

Regulatory Advisory

September 11, 2018

MEDICARE SHARED SAVINGS PROGRAM PROPOSED RULE: ACCOUNTABLE CARE ORGANIZATIONS-PATHWAYS TO SUCCESS

AT A GLANCE

The Centers for Medicare & Medicaid Services (CMS) Aug. 17 published a <u>proposed rule</u> that would make several changes to the Medicare Shared Savings Program (MSSP), including to the structure of payments made to accountable care organizations (ACOs) and other aspects of participation in the MSSP. Comments on the proposed rule are due to CMS by Oct. 16.

Our Take

We acknowledge CMS's interest in encouraging providers to more quickly move toward accepting risk, but are <u>deeply</u> <u>concerned</u> that its proposal to shorten the length of time in which ACOs can participate in an upside-only model and reduce the amount of shared savings ACOs can earn across tracks ignores the reality that providers come from different starting points and will have different learning curves when moving toward value-based care. We are also carefully evaluating the agency's proposals to offer different participation opportunities to physician- and hospital-led ACOs. Such a distinction between these two types of ACOs is subjective and not reflective of how ACOs actually operate.

What You Can Do

- ✓ Participate in an AHA members-only webinar on Wednesday, Sept. 12 at 1:30 p.m. ET to provide feedback on your concerns with this regulation. To register for this 60-minute webinar, visit here.
- ✓ Share this advisory with your chief medical officer, chief financial officer and other members of your senior management team, as well as your ACO leadership team and others involved in shared savings arrangements.
- ✓ Assess the potential impact of the proposed payment and quality changes on your Medicare revenue and operations.
- ✓ Submit comments to CMS with your specific concerns by Oct. 16 at <u>www.regulations.gov</u>.

Further Questions

For additional questions, please contact Shira Hollander, senior associate director for policy development, at (202) 626-2329 or shollander@aha.org.

Key Takeaways

The proposed rule would:

- Participation Options: Discontinue
 Tracks 1 and 2 of the MSSP and
 instead offer a BASIC Track with a
 glide path to risk and an
 ENHANCED Track that mirrors the
 current Track 3.
- Agreement Period: Extend the agreement period from three to five years, with July 1, 2019 as the earliest available start date.
- Risk and Reward: Offer lower levels of shared savings (25-40%) for ACOs in the first four levels of the BASIC Track's glide path than are currently available to any ACO.
- Upside-only Risk: Restrict ACOs to a maximum of one to two years of upside-only risk.
- Low- and High-Revenue ACOs:
 Provide different participation options to ACOs depending on whether they qualify as "low-" or "high-revenue" ACOs.
- Assignment Methodology: Permit ACOs to annually elect their beneficiary assignment methodology.
- Waivers: Expand access to waivers of the Skilled Nursing Facility 3-Day rule and certain restrictions on the coverage of telehealth.
- Beneficiary Incentives: Enable ACOs to establish beneficiary incentive programs.
- Benchmarking Methodology:

 Factor regional expenditures into benchmarks beginning in the first agreement period, but reduce the weight of regional factors in calculating the benchmark.



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BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) published its proposed rule for the Medicare Shared Savings Program (MSSP) in the <u>Aug. 17 Federal Register</u>. The rule would make several changes to the structure of payments to accountable care organizations (ACOs) and to other aspects of participation in the MSSP. Comments are due to CMS by Oct.16, and most changes are effective July 1, 2019, except where otherwise noted. CMS estimates its proposed changes would result in approximately \$2.24 billion in lower overall federal spending over 10 years and a decrease in the number of ACOs that participate in the program.

REDESIGNED MSSP PARTICIPATION OPTIONS

Due to a variety of concerns it has about the financial results of the MSSP program, and participants' ability and willingness to transition to two-sided risk, CMS proposes to redesign the MSSP's participation options. Specifically, CMS proposes to discontinue Tracks 1 and 2 and the deferred renewal option, which allowed ACOs in Track 1 in their first agreement period to defer renewal for a second agreement period in a two-sided risk model by one year. Instead, CMS would offer two tracks – BASIC and ENHANCED – that eligible ACOs could enter for an agreement period of not less than five years. CMS would not offer any additional application cycles for the Center for Medicare & Medicaid Innovation (CMMI) Track 1+ Model.

Under the BASIC Track of the new program, eligible ACOs would begin under a one-sided model and incrementally phase-in risk and potential reward over the course of a single agreement period. This approach is referred to as a "glide path" to risk. The ENHANCED Track, which is based on the MSSP's existing Track 3, would offer ACOs the highest level of risk and potential reward. The rule proposes to require ACOs to enter one of these two tracks for agreement periods beginning on July 1, 2019 and in subsequent years. For agreement periods beginning on July 1, 2019, the length of the agreement would be five years and six months. In subsequent years, the length of the agreement period would be five years.

Creating a BASIC Track with Glide Path to Performance-based Risk

CMS proposes to create a glide path to risk in the BASIC Track that comprises five levels: an upside-only model available only for one or two years (Levels A and B), and three levels of progressively higher risk and potential reward (Levels C, D, and E). CMS proposes to automatically advance ACOs at the start of each participation year along the glide path until they reach the maximum Level E, which is designed to be the same as the existing CMMI Track 1+ Model. However, ACOs that wish to do so would be allowed to skip a level or levels during the agreement period, except for ACOs at Level D, which would automatically transition to Level E at the start of the next performance year. ACOs would not be permitted, at any point, to transition to a lower level of risk. ACOs with agreement periods beginning July 1,

2019 would be permitted to remain at the level of the BASIC Track at which they entered through the 2020 performance year.

Levels of Risk and Reward in the BASIC Track's Glide Path. CMS proposes significant changes to the amounts of shared savings and losses that ACOs in the proposed BASIC and ENHANCED Track would be exposed to, as compared with current ACOs in existing tracks. For example, the current shared savings rate for Track 1 ACOs is 50 percent, which would be reduced to 25 percent in the proposed Levels A and B of the BASIC Track. The following levels of shared savings and shared loss rates would be available to ACOs, once the minimum savings rate (MSR) or minimum loss ratio (MLR), respectively, is met or exceeded:

Levels	Levels A and B	Level C	Level D	Level E	ENHANCED Track (Current Track 3)
Shared Savings (once MSR is met or exceeded)	1st dollar savings at a rate of up to 25% based on quality performance; not to exceed 10% of updated benchmark	1st dollar savings at a rate of up to 30% based on quality performance, not to exceed 10% of updated benchmark	1st dollar savings at a rate of up to 40% based on quality performance, not to exceed 10% of updated benchmark	1st dollar savings at a rate of up to 50% based on quality performance, not to exceed 10% of updated benchmark (same as current Track 1 and Track 1+)	1st dollar savings at a rate of up to 75% based on quality performance, not to exceed 20% of updated benchmark
Shared Losses (once MLR is met or exceeded)	N/A	1st dollar losses at a rate of 30%, not to exceed 2% of ACO participant revenue capped at 1% of updated benchmark	1st dollar losses at a rate of 30%, not to exceed 4% of ACO participant revenue capped at 2% of updated benchmark	1st dollar losses at a rate of 30%, not to exceed percentage of revenue specified in the revenue-based nominal amount standard under the Quality Payment Program (QPP) (8% of ACO participant revenue in 2019 – 2020), capped at a percentage of updated benchmark that is 1 percentage point higher than the expenditure-based nominal amount standard (4% of updated benchmark in 2019-2020)	1st dollar losses at a rate of 1 minus final sharing rate (between 40% -75%), not to exceed 15% of updated benchmark
Alternative Payment	Merit-based Incentive Payment	MIPS APM	MIPS APM	Advanced APM	Advanced APM

