Centers for Medicare & Medicaid Services
Long-term Enhanced ACO Design (LEAD) Model
Frequently Asked Questions

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Application and Timelines

What are LEAD's application and implementation timelines?

The LEAD Request for Applications (RFA) will be available March 31, 2026, and applications will be due May 17, 2026, at 11:59 PM ET. Applicants will be notified of selection decisions in early Summer 2026, when onboarding starts. Selected Accountable Care Organizations (ACOs) may choose to participate in an optional implementation period. To do so, they will finalize Implementation Period Participation Agreements and submit provider lists in August and September 2026. This optional implementation period will take place from September 15, 2026, through December 31, 2026, to allow ACOs to begin voluntary alignment. LEAD will be implemented from January 1, 2027, to December 31, 2036 (over ten Performance Years).

Will there be future application cycles or cohorts?

LEAD expects there will be future opportunities to apply for the model, although details are not yet available. Participation parameters and expectations may change based on early model years. Those interested in participating in LEAD are strongly encouraged to apply in the
first cohort. To receive additional information and support, organizations that are interested in applying in a future cohort should fill out the Letter of Interest that will be available on the LEAD webpage by April 18, 2026. The Letter of Interest (LOI) will be due by May 17, 2026 at 11:59pm. The LOI is not required for eligibility in a future cohort, nor is it binding.

When will CMS release the LEAD Financial Methodology Paper for 2027?

The LEAD Financial Methodology Paper will be published in Summer 2026.

If I submit a LEAD application, am I required to participate in 2027 if my ACO is accepted? When are LEAD ACOs required to submit their Participant Tax Identification Number (TINs) to CMS? What are the deadlines for adding and dropping TINs from the 2027 Participant List?

No, LEAD applications are non-binding. You can apply to LEAD, be accepted, and decide not to participate in 2027.

ACOs that are selected for LEAD participation will have until August 5, 2026 to add Participant TINs to their Participant TIN lists for 2027. ACOs then have until September 8, 2026 to remove any TINs they do not want to be on their final Participant TIN list for the Performance Year.

September 8, 2026 is also the deadline for resolving any TIN overlaps with the Shared

Savings Program, i.e., if a TIN has been submitted as part of Participant list for a LEAD ACO and a Shared Savings Program ACO, the TIN must be dropped from one of the ACO's participant lists in order to eliminate the overlap by September 8.

Model Design and Purpose

How will LEAD support rural health care providers?

LEAD will support rural health care providers by:

- Offering an add-on payment that will not be reconciled to help them create necessary infrastructure to be in an ACO.
- Allowing lower beneficiary alignment minimums for ACOs with health care providers new to ACOs, including rural health care providers.
- Including health care providers who treat dually eligible beneficiaries through a Medicaid integration component to the model.

What is the CMS Administered Risk Arrangement (CARA) initiative?

The CARA initiative is a digital data-sharing and payment system designed as a voluntary, modular component of total cost of care (TCOC) models and programs that reduces implementation barriers for ACOs seeking to establish meaningful financial and clinical relationships with Preferred Providers, or downstream specialists and provider organizations. CARA will be initially tested within LEAD among ACOs that maintain two-sided risk. CARA's flexible design enables potential scaling to other TCOC contexts based on demonstrated success and market uptake.

CARA creates a structured, yet flexible, framework to support ACO development of customized risk-sharing arrangements with Preferred Providers without driving consolidation. The initiative does this by: (1) sharing episode data with ACOs and the Preferred Providers with whom they enter into episode-based risk arrangements (EBRAs), (2) providing common contracting frameworks by enabling export of episode information into contracting templates,
(3) allowing for configurable episode design, and (4) making payment to ACOs and Preferred Providers based on their EBRAs.

What are the key features of the LEAD benchmarking methodology?

LEAD's benchmarking methodology builds on ACO REACH and the Shared Savings Program to create a pathway towards sustainable, long-term benchmarks and savings for different types of ACOs.

- **Long-Term Benchmark Stability:** LEAD offers a 10-year performance period with no traditional rebasing, giving ACOs time to invest in care transformation and

see returns over the long term.

- **Predictable, Accurate Annual Updates:** Benchmarks will be updated using a blend of a prospective trend factor plus observed national and regional spending. Guardrails will be applied to the prospective trend factor to support accuracy and mitigate large forecasting misses. This approach aims to provide more predictable year-to-year
benchmark growth while creating an opportunity for efficient ACOs to "beat" the trend and generate durable savings.

- **A Realistic Starting Point for Higher-Spending Organizations:** ACOs whose aligned beneficiaries have higher historical Medicare costs compared to other beneficiaries in the same geographic region are not required to immediately be measured against a benchmark that incorporates regional spending. High-spending ACOs will have a
benchmark based purely on their aligned beneficiaries' own historical spending, plus additional payment support, creating a viable pathway to improve efficiency over time.

- **Recognition of Prior Performance:** ACOs whose aligned beneficiaries have lower historical spending than other beneficiaries in their region will be eligible for a positive regional efficiency adjustment. ACOs that have already generated savings in ACO REACH or the Shared Savings Program may receive a regional efficiency adjustment or a prior savings adjustment, whichever is higher. Both of these adjustments will reflect the ACO's own unique risk profiles.

- **Transition toward a regional rate book:** Over time, as ACO spending levels converge within a region, LEAD is designed to move toward a more standardized regional rate book, reducing reliance on historical spending and promoting greater equity across participants.

Together, these features are intended to create more predictable, durable, and equitable benchmarks that reward long-term cost reduction and support sustained participation.

How will LEAD support providers who serve High Needs beneficiaries?

LEAD will not include a distinct High Needs ACO type. Instead, under LEAD, High Needs policies will be applied to all beneficiaries who meet the High Needs criteria across all ACOs.

This beneficiary-level approach is intended to benefit all ACOs. ACOs that do not specialize in complex care will receive more accurate benchmarks and risk adjustment for their High Needs beneficiaries. At the same time, organizations that focus on serving complex populations will be able to serve their entire eligible Medicare fee-for-service population within LEAD—not just beneficiaries who meet the High Needs criteria.

The High Needs beneficiary category will have its own historical benchmark calculation reflecting a separate trend factor and risk adjustment methodology. Concurrent risk adjustment—first implemented for High Needs beneficiaries in ACO REACH—will be applied to all High Needs beneficiaries in LEAD. High Needs individuals often experience more rapid changes in health status than the average Medicare beneficiary. Compared to a purely prospective risk adjustment approach, a concurrent methodology that incorporates diagnoses documented during the performance year more accurately reflects shifts in health status for this population.

To support participation by organizations that disproportionately serve complex patients, LEAD will provide lower beneficiary alignment minimums for ACOs whose aligned population includes more than 40 percent High Needs beneficiaries, in recognition of the fact that organizations that specialize in care for High Needs beneficiaries typically have smaller patient panels.

