

Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Extreme and Uncontrollable Circumstances Policies for Performance Year 2017

[CMS-1701-F2 and CMS -1702-F]

Summary of Final Rules

On December 21, 2018, the Centers for Medicare & Medicaid Services (CMS) placed on public display two final rules related to the Medicare Shared Savings Program (MSSP).¹ The rules were published sequentially in the December 31, 2018 issue of the *Federal Register* (83 FR 67816-68082). The first rule (CMS-1701-F2) completes the process of finalizing regulations implementing the redesign of the program participation options for MSSP Accountable Care Organizations (ACOs), a process that was started in the November 2018 MSSP final rule (CMS-1701-F).² The second rule (CMS-1702-F) addresses policies for managing the impact of extreme and uncontrollable circumstances on ACOs for performance year 2017 that originally were established as an Interim Final Rule with Comment Period (CMS-1702-IFC).

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¹ The MSSP program was authorized by section 3022 of the Affordable Care Act (ACA), by adding a new section 1899 to the Social Security Act (SSA). Relevant regulations are found in 42 CFR Part 425.

² The November 2018 MSSP final rule was issued along with the November 2018 Medicare CY 2019 Physician Fee Schedule final rule (83 FR 59940-59990)

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I. Introduction

In the August 2018 MSSP proposed rule (83 FR 41786-41951), CMS reviewed the past performance of the program for the one-sided risk Track 1 (shared savings only), the two-sided risk Track 2 and Track 3 (shared savings and losses), and the hybrid Track 1+ that is an Innovation Center model but shares features with Track 2 and Track 3 (including two-sided risk). CMS concluded that performance as measured by Medicare program savings generally was better for two-sided risk models and proposed revisions to the program participation options designed to accelerate the transition of all MSSP ACOs to two-sided risk bearing (BASIC and ENHANCED tracks). To facilitate rapid adoption of the redesigned tracks, CMS proposed that they would become available to new and existing ACOs starting July 1, 2019.

The proposed July start date, however, would have precluded continuous program participation by ACOs whose existing participation agreements were scheduled to end on December 31, 2018, yet wished to remain in the MSSP on a redesigned track. To address the needs of this cohort, CMS proposed an option by which the ACOs could extend their existing participation agreements for six months (January 1 through June 30, 2019).³ To implement the six-month extension, CMS issued the November 2018 MSSP final rule to ensure participation continuity and to finalize time-sensitive policy issues for these ACOs created by the mid-year start date (e.g., repayment mechanism duration). The mid-year start date similarly would pose potential questions (e.g., historical benchmark rebasing) for ACOs whose agreements extended through performance year 2018 but wished instead to transition into the new tracks as soon as possible (“early renewals”); CMS also addressed these questions in the November 2018 final rule. Additional policies finalized in the November 2018 final rule, unrelated to track redesign, involved revisions to the beneficiary voluntary alignment option (triggered by the Bipartisan Budget Act of 2018, “BBA of 2018”); updating the definition of primary care services used for beneficiary assignment to ACOs; changes to electronic health record (EHR) usage requirements to promote interoperability; streamlining of the ACO quality measure set; and adjustments to quality and cost performance calculations for ACOs affected by extreme and uncontrollable circumstances during performance year 2018 and subsequently.

³ This cohort includes ACOs who started new agreement periods on January 1, 2016 plus those starting on January 1, 2015 who were eligible to defer transition to two-sided risk for an additional year.

In this final rule (December 2018 MSSP final rule), published in the December 31, 2018 issue of the *Federal Register* (83 FR 67816-68033), CMS completes finalizing the remaining policies from the August 2018 MSSP proposed rule including those that address:

- Structural details of the redesigned participation options (BASIC Levels A through E plus ENHANCED tracks), modified to increase shared savings rates for most levels of the BASIC track and to allow some Track 1+ Model high revenue ACOs to renew at Level E for one agreement period;
- Changes to repayment mechanism arrangements, modified to lower the guaranteed amount for some ACOs;
- Revisions to ACO benchmarking methodology that introduce regional trend factors earlier (in the first agreement period) but reduce maximal weighting of the regional factors, and that allow risk score growth (capped) and decline (not capped) over an agreement period;
- Actions to strengthen program integrity including financial performance monitoring and accountability for shared losses when agreements are terminated early;
- Optional annual election of beneficiary assignment methodology (prospective or preliminary prospective with retrospective reconciliation);
- Expansion of the applicability of waivers for telehealth services and Skilled Nursing Facility (SNF) 3-day rule for many ACOs;
- Requirements for a CMS-approved beneficiary incentive payment program for qualifying primary care services; and
- Changes to beneficiary notification requirements, with timeline and format modifications.

CMS also discusses input received in response to requests for comments about adopting an opt-in methodology for beneficiary assignment to ACOs, and fostering collaboration between ACOs and stand-alone Part D sponsors to improve pharmacy care coordination for beneficiaries. No definitive steps are outlined for future action regarding either topic. Finally, CMS states that new and existing ACOs interested in applying to the new BASIC or ENHANCED track must complete the non-binding Notice of Intent to Apply (NOIA), available January 2-18, 2019 (download available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/SSP-NOI-Memo.pdf>; includes the redesigned tracks, SNF 3-day rule waiver, and beneficiary incentive program).

II. Provisions of the August 2018 Proposed Rule and Analysis of and Responses to Public Comments

A. Redesigning Participation Options to Facilitate Performance-Based Risk

1. Modified Participation Options under 5-year Agreement Periods

In developing its proposed policies in the August 2018 proposed rule, CMS stated that it considered a number of factors in light of the program's financial results and stakeholders' feedback on program design. First, CMS believed that the current design (allowing up to 6 years of participation in a one-sided model) lacked sufficiently incremental progression to

performance-based risk. Only 18 percent of the program’s participating ACOs are under a two-sided risk model after the fifth year of implementing the program. On the other hand, CMS was encouraged by ACO participation in the Track 1+ Model (55 participants began on January 1, 2018 – the largest cohort to participate in a given performance year), which allows for participation in an Advanced Alternative Payment Model (APM), while accepting more moderate levels of risk. Second, CMS was concerned that it did not have adequate tools to address ACOs with a pattern of negative financial performance, as Track 1 ACOs are not liable to repay any portion of their losses to CMS. Third, CMS was concerned that differences in performances of ACOs indicate a pattern where low revenue ACOs outperformed high revenue ACOs that are in a better position to influence change in FFS utilization. Fourth, CMS believed that it could reduce and eliminate redundancy by permitting choices of risk level and assignment methodology within an ACO’s agreement period. Fifth, CMS believed that longer agreement periods could improve program incentives and support the transitions of ACOs into performance-based risk, when coupled with changes to the benchmarking methodology.

In consideration of these issues and its analysis of comments, CMS finalizes its proposals to redesign the program’s participation options by discontinuing Track 1, Track 2 and the deferred renewal option, and instead offering two tracks that eligible ACOs would enter into for an agreement period of at least 5 years:

- (1) BASIC track, which would include an option for eligible ACOs to begin participation under a one-sided model and incrementally phase-in risk (calculated based on ACO participant revenue and capped at a percentage of the ACO’s updated benchmark) and potential reward over the course of a single agreement period, an approach referred to as a glide path; and
- (2) ENHANCED track, based on the program’s existing Track 3, for ACOs that take on the highest level of risk and potential reward.

CMS incorporates the BASIC track in its regulations at §425.605, and discontinues the deferred renewal option at §425.200(b)(3) and §425.200(e). The ENHANCED track is implemented under §425.600(a)(3) and §425.610, based on the program’s existing Track 3. With respect to the new names, CMS stated that “enhanced” is more indicative of the increased levels of risk and potential reward available to ACOs under this option, and that “basic” suggests a foundational level that provides a “glide path” to increased risk sharing.

CMS finalizes changes to specify that ACOs will agree to participate for a period of not less than 5 years for agreement periods beginning on July 1, 2019 and in subsequent years. CMS also finalizes revisions to §425.502(e)(4)(v) which removes language based on 3-year agreements in specifying the calculation of the quality improvement reward as part of determining the ACO’s quality score.

In general, commenters supported CMS’ overall framework and supported its proposal to pursue a tiered approach to introducing downside financial risk for ACOs. Other commenters disagreed with the more aggressive transition of ACOs to performance-based risk and expressed concern

that the changes in program requirements may cause ACOs to end their participation with the program and create a barrier to entry for ACOs to enter the program. Overall, commenters also favored the proposal to move from three to five-year agreement periods citing greater predictability for providers and health systems. CMS also discusses other comments received, many of which cover topics that are discussed elsewhere in this final rule and this summary.

In response to comments about the potential impact of the proposed redesign on program participation, CMS replies that it believes that the benefits associated with making the BASIC track's glide path available to eligible ACOs, including the incremental risk and reward, outweigh the risk of reduced ACO participation. It also notes that the required transition to the two-sided model must also be viewed in light of other changes CMS is making in the final rule to other program design elements, such as the benchmarking methodology, the level of performance-based risk, and availability of the SNF 3-day Rule Waiver, among others. CMS notes in response to comments about the length of the agreement period, that during previous rulemaking in 2011, it had received a large number of comments favoring extending the length of the agreement period to five years. It now believes that extending the agreement period to five years allows ACOs to gradually transition to risk and establish an operational structure to support quality reporting and other MSSP requirements.

2. Creating a BASIC Track with Glide Path to Performance-Based Risk

a. Phase-in of Performance-based Risk in the BASIC Track

After consideration of comments, CMS finalizes with modification its proposal governing the BASIC track. These policies are codified in a new section of the regulation at §425.605.

Within the BASIC track, CMS finalizes its proposed glide path that includes 5 levels: a one-sided risk model available only for the first 2 consecutive performance years of a 5-year agreement period (Levels A and B), and three levels of progressively higher risk and potential reward in performance years 3 through 5 of the agreement period (Levels C, D, and E). ACOs will be automatically advanced at the start of each participation year along the progression of risk/reward levels until they reach the track's maximum level of risk/reward (designed to be the same as Track 1+ Model). For those ACOs entering the BASIC track's glide path for an agreement period beginning July 1, 2019, they may remain for performance year 2020 at the same level of BASIC track glide path at which the ACO entered for the 6-month period. In subsequent years, these ACOs will automatically advance to the next level.

With respect to participation options within the BASIC track, ACOs new to the program will have the flexibility to enter the glide path at any one of the five levels. ACOs that previously participated in Track 1 (or a new ACO where a specified percentage of its ACO participants have recent prior experience in Track 1) would be ineligible to enter the glide path at Level A (limiting the duration of their participation under one-sided risk). CMS also will permit ACOs in the BASIC track to more rapidly transition (i.e., skip a level or levels) during the agreement period. Level E (the last, highest-risk level) must be entered into no later than the ACO's fifth

performance year. As discussed further below, CMS finalizes a modification to allow new legal entities that are low revenue ACOs and inexperienced with performance-based risk Medicare ACO initiatives to forgo automatic advancement to Level C to remain in Level B for an additional performance year, and then be automatically advanced to Level E.

CMS finalizes its proposal that savings would be calculated based on the same methodology used to determine shared savings under the program's existing tracks. CMS, however, modifies its proposed maximum shared savings rate and is finalizing shared savings rates of 40 percent for Levels A and B and 50 percent for Levels C, D, and E. In the proposed rule, CMS had set a 25 percent sharing rate for Levels A and B, 30 percent sharing rate for Level C, 40 percent for Level D, and 50 percent for Level E.

CMS states that, in general, commenters understood and agreed with the need to introduce the BASIC track's five level glide path as an incremental approach to higher levels of risk and reward. A majority of commenters, however, were opposed to limiting the amount of time an ACO can participate under a one-sided model from six to two years and provided various suggestions for CMS to adopt a more gradual approach to risk. In addition, most commenters favored an option that would extend the time any ACO can participate in a one-sided model to three years, as opposed to two, stating that it takes longer than two participation years to implement meaningful change. CMS disagrees with commenters' suggestions to allow all ACOs or select ACOs (based on geography or provider composition) to remain under the one-sided model for an extended time or even indefinitely, as this would just maintain, at best, the status quo of the program. However, CMS recognizes that reducing the total duration under one-sided risk may create an additional burden, particularly for rural or physician-led ACOs and finalizes a modification (discussed in section II.A.5.c of the final rule) that permits inexperienced low revenue ACOs to stay in a one-sided model of the BASIC track's glide path for an additional performance year.

CMS received numerous comments concerning its proposal to set the sharing rate for the one-sided model not to exceed 25 percent. Most commenters had serious concerns about reducing the shared savings rate from 50 percent (as currently available under Track 1) to 25 percent, asserting that doing so would deter new entrants into the program. In addition, commenters asserted that a higher sharing rate was necessary for it to enable ACOs to make sizable investments in health information technology and population health management, among other investments. CMS states that it is generally persuaded by the views that the reward-to-risk ratio for participating in the program, as proposed, is generally unattractive to ACOs, and agrees that more generous sharing rates would sustain broader participation in the program. Thus, CMS modified its policy to shared savings rate of 40 percent for Levels A and B and 50 percent for Levels C, D, and E.

CMS summarizes the phase-in schedule of levels of risk/reward by year for the BASIC track's glide path compared with the ENHANCED track in Table 3 (reproduced below).

TABLE 3—COMPARISON OF RISK AND REWARD UNDER BASIC TRACK AND ENHANCED TRACK

	BASIC Track’s Glide Path				ENHANCED Track (Track 3)
	Level A & Level B (one-sided model)	Level C (risk/reward)	Level D (risk/reward)	Level E (risk/reward)	
Shared Savings (once MSR met or exceeded)	1 st dollar savings at a rate of up to 40% based on quality performance; not to exceed 10% of updated benchmark	1 st dollar savings at a rate of up to 50% based on quality performance, not to exceed 10% of updated benchmark	1 st dollar savings at a rate of up to 50% based on quality performance, not to exceed 10% of updated benchmark	1 st dollar savings at a rate of up to 50% based on quality performance, not to exceed 10% of updated benchmark	No change. 1 st dollar savings at a rate of up to 75% based on quality performance, not to exceed 20% of updated benchmark
Shared Losses (once MLR met or exceeded)	N/A	1 st dollar losses at a rate of 30%, not to exceed 2% of ACO participant revenue capped at 1% of updated benchmark	1 st dollar losses at a rate of 30%, not to exceed 4% of ACO participant revenue capped at 2% of updated benchmark	1 st dollar losses at a rate of 30%, not to exceed the percentage of revenue specified in the revenue-based nominal amount standard under the Quality Payment Program (for example, 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 (for example, 4% of updated benchmark in 2019 – 2020)	No change. 1 st dollar losses at a rate of 1 minus final sharing rate (between 40% 75%), not to exceed 15% of updated benchmark

Annual choice of beneficiary assignment methodology? (see section II.A.4.c. of this final rule)	Yes	Yes	Yes	Yes	Yes
Annual election to enter higher risk? ³ (see section II.A.4.b. of this final rule, and section II.A.5.c of this final rule)	Yes, but new low revenue ACOs, may elect an additional year under Level B if they commit to completing the remainder of their agreement under Level E	Yes	No; ACO will automatically transition to Level E at the start of the next performance year	No; maximum level of risk / reward under the BASIC track	No; highest level of risk under Shared Savings Program
Advanced APM status under the Quality Payment Program? ^{1, 2}	No	No	No	Yes	Yes

Notes: ¹ To be an Advanced APM, an APM must meet the following three criteria: 1. CEHRT criterion: requires participants to use certified electronic health record technology; 2. Quality Measures criterion: provides payment for covered professional services based on quality measures comparable to those used in the quality performance category of the Merit-based Incentive Payment System (MIPS); and 3. Financial Risk criterion: either (1) be a Medical Home Model expanded under CMS Innovation Center authority; or (2) require participating APM Entities to bear more than a nominal amount of financial risk for monetary losses. See, for example Alternative Payment Models in the Quality Payment Program as of February 2018, available at <https://www.cms.gov/Medicare/Quality-Payment-Program/ResourceLibrary/Comprehensive-List-of-APMs.pdf>.

² As proposed, BASIC track Levels A, B, C and D would not meet the Financial Risk criterion and therefore would not be Advanced APMs. Level E of the BASIC track and the ENHANCED track would meet all three Advanced APM criteria and thus would qualify as Advanced APMs. These preliminary assessments reflect the policies discussed in this final rule. CMS will make a final determination based on the policies adopted in this final rule.

³ An eligible new legal entity (not identified as a re-entering ACO), identified as a low revenue ACO and inexperienced with performance-based risk Medicare ACO initiatives that elects to enter the BASIC track's glide path at Level A is automatically advanced to Level B for performance year 2 (or performance year 3 for ACOs entering an agreement period beginning on July 1, 2019). Prior to the automatic advancement of the ACO to Level C, the ACO may elect to remain in Level B for performance year 3 (performance year 4 for ACOs entering an agreement period beginning on July 1, 2019). For an ACO that elects to remain in Level B for an additional performance year, the ACO is automatically advanced to Level E at the start of performance year 4 (or performance year 5 for ACOs entering an agreement period beginning on July 1, 2019).

b. Calculation of Loss Sharing Limit

CMS states that it has concerns about the use of self-reported information for purposes of determining the loss sharing limit in the context of a permanent, national program. Based on its experience with the Track 1+ Model, CMS believes a simpler approach that achieves similar results would be to consider the total Medicare Parts A and B FFS revenue of ACO participants (Taxpayer Identification Numbers (TINs) and CMS Certification Numbers (CCNs)) based on claims data, without directly considering their ownership and operational interests (or those of related entities).

CMS finalizes its proposed approach where it will calculate a revenue-based loss sharing limit for all BASIC track ACOs, and cap this amount as a percentage of the ACO’s updated historical benchmark. Generally, calculation of the loss sharing limit would include the following steps:

- Determine ACO participants’ total Medicare FFS revenue, which includes total Parts A and B FFS revenue for all providers and suppliers that bill for items and services through the TIN, or a CCN enrolled in Medicare under the TIN, of each ACO participant in the ACO for the applicable performance year.
- Apply the applicable percentage under the phase-in schedule to this total Medicare Parts A and B FFS revenue for ACO participants to derive the revenue-based loss sharing limit.
- Use the applicable percentage of the ACO’s updated benchmark, instead of the revenue-based loss sharing limit, if the loss sharing limit as a percentage of total Medicare Parts A and B FFS revenue for ACO participants exceeds the amount that is the specified percentage of the ACO’s updated historical benchmark, based on the phase-in schedule. In that case, the loss sharing limit is capped and set at the applicable percentage of the ACO’s updated historical benchmark for the applicable performance year.

To illustrate, Table 5 in the final rule (reproduced below) provides a hypothetical example of the calculation of the loss sharing limit for an ACO participating under Level E of the BASIC track. This example would be relevant, under the policies, for an ACO participating in BASIC track Level E for the performance years beginning on July 1, 2019, and January 1, 2020. In this scenario, 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.

Table 5 – Hypothetical Example of Loss Sharing Limit Amounts for ACO in Level E of the Basic Track

[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

CMS notes that this approach is different from its approach to calculating benchmark and performance year expenditures for assigned beneficiaries, which it truncates at the 99th percentile of national Medicare FFS expenditures and excludes Indirect Medical Education (IME), Disproportionate Shared Hospital (DSH), and uncompensated care payments. Its approach to determining a revenue-based loss sharing limit as illustrated in Table 5 is total revenue uncapped by truncation, as CMS believes this best represent the ACO's capacity to bear performance-based risk.

Several commenters urged CMS to exclude hospital add-on payments, such as IME, DSH, and uncompensated care payments, in determining an ACO's participant revenue. CMS reiterates that its necessary to include those payments and to include total revenue uncapped by truncation to accurately determine a revenue-based loss sharing limit.

3. Permitting Annual Participation Elections

a. Permitting Election of Different Levels of Risk within the BASIC Track's Glide Path

CMS finalizes its proposal to allow ACOs that enter an agreement period under the BASIC track's glide path an opportunity to elect to enter higher levels of performance-based risk within the BASIC track within their agreement period. ACOs, for example, could skip a level, but could not go back to a lower level of risk. CMS notes that an ACO entering the glide path at Level D would automatically transition to Level E in the following year, and once an ACO is at Level E, the ACO must remain at this level for the duration of the agreement period.

CMS adds a new section to the MSSP regulations at §425.226 to govern annual participation elections. Specifically, CMS allows an ACO in the BASIC track's glide path to annually elect to accept higher than required levels of performance-based risk (compared to the automatic glide path advancement timeline), as available within the glide path, within its current agreement period. CMS makes several other related changes:

- The annual election for a change in the ACO's level of risk and potential reward must be made in the form and manner, and according to the timeframe, established by CMS.
- An ACO executive who has the authority to legally bind the ACO must certify the election to enter a higher than required level of risk and potential reward within the agreement period.
- The ACO must meet all applicable requirements for the newly selected level of risk, which in the case of ACOs transitioning from a one-sided model to a two-sided model include establishing an adequate repayment mechanism and electing the Minimum Savings Rate (MSR)/Minimum Loss Rate (MLR) that will apply for the remainder of their agreement period under performance-based risk.
- The ACO must elect to change its participation option before the start of the performance year in which the ACO wishes to begin participating under a higher than required level of risk and potential reward. CMS states that it envisions the timing of an ACO's election would generally follow the timing of the MSSP's application cycle.

If, for example, an eligible ACO enters the glide path in year 1 at Level A (one-sided model) and elects to enter Level D (two-sided model) for year 2, the ACO would automatically transition to Level E (highest level of risk/reward under the BASIC track) for year 3, and would remain in Level E for year 4 and year 5 of the agreement period. CMS notes that its policy to allow ACOs to elect to transition to higher than required levels risk and potential reward within an agreement period in the BASIC track's glide path does not alter the timing of benchmark rebasing. CMS would continue to assess the ACO's 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.

Commenters were generally in favor of CMS' proposal permitting election of different levels of risk within the BASIC Track's glide path. Some commenters favored allowing an ACO that elected to advance to a higher level to remain at that higher level until it reached the performance year it would have been at that level based on the normal glide path. A few commenters favored allowing ACOs to glide backward and select a lower level of risk if the ACO experienced losses or found it was not ready to bear risk. Other commenters favored even more flexibility by suggesting that ACOs be allowed to move from the BASIC track to the ENHANCED track within their agreement period. In response, CMS reiterates its goal to advance ACOs to take on additional risk and that ACOs should evaluate whether they are capable of undertaking greater risk before electing to move to a higher than required level of risk. It declines to adopt commenters' suggestions. CMS also declines at this time to allow ACOs to move between levels of risk and reward under the ENHANCED track and the BASIC track within a single agreement period. It notes, however, that ACOs seeking to make this transition could elect to terminate their participation agreement under the BASIC track and "renew early" to enter the ENHANCED track (this would involve rebasing of the historical benchmark).

b. Permitting Annual Election of Beneficiary Assignment Methodology

As background, Section 1899(c)(1) of the Act, as amended by section 50331 of the BBA of 2018, provides that the Secretary shall determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on utilization of primary care services furnished by physicians in the ACO and, in the case of performance years beginning on or after January 1, 2019, services provided by a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC). The BBA of 2018 mandated that, for agreement periods entered into or renewed on or after January 1, 2020, ACOs in a track that provides for retrospective beneficiary assignment will have the opportunity to choose a prospective assignment methodology, rather than the retrospective assignment methodology, for the applicable agreement period. CMS notes that the statute does not expressly require that the beneficiary assignment methodology be determined by track. Under its regulations, CMS has established two claims-based beneficiary assignment methodologies (prospective assignment and preliminary prospective assignment with retrospective reconciliation) that currently apply to different program tracks, as well as a non-claims-based process for voluntary alignment that applies to all program tracks and is used to

supplement claims-based assignment.⁴ In the CY 2017 PFS final rule (81 FR 80501 through 80510), CMS augmented the claims-based beneficiary assignment methodology by finalizing a policy where beneficiaries may voluntarily align with an ACO by designating a “primary clinician” (referred to as a “main doctor” in the prior rulemaking) they believe is responsible for coordinating their overall care using MyMedicare.gov, a secure, online, patient portal.

CMS finalizes its proposal to allow all ACOs a choice of prospective assignment for agreement periods beginning July 1, 2019 and in subsequent years. CMS will offer ACOs entering agreement periods in the BASIC track or ENHANCED track, beginning July 1, 2019 and in subsequent years, the option to choose either prospective assignment or preliminary prospective assignment with retrospective reconciliation, prior to the start of their agreement period (at the time of application). CMS will also allow ACOs to switch their selection of beneficiary assignment methodology on an annual basis or retain the same beneficiary assignment methodology. CMS does not believe the statute requires that it must continue to specify the applicable beneficiary assignment methodology for each track of the MSSP

Under this approach, an ACO will choose the beneficiary assignment methodology at the time of application to enter or re-enter the MSSP or to renew its participation for another agreement period. If the ACO’s application is accepted, the ACO will remain under that beneficiary assignment methodology for the duration of its agreement period, unless the ACO chooses to change the beneficiary assignment methodology through the annual election process. To change the approach, the ACO must indicate its desire to change assignment methodology before the start of the performance year in which it wishes to begin participating under the alternative assignment methodology. The ACO’s selection of a different assignment methodology will be effective at the start of the next performance year, and for the remaining years of the agreement period, unless the ACO again chooses to change the beneficiary assignment methodology. CMS codifies these policies in a new section of the MSSP regulations at §425.226.

CMS also finalizes conforming changes to its regulations at §§425.400 and 425.401 (assignment of beneficiaries), §425.702 (aggregate reports) and §425.704 (beneficiary-identifiable claims data) to reference either preliminary prospective assignment with retrospective reconciliation or prospective assignment instead of referencing the track to which a particular assignment methodology applies. CMS clarifies that these changes will have no effect on the voluntary alignment process under §425.402(e). The voluntary alignment process will occur regardless of the ACO’s track or claims-based beneficiary assignment methodology.

Commenters were supportive of these proposals and cited, among other reasons for their support, that the annual choice of assignment methodology for all ACOs removes challenges caused by uncertainty of retrospective reconciliation; assists ACOs in planning and designing care management strategies; and levels the playing field between different types of ACOs. Other comments included that CMS should ensure it provides accurate and timely reporting so that

⁴ Under both claims-based approaches prospective assignment is based on a two-step assignment methodology, but with retrospective reconciliation final assignment is determined after the performance year ends, whereas limited adjustments are done at year’s end for the prospective approach.

ACOs can make an informed annual determination, and that ACOs be limited in how often they can switch approaches to prevent gaming of the system.

In response, CMS acknowledges the overwhelming support of its proposal to provide flexibility to ACOs in their choice of beneficiary assignment methodology consistent with Section 1899(c)(2) of the Act. It also agrees that timely reporting and data collection are critical for ACOs to make an informed decision, and reminds readers that under §425.702 it provides ACOs with aggregate quarterly reports that identifies prospective and preliminary prospective assigned beneficiaries as well as utilization and expenditure data. Likewise, under §425.704, CMS provides ACOs with monthly claim and claim line feed files. It also disagrees with the commenters' assertion that the election should only occur once during the contract term to prevent gaming and believes that ACOs need flexibility. CMS also emphasizes in response to a comment that the term "assignment" for purposes of the MSSP in no way implies any limits, restrictions, or diminishment of the rights of Medicare FFS beneficiaries to exercise freedom of choice in the physicians and other health care practitioners from whom they receive covered services.

4. Determining Participation Options based on Medicare FFS Revenue and Prior Participation

In this section, CMS describes considerations related to, and policies for, distinguishing among ACOs based on their degree of control over total Medicare Parts A and B FFS expenditures for their assigned beneficiaries by identifying low revenue versus high revenue ACOs, experience of the ACO's legal entity and ACO participants with the MSSP and performance-based risk Medicare ACO initiatives, and prior performance in the MSSP.

a. Differentiating between Low Revenue ACOs and High Revenue ACOs

To define low revenue ACOs and high revenue ACOs for purposes of determining ACO participation options, CMS states that an ACO's ability to control the expenditures of its assigned beneficiary population can be gauged by comparing the total Medicare Parts A and B FFS revenue of its ACO participants to total Medicare Parts A and B FFS expenditures of its assigned beneficiary population. In particular, high revenue ACOs, which typically include a hospital billing through an ACO participant TIN, are generally more capable of accepting higher risk compared with low revenue ACOs. CMS notes that this claims-based measure is consistent with the self-reported composition approach used in the Track 1+ Model that indicates the presence of an ownership interest or operational interest by an IPPS hospital, cancer center, or rural hospital with more than 100 beds. Thus, CMS believes that using an ACO participant's total Medicare Parts A and B FFS revenue to classify ACOs would serve as a proxy for ACO participant composition.

After consideration of public comments, CMS finalizes its proposal with modification to use a 35 percent threshold (instead of the 25 percent proposed) to determine low revenue versus high revenue ACOs by comparing the total Medicare Parts A and B FFS revenue of ACO participants to the total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries.

CMS adds new definitions at §425.20 for “high revenue ACO,” and “low revenue ACO”, as follows:

- “High revenue ACO” means an ACO whose total Medicare Parts A and B FFS revenue of its ACO participants is at least 35 percent of the total Medicare Parts A and B FFS expenditures for the ACO’s assigned beneficiaries. These data are based on the most recent calendar year for which 12 months of data are available.
- “Low revenue ACO” means an ACO whose total Medicare Parts A and B FFS revenue of its ACO participants is less than 35 percent of the total Medicare Parts A and B FFS expenditures for the ACO’s assigned beneficiaries. These data are based on the most recent calendar year for which 12 months of data are available.

CMS establishes policies to address issues for when ACOs are close to the threshold percentage and ACO participant list changes during the agreement period potentially change their classification as a low revenue ACO. In particular, CMS was particularly concerned that an ACO may be eligible to continue for a second agreement period in the BASIC track at the time of application as a lower revenue ACO, but seek to add higher-revenue ACO participants, thereby avoiding having to participate under the ENHANCED track.

To ensure continued compliance of ACOs with the eligibility requirements for participation in the BASIC track, CMS finalizes its approach in §425.600(e). If, during the agreement period, the ACO meets the definition of a high revenue ACO, CMS proposes that the ACO would be permitted to complete the remainder of its current performance year under the BASIC track, but would be ineligible to continue participation in the BASIC track after the end of that performance year unless it takes corrective action, for example by changing its ACO participant list. CMS finalizes its proposal to take compliance action, up to and including termination of the participation agreement, as specified in §§425.216 and 425.218, to ensure the ACO does not continue in the BASIC track for subsequent performance years of the agreement period. For example, CMS may take pre-termination actions as specified in §425.216, such as issuing a warning notice or requesting a corrective action plan. To remain in the BASIC track, the ACO would be required to remedy the issue. For example, the ACO could remove an ACO participant from its ACO participant list, so that the ACO can meet the definition of low revenue ACO. If corrective action is not taken, CMS would terminate the ACO’s participation under §425.218.

While some commenters generally supported the proposed distinction between low revenue ACOs and high revenue ACOs, many others expressed concern about this distinction and found it arbitrary or unfounded. Several commenters disagreed that high revenue ACOs have a higher degree of control over Part A and B expenditures. MedPAC, for example, explained that physician-only ACOs have, in effect, a larger incentive to reduce hospital-provided services than ACOs in which hospitals participate (as reduced expenditures for costly hospital services represent foregone revenue for the hospital). Commenters also offered various alternative suggestions to use multiple sources of data to determine participation options and alternative approaches to identifying low revenue ACOs and high revenue ACOs. CMS disagrees with commenters that its bifurcated approach is arbitrary and note that it is informed by its early experience with the Track 1+ Model. CMS also declines to adopt commenters’ suggestions on

other sources of data as it believed that doing so would prove even more complex and less transparent.

Other commenters offered alternative suggestions for threshold percentages. A few argued, for example, that the proposed 25 percent threshold would incorrectly deem moderate revenue ACOs, especially rural ACOs or urban ACOs, as high revenue ACOs. These commenters suggested that CMS exempt these ACOs or increase the threshold, as high as 60 percent. Other commenters suggested raising the threshold to various levels including 30 or 40 percent. CMS agrees with the commenters' concerns that the threshold proposed be raised to allow additional ACOs with small hospitals and clinics, including rural hospitals, to be classified as low revenue ACOs. CMS increases the threshold from 25 percent to 35 percent, and states that its modeling shows that the increased threshold would increase the number of low revenue ACOs by thirty-one.

b. Restricting ACOs' participation in the BASIC track prior to transitioning to participation in the ENHANCED track

CMS finalizes its proposed policies for restricting ACOs' participation in the BASIC track prior to transitioning to participation in the ENHANCED track. High revenue ACOs will be limited to, at most, a single agreement period under the BASIC track prior to transitioning to participation under the ENHANCED track. In contrast, CMS will limit low revenue ACOs to, at most, two agreement periods under the BASIC track for a total of 10 years under the BASIC track (10.5 in the case of an ACO that participates in an agreement period that begins on July 1, 2019). These agreements do not need to be sequential, so an ACO could transition to the ENHANCED track after one agreement under the BASIC track and then return back to the BASIC track.

CMS specify these requirements for low revenue ACOs and high revenue ACOs in revisions to §425.600.

A few commenters agreed with CMS' proposed approach to allow low revenue ACOs up to two agreement periods under the BASIC track, while requiring high revenue ACOs to move more quickly to the ENHANCED track. Some commenters, for example, suggested that all ACOs be allowed to remain in the BASIC track in Level E, or a track that meets the nominal risk requirements under the Quality Payment Program. MedPAC, suggested that CMS consider allowing all ACOs to operate in the BASIC track for two agreement periods, suggesting that it had enough downside risk to encourage ACOs to control costs. One commenter suggested that while it was reasonable to ask high revenue ACOs to take on greater risk, CMS should also take into account that larger systems must invest in change across a much broader delivery "footprint" and so may be required to make investments over multiple years to make the necessary transformative system changes. CMS was not persuaded and continues to believe that requiring ACOs to transition to the ENHANCED track, with the highest level of risk and potential reward, could drive ACOs to more aggressively pursue the program's goals of lowering growth in FFS expenditures and improving quality. CMS also declined commenter's suggestions that certain ACOs (i.e., small, rural, and physician-only ACOs) be exempt from transitioning to performance-based risk.

- c. Determining participation options based on prior participation of ACO Legal Entity and ACO participants

In this section, CMS finalizes modifications to its regulations to address the following issues:

- Allowing flexibility for ACOs currently within a 3-year agreement period to transition quickly to a new agreement period under the BASIC or ENHANCED tracks.
- Establishing definitions to more clearly differentiate ACOs applying to renew for a second or subsequent agreement period and ACOs applying to reenter the program.
- Revising the criteria for evaluating an ACO’s prior participation in the MSSP to determine the eligibility of ACOs seeking to renew or re-enter the program.
- Establishing criteria for determining the participation options available to an ACO based on its experience with performance-based risk Medicare ACO initiatives and on whether the ACO is low revenue or high revenue.
- Establishing policies that more clearly differentiate the participation options, and the applicability of program requirements that phase-in over time.

Definitions of renewing and re-entering ACOs. CMS defines in its regulations a renewing ACO and an ACO re-entering after termination or expiration of their participation agreement. CMS states that the lack of a definition of a renewing ACO has caused some confusion among applicants.

Definition of renewing ACO: An ACO 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 under §425.220 and immediately enters a new agreement period to continue its participation in the program.

Definition of “Re-entering ACO”: An ACO that does not meet the definition of a “renewing ACO” and meets **either** of the following conditions:

- (1) Is the same legal entity as an ACO, identified by TIN according to the definition of ACO in §425.20, 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 under §425.218 or §425.220.
- (2) Is a new legal entity that has never participated in the MSSP and is applying to participate in the program and more than 50 percent of its ACO participants were included on the ACO participant list under §425.118, of the same ACO in any of the 5 most recent performance years prior to the agreement start date.

CMS provides several examples that illustrate the application of the definition of re-entering ACO. For example, if the ACO were the same legal entity (i.e., same TIN) that previously

participated CMS would treat this ACO as a re-entering ACO. Likewise, if the ACO were a different legal entity (i.e., different TIN), but more than 50 percent of its ACO participants were part of the same ACO previously (any of the 5 most recent performance year prior to the agreement start date), then CMS would also treat this ACO as a re-entering ACO.

CMS states its belief that looking at the experience of the ACO participants, in addition to the legal entity, would be a more robust check on prior participation. CMS chose the 5-year look back period to determine whether an ACO is experienced or inexperienced as it aligns with its performance-based risk Medicare ACO initiatives. It believes that its choice of 50 percent best identifies ACOs with significant participant overlap.

Some commenters believed the distinctions for determining participation options, including evaluating whether ACOs are new, renewing, or re-entering, add complexity to the program. Others opposed the approach and suggested that CMS forgo the policy. A few commenters indicated some confusion over the early renewal policies. One commenter, for example, stated it was unclear whether the opportunity to terminate early and begin a new 5-year agreement period is open to all ACOs. CMS acknowledges that its approach adds complexity, but that it provides needed clarification to the program's regulations and bolsters program integrity. In response for clarification, CMS clarifies that the proposed definition of renewing ACO, in combination with its proposal to discontinue use of the "sit-out" period after termination under §425.222(a), would create the flexibility for any ACO within an agreement period to voluntarily terminate its current participation agreement and (if eligible) enter a new agreement period under the BASIC track or ENHANCED track, beginning at the start of the next performance year after the termination date of its previous agreement period, as early as July 1, 2019, thereby avoiding an interruption in participation. CMS would consider these ACOs to have effectively renewed their participation early.

d. Eligibility requirement and application procedures for renewing and re-entering ACOs

CMS finalizes revisions to its regulations to more clearly set forth the eligibility requirements and application procedures for renewing ACOs and re-entering ACOs. CMS revises §425.222 to address limitations on the ability of re-entering ACOs to participate in the MSSP for agreement periods beginning before July 1, 2019. In addition, CMS revises §425.224 to address general application requirements and procedures for all re-entering ACOs and all renewing ACOs. These policies are discussed in more detail below.

In revising §425.222, CMS finalizes its proposal to remove the required "sit-out" period for terminated ACOs, to facilitate transition of ACOs new agreements under the participation options established in this final rule. CMS notes that if left unchanged, the "sit-out" policy would prevent existing, eligible Track 1 ACOs from quickly entering an agreement period under the proposed BASIC track or existing Track 2 ACOs from entering a new agreement (level E of the BASIC track or the ENHANCED track). Eliminating the "sit-out" period also allows ACOs that deferred renewal in a second agreement to more quickly transition to the BASIC track or ENHANCED track. This ensures that there is not a gap in time between when an ACO concludes an agreement and when it begins the new agreement period.

In revising §425.224, CMS makes certain policies applicable to both renewing ACOs and re-entering ACOs to incorporate other technical changes. One of the primary changes includes adding a requirement (consistent with the current provision at §425.222(c)(3)), that ACOs previously in a two-sided model would need to reapply to participate in a two-sided model. A renewing or re-entering ACO that was previously under a one-sided model of the BASIC track's glide path may only reapply for participation in a two-sided model.

CMS also finalizes modifications to its evaluation criteria specified in §425.224(b) for determining whether an ACO is eligible for continued participation in the program in order to permit them to be used in evaluating both renewing ACOs and re-entering ACOs, to adapt some of these requirements to longer agreement periods (i.e., 5 years instead of 3), and to prevent ACOs with a history of poor performance from participating in the program. The criteria include: (1) whether the ACO has a history of compliance with the program's quality performance standard; (2) whether an ACO under a two-sided model repaid shared losses owed to the program; (3) the ACO's history of financial performance; and (4) whether the ACO has demonstrated in its application that it has corrected the deficiencies that caused it to perform poorly or to be terminated.

CMS also finalizes its proposal to discontinue use of the requirement at §425.600(c), under which an ACO with net losses during a previous agreement period must identify in its application the causes for the net loss and specify what safeguards are in place to enable it to potentially achieve savings in its next agreement period. It believes the financial performance review criterion will be more effective in identifying ACOs with a pattern of poor financial performance. CMS notes that for ACOs identified as re-entering ACOs (greater than 50 percent of their ACO participants have recent prior participation in the same ACO), it would determine eligibility of the re-entering ACO to participate in the program based on the past performance of the predecessor entity.

CMS received few comments directly addressing the proposal to remove the "sit-out" period after termination, but the comments received were generally supportive. Commenters believed that this "sit-out" period was unnecessary and shuts healthcare providers out of participating in an essential CMS program. CMS agrees and believes removing the "sit-out" period is necessary to help facilitate transition of ACOs to new agreements. One commenter suggested that CMS revisit the evaluation criterion for poor quality performance in light of the longer agreement periods (not less than 5 years). CMS states that, as with other program policies, it may revisit this issue in future rulemaking.

e. Evaluation Criteria for Determining Participation Options

In the August 2018 proposed rule, CMS expressed concern about the vulnerability of certain program policies to gaming by ACOs seeking to continue in the program under the BASIC track's glide path, as well as the need to ensure that an ACO's participation options are commensurate with the experience of the organization. In particular, CMS believed that some restrictions were needed to prevent all current and previously participating Track 1 ACOs from taking advantage of additional time under a one-sided model in the BASIC track's glide path and

instead to encourage more rapid progression to performance-based risk. CMS had similar concerns about new ACOs identified as re-entering ACOs. CMS preferred an approach that would help ensure that ACOs, whether they are initial applicants to the program, renewing ACOs or re-entering ACOs, be treated comparably.

Thus, CMS finalizes its proposal to identify the available participation options for an ACO (regardless of whether it is applying to enter, re-enter, or renew its participation in the program) by considering all of the following factors: (1) whether the ACO is a low revenue ACO or a high revenue ACO; and (2) the level of risk with which the ACO or its ACO participants has experience based on participation in Medicare ACO initiatives in recent years.

CMS finalizes its proposed definitions of how it defines “experienced” and “inexperienced” with performance-based risk Medicare ACOs at §425.20. It also defines a “performance-based risk Medicare ACO”. These are summarized in the table below:

Term	Definition
Performance-based risk Medicare ACO initiative	<p>Defines as an initiative implemented by CMS that requires an ACO to participate under a two-sided model during its agreement period.</p> <p>Includes Track 2, Track 3 or the ENHANCED track, and the BASIC track (including Level A through Level E). Also includes Innovation Center ACO Models involving two-sided risk: the Pioneer ACO Model, Next Generation ACO Model, the performance-based risk tracks of the Comprehensive End-Stage Renal Disease (ESRD) Care (CEC) Model (including the two-sided risk tracks for Large Dialysis Organization (LDO) ESRD Care Organizations (ESCOs) and non-LDO ESCOs), and the Track 1+ Model. Also includes other models involving two-sided risk as may be specified by CMS.</p>
Experienced with performance-based risk Medicare ACO initiatives	<p>Defines as an ACO that CMS determines meets <i>either</i> of the following criteria:</p> <p>(1) 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 Track 2 or Track 3.</p> <p>(2) 40 percent or more of the ACO’s ACO participants participated in a performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a MSSP agreement period under Track 2 or Track 3, in any of the 5 most recent performance years prior to the agreement start date.</p>
Inexperienced with performance-based risk Medicare ACO initiatives	<p>Defines as an ACO that CMS determines meets <i>all</i> of the following criteria:</p>

Term	Definition
	<p>(1) 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 Track 2 or Track 3.</p> <p>(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 MSSP agreement period under Track 2 or Track 3, in each of the 5 most recent performance years prior to the agreement start date.</p>

CMS clarifies that in applying the “40 percent threshold” it would not limit its consideration to ACO participants that participated in the same ACO or the same performance-based risk Medicare ACO initiative during the look-back period. CMS will make a cumulative determination. It will determine it cumulatively based on percentage of ACO participants have participated in a performance-based risk Medicare ACO initiative in any of the 5 most recent performance years prior to the start of the agreement period. For example, for applicants applying to enter the BASIC track for an agreement period beginning on July 1, 2019, it will consider what percentage of the ACO participants participated in any of the following during 2019 (January – June), 2018, 2017, 2016, and 2015: Track 2 or Track 3, the Track 1+ Model, the Pioneer ACO Model, the Next Generation ACO Model, or the performance-based risk tracks of the Comprehensive End-Stage Renal Disease Care (CEC) Model. For future years, CMS will also consider participation in the BASIC or ENHANCED tracks. CMS examined other thresholds but believes this threshold is consistent with its Track 1+ model requirement and will not be overly restrictive, citing its data that the maximum percentage data observed for these applicants was 30 percent.

With respect to the “5 performance year look back” period, CMS considered a shorter look back period that was longer than 1 performance year (such as three years) or a longer period than 5 years. CMS states that it wants to avoid ACOs entering the BASIC track’s glide path for one or two years under the one-sided risk model, terminating their agreement, and then trying to enter the program again.

ACOs that previously participated in Track 1 of the MSSP or new ACOs, for which the majority of their ACO participants previously participated in the same Track 1 ACO, that are eligible to enter the BASIC track’s glide path, may enter a new agreement period under either Level B, C, D or E. In other words, these ACOs would not be eligible to participate under Level A of the glide path, but still would be able to spend one year in a one-sided model (Level B). CMS clarifies that the policy restricting entry into the BASIC track’s glide path applies consistently to any former Track 1 ACO and any new ACO that is identified as a re-entering ACO because of its ACO participants’ recent prior participation in the same Track 1 ACO, regardless of how many performance years or agreement periods during which the ACO participated under Track 1.

In response to comments, CMS finalizes a modification to its proposals to allow an additional participation option in the BASIC track’s glide path for ACO legal entities without prior

experience in the MSSP (that is, new legal entities that are not identified as re-entering ACOs) that are identified as low revenue ACOs. To be eligible for the BASIC track's glide path, these ACOs would have been determined to be inexperienced with performance-based risk Medicare ACO initiatives based on an evaluation of their ACO legal entity and also ACO participants (according to the 40 percent threshold). CMS will allow these ACOs to participate under a one-sided model for up to three performance years (or four performance years for ACOs entering an agreement period beginning July 1, 2019). However, in exchange for this additional year under a one-sided model, these ACOs would forfeit their progression along the glide path to Level C and Level D and therefore automatically advance to Level E for the remaining performance years of their agreement period.

An ACO identified as a high revenue ACO with experience with performance-based risk Medicare ACO initiatives would be limited to the ENHANCED track, regardless of whether the ACO is new legal entity, a re-entering ACO, or a renewing ACO.

CMS produces three tables in this section (reproduced below) that explain how the regional adjustment weights would apply and the participation options available:

- Table 6- Examples of Phase-In of Modified Regional Adjustment Weights Based on Agreement Start Date and Applicant Type
- Table 7 – Participation Options for Low Revenue ACOs Based on Applicant Type and Experience with Risk
- Table 8 – Participation Options for High Revenue ACOs Based on Applicant Type and Experience with Risk

These new provisions for the selection of risk model are at §425.600. CMS also discontinues the option for certain applicants (i.e., former Physician Group Practice demonstration and Pioneer ACO participants) to use a condensed application when applying to participate in the MSSP.

Table 6—Examples of Phase-In of Modified Regional Adjustment Weights Based on Agreement Start Date and Applicant Type

Applicant Type	First time regional adjustment used: 35 percent or 15 percent (if spending above region)	Second time regional adjustment used: 50 percent or 25 percent (if spending above region)	Third and subsequent time regional adjustment used: 50 percent or 35 percent (if spending above region)	Fourth and subsequent time regional adjustment used: 50 percent weight
<u>New entrant</u> 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	Applicable to fourth agreement period starting in 2035 and all subsequent agreement periods
<u>Renewing ACO</u> 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	Applicable to sixth (2012/2013) or fifth (2016) agreement period starting in 2035 and all subsequent agreement periods
<u>Early renewal</u> 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 as follows: 35 percent or 25 percent (if spending above region)	Applicable to third agreement period starting on July 1, 2019	Applicable to fourth agreement period starting in 2025	Applicable to fourth agreement period starting in 2030 and all subsequent agreement periods
<u>Re-entering ACO</u> with initial start date in 2014 whose agreement expired December 31, 2016 (did not renew) and <u>re-enters</u> 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	Applicable to fourth agreement period starting in 2035 and all subsequent agreement periods

<p><u>Re-entering ACO</u> with second agreement period start date in 2017 terminated during performance year 2 (2018) and <u>re-enters</u> second agreement period starting on July 1, 2019</p>	<p>Applicable to second agreement period starting on July 1, 2019 (ACO considered to be reentering a second agreement period)</p>	<p>Applicable to third agreement period starting in 2025</p>	<p>Applicable to fourth agreement period starting in 2030</p>	<p>Applicable to fourth agreement period starting in 2035 and all subsequent agreement periods</p>
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Table 7—Participation Options for Low Revenue ACOs Based on Applicant Type and Experience with Risk

Applicant type	ACO experienced or inexperienced with performance based risk Medicare ACO initiatives	Participation Options ¹			Agreement period for policies that phase-in over time (benchmarking methodology and quality performance)
		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)	
New legal entity	Inexperienced	Yes - glide path Levels A through E, new legal entities (not reentering ACOs) that are low revenue ACOs may elect to enter in Level A, transition to Level B, and remain in Level B for an additional performance year prior to being automatically advanced to Level E for the remaining performance years of their agreement period	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	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

Applicant type	ACO experienced or inexperienced with performance based risk Medicare ACO initiatives	Participation Options ¹			Agreement period for policies that phase-in over time (benchmarking methodology and quality performance)
		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)	
	ACOs identified as re-entering ACOs because more than 50 percent of their ACO participants have recent prior experience in a Track 1 ACO				same agreement period in which the ACO was participating at the time of termination; or (3) applicable agreement period ² 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 ² 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

Applicant type	ACO experienced or inexperienced with performance based risk Medicare ACO initiatives	Participation Options ¹			Agreement period for policies that phase-in over time (benchmarking methodology and quality performance)
		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)	
Renewing ACO	Experienced - including former Track 1 ACOs that deferred renewal under a two-sided model	No	Yes	Yes	Subsequent consecutive agreement period

Notes: ¹ Low revenue ACOs may operate under the BASIC track for a maximum of two agreement periods.

²CMS considers the participation of the ACO in which a majority of the new ACO's participants were participating: (1) If the participation agreement of the other ACO was terminated, then the new ACO reenters the program at the start of the same agreement period in which the other ACO was participating at the time of termination from the MSSP, beginning with the first performance year of that agreement period. (2) If the participation agreement of the other ACO expired without having been renewed, then the new ACO reenters the program under the other ACO's next consecutive agreement period in the MSSP. (3) If the other ACO is currently participating in the program, the new ACO would be considered to be entering into the same agreement period in which this other ACO is currently participating, beginning with the first performance year of that agreement period.

Table 8 – Participation Options for High Revenue ACOs Based on Applicant Type and Experience with Risk

Applicant type	ACO experienced or inexperienced with performance based risk Medicare ACO initiatives	Participation Options ¹			Agreement period for policies that phase-in over time (benchmarking methodology and quality performance)
		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)	
New legal entity	Inexperienced	Yes - glide path Levels A through E	Yes	Yes	First agreement period
New legal entity	Experienced	No	No	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 ² 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	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 ² for new ACO identified as re-entering because of ACO participants' experience in the same ACO

Applicant type	ACO experienced or inexperienced with performance based risk Medicare ACO initiatives	Participation Options ¹			Agreement period for policies that phase-in over time (benchmarking methodology and quality performance)
		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)	
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 (Except for a one-time renewal option for ACOs with a first or second agreement period beginning in 2016 or 2017 that participated in Track 1+ Model)	Yes	Subsequent consecutive agreement period

Notes: ¹ High revenue ACOs that have participated in the BASIC track are considered experienced with performance-based risk Medicare ACO initiatives and are limited to participating under the ENHANCED track for subsequent agreement periods.

² CMS considers the participation of the ACO in which a majority of the new ACO's participants were participating: (1) If the participation agreement of the other ACO was terminated, then the new ACO reenters the program at the start of the same agreement period in which the other ACO was participating at the time of termination from the MSSP, beginning with the first performance year of that agreement period. (2) If the participation agreement of the other ACO expired without having been renewed, then the new ACO re-enters the program under the other ACO's next consecutive agreement period in the MSSP. (3) If the other ACO is currently participating in the program, the new ACO would be considered to be entering into the same agreement period in which this other ACO is currently participating, beginning with the first performance year of that agreement period.

g. Monitoring for Financial Performance

CMS noted in the August 2018 proposed rule that its current regulations (§425.316) are insufficient to monitor ACO's financial performance, as they do not specifically authorize termination or remedial action for poor financial performance. With added experience, CMS believes additional provisions are necessary to address poor financial performance, particularly for ACOs that may otherwise be in compliance with program requirements. CMS states that just as poor quality performance can subject an ACO to remedial action or termination, an ACO's failure to lower growth in Medicare FFS expenditures should be the basis for CMS to take pre-termination actions under §425.216, including a request for corrective action by the ACO, or termination of the ACO's participation agreement under § 425.218.

CMS finalizes its proposal, with a modification to its applicability date, to modify §425.316 to add a provision for monitoring ACO financial performance. Specifically, CMS finalizes its proposal to monitor for whether the expenditures for the ACO's assigned beneficiary population are "negative outside corridor," meaning that the expenditures for assigned beneficiaries exceed the ACO's updated benchmark by an amount equal to or exceeding either the ACO's negative MSR under a one-sided model, or the ACO's MLR under a two-sided model.⁵ If the ACO is negative outside corridor for a performance year, CMS may take any of the pre-termination actions set forth in §425.216. If the ACO is negative outside corridor for another performance year of the ACO's agreement period, CMS may immediately or with advance notice terminate the ACO's participation agreement under §425.218.

CMS modifies the applicability of its financial performance monitoring policy to performance years beginning on July 1, 2019 and in subsequent performance years.

Based on its experience, CMS notes that ACOs in two-sided models tend to terminate their participation after sharing losses for a single year in Track 2 or Track 3. CMS data show that about 10 percent (19 out of 194 ACO that renewed for a second agreement period under Track 1) were negative outside corridor in their first 2 performance years in their first agreement period. While a few of these showed improvement in subsequent years, others had multiple years of losses. CMS was concerned that these ACOs are allowed to take advantage of the potential benefits of program participation despite poor financial performance. CMS also indicates that it was concerned that ACOs may seek to obtain reinsurance to help offset their liability for shared losses as a way to enable their continued participation. CMS did not want to prohibit these arrangements, but believes its financial monitoring approach will be effective in removing ACOs with a history of poor financial performance.

⁵ 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.

Most commenters opposed the proposal to monitor ACOs for poor financial performance and potentially terminate ACOs with 2 performance years of significant losses (negative outside corridor). Commenters were particularly concerned that these provisions, if implemented, would provide CMS with too much discretion to terminate ACO participation in the program and further discourage ACOs participating in the program. Further, some commenters viewed the proposed approach as unnecessary given that ACOs are automatically advanced to performance-based risk. CMS was not convinced of these arguments or others. CMS continues to believe that this approach is necessary to help it address ACOs that may continue in the program despite poor financial performance (as they may find the advantages of continued participation outweigh the amount of shared losses owed). CMS does modify the applicability of its financial performance monitoring policy to performance years beginning on July 1, 2019 and in subsequent performance years.

5. Requirements for ACO participation in Two-sided Models

In this section, CMS addresses requirements related to an ACO's participation in performance-based risk, including election of the MSR/MLR for ACOs in the BASIC track's glide path and issues related to the repayment mechanism.

a. Election of MSR/MLR by ACOs

As background, the Minimum Savings Rate (MSR) and the Minimum Loss Rate (MLR) are designed to protect an ACO earning shared savings or being liable for shared losses when the change in expenditures represent normal, or random variation rather than an actual change in performance. Under Track 1, a variable MSR is assigned based on the number of assigned beneficiaries. ACOs applying to a two-sided model (currently, Track 2, Track 3 or the Track 1+ Model) may select from the following options:

- Zero percent MSR/MLR
- Symmetrical MSR/MLR in a 0.5 percent increment between 0.5-2.0 percent
- Symmetrical MSR/MLR that varies based on the number of assigned beneficiaries

After considering the comments received, CMS finalizes the policies governing the MSR/MLR for ACOs in the BASIC track, with a modification to include a new paragraph at §425.605(b)(2)(ii)(D) to provide that ACOs that elect the option to participate in a third year under a one-sided model will select their MSR/MLR prior to transitioning to Level E.

Under the final policies, CMS makes a distinction between one-sided and two-sided models:

- ACOs in a one-sided model of the BASIC track's glide path will have a variable MSR based on the number of beneficiaries assigned to the ACO. The variable MSR will be determined using the same methodology that is currently used for Track 1.

- ACOs in a two-sided model of the BASIC track will be able to choose among the MSR/MLR options that are available to ACOs participating in Track 2 or the ENHANCED track.
- ACOs participating under Level A or B of the BASIC track's glide path will choose the MSR/MLR to be applied before the start of their first performance year in a two-sided model. This selection will occur before the ACO enters Level C, D or E of the BASIC track's glide path, depending on whether the ACO is automatically transitioned to a two-sided model (Level C or E) or elects to more quickly transition to a two-sided model within the glide path (Level C, D, or E), and will be in effect for the duration of the agreement period that the ACO is under two-sided risk.

A number of commenters supported a combination of a lower MSR and higher sharing rates for low revenue ACOs participating in the BASIC track and offered several different alternatives. CMS notes several changes it has made in this final rule to increase incentives for low revenue ACOs participating in the BASIC track. This includes finalizing an exception that will permit new legal entities determined to be low revenue and inexperienced to participate for 3 performance years under a one-sided model within the BASIC track's glide path. CMS also states its belief that the use of a variable MSR for ACOs in one-sided models is appropriate to protect the Trust Funds from paying shared savings for savings that may have resulted from random variation rather than from care coordination and quality improvement by the ACO.

b. Modifying the MSR/MLR to Address Small Population Sizes

Under current regulations, for all ACOs in Track 1 and ACOs in a two-sided risk model that have elected the variable MSR/MLR, CMS determines the MSR and MLR (if applicable) for the performance year based on the number of beneficiaries assigned to the ACO for the performance year. If an ACO's performance year assigned beneficiary population falls below 5,000, the ACO remains eligible for shared savings/shared losses but the following policies apply (as specified in §425.110(b)(1)): (1) the MSR and MLR will be set at a level consistent with the number of assigned beneficiaries; and (2) those at a fixed MSR/MLR, the MSR/MLR will remain fixed at the level consistent with their choice at the start of the agreement period.

To implement the requirement for the variable MSR/MLR for populations smaller than 5,000 assigned beneficiaries the CMS Office of the Actuary (OACT) calculates these ranges. If, for example, the population falls to 1,000 or 500, the MSR would correspondingly rise to 8.7 percent or 12.2 percent respectively – a higher number based on the greater random variation that can occur. Table 9 in the final rule (reproduced below) shows how the MSR can vary (the MLR is equal to the negative MSR). CMS is concerned about the potential for rewarding ACOs with a static MSR/MLR that are unable to maintain a minimum population for 5,000 beneficiaries.

Number of Beneficiaries	MSR (low end of assigned beneficiaries) (percent)	MSR (high end of assigned beneficiaries) (percent)
1 – 499	≥12.2	
500 – 999	12.2	8.7
1,000 – 2,999	8.7	5.0
3,000 – 4,999	5.0	3.9
5,000 – 5,999	3.9	3.6
6,000 – 6,999	3.6	3.4
7,000 – 7,999	3.4	3.2
8,000 – 8,999	3.2	3.1
9,000 – 9,999	3.1	3.0
10,000 – 14,999	3.0	2.7
15,000 – 19,999	2.7	2.5
20,000 – 49,999	2.5	2.2
50,000 – 59,999	2.2	2.0
60,000 +	2.0	2.0

CMS finalizes its proposal to modify §425.110(b) to provide that it will use a variable MSR/MLR when performing shared savings and shared losses calculations if an ACO’s assigned beneficiary population falls below 5,000 for the performance year, regardless of whether the ACO selected a fixed or variable MSR/MLR. CMS revises the applicability date, such that the new policy will apply to performance years beginning on or after July 1, 2019, rather than January 1, 2019.

If the ACO’s assigned beneficiary population increases to 5,000 or more for subsequent performance years in the agreement period, the MSR/MLR reverts to the fixed level selected by the ACO at the start of the agreement period (or before moving to risk for ACOs on the BASIC track’s glide path), if applicable. CMS will specify the additional ranges for the MSR (when the ACO’s population falls below 5,000 assigned beneficiaries) through revisions to the table at §425.604(b), for use in determining an ACO’s eligibility for shared savings for a performance year. CMS also made some technical changes to reorganize the provisions at §425.110.

CMS did not receive any comments on its proposal.

c. ACO Repayment Mechanisms

Currently, under the repayment mechanