanism or, if selected by the ACO, the Non-Primary Care Capitation Payment or Advanced Payment Option.

All ACOs must agree to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data received from CMS and to prevent unauthorized use or access to it, consistent with the HIPAA Privacy and Security Rules, 45 C.F.R. Part 160 and Part 164, Subparts A, C, and E and other applicable privacy and security requirements.

XIV. Evaluation

All ACOs will be required to cooperate with efforts to conduct an independent, federally funded evaluation of the model by CMS and/or its designees, which may include but is not limited to: participation in surveys; interviews; site visits; and other activities that CMS determines necessary

to conduct a comprehensive formative and summative evaluation.[27] The evaluation will assess the impact of LEAD on the goals of the model as well as how well the CARA initiative meets its goals. The evaluation will be used to inform policy makers about the effects of LEAD and the CARA initiative on beneficiary outcomes. To do so, the evaluation will seek to understand the behaviors of providers, suppliers, and beneficiaries; the impacts of financial risk; the effects of various payment arrangements, Benefit Enhancements, and Beneficiary Engagement Incentives; the impact of the model on beneficiary engagement and experience; and other factors associated with patterns of results. Each ACO must require its Participant TINs, Participant Providers and Preferred Providers to participate and cooperate in any such independent evaluation activities conducted by CMS and/or its designees. If an ACO, or the ACO's Participant TINs, Participant Providers, or Preferred Providers, does not provide the data necessary for CMS and/or its designees to complete the evaluation, upon request, CMS may terminate the ACO's PY PA.

XV. Additional CMS Supports

A. Tech Enabler

To facilitate the adoption of innovative tools, LEAD includes a Tech Enabler Initiative that is designed to reduce administrative barriers to adoption of technology that may improve outcomes and increase operational efficiencies for providers. CMS will work with provider organizations to identify high-value technology and artificial intelligence (AI) use cases, build out tech application requirements, and establish a channel for vendors to publicly share key features of their technology applications and how they support identified use cases and align with CMS tech application requirements. This process is intended to reduce the administrative burden of tech adoption for ACOs - particularly small, provider-led ACOs - to compare and select the numerous available technology applications and platforms. Adoption of the vendor technologies is completely optional for LEAD participants and will not affect or reflect any evaluation or determination by CMS.

In its early years, LEAD will prioritize 1-2 use cases where technology, including AI, may improve outcomes and increase efficiency for the different types of providers participating in LEAD. Technology use cases would be selected based on input from LEAD participants. Potential use cases could include but are not limited to:

- **Care Navigation:** Tech/AI-enabled care navigation for patients that help beneficiaries understand their health conditions and find high-value care and providers

[27] In accordance with 42 C.F.R. § 403.1110(b), "Any State or other entity participating in the testing of a model under section 1115A of the Act must collect and report such information, including 'protected health information' as that term is defined at 45 C.F.R. § 160.103, as the Secretary determines is necessary to monitor and evaluate such model. Such data must be produced to the Secretary at the time and in the form and manner specified by the Secretary."

- **Condition Management:** Digital tools and apps that connect care plans and help patients manage chronic conditions, such as tools that support healthy lifestyle changes for managing diabetes or cardio-metabolic health
- **Community Providers:** Digital tools that support ACOs in identifying, communicating, and contracting with community-based organizations.

B. Rapid Cycle Innovation Program

As part of learning and diffusion efforts to support LEAD model success, LEAD participants will have optional opportunities to conduct time-limited quality improvement tests—also called rapid randomized controlled trials (Rapid RCTs). Using rapid RCTs, participants can quickly assess the impact of specific prevention and care delivery strategies that align to their own goals and the goals of the model. Strategies found to be effective can then be rapidly shared with all eligible participants and the broader field where applicable.

For example, LEAD ACOs can conduct a test to identify the best method of engaging Participant Providers in their preventive care plans, how to optimize use of new technologies they are considering as an organization, or the best way to communicate with participating providers to encourage evidence-based chronic condition management or proactive preventive care. The time-bound, limited scope of the Rapid RCTs will complement the model evaluation by offering evidence to support participant performance more quickly and at a more tactical level. Rapid RCTs will also enable testing and diffusion of innovative strategies, including the waivers outlined in section VII.E. CMS will work with LEAD ACOs to confirm priority Rapid RCT topics that align to LEAD goals and support quality measures.

C. Learning System

CMS designs, implements, and manages a cross-model "learning system" that will be available to LEAD participants. This learning system uses quality improvement and implementation science principles, and integrates lessons learned from active and past CMS Innovation Center models, to accelerate successful model implementation and improve participant outcomes.

LEAD ACOs will have the opportunity to participate in various group-learning forums to share experiences and learn from their peers. This includes a virtual CMS platform that enables access to foundational resources while simultaneously providing a virtual infrastructure for peer-to-peer collaboration, networking, and real-time problem solving with participants in LEAD and other CMS Innovation Center models.

Appendix A: Glossary of Key Terms

ACCOUNTABLE CARE ORGANIZATION (ACO) has the meaning given at 42 C.F.R. § 425.20 and refers to a legal entity that is recognized and authorized under applicable State, Federal, or Tribal law, is identified by a TIN and is formed by one or more Participant TINs(s).

ACCOUNTABLE CARE PROSPECTIVE TREND (ACPT) has the meaning given at 42 C.F.R. § 425.660 and refers to a fixed projected growth rate determined at the beginning of the ACO's agreement period based on national fee-for-service Medicare expenditures projected by the CMS Office of the Actuary.

BASE YEARS are the three most recent calendar years before an ACO's first Performance Year. The most distant year is Base Year 1, the next year is Base Year 2, and the most recent year is Base Year 3. For example, for an ACO that begins LEAD participation in 2027, Base Year 1 is 2024, Base Year 2 is 2025, and Base Year 3 is 2026.

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 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 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: the term "Beneficiary Engagement Incentive" means beneficiary-level incentives ACOs are allowed to offer beneficiaries to facilitate access to high-value services, improve beneficiaries' health outcomes, or improve quality of life. Examples include the Chronic Disease Prevention Beneficiary Engagement Incentive, the Part B Cost Sharing Support Beneficiary Engagement Incentive, and the Substance Access Beneficiary Engagement Incentive. Acceptance into the LEAD Model is not contingent upon the ACO implementing any particular Beneficiary Engagement Incentive.

BENEFIT ENHANCEMENTS: CMS will use the authority under section 1115A(d)(1) of the Act to conditionally waive certain Medicare payment requirements in order to further emphasize high-value services and support the ability of ACOs to manage the care of beneficiaries. This suite of payment rule waivers is referred to as Benefit Enhancements. Acceptance into LEAD is not contingent upon the ACO implementing any particular Benefit Enhancement.

CMS-ADMINISTERED RISK ARRANGEMENTS (CARA) is a CMMI initiative and innovative payment system that will be nested within LEAD as a voluntary component offered to LEAD ACOs that elect the Global Risk Option. CARA seeks to facilitate greater and more robust relationships between LEAD

ACOs and their specialists and provider organizations by enabling episode-based risk arrangements between these entities and ultimately making CMS-administered payments to ACO and specialist participants.

COVERED SERVICES refers to the scope of health care benefits described in sections 1812 and 1832 of the Social Security Act for which payment is available under Part A or Part B of Title XVIII of the Social Security Act.

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. A discount may also be used as part of the pricing methodology for specialty episodes in the CMS Administered Risk Arrangements initiative, defined above. The discount percentage aims to balance savings for CMS with incentives and achievable targets for model participants.

DUAL ELIGIBLES Dual eligibles are individuals who are entitled to Medicare Part A and/or Part B and are eligible for some form of Medicaid benefit.

ENHANCED PRIMARY CARE CAPITATION AMOUNT refers to one of two components of the Primary Care Capitation Payment. The Enhanced Primary Care Capitation 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 Primary Care Capitation Amount that an ACO is eligible to receive is the larger of (1) the difference between 7% of the Performance Year Benchmark and the estimated Base Primary Care Capitation Amount, or (2) 2% of the Performance Year Benchmark. CMS will recoup the Enhanced Primary Care Capitation Amount in full at the close of the relevant Performance Year.

EPISODE means an episode of care, meaning the set of all medical services and supplies provided to a patient for a specific health condition or procedure over a defined period.

EPISODE-BASED COST MEASURES (EBCM) are CMS measures that assess the risk-adjusted cost to Medicare for items and services furnished under Medicare Parts A and B during a specific episode of care. EBCMs are a part of the Merit-based Incentive Payment System cost performance category that assesses the costs of care provided to Medicare patients.

EPISODE-BASED RISK ARRANGEMENTS (EBRA) are the financial partnerships between ACOs and independent specialists or provider organizations centered around episodes of care where the independent provider is accountable for the cost and quality of care delivered during specific clinical episodes for ACO-attributed beneficiaries.

FEE REDUCTION refers to a reduction in Medicare FFS payments to Participant Providers and relevant Preferred Providers who, pursuant to a written agreement with the ACO, have agreed to receive such reduced FFS payment for covered services furnished to LEAD Beneficiaries under the ACO's selected capitation payment mechanism.

FINANCIAL BENCHMARK refers to the cost target used to assess ACO's financial performance and eligibility for an earned Shared Savings payment.

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 the amount of Other Monies Owed, and calculates the net amount owed by either CMS or the ACO for the Performance Year.

FULL-BENEFIT DUAL ELIGIBLE INDIVIDUAL has the meaning given at 42 C.F.R. § 423.772 and refers to a dual eligible individual who is determined eligible by the State for medical assistance for full benefits under title XIX of the Social Security Act for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Social Security Act.

HIGH NEEDS POPULATION beneficiaries with complex health care needs who meet the high needs eligibility criteria for LEAD.

IMPLEMENTATION PERIOD PARTICIPATION AGREEMENT (IP PA) refers to the written agreement between the ACO and CMS that govern the ACO's participation in LEAD for the Implementation 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 participating in LEAD.

LEAD BENEFICIARY means a Medicare beneficiary who has been aligned to a LEAD ACO for a given Performance Year as described in Section VII.B of this document.

LEAD PARTICIPATION AGREEMENT CARA AMENDMENT (LPACA) is a formal agreement that eligible LEAD ACOs must execute to participate in the CMS-Administered Risk Arrangements (CARA) initiative. The LPACA formally establishes the ACO's commitment to participate in CARA, ensures the ACO has the appropriate risk-bearing capability through Global Risk Option election, grants access to advanced CARA module features necessary for episode-based risk arrangement formation, and provides the legal framework for CMS to support episode-based risk arrangements between the ACO and their specialty providers.

LOOKBACK PERIOD means the 12-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both.

MARKETING ACTIVITIES refers to distribution of marketing materials or other activities, including voluntary alignment activities, conducted by or on behalf of the ACO or its Participant Providers or Preferred Providers, when used to educate, notify, or contact beneficiaries regarding the ACO's participation in LEAD.

MARKETING MATERIALS refers to general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, webpages, mailings, social media, or other materials sent by or on behalf of the ACO or its Participant Providers or Preferred Providers when used to educate, notify, or contact beneficiaries regarding LEAD.

NEWLY ENTERING ACO refers to an ACO that meets all of the following three criteria: 1) the legal entity has not participated in an Medicare ACO initiative previously or currently; 2) less than 40% of the Participant TINs have participated in a Medicare ACO initiative in the past 5 years; 3) less than 50% of Participant Providers have participated in a Medicare ACO initiative in the past 5 years.

NON-PRIMARY CARE CAPITATION (NPCC) PAYMENT refers to a monthly prospective, population-based payment from CMS to an ACO for non-primary care services provided to aligned beneficiaries by all Participant Providers and those Preferred Providers who have opted to participate in this payment mechanism.

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.

OTHER MONIES OWED means any monetary amount owed to CMS by the ACO or vice versa that is neither Shared Savings nor Shared Losses.

OWNERSHIP INTEREST refers to possession of equity in the capital, the stock, or the profits of the subject entity.

PARENT COMPANY means the legal entity that exercises a controlling interest, through the ownership of shares, the power to appoint voting board members, or other means, in an organization, directly or through a subsidiary or subsidiaries, and which is not itself a subsidiary of any other legal entity.

PARTICIPANT PROVIDER means an individual or entity that: (1) is a Medicare-enrolled provider or supplier (as such terms are defined in 42 C.F.R. § 400.202); (2) is identified on the Participant TIN List by TIN or Legacy TIN (if applicable); (3) bills for items and services it furnishes to Original Medicare beneficiaries under a Medicare billing number assigned to a TIN in accordance with applicable Medicare regulations; (4) is not a Preferred Provider nor a Prohibited Participant; and (5) has agreed, pursuant to a written agreement with the ACO, to participate in the model and to comply with care improvement objectives and model quality performance standards.

PARTICIPANT TIN refers to an entity identified by a Medicare-enrolled billing TIN through which one or more Participant Providers bill Medicare, that alone or together with one or more provider/supplier

billing through the Participant TINs compose an ACO, and that is included on the Participant TIN List that is required under the PY PA.

PARTICIPANT TIN LIST refers to the list of Participant TINs that are participating in LEAD with a given ACO during the Performance Year and their TIN is included on the list.

PERFORMANCE-BASED RISK refers to an initiative implemented by CMS that requires an ACO to participate under a two-sided model during its agreement period.