For dually eligible beneficiaries in Original Medicare, meaning those who are eligible to receive benefits from both Medicare and Medicaid, LEAD aims to support the integration of Medicare and Medicaid services. CMS will select two states to partner on developing an ACO-Medicaid partnership framework during an initial planning phase.

How is LEAD supporting Medicare-Medicaid integration for ACOs?

LEAD 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 Medicaid organizations 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 Medicaid organizations.

How will the LEAD Model make Americans healthy again?

The LEAD Model will make Americans healthy again by strengthening primary care through prospective, capitated payments that support preventive and proactive care and by holding ACOs accountable for clinically meaningful quality measures focused on prevention and chronic disease management. As part of LEAD, ACOs would also have the flexibility and support needed to design prevention initiatives that address the needs of the population they serve (e.g., chronic disease management, falls prevention). In addition, LEAD will include Benefit Enhancements (or Medicare waivers) and Beneficiary Engagement Incentives that promote and support healthy living activities, such as healthy eating, physical activity, and stress management.

At first glance, the Global discount could deter ACOs who would otherwise prefer full-risk arrangements. How does LEAD support the financial sustainability of participants in the Global Risk Option?

CMS aims to support all LEAD ACOs in generating fiscal sustainability while improving quality of care and generating savings for taxpayers as well.

First, higher-spending ACOs have access to the Administrative Add-On (1.5%) and a ramp-up of

the Global discount rate starting at 1.75%. The Global discount rate is based on the ACO's benchmark and thus it does not increase in value as an ACO earns greater shared savings.

Second, LEAD's Global benchmark discount rate is balanced by several upward benchmark design elements. LEAD's prior savings adjustment (which applies to ACOs that participated in either ACO REACH or the Shared Savings Program) and regional efficiency adjustment are both intended to avoid disadvantaging ACOs that are already providing efficient care. The caps applied to these adjustments are risk-standardized to account for the severity and case mix of an ACO's assigned beneficiary population. LEAD updates benchmarks using a blend of a prospective trend factor (the Accountable Care Prospective Trend) and observed national and regional spending, with guardrails intended to improve predictability while still preserving an opportunity for efficient ACOs to outperform the benchmark trend.

LEAD's risk adjustment approach should provide more accurate benchmarking, especially via application of concurrent risk adjustment to High Needs beneficiaries across all ACO types.

LEAD will also transition to a rate book-based approach in the second half of the model, which should be particularly beneficial to lower-spending ACOs, and it will not rebase during its 10- year term to avoid disadvantaging ACOs that meaningfully improve care and achieve savings.

Third, LEAD provides several unique features to empower ACOs to innovate and drive down the cost of care meaningfully, including up-front capitated payments to support investment in new capabilities (e.g., primary care capitation [PCC] equal to 7% of total benchmark including Enhanced PCC); tools to facilitate collaboration with high-value specialists via CMS- administered risk arrangements (CARA) and the Part B cost-sharing waiver; Medicare/Medicaid integration in select states; and numerous benefit enhancements (BEs) and beneficiary engagement incentives (BEIs) such as an expanded Medical Nutrition Therapy benefit and a Chronic Disease Prevention Reward; and the use of signed voluntary alignment (SVA) to support growth alongside innovation. Because the discount is a fixed percentage of the ACO's benchmark, any incremental savings that an ACO generates once the discount has been overcome accrue directly to the ACO.

CMS also aims to simplify operational excellence via streamlined quality reporting.

We encourage applicants to consider the global discount in the context of broader benchmark design - for example, the risk-adjusted cap for prior savings and regional efficiency adjustments, integrated high needs benchmarking, etc. - and the ability to deploy LEAD's unique payment options, flexibilities, and supports. Taken together, we expect LEAD's design elements to increase benchmarks from the base components (base year historical spending and trends), which can offset the global discount. This therefore reduces the gross savings ACOs need to generate to overcome the discount and supports them in retaining net savings beyond shared savings rate approaches.

Taken together, we would encourage applicants to consider the Global discount in the context of broader benchmark design - for example, the prior savings and regional efficiency adjustments (with a risk-adjusted cap), integrated high needs benchmarking, etc. - and the ability to deploy LEAD's unique payment options, flexibilities, and supports to improve quality and generate increased savings.

Overall, we believe LEAD's 10-year model with no rebasing supports pathways to success for all ACOs. We hope it will be of particular interest to ACOs that are higher-spending, continuing participation from ACO REACH, serve a large proportion of High Needs beneficiaries, or intend to significantly grow and innovate their model of care using unique tools and flexibilities.

Model Overlap and Comparisons

How will LEAD compare with ACO REACH and the Shared Savings Program?

LEAD builds on lessons from both ACO REACH and the Shared Savings Program, while adding several features designed to broaden participation and strengthen model incentives. Below, we compare key model features at a high level; additional information about these features can be found throughout the FAQs.

- **Participation Incentives:** LEAD includes a capitated payment equal to 1.5 percent of the benchmark for higher-spending ACOs that does not need to be repaid to CMS to encourage participation by organizations with costs above regional peers (including those serving more complex, higher-cost populations). This incentive is not available in ACO REACH or the Shared Savings Program.

- **Participation approach:** Like the Shared Savings Program, LEAD uses a whole TIN participation approach, whereas ACO REACH used a TIN-National Provider Identifier (NPI) participation approach. Whole TIN alignment is intended to provide greater stability and operational simplicity.

- **Risk-sharing options:** LEAD offers a full-risk option, like ACO REACH. This differs from the Shared Savings Program, which does not have a comparable full-risk track; its highest-risk option is the ENHANCED Track, with up to 75 percent shared savings and losses.

- **Prospective and capitated payments:** LEAD will incorporate the same options for prospective and capitated payments as ACO REACH, with the addition of one new capitated payment option, non-primary care capitation, to support capitated payment arrangements with specialists. The Shared Savings Program does not currently have capitated payment options, with the exception of the primary care payments available in ACO PC Flex.

- **Benchmark methodology:** In LEAD, as in the Shared Savings Program, an ACO's historical Base Year expenditures will be calculated based on the three years prior to the start of the ACO's first performance year, also referred to as Base Years (BYs). Similar to the Shared Savings Program, benchmarks are based largely on historical spending, with the opportunity for eligible ACOs to earn a positive regional adjustment and prior savings adjustment. The methodology for annual benchmark updates also closely follows the Shared Savings Program, using a three-way blend of regional and national spending growth with a prospective Accountable Care Prospective Trend (ACPT) component. LEAD includes additional guardrails that limit how much ACPT can increase or decrease benchmarks, and it does not use the regional trend adjustment approach used in ACO REACH.

- **Alignment methodology:** LEAD's alignment approach is generally consistent with the ACO REACH methodology and will include both claims-based alignment and voluntary alignment. LEAD participants may select a "Hybrid Alignment" option, which would allow ACOs to add beneficiaries through voluntary alignment on a monthly basis and to add new Participant TINs, that can contribute additional claims-aligned beneficiaries, once during the performance year.