Model (APM)	System (MIPS)		
under QPP	APM		

As demonstrated above, the rates of shared savings and losses gradually increase across the BASIC Track's levels until they reach 50 percent and 30 percent, respectively, in Level E, which are the same shared savings and loss rates as Track 1+. The shared loss rates remain constant at 30 percent across Levels C, D and E, but the loss sharing limit – the amount at which losses are capped – gradually increases. CMS would calculate the loss-sharing limit by calculating an ACO's total Medicare fee-for-service (FFS) revenue for the applicable performance year and then applying to that number the applicable percentage of revenue listed in the table. CMS would also apply the percentage of benchmark number to the ACO's total updated benchmark expenditures. The loss-sharing limit would be the lower of the two numbers that result from the percentage applications. CMS includes the following hypothetical as Table 4 in the rule to illustrate this calculation. In this hypothetical, the ACO's loss sharing limit would be set at \$1,090,479 (8 percent of ACO participant revenue) because this amount is less than 4 percent of the ACO's updated historical benchmark expenditures:

Hypothetical Example of Loss Sharing Limit Amounts for ACO in Basic Track Level E

[A] ACO's Total Updated Benchmark Expenditures	[B] ACO Participants' Total Medicare Parts A and B FFS Revenue	[C] 8 percent of ACO Participants' Total Medicare Parts A and B FFS Revenue ([B] x .08)	[D] 4 percent of ACO's Updated Benchmark Expenditures ([A] x .04)
\$93,411,313	\$13,630,983	\$1,090,479	\$3,736,453

Participation Options Based on Medicare FFS Revenue and Prior Participation

As part of its redesign of the MSSP program, CMS is proposing policies to distinguish among ACOs and restrict some ACOs to only certain participation options. As described in detail below, CMS proposes to distinguish between "low-revenue" and "high-revenue;" "new," "renewing," and "reentering" ACOs; and "experienced" and "inexperienced" ACOs.

<u>Defining Low- and High-revenue ACOs</u>. To define low- and high-revenue ACOs, CMS proposes to assess the degree of control an ACO holds over the Medicare expenditures of its assigned beneficiaries. CMS proposes to gauge control by comparing the total Medicare Part A and Part B FFS revenue of an ACO's participants (or providers and suppliers) with the total Medicare Part A and Part B FFS expenditures of its assigned beneficiaries. **If an ACO's Medicare Part A and B FFS revenue is 25 percent or more of the Medicare Part A and B FFS expenditures for its assigned beneficiaries, CMS would consider that ACO "high-revenue."**

For ACOs with a July 1, 2019 agreement start date, CMS proposes to determine whether the ACO is low- or high-revenue using expenditure data from the most recent calendar year for which 12 months of data are available. CMS would inform ACOs as to whether they qualify as high- or low-revenue before they would be required to execute a participation agreement. CMS also includes proposals to address the issue of when ACOs are close to the revenue threshold or cross it during an agreement period.

<u>Defining Renewing and Re-Entering ACOs</u>. CMS proposes to clarify the difference between renewing ACOs and re-entering ACOs. CMS proposes to define a renewing ACO as one that continues its participation in the program for a consecutive agreement period, without a break in participation, because it is either: (1) an ACO whose participation agreement expired and that immediately enters a new agreement period to continue its participation in the program; or (2) an ACO that terminated its current participation agreement and immediately enters a new agreement period to continue its participation in the program.

CMS proposes to define a re-entering ACO as an ACO that does not meet the definition of a renewing ACO and meets either of the following conditions:

- Is the same legal entity as an ACO, identified by taxpayer identification number (TIN), that previously participated in the program and is applying to participate in the program after a break in participation, because it is either: (a) an ACO whose participation agreement expired without having been renewed; or (b) an ACO whose participation agreement was terminated; or
- 2) Is a new legal entity that has never participated in the Shared Savings Program and is applying to participate in the program and more than 50 percent of its ACO participants were included on the ACO participant list of the same ACO in any of the five most recent performance years prior to the agreement start date.

All other ACOs would be considered new entities.

Eligibility Requirements and Application Procedures for Renewing and Re-entering ACOs. CMS makes several proposals to clarify the eligibility requirements and application procedures for renewing and re-entering ACOs. For example, CMS would remove the required "sit-out" period for terminated ACOs so as to enable ACOs in current agreement periods to quickly transition to the proposed participation options included in the rule under new agreements. **CMS also makes several proposals for evaluating ACOs' prior quality and financial performance, as well as timeliness of repayment of shared losses, in order to prevent ACOs with a history of poor performance from participating in the MSSP.** For example, CMS proposes to add a financial performance review criterion to allow it to evaluate whether an ACO generated losses that were "negative outside corridor" for two performance years of the ACO's previous agreement period. "Negative outside corridor" describes the situation in which an ACO's benchmark minus performance year expenditures are less than or equal to the negative MSR for ACOs in a one-sided model, or the MLR for ACOs in a two-sided model.

<u>Defining Experienced vs. Inexperienced ACOs</u>. CMS proposes the following definitions to differentiate between ACOs with prior experience in the program and those without. The distinction would be governed by prior participation in a performance-based risk Medicare ACO initiative. These are initiatives implemented by CMS that require an ACO to participate under a two-sided model during its agreement period. This definition includes the existing Track 2 and Track 3, the proposed BASIC and ENHANCED Tracks, and several CMMI ACO Models

involving two-sided risk including, among others, the Track 1+ Model and the Next Generation ACO Model.

- Experienced with performance-based risk Medicare ACO initiatives: Defined as an ACO that meets either of the following criteria:
 - The ACO is the same legal entity as a current or previous ACO that is participating in, or has participated in, a performance-based risk Medicare ACO initiative, or that deferred its entry into a second MSSP agreement period under a two-sided model¹; or
 - 2) Forty percent or more of the ACO's participants participated in a performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a second MSSP agreement period under a two-sided model, in any of the five most recent performance years prior to the agreement start date.
- Inexperienced with performance-based risk Medicare ACO initiatives: Defined as an ACO that meets all of the following criteria:
 - The ACO is a legal entity that has not participated in any performance-based risk Medicare ACO initiative, and has not deferred its entry into a second MSSP agreement period under a two-sided model; and
 - 2) Less than 40 percent of the ACO's participants participated in a performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a second MSSP agreement period under a two-sided model, in each of the five most recent performance years prior to the agreement start date.

CMS clarifies that its consideration of the forty percent threshold would not be limited to ACO participants that participated in the same ACO or the same performance-based risk Medicare ACO initiative during the look-back period. Instead, CMS would consider what percentage of the ACO participants participated in *any* performance-based risk Medicare ACO initiative including, in future years, the proposed BASIC and ENHANCED tracks.

<u>Criteria for Determining Participation Options</u>. Using the above definitions of low- and high-revenue, new, re-entering and renewing ACOs, and experienced and inexperienced ACOs, CMS makes several proposals to govern the participation options available to a particular ACO. Due to its concerns that certain MSSP policies are susceptible to gaming, some of these proposals are designed to prevent ACOs from taking advantage of additional time under the proposed BASIC Track's one-sided levels and instead encourage more rapid progression to performance-based risk. These options are summarized in the tables below and described in more detail in the text that follows. A more fulsome summary of the proposed participation options is available in Appendix A.

Participation Options for Low Revenue ACOs Based on Applicant Type and Experience with Risk:

¹ The deferred renewal option allows ACOs in Track 1 in their first agreement period to defer renewal for a second agreement period in a two-sided risk model by one year.

