Long-term Enhanced Accountable Care Organization (ACO) Design (LEAD)
Request for Applications (RFA) Webinar
April 9, 2026

>>Maiya MacAlpine, Deloitte: Hello, and welcome to the Long-term Enhanced Accountable Care Organization (or ACO) Design (LEAD), Request for Applications Webinar. Thank you for joining us today. Next slide, please.

Before we get started, we'll share some brief housekeeping remarks. During today's presentation, all participants will be in listen-only mode. We recommend that you listen via your computer speakers, but we will also have the option to dial in from your phone. The dial-in information is available on the screen.

Today's presentation is being recorded. If you have any objections, please disconnect from the call at this time. Closed captioning is also available at the bottom of your screen. Additionally, at the end of the webinar, you will be directed to a brief survey to collect your feedback on the event. Next slide, please.

Now we'll review our agenda for today. First, we will use most of our time today, sorry, first we will begin with welcome and introductions. And then, we will use most of our time today to discuss LEAD eligibility and participation requirements, as well as the financial methodology. This will be followed by an overview of the quality and Healthy Living Strategy, as well as the CMS-Administered Risk Arrangements, or CARA. We will then review the application process and timeline. Afterwards, we will spend the rest of the session answering common questions you submitted in your registration forms. With any remaining time, we will take questions live from the audience. Please feel free to submit any questions you have in the Q&A box.

If we do not get to your question, we welcome you to e-mail the LEAD team at LEAD@cms.hhs.gov. We will share this e-mail address in the chat. We will aim to answer any unaddressed questions via e-mail or upcoming FAQs. This slide deck, along with the recording, and a transcript of today's event will be available on the LEAD Model webpage in the coming weeks. I'll now pass it over to Lucy for welcome and introductions. Next slide, please.

>>Lucy Sola, CMS: Good afternoon, everyone. My name is Lucy Sola, and I am the Model Co-Lead for the LEAD Model of the CMS Innovation Center. On behalf of the CMS Innovation Center, or CMMI as we like to call it, we would like to welcome you to the session.

Here at CMMI, we develop and test new health care payment and service delivery models aiming to improve patient care and lower costs. The LEAD Model builds upon the CMS Innovation Center’s earlier accountable care work, and utilizes improved

benchmarking to appeal to a broader mix of health care providers, including those with specialized patient populations, and those new to Accountable Care Organizations, or ACOs.

We know that historically, many health care providers have not participated in ACO models because of financial or administrative challenges. LEAD is designed to address these barriers by offering enhanced flexible cash flow payments, in addition to greater freedom and tools to support ACOs with spending time with patients and meeting patient needs. Next slide, please.

Now I'll introduce the rest of today's speakers. We are joined today by Meredith Yinger the Co-Model Lead for the LEAD Model, Harland McGee the Finance Lead for the LEAD Model, and Zachary Howard the Legal Lead for the CARA initiative at the CMS Innovation Center. Next slide, please.

As a refresher, LEAD is a nationwide, ten-year voluntary ACO model that will run from January 1st, 2027 through December 31st, 2036. There are three main goals for the LEAD Model that were also discussed in the LEAD Overview Webinar.

First, LEAD aims to increase the scope of ACOs to include more small, rural, and independent health care providers and community health centers. Prior CMS ACO models have shown potential to enhance aspects of care and reduce costs. However, certain providers including those with smaller practices or those that are serving a large portion of High Needs patients have faced barriers to participation. Under LEAD, those providers who are often underrepresented in ACO models may have significant opportunity to achieve savings and improve quality of care delivered.

Secondly, LEAD is designed to enhance evidence-based prevention and care coordination for more patients, including those with High Needs, and those that are dually eligible for Medicare and Medicaid. These High Needs patients typically have higher utilization rates in costly care settings that can be better managed through intensive coordinated outpatient care, to result in cost savings.

Third, LEAD aims to empower patients to be more actively involved in their care. LEAD allows patients to choose their desired care provider, and allows ACOs to offer in-kind items and services, such as wearables, for patients to have more ownership to achieve their health goals. This is all aligning with the CMS Innovation Center goal to test health care payment and service delivery models that have the potential to lower Medicare spending while maintaining and improving the quality of care for beneficiaries. Next slide, please.

Now I will share more information about eligibility and participation requirements for the LEAD Model. Next slide.

To begin, let's discuss what Accountable Care Organizations are. ACOs are a group of health care providers that have come together, and they can be a group of Medicare-enrolled doctors, hospitals suppliers, and other health care professionals, that work together to take accountability for the quality and Medicare total cost of care for their aligned beneficiaries. If the ACO includes Medicare-enrolled providers and suppliers billing under separate Tax Identification Numbers, or what we'll refer to as TINs throughout this presentation, the ACO must be a distinct legal entity with its own TIN. The ACOs must have a governing body with 75% of voting control held by Participant or Preferred Providers, and they must have a mechanism to include beneficiary representation.