- **Specialty care integration:** LEAD's CARA initiative builds on the Shadow Bundling concept tested in ACO REACH. In ACO REACH, ACOs received data on specialist performance, but many found it difficult to convert that information into effective downstream arrangements. Under LEAD, CMS will facilitate arrangements between ACOs and specialty providers to support stronger specialty integration and accountability. For more details, see the FAQ on CARA and specialty care.

- **Treatment of High Needs and dually eligible populations:** LEAD includes targeted model policies focused on integrating care for High Needs and dually eligible beneficiaries, going beyond existing ACO models in its approach to care integration for these populations.

What is the process for ACO REACH participants to transition to LEAD?

ACOs that participated in the ACO REACH model in PY 2026 are eligible to submit an abbreviated application for LEAD. 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 LEAD. 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 deemed ineligible for participation in LEAD. CMS reserves the right to request additional information or documentation from any applicant during the review process.

ACO REACH participants transitioning to LEAD will be considered Renewing ACOs (in addition to those who have previously participated in the Shared Savings Program).

Renewing ACOs are subject to the same benchmarking methodology as other LEAD participants, but with equal weight placed on each of the three Base Years (rather than the 10/30/60 weighting that will apply to Newly Entering LEAD ACOs). Former ACO REACH participants will also be eligible for a prior savings adjustment based on their performance in ACO REACH.

Will an ACO's voluntary alignment attestations carry over from ACO REACH to LEAD?

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 established relationships between ACOs, providers, and beneficiaries. 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. ACOs that wish to carry ACO REACH alignment over to LEAD are required to participate in the 2026 LEAD Implementation Period.

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

Can an organization participate in both LEAD and the Shared Savings Program at the same time? What about other CMS models?

No, overlaps between models that feature shared savings components, such as the Shared Savings Program, will not be allowed. Participant TINs will not be permitted to

participate concurrently in LEAD and the Shared Savings Program, ACO Primary Care Flex (ACO PC Flex), or the Kidney Care Choices (KCC) model.

Participant TIN overlap will be permitted with the Guiding an Improved Dementia Experience (GUIDE) Model, the Ambulatory Specialty Model (ASM), Enhanced Oncology Model (EOM), and Transforming Episode Accountability Model (TEAM). In some circumstances, Participant TINs can also simultaneously participate in the ACCESS model; please refer to the ACCESS Model Request for Applications for more information. Participant TIN overlap will also be permitted in certain circumstances for participants in AHEAD Hospital Global Budgets and Primary Care AHEAD; please refer to the April 2026 AHEAD Model Overlaps policy.
Simultaneous participation is not permitted with LEAD and the Maryland Primary Care Program (MDPCP).

Eligibility and Participation

Can a participant change between Global and Professional Risk Options?

Before signing the Performance Year Participation Agreement, an ACO may switch from the Global Risk Option to the Professional Risk Option. After signing the Performance Year Participation Agreement, [1]Renewing ACOs are prohibited from switching from the Global Risk Option to the Professional Risk Option. 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 Performance Year Participation Agreement.

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 four years. After four years, the ACO will then have the option to move to the Global Risk Option for greater potential rewards and flexibility.

How do health care providers participate in LEAD ACOs?

Health care organizations can participate in LEAD ACOs at the TIN level. TINs that contract with LEAD ACOs to participate will be considered Participant TINs. ***Participant TINs*** take direct financial accountability for cost and quality and drive beneficiary alignment under the model.

Participant Providers are Medicare enrolled providers and suppliers, including clinicians, Federally Qualified Health Centers (FQHCs), Rural Health Clinics (RHCs), and Critical Access Hospitals (CAHs) that bill under a Participant TIN. All provider and suppliers that bill under the Participant TIN must agree to participate in LEAD. Certain Participant Providers are required to participate in the capitated payment option that the ACO has selected (see Payment section below).

Preferred Providers are clinicians and health care organizations that can take indirect

financial accountability for cost and quality of care. These providers do not drive beneficiary alignment or quality performance for the ACO and participation in capitated payments is optional. They are typically, though not required to be, specialists and institutional providers (e.g., post- acute care) and identified on the Preferred Provider List by name, NPI, and individual/organizational TIN (if applicable).

The table below summarizes the difference between Participant TINs and Preferred Providers.

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

Relationship to ACO	Participant TIN Participation Features	Preferred Provider Participation Features
Access to Benefit Enhancements	Optional	Optional
Eligible for Shared Savings	Yes	Yes
Whole TIN Participation	Yes	No
CARA Eligible[1]	No	Yes

LEAD will also test new structures for payment arrangements with specialists through CARA. Through CARA, CMS will administer voluntary, episode-based risk arrangements between ACOs and specialists to facilitate stronger Preferred Provider relationships with these downstream health care providers.

Are there any restrictions or penalties for terminating an ACO's participation in LEAD?

LEAD is a voluntary model. ACOs can choose to leave at any time. However, to determine whether ACOs can succeed in improving quality and reducing costs over a longer period, ACOs will be incentivized to participate in the model for a minimum of two performance years (i.e., PY2027 and PY2028 for ACOs starting LEAD participation in PY2027).

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

[1]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.

PY benchmark reduced by 2% at Final Settlement for the ACO's first PY.

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.

Additional termination requirements will be detailed in the Performance Year Participation Agreement.

How does CMS determine whether an ACO is Newly Entering or Renewing?

LEAD ACOs must meet all the following three criteria in order to be considered a Newly Entering ACO:

1) the legal entity has not participated in a Medicare ACO initiative previously or currently;
2) less than 40% of the ACO's Participant TINs have participated in a Medicare ACO initiative in the past 5 years; and less than 50% of the ACO's Participant Providers have participated in a Medicare ACO initiative in the past 5 years.

ACOs that do not meet all the above criteria will be considered Renewing ACOs. In other words, Renewing ACOs include those that meet one or more of the following criteria:

1. the legal entity has participated in a Medicare ACO initiative previously or currently;

2. 40% or more of the ACO's Participant TINs have participated in a Medicare ACO initiative in the past 5 years; or

3. 50% or more of the ACO's Participant Providers have participated in a Medicare ACO initiative in the past 5 years.

Do ACOs need to meet alignment minimums during the application window (i.e., by May 17, 2026)?

No, ACOs will not be required to meet beneficiary alignment minimums at the time of LEAD application. ACOs will be required to meet alignment minimums in order to begin participation in PY 2027. However, ACOs that are just short of the alignment minimums (10% or less) will be able to use one of their two available alignment buffers in order to begin PY 2027 participation. This will provide the ACO an opportunity to grow their ACO before the alignment minimum check ahead of PY 2028.

How are LEAD service areas determined?

To be aligned to an ACO, a beneficiary must reside in a county in the ACO's service area, which includes both the Core Service Area (CSA) and the Expanded Service Area (ESA).

The CSA includes the counties in which the LEAD ACO's Participant Providers have

physical office locations. The ESA includes the counties adjacent to the Core Service Area. Based on the list of the Participant Providers submitted by the ACO ahead of each performance year, CMS will identify the LEAD ACO's service area. The counties in which the ACO operates its Core Service Area will not need to be neighboring. For example, the ACO could operate in multiple counties in the same state or more than one state.