PERFORMANCE YEAR BENCHMARK refers to a risk-adjusted and trended estimate of expected Medicare Part A and Part B expenditures for an ACO's assigned beneficiary population during a specific Performance Year, constructed according to LEAD's financial methodology.

PERFORMANCE YEAR PARTICIPATION AGREEMENT (PY PA) refers to the written agreement between the ACO and CMS that govern the ACO's participation in LEAD for the Performance Year.

PERSON OR ENTITY WITH AN OWNERSHIP OR CONTROL INTEREST refers to a person that (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.

PREFERRED PROVIDER means Medicare provider or supplier that: (1) is a Medicare-enrolled provider (as defined at 42 C.F.R. § 400.202) or supplier (as defined in 42 C.F.R. § 400.202); (2) is identified on the ACO's Preferred Provider List by name, NPI, individual TIN, organizational TIN, Legacy TIN or CCN (if applicable), and CMS Certification Number (CCN) (if applicable); (3) bills for items and services it furnishes to Original Medicare beneficiaries under a Medicare billing number assigned to a TIN in accordance with applicable Medicare regulations; (4) is not a Participant Provider nor a Prohibited Participant; and (5) has agreed to participate in the model pursuant to a written agreement with the ACO.

PREFERRED PROVIDER LIST refers to the list that identifies each Preferred Provider that is approved by CMS for participation in LEAD 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 in which each Preferred Provider participates, as updated from time to time in accordance with the model PY PA.

PRIMARY CARE CAPITATION (PCC) PAYMENT refers to a monthly prospective, population-based payment from CMS to an ACO for primary care services provided to aligned beneficiaries by all Participant Providers and those Preferred Providers who have opted to participate. The Primary Care Capitation Payment amount for an ACO 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 Primary Care Capitation Amount.

PRIMARY CARE CAPITATION PAYMENT- ELIGIBLE SERVICES means the set of services furnished by a PCC-Eligible Provider/Supplier on behalf of a PCC-Eligible Participant and include the list of current procedural terminology (CPT40)/healthcare common procedure coding system (HCPCS) codes listed in Appendix D.

PRIMARY CARE QUALIFIED EVALUATION AND MANAGEMENT (PQEM) SERVICES means a claim for a primary care service provided by a primary care specialist or one of the selected non-primary care specialists and identified by the Healthcare Common Procedure Coding System (HCPCS) codes listed in Appendix C.

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; and/or (4) excluded or otherwise prohibited from participation in Medicare or Medicaid.

RENEWING ACO refers to an ACO that meets one or more of the following three criteria: 1) the legal entity has participated in an Medicare ACO initiative previously or currently; 2) 40% or more of the Participant TINs have participated in a Medicare ACO initiative in the past 5 years; 3) 50% or more of Participant Providers have participated in a Medicare ACO initiative in the past 5 years.

SHARED LOSSES means any monetary amount owed to CMS by the ACO due to expenditures for Medicare Parts A and B items and services furnished to LEAD Beneficiaries during a Performance Year (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 Performance Year benchmark for that Performance Year. CMS determines Shared Losses in accordance with the ACO's selected risk sharing option and selected capitation payment mechanism.

SHARED SAVINGS means the monetary amount owed to the ACO by CMS due to expenditures for Medicare Parts A and B items and services furnished to LEAD Beneficiaries during a Performance Year (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) that are lower than the ACO's final Performance Year Benchmark for that Performance Year. CMS determines Shared Savings in accordance with the ACO's selected risk sharing option and selected capitation payment mechanism.

TAXPAYER INDENTIFICATION NUMBER (TIN) has the meaning given at 42 C.F.R. § 425.20 and refers to a Federal taxpayer identification number or employer identification number.

TERMINATION WITHOUT LIABILITY (TWL) LEAD allows ACOs to terminate its written agreement with CMS by a certain date (i.e., the TWL Date) to avoid liability for Shared Losses for that Performance Year. The TWL Date for a Performance Year is the later of either: a) February 28 of the Performance Year or b) 30 Days after CMS distributes the Performance Year Benchmark Report for the Performance Year to the ACO. The TWL Date will be no later than August 31 of a Performance Year. There is no Termination Without Liability Date for the ACO's first Performance Year. ACOs must request TWL in writing.

TOTAL CARE CAPITATION (TCC) is a per-beneficiary, per-month capitated payment for all services provided to aligned beneficiaries by all Participant TINs and those Preferred Providers who have opted to participate in TCC Payment. This capitation payment mechanism is only available to ACOs participating in Global Risk.

VOLUNTARY ALIGNMENT means the process whereby CMS aligns to an ACO those beneficiaries who have designated a Participant TIN or Provider/Supplier 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.

Appendix B: Application Questionnaire

CMS will safeguard any information submitted in accordance with applicable federal privacy and security laws, regulations, and CMS policies.
The application can be found and completed at: https://app.innovation.cms.gov/LEAD/IDMLogin.

CMS provides no opinion on the legality of any contractual or financial arrangement that the applicant may disclose, propose, or document in this application. The receipt by CMS of any such information in the course of the application process or otherwise shall not be construed as a waiver or modification of any applicable laws, rules, or regulations, and will not preclude CMS, HHS, the HHS 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.

Questions about the application for the LEAD Model should be directed to LEAD@cms.hhs.gov.

ACO LEGAL ENTITY INFORMATION
Confirm ACO Legal Entity Information

1. Applicant Organization Information:
   Note: If your organization is not listed in the "Legal Entity Name" search, choose "+ New Organization" to add a record. Contact the CMMI Help Desk at CMMIForceSupport@cms.hhs.gov to make changes to the existing organizational information.
   * Legal entity name:
   * Trade name/doing business as (DBA) name:
   * Street Address:
   * City:
   * State:
   * Zip Code:
   * Taxpayer identification number (TIN):
   *Dun & Bradstreet Number System (DUNS), if applicable:
   *Applicant organization website:

Contact Information

2. Please provide contact information for your organization's representatives. There must be at least one person per role and the same person may be identified for multiple roles.

Role	**Name**	**Title**	**Phone**	**Email**	**Application POC? Y/N**
Executive Contact					

Entity Primary Contact					
Entity Secondary Contact					
IT/Technical Contact					

ACO Organization Profile

3. Identify what type of entity best describes the applicant ACO. (Note: describe the applicant ACO itself, not the individuals and entities the applicant ACO expects will provide Primary Care Services). Check only one:
    - Medical group practice
    - Network or group of physician practices (e.g. an Independent Practice Association, or IPA, with a contractual agreement to provide health care for patients in a health plan network or integrated system)
    - Hospital system(s)
    - Integrated delivery system
    - Partnership of hospital system(s) and medical practices
    - Management services organization / 'convener' (i.e., an organization that provides administrative and supportive services to facilitate the participation of Medicare-enrolled providers or suppliers in value-based care).
        - If yes, Management Services Organization / 'convener' name:
    - Insurer
    - Other (please describe):

4. Select the alignment frequency for PY 2027. Options include:
    - **Prospective alignment**- claims-based alignment conducted annually, prior to the start of each PY.
    - **Hybrid alignment**- claims-based alignment conducted for new TINs added during bi-annual TIN addition opportunity plus voluntary aligned beneficiaries added on a monthly basis.

5. Select whether the Applicant ACO expects that 40 percent or more of its aligned beneficiaries will be High Needs.
    - Yes
    - No

6. ACOs that are seeking to qualify as High Needs ACOs must offer certain care delivery capabilities. If the applicant ACO is seeking to qualify as a High Needs ACO, please describe how the Applicant will fulfill the following requirements:
   - 24/7 access to a healthcare provider with access to patients' electronic medical record
   - Providers with training in advanced care planning conversations
   - The ability to deliver care in patients' homes

7. Select whether the ACO expects to be a lower-spending or a higher-spending ACO, per Section V.B of the RFA. CMS is asking this question for forecasting purposes, but an ACO's final designation under the model will be determined by an analysis conducted by CMS. There is no penalty for selecting a response to this question that differs from CMS's final determination.
   - Higher-spending ACO
   - Lower-spending ACO

   7b. Please provide an explanation for why the Applicant expects to be a higher-spending or lower-spending ACO.

8. Select the risk option for PY 2027. Options include:
   - **Professional Risk Option**- eligible to receive up to 50% of total savings subject to symmetrical risk share corridors relative to their established PY Benchmark. Also liable for up to 50% of total losses relative to their established PY Benchmark. ACOs electing the Professional Risk Option must remain in this risk option for at least 4 PYs before moving to the Global Risk Option. Professional Risk Option is not subject to a discount rate.
   - **Global Risk Option**- eligible for up to 100% of savings relative to their established PY benchmark. Also liable for up to 100% of total losses relative to their established PY Benchmarks. Only those ACOs participating in the Global Risk Option would be eligible to receive a positive regional efficiency adjustment.

9. Select the Prospective Payment for PY 2027. Options Include:
   - **Primary Care Capitation**- A per-beneficiary, per-month (PBPM) capitated payment for primary care services provided to aligned beneficiaries by all Participant TINs and those Preferred Providers who have opted to participate in PCC Payment.
   - **Total Care Capitation**- A PBPM capitated payment for all services provided to aligned beneficiaries by all Participant TINs and those Preferred Providers who have opted to participate in TCC Payment. This Capitation Payment Mechanism is only available to ACOs participating in Global Risk Option.
   - **Non-Primary Care Capitation**– A PBPM capitated payment for all services provided to aligned beneficiaries by non-primary care Preferred Providers who have opted to

participate in NPCC Payment. This payment option can only be selected by ACOs that have also chosen the PCC.

- **Advanced Payment Option**– A PBPM advanced payment for all services provided to aligned beneficiaries by non-primary care Preferred Providers who have opted to participate in the APO. This payment option can only be selected by ACOs that have also chosen the PCC.

*Accepted applicants will have the opportunity to request to change these selections by a deadline specified by CMS prior to beginning performance; such request will be subject to CMS for approval.

10. The CMS Innovation Center will test the CMS-Administered Risk Arrangements (CARA) Initiative as a voluntary component within the LEAD Model. CARA will facilitate downstream episode-based risk arrangements between ACOs and their specialists and provider organizations through CMS-administered payments. Beginning in PY2027, all LEAD ACOs will be able to request certain episodic data and pricing information from CMS for acute medical, procedural, and chronic condition episode-based cost measures (EBCMs). Eligible LEAD ACOs can use this CMS-provided data to identify specialists and provider organizations for downstream episode-based risk arrangements. CMS will administer payments based on terms negotiated between participating LEAD ACOs and the specialists/provider organizations with whom they form episode-based risk arrangements. Participation is only applicable to ACOs who meet CARA eligibility requirements:

    1. An ACO must sign the LEAD Model Participation Agreement; and

    2. An ACO must participate in the Global Risk Option.

    If your ACO is interested in receiving more information about the CARA Initiative select "Yes". Select "No" if you do not wish to receive more information about CARA. Selecting "No" will not have an impact on an ACO's ability to participate in CARA.

    - Yes
    - No

11. CMS will select two states to test LEAD Medicare-Medicaid integration features. During an initial planning phase beginning with the release of this Request for Applications and running through December 2027, CMS will identify two states that are interested in partnering to test this component of LEAD and work with selected states to develop the framework for ACO-Medicaid partnership arrangements. This framework will help define how ACOs and state Medicaid agencies (SMAs) or Medicaid managed care organizations (MCOs) can work together to exchange data, coordinate care to improve outcomes, including preventing avoidable hospitalizations and helping patients remain engaged in their communities, and potentially share in savings generated by the partnership. Pending successful completion of the planning period, ACOs in the selected states would have the opportunity to enter partnership arrangements with SMAs or MCOs.

If your ACO is potentially interested in entering a Medicaid partnership arrangement if this option becomes available in your state, please select "yes." Otherwise select "no." Your selection is non-binding and will not have an impact on an ACO's ability to participate in a Medicaid partnership arrangement.

- Yes
- No

12. Provide an executive summary describing the applicant ACO including: a narrative description of entities and individuals that comprise the ACO, the history / context surrounding the formation of the ACO, the ACO's strategy and goals, the ACO's planned focus (geographic, beneficiary populations, planned care coordination, etc.), and the historical and expected role of the applicant ACO relative to the individuals and entities the applicant ACO expects will be Participant TINs (e.g., the ACO's experience providing direct patient care vs providing supportive services to Medicare healthcare providers).