To be aligned to an ACO, a beneficiary must reside in a county in the ACO service area, and the service area consists of the Core Service Area and the Extended Service Area. The Core Service Area is the area where, or the counties where, ACO Participants have physical office locations. And those counties do not need to be contiguous, so an ACO is able to operate in multiple counties in the same state, or across multiple states. 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 are able to propose an alternative approach to CMS to define the ACO’s service area. These 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. Next slide, please.

LEAD ACOs will have to maintain and submit a Participant TIN list and Preferred Provider list before each performance year. Medicare-enrolled providers and suppliers may participate in a LEAD ACO as a Participant TIN, or as a Preferred Provider. Participant TINs cannot also be Preferred Providers in the same ACO, and Preferred Providers must be identified on the ACOs Preferred Provider list, and also must not be a Participant in the same ACO.

On this slide, we share some similarities and differences across Participant TINs and Preferred Providers. Notably the key differences are, Participant TINs are the ones that have direct responsibility for driving beneficiary alignment in the model, they must report quality, and they must participate in capitated payments. Next slide, please.

Next, we'll go over LEAD’s beneficiary alignment policies. So, LEAD introduces a new option for more timely beneficiary alignment and more transparency for ACOs. LEAD ACOs will receive beneficiary alignment in two ways.

The first is claims-based alignment, which is when we are looking for at a beneficiary's claims history and identifying utilization patterns. Beneficiaries that are receiving most of their primary care services from a Participant TIN will be eligible to be claims-based aligned to a LEAD ACO, and this will be performed prospectively based off of a one-year look back period of qualifying claims. The look back period will be prior to the start of the performance year, and for the first initial alignment run it will be from October 1st to September 30th prior to the performance year starting. And then, for the mid-year updates that we are introducing Hybrid Alignment, which we'll talk a little bit about in a moment, the look back period will be from January 1st to December 31st prior to the performance year.

The other mechanism for aligning beneficiaries to LEAD ACOs is through voluntary alignment, which will allow beneficiaries to choose a provider affiliated with their ACO as their primary provider practice or other source of care. And this is really meant to reinforce the central principle of patient choice and strengthening longitudinal beneficiary-provider relationships.

LEAD ACOs may select from two alignment approaches, and these are mostly dealing with the timeliness of their alignment. So, the first is the Prospective Alignment approach, which will be conducted prior to the start of each performance year, and there are no alignment updates during the performance year. The second option, which is new in LEAD, is allowing ACOs, is the Hybrid Alignment option, which allows ACOs to update their beneficiary lists during the performance year.

Voluntary alignment will be updated monthly, and claims-based alignment will be updated one additional time during the performance year specifically for ACOs that are adding new Participants during the PY. One thing that is important to note here, is that eligible beneficiaries and Participant TINs can only be added mid-year, but they cannot be dropped and they must not be overlapping with another model to be added into LEAD. Next slide, please.

On this slide, we discuss the eligibility criteria for ACOs to be able to receive lower alignment minimums due to being, serving a high proportion of High Needs beneficiaries, or because they are Newly Entering into ACO models. So in LEAD, participating ACOs will be designated as being able to receive these lowered alignment minimums if more than 40% of their total aligned beneficiary population meets High Needs eligibility criteria. I will talk about that criteria in two slides. And the ACO must have the required care delivery capabilities to specialize in caring for these High Needs beneficiaries. So, they must have access to 24/7 support for health care provider, providers with training in advanced care planning conversations, and the ability to deliver care in patient homes.

The next criteria is what we call a "Newly Entering ACO" in the RFA. And Newly Entering ACOs will be eligible to receive lowered alignment minimums as well. They must meet the following three criteria on the slide. So the ACO entity hasn't participated in the Shared Savings Program or in ACO REACH previously, fewer than 40% of the ACOs Participant TINs have participated in the Shared Savings Program or ACO REACH in the past five years, and then less than 50% of the ACO's Participant Providers have participated in Medicare ACO initiatives for the past five years. If those three things are true, then they would be considered a Newly Entering ACO. We can go to the next slide, please.

Okay, this slide goes over the beneficiary alignment minimums. So ACOs will be required to maintain a minimum number of beneficiaries, so that CMS can reliably calculate capitation payments and financial benchmarks. For most ACOs, the required minimum number of beneficiaries during the First Performance Year is going to be 5,000 aligned beneficiaries. And 3,000 of those beneficiaries must be aligned in one of the base years to allow for accurate calculation of the benchmark.

Under certain circumstances, like I talked about on the previous slide, like them serving a high proportion of High Needs beneficiaries, or being new to ACO models, ACOs may be eligible to participate at lower beneficiary alignment minimums. And this table here outlines each of those different scenarios, and what the alignment minimums look like. What you'll see and notice is, at the bottom row, once we hit Performance Year 5, alignment minimums will stay steady for the rest of the model. Next slide, please.