Some ACOs have a clinical model that does not necessarily rely on physical practice locations (e.g., through delivery of services in locations other than a health care provider's office, such as a beneficiary's home). ACOs that do not have a physical practice-based clinical model may submit an alternative to the county-by-county physical practice location CSA standard. CMS retains sole discretion to accept or reject alternative CSAs.

Will LEAD offer Termination Without Liability (TWOL) in the first performance year?

Yes. CMS recognizes that PY 2027 represents LEAD's first year and that ACOs may need time to assess
the reports that we anticipate issuing in late 2026 (e.g., alignment and benchmark reports). As a result, LEAD will offer termination without liability (TWOL) provided that the withdrawing ACO notifies CMS on or before February 28, 2027. CMS will waive the Retention Incentive for ACOs that withdraw from the model by February 28 and otherwise comply with all requirements for TWOL.

Beneficiaries and Alignment

How will CMS align a Medicare beneficiary to a LEAD ACO?

LEAD ACOs will receive beneficiary alignment in two ways:

- The first will be **claims-based alignment**, which aligns Medicare beneficiaries to ACOs based on their claims history and utilization patterns.
- The second will be **voluntary alignment**, where Medicare beneficiaries can actively choose to align to an ACO by choosing a provider affiliated with that ACO as their primary provider or other source of care. Voluntary alignment can occur in a healthcare setting, or in a patient's home when there is a pre-existing relationship with a provider affiliated with the ACO.

Additionally, ACOs will select one of two alignment approaches:

- With **prospective alignment**, beneficiary alignment is conducted before the start of each performance year. No alignment updates take place during the performance year.
- With **hybrid alignment**, ACOs can update their alignment during the performance year. Voluntary alignment will be updated monthly. Claims-based alignment will

be set prospectively, but for ACOs that have new Participant TINs during the performance year, claims-based alignment will be updated once, mid-performance year, for the newly added Participant TINs. Eligible beneficiaries can only be added mid-year; they cannot be dropped.

How does the Whole TIN participant approach impact claims-based alignment?

LEAD's alignment methodology prioritizes primary care relationships within Participant TINs. When aligning a beneficiary to a LEAD ACO, CMS will first check to see if 10% or more of a beneficiary's allowable charges for Primary Care Qualified Evaluation and Management (PQEM) services in the lookback period were billed by primary care specialists (specialties defined in Appendix D of the RFA). If so, alignment will be based solely on primary care providers. If less than 10% of PQEM allowable charges in the lookback period were billed by primary care specialties, CMS will consider select non-primary care specialists in alignment. The beneficiary is ultimately 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. FQHCs and RHCs will be considered primary care specialists due to the comprehensive nature of care provided in those settings.

What is the minimum number of beneficiaries an ACO must have aligned to participate in LEAD?

To participate in LEAD, ACOs must have 5,000 aligned beneficiaries in Performance Year 1, with 3,000 beneficiaries aligned in at least one of the Base Years. If an ACO has a high proportion of High Needs beneficiaries (defined as more than 40% of their aligned beneficiaries meeting the High Needs Eligibility criteria), the ACO will be permitted to participate at lowered alignment minimums of 800 in Performance Year 1, with at least 500 claims-based beneficiaries aligned in at least one of the Base Years. For Newly Entering ACOs, the ACO must have 1,000 beneficiaries in Performance Year 1, with 600 claims-based beneficiaries aligned in at least one of the Base Years. Alignment minimums for Newly Entering and ACOs with a large proportion of High Needs beneficiaries will slowly grow over the course of the model. More details will be included in the Request for Applications.

As part of Hybrid Alignment, ACOs have the option to add new TINs to their Participant TIN list during the Performance Year (PY) and CMS will re-run claims-based alignment to add new beneficiaries. When will these beneficiaries become officially aligned to the ACO during the PY? Will CMS update benchmarks and prospective payment rates to account for these newly aligned beneficiaries?

LEAD ACOs that have elected Hybrid alignment will be able to add new Participant TINs to their Participant TIN list early in the PY. Beneficiaries that are added as part of the second claims-based alignment will be considered aligned to the ACO effective April 1 of the PY. CMS will update PY benchmarks and prospective payment rates to reflect the

addition of these new beneficiaries. More specific information will be available in future guidance documents.

The LEAD RFA indicates that all Non-Physician Practitioners are considered primary care clinicians for the purposes of LEAD's alignment methodology and capitated payments. The RFA also notes that all services provided by FQHCs and RHCs are considered primary care. Will CMS take any steps to exclude from LEAD's alignment calculations and payment mechanisms Non-Physician Practitioners (NPPs) or CMS Certification Numbers (CCNs) that do not provide primary care services?

CMS recognizes that certain NPPs and CCNs primarily furnish specialty care services and, therefore, ACOs may not want them to be included for alignment or Primary Care Capitation purposes. Due to limitations in the data with respect to accurately identifying the specialties in which NPPs practice and CCNs operate, CMS intends to implement an alternative methodology for specialty identification. This will allow for the exclusion of specialty-focused NPPs and CCNs beginning in Performance Year 2028 or sooner. CMS will issue additional guidance regarding this process in forthcoming communications.

How does the LEAD Model ensure accurate beneficiary alignment for individuals who had a skilled nursing facility (SNF) stay?

The LEAD Model adopts the same alignment methodology as the Medicare Shared Savings Program (MSSP). Under this approach, CMS excludes SNF Primary Care Qualified Evaluation and Management (PQEM) claims billed under Current Procedural Terminology (CPT) codes 99304–99318 from the beneficiary alignment algorithm when those claims are submitted during a period that coincides with an active SNF facility stay. This exclusion extends to claims submitted by Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs).

This exclusion is applied when both of the following conditions are satisfied:

1. A professional service is billed under CPT codes 99304–99318, **or** an Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC) submits a claim containing a qualifying CPT code within that range; **and**

2. A SNF facility claim present in CMS's claims files reflects dates of service that overlap with the date of service for the professional, FQHC, or RHC service in question.

Payment Methodology

How does LEAD's risk-sharing methodology work?

LEAD will allow ACOs to choose a level of financial risk that fits their experience.

- **Global Risk Option:** ACOs will be able to earn up to 100% of shared savings but will also be responsible for up to 100% of losses. ACOs that elect this option will

have opportunities to access broader capitated payments and additional beneficiary engagement tools.

- **Professional Risk Option:** ACOs will be able to earn up to 50% of shared savings while capping potential losses at 50%. ACOs that choose this option will have to remain in the Professional Risk Option for at least four years. After four years, ACOs have the option, but will not be required, to move to the Global Risk Option.

Like ACO REACH, LEAD will include risk corridors and optional stop-loss policies to provide additional risk mitigation strategies, described here.

Does LEAD offer any prospective payments? If so, what are the options?

LEAD will provide ACOs with monthly prospective payments to support enhanced care investments and greater flexibility to deliver patient-centered care. LEAD includes:

- **Primary Care Capitation (PCC):** Monthly capitated payments for primary care services delivered by the ACO's Participant and Preferred Providers. PCC includes both the Base PCC, which covers the cost of delivering primary care services to aligned beneficiaries, and the Enhanced PCC (EPCC), which provides ACOs with upfront cash flow to invest in infrastructure, staffing and workflow changes, and other improvements to support ACOs' performance. The EPCC must be paid back to CMS in full at the end of the Performance Year. ACOs enrolled in the Professional Risk Option are required to select PCC, while ACOs enrolled in the Global Risk Option can choose between PCC and Total Care Capitation (TCC).

- **Total Care Capitation (TCC):** For those in the Global Risk Option, LEAD will also offer the option of capitated payments for all Medicare Parts A and B services delivered by the ACO's Participant and Preferred Providers, including both primary and specialty care.

- **Non-Primary Care Capitation (NPCC):** ACOs that select PCC have the option of also selecting NPCC, which is a monthly capitated payment covering non-primary care services provided by enrolled Participant and Preferred Providers (e.g., specialists and post-acute care facilities). NPCC is a new payment option in LEAD and is a true capitated payment; unlike APO, NPCC is not reconciled based on fee-for-service (FFS) billing.

- **Advanced Payment Option (APO):** Also optional for ACOs that elect PCC, APO will be an upfront monthly payment for non-primary care services delivered by enrolled Participant and Preferred Providers that will be reconciled against actual FFS billing throughout the performance year.

- **Add-On Capitation Payments:** ACOs with higher-than-average spending compared to their region will be eligible for an additional capitated payment, calculated as a percent of the ACO's benchmark. This payment is designed as an

upfront benchmark adjustment to encourage investments in primary care and other services that will enable eligible ACOs to reduce Medicare expenditures for LEAD-aligned beneficiaries over time. This payment will not be reconciled at the end of the Performance Year, and it will not be included in Performance Year expenditures when calculating shared savings/losses.

How does LEAD's alignment methodology and Primary Care Capitation mechanism work for Federally Qualified Health Centers (FQHCs) and Rural Health Centers (RHCs)? Does it include services typically paid through the FQHC Prospective Payment System (PPS) or the RHC All- Inclusive Rate (AIR)?

Yes. To account for the comprehensive nature of care delivered in those settings, LEAD treats all services provided by FQHCs and RHCs as primary-care services for purposes of beneficiary alignment and calculating Primary Care Capitation (PCC). All FQHC and RHC CMS Certification Numbers in Participant TINs will be enrolled in Primary Care Capitation (or Total Care Capitation (TCC), if the LEAD ACO is in the Global Risk Option and elects TCC). The PCC calculation and accompanying fee reduction will include FQHC and RHC visits that are typically paid at the PPS or AIR rate, respectively, as well as care management and care coordination
services. As a result, LEAD's alignment methodology and capitated payments will support participation by FQHCs and RHCs.

The Base PCC calculation also includes a safeguard for FQHCs and RHCs to ensure ACOs are appropriately funded for beneficiaries aligned through these providers. Under this "FQHC/RHC True-up," if an ACO's PCC payments are lower than the corresponding fee reductions for beneficiaries aligned through FQHCs or RHCs, CMS will make an additional payment to cover the difference, applied in the following quarter. This adjustment can only increase payments, not reduce them. Because these adjustments are part of the base PCC, they will count toward ACOs' PY Expenditures for the purpose of calculating Shared Savings/Losses.

Is the 3% quality withhold taken out of capitated payments and then repaid at settlement?

No, the 3% quality withhold is not deducted from capitated payments during the performance year.

The 3% quality withhold is applied only during financial settlement, when CMS calculates the ACO's shared savings or shared losses. At that point, CMS determines how much of the 3% the ACO has earned back based on its quality performance. The withhold does not otherwise affect payment amounts during the performance year.

The RFA includes a provision requiring LEAD ACOs to share in 1% of total downside risk with Participant TINs. Will CMS require Participant TINs to have a repayment mechanism for the downside risk that is being "passed on" to them from their ACO?

LEAD requires ACOs to allocate at least 1% of the ACO's total downside risk on average across all of its Participant TINs. Each Participant TIN is not required to take on 1% of the

ACO's total downside risk. The goal of this policy is to prevent ACOs from holding all of the downside risk in LEAD and to instead transfer some of that accountability to their Participant TINs. However, it is designed to provide maximum flexibility to ACOs to determine how to distribute the risk appropriately amongst the ACO's Participant TINs. The ACO, through its agreement with CMS, will still be solely responsible for repaying all losses to CMS (and is required to establish a financial guarantee). CMS will not require ACO Participant TINs to secure a financial guarantee or other repayment mechanism.

What is the Administrative Add-on capitation payment and which ACOs are eligible to receive it?

The Administrative Add-on is an upfront benchmark adjustment equal to 1.5% of an ACO's performance year benchmark. The Administrative Add-on is paid as a monthly capitated payment to higher-spending ACOs. Higher-spending ACOs are those that have higher than average baseline Medicare spending in their region.

This payment is intended to allow higher-spending ACOs to immediately begin investing in primary care transformation and enhanced services, which will ultimately facilitate the ACO's ability to reduce Medicare expenditures for its aligned beneficiaries.

The Administrative Add-on will not be included in performance year expenditures for the purpose of calculating shared savings/losses. It also does not have to be repaid at financial settlement. For higher-spending ACOs in the Global Risk Option, the Administrative Add-on will be calculated before the application of the discount.

Will all Participant Providers that bill under a Participant TIN be required to participate in PCC?

CMS will automatically include Participant Providers with primary care specialties in PCC. This includes all Nurse Practitioners and Physician Assistants, as well as all FQHCs and Rural Health Clinics (RHCs). Participant Providers with non-primary care specialties will not be included in PCC, either for PCC calculations or related claims reductions. Please refer to Section X of the LEAD RFA for more information.

How will LEAD handle significant, anomalous, and highly suspect (SAHS) billing activity and skin substitute expenditures in base years?

CMS recognizes the importance of accuracy in setting benchmarks and consistency across the CMS portfolio. In light of SAHS activity from 2023-2025 and changes to reimbursement for Healthcare Common Procedure Coding System (HCPCS) codes related to skin substitutes in the Physician Fee Schedule (PFS) for years 2026 and after, reducing the impact of these items should enhance the
accuracy of LEAD's financial calculations for 2027 and beyond.

Accordingly, LEAD will remove:

- **100% of SAHS billing activity** from ACO historic spending, national/regional observed expenses (used in setting benchmark trend factors), regional efficiency calculations, risk adjustment model recalibration, stop-loss calculations (including attachment points, charges, and payouts), and calculation of financial guarantee amounts.
    - Example: HCPCS Codes A4352, A4353, A6197, L0486, L1852, and L3916 were determined to be SAHS for PY 2025; LEAD will remove all expenditures associated with those codes with 2025 dates of service from the calculations described

- **65% of skin substitute expenditures** across 2024-2025 from ACO historic spending, national/regional observed expenses (used in setting benchmark trend factors), and regional efficiency calculations.