13. Complete whether the applicant ACO previously participated in any of the Shared Savings initiatives and/or CMMI Models below:

Model/Program	**X if applicable and complete remaining fields**	**Contract ID, if applicable**	**Date Range**
Accountable Health Communities Model			
Achieving Healthcare Efficiency through Accountable Design (AHEAD) Model			
ACO Investment Model (AIM)			
ACO Primary Care Flex (ACO PC Flex) Model			
ACO REACH			
Advance Payment ACO Model			
Care Management for High-Cost Beneficiaries Demonstration			
Comprehensive ESRD Care (CEC) Model			
Comprehensive Kidney Care Contracting (CKCC) Options of			

Model/Program	X if applicable and complete remaining fields	Contract ID, if applicable	Date Range
the Kidney Care Choices (KCC) Model			
Comprehensive Primary Care (CPC) Initiative			
Comprehensive Primary Care Plus (CPC+) Model			
Guiding an Improved Dementia Experience (GUIDE) Model			
Independence at Home Medical Practice Demonstration (IAH)			
Kidney Care First (KCF) Option of the KCC Model			
Maryland Total Cost of Care Model, Maryland Primary Care Program			
Medicare Shared Savings Program (Shared Savings Program)			
Multi-payer Advanced Primary Care Practice Demonstration with a Shared Savings arrangement (MAPCP)			
Program of All-Inclusive Care for the Elderly (PACE)			
Pioneer ACO Model			
Physician Group Practice Transition Demonstrations			
Primary Care First (PCF) Model Options			
Vermont Medicare ACO Initiative			

14. Describe the applicant ACO's relationship (e.g., geographic, years of experience, relative dominance in major areas of service delivery, ownership interest) to other health care entities in its market. Please include information on the applicant ACO's market share in its primary service area for professional and hospital services and on organizations that are considered main competitors in the applicant ACO's primary service area. (3000 Characters)

FINANCIAL GUARANTEE

An ACO that participates in the LEAD Model must secure a financial guarantee to ensure CMS is able to recoup amounts owed to CMS under the model. If an applicant ACO is selected to participate in the model, the ACO must submit draft and final financial guarantee documentation for CMS review and approval. As detailed in Section IX.E of the RFA, ACOs that elect to receive the Enhanced Primary Care Capitation have the option to secure a separate financial guarantee (one to cover Enhanced Primary Care Capitation and another to cover Shared Losses and the base Primary Care Capitation amount).

CMS will estimate an applicant ACO's financial guarantee amount based on beneficiary alignment estimates from providers on the Participant TIN List, due to CMS on August 3, 2026, risk sharing elections from this application and other relevant data. CMS anticipates this information will be provided to ACOs in Q4 2026. Financial guarantees will be due December 31, 2026 via 4i.

LEAD will have a mandatory draft period for financial guarantees, meaning LEAD ACOs will be required to submit draft financial guarantees for CMS to review. The due date for draft financial guarantees will be shared after ACOs are accepted into LEAD. The purpose of the draft is to correct any deficiencies in language ahead of the deadline. A template with the draft financial guarantee language will be made available to accepted ACOs by August 3, 2026.

I acknowledge that, if selected to participate in the LEAD Model, a financial guarantee is a requirement of participation, and that documentation of compliance with this requirement is due to CMS by December 31, 2026.

[ ] I agree to the above statement

Select the Financial guarantee(s) that your ACO intends to use to repay CMMI for any Shared Losses or Other Monies Owed.

a. Funds placed in escrow
b. Surety bond
c. A line of credit that the Medicare program can draw upon, as evidenced by a letter of credit
d. A combination of the above options (for ACOs electing to obtain a separate guarantee for the Enhanced Primary Care Capitation)
e. Unknown

ORGANIZATIONAL READINESS

Incorporation, Licensure, and Structure

1. Please attach a proposed organizational chart for the applicant ACO. The proposed organizational chart should depict the legal structure and the proposed operational composition of the ACO itself, including the proposed governing body; the leadership team; any relevant operating bodies or committees (e.g., compliance team, data team); persons with an ownership or control interest (as defined in Appendix A of the RFA) in the ACO; and any individuals or entities that the applicant ACO expects will perform functions or services related to the applicant ACO's participation in the LEAD Model (e.g., third party vendors, partners). Note: Inclusion of the individuals and entities the applicant ACO expects will be primary care providers in the proposed organizational chart for the applicant ACO is optional.

2. Complete and upload the Ownership Interest template to provide CMS with a full and complete understanding of the ownership interests in the applicant ACO, as well as the ownership interests in the entities with an ownership interest in the applicant ACO. Each party with at least 5% ownership interest in the applicant ACO should be listed.

Table 1. Ownership and Control Interests:

Name of person	Percent ownership interest in the Applicant ACO	Type; select from: -Private individual -Publicly traded company -Privately held company -Investment firm (private equity, venture capital, etc.) -Other (please describe)	If privately held company, investment firm, or other, please provide a complete description of all ownership interests in the privately held company, investment firm, or other, including their name, percent ownership and description (private individual, public company, private company, investment firm, other)*

Note: If a privately held company with an ownership or control interest in the applicant ACO is a subsidiary of another privately held company, please also list the Parent Company(ies) and ownership interests in that privately held (parent) company.

Leadership Team

3. Indicate whether the applicant ACO has or will have a leadership team exclusive to the ACO.

- Yes
- No

4. Complete the table below with information specific to the applicant ACO's proposed leadership team. The leadership team may include, but is not limited to: Key Executives (as that term is defined in Appendix A of the RFA); finance officers; clinical improvement officers; compliance officers; information systems leadership; and the individual responsible for maintenance and stewardship of clinical data. For each identified leadership team member, please attach a resume or curriculum vitae (CV). If specific individuals have not yet been identified, please provide the anticipated date by which the individual will be identified and indicate the "Position/Role" intended for the TBD individuals to serve.

   Indicate whether the individual has an ownership or control interest in the applicant ACO or is a person with an ownership or control interest in an entity that the applicant ACO expects will be a Participant TIN that includes a primary care provider. If so, please indicate the entity in which the individual has an ownership or control interest and identify the nature and amount of the ownership or control interest.

   Table 2. Applicant ACO's Proposed Leadership Team

Leadership Team Member	Position/Role	CV or resume attached	Ownership or control interest	

   For each individual included on the proposed leadership team, please select an option that best describes each individual:

   - The individual has ownership or control interest in the applicant ACO;
   - The individual has ownership or control in an entity that the applicant ACO expects will be a Participant TIN that includes a primary care provider; or
   - Not applicable.

   If the individual has ownership or control interest, indicate the entity and identify the nature and amount of the ownership or control interest. (1000 characters)

Governing Body

5. Complete the table below with information specific to the applicant ACO's proposed governing body. If the applicant ACO expects an individual to be a primary care provider or a representative thereof, please also provide the legal name of the entity under which the individual is expected to participate in the ACO. If specific individuals have not yet been identified, please provide the anticipated date by which the individual will be identified and indicate the "Position/Role" you intend for the TBD individuals to serve.

Table 3. Applicant ACO's Proposed Governing Body

Name	Legal Business Name (if applicable)	Title of Role	CV or resume attached	Percent of Board Control	*Other Board commitment(s)	**Ownership or control interests

- Is the individual currently serving or will be concurrently serving on another governing body?
    - Yes
    - No
    - Not applicable
- Select an option that best describes the individual:
    - The individual has ownership or control interest in the applicant ACO
    - The individual has ownership or control in an entity that the applicant ACO expects will be a Participant TIN that includes a primary care provider
    - Not applicable
- If the individual has ownership or control interest, indicate the entity and identify the nature and amount of the ownership or control interest. (1000 characters)

Oversight and Representation

6. Upload the compliance plan intended for use by the applicant ACO and specify whether the proposed compliance officer reports directly to the proposed governing body. Note: A tip sheet for creating a LEAD Model compliance plan is available on the LEAD Model website.

7. Please describe how responsibilities and accountability will be shared across the leadership team and governing body structures in the applicant ACO. Please also describe how the leadership team and/or governing body structures will inform the owners of the applicant ACO regarding the applicant ACO's performance in the LEAD Model and the activities the applicant ACO is undertaking for the purpose of its participation in the LEAD Model. (3000 Characters)

8. ACOs must choose to engage beneficiaries in their governance process through one of the channels described below. Select the option which the ACO will include:

- Beneficiary Representation on Governance Body:
    - At least one of the individuals serving on the governing body as a Medicare beneficiary must hold voting rights. Caregivers may serve in the beneficiary's place if that is a more suitable fit for the governing body. In cases where beneficiary representation on the ACO governing body is prohibited by state law, the ACO shall opt for the second option to meet this requirement (Beneficiary and Consumer Advisory Committee).

- Beneficiary and Consumer Advisory Committee:
    - The advisory committee must be a reasonably representative sample of an ACO's aligned beneficiaries, reflecting their geography and demographics, with a minimum of 5 members.
    - The advisory committee must meet regularly (at least twice per year) and document their meetings.

  Please describe how the governing body will ensure that the interests of beneficiaries and providers and suppliers will be represented adequately. Specifically, explain how the Medicare beneficiary or caregiver will participate in the governing body. If the ACO has opted to use an independent beneficiary advisory committee created by the ACO, please explain how the ACO will incorporate the feedback from the committee into the ACO Governance process. Please describe any means by which the applicant ACO will ensure beneficiary representation and/or consumer representation (e.g., through a committee, meeting and/or communication infrastructure), and the rationale for the proposed or existing composition of the governing body and voting power distribution. (3000 characters)

Disclosures

9. Disclose the following with respect to the applicant ACO, persons with an ownership or control interest (as defined in Appendix A of the RFA) in the applicant ACO, Key Executives (as defined in Appendix A of the RFA), equity partners (e.g., private equity or venture capital), and individuals and entities that the applicant ACO expects will be a Participant TIN, that includes Participant TINs, and Preferred Providers (if applicable): (i) any sanctions or corrective action plans imposed under Medicare, Medicaid, or state licensure authorities within the last three years (including corporate integrity agreements); (ii) any fraud investigations initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to the Medicare program, including any debts owed under an Innovation Center model, or any agency of the federal government; (iv) any awards of a CMS contract in the past 5 years, and, if applicable, the contract number and period of performance for such award; (v) whether any such individuals or entities are on a government suspension, debarment, or exclusion list relating to procurement and non-procurements; (vi) any instances of criminal conduct; and (vii) any instances of bankruptcy.

Table 4. Program Integrity Information

Individual or entity	Federal or State Agency or Accrediting Body	Description of Infraction (including date)	Resolution Status (including date)

Information on ACO partners / vendors

10. In the table below, please list separately any core ACO functions, including, but not limited to, beneficiary engagement and communication, care coordination, marketing, data and analytics, provider contracting, financial analysis and management, payment processing, and legal and compliance, that the applicant ACO expects will be contracted out and performed by a third party partner or vendor. For each expected function that will be contracted out please complete the additional fields.

Table 5. Functions Performed by Third Party Partners or Vendors

Core Function	Activity Description	Expected contract size ($/year) and duration	Third party partner or vendor name (if known)	If a vendor is identified, has the vendor been involved in either (1) any fraud investigations initiated, conducted, or resolved within the last five years, or (2) any instances of criminal conduct?

REVENUE SOURCES AND PAYMENT ARRANGEMENTS

Revenue Sources

1. What percentage of the applicant ACO's total clinical revenues in the last fiscal year was derived from the following sources?

   Note: The applicant ACO may approximate this through summation of revenue received by all individuals and entities the applicant ACO expects will be Participant TIN and Preferred Providers:

   - Original Medicare
   - Medicare Advantage
   - Other Medicare health plan (e.g., PACE, Medicare cost plans)
   - Medicaid
   - TRICARE
   - Indian Health Service
   - Commercial health plans
   - Self-pay patients
   - Other
     - Describe your other source:

   TOTAL = 100

2. Please describe up to five instances of the Applicant ACO's performance under prior or current outcomes-based contracts by completing the Outcomes-Based Contracts Template as follows:

   - Under "Arrangement," please provide a name for the arrangement, if applicable: if not, simply number the arrangement.
   - Under "other party(ies)," please identify the other entity with whom the Applicant ACO entered into the arrangement (whether a payer, a provider/supplier entity, CMS or CMMI, etc.). Please specifically note any proposed Participant TINs or Preferred Providers.
   - Under "Number of Years," please indicate whether the Applicant ACO serves as the primary administrator or operator of the arrangement, whether some or all of the Applicant ACO's proposed Participant TINs or Preferred Providers participated in the arrangement as direct patient care providers, or both, or otherwise describe the functions and services the Applicant ACO was contracted to provider.
   - Under "Number of Beneficiaries," please indicate the number of beneficiaries included in the arrangement if the arrangement spanned a single year, or, if the arrangement spanned multiple years, the annual average number of beneficiaries included.
   - Under "Scope," please provide details on the elements covered in the arrangement (e.g., risk and accountability, payment mechanism or approach, whether there were quality incentives).
   - Under "Results," please indicate gross or Shared Savings generated, data on cost reduction and/or improvement in quality outcomes, or other measures of success.

   Please provide numerical data where possible. Note: If your Applicant ACO does not have any prior or current ACO experience, please upload a blank template. Only 1 file is permitted to be uploaded for this question.

Implementation Plan

3. Describe, in detail, how the applicant ACO intends to fund and structure its prospective payments with Participant TINs and Preferred Providers, if applicable, in the LEAD Model. In providing a response, please address the following:

   How will the applicant ACO implement the prospective payments made by CMS to support team-based care and provide independent practices and primary care providers cash flow for investments in operations? (3000 Characters)

   How will the applicant ACO use any revenue from prospective payments not distributed to Participant TINs and Preferred Providers? (3000 Characters)

BENEFICIARY AND CAREGIVER EXPERIENCE

1. Describe the applicant ACO's historical and planned care delivery activities. (e.g. workflows, care pathways, protocols, screening, interprofessional team processes, education, risk assessments, patient optimization, etc.) (3000 characters)

2. Describe the applicant ACO's historical and planned approaches to improving beneficiary access to care. (3000 characters)

PREVENTATIVE CARE

1. Describe how the applicant ACO plans to incentivize preventative, coordinated care while empowering beneficiaries to take greater control of their health. In particular, describe how the expected mix of providers and suppliers will allow the applicant ACO to ensure that it will serve Medicare patients, achieve the goals of the LEAD Model as described in the RFA, and otherwise reduce health care costs and improve beneficiary quality of care and address health disparities. (3000 Characters)

2. Describe the applicant ACO's historical and planned approach for delivering coordinated, proactive, and preventative care. Please describe the roles the applicant ACO plans to establish within a care team, examples of specific care improvement interventions and preventative measures they could undertake, and the process by which the care team will communicate with for proactive care. (3000 characters)

DATA AND HEALTH INFORMATION TECHNICAL CAPABILITIES

1. Describe the applicant ACO's current capabilities to utilize tools to ingest bulk Medicare claims data related to the applicant ACO's assigned population for purposes of clinical treatment, care management and coordination, quality improvement activities, population-based activities relating to improving health or reducing health care costs, and provider incentive design and implementation. In providing a response, please address whether the applicant ACO's current software can ingest, process, and transmit data in a Fast Healthcare Interoperability Resources (FHIR®)-compliant format. Describe the applicant ACO's experience developing and/or using application programming interfaces (APIs) to ingest, transmit, or otherwise use data. (3000 characters)

2. Describe the applicant ACO's capabilities and ability to securely transfer patient data and care plans between health care settings both inside and outside the applicant ACO for purposes of care management and care coordination. (3000 characters)

Data and Health Information Technology to Inform Clinical Care

3. Describe the applicant ACO's and expected Participant TINs current ability to use electronic health record (EHR) data and digital tools to understand patient risk, risk stratify patients, and use this information for decision-making. (3000 characters)

4. Describe the applicant ACO's historical and planned use of health information technology (health IT) tools, including internally and to support Participant TINs, Preferred Providers and beneficiaries. (3000 characters)

Attestation and Signature

I have read the contents of this application. By my signature, I certify to the best of my knowledge, information, and belief that the information contained herein is true, correct, and complete, that I am authorized to sign this application on behalf of the ACO. I authorize the Centers for Medicare & Medicaid Services (CMS) to verify this information. If I become aware that any information in this application is not true, correct, or complete, I agree to notify CMS of this fact immediately and to provide the correct and/or complete information.

[signature block]

Appendix C. Specialty and HCPCS Codes Used for Beneficiary Alignment

Table C1: Codes Used to Identify Primary Care Specialists

Code[28]	Specialty
1	General Practice
8	Family Medicine
11	Internal Medicine
37	Pediatric Medicine
38	Geriatric Medicine
50	Nurse Practitioner
89	Clinical Nurse Specialist
97	Physician Assistant

Table C2: Codes Used to Identify Selected Non-Primary Care Specialists

Code	Specialty
6	Cardiology
10	Gastroenterology
12	Osteopathic manipulative medicine
13	Neurology
16	Obstetrics/gynecology
17	Hospice and palliative care
23	Sports medicine
25	Physical medicine and rehabilitation
26	Psychiatry
27	Geriatric psychiatry
29	Pulmonology

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

39	Nephrology
44	Infectious disease
46	Endocrinology
66	Rheumatology
70	Multispecialty clinic or group practice
79	Addiction medicine
82	Hematology
83	Hematology/oncology
84	Preventative medicine
90	Medical oncology
98	Gynecological/oncology
86	Neuropsychiatry

Table C3: PQEM Codes used for Claims-Based Alignment

(subject to slight modifications ahead of each Performance Year)

HCPCS	Long Descriptor
96160	Administration of patient-focused health risk assessment instrument
96161	Administration of caregiver-focused health risk assessment instrument
99201	New Patient, brief
99202	New Patient, limited
99203	New Patient, moderate
99204	New Patient, comprehensive
99205	New Patient, extensive
99211	Established Patient, brief
99212	Established Patient, limited
99213	Established Patient, moderate
99214	Established Patient, comprehensive
99215	Established Patient, extensive
99304	Initial Nursing Facility Care
99305	Initial Nursing Facility Care
99306	Initial Nursing Facility Care
99307	Subsequent Nursing Facility Care
99308	Subsequent Nursing Facility Care
99309	Subsequent Nursing Facility Care

HCPCS	Long Descriptor
99310	Subsequent Nursing Facility Care
99315	Nursing Facility Discharge Services
99316	Nursing Facility Discharge Services
99318	Other Nursing Facility Care
99324	New Patient, brief
99325	New Patient, limited
99326	New Patient, moderate
99327	New Patient, comprehensive
99328	New Patient, extensive
99334	Established Patient, brief
99335	Established Patient, moderate
99336	Established Patient, comprehensive
99337	Established Patient, extensive
99339	Brief
99340	Comprehensive
99341	New Patient, brief
99342	New Patient, limited
99343	New Patient, moderate
99344	New Patient, comprehensive
99345	New Patient, extensive
99347	Established Patient, brief
99348	Established Patient, moderate
99349	Established Patient, comprehensive
99350	Established Patient, extensive
99354	Prolonged visit, first hour
99355	Prolonged visit, additional 30 mins
G2212	Prolonged visit, additional 15 mins
99421	Online digital, Established Patient, 5–10 mins
99422	Online digital, Established Patient, 10–20 mins
99423	Online digital, Established Patient, 21+ mins
99424	Principal Care Management (PCM)
99425	Principal Care Management (PCM)
99426	Principal Care Management (PCM)
99427	Principal Care Management (PCM)
99437	Principal Care Management (PCM)
99441	Phone, Established Patient, 5–10 mins
99442	Phone, Established Patient, 10–20 mins
99443	Phone, Established Patient, 21+ mins
GFCI1	Post-Discharge Telephonic Follow-up Contacts Intervention
G2010	Remote evaluation, Established Patient
G2012	Brief communication technology-based service, 5-10 mins of medical discussion
G2252	Brief communication technology-based service, 11-20 minutes of medical discussion
99457	Remote Physiologic Monitoring

HCPCS	Long Descriptor
99458	Remote Physiologic Monitoring
G9481	Remote in-home visit for the evaluation and management of a new patient for use only in a Medicare-approved CMS Innovation Center demonstration project, which requires these 3 key components: a problem focused history; a problem focused examination; and straightforward medical decision making, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are self limited or minor. typically, 10 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology or just “Remote e/m new pt 10mins” for short, used in Medical care.
G9482	Remote in-home visit for the evaluation and management of a new patient for use only in a Medicare-approved CMS Innovation Center demonstration project, which requires these 3 key components: an expanded problem focused history; an expanded problem focused examination; straightforward medical decision making, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of low to moderate severity. typically, 20 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology.
G9483	Remote in-home visit for the evaluation and management of a new patient for use only in a Medicare-approved CMS Innovation Center demonstration project, which requires these 3 key components: a detailed history; a detailed examination; medical decision making of low complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of moderate severity. typically, 30 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology
G9484	Remote in-home visit for the evaluation and management of a new patient for use only in a Medicare-approved CMS Innovation Center demonstration project, which requires these 3 key components: a comprehensive history; a comprehensive examination; medical decision making of moderate complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of moderate to high severity. typically, 45 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology

HCPCS	Long Descriptor
G9485	Remote in-home visit for the evaluation and management of a new patient for use only in a Medicare-approved CMS Innovation Center demonstration project, which requires these 3 key components: a comprehensive history; a comprehensive examination; medical decision making of high complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of moderate to high severity. typically, 60 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology.
G9486	Remote in-home visit for the evaluation and management of an established patient for use only in a Medicare-approved CMS Innovation Center demonstration project, which requires at least 2 of the following 3 key components: a problem focused history; a problem focused examination; straightforward medical decision making, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are self limited or minor. typically, 10 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology
G9487	Remote in-home visit for the evaluation and management of an established patient for use only in a Medicare-approved CMS Innovation Center demonstration project, which requires at least 2 of the following 3 key components: an expanded problem focused history; an expanded problem focused examination; medical decision making of low complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of low to moderate severity. typically, 15 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology
G9488	Remote in-home visit for the evaluation and management of an established patient for use only in a Medicare-approved CMS Innovation Center demonstration project, which requires at least 2 of the following 3 key components: a detailed history; a detailed examination; medical decision making of moderate complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of moderate to high severity. typically, 25 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology

HCPCS	Long Descriptor
G9489	Remote in-home visit for the evaluation and management of an established patient for use only in a Medicare-approved CMS Innovation Center demonstration project, which requires at least 2 of the following 3 key components: a comprehensive history; a comprehensive examination; medical decision making of high complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of moderate to high severity. typically, 40 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology
98016	Virtual Check-in Service
99439	Non-complex chronic care management services, additional 30 min
99487	Extended care coordination time for especially complex patients (first 60 mins)
99489	Additional care coordination time for especially complex patients (30 mins)
99490	Comprehensive care plan establishment/implementations/revision/monitoring
99491	Chronic care monitoring service, moderate
G0506	Additional work for the billing provider in face-to-face assessment or CCM planning
G2058	Non-Complex Chronic Care Management Service
G2064	Comprehensive care management, physician
G2065	Comprehensive care management, clinical staff
GCDRA	Cardiovascular Risk Assessment and Risk Management Services
GCDRM	Cardiovascular Risk Assessment and Risk Management Services
99483	Cognitive assessment and care plan services
99484	Monthly services furnished using BHI models
99492	Initial psychiatric collaborative care management, first 70 mins
99493	Subsequent psychiatric collaborative care management, first 60 mins
99494	Initial or subsequent psychiatric collaborative care management, additional ’30 mins
G2214	Psychiatric collaborative care management
99495	Communication (14 days of discharge)
99496	Communication (7 days of discharge)
G2001	Brief (20 minutes) in-home visit for a new patient post-discharge. for use only in a Medicare-approved CMMI model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility within 90 days following discharge from an inpatient facility and no more than 9 times.)
G2002	Limited (30 minutes) in-home visit for a new patient post-discharge. for use only in a Medicare-approved CMMI model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility within 90 days following discharge from an inpatient facility and no more than 9 times.)
G2003	Moderate (45 minutes) in-home visit for a new patient post-discharge. for use only in a Medicare-approved CMMI model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility within 90 days following discharge from an inpatient facility and no more than 9 times.)

HCPCS	Long Descriptor
G2004	Comprehensive (60 minutes) in-home visit for a new patient post-discharge. for use only in a Medicare-approved CMMI model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility within 90 days following discharge from an inpatient facility and no more than 9 times.)
G2005	Extensive (75 minutes) in-home visit for a new patient post-discharge. for use only in a Medicare-approved CMMI model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility within 90 days following discharge from an inpatient facility and no more than 9 times.)
G2006	Brief (20 minutes) in-home visit for an existing patient post-discharge. for use only in a Medicare-approved CMMI model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility within 90 days following discharge from an inpatient facility and no more than 9 times.)
G2007	Limited (30 minutes) in-home visit for an existing patient post-discharge. for use only in a Medicare-approved CMMI model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility within 90 days following discharge from an inpatient facility and no more than 9 times.)
G2008	Moderate (45 minutes) in-home visit for an existing patient post-discharge. for use only in a Medicare-approved CMMI model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility within 90 days following discharge from an inpatient facility and no more than 9 times.)
G2009	Comprehensive (60 minutes) in-home visit for an existing patient post-discharge. for use only in a Medicare-approved CMMI model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility within 90 days following discharge from an inpatient facility and no more than 9 times.)
G2013	Extensive (75 minutes) in-home visit for an existing patient post-discharge. for use only in a Medicare-approved CMMI model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility within 90 days following discharge from an inpatient facility and no more than 9 times.)
99497	ACP first 30 mins (subject to exclusion if beneficiary has an overlapping inpatient stay, per proposed Medicare Shared Savings Program regulation)
99498	ACP additional 30 mins (subject to exclusion if beneficiary has an overlapping inpatient stay, per proposed Medicare Shared Savings Program regulation)
G0076	Brief (20 minutes) care management home visit for a new patient.
G0077	Limited (30 minutes) care management home visit for a new patient.
G0078	Moderate (45 minutes) care management home visit for a new patient.
G0079	Comprehensive (60 minutes) care management home visit for a new patient.
G0080	Extensive (75 minutes) care management home visit for a new patient.

HCPCS	Long Descriptor
G0081	Brief (20 minutes) care management home visit for an existing patient.
G0082	Limited (30 minutes) care management home visit for an existing patient.
G0083	Moderate (45 minutes) care management home visit for an existing patient.
G0084	Comprehensive (60 minutes) care management home visit for an existing patient.
G0085	Extensive (75 minutes) care management home visit for an existing patient.
G0086	Limited (30 minutes) care management home care plan oversight.
G0087	Comprehensive (60 minutes) care management home care plan oversight.
G0317	Prolonged nursing facility evaluation and management service
G0318	Prolonged home or residence evaluation and management
G0402	Welcome to Medicare visit
G0438	Annual wellness visit
G0439	Annual wellness visit
G0442	Annual alcohol misuse screening
G0443	Annual alcohol misuse counseling
G0444	Annual depression screening
G0463	Professional Services Provided in ETA Hospitals
G3002	Chronic pain management and treatment, monthly bundle including, diagnosis;
G3003	Additional 15m pain management
99417	Prolonged outpatient evaluation and management service(s) time with or without direct patient contact beyond the required time of the primary service when the primary service level has been selected using total time, each 15 minutes of total time
99406	Counseling to Prevent Tobacco
99407	Counseling to Prevent Tobacco
G0101	Cervical or Vaginal Cancer Screening
G0136	Cervical or Vaginal Cancer Screening
G2086	Office Based Opioid Use Disorder Services
G2087	Office Based Opioid Use Disorder Services
G2088	Office Based Opioid Use Disorder Services
96202	Caregiver Behavior Management Training CPT
96203	Caregiver Behavior Management Training CPT
97550	Codes for caregiver training services
97551	Codes for caregiver training services
97552	Codes for caregiver training services
GCTD1	Direct Care Caregiver Training Services
GCTD2	Direct Care Caregiver Training Services
GCTD3	Direct Care Caregiver Training Services
GCTB1	Individual Behavior Management/Modification Caregiver Training Services
GCTB2	Individual Behavior Management/Modification Caregiver Training Services
G0023	Principal Illness Navigation (PIN) services
G0024	Principal Illness Navigation (PIN) services
99446	Interprofessional Consultation Services
99447	Interprofessional Consultation Services

HCPCS	Long Descriptor
99448	Interprofessional Consultation Services
99449	Interprofessional Consultation Services
99451	Interprofessional Consultation Services
99452	Interprofessional Consultation Services
G0019	Community Health Integration services HCPCS
G0022	Community Health Integration services HCPCS
GPCM1	Behavioral health integration add-on when furnished with advanced primary care management services
GPCM2	Behavioral health integration add-on when furnished with advanced primary care management services
GPCM3	Psychiatric collaborative care model add-on when furnished with advanced primary care management services
G2014	Limited (30 minutes) care plan oversight. for use only in a Medicare-approved CMMI model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility within 90 days following discharge from an inpatient facility and no more than 9 times.)
G2015	Comprehensive (60 mins) home care plan oversight. for use only in a Medicare-approved CMMI model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility within 90 days following discharge from an inpatient facility.)
G0519	Management of new patient-caregiver dyad with dementia, low complexity, for use in CMMI Model
G0520	Management of new patient-caregiver dyad with dementia, moderate complexity, for use in CMMI Model
G0521	Management of new patient-caregiver dyad with dementia, high complexity, for use in CMMI Model
G0522	Management of a new patient with dementia, low complexity, for use in CMMI Model
G0523	Management of a new patient with dementia, moderate/severe complexity, for use in CMMI Model
G0524	Management of established patient-caregiver dyad with dementia, low complexity, for use in CMMI Model
G0525	Management of established patient-caregiver dyad with dementia, moderate complexity, for use in CMMI Model
G0526	Management of established patient-caregiver dyad with dementia, high complexity, for use in CMMI Model
G0527	Management of established patient with cognitive impairment with dementia, low complexity, for use in CMMI Model
G0528	Management of established patient with cognitive impairment, moderate/high complexity, for use in CMMI Model
GSPI1	Safety Planning Interventions
G2211	Complex Evaluation and Management Services Add-on

HCPCS	Long Descriptor
G0537	Administration of a standardized, evidence-based atherosclerotic cardiovascular disease (ascvd) risk assessment, 5-15 minutes, not more often than every 12 months
G0538	Atherosclerotic cardiovascular disease (ascvd) risk management services; clinical staff time; per calendar month
G0539	Caregiver training in behavior management or modification for caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; initial 30 minutes
G0540	Caregiver training in behavior management or modification for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; each additional 15 minutes
G0541	Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (without the patient present), face-to-face; initial 30 minutes
G0542	Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (without the patient present), face-to-face; each additional 15 minutes
G0543	Group caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (without the patient present), face-to-face with multiple sets of caregivers
G0544	Post discharge telephonic follow-up contacts performed in conjunction with a discharge from the emergency department for behavioral health or other crisis encounter, 4 calls per calendar month
G0556	Advanced primary care management services for a patient with one chronic condition or fewer, per calendar month
G0557	Advanced primary care management services for a patient with multiple (two or more) chronic conditions, per calendar month
G0558	Advanced primary care management services for a patient that is a qualified Medicare beneficiary with multiple (two or more) chronic conditions, per calendar month
G0560	Safety planning interventions, each 20 minutes personally performed by the billing practitioner, including assisting the patient in the identification of personalized elements of a safety plan

Appendix D. HCPCS Codes Used to Calculate Primary Care Capitation Payment

Codes used to calculate the Base PCC Amount are subject to sufficient claims history and are subject to change.

HCPCS	Long Descriptor
96160	Administration of patient-focused health risk assessment instrument
96161	Administration of caregiver-focused health risk assessment instrument
99201	New Patient, brief
99202	New Patient, limited
99203	New Patient, moderate
99204	New Patient, comprehensive
99205	New Patient, extensive
99211	Established Patient, brief
99212	Established Patient, limited
99213	Established Patient, moderate
99214	Established Patient, comprehensive
99215	Established Patient, extensive
99304	Initial Nursing Facility Care
99305	Initial Nursing Facility Care
99306	Initial Nursing Facility Care
99307	Subsequent Nursing Facility Care
99308	Subsequent Nursing Facility Care
99309	Subsequent Nursing Facility Care
99310	Subsequent Nursing Facility Care
99315	Nursing Facility Discharge Services
99316	Nursing Facility Discharge Services
99318	Other Nursing Facility Care
99324	New Patient, brief
99325	New Patient, limited
99326	New Patient, moderate
99327	New Patient, comprehensive
99328	New Patient, extensive
99334	Established Patient, brief
99335	Established Patient, moderate
99336	Established Patient, comprehensive
99337	Established Patient, extensive
99339	Brief
99340	Comprehensive
99341	New Patient, brief
99342	New Patient, limited
99343	New Patient, moderate
99344	New Patient, comprehensive
99345	New Patient, extensive
99347	Established Patient, brief
99348	Established Patient, moderate
99349	Established Patient, comprehensive

HCPCS	Long Descriptor
99350	Established Patient, extensive
99354	Prolonged visit, first hour
99355	Prolonged visit, additional 30 mins
G2212	Prolonged visit, additional 15 mins
99421	Online digital, Established Patient, 5–10 mins
99422	Online digital, Established Patient, 10–20 mins
99423	Online digital, Established Patient, 21+ mins
99424	Principal Care Management (PCM)
99425	Principal Care Management (PCM)
99426	Principal Care Management (PCM)
99427	Principal Care Management (PCM)
99437	Principal Care Management (PCM)
99441	Phone, Established Patient, 5–10 mins
99442	Phone, Established Patient, 10–20 mins
99443	Phone, Established Patient, 21+ mins
GFCI1	Post-Discharge Telephonic Follow-up Contacts Intervention
G2010	Remote evaluation, Established Patient
G2012	Brief communication technology-based service, 5-10 mins of medical discussion
G2252	Brief communication technology-based service, 11-20 minutes of medical discussion
98016	Virtual Check-in Service
99439	Non-complex chronic care management services, additional 30 min
99487	Extended care coordination time for especially complex patients (first 60 mins)
99489	Additional care coordination time for especially complex patients (30 mins)
99490	Comprehensive care plan establishment/implementations/revision/monitoring
99491	Chronic care monitoring service, moderate
G0506	Additional work for the billing provider in face-to-face assessment or CCM planning
G2064	Comprehensive care management, physician
G2065	Comprehensive care management, clinical staff
GCDRA	Cardiovascular Risk Assessment and Risk Management Services
GCDRM	Cardiovascular Risk Assessment and Risk Management Services
99483	Cognitive assessment and care plan services
99484	Monthly services furnished using BHI models
99492	Initial psychiatric collaborative care management, first 70 mins
99493	Subsequent psychiatric collaborative care management, first 60 mins
99494	Initial or subsequent psychiatric collaborative care management, additional ’30 mins
G2214	Psychiatric collaborative care management
99495	Communication (14 days of discharge)
99496	Communication (7 days of discharge)
99497	ACP first 30 mins (subject to exclusion if beneficiary has an overlapping inpatient stay, per proposed Medicare Shared Savings Program regulation)
99498	ACP additional 30 mins (subject to exclusion if beneficiary has an overlapping inpatient stay, per proposed Medicare Shared Savings Program regulation)
G0076	Brief (20 minutes) care management home visit for a new patient.
G0077	Limited (30 minutes) care management home visit for a new patient.
G0078	Moderate (45 minutes) care management home visit for a new patient.

HCPCS	Long Descriptor
G0079	Comprehensive (60 minutes) care management home visit for a new patient.
G0080	Extensive (75 minutes) care management home visit for a new patient.
G0081	Brief (20 minutes) care management home visit for an existing patient.
G0082	Limited (30 minutes) care management home visit for an existing patient.
G0083	Moderate (45 minutes) care management home visit for an existing patient.
G0084	Comprehensive (60 minutes) care management home visit for an existing patient.
G0085	Extensive (75 minutes) care management home visit for an existing patient.
G0086	Limited (30 minutes) care management home care plan oversight.
G0087	Comprehensive (60 minutes) care management home care plan oversight.
G0317	Prolonged nursing facility evaluation and management service
G0318	Prolonged home or residence evaluation and management
G0402	Welcome to Medicare visit
G0438	Annual wellness visit
G0439	Annual wellness visit
G0442	Annual alcohol misuse screening
G0443	Annual alcohol misuse counseling
G0444	Annual depression screening
G0463	Professional Services Provided in ETA Hospitals
G3002	Chronic pain management and treatment, monthly bundle including, diagnosis;
G3003	Additional 15m pain management
99417	Prolonged outpatient evaluation and management service(s) time with or without direct patient contact beyond the required time of the primary service when the primary service level has been selected using total time, each 15 minutes of total time
G0136	Cervical or Vaginal Cancer Screening
97550	Codes for caregiver training services
97551	Codes for caregiver training services
97552	Codes for caregiver training services
GCTD1	Direct Care Caregiver Training Services
GCTD2	Direct Care Caregiver Training Services
GCTD3	Direct Care Caregiver Training Services
GCTB1	Individual Behavior Management/Modification Caregiver Training Services
GCTB2	Individual Behavior Management/Modification Caregiver Training Services
G0023	Principal Illness Navigation (PIN) services
G0024	Principal Illness Navigation (PIN) services
99446	Interprofessional Consultation Services
99447	Interprofessional Consultation Services
99448	Interprofessional Consultation Services
99449	Interprofessional Consultation Services
99451	Interprofessional Consultation Services
99452	Interprofessional Consultation Services
G0019	Community Health Integration services HCPCS
G0022	Community Health Integration services HCPCS
GPCM1	Behavioral health integration add-on when furnished with advanced primary care management services

HCPCS	Long Descriptor
GPCM2	Behavioral health integration add-on when furnished with advanced primary care management services
GPCM3	Psychiatric collaborative care model add-on when furnished with advanced primary care management services
G0519	Management of new patient-caregiver dyad with dementia, low complexity, for use in CMMI Model
G0520	Management of new patient-caregiver dyad with dementia, moderate complexity, for use in CMMI Model
G0521	Management of new patient-caregiver dyad with dementia, high complexity, for use in CMMI Model
G0522	Management of a new patient with dementia, low complexity, for use in CMMI Model
G0523	Management of a new patient with dementia, moderate/severe complexity, for use in CMMI Model
G0524	Management of established patient-caregiver dyad with dementia, low complexity, for use in CMMI Model
G0525	Management of established patient-caregiver dyad with dementia, moderate complexity, for use in CMMI Model
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G0528	Management of established patient with cognitive impairment, moderate/high complexity, for use in CMMI Model
GSPI1	Safety Planning Interventions
G0537	Administration of a standardized, evidence-based atherosclerotic cardiovascular disease (ascvd) risk assessment, 5-15 minutes, not more often than every 12 months
G0538	Atherosclerotic cardiovascular disease (ascvd) risk management services; clinical staff time; per calendar month
G0539	Caregiver training in behavior management or modification for caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; initial 30 minutes
G0540	Caregiver training in behavior management or modification for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face; each additional 15 minutes
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Appendix E. CARA Initiative Details

E.1 CARA Overview and Objectives

CARA is integrated within the CMS 4Innovation (4i) platform, which allows for digital data sharing and enables participating LEAD ACOs to establish and manage episode-based risk arrangements (EBRAs) with specialty care providers who must be Preferred Providers. Through the CARA module on 4i, participating ACOs can request access to certain episode data, configure episode designs, and export episode designs into narratives that can be used for specialist negotiations. Upon CMS approval of submitted episode designs, CARA episodes would begin to trigger in the next Performance Year, and the system would provide participating ACOs with the opportunity to access certain performance data through the platform. CMS will account for a Preferred Provider's performance on spending by capturing CARA-related costs in the ACO's Performance Year expenditures. LEAD ACOs and Preferred Providers are incentivized to negotiate appropriate target prices that maintain Preferred Provider engagement while preserving the ACO's ability to reduce Performance Year expenditures. For example, a target price set too high may negatively affect an ACO's Performance Year expenditure because there is insufficient downward pressure to reduce the episode FFS spending, while a target price set too low may not encourage Preferred Provider participation in CARA due to a lack of opportunity to find efficiencies to reduce FFS spending below the target price. This integrated approach streamlines the administrative burden of establishing EBRAs while enabling ACOs to maintain appropriate oversight and standardization of episode-based contracting processes.