This slide goes over the High Needs beneficiary eligibility criteria. And this is the criteria I was mentioning two slides ago, where this is how we are going to be defining if an ACO is meeting 40% or more of their beneficiaries meeting that High Needs eligibility criteria. So, the criteria are the ones on the screen here, and I'll talk through them quickly.

The beneficiary must have at least one significant chronic condition, which would be identified through the prospective or concurrent risk model, and they would need to have a risk score of over 3.0. Or, if they have end-stage renal disease then they would need to have an ESRD risk score of over 0.35.

They must have a condition that impairs their mobility, and this would be defined through mobility impairment ICD-10 codes. They need to, if they are falling below that risk score of 3, but are within the 2 to 3 range on the prospective risk score model, then and they have two or more unplanned hospital admissions in the past 12 months. Then they would be identified as a High Needs beneficiary.

Frailty is another measure. So, we will be using the Kim Frailty Index to identify frailty in the beneficiary population. And the Kim Claims-based Frailty Index is a multifactorial measurement, measure, that incorporates diagnoses, service utilization, and Durable

Medical Equipment utilization from Medicare claims, and it ultimately measures frailty and generates a score. So, we will be looking for beneficiaries that are the scoring over 0.35, or in the moderate to severely frail category on the Kim Frailty Index. Or, if they have evidence of frailty via certain DME claims, including home use of hospital beds and transfer equipment. Then, the final criteria we'll look at is whether they have qualified for or received 45 Medicare-covered days in a Skilled Nursing Facility within the past 12 months. Next slide, please.

This slide goes over the future that we are testing in LEAD around Medicaid integration for dually eligible beneficiaries. LEAD will test a new approach to incentivize better Medicare and Medicaid integration for dually eligible beneficiaries in Original Medicare. The goal of this is to expand access to integrated care for beneficiaries that are dually eligible for Medicare and Medicaid, and those that have previously been left out of managed care integration programs previously.

Since this is such a new feature in the LEAD Model, CMS will be engaging in a planning phase to develop a framework for partnering with two states to support improved Medicare and Medicaid integration. If we, pending successful completion of that planning period, LEAD will then pilot a program for LEAD ACOs to partner with Medicaid organizations to share data and coordinate care and share in savings.

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. CMS will align beneficiaries to a LEAD ACO if they are enrolled for benefits in an organization or program that has a partnership agreement with the LEAD ACO. Next slide, please.

This slide goes over the overlaps policy for the LEAD Model. Please keep in mind that the overlaps policy in the RFA is preliminary in nature, and additional guidance will be forthcoming, with full detail on overlaps. If your organization is considering simultaneous participation, please closely review the current overlaps policies published on each model's web page. But I will go over it at a high level today.

To start with the Shared Savings Program, Participant TINs are not permitted to participate concurrently in LEAD and the Shared Savings Program or other Innovation Center models with shared savings components, such as the KCC model. A LEAD Participant TIN may not also be a Preferred Provider in the same LEAD ACO. And then, overlaps are permitted between LEAD ACOs and Participant Providers in some cases with the GUIDE Model, the TEAM Model, the ACCESS Model, the ASM Model, and the EOM Model.

A beneficiary can only be aligned to one ACO and one Shared Savings Model, such as LEAD, in a given performance year. And, Preferred Providers are able to participate in more than one LEAD ACO, a Participant TIN, in a different LEAD ACO or Medicare Shared Savings Program, as a Participant there. And with that, my time will come to an end, and I will pass it over to Harland. Next slide, please.

>>Harland McGee, CMS: Hey everybody. My name is Harland McGee, and I'm the Finance Lead for the ACO LEAD Model.

Before we jump into some slides on the methodology, I did want to, just have a couple of notes on the overall goal and policy. As we spoke about in the previous webinar, the main strategy with some of the changes in the financial methodology, is to establish long-term incentives that should drive long-term participation. And, we want to avoid potentially punishing ACOs for successfully generating savings. With that said, let's dive in. Next slide, please.

Starting with our risk sharing options. We will be featuring two risk sharing options, which should look identical to what we feature in ACO REACH today. The Professional Risk Option, which many of you are familiar with, 50% shared savings and losses. We will be featuring CMMI's flagship Global Risk Option as well, which is 100% shared savings and losses. It should be noted that for ACOs that participate in the Global Risk Option, there will be a discount rate that is applied. What is different in ACO LEAD compared to ACO REACH, is that the discount rate will be different depending on the ACO’s status as either a higher-spending or a lower-spending ACO.

An ACO with a baseline average expenditure that is lower than your regional operating areas average regional expenditures will be subject to the 3% static discount rates. And an ACO that has higher-spending compared to their regional operating area will be receiving a 1.75% discount rate in Performance Year 2027. Now that discount rate, as we've outlined in the RFA, will increase by 25 points, or 0.25% annually, until we get to the point where that discount rate is equal to the lower-spending ACOs in 2031. Additionally, as a risk mitigation strategy, ACO LEAD will be featuring the risk corridors similar to what we have in ACO REACH today. This is to protect the ACOs as well as CMMI from any outlier performance years that result in catastrophic losses or catastrophic shared savings payouts.

On either side, an additional risk mitigation strategy that will be featured in LEAD is the optional stop-loss policy. This would mitigate ACO's risk for very high-cost beneficiaries. It's going to exist almost identically to the way it's featured in ACO REACH today. There's going to be a stop-loss charge that is applied in your total cost of care, and we will be bringing back the budget neutrality factor that creates the scenario

where the collected charges, or the total amount in the pool, that are paid out for stop-loss payments. Next slide, please.

Okay, in terms of benchmark methodology and benchmark construction. Starting with calculating our baseline benchmarks, LEAD will be using purely historical expenditures for calculating the baseline. We will be taking an average of the historical claims from the base years. The base years will be 2024 through 2026.

Additionally, LEAD will feature three different beneficiary categories. The Aged and Disabled as one bucket, ESRD is another bucket, and High Needs based on the High Needs eligibility criteria that Lucy had mentioned earlier in the presentation, will be our third beneficiary category. Each of the categories will have their baseline benchmarks calculated separately for the voluntarily aligned, as well as the claims aligned.

And the base years will get different weightings depending on if you are a new ACO with no prior experience, or if you're an ACO coming from the Shared Savings Program or ACO REACH. For the ACOs with no prior experience, the Base Years 1, 2, and 3 will be weighted at 10, 30 and 60%. And for the ACOs that have prior experience in either the Shared Savings Program or in ACO REACH, we're going to weight them equally, so that we're not punishing the ACO for continually and consecutively reducing expenditures in the most recent performance years.

Additionally, we will be applying benchmark adjustments. The prior savings adjustment will be featured as 50% of the annual average savings in Base Years 1 through 3 if you had savings in those. This is really only applicable for those ACOs that have previous experience in the Shared Savings Program or in ACO REACH.

We will also be featuring a positive-only regional efficiency adjustment. This is only eligible to ACO that participate in the Global Risk Option. The weight of this adjustment will be calculated as 50% of the difference between the ACO's historical spending and the higher of regional average. So, you also have to be a low-spending ACO to qualify for the positive regional efficiency adjustment. There will be no negative regional efficiency adjustment for any ACO that has baseline expenditures that actually exceeds or is higher than your regional spending.

Both of these adjustments will be capped. The cap will be a little bit different in ACO LEAD than it was in ACO REACH. It's worth noting that the 5% of USPCC will be risk adjusted, so that we are calculating any changes in the risk profiles between your ACO and the collective population. Next slide, please.

In terms of trending, LEAD will feature a 2/3rd weighted national regional blend, combined with a 1/3rd weighted ACPT. In the RFA, we've outlined how the guardrails

work. But there will be guardrails applied to the ACPT, so that the ACPT cannot differ so much from the national regional trends in a way that negatively impacts ACOs.

In terms of risk adjustment, this is another new area of ACO LEAD. The High Needs will be risk adjusted featuring CMMI's Concurrent Risk Adjustment Model. We'll be using Version 2, which is basically the Concurrent Model that has been updated to account for the changes between V 24 and V 28, meaning it will be built on the V 28 chassis.

ESRD will be using the 2023 CMS-HCC Prospective Model that is currently used today. And for the Aged and Disabled population, we will be using the 2024 V 28 CMS-HCC Prospective Model, but we will be changing the calibration to remove the High Needs population from the reference pop. Next slide, please.

We will also feature several capitated payment options, starting out with the Primary Care Capitation. This is similar to what's being featured in ACO REACH today. This is capitated, monthly capitated payments for primary care services, delivered by ACO Participant and Preferred Providers.

We will be bringing back the Enhanced Primary Care Capitation that existed in ACO REACH. This is an additional upfront, capitated payment on top of your base PCC. And one of the major differences between EPCC and base PCC is that your base PCC, if you elect that only, that's simply just taken out of your total cost of care. But the EPCC will be a side, separate calculation. And that additional upfront capital does need to be repaid back to CMS. It will not be calculated as part of your total cost of care, it will be a separate outside payment.

In terms of the Total Care Capitation, this is a monthly capitated payment for all Medicare Part A&B services delivered by an ACO. And this would only be eligible for ACOs in the Global Risk Option. Next slide, please.

For ACOs that select the Primary Care Capitation, but you, but do want some sort of monthly capitated payment for specialist services, we, ACO LEAD will be featuring the Advanced Payment Option. For those of you familiar with ACO REACH, this this will function almost identically to what we have in ACO REACH today. This is an upfront monthly payment that is reconciled, again not as part of your total cost of care, but against actual fee-for-service billing, with a true-up done at the end of the performance year. So, if these upfront monthly payments are higher than your actual fee-for-service billing, you will owe that money back to CMS, the net difference. However, if the capitated payments are lower, then CMS will write you a check for the difference.