Applicant Type	Inexperienced or Experienced	BASIC Track Glide Path	BASIC Track Level E	ENHANCED Track
New legal entity	Inexperienced	Yes, Levels A – E	Yes	Yes
New legal entity	Experienced	No	Yes	Yes
Re-entering ACO	Inexperienced	Yes, Levels B – E	Yes	Yes
Re-entering ACO	Experienced	No	Yes	Yes
Renewing ACO	Inexperienced	Yes, Levels B – E	Yes	Yes
Renewing ACO	Experienced	No	Yes	Yes

Participation Options for High Revenue ACOs Based on Applicant Type and Experience with Risk:

Applicant Type	Inexperienced or Experienced	BASIC Track Glide Path	BASIC Track Level E	ENHANCED Track
New legal entity	Inexperienced	Yes, Levels A – E	Yes	Yes
New legal entity	Experienced	No	No	Yes
Re-entering ACO	Inexperienced	Yes, Levels B – E	Yes	Yes
Re-entering ACO	Experienced	No	No	Yes
Renewing ACO	Inexperienced	Yes, Levels B – E	Yes	Yes
Renewing ACO	Experienced	No	No	Yes

Participation Options for Low- and High-Revenue ACOs. CMS proposes to limit high-revenue ACOs to a single agreement under the BASIC Track, before requiring them to transition to the ENHANCED Track. Conversely, CMS proposes to allow low-revenue ACOs to participate in two agreement periods in the BASIC Track before they would be required to transition to the ENHANCED Track. Low-revenue ACOs would not be required to participate in two consecutive agreement periods in the BASIC Track; instead, they could transition to ENHANCED after one agreement period and then return back to the BASIC Track.

CMS bases this proposal on its belief that high-revenue ACOs typically include a hospital billing through an ACO participant tax identification number (TIN), and thus the ACO would be better equipped to generate savings. Moreover, CMS believes that high-revenue ACOs are more prepared to accept higher amounts of risk as compared with low-revenue ACOs, due to their degree of control over the Medicare expenditures for their assigned beneficiaries. **CMS seeks comment on whether it should also create a glide path for ACOs entering the ENHANCED Track, and whether such a path should be available only to low-revenue ACOs or to all ACOs.** CMS also seeks comment on several approaches to allow low-revenue ACOs to have potentially greater access to shared savings compared to high-revenue ACOs.

Participation Options for Experienced and Inexperienced ACOs. CMS proposes to allow only inexperienced ACOs that are new legal entities – regardless of whether they are low-or high-revenue – to enter the BASIC Track's glide path at Level A. Inexperienced re-entering or renewing ACOs, which based on the definitions listed above includes ACOs that previously participated in Track 1 or for which the majority of their ACO participants participated in the same Track 1 ACO, would be permitted to enter the BASIC Track's glide path at Level B. This proposal also would apply to both low- and high-revenue ACOs and would offer these ACOs one year (or 18 months if they participate in the six-month agreement period from July 1, 2019 –

Dec. 31, 2019) with upside-only risk. Experienced, low-revenue ACOs – whether new, reentering, or renewing – would be permitted to participate only in Level E of the BASIC Track or in the ENHANCED Track. Experienced, high-revenue ACOs – whether new, reentering, or renewing – would be permitted to participate *only* in the ENHANCED Track.

Monitoring for Financial Performance. Due to CMS's belief that its current regulations are insufficient to monitor and address ACOs' financial performance, CMS makes several proposals to qualify an ACO's failure to lower growth in Medicare FFS expenditures as grounds for pre-termination actions and potentially termination, similarly to how poor quality performance can subject an ACO to remedial action or termination. Specifically, CMS proposes to monitor for whether expenditures for an ACO's assigned beneficiaries are "negative outside corridor," meaning, as described above, that the expenditures for assigned beneficiaries exceed the ACO's updated benchmark by an amount equal to or greater than the ACO's negative MSR under a one-sided model or the ACO's MLR under a two-sided model.²

CMS proposes that if an ACO is negative outside corridor for a single performance year, the agency may take a host of pre-termination actions. If the ACO is negative outside corridor for an additional performance year of the same agreement period, CMS proposes that it may immediately or with advance notice terminate the ACO's participation. CMS proposes to implement financial performance monitoring for performance years beginning in 2019 and subsequent years. CMS believes this proposal would address its concerns about ACOs that have been allowed to take advantage of the benefits of participation in the MSSP despite having poor financial performance.

ACOs' Election of MSR/MLR

In this section, CMS proposes requirements related to the election of the MSR/MLR for ACOs in the BASIC Track's glide path. The MSR and MLR are designed to protect CMS and ACOs when changes in expenditures represent normal or randomly variable changes, rather than actual change in performance. Under the existing Track 1 program, CMS assigns ACOs a variable MSR based on the number of assigned beneficiaries. Current Track 2, 3 and 1+ participants can select from the following options:

- Zero percent MSR/MLR (offering ACOs immediate savings but no protection from shared losses);
- Symmetrical MSR/MLR in a 0.5 percent increment between 0.5 and 2.0 percent; or
- Symmetrical MSR/MLR that varies based on the number of assigned beneficiaries.

CMS proposes to extend the existing structure to ACOs participating in the BASIC Track. In other words, ACOs in the upside-only levels of the BASIC Track would have a variable

² For purposes of this proposed rule, an ACO is considered to have shared savings when its benchmark minus performance year expenditures are greater than or equal to the MSR. An ACO is "positive within corridor" when its benchmark minus performance year expenditures are greater than zero, but less than the MSR. An ACO is "negative within corridor" when its benchmark minus performance year expenditures are less than zero, but greater than the negative MSR for ACOs in a one-sided model or the MLR for ACOs in a two-sided model. An ACO is "negative outside corridor" when its benchmark minus performance year expenditures are less than or equal to the negative MSR for ACOs in a one-sided model or the MLR for ACOs in a two-sided model.

MSR based on the number of assigned beneficiaries and ACOs in Levels C, D, and E would have the same options as currently available to ACOs in a two-sided model (as listed above). Participants in the ENHANCED track would also be able to choose from the options listed above. CMS states its belief that providing the same MSR/MLR options for BASIC Track ACOs under two-sided risk as ENHANCED Track ACOs would reduce complexity and establish more equal footing between risk models.

CMS also includes in this section various proposals to modify the MSR/MLR if an ACO's performance year assigned beneficiary population falls below 5,000. These include a proposal to use a variable MSR/MLR when performing shared savings and shared losses calculations if an ACO's assigned beneficiary population falls below 5,000, regardless of whether the ACO selected a fixed or variable MSR/MLR. This proposal is a change from current regulations where ACOs in two-sided models that selected a fixed MSR/MLR remain with that fixed MSR/MLR even if their assigned beneficiary populations fall below 5,000.

Annual Participation Elections

Election of Differing Levels of Risk within the BASIC Track's Glide Path. As mentioned above, CMS proposes to permit ACOs in the BASIC Track's glide path to annually elect to accept higher levels of performance-based risk than required. As such, CMS proposes several requirements to establish annual participation elections, including that ACOs must elect to change their participation options before the start of the performance year. CMS envisions that the timing of this election would generally follow the timing of the MSSP's application cycle. CMS clarifies that this proposal would not alter the timing of benchmark rebasing; it would continue to assess ACOs' financial performance using the historical benchmark established at the start of the ACO's current agreement period, as adjusted and updated consistent with its benchmarking methodology.