- **100% of skin substitute expenditures** across 2023-2025 from LEAD's stop loss calculations (including attachment points, charges, and payouts) and calculation of the financial guarantee amount, and from 2023 expenditures used in risk adjustment model recalibration.

CMS will not modify prior savings from settlements in the Shared Savings Program or ACO REACH in calculating LEAD's prior savings adjustment. Note that all SAHS billing activity was already removed from settlements in the relevant years.

CMS is removing 65% of skin substitute expenditures from most benchmark factors in order to avoid unintended differences across our portfolio of models and programs. The Shared Savings Program applies truncation to historic expenditures in setting benchmarks, capping an assigned beneficiary's annualized expenditures at the 99th percentile of national Medicare FFS per capita expenditures for assignable beneficiaries; we estimate for CY 2025 that this may remove approximately 65% of skin substitute billing activity from expenditures for Shared Savings Program ACOs. LEAD's policy is intended to promote consistency and minimize unintended program differences for ACOs as they consider participating in one of CMS's ACO programs.

CMMI expects that removing 65% of skin substitute expenditures from LEAD ACO benchmark calculations as discussed above should have minimal effect on ACO shared savings in the aggregate (and therefore on total CMS spending). In particular, removing skin substitute expenditures from ACO historic expenditures would, by itself, decrease benchmarks. However, removing skin substitute expenditures from national/regional observed spending in base years 2024 and 2025 effectively reduces the "starting point" level of spending in trend calculations and therefore increases the calculated trend. Combined, the two impacts of the carveout – the benchmark reduction (via ACO historic expenditures) and increase (via trend calculations) – should minimize advantage or disadvantage to any particular ACO.

Benchmarking

How does LEAD's benchmarking methodology work?

LEAD benchmarks are built by calculating a fixed three-year historical baseline, trending

that baseline forward using a blend of national, regional, and prospective growth factors, applying benchmark adjustments and risk adjustment, and then applying the quality withhold and any applicable discount.

- The starting point is a three-year historical baseline. CMS will use the three most recent calendar years before the first performance year as the ACO's Base Years. For ACOs entering in PY 2027, those years are CY 2024, CY 2025, and CY 2026. That baseline
  period stays fixed over the ACO's participation, although expenditures are recalculated each year using the ACO's current participant TIN list.

- Historical spending is weighed differently for Newly Entering and Renewing ACOs. For Newly Entering ACOs, the three Base Years are weighted 10% / 30% / 60%, respectively, giving more weight to the most recent year. For Renewing ACOs with prior ACO REACH or Shared Savings Program experience, the Base Years are weighted equally.

- CMS then applies ACO-specific benchmark adjustments, depending on whether an ACO meets the eligibility criteria for an adjustment. Benchmark adjustments will generally be subject to a cap, set at 3%-5% of risk standardized national per capita spending and adjusted for an individual ACO's population risk. The ACO specific benchmark adjustments include:

    - A positive regional efficiency adjustment for lower-spending ACOs in the Global Risk track;
    - A prior savings adjustment for previous ACO REACH and Shared Savings Program ACOs, based on savings generated in the three years before the LEAD agreement period; (ACOs that are eligible for both a positive regional efficiency adjustment and prior savings adjustment will receive the higher of the two); and
    - a 1.5% Administrative Add-on capitation payment for higher-spending ACOs.

- The historical baseline is then trended forward to the performance year. CMS uses a three-way blended update factor. Two-thirds of the update reflects actual spending growth through a two-way blend of national and regional growth rates. The remaining one-third reflects a prospectively set growth rate, the Accountable Care Prospective Trend (ACPT). In order to promote stability, the ACPT is subject to guardrails that limit how far the three-way blended trend with ACPT can diverge from the two-way national/regional trend.

- The benchmark is then risk adjusted using the prospective CMS-HCC model for Aged & Disabled and ESRD beneficiaries and the concurrent HCC model for High Needs beneficiaries.

- Finally, CMS applies the quality withhold and, for ACOs in the Global Risk Option,

the discount. A 3% quality withhold applies to all ACOs and can be earned back based on quality performance. For ACOs in the Global Risk Option, CMS also applies a discount to the benchmark. That discount is 3% for lower-spending ACOs, while higher-spending ACOs start at 1.75% and phase up to 3% over time.

Which years are used to set a LEAD ACO's benchmark?

For Newly Entering ACOs, CMS will calculate the baseline using 100% historical claims from those three years, with more weight placed on the most recent year to better reflect current spending patterns:

- 10% for Base Year 1 (the oldest year)
- 30% for Base Year 2
- 60% for Base Year 3 (the most recent year)

For Renewing ACOs (i.e., those with prior experience in ACO REACH or the Shared Savings Program), CMS will use the same Base Years to calculate the benchmark but will weigh them equally (i.e., 33%/33%/33%). This approach avoids more heavily weighting recent years in which an ACO may have successfully reduced expenditures and is consistent with the methodology that is currently used in the Shared Savings Program. For 2027 LEAD ACOs, the Base Years are 2024, 2025, and 2026.

How and when does CMS determine whether a LEAD ACO is higher-spending or lower- spending? Can the designation change during a PY?

CMS will determine whether an ACO is higher- or lower-spending before the beginning of each PY and the determination cannot change during the PY. To make the determination, CMS will compare the ACO's historical base benchmark (calculated based on expenditures during the three base years) to historical spending for the rest of the eligible population of Medicare beneficiaries in the ACO's region in Base Year 3. If the historical base benchmark is higher than average spending for the rest of the eligible Medicare beneficiaries in the region, the ACO will be considered higher-spending. If the historical base benchmark is lower than average spending for the rest of the eligible Medicare beneficiaries in the region, the ACO will be considered lower-spending. For the purposes of this calculation, "region" will be defined as the ACO's county-based service area, and regional expenditures will be calculated using a population-weighted county average, with the population weighting reflecting the proportion of the ACO's aligned beneficiary population in each county. This approach to population weighting is similar to the Shared Savings Program methodology described at 42 CFR 425.654(b).

CMS uses the base years for this determination in order to avoid penalizing organizations who begin as higher-spending and successfully reduce spending throughout their performance in the model. Annual updates to an ACO's higher- or lower-spending designation will solely

reflect changes to the ACO's Participant TIN list, i.e. if newly added or dropped Participant TINs have higher or lower spending in the base years.

How will benchmarks be determined for new beneficiaries when TINs are added mid-year as part of Hybrid Alignment?

LEAD ACOs that elect hybrid alignment will have one mid-year opportunity to add new ACO Participant TINs to their Participant Lists and have the beneficiaries associated with their newly added TINs become aligned to the ACO. This policy aims to improve alignment accuracy, support ACOs' growth, and encourage participation by smaller or emerging provider organizations.

When new participant TINs are added, CMS will re-calculate Base Year expenditures to incorporate historical expenditures for the newly added TINs and update benchmarks and capitated payments accordingly.