In terms of the Non-Primary Care Capitated payments, this is for ACOs that don't want something as complicated as APO, but do want some sort of monthly capitated payment for your specialty providers. There's, this will be a monthly, just true capitated payment.

And this one will be reconciled against your total cost of care, as opposed to the APO true-up payment that's done at the end of the year.

Lastly, one of the most popular features of ACO LEAD, we will be featuring the administrative add-on payment. This is only for high-spending ACOs, so an ACO with again, a baseline expenditure that is higher than your regional average. You'll be eligible for 1.5% of your benchmark in total that's delivered as a monthly capitated payment. And what's interesting about this feature, is that this does not impact your shared savings calculation, meaning it's not part of your total cost of care, and it does not have to be repaid back to CMS. That's just your money to keep. Next slide, please.

We've made some changes to the financial guarantee after talking with some industry leaders. But for those of you not familiar, the financial guarantee is a risk mitigation factor which ensures that in case of termination that money gets paid back to CMS. I'm sorry, I'm having trouble with my screen here. For those ACOs that are in the Professional Risk Option, you will be able to select to sort of bifurcate, and get potentially two financial guarantees. One that will cover your shared losses and your base PCC, and one that can cover your Enhanced Primary Care Capitation option.

But we still retain the option for you to get a financial guarantee for the combined based PCC and the Enhanced PCC for those of you that do not want to have two separate agreements. But this would allow for some of you ACOs if you potentially wanted to get two different forms. Perhaps you wanted to get a surety bond for your shared losses and base PCC, but it's too expensive to do a surety bond for that combined with your EPCC, you could potentially just do an escrow account for the EPCC payments as well.

Lastly, we will be featuring the Retention Incentive. This will be a 2% withhold that ACOs can earn back. In ACO REACH, it was formerly called the Retention Withhold, but it's, it affectively features the same way. And with that, I will be passing the mic back to Meredith to review some of the quality features. Thank you.

>>Meredith Yinger, CMS: Thanks so much Harland. Hi everyone. I'm Meredith Yinger, I'm the other Co -Lead of the LEAD Model. Thank you again for being with us today. Let's go to the next slide.

We're going to talk about LEAD’s quality measurement and Healthy Living Strategies. So LEAD’s quality approach really focuses on meaningful measurement, as well as minimizing burden to ACOs and the providers participating in them. LEAD ACOs will have 3% of their annual benchmark held at risk based on their quality performance on the LEAD quality measures.

LEAD also features a High Performers Pool and a Continuous Improvement or Sustained Exceptional Performance adjustment to incentivize ongoing meaningful quality

improvement throughout participation in the model. And finally, each LEAD ACO will choose a prevention intervention based on the unique needs of their own patient population, and implement a Prevention and Quality Plan and report to CMS on that intervention. And folks who do that successfully can earn additional quality points as well. And we'll talk about the scoring here, in two or so slides.

It's also important to note that LEAD is implementing two new electronic clinical quality measures, or eCQMs. These are the Controlling High Blood Pressure measure and the Diabetes: Glycemic Status Assessment measure. These are going to be implemented slowly during the first four years of the model. And the goal here is really to meet ACOs and providers where they are, in terms of their readiness to report eCQMs. But these measures are really essential for LEAD’s prevention focus. And we're focused on using electronic health data for ACO's aligned Medicare beneficiaries to measure quality performance. So, we'll only require reporting on aligned Medicare beneficiaries.

To talk a little bit about how these measures will be phased in, in 2027 and 2028 reporting these eCQMs will be optional for participating LEAD ACOs, but those who do decide to report the data to CMS can receive bonus quality points for doing so. In 2029 and 2030, quality points will be awarded to ACOs who successfully report data. And then 2031 onwards, we'll move into full pay for performance for these new measures. The goal of this strategy is really to provide ACOs with support in adopting these new measures and so there will be likely multiple submission options available to ACOs, and more information on that will be forthcoming. Let's go to the next slide, please.

Okay, so this slide lists all of the measures in the LEAD quality measure set. There are four claims-based measures, which are those that CMS calculates, and ACOs don't have to report any data. It also includes the CAHPS measure, which is a patient-reported survey measure. And the two new eCQMs, that we just talked about. We're going to talk a little bit about how each of these are scored on the next slide, but you can see here on the right hand column, that once we move into a pay for performance posture for all of the measures you're able to achieve a total of ten points per measure. Let's go to the next slide, please.

Awesome. So, this slide lays out how we will calculate each ACO’s quality score, and then how that will ultimately be used to determine the ACO’s earned-back percentage for their benchmark. So, like I mentioned, we start by totaling points for each measure.

For the purposes of today's discussion, I'm going to focus in on how we're going to calculate these scores for 2027 and 2028. And so, I mentioned that reporting those eCQM measures are optional for those two years. So, we will sum the total points earned for the other five measures, divide by the maximum total points to get that initial quality score, and then we'll go ahead and adjust that quality score based on the other achievements of

the ACO. So in 2027 and 2028, if the ACO decides to report eCQM measures to CMS, they can get between a 0 and 2.5% adjustment. ACOs can also get an adjustment for reporting on their PQP, which we talked about in the last slide.