Election of Beneficiary Assignment Methodology. Section 1899(c)(1) of the Social Security Act (the Act), as amended by the Bipartisan Budget Act of 2018 (BiBA), requires CMS to determine an appropriate assignment methodology that is based on utilization of primary care services furnished by physicians in the ACO and, beginning on or after Jan. 1, 2019, services provided by a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC). The current MSSP offers two claims-based beneficiary assignment methodologies, including prospective assignment and preliminary prospective assignment with retrospective reconciliation. CMS also offers a non-claims based process for voluntary alignment, discussed below. There is no pure retrospective assignment methodology.

The Bipartisan Budget Act of 2018 (BiBA) mandated that ACOs be allowed to choose prospective assignment for agreement periods beginning on or after Jan. 1, 2020. **To that end, CMS proposes to allow ACOs to choose prospective assignment for agreement periods beginning July 1, 2019 and in subsequent years.** Thus, ACOs in the BASIC or ENHANCED tracks would have the option to choose either prospective assignment or preliminary prospective assignment with retrospective reconciliation prior to the start of their agreement period. CMS also proposes to allow ACOs to switch their beneficiary assignment selection on an annual basis. ACOs would select their preferred beneficiary assignment methodology at the time of application. This process would have no effect on the voluntary alignment process, but

CMS would adjust ACOs' historical benchmarks to reflect their election of a different assignment methodology.

Advance Notice for and Payment Consequences of Termination

Under current regulations, CMS may terminate the participation of an ACO when the ACO fails to comply with any program requirements. ACOs may also voluntarily terminate their participation agreements with 60-days' notice to CMS. ACOs that voluntarily terminate their agreements may still share in savings for a performance year if they terminate with an effective date of Dec. 31, and meet other requirements. Currently, ACOs are not liable for shared losses if they terminate their participation prior to Dec. 31 of a given year.

In this rule, CMS makes several proposals related to termination. First, CMS proposes to reduce the minimum notification period for ACOs voluntarily terminating participation from 60 to 30 days. This would allow ACOs to base their decision on three quarters of feedback reports, instead of two. **CMS also proposes June 30 as a deadline for effective date of termination for ACOs to withdraw without liability for any portion of shared losses.** For ACOs that voluntarily terminate after June 30, CMS would pro-rate the shared-loss amount by the number of months during the year in which the ACO was in the program. CMS also proposed to pro-rate shared losses for ACOs that are involuntarily terminated by CMS for any portion of the year during which the termination becomes effective.

Participation Options for Agreement Periods Beginning in 2019

CMS proposes July 1, 2019 as the first start date that would be available for ACOs to enter an agreement period under the proposed new program. CMS anticipates that the application cycle for the July 1, 2019 start date would begin in early 2019 and therefore would not hold the application cycle that would have otherwise taken place during calendar year (CY) 2018 for a Jan. 1, 2019 start date. CMS proposes that after the July 1, 2019 start date, it would resume its usual process of annual application cycles in advance of Jan. 1 agreement start dates.

CMS proposes that ACOs entering an agreement period beginning on July 1, 2019 would have participation agreements lasting five years and six months, of which the first performance year would be defined as the six month period between July 1, 2019 and Dec. 31, 2019. CMS also makes several proposals to address ACOs that would have a lapse in participation due to their first or second 3-year agreement expiring on Dec. 31, 2018, including the following specific opportunities for ACOs:

- ACOs that entered a first or second agreement period with a Jan. 1, 2016 start
 date would be able to voluntarily elect to extend their agreement for an optional
 fourth performance year, defined as the six-month period from Jan. 1, 2019
 through June 30, 2019. This would erase any gap in participation due to the July 1,
 2019 start date of the revised program.
- Existing ACOs that want to quickly move to a new participation agreement under the
 proposed BASIC and ENHANCED tracks could voluntarily terminate their participation
 agreements with an effective termination date of June 30, 2019, and apply to enter a
 new agreement with a July 1, 2019 start date to continue participation in the program.

This proposal would apply to ACOs that entered the program in 2017, 2018, and in 2015, if they deferred renewal by one year.

To determine financial and quality performance for the two proposed six-months performance years during calendar year 2019, CMS proposes to use an approach that would maintain financial reconciliation and quality performance determinations based on a 12-month calendar year period, but would prorate shared savings/shared losses for each potential six-month period of participation during 2019. CMS also makes several proposals to address issues unique to the six-month periods, including issues related to the ACO participant list, beneficiary assignment, the quality reporting period, benchmark methodology, and the methodology for determining shared savings and losses, among others. As mentioned above, CMS also proposes a one-time exception to its proposed automatic advancement policy, under which the policy would not apply to the second performance year for an ACO entering the BASIC Track's glide path on July 1, 2019. That is, they would be able to remain at the level of the BASIC Track at which they entered through the 2020 performance year.

WAIVERS

In furtherance of its belief that performance-based risk bearing ACOs could achieve greater savings if they were given increased flexibility to enhance more coordinated care, CMS makes several proposals to expand access to waivers for risk-bearing ACOs. If this proposed rule is finalized, eligible ACOs would include ACOs in Levels C, D, and E of CMS's proposed BASIC Track and those in the proposed ENHANCED Track.

Shared Savings Program Skilled Nursing Facility (SNF) 3-Day Waiver

CMS proposes to expand the applicability of the SNF 3-Day rule waiver to also include risk-bearing ACOs electing preliminary prospective beneficiary assignment. ACOs with prospective beneficiary assignment already qualify for the waiver. CMS also proposes to extend the waiver by allowing application of it to SNF services furnished under swing bed arrangements between Critical Access Hospitals and certain small, rural hospitals, if those services fall under a written agreement between the swing bed operator and a waiver-eligible ACO. CMS proposes to make these changes applicable beginning with waivers approved for performance years beginning on July 1, 2019 and subsequent years.

Billing and Payment for Telehealth Services

CMS proposes regulatory changes for the coverage of approved telehealth services furnished during performance years 2020 and beyond by risk-bearing ACOs with prospectively assigned beneficiaries. Specifically, consistent with changes included in the BiBA, restrictions on the originating site and geographic location would not apply to payment for telehealth services for these entities. These changes would allow payment for telehealth services originating in a beneficiary's home and from geographic locations that would otherwise be prohibited. However, no facility fee would be paid to the originating site when services originate from the beneficiary's home, and no payment would be made for a service delivered in

the home if it was not appropriate to do so. The expanded telehealth policy would apply to the proposed risk-bearing ACOs listed above, as long as they continue to elect prospective beneficiary assignment. CMS also proposes to offer the expanded telehealth policy to current Track 3 and Track 1+ Model ACOs.

In addition, CMS proposes various protections for beneficiaries that might be charged by ACOs or their participants for telehealth services that would have otherwise been covered if the beneficiary were prospectively assigned. CMS anticipates this situation could arise if an ACO and/or clinician fails to verify whether or not a beneficiary was prospectively assigned to their ACO prior to furnishing services or due to other intentional or unintentional billing errors. In the event that the situation leads to claim rejection, CMS proposes to prohibit ACOs from charging the beneficiary for expenses incurred in delivering the telehealth services. CMS also proposes to require ACOs to return to the beneficiary any monies collected for such services and proposes to subject certain ACOs to compliance actions.

BENEFICIARY ENGAGEMENT

Beneficiary Incentives

CMS proposes implementing regulations to allow eligible ACOs to establish the beneficiary incentive programs established by the BiBA. Under the BiBA, eligible ACOs include those bearing two-sided risk; thus, CMS proposes that current Track 2 and 3 ACOs and, if finalized, future BASIC ACOs in Levels C, D and E and ENHANCED ACOs would be eligible to establish beneficiary incentive programs. CMS proposes July 1, 2019 as the start date for incentive program implementation. The BiBA mandates and CMS proposes that these incentive programs would be available to all eligible FFS beneficiaries, regardless of assignment methodology. Because the Track 1+ Model is a CMMI model and not an MSSP ACO, Track 1+ ACOs were not included in the BiBA legislation nor in CMS's proposals in this rule with respect to beneficiary incentive programs.

CMS proposes that eligible ACOs that establish an approved beneficiary incentive program would be allowed to provide incentive payments directly to assigned beneficiaries upon their receipt of qualifying primary care services³ from an ACO professional with a primary care designation or a Federally Qualified Health Center (FQHC) or Rural Health Center (RHC). In accordance with the BiBA, CMS proposes that the incentive payment could be up to \$20, updated annually. The payment would be required to be identical for each FFS beneficiary, unrelated to any other health insurance policy or plan, and made within 30 days of the delivery of each qualifying service. CMS proposes to allow ACOs to vary the incentive payment type (e.g., gift cards or checks but no cash for reasons of program integrity), but to require ACOs to disburse payment directly to eligible beneficiaries. CMS

³ Qualifying primary care services include office, nursing facility, home, domiciliary, transitional and chronic care management, the Welcome to Medicare and annual wellness visits, and FQHC and RHC services, furnished through the ACO by a primary care physician (MD/DO), physician assistant, nurse practitioner, or clinical nurse specialist.

proposes to require ACOs to maintain records of each incentive payment and fully fund all of the operational costs of its incentive program.

As directed by the BiBA, CMS proposes that incentive payments would be disregarded in the calculation of ACO benchmarks and shared savings and losses. The BiBA also requires the Secretary of the Department of Health and Human Services to report to Congress by Oct. 1, 2023 about the impact of an ACO beneficiary incentive program on Medicare spending; CMS proposes to extend its monitoring methodology to include the incentive program if it is finalized. To operationalize other provisions of the BiBA, CMS also proposes to require ACOs to publicly report certain incentive payment information on their public reporting pages. CMS also proposes to prohibit the advertisement of incentive programs but is considering requiring ACOs to notify their beneficiaries about their approved incentive programs using CMS-approved outreach materials. CMS solicits comments on some options for beneficiary notification.

Beneficiary Notifications

To make information about the MSSP and ACOs easier for beneficiaries to access and digest, CMS plans to make the written Beneficiary Information Notice, which ACOs must currently provide upon request, a more comprehensive source of information about the MSSP. To that end, CMS proposes to require the Notice to contain additional content beginning on July 1, 2019, specifically around beneficiaries' option to designate a primary clinician to coordinate their care and thereby trigger voluntary alignment of the beneficiary to the ACO. CMS also proposes to require ACOs to give beneficiaries information about primary clinician choice and voluntary alignment at the beneficiary's first primary care visit of each performance year. CMS includes several requests for comment about various elements of delivering and disseminating notifications to beneficiaries.

Opt-in Assignment Methodology

In response to expressed interest and support from stakeholders, CMS uses this rule to explore options for developing a possible opt-in methodology to assign beneficiaries to ACOs, but stops short of actually proposing a methodology. CMS explains its belief that an opt-in methodology could allow ACOs to better target care coordination and provide an incentive to ACOs to compete against one another. CMS also reports that stakeholders that support this methodology believe it promotes beneficiary free choice and engagement and makes assignment more patient-centered.

In its discussion of possible opt-in methodologies, CMS explains the difference between voluntary alignment and an opt-in methodology. With voluntary alignment, beneficiaries directly opt into care by a specific primary clinician, but only indirectly opt in to the clinician's ACO by doing so. With opt-in assignment, beneficiaries would opt-in directly to a specific ACO. CMS includes in its discussion about an opt-in assignment methodology the following issues, among others:

<u>Process issues</u>. CMS discusses many actions ACOs would be required to take under an opt-in methodology, including reporting to CMS, beneficiary notification, and others.
 CMS notes that an MSSP opt-in process could borrow from Medicare Advantage (MA).
 CMS also notes that ACOs keeping beneficiaries informed about their composition and the option to withdraw would be essential for ACOs to manage beneficiary satisfaction.

- ACO marketing. CMS anticipates also borrowing guidelines and requirements from MA
 plan enrollment for an MSSP opt-in option. ACOs would be expected to provide
 complete and accurate information to inform beneficiary opt-in decision-making and to
 not market selectively or discriminately based on beneficiary health status. CMS would
 also require ACOs to track their notification of beneficiaries about opt-in opportunities
 and beneficiaries' responses.
- <u>Primary care service requirement</u>. CMS expresses concern that a beneficiary could opt in to an ACO without ever having received a primary care service from that ACO's participants, causing the ACO to be held accountable for the cost and quality of the beneficiary's care despite not having provided that care. CMS discusses options to address this concern.
- Historical benchmark adjustment. CMS discusses several issues related to how
 assignment based solely on beneficiary opt-in decisions could negatively impact the
 suitability and reliability of historical benchmark calculations made using opt-in
 beneficiary data. For example, there would likely be a large disconnect between
 beneficiaries opting in to assignment to an ACO and the beneficiaries assigned to the
 ACO on the basis of historical claims. CMS discusses similar difficulties in attempting to
 set a benchmark adjustment for the Pioneer ACO Model.

In discussing how to factor an opt-in based methodology into the MSSP, CMS considers allowing ACOs to elect an opt-in based assignment methodology, but still using the existing assignment methodology to first determine if an ACO is eligible to participate in the MSSP. If an ACO chooses not to elect opt-in based assignment methodology, CMS would continue to assign beneficiaries to the ACO based on the existing assignment methodology.

CMS also considers discontinuing the existing assignment methodology and applying a hybrid opt-in-based assignment methodology program-wide. Under such an approach, a beneficiary would be prospectively assigned to an ACO if he or she opted in to assignment to the ACO or voluntarily aligned with the ACO by designating an ACO professional as his or her primary clinician. If the ACO did not reach the required minimum of 5,000 assigned beneficiaries from beneficiary opt-ins and voluntary alignment, CMS would assign beneficiaries to the ACO using a modified claims-based methodology. This methodology would be based on whether beneficiaries received the plurality of their primary care services from the ACO and received at least seven primary care services from one or more ACO professionals during the assignment window.

CMS considers several elements of how this hybrid approach would work, including allowing beneficiaries to select from all opt-in ACOs without geographic restrictions. CMS also indicates that it would not alter its approach to benchmark year beneficiary assignment for ACOs electing opt-in assignment, but it would change its approach to annual risk adjustment of historical benchmark expenditures. Finally, CMS indicates that it would establish program integrity requirements for an opt-in-based assignment methodology similar to those associated with voluntary alignment.

REFINEMENTS TO BENCHMARKING METHODOLOGY

Risk Adjustment Methodology for Adjusting Historical Benchmark Each Performance Year

CMS recognizes competing concerns regarding its methodology for adjusting ACOs' historical benchmark. On the one hand, stakeholders have indicated that the current approach is difficult to understand and does not adequately adjust for changes in beneficiaries' health status between the benchmark and performance years, making it difficult for ACOs to predict performance and realize savings. On the other hand, CMS is concerned about provider coding initiatives that increase coding so as to maximize performance year risk scores. To address these competing concerns, CMS proposes to switch to using full CMS Hierarchical Condition Category (HCC) risk adjustment for all assigned beneficiaries between the benchmark period and the performance year. The resulting risk score would be subject to a symmetrical cap of positive or negative three percent over the length of the agreement period, for agreement periods beginning on July 1, 2019 and in subsequent years. In other words, the risk score applied to historical benchmark expenditures to capture changes in beneficiaries' health status between the benchmark period and the performance year would never be reduced or increased by more than three percent.