Can a higher-spending ACO receive both the Administrative Add-on and Prior Savings Adjustment?

Yes, higher-spending ACOs that have previously participated in the Shared Savings Program or ACO REACH and successfully earned savings are eligible to receive both the Administrative Add-on and Prior Savings Adjustment.

If a LEAD ACO includes Participant TINs that have participated in multiple different predecessor ACOs, or that have participated in different predecessor ACOs for different base years (BYs), how will CMS determine which predecessor ACO to base the Prior Savings Adjustment Calculation on?

To determine whether a LEAD ACO is eligible for a Prior Savings Adjustment, CMS will first determine whether the LEAD ACO has sufficient continuity with one or more predecessor REACH or Shared Savings Program ACOs. A predecessor ACO may contribute to the LEAD ACO's Prior Savings Adjustment if at least 40% of the LEAD ACO's Participant TINs participated in that predecessor ACO. If one predecessor ACO meets the 40% threshold, the LEAD ACO's Prior Savings Adjustment will be based on that predecessor ACO's savings history. If more than one predecessor ACO meets the 40% threshold, CMS will calculate a beneficiary-weighted average of the two predecessor ACOs' per-beneficiary savings, weighted based on the beneficiaries associated with the LEAD Participant TINs from each qualifying predecessor ACO.

If the LEAD ACO's Participant TINs participated in different ACOs in different base years, CMS will identify the qualifying predecessor ACO or ACOs based on BY3, the most recent base year. For BY1 and BY2, CMS will include savings for a qualifying BY3 predecessor ACO only if at least 30% of the LEAD ACO's Participant TINs participated in that same predecessor ACO in the applicable year (i.e., if a LEAD ACO meets the 40% threshold for BY3, it will have the lower 30% threshold for BY1 and BY2 to avoid losing eligibility based on changes to a small number of Participant TINs in earlier base years). If the 30% threshold is not met for BY1 or BY2, savings for that predecessor ACO for that year will be set to

$0. CMS will not substitute a different predecessor ACO for BY1 or BY2.

LEAD includes incentives for higher-spending ACOs, but are there any parallel incentives for higher- spending TINs within lower-spending ACOs?

LEAD includes a policy designed to ensure that lower-spending ACOs are not unintentionally disadvantaged when they recruit higher-spending organizations that have not previously participated in accountable care models. Under this policy, higher-spending TINs that have not participated in
either the Shared Savings Program or ACO REACH in the two years prior to the ACO's first performance year will be excluded from the calculation of the Regional Efficiency Adjustment (REA) for lower- spending ACOs. This approach is intended to remove a potential disincentive for lower-spending ACOs to partner with clinics, physician practices, and other organizations that have historically had higher Medicare expenditures, while continuing to encourage broader participation in accountable care.
Additional details regarding the eligibility criteria and calculation methodology will be provided in the PY 2027 LEAD Alignment & Financial Methodology Paper.

***Updated*: How will LEAD's approach to setting Voluntary Aligned benchmarks account for changes in the voluntarily aligned population between the base years and the Performance Year?**

For PY 2027, CMS will calculate benchmarks for voluntarily aligned beneficiaries by looking back at those same beneficiaries' historical expenditures in the base years (CY 2024-CY 2026) and trending them forward to the current performance year. This methodological approach is necessary because CMS cannot simulate which beneficiaries "would have been" voluntarily aligned in the base years. However, because this approach tracks a fixed pool of beneficiaries longitudinally, base line expenditures may not fully reflect aging and mortality in the aligned population, particularly as the length of time between the base years and applicable performance year increases. It also may not accurately reflect costs for beneficiaries who become high needs during the performance year, but were not high needs during base years.

CMS will be applying several policies to account for these complexities:

1) CMS will calculate voluntarily aligned Historical Baseline Expenditures for the High Needs beneficiary category using only BY3 expenditures.

2) A beneficiary will only contribute expenditures to the voluntarily aligned High Needs Historical Benchmark if the beneficiary met the High Needs eligibility criteria during BY3. If a beneficiary is voluntarily aligned and classified as High Needs in PY2027, but did not meet the High Needs eligibility criteria during BY3, that beneficiary would not contribute expenditures to the voluntarily aligned High Needs Historical Benchmark.

3) Voluntarily aligned High Needs beneficiaries who were not High Needs in BY 3 will

also be excluded from the calculation of an ACO's average High Needs risk score in BY 3 for the purposes of applying the risk score growth cap. This exclusion ensures that the reference-year average risk score reflects the same beneficiary population used to define the High Needs cohort.

4) CMS will also apply a minimum beneficiary threshold for voluntarily aligned benchmarks. If an ACO has fewer than 500 voluntarily aligned beneficiaries across all beneficiary categories that can contribute historical expenditures in Base Year 3, CMS will not calculate separate voluntarily aligned benchmarks and will instead apply the corresponding claims-aligned benchmarks to the ACO's voluntarily aligned beneficiaries. For purposes of the 500-beneficiary threshold, voluntarily aligned beneficiaries in the High Needs category will only be counted if they met the High Needs eligibility criteria during BY3.

5) As part of its voluntary alignment benchmark methodology, CMS expects to shift towards calculating voluntary alignment benchmarks by using expenditures for beneficiaries that were voluntarily aligned to the ACO during early model performance years (i.e., based on beneficiary costs during a time period in which they were voluntarily aligned to the ACO). This would ensure that benchmark expenditures appropriately reflect mortality and population aging.

Risk Adjustment

Which risk adjustment model will be used, including the approach for High Needs populations?

CMS will use different risk adjustment approaches depending on the beneficiary category.

For beneficiaries in the Aged & Disabled category, benchmarks will be risk adjusted using a modified version of the prospective 2024 CMS Hierarchical Condition Categories (CMS-HCC) risk

adjustment model (Version 28). This model will be recalibrated to reflect the exclusion of beneficiaries in the High Needs category so that risk scores more accurately predict spending for the remaining population.

For beneficiaries in the End-Stage Renal Disease (ESRD) category, CMS will use the 2023 CMS- HCC ESRD risk adjustment model, consistent with current Medicare policy.

Beneficiaries identified as High Needs will be risk adjusted separately using CMMI HCC concurrent risk adjustment model, which uses diagnoses from the current year rather than the prior year. The concurrent model better captures the higher and more variable care needs of this population. The concurrent model will be applied to all High Needs beneficiaries aligned to LEAD ACOs, regardless of whether they are aligned to a High Needs ACO. LEAD will use an updated version of the concurrent model, which was first

used in ACO REACH, that aligns with the Version 28 CMS-HCC structure and is recalibrated using data from the High Needs population.

Will there be any limits on risk score growth?

CMS will apply a 3% risk score growth cap for the Aged & Disabled and ESRD populations using Base Year 3 (i.e., the year immediately before the ACO's first performance year) 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.

The RFA indicates that CMS will begin to implement an AI-inferred risk adjustment model in PY 2029 after "shadow testing" the model in 2028. What does this mean for ACOs?