And finally, beginning in the Second Performance Year, they can achieve a continuous improvement multiplier as well. Once we make all those adjustments, that gets us our total quality score, which is multiplied by the quality withhold to determine what percentage the ACO will earn back on their benchmark. Let's go to the next slide, please.

All right, so I mentioned that LEAD has a robust Healthy Living Strategy. The model is really focused on advancing preventive care, empowering beneficiaries, and ultimately supporting them in achieving the best possible health. So, the Prevention and Quality Plan that I mentioned before is a key part of this Healthy Living Strategy. It also includes the Tech Enabler Initiative. This is an initiative that is designed to remove barriers that we've heard about from ACOs in their ability to partner with and contract with third party innovative partners, like digital tools or other technology companies, that ultimately help them improve care for their beneficiaries.

The Healthy Living Strategy also includes Benefit Enhancements and Patient Incentives. And these really are innovative flexibilities that allow ACOs to better engage their aligned beneficiaries in their care, or expand coverage, or remove barriers to coverage for Medicare services.

Finally, the last thing I want to mention on this slide. We have an additional flexibility in the model that's not formally part of the Healthy Living Strategy, but we wanted to make sure that folks on the webinar were aware of it. That's the Certified Electronic Health Record Technology, or CEHRT, flexibility. And this includes a one-year transitional pathway for clinicians who weren't previously required to use CEHRT, as well as a three-year deferral for the CEHRT requirement for those who meet specific capabilities upfront. This flexibility is really meant to ensure that folks are not precluded from joining the model because of the CEHRT flexibility, but they're able to sort of get there overtime. This flexibility does not impact the eCQM reporting timeline, I'll just call that out specifically.

All right, let's go ahead and go to the next slide. And I'm going to pass it to my colleague Zach, to talk about CARA.

>>Zach Howard, CMS: Thank you very much Meredith. As a reminder, I am Zach Howard the Legal Lead for CARA, which stands for CMS-Administered Risk Arrangements. Next slide, please.

As a high-level overview, CARA is a voluntary initiative contained within LEAD, where LEAD Participant ACOs may join if they would like to. Specifically, CARA allows

LEAD Participant ACOs to test new structures for payment arrangers and arrangements with specialists. LEAD ACOs in the Global Risk Option can participate in CARA to contract directly with specialist, otherwise known as Preferred Providers, for specific quality and cost outcomes. This is intended to reduce barriers for ACOs to establish meaningful, episode-based risk arrangements with these specialists, also known as Preferred Providers. CARA contains three key components that we'll talk about here.

First of all, we have the data initiative where LEAD ACOs will receive reports to support identification of Preferred Providers and potential episodes of care for episode-based risk arrangements. These are similar to those provided in the shadow bundles, shadow bundles data initiative within ACO REACH. Next, the second big thing is, performance adjustments within LEAD will be based on quality measures. Adjustments will range from 10 to 100%, and they will be negotiated privately by the ACOs and their specialists.

And also, just to call out the unique, most unique episode within this CARA initiative is kind of the third big pillar that we want to talk about today, is the Resilience and Independence in a Safe Environment, otherwise known as RISE, to Age in Place Episode, which aims to increase activities of daily living and decrease acute events for Medicare beneficiaries. Really at the end of the day, this is focused on preventing falls for Medicare beneficiaries. RISE provides a bundled payment for interdisciplinary care, for an interdisciplinary care team to deliver comprehensive fall prevention interventions. Next slide, please.

Okay, let's talk about the CARA episode options here. CARA offers acute medical and procedural episode-based cost measures, or EBCMs at baseline, and will phase in chronic condition EBCMs in the early years of the initiative. These include acute inpatient medical conditions which could involve sepsis, psychoses and related conditions, and intracranial hemorrhages, just a few examples. A few other chronic conditions could include things such as diabetes, heart failure, chronic kidney disease, and end-stage renal disease. Another example is general surgical procedures, and then any other conditions and procedures which are included in this slide for reference, that you can look back on the recording later.

ACOs have two major participation options within CARA, if they do select to join CARA, after joining LEAD. In the Default Option, ACO can select ECBMs based on CMS's methodology, so CMS will be giving them the data and the methodology. ACOs are not permitted to change episode construction in this participation option, but can specify discounts or premiums to target prices, select quality measures for performance adjustment, and performance adjustment specification. All of these however are subject to CMS review and approval.

Alternatively, the Maximal Flexibility Option, more simply known as the MAX Flex Option, allows ACOs to select existing EBCM categories and customize the episode by specifying more modifications. So, kind of more of a choose-your-own-adventure style of an option, rather than the Default Approach. ACOs selecting this option may partner with external vendors to assist in the alternative episode construction methodologies. Again, that's the MAX Flex Option. Next slide, please.