CMS anticipates this approach would eliminate a distinction between newly and continuously assigned beneficiaries, which has caused some of the concerns listed above. Additionally, when CMS modeled this approach, it found that 86 percent of the ACOs that received a demographic risk adjustment for their continuously assigned beneficiaries would have received a larger positive adjustment had this policy been in place. CMS believes this approach could reduce the incentive for ACOs to avoid complex patients and perhaps be willing to accept higher levels of risk. CMS also believes that the use of the symmetrical three percent cap would allow ACOs to more easily predict the impact of risk adjustment on their benchmarks.

Use of Regional Factors When Establishing and Resetting ACOs' Benchmarks

Applying Regional Expenditures in Determining the Benchmark for an ACO's First Agreement Period. Under current regulations, CMS applies a regional adjustment to ACOs' historical benchmarks to rebase them for ACOs entering a second or subsequent agreement period in 2017 or later years. The percentage adjustment is phased in over time and ultimately reaches 70 percent. Due to the more accurate benchmarks CMS believes it has achieved using this approach, CMS proposes to incorporate regional expenditures into the historical benchmarking methodology starting with the first agreement period for all ACOs entering the program beginning on July 1, 2019. When calculating the historical benchmark for an ACO in its first agreement period, CMS would weight the three benchmark years – the three calendar years prior to the start of the agreement period – at 10 percent, 30 percent, and 60 percent, respectively. This differs from the equal weights that are used in resetting the benchmark for ACOs entering a second or subsequent agreement period.

<u>Modifying the Regional Adjustment</u>. CMS also proposes changes to the calculation and phase in of the regional adjustment to the benchmark. Specifically, CMS proposes changes to limit the

magnitude of the regional adjustment by reducing the weight that is applied to the adjustment and imposing an absolute dollar limit on the adjustment. CMS proposes modifying the schedule of weights applied to in the regional adjustment as follows, reducing the maximum weight from 70 percent to 50 percent:

Schedule for Level of Regional Adjustment					
Timing when regional adjustment is applied	ACO's historical spending is lower than its region	ACO's historical spending is higher than its region			
First agreement period in which new weights would apply to regional adjustment	35% weight	25% weight			
Second agreement period in which new weights would apply to regional adjustment	50% weight	35% weight			
Third or subsequent agreement period in which new weights would apply to regional adjustment	50% weight	50% weight			

The "timing" of when a regional adjustment would be applied would depend on ACOs' agreement start dates, whether they are new, renewing or re-entering ACOs, and whether these proposals are finalized as proposed. For example, if CMS's proposal to factor regional expenditures in to the historical benchmark for ACOs' first agreement period is finalized, the first time a new ACO beginning participation in the MSSP on July 1, 2019 would be subject to a regional adjustment would be for the historical benchmark that would be applied to its first agreement period beginning July 1, 2019. Because CMS rebases ACOs' historical benchmarks for each agreement period, the "second time" the ACO would be subject to a regional adjustment would be to calculate the rebased benchmark for its second agreement period and the "third time" would be to calculate the rebased benchmark for its third agreement period and any subsequent agreement periods. See Appendix B of this Advisory for examples from CMS of the phase-in of its proposed regional adjustment weights based on agreement start date and applicant type.

CMS also proposes to cap the regional adjustment amount at a flat dollar amount equal to five percent of national per capita Medicare FFS expenditures for assignable beneficiaries, calculated separately for each Medicare enrollment population (disabled, aged/dual eligible, aged/non-dual eligible, and end stage renal disease). CMS believes this approach would provide meaningful reward for ACOs that are efficient relative to their regions, while reducing potential windfall gains for ACOs with lower relative costs.

Modifying the Methodology for Calculating Benchmark Trend and Update Factors. When establishing and rebasing an ACOs' historical benchmark, CMS uses a "trend factor" to trend forward the expenditures in the first two years on which the benchmark is based to the third benchmark year. Similarly, CMS uses an "update factor" to update ACOs' benchmarks from the third benchmark year to the relevant performance year. Regarding the use of regional expenditures to trend forward ACOs' benchmark years, CMS proposes to use a "national-regional blend" – a blend of national and regional growth rates – to trend

forward benchmark years when establishing or resetting an ACO's historical benchmark. CMS also proposes to use a national-regional blend to calculate an ACO's update factor. CMS believes this approach addresses stakeholder concerns that the use of purely regional trend and update factors may limit the incentive to reduce spending growth, especially for ACOs that serve a high proportion of beneficiaries in select counties making up its regional service area.

To calculate the national-regional blend, CMS proposes to calculate a weighted average of national FFS and regional trend factors, where the weight assigned to the national component would represent the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO. The weight assigned to the regional component would be equal to one minus the national weight. As an ACO's penetration in its region increases, this approach would result in a higher weight being placed on the national component of the blend and a lower weight on the regional component, reducing the extent to which the trend factors reflect the ACO's own expenditure history. However, CMS notes that most ACOs do not currently have significant penetration in their regional services areas and therefore would see a higher weight on the regional component of the trend factor. Thus, CMS anticipates that the overall impact of this proposed policy on benchmarks would be small.

CMS indicates that the proposed blended trend and update factors would apply to all agreement periods starting on July 1, 2019 or in subsequent years, regardless of whether it is an ACO's first, second, or subsequent agreement period.

UPDATES TO PROGRAM POLICIES

Revisions to Policies on Voluntary Alignment

As discussed above, the MSSP currently includes a voluntary alignment option. However, CMS proposes several revisions to this option for performance year 2019 and subsequent years to execute certain policies mandated by the BiBA. Specifically, CMS proposes that a beneficiary would be voluntarily aligned to an ACO by designating a "primary clinician" from that ACO, regardless of specialty, and that a beneficiary who does so would not be assigned to an ACO in which that primary clinician does not participate. CMS also proposes to allow beneficiaries to voluntarily align to a primary clinician without receiving any services (including primary care) from a professional within the primary clinician's ACO during the 12-month assignment window. CMS also proposes to require ACO participants to notify beneficiaries of the option to designate a primary clinician and encourage beneficiaries to periodically check and update their designations.

CMS proposes one exception to voluntary alignment using CMMI's section 1115(A) waiver authority. Under this exception, voluntary alignment would be overridden when a beneficiary is assigned to a CMMI model participant, the model's claims-based assignment is based solely on services other than primary care, and the waiver is necessary solely for the purposes of testing the CMMI model.

Revisions to the Definition of Primary Care Services Used in Beneficiary Assignment

To implement other provisions of the BiBA and provisions of the 21st Century Cures Act, CMS proposes to update its definition of primary care services. This proposal includes adding existing Current Procedural Terminology (CPT) codes and Healthcare Common Procedure Coding System (HCPCS) G-codes to the definition of primary care services. CMS also proposes to add the G-code add-ons it proposed in the CY 2019 Physician Fee Schedule Proposed Rule, if finalized. These include G-codes for visit complexity for primary care office visits and for office visits with certain specialties, and a G-code for prolonged evaluation and management (E/M) or psychotherapy services.

Extreme and Uncontrollable Circumstances Policies

In Dec. 2017, CMS issued an <u>interim final rule</u> with comment period (IFC) in which it adopted policies to address quality performance scoring and shared loss determinations for MSSP ACOs experiencing extreme and uncontrollable circumstances in 2017. In this rule, CMS proposes to address the effects of extreme and uncontrollable circumstances for performance years 2018 and beyond. CMS includes in these proposals details about how it would address ACOs with a six-month performance year in 2019.

Applying trigger criteria. For performance years 2018 and later, CMS proposes to continue using the criteria it defined in the IFC as automatic triggering events for the MSSP's extreme circumstances policy. These triggers would continue to be aligned with those applicable to MIPS-eligible clinicians as adopted under the QPP. Once triggered, the extreme circumstances policy would apply to any MSSP ACO within an affected area if CMS determines that 20 percent or more of an ACO's assigned beneficiaries resided in the affected area and/or the ACO's legal entity was located in the affected area.

ACO Quality Performance Scoring. CMS proposes that for a performance year in which an ACO experiences extreme and uncontrollable circumstances, CMS would set the ACO's minimum quality score to the mean MSSP score. However, if the ACO is able to completely report all quality measures, CMS would use the higher of the mean MSSP score or the ACO's own score. For ACOs that do receive the mean MSSP score during a particular year, CMS would calculate quality improvement for the first post-disaster year by comparing the most recently available ACO-specific, pre-disaster, quality score to the ACO-specific score for the year immediately following the disaster.

MIPS APM Scoring Standard. If the proposed BASIC and ENHANCED tracks are finalized, CMS anticipates those tracks would be considered MIPS APMs and the QPP's APM scoring standard would apply to each ACO and their clinicians. Should an ACO be affected by extreme circumstances and unable report quality performance data for a particular year, the MIPS quality

⁴ CMS proposes to add CPT codes and HCPCS G-codes associated with the following services: advance care planning services; administration of health risk assessment services; prolonged evaluation and management or psychotherapy service(s) beyond the typical service time of the primary procedure; annual depression screening service; alcohol misuse screening service; and alcohol misuse counseling service.

category performance score would be reweighted to zero for the ACO's MIPS-eligible clinicians. Additionally, revised MIPS category score weights would be assigned as follows: 75 percent for the Promoting Interoperability category and 25 percent for the Improvement Activities category.

<u>Mitigating Shared Losses</u>. In the IFC, CMS established a policy to reduce the shared losses of ACOs experiencing extreme and uncontrollable circumstances in 2017. In this rule, CMS proposes to extend its reduction calculation formula for performance years 2018 and beyond. That formula would mitigate shared losses as follows:

Reduction = Shared Losses x (affected months/total performance year months)

x (affected assigned ACO beneficiaries/total ACO assigned

beneficiaries)

CMS notes that all ACOs would continue to be entitled to any shared savings they achieve, though an ACO's savings could be affected if its quality score was changed by the extreme circumstances policy.

Historical Benchmark Calculations for Affected ACOs. In this section, CMS explains its concern that extreme and uncontrollable circumstances could greatly – and unpredictably – impact expenditures for assigned beneficiaries used to determine an ACO's historical benchmark. Expenditure increases would later result in higher historical benchmarks for affected years while expenditure decreases would produce lower benchmarks. However, CMS believes that the regional factors it proposes in this rule would inherently adjust for year-to-year expenditure variations, such as those that might occur related to extreme circumstances and their aftermath. CMS declines to propose an adjustment other than regional benchmarking to account for expenditure variations, but invites comments on whether and how it could do so.

Program Data and Quality Measures

CMS does not propose changes to the basic methodology for determining ACO quality performance. However, CMS solicits input on ways to enhance the program's measure set. This includes ways to align the MSSP measure set with the agency's "Meaningful Measures" initiative that seeks to streamline and prioritize the measures used across CMS's quality measurement and value programs so they focus on the most important issues.

CMS also expresses an interest in using the MSSP to support the agency's broader effort to address the opioid epidemic. CMS is exploring ways of providing aggregated Medicare part D data on opioid utilization to assist ACOs with efforts to address opioid misuse.

CMS also is considering adopting three measures for future program years that use Medicare part D data. All three measures are endorsed by the National Quality Forum (NQF), and their NQF identification numbers are included below. All three measures exclude patients with cancer, and those enrolled in hospice in order to focus the measure on the most appropriate population.

 Use of opioids at high dosage in persons without cancer (NQF #2940). The measure reports the proportion of Medicare Part D beneficiaries 18 years or older receiving

- prescriptions for opioids with a daily dosage of morphine milligram equivalent (MME) greater than 120 mg for 90 consecutive days or longer.
- <u>Use of opioids from multiple providers in persons without cancer (NQF #2950)</u>. The
 measure reflects the proportion of Medicare Part D beneficiaries 18 years or older
 receiving prescriptions for opioids from four or more prescribers AND four or more
 pharmacies.
- Use of opioids from multiple providers and at high dosage in persons without cancer (NQF #2951). The measure reports the proportion of Medicare Part D beneficiaries 18 years or older with a daily dosage of MME greater than 120 mg for 90 consecutive days or longer, AND who received opioid prescriptions from four or more prescribers AND four or more pharmacies.

Proposed Changes to Certified Electronic Health Record (EHR) Use and Measurement

CMS proposes several changes to align participation in the MSSP with provisions in the QPP that promote the use of certified EHRs and the interoperable access, exchange and use of health information. CMS proposes to add a requirement that all ACOs demonstrate that at least 50 percent of eligible clinicians participating in the ACO use a certified EHR to document and communicate clinical care to their patients or other health care providers. This requirement would be included in the attestation and certification upon application to participate in the MSSP and in the annual certification process. CMS proposes that the threshold requirement would be effective with the performance year beginning Jan. 1, 2019.

CMS also proposes to require ACOs in tracks or models that meet the financial risk standard to be Advanced APMs to demonstrate that at least 75 percent of eligible clinicians in each participating Advanced APM use a certified EHR to document and communicate clinical care to their patients or other health care providers. CMS states that this proposal aligns with the proposal in the CY 2019 Physician Fee Schedule proposed rule to increase the threshold level for certified EHR use by eligible clinicians participating in Advanced APMs under the QPP. CMS also states the agency reserves the right to monitor, assess and/or audit an ACO's compliance with the proposed requirement and take compliance actions when ACOs fail to meet or exceed the required certified EHR use threshold. The proposed threshold requirement would be effective with the performance year beginning Jan. 1, 2019.

Additionally, CMS proposes to remove the use of certified EHR technology measure (ACO-11) from the Shared Savings Program quality measure set beginning Jan. 1, 2019. The proposal would revise the current requirement under which ACOs report the percentage of eligible clinicians meeting the Promoting Interoperability Performance Category base score to meet the ACO-11 measure. CMS states the removal of the ACO-11 measure from the quality measure set would not affect policies under MIPS for reporting on the Promoting Interoperability Performance Category and scoring under the APM Scoring Standard for MIPS-eligible clinicians in MIPS APMs.

Request for Information on Coordination of Pharmacy Care for ACO Beneficiaries

CMS includes in the rule a request for information on how Medicare ACOs, specifically MSSP ACOs, and Part D plan sponsors could work together and be encouraged to improve the

coordination of pharmacy care for Medicare FFS beneficiaries. CMS believes there are possible synergies between ACOs and Part D stand-alone prescription drug plan sponsors such as improved formulary compliance by clinicians, enhanced delivery of pharmacist counseling services to patients and more widespread implementation of medication therapy management. CMS seeks information about any such existing partnerships, barriers to forming such partnerships, and ways the agency can reduce barriers and enable data sharing. CMS also seeks comments on how it could support innovative business arrangements to financially reward plan sponsors for improved beneficiary outcomes.

APPLICABILITY OF PROPOSED POLICIES TO EXISTING TRACK 1+ MODEL ACOS

The Track 1+ Model established by CMMI was designed to offer ACOs a two-sided risk option with lower levels of potential losses than those available in Tracks 2 and 3 of the MSSP. The application cycles for Track 1+ were intended to be aligned with those of the MSSP and were to occur in 2018, 2019 and 2020. However, CMS has not offered an application cycle for Track 1+ participation to begin on Jan. 1, 2019 as the proposed BASIC Track Level E replicates many of the elements of the Track 1+ Model. If the proposals in this rule are finalized, CMS would also not offer an application cycle for Track 1+ participation to begin on Jan. 1, 2020. Existing Track 1+ ACOs would be able to complete their agreement periods under the Track 1+ models, or they could terminate their Track 1+ agreements and apply to enter new agreements under the proposed BASIC Track Level E or ENHANCED Track. CMS discusses in the rule how it would apply specific proposed policy changes to Track 1+ Model ACOs.

NEXT STEPS

The AHA will host a members-only webinar on Sept. 12 at 1:30 p.m. ET to discuss the provisions of the proposed rule and gather input from the field for AHA's comment letter and advocacy to CMS. To register for this 60-minute webinar, visit here.

The AHA encourages members to submit comments on how CMS's proposals would affect their facility. Comments are due Oct. 16 by 5 p.m. ET and may be submitted electronically at http://www.regulations.gov. Follow the instructions for "submitting a comment."

CMS also accepts written comments (an original and two copies) via regular or overnight/express mail.

FURTHER QUESTIONS

For further questions, please contact Shira Hollander, senior associate director for policy development, at (202) 626-2329 or shollander@aha.org.

APPENDIX A

TABLE 6: PARTICIPATION OPTIONS FOR LOW-REVENUE ACOS BASED ON APPLICANT TYPE AND EXPERIENCE WITH RISK

		Participation Options				
Applicant type	ACO experienced or inexperienced with Performance based risk Medicare ACO initiatives	BASIC track's glide path (option for incremental transition from one- sided to two-sided models during agreement period)	BASIC track's Level E (track's highest level of risk / reward applies to all performance years during agreement period)	ENHANCED track (program's highest level of risk / reward applies to all performance years during agreement period)	Agreement period for policies that phase-in over time (benchmarking methodology and quality performance)	
New legal entity	Inexperienced	Yes - glide path Levels A through E	Yes	Yes	First agreement period	
New legal entity	Experienced	No	Yes	Yes	First agreement period	
Re- entering ACO	Inexperienced - former Track 1 ACOs or new ACOs identified as re-entering ACOs because more than 50 percent of their ACO participants have recent prior experience in a Track 1 ACO	Yes - glide path Levels B through E	Yes	Yes	Either: (1) the next consecutive agreement period if the ACO's prior agreement expired; (2) the same agreement period in which the ACO was participating at the time of termination; or (3) applicable agreement period for new ACO identified as re-entering because of ACO participants' experience in the same ACO	
Re- entering ACO	Experienced - including former Track 1 ACOs that deferred renewal under a two-sided model	No	Yes	Yes	Either: (1) the next consecutive agreement period if the ACO's prior agreement expired; (2) the same agreement period in which the ACO was participating at the time of termination; or (3) applicable agreement period for	

					new ACO identified as re-entering because of ACO participants' experience in the same ACO
Renewing	Inexperienced - former	Yes - glide path	Yes	Yes	Subsequent consecutive agreement
ACO	Track 1 ACOs	Levels B through E			period
Renewing	Experienced - including	No	Yes	Yes	Subsequent consecutive agreement
ACO	former Track 1 ACOs that				period
	deferred renewal under a				
	two-sided model				

TABLE 7: PARTICIPATION OPTIONS FOR HIGH-REVENUE ACOS
BASED ON APPLICANT TYPE AND EXPERIENCE WITH RISK

		Participation Options			
Applicant	ACO experienced or	BASIC track's	BASIC track's	ENHANCED track	Agreement period for policies that
type	inexperienced with	glide path (option	Level E (track's	(program's highest	phase-in over time (benchmarking
	Performance based risk	for incremental	highest level of risk /	level of risk / reward	methodology and quality
	Medicare ACO initiatives	transition from one-	reward applies to all	applies to all	performance)
		sided to two-sided	performance years	performance years	
		models during	during agreement	during agreement	
		agreement period)	period)	period)	
New legal	Inexperienced	Yes - glide path	Yes	Yes	First agreement period
entity		Levels A through E			
New legal	Experienced	No	No	Yes	First agreement period
entity					
Re-	Inexperienced - former	Yes - glide path	Yes	Yes	Either: (1) the next consecutive
entering	Track 1 ACOs or new ACOs	Levels B through E			agreement period if the ACO's prior
ACO	identified as re-entering				agreement expired; (2) the same
	ACOs because more than				agreement period in which the ACO
	50 percent of their ACO				was participating at the time of
	participants have recent				termination; or (3) applicable
	prior experience in a Track				agreement period for new ACO
	1 ACO				identified as re-entering because of

					ACO participants' experience in the same ACO
Re- entering ACO	Experienced - including former Track 1 ACOs that deferred renewal under a two-sided model	No	No	Yes	Either: (1) the next consecutive agreement period if the ACO's prior agreement expired; (2) the same agreement period in which the ACO was participating at the time of termination; or (3) applicable agreement period for new ACO identified as re-entering because of ACO participants' experience in the same ACO
Renewing ACO	Inexperienced - former Track 1 ACOs	Yes - glide path Levels B through E	Yes	Yes	Subsequent consecutive agreement period
Renewing ACO	Experienced - including former Track 1 ACOs that deferred renewal under a two-sided model	No	No	Yes	Subsequent consecutive agreement period

APPENDIX B

TABLE 5: EXAMPLES OF PHASE-IN OF PROPOSED REGIONAL ADJUSTMENT WEIGHTS
BASED ON AGREEMENT START DATE AND APPLICANT TYPE

Applicant Type	First time regional adjustment used: 35 percent or 25 percent (if spending above region)	Second time regional adjustment used: 50 percent or 35 percent (if spending above region)	Third and subsequent time regional adjustment used: 50 percent weight
New entrant with start date on July 1, 2019	Applicable to first agreement period starting on July 1, 2019	Applicable to second agreement period starting in 2025	Applicable to third agreement period starting in 2030 and all subsequent agreement periods
Renewing ACO for agreement period starting on July 1, 2019, with initial start date in 2012, 2013, or 2016	Applicable to third (2012/2013) or second (2016) agreement period starting on July 1, 2019	Applicable to fourth (2012/2013) or third (2016) agreement period starting in 2025	Applicable to fifth (2012/2013) or fourth (2016) agreement period starting in 2030 and all subsequent agreement periods
Early renewal for agreement period starting on July 1, 2019, ACO with initial start date in 2014 that terminates effective June 30, 2019	Currently applies to second agreement period starting in 2017	Applicable to third agreement period starting on July 1, 2019	Applicable to fourth agreement period starting in 2025 and all subsequent agreement periods
Re-entering ACO with initial start date in 2014 whose agreement expired December 31, 2016 (did not renew) and re-enters second agreement period starting on July 1, 2019	Applicable to second agreement period starting on July 1, 2019 (ACO considered to be reentering a second agreement period)	Applicable to third agreement period starting in 2025	Applicable to fourth agreement period starting in 2030 and all subsequent agreement periods
Re-entering ACO with second agreement period start date in 2017 terminated during performance year 2 (2018) and re-enters second agreement period starting on July 1, 2019	Applicable to second agreement period starting on July 1, 2019 (ACO considered to be reentering a second agreement period)	Applicable to third agreement period starting in 2025	Applicable to fourth agreement period starting in 2030 and all subsequent agreement periods