E.2 Episode Types and Customization

CARA will offer two participation options for each episode: the Default Approach and a Maximal Flexibility (or "Max Flex") Option. All LEAD ACOs meeting the eligibility requirements can access a drop-down menu to select episodes constructed by CMS predicated on the EBCM methodology with slight modifications to align within a LEAD performance year, as well as the newly developed RISE to Age in Place episode. Participating LEAD ACOs that do not seek to modify the CMS-constructed episodes would select the episode and the Default Approach. ACOs seeking customized episodes would select an episode and the Max Flex Option, which allows ACOs to specify modifications. For example, an ACO selecting an EBCM and the Max Flex Option could substitute the methodology with an alternative episode grouper construction methodology. All customizations will be subject to CMS review and validation through the 4i platform to ensure clinical appropriateness and operational feasibility. CMS will validate all proposed episode details to ensure clinical appropriateness and operational feasibility before implementation.

EBCMs represent a comprehensive set of measures that will form the foundation of CARA's episode offerings, focusing on conditions and procedures that are designated as high cost, demonstrate significant variability in resource use, or represent high-impact clinical conditions. CARA will specifically include acute medical, procedural, and chronic condition episodes from the EBCM portfolio, selected for their ability to capture the full spectrum of care delivery across different clinical contexts and timeframes (see full list below). CMS intends to offer acute medical and

procedural EBCMs at baseline and phase in chronic condition EBCMs early in the initiative. These three-episode categories provide broad coverage of healthcare delivery patterns: acute medical episodes address urgent clinical conditions requiring immediate intervention, procedural episodes encompass surgical and other interventions with defined start and end points, and chronic condition episodes capture the ongoing management of long-term health conditions that require sustained specialist involvement. These measures are established within CMS's Quality Payment Program (QPP) as part of the Merit-Based Incentive Payment System (MIPS) cost category, where they serve to promote high-value care delivery across the Medicare system by assessing the risk-adjusted cost to Medicare for items and services furnished during specific episodes of care.

The selection of acute medical, procedural, and chronic condition EBCMs for CARA represents a strategic evolution from the existing shadow bundles data initiative, which has been providing nested episode bundle data using BPCI Advanced methodology to ACOs in programs such as ACO REACH, the Shared Savings Program, and the Kidney Care Choice Model. CARA's adoption of EBCM methodology reflects the need for a familiar, tested set of episodes that Preferred Providers would be accustomed to given their broad use in the Quality Payment Program.

The EBCMs are constructed using comprehensive Medicare Parts A and B claims data and incorporate sophisticated risk adjustment methodologies that account for patient factors such as age and disease complexity. By leveraging these established, evidence-based measures within CARA, CMS can provide ACOs and specialists with standardized, reliable episode definitions that have already been tested and validated across multiple payment models and quality programs, while building upon the proven foundation of data sharing that has supported ACO decision-making in identifying high-value specialist partnerships.

EBCMs Considered for Inclusion in CARA
Acute Inpatient Medical Conditions (sepsis, psychoses and related conditions, intracranial hemorrhage or cerebral infarction, respiratory infection hospitalization, inpatient chronic obstructive pulmonary disease [COPD] exacerbation, lower gastrointestinal hemorrhage, inpatient percutaneous coronary intervention [PCI])
Common Chronic Conditions (diabetes, heart failure, chronic kidney disease [CKD], end-stage renal disease [ESRD], asthma/chronic obstructive pulmonary disease [COPD])
Mental Health Chronic Conditions (depression)
Musculoskeletal/Rheumatologic Chronic Conditions (low back pain, rheumatoid arthritis)
Oncology Chronic Conditions (prostate cancer)
Kidney Transplant Management – Chronic Condition
Orthopedic Procedures (knee arthroplasty, elective primary hip arthroplasty, lumbar spine fusion for degenerative disease [1-3 levels])

EBCMs Considered for Inclusion in CARA
Cardiovascular Procedures (elective outpatient percutaneous coronary intervention [PCI], non-emergent coronary artery bypass graft [CABG], revascularization for lower extremity chronic critical limb ischemia)
General Surgery Procedures (melanoma resection, colon and rectal resection, femoral or inguinal hernia repair, lumpectomy, partial mastectomy, simple mastectomy)
Urologic Procedures (renal or ureteral stone surgical treatment)
Ophthalmologic Procedures (cataract removal with intraocular lens [IOL] implantation)
Gastroenterology Procedures (screening/surveillance colonoscopy)
Vascular Access/Renal Procedures (hemodialysis access creation, acute kidney injury requiring new inpatient dialysis)

ACOs participating in the RISE to Age in Place episode can utilize a defined payment structure to support high-cost beneficiaries experiencing limitations in their ADLs through comprehensive falls prevention interventions. The episode directly supports LEAD's requirement for ACOs to develop PQPs by providing a structured intervention option that ACOs can select as part of their needs assessment and prevention strategy development. Following an initial screening assessment to determine eligibility and care needs, participating ACOs and their identified health care partners may access bundled payment for an interdisciplinary care team likely comprising of OTs, PTs and RNs, who collaborate to deliver comprehensive falls prevention interventions including risk assessments, medication management, strength training, balance exercises, and health care provider communication plans.

Unlike the EBCM episodes, the RISE to Age in Place episode operates without a target price structure. Instead, applicable entities can bill Level II HCPCS (non-payable zeroed-out G-codes) for a bundle of OT and RN services through the Medicare Shared Systems to receive a prospective payment from the IPC. These G-Codes are stratified by beneficiary acuity levels, recognizing that individual beneficiaries require varying intensities of provider visits and associated budgets. The prospective payment structure of the RISE to Age in Place episode rates enables ACOs and their partners to deliver personalized, clinically appropriate care that addresses the unique needs and circumstances of each beneficiary while supporting successful aging in place.

Included in the RISE to Age in Place episode is the flexibility for the LEAD ACO to provide home modifications to a beneficiary in a RISE to Age in Place episode. CMS expects to make a determination that the Anti-kickback Statute Safe Harbor for CMS-sponsored model patient incentives (42 CFR § 1001.952(ii)) is available to protect home modifications furnished by LEAD participants who have opted in to the RISE to Age in Place episode to an eligible beneficiary when determined that a home modification would decrease a beneficiary's fall risk subject to compliance with all applicable laws and regulations and the PY PA (See Section II.C.). The home modifications

would serve as in-kind remuneration offered to eligible beneficiaries, similar to the Guiding an Improved Dementia Experience (GUIDE) Model Environmental Modification Benefit. In addition to OT and RN services to assess fall risk, the RISE to Age in Place episode would enable Medicare providers to conduct comprehensive falls prevention interventions in the beneficiary's home environment. If warranted, any home modifications completed by a handyperson would be paid by the ACO, rather than with Trust Fund dollars.

E.3 Episode Risk Parameters and Negotiation Process

Episode risk parameters are negotiated independently between ACOs and Preferred Providers. However, the ACO must enter and submit the final episode risk parameters for CMS review and finalization in 4i.

The episode risk parameters include:

- Episode selection and construction parameters
- Target price establishment (except for the RISE to Age in Place episode, which does not have a target price)
- Quality measures for performance adjustment
- Performance adjustment specifications

CMS reviews all proposed episode risk parameters to ensure clinical appropriateness and operational feasibility before implementation. While CMS will not require ACOs to submit evidence of their executed EBRA, CMS will require ACOs to:

1. Provide identifying information of the Preferred Provider with whom they have entered into an EBRA,
2. Attest that the episodes within their executed EBRA match those that have been approved by CMS in 4i, and
3. Attest that the executed EBRA includes provisions delegating the ACO's rights to pay and recoup payments from the Preferred Provider in the agreement.

E.4 Payment Calculation and Benchmark Methodology

CMS will take into account a Preferred Provider's performance on spending by capturing CARA-related costs in the ACO's Performance Year expenditures during LEAD's Final Financial Settlement. As part of LEAD's Final Financial Settlement, CMS will compare the CARA episode payments against the risk-adjusted target price, to calculate the Preferred Providers performance. Preferred Providers would be eligible to receive reconciliation payments when their FFS payments fall below the negotiated target price or may owe repayments when payments exceed the target price.

The RISE to Age in Place episode integrates health care provider-based payments directly into ACOs' Medicare TCOC spend without establishing a separate target price, distinguishing it from the EBCM episodes that utilize separate target pricing and reconciliation processes.

E.5 Implementation Timeline

Baseline Data Delivery (2027)

- ACOs sign the LPACA, which includes data sharing requirements, and submits a HIPAA-Covered Data Disclosure Request Form.
- LEAD implementation contractor delivers annual report with target prices to all LEAD ACOs to support ACO decision-making regarding CARA participation.

Episode Risk Parameters Submission and EBRA Validation (End of 2027 and every end of the year thereafter)

- ACOs submit proposed episode risk parameters terms with Preferred Providers via 4i platform.
- CMS reviews and finalizes proposed episode risk parameters.
- ACOs enter information to identify Preferred Providers with whom the ACO has executed an EBRA and attest to delegation of rights to CMS.
- Episodes begin triggering in subsequent Performance Year,

Episode Activation (Beginning January 1, 2028, and every first of the year thereafter)

- CARA episode triggering commences

Annual Report (Tentatively Quarter 2 of 2028 and every year thereafter)

- LEAD implementation contractor provides comprehensive annual performance report to support identification of beneficiaries under each party's financial responsibility and tracking of performance across EBRAs.

Quarterly Performance Reports (Tentatively starting in Quarter 1 of 2028 and every quarter thereafter)

- LEAD implementation contractor provides quarterly performance reports with more current data to support tracking of performance across EBRAs.

LEAD Financial Settlement

- Episode costs (including the payments for the RISE to Age in Place episode) are included in the ACO's final financial settlement methodology.
- CMS completes LEAD final financial settlement process by the specified deadline following the Performance Year.
- Preferred Providers may receive reconciliation payments or owe repayments based on performance relative to negotiated target prices.

E.6 Evaluation Framework

CARA evaluation will be conducted as an optional task under the LEAD evaluation contract, with the evaluation's analyses potentially including:

Quantitative Analyses:

- Spending assessment for episodes against pre-CARA baseline spending
- ACO longitudinal performance tracking on quality measures used for episode payments
- Accommodation for adding or removing episode types over time

Qualitative Analyses:

- ACO leader perceptions of CARA through primary data collection
- Insights from ACO surveys, prevention surveys, and beneficiary focus groups
- Assessment of episode payment impacts

E.7 Eligibility and Requirements

LEAD ACOs participating in CARA must:

- Elect the Global Risk Option under LEAD
- Submit proposed episode risk parameters through the 4i platform for CMS review and finalization
- Comply with CMS requirements for clinical appropriateness and operational feasibility of proposed episode risk parameters
- Submit information necessary for CMS to begin episode data sharing
- Participate in data sharing and performance reporting requirements

E.8 Future Scalability

The modular design of CARA enables potential expansion to other TCOC contexts based on demonstrated success and market uptake within LEAD. CMS will evaluate the effectiveness of facilitated ACO and specialist partnerships before broader implementation across the CMS portfolio, with CARA providing insights into episode characteristics that could inform future bundled-payment episode policies.

E.9 CARA Module Participation Instructions

E.9.1 CARA Module Access

Instructions: CARA participation is optional and requires specific eligibility criteria to be met. LEAD ACOs that sign the LEAD PY PA in 4i and elect the Global Risk Option will be eligible to opt-in and access the CARA module in 4i.

4i Platform Integration: All eligible LEAD ACOs that sign the LEAD PY PA in 4i and that elect the Global Risk Option will be permitted to navigate a limited view of the CARA module in 4i. This limited view provides access to:

- CARA program overview and requirements
- Eligibility verification functionality
- Basic episode risk parameter input

CARA Opt-in process: Eligible LEAD ACOs that opt-in to CARA, through election of the Global Risk Option and execution of a LEAD Participation Agreement CARA Amendment (LPACA), will receive permission to access the extended view of the CARA module, enabling:

- Functionality to select and edit episode risk parameters based on a menu of episodes that CMS makes available to participants
- Submission of proposed episode risk parameters for CMS review
- Access to supportive features and resources, including language regarding provisions or requirements that should be included in EBRAs with Preferred Providers

E.9.2 Eligibility Verification

Critical Requirement: CARA participation is limited to LEAD ACOs in the Global Risk Option that sign the LEAD PY PA in 4i.

Eligibility Verification Process: The 4i platform will include an automated eligibility verification on your ACO's status of signing the LEAD PY PA in 4i, as well as selection of episodes as part of EBRA formation. This verification will ensure that only ACOs that signed the LEAD PY PA and are participating in the Global Risk Option can access CARA functionality.

Confirmation Statement: As part of the opt-in process, the 4i platform will require confirmation that your organization understands CARA participation requires selection of the Global Risk Option and acceptance of 100% downside and upside risk based on Medicare TCOC performance.

Specialist Eligibility Verification: Once the LEAD ACO opts-in to CARA and signs the LPACA, the LEAD ACO may invite the Preferred Providers with whom they have entered into an EBRA to access limited features of the CARA module on 4i. To ensure that the Preferred Providers are Medicare-enrolled, the 4i system will complete a verification of Medicare provider enrollment status through the PECOS (Provider Enrollment, Chain, and Ownership System) database.