CMS is currently developing a new AI-inferred risk adjustment model with the goal of improving the accuracy of risk adjustment and reducing the reliance on diagnosis coding. CMS will conduct significant testing and validation of the model before moving forward with implementation. Testing and validation will focus on not just the model's overall predictive accuracy, but also on whether the model performs appropriately across beneficiary subgroups, provider types, and participant characteristics; whether it avoids systematic over- or under-prediction for key populations; and whether the resulting benchmarks and payments are stable and consistent with the model's policy goals. In PY 2028, CMS will begin sharing AI- inferred risk scores with ACOs so they can understand how the implementation of the new risk adjustment model would impact scores at the beneficiary level.

In PY 2029, pending successful validation and shadow testing, CMS will use a blend of AI-inferred risk scores and risk scores calculated using the CMMI HCC Prospective Risk Adjustment Model V1 (a modified version of the CMS-HCC Risk Adjustment Model (Version 28)), weighted at 1/3rd and 2/3rd respectively, for payment. 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 PY thereafter, CMS will fully integrate the AI-inferred risk adjustment model and use 100% of AI-inferred risk scores for the Aged & Disabled population. The application and use 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.

Quality and Data Reporting

What data will CMS share with LEAD participants?

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, such as ACO REACH. Reports may include:

- 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.
- Utilization and Expenditure data.
- Benchmark and other financial reports.
- Annual Quality reports.
- Quarterly Quality reports.
- Beneficiary level reports.
- Estimated continuous improvement/sustained exceptional performance (CI/SEP) change thresholds reports.

For which patients will LEAD ACOs be required to report eCQM data? What will the reporting requirements be?

LEAD ACOs will be required to report eCQM data only for Medicare beneficiaries aligned to the LEAD ACO. In 2027 and 2028, eCQM reporting is optional for LEAD ACOs. Those who do report eCQM data will receive bonus points towards their quality score. In 2029 and 2030, LEAD ACOs will be scored based on successful reporting of eCQMs before transition to full pay for performance in 2031. More information on data submission options will be provided in the LEAD Quality Methodology.

What is LEAD's quality measurement strategy?

LEAD will offer ACOs clear, achievable criteria rooted in a small, targeted set of familiar quality measures to reduce provider burden. LEAD's measure set includes four claims-based measures, one patient experience measure, and two electronic clinical quality measures (eCQMs) that will be phased in throughout the first half of the model to align with LEAD's focus on prevention, with the first two years reporting being optional. CMS aims to minimize eCQM reporting burdens for ACOs by focusing on reporting for aligned Medicare beneficiaries. Specifically, LEAD's quality measure set includes:

- All-cause unplanned admissions for older adults with multiple chronic conditions (claims-based)
- Days at home for patients with complex, chronic conditions (claims-based)
- Timely follow-up after acute events for certain chronic conditions (claims-based)
- Patient experience: Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey (patient-reported)
- Diabetes care – Glycemic Status Assessment greater than 9% (eCQM) - *reporting optional for Performance Years 2027 and 2028*
- Blood pressure control (eCQM) - *reporting optional for Performance Years 2027 and 2028*

Similar to ACO REACH, LEAD will include a Continuous Improvement/ Sustained Exceptional Performance (CI/SEP) component and a High Performers Pool to reward ACOs that attain statistically significant improvement year-over-year and high overall performance. ACOs will also be able to attain additional quality points by submitting a Prevention Quality Plan detailing a prevention intervention being implemented to enhance the wellbeing of aligned beneficiaries.

ACOs have 3% of their benchmark at risk for quality, which they can earn back based on performance. Payments are not withheld during the year; at financial settlement, only the portion not earned back is applied when calculating shared savings/losses.

What is the Prevention and Quality Plan? How does it relate to quality performance?

Starting in PY 2027, CMS will require all LEAD ACOs to develop a Prevention and Quality Plan (PQP) that outlines a prevention intervention each ACO intends to implement to drive care delivery transformation in preventive care. CMS expects ACOs to design new, or expand existing, preventive care delivery interventions that align with LEAD's goals of improving beneficiaries' wellbeing and health outcomes.

ACOs will begin Phase I of PQP development and implementation in PY 2027, during which they will identify prevention goals and design the intervention. During this phase,

ACOs must identify and report specific measures they will use to track the impact of their intervention, and they are encouraged to establish partnerships with community-based or other local organizations to support development and implementation of the PQP.

ACOs will be able to earn up to 5 additional percentage points in their first and second performance years, and up to 10 additional percentage points per PY thereafter upon meeting PQP-related goals. More information is available in Section XI of the LEAD RFA.

Healthy Living Strategy and Model Flexibilities

What new Benefit Enhancements (BEs) will be included in LEAD?

- **Medical Nutrition Therapy:** Through this B E, CMS would expand the conditions for which beneficiaries may receive covered Medical Nutrition Therapy, beyond diabetes or renal disease, for Medicare beneficiaries in LEAD ACOs taking full risk. This B E would expand coverage for Medical Nutrition Therapy among beneficiaries with other diet- sensitive conditions thus supporting the management of chronic diseases and promoting a healthier lifestyle among Medicare beneficiaries.

- **Part D Premium Buydown:** Through this B E, which will be available by 2029, CMS would allow qualifying ACOs to partially or fully offset a beneficiary's Part D premium for a given model performance year. This B E would reduce cost-related burdens associated with accessing Part D drugs while improving health outcomes.

What new Beneficiary Engagement Incentives (BEIs) will be offered through LEAD?

New BEIs available under the LEAD Model include:

- **Chronic Disease Prevention Reward:** This BEI would enable ACOs to offer healthy food products to support beneficiaries' health as beneficiaries engage in healthy living activities (e.g., exercising) and participate in evidence-based programs that support the prevention and management of chronic diseases.

- **Substance Access BEI:** This BEI would enable ACOs and their health care providers to consult with their aligned patients about the possible benefits of hemp products, which would be at the ACO's expense and only in states where such products are legal.

LEAD ACOs will have the choice of whether to implement any or all the BEs and BEIs offered under the model. Acceptance into LEAD is NOT contingent upon an ACO agreeing to implement any BE or BEI. LEAD ACOs that choose to implement BEs and/or BEIs must provide CMS with a proposed implementation plan for each BE or BEI it plans to offer, including how they will cover the cost of the services or products.

What is the Substance Access BEI and where is it available?

The Substance Access BEI gives model participants the option of consulting with their patients about the possible use of eligible hemp products. The implementation of this BEI and any related dispensing would be funded entirely at the participant's expense; CMS would not cover the cost of such products. Further, CMS will have strict program integrity safeguards to ensure that these incentives do not result in program or patient abuse.

The Substance Access BEI is only available to participants in states where the eligible hemp products are considered legal.

The Substance Access BEI is also being made available to participants in the ACO REACH Model in performance year 2026 and the Enhancing Oncology Model starting in performance period 6. More information is available in the Substance Access BEI Frequently Asked Questions.