Okay, how do you participate in CARA? So first of all, like I said earlier, you have to already be participating in LEAD to participate in CARA. So, once you get that out of the way, if you would like to join CARA, CARA is integrated into the 4Innovation, otherwise known as 4i platform, which allows for digital data sharing between ACOs and CMS. LEAD ACOs must access the CARA module and 4i platform to select episodes for participation, identify any potential specialists they'd like to contract with, and enter into negotiated episode target prices with those specialists.

Next step is, CMS will provide episodic data and pricing information, as applicable, to ACOs, to facilitate setting up their own episode-based risk arrangements, otherwise known as EBRAs, with their Preferred Providers. Next is, you might expect the ACOs and specialists will then enter into an episode-based risk arrangement (EBRA), essentially a contract in order to carry out these episodes. Next, specialists will deliver care and bill through Medicare fee-for-service. CMS will then reconcile concurrently with LEAD settlement. If the fee-for-service amount is less than the target price, the specialist receives payment. Alternatively, if the fee-for-service amount is greater than the target price previously agreed upon, these specialists owe repayment.

Now I will pass it back to Meredith. And we can go to the next slide.

>>**Meredith Yinger, CMS:** Thanks Zach. All right, let's talk briefly about the application process and timeline, and then we will transition to Q&A. So next slide, please.

Okay, so the headline here is that the LEAD application is now available, at the link here in the slide, but this link is also featured on the LEAD Model webpage on the CMMI website. Applications are due by May 17th at 11:59 PM Eastern Time. There is an abbreviated application for current 2026 ACO REACH Participants, available at the same link.

Organizations who are interested in future cohorts and are not yet ready to apply to LEAD for the 2027 Performance Year are encouraged to submit a Letter of Interest to us by May 17th. I'll note that this LOI is not yet available, but we anticipate making it available by April 20th. We will put a link on the LEAD webpage once it is available. The LOI is not required in order to be eligible for a future cohort, it's just a tool for us to communicate with you all.

And finally, there is a New Entrant tool available for ACOs that are potentially trying to determine whether they would qualify as Newly Entering in LEAD. The tool is available in the same link as the LEAD application, under the Helpful Resources tab. There's a template, we ask you to fill in some information and then send the template to us via the LEAD Help Desk, by April 27th at 11:59 PM, and we will share information back with you to help you understand your status. And finally, if you have any questions, you can reach out to us at LEAD@cms.hhs.gov. We are very actively monitoring the Help Desk. All right, let's go to the next slide.

And very quickly, let's talk about the timeline here. So, I mentioned the application is open, it's due by May 17th. We will notify applicants that were selected by early summer 2026, and begin onboarding those ACOs into the model. Folks who are planning to participate in 2027 will have to upload their Participant TINs into 4i by August 5th, 2026 and by September 8th, folks will have to drop any Participant TINs you no longer want included in your list. And beginning on September 15th will be our optional implementation period that goes through December 15th. And then the model launches on January 1st, 2027.

All right, let's go ahead and move into Q&A here. I'm going to invite our speakers to all turn their cameras back on. We have received almost 200 very detailed and impressive questions in the Q&A, so thank you everybody for your interest.

I'm going to start with a very common question we've been hearing which is: "For folks who are currently participating in the ACO REACH Model, but they are planning to make changes to their entity for various reasons for LEAD, are they eligible to fill out that abbreviated application?"

We are going to post some additional information on this in Salesforce, which is at that link to our LEAD application, in the Helpful Resources tab, very soon. We've been working on this for you all for the past couple of days. And we'll also probably send a message out in a couple of other ways as well. But we hear you, more information is coming.

Okay Zach, I'm going to come to you for a question that I've been hearing about CARA, which is: "Could you clarify sort of the timing of CARA participation, and what it means for a LEAD ACO that's joining in 2027?"

>>Zach Howard, CMS: Yeah, thank you Meredith. That is a great question, and I know there's been a bit of confusion on that topic.

So, the first year that CARA Participants, if you are a LEAD Participant and choose to participate in CARA, will actually be triggering episodes, so the episodes will actually be happening and you're getting setting up payments and getting payments for them, will be

in 2028, calendar year 2028, or Performance Year 2028. 2027 is for LEAD Participants to kind of engage in research, and determine if they do want to be part of CARA. And because there are a few more moving parts of CARA, with having to pick out your episodes, determinate if you want to do the Default Option or the MAX Flex Option, and then having to actually negotiate the EBRAs with your Preferred Providers, we're essentially giving an extra year before CARA starts in earnest, then LEAD. So, 2027 LEAD starts, LEAD Participants can actually research and figure out if they want to join CARA. There is a timeline that we'll have more information on it at a later date on when they can join CARA in 2027, and then the episodes will actually start triggering in 2028.

>>**Meredith Yinger, CMS:** Thanks so much. Lucy I'm coming to you next. Another very common question we get is: “Whether ACOs can apply to both LEAD and the Medicare Shared Savings Program simultaneously, and if so, when do they really have to decide which program they're going to participate in in 2027?”

>>**Lucy Sola, CMS:** Yeah, ACOs are able to, are able to apply to both LEAD and the Shared Savings Program simultaneously. And the final deadline for dropping providers and resolving those overlaps would be September 8th of 2026. So, you will either need to drop the TINs from the SSP roster or the LEAD roster.

>>**Meredith Yinger, CMS:** Thank you. Okay Harland, coming to you next. I think I probably saw 25 questions about the higher-spending and lower-spending designation, if not more. Can you talk about: “How that designation is determined, and is it a one-time, can it change? If so, when can it change?” Those kinds of details.

>>**Harland McGee, CMS:** Yeah, sure thing. I'm seeing a lot of questions in the chat about that as well, and just, I hope if it makes it easier, I can try to take a step back and explain it a little bit more.

The way I like to think about it, is similarly to how the regional efficiency adjustment is applied in the Shared Savings Program. What we do, is after establishing your baseline, we compare that to your operating regional average, and we create like a comparison group that has the same risk profile and the same weighting of High Needs versus AD beneficiaries. And then when we could do that comparison, if you are lower, and the regional average is higher, then you're considered a low-spending ACO, and you're eligible for the regional efficiency adjustment and all the things that come with the low-spending ACOs. And if in that comparison you come in higher, then you are eligible for all of the higher-spending ACO benefits.

So, one way to think about it would be if you're eligible for the regional efficiency adjustment that's it, you're a low-spending ACO, and if you're not eligible for that, then you're a high-spending ACO. And just like, how we update the benchmarks on an annual basis, and we have to recalculate what that regional efficiency adjustment is, you know

that determination can be changed on an annual basis prior to the performance year, but not during the performance year. So, and I think that's a big distinction with the Hybrid Alignment right now. But prior to the performance year, we'll take into account you know, whatever changes in your alignment and your risk profiles are, and redetermine on an annual basis whether you qualify for the low-spend or the high-spend, as the ACO evolves throughout the program.

>>**Meredith Yinger, CMS:** Thank you. The next question, I've seen a couple times. I'll go ahead and take it myself. And that is: "Which individual providers that bill under a Participant TIN are required to participate in Primary Care Capitation?"

So, we've noted for the purposes of LEAD, that participation is at the full TIN level. And so, when we go to determine PCC payment amounts and fee reductions, we will take a look at all of the individual providers that are billing under the TIN, at both the NPI and the CCN level. Primary care specialists will be automatically, sort of, enrolled in PCC. Non-primary care specialists will be ineligible for PCC calculations and fee reductions. And for the purposes of this, all services provided by FQHCs and RHCs are generally considered primary care, so FQHCs and RHC CCNs will be enrolled in PCC. There's more information on this in the RFA, I'm not going to try to remember the section number offhand, but encourage folks to go look at it. There's a nice big table there for you as well.

Okay, we've been scrolling through the Q&A trying to come up with a couple more common questions here. So Lucy, I think I'm going to come to you on a common question we get about Hybrid Alignment, which is: "Will beneficiaries that are added during that mid-year additional claims-based alignment window be added from that point forward, or for the entire performance year?"

>>**Lucy Sola, CMS:** It's from that point forward. And the benchmarks and capitated payments will update accordingly from that point forward as well. And more details on that will be in the financial methodology papers that we publish.

>>**Meredith Yinger, CMS:** Thanks. Harland, another common one was a question about the Concurrent Risk Adjustment Model we're using in LEAD for High Needs beneficiaries, which we're calling Version 2, and whether that is based on V 24 or V 28.

>>**Harland McGee, CMS:** Yeah, that that's a good question. In a nutshell, yes, it's been updated on the V 28 chassis, whereas the previous concurrent model was using the V 24 chassis.

>>**Meredith Yinger, CMS:** Thanks so much. One more, just for fun. There's a question about: "Whether the 3% quality withhold is deducted from prospective payments, or if

it's netted out during shared savings?" The answer is that it's netted out during shared savings. We don't reduce capitated payments based on the quality withhold.

All right. I think with that we should go ahead and wrap up, we're coming up on time here. Thank you everyone for joining us, and for your great questions. Another plug to please submit any questions to the Help Desk at LEAD@cms.hhs.gov, and we'll do our best to answer the remaining questions.

We also have some additional opportunities coming up in the next several weeks, including an Application Office Hour on Tuesday April 21st at 1:00 PM Eastern, as well as an Alignment and Financial Methodology Office hour on May 5th. So, we're hoping to continue answering your detailed questions there. Please join us. Next slide, please.

And lastly, again here's where you can access all of our materials, the link to our Help Desk and we've provided all of these links for you in the chat. We encourage folks to sign up to the LEAD Model listserv, which is where we send all of the major model updates first. And finally, please fill out the post event survey.

Thank you very much for joining us today, we appreciate it. This concludes our event. We hope all of this was very helpful.