E.9.3 Attestation Requirements

Input Specialist Identification Information: As part of the attestation, the ACO must enter the Preferred Provider with whom they have an executed EBRA. This will allow CMS to know which Preferred Providers are subject to CARA requirements.

Representative Authorization: To ultimately trigger episodes for CMS payment, LEAD ACOs that opt-in to CARA must identify a representative with the authority to bind the ACO. This representative must be designated within the 4i CARA module, have appropriate organizational authority to execute binding agreements, and have knowledge of the elements included in the required attestation, as identified below.

Required Attestation Process: The authorized representative must sign an attestation in the CARA module that confirms the following three critical elements:

- **Episode-based Risk Arrangement Execution**: Confirmation that the EBRA has been executed with the Preferred Provider with clauses on the ACO's delegation of rights to CMS for payment and recoupment
- **Effective Date Verification**: Documentation of the effective date of the executed EBRA
- **Episode Matching Confirmation**: Verification that the episode(s) in the executed EBRA match the episode(s) configured in 4i

Attestation Compliance: Attestation with all required elements must be completed before episodes can be triggered for CMS payment. The attestation serves as confirmation to CMS to begin episode bundling per the episode information finalized in 4i. False attestation may result in model compliance violations and associated penalties. Additionally, in the event that there is a discrepancy between the finalized episode information contained within 4i and the ACO and Preferred Provider's executed EBRA, CMS will use the finalized episode information contained within 4i as the basis for any episode reconciliation calculation.

E.9.4 Episode Selection Approach

Instructions: CARA offers two distinct approaches for ACOs to propose episode risk parameters for CMS review: a Default Approach leveraging standardized episode methodologies and a Maximal Flexibility (or "Max Flex") Option that enables flexibility over episode construction, for episode selection to accommodate varying organizational capabilities and strategic objectives. For each episode, you can select your preferred approach between selecting from pre-designed episodes using established methodologies and defining custom episode construction methodology.

Selecting Episode Risk Parameters and Auto-Population: Within the CARA module, participants will follow this streamlined selection process:

- **Episode Selection**: Participant selects from the CMS EBCMs (Default Approach) or a custom episode (Max Flex Option). When selecting the episode, certain fields will auto-populate the Category field with the corresponding clinical episode category. For example:
    - If Elective Outpatient PCI, Revascularization for Lower Extremity Chronic Critical Limb Ischemia, or Non-Emergent CABG episodes are selected, the system will automatically populate "Cardiovascular Procedure" for the Category field
    - Similar auto-population will occur for other clinical episode categories based on the selected episode
- **Custom Episode Creation**: For both the Default Approach and Max Flex Option, participants will have the ability to customize certain parameters, with the Max Flex Option allowing for the most customization.
    - **Default Approach Selection**:

        - Episode construction limited to EBCM methodology with slight modifications to align within a LEAD performance year. For example, episode trigger codes, episode length, episode exclusions cannot be changed.
        - Participant specifies elements such as negotiated target price, discount percent, and performance adjustment.
    - **Maximal Flexibility Selection**:
        - Participant must select from list of eligible EBCM episode types; however, participant determines episode construction. For example, participant identifies episode trigger codes, length, exclusions, etc.

Participant specifies elements such as negotiated target price, discount percent, and performance adjustment.

4i Platform Integration:

- All episode selection processes will be conducted through the dedicated CARA module within 4i
- Auto-population functionality reduces manual entry errors and ensures consistency across episode categories
- Custom episode creation will include built-in guidance and checks, as well as CMS review and finalization of proposed episode risk parameters, to maintain clinical appropriateness

E.9.5 Discount/Premium to Target Price

Instructions: Beginning in 2027, CMS will package and price acute medical and procedural episodes using the EBCM methodology with slight modifications to align within a LEAD performance year and deliver reports, pursuant to execution of the LPACA and submission of a data request, with this data to all LEAD ACOs to use to negotiate a discount or premium to the target price with Preferred Providers. Chronic condition EBCMs will be phased in the early years of the initiative.

Discount and Premium Ranges: ACOs and Preferred Providers will have the opportunity to enter negotiated discount/premium ranges to the target price for different episodes.

E.9.6 Quality Measure Selection

The CARA initiative incorporates quality measurement requirements to ensure that EBRAs maintain and improve care quality while achieving cost efficiencies. All participating ACOs and their Preferred Providers must demonstrate performance on standardized quality measures that align with CMS quality improvement objectives and support the overall goals of LEAD.

For all participants, regardless of whether they select default or custom episodes, the 4i platform will provide a dropdown menu that includes the following quality measure options:

- Q484: Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions
    - Employed in MIPS

    - Collection Type: Administrative Claims
    - Targets appropriate management of complex patient populations
- Other MIPS-comparable measure
    - Allows flexibility for episode-specific or specialty-appropriate quality measures

Participating LEAD ACOs may select multiple quality measures for each EBRA. Unless the participating LEAD ACO has a specific MIPS-comparable measure in mind, they are encouraged to select the Q484: Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions.

Custom Quality Measure Specification: If an ACO selects "Other MIPS-comparable measure," a prompt will appear requesting upload of measure specifications to the platform. CMS will provide a standardized template for measure specification uploads to ensure consistency and facilitate validation of proposed quality measures.

Quality Measure Integration Process: The selected quality measures will be integrated into the EBRAs and used to calculate performance adjustments. All quality measures must demonstrate clinical relevance to the selected episode types and align with evidence-based care standards.

E.9.7 Performance Adjustment Selection

Information: Performance adjustments represent a critical component of CARA arrangements, linking quality performance directly to financial outcomes. These adjustments provide incentives for continuous quality improvement while maintaining appropriate risk-sharing between ACOs and Preferred Providers.

Parameters: The performance adjustment terms are negotiated directly between ACOs and Preferred Providers and shared with CMS on the 4i platform, with the following requirements:

- Minimum Adjustment: No less than 10%
- Maximum Adjustment: No greater than 100%
- Negotiation Flexibility: ACOs and Preferred Providers have full discretion to establish adjustment percentages within these parameters

E.9.8 Episode Pricing and Financial Settlement Process

CMS Episode Pricing Timeline: CMS will complete LEAD's Final Financial Settlement following the Performance Year, which will include a process to evaluate CARA episode performance by comparing actual FFS payments against the negotiated risk-adjusted target prices established between ACOs and specialists. Based on this comparison, Preferred Providers may receive reconciliation payments when their FFS expenditures fall below the negotiated target price or may owe repayments when expenditures exceed the target price.

Benchmark Integration and Risk Adjustment: CARA-related costs will be included in the ACO's Performance Year expenditures to maintain aligned financial incentives. Risk adjustment will be

incorporated into the target price to account for beneficiary acuity differences. This integration ensures that:

- Preferred Provider performance directly impacts ACO Medicare total cost of care outcomes
- Financial incentives remain aligned between ACOs and participating specialists

Preferred Provider Payment and Recoupment:

- **Reconciliation Payments**: Preferred Provider may receive reconciliation payments if their FFS expenditures fall below the negotiated target price
- **Repayment Obligations**: Preferred Provider may owe repayment if FFS expenditures exceed the target price

Appendix F: LEAD Benefit Enhancements Used in Previous ACO Models

3-Day Skilled Nursing Facility (SNF) Rule Waiver Benefit Enhancement

Under this Benefit Enhancement, LEAD ACOs could receive a conditional waiver of the three-day inpatient stay rule to allow eligible LEAD beneficiaries to receive Medicare-covered SNF services from qualified SNFs or swing-bed hospitals that are LEAD Participant Providers or Preferred Providers either directly or with an inpatient stay of fewer than three days. More specifically, CMS seeks to waive the requirement in section 1861(i) of the Act. By waiving this rule which requires having a three-consecutive day stay in an inpatient hospital, the 3-Day SNF waiver would improve access to timely and medically-appropriate care while reducing costs associated with unnecessary hospitalizations.

An ACO beneficiary will be eligible to receive covered SNF services under the terms of this Benefit Enhancement if (1) the beneficiary does not reside in a SNF or long-term care setting at the time of the admission to the SNF or swing-bed hospital; and (2) the beneficiary meets all other CMS criteria for coverage of SNF services, including that the beneficiary must:

- Be medically stable
- Have confirmed diagnoses (e.g., does not have conditions that require further testing for proper diagnosis)
- Not require inpatient hospital evaluation or treatment, and
- Have an identified skilled nursing or rehabilitation need that cannot be provided on an outpatient basis or through home health services.

ACOs will identify the SNFs and swing-bed hospitals with which they will partner in this Benefit Enhancement. Partner SNFs and swing-bed hospitals may be either LEAD Participant Providers or Preferred Providers. Through the Implementation Plan, ACOs may be asked to describe whether the identified LEAD Participant Providers and Preferred Providers have the appropriate staff capacity and necessary infrastructure to carry out proposed coordination activities. In addition to the information the ACO includes in its Implementation Plan, the SNF partner must have an overall rating of three or more stars under the CMS 5-Star Quality Rating System in at least seven of the previous twelve months, as reported on the Medicare Nursing Home Compare website, with the exception of swing-bed hospitals which do not have to meet this requirement. This standard is subject to change in response to new scoring methodologies designed by CMS outside of the CMS 5-Star Quality Rating System.

Telehealth Benefit Enhancement

This Benefit Enhancement would facilitate access to synchronous telehealth services by a) waiving the rural geographic component of originating site requirements, b) allowing the originating site to include a beneficiary's home, and c) waiving the originating site fee requirement when the beneficiary's home serves as the originating site for services furnished to an aligned beneficiary by a Participant and Preferred Provider approved to use the waiver. More specifically, CMS seeks to waive the requirements under section 1834(m)(4)(C) of the Act, 42 C.F.R. § 410.78(b)(3)-(4), section

1834(m)(4)(B) of the Act, section 1834(m)(2)(B) of the Act and 42 C.F.R. § 414.65(b). While COVID-era telehealth flexibilities similarly expand access to synchronous telehealth services, COVID-era telehealth flexibilities for non-behavioral/mental health care are temporary and might sunset on January 30, 2026.[29]

In addition, this Benefit Enhancement conditionally waives the interactive telecommunications system requirement under section 1834(m)(1) of the Social Security Act and 42 C.F.R. § 410.78(b) for two key services furnished using asynchronous store and forward technologies—these services are dermatology and ophthalmology services given their reliance on digital images to inform medical diagnosis and treatment. Asynchronous telehealth includes the transmission of recorded health history (for example, retinal scanning and digital images) through a secure electronic communications system to a practitioner, usually a specialist, who uses the information to evaluate the case or render a service outside of a real-time interaction. Asynchronous telecommunication systems in single media format do not include telephone calls, images transmitted via facsimile machines, and text messages or electronic mail without visualization of the patient. Payment will be permitted for dermatology and ophthalmology services furnished to eligible beneficiaries using asynchronous telehealth in single or multimedia formats that is used as a substitute for an interactive telecommunications system. Distant site practitioners will bill for these services using CMS Innovation Center specific asynchronous telehealth codes (G9868 – G9870). The distant site practitioner must be a Participant Provider or Preferred Provider who has elected to participate in this Benefit Enhancement.

Post-Discharge Home Visits Benefit Enhancement

This Benefit Enhancement offers to ACOs a conditional waiver of the requirement for direct supervision to allow payment for certain home visits furnished to eligible, non-homebound beneficiaries by auxiliary personnel (as defined in 42 C.F.R. § 410.26(a)(1)) under general supervision, rather than direct supervision, incident to the professional services of physicians or other practitioners that are LEAD Participant Providers or Preferred Providers. Through this waiver, CMS seeks to waive the requirement in 42 C. .R. § 410.26(b)(5)F that services and supplies furnished incident to the service of a physician (or other practitioner) ("incident to" services) must be furnished under the direct supervision of the physician (or other practitioner). This waiver would facilitate and streamline the provision of timely home visits, thus improving care transitions, addressing challenges after discharge, and preventing hospital readmissions.

Payment will be made for these home visits only when they are furnished following the beneficiary's discharge from an acute inpatient hospital, inpatient psychiatric facility, inpatient rehabilitation facility, long-term care hospital, or skilled nursing facility. Further, the beneficiary must not qualify for Medicare coverage of home health services (or qualifies for Medicare coverage of home health services on the sole basis of living in a medically underserved area), including under the proposed Home Health for Non-Homebound Beneficiaries Benefit Enhancement.

[29] https://telehealth.hhs.gov/providers/telehealth-policy/telehealth-policy-updates

Care Management Home Visits Benefit Enhancement

This Benefit Enhancement offers to LEAD ACOs a conditional waiver of the requirement for direct supervision to allow for payment for certain home visits that are furnished to eligible beneficiaries proactively and in advance of potential hospitalization. The items and services provided as part of these home visits are those that would be covered under Medicare Part B as "incident to" the services of a physician or other practitioner and would be furnished by auxiliary personnel (as defined in 42 C.F.R. § 410.26(a)(1)) under general supervision, rather than direct supervision. As such, CMS seeks to waive the requirement in 42 C.F.R. § 410.26(b)(5) that services and supplies furnished incident to the service of a physician (or other practitioner) ("incident to" services) must be furnished under the direct supervision of the physician (or other practitioner).

These care management home visits are intended to supplement, rather than substitute for, visits to a primary care practitioner in a traditional routine outpatient health care setting. As such, these home visits are not intended to be performed on an ongoing basis, nor to serve as a substitute for the Medicare home health benefit or as the primary mechanism to meet beneficiaries' care needs.

Further, LEAD Participant Providers and Preferred Providers who have elected to offer this Benefit Enhancement will be able to receive payment for services furnished to eligible beneficiaries under the following circumstances:

- The beneficiary is determined to be at risk of hospitalization;
- The beneficiary does not qualify for Medicare coverage of home health services (unless the sole basis for qualification is living in a medically underserved area);
- The beneficiary is not currently utilizing the Post-Discharge Home Visits Benefit Enhancement or the Home Health Homebound Benefit Enhancement; and
- The services are furnished in the beneficiary's home by auxiliary personnel under the general supervision of a LEAD Participant Provider or Preferred Provider who is a physician or other practitioner after a LEAD Participant Provider or Preferred Provider has initiated a care management plan that includes such services.

Home Health Homebound Waiver Benefit Enhancement

This Benefit Enhancement offers LEAD ACOs the opportunity of a waiver of the requirement to have a homebound status prior to accessing Medicare-covered home health services. Currently, to receive Medicare reimbursement for home health care services, a Medicare beneficiary must be homebound as required by sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act and 42 U.S.C. § 1395n(a)(2)(A).

Homebound beneficiaries are entitled to Medicare reimbursement for the following services: skilled nursing care; home health aides; physical therapy; occupational therapy; speech-language pathology; medical social services; certain medical supplies; and DME. Currently, the homebound requirement focuses on a beneficiary's functional limitations rather than the underlying health condition or comorbidities often present in this population. Unless homebound status is certified, skilled nursing care services in the home are not reimbursable by Medicare for a beneficiary residing

in their home. By waiving the requirement of homebound status, eligible beneficiaries with complex chronic conditions would be able to access critical home health services that can lead to decrease in hospital readmissions with the potential to significantly reduce costs for both the Medicare program and participating ACOs.

All LEAD ACOs would be eligible to submit their selection of this waiver for their aligned beneficiaries and will submit a corresponding Implementation Plan at a date specified by CMS. Specifically, to qualify for home health services under this waiver, beneficiaries must (1) otherwise qualify for home health services under 42 C.F.R. § 409.42 except that the beneficiary is not required to be confined to the home; and (2) meet the criteria as outlined in the Homebound Home Health Waiver Form developed by CMS. Eligible beneficiaries must be aligned to an ACO, have at least two chronic conditions, and meet one of the three following criteria: inpatient service utilization, frailty, and/or social isolation.

A beneficiary would not be eligible to receive covered home health services under this waiver if they are receiving services under the post-discharge visits or care management home visits BE. The services would be furnished in the beneficiary's home or place of residence during the certified episode of care period. This waiver will be monitored by CMS's monitoring contractor to maintain program integrity. CMS will review completed waiver forms to ensure Participant and Preferred Providers are attesting and supporting a beneficiary's need for home health care.

Concurrent Care for Beneficiaries that Elect the Medicare Hospice Benefit Enhancement

To ease care transitions and ensure hospice-eligible beneficiaries face a less stark transition and choice between electing or foregoing hospice care, LEAD aims to waive the requirement that beneficiaries who elect the Medicare hospice benefit give up their right to receive curative care as a condition of electing the hospice benefit. More specifically, CMS seeks to waive the requirement in section 1812 of the Act (and the implementing regulations at 42 C.F.R. § 418.24(e)(2)) to forgo curative care as a condition of electing the hospice benefit so that Medicare beneficiaries can receive curative care with respect to their terminal illness. Under this waiver, ACOs would work with their hospice providers, as well as non-hospice health care providers, to define and provide a set of concurrent care services related to a hospice enrollee's terminal condition and related conditions that are appropriate to provide on a transitional basis and align with the enrollee's wishes. For example, this may include the continuation of chemotherapy services, blood transfusions, or dialysis in the form of "bridge services" or permit a beneficiary to conclude a course of therapy while transitioning into hospice. Of significance, this provision of concurrent care under the Benefit Enhancement does not change the necessary criteria for hospice benefit eligibility or the requirement that the elected hospice provider provide all services and levels of care available under the hospice benefit.

CMS would offer this Benefit Enhancement to LEAD ACOs as a tool to reduce Medicare total cost of care and improve quality of care. Several studies have shown reductions in Medicare total cost of care because of lower expenditures related to emergency department visits, ambulance services, acute care hospital stays, and diagnostic tests and procedures. Studies have also demonstrated

negative impact of having to make a stark decision between curative and hospice care on timely referrals and access to hospice and the beneficial impact of offering both palliative and curative care, which includes better pain and symptom management, improved care coordination and case management, shared decision making, and timelier incorporation of patient-centered goals into the plan of care.[30] Through allowing for plans of care to include concurrent care services, which will often be naturally time-bound and reflect transitional care, this waiver aims to allow beneficiaries who elect to utilize their hospice benefit to experience a more compassionate and smoother transition into hospice.

Similar to the approach used for the 3-Day Skilled Nursing Facility Rule Waiver, LEAD ACOs would identify the hospices with which they would partner in this Benefit Enhancement. Likewise, ACOs will be able to identify non-hospice health care providers included under this Benefit Enhancement. These partner hospices and non-hospice health care providers must be either Participant Providers or Preferred Providers. Through the application and an Implementation Plan, ACOs would be asked to: (1) describe how the identified Participant Providers and Preferred Providers would have the appropriate staff capacity and necessary infrastructure to carry out proposed care coordination activities, and consistent with existing Hospice Conditions of Participation;[31] (2) explain how they would ensure, while working with partner hospices and other non-hospice health care providers and suppliers, that an appropriate plan of care would be developed for beneficiaries receiving concurrent care and that the beneficiary would be fully informed of what care or services would be included in the care plan, what would not, what clinician or organization would be providing which services, how care coordination would be achieved, and whether there are any limitations, including services provided for transitional purposes only. The ACO will be expected to ensure that the beneficiary, or as applicable, his or her representative, is fully aware of the care plan and informed of the beneficiary's right to revoke the hospice election at any time consistent with current law. This focus on transparency as a means of safeguarding patient rights is intended to build in concept from the FY 2020 Hospice Wage Index Final Rule (84 FR 38484) as it concerns the addendum to the hospice election statement.[32]

Nurse Practitioner (NP) and Physician Assistant (PA) Services Benefit Enhancement

LEAD plans to make available the Nurse Practitioner (NP) and Physician Assistant (PA) Services Benefit Enhancement. This Benefit Enhancement would allow ACOs to increase flexibility in care delivery, improving care coordination for their aligned beneficiary populations. The NP/PA Services

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[30] See generally Spettell, CM et al. A Comprehensive Case Management Program to Improve Palliative Care. 12 J. Palliative Med. 827 (2009) (Aetna's concurrent benefits approach and comprehensive case management, beginning in 2004); see, e.g. Wright, A, et al. Letting Go of the Rope - Aggressive Treatment, Hospice Care, and Open Access, 357 New. Eng. J. Med. 324, 324 (2007). (describing a range of such programs); see, e.g. Ciemins et al., (studying "a home-based palliative care program . . . designed to provide concurrent disease-modifying and comfort care to home health patients with advanced illness in an open community-based system of care").

[31] https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Hospice.html https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Hospice.html

[32] CMS. Final Rule FY 2020 Hospice Payment Rates and Wage Index (84 FR 38484). August 6, 2019. https://www.federalregister.gov/documents/2015/08/06/2015-19033/medicare-program-fy-2016-hospice-wage-index-and-payment-rate-update-and-hospice-quality-reporting

Benefit Enhancement seeks to limit Medicare expenditures by providing a streamlined approach for certifying and ordering care, avoiding duplicative work. This Benefit Enhancement would capitalize on established relationships between a beneficiary and a NP or PA to reduce impediments to better coordinate care for beneficiaries and bridge potential gaps in coverage to provide more equitable access to health care.

Eligible NPs or PAs must serve as either Participant Providers or Preferred Providers. Building upon NP or PA authorization of Home Health, as authorized by section 3708 of the CARES Act, this Benefit Enhancement would allow ACOs to extend flexibilities under which NPs/PAs could undertake the following activities to the extent permitted under applicable state law:

- NP/PA Hospice Care Certification – Under existing Medicare law at section 1814(a)(7)(A)(i)(I) of the Act, only a treating physician may certify a beneficiary's need for hospice care. By waiving this requirement, eligible NPs or PAs in LEAD would be able to provide the initial certification that a patient is terminally ill and in need of hospice care is necessary to test LEAD. This flexibility is expected to provide a LEAD beneficiary a more seamless transition to hospice care, reducing complexity in accessing hospice care and delays in placement and improving the quality of care for beneficiaries for whom such treatment is appropriate.
- NP/PA Certification of Need for Diabetic Shoes – Under existing Medicare law at section 1861(s)(12)(A), only a treating physician who is managing a beneficiary's diabetic condition may document and certify a beneficiary's need for diabetic shoes. Under the applicable local coverage determination, CMS permits NPs or PAs practicing "incident to" the physician supervising the beneficiary's diabetic condition to certify the need for diabetic shoes. By waiving this requirement, eligible NPs or PAs in LEAD would be able to document and certify a beneficiary's need for diabetic shoes, regardless of whether such certification is incident to the care of a supervising physician, is necessary to test LEAD. This would allow NPs or PAs treating LEAD Beneficiaries with diabetes to document and certify the need for therapeutic shoes, which is expected to reduce delays in patients accessing this benefit and avoid the costs of an additional clinician visit. We do not intend to waive any requirements at section 1861(s)(12)(B) and (C), including that a podiatrist or other qualified individual prescribe the particular type of shoes and fit and furnish the shoes.
- NP/PA Certification of Cardiac Rehabilitation Care Plan of Cardiac Rehabilitation – Under existing Medicare law at section 1861(eee)(2)(C), only a treating physician may establish, review, and sign a written care plan for a beneficiary's cardiac rehabilitation. By waiving this requirement, eligible NPs or PAs in LEAD would be able to establish, review, and sign a written care plan for a LEAD Beneficiary's cardiac rehabilitation which is necessary to test LEAD. Such a flexibility is expected to increase an NP's or PA's involvement in a LEAD Beneficiary's cardiac treatment, improving quality by easily connecting LEAD Beneficiaries to these critical treatments when medically necessary and appropriate, and reducing cost by decreasing the number of clinician visits that a LEAD Beneficiary would need to obtain these services.
- NP/PA Certification of Plan of Care for Home Infusion Therapy – Under existing Medicare law at section 1861(iii)(1)(A), NPs may be "applicable providers" for the purpose of providing care

related to home infusion therapy, permitting NPs or PAs to be the attending health care provider for a patient receiving home infusion therapy. However, section 1861(iii)(1)(B) and 42 C.F.R. § 414.1515(b) require a physician exclusively to establish and periodically review a plan prescribing the type, amount, and duration of infusion therapy services to be furnished to a beneficiary. In addition, 42 C.F.R. § 414.1515(c) requires that an ordering physician sign and date a home infusion therapy plan. By waiving this requirement, eligible NPs or PAs in LEAD would be able to establish, review, sign, and date a LEAD Beneficiary's home infusion therapy plan of care prescribing the type, amount, and duration of infusion therapy services to be furnished to a LEAD beneficiary. This Benefit Enhancement is expected to promote a LEAD Beneficiary's quality of care by increasing his or her access to home infusion care, and by positioning an NP or PA who treats the LEAD Beneficiary to determine the best treatment plan for that beneficiary. In addition, this flexibility could drive down cost to the Medicare program by reducing the number of office visits a LEAD Beneficiary would require.

- NP/PA Referrals for Medical Nutrition Therapy – Under existing Medicare law at section 1861(vv)(1) and the regulations at 42 C.F.R. § 410.132(a), referrals for medical nutrition therapy may only be made by a physician. By waiving this requirement, eligible NPs or PAs in LEAD would be able to make such referrals. This Benefit Enhancement would allow NPs or PAs treating LEAD Beneficiaries with diabetes or renal disease to refer such beneficiaries to dietitians or nutrition professionals for medical nutrition therapy. Medical nutrition therapy has been shown to be an effective and affordable way to achieve better care for patients and lower costs for health systems.[33]
- NP/PA Certification of Pulmonary Rehabilitation Care Plan for Pulmonary Rehabilitation – Under existing Medicare law at section 1861(fff)(1) of the Act and the implementing regulations at 42 C.F.R. § 410.47(b)(2)(v) only a physician may establish, review, and sign an individualized pulmonary rehabilitation treatment plan for a beneficiary's pulmonary rehabilitation. By waiving these requirements, eligible NPs or PAs in LEAD would be able to establish, review, and sign a written care plan for a LEAD Beneficiary's pulmonary rehabilitation. Such a flexibility is expected to increase an NP's or PA's involvement in a LEAD Beneficiary's pulmonary treatment, improving quality and increasing accessibility by easily connecting LEAD Beneficiaries to these critical treatments when medically necessary and appropriate, and reducing cost by decreasing hospitalizations and the number of clinician visits that a LEAD Beneficiary would need to obtain these services.

[33] https://pubmed.ncbi.nlm.nih.gov/30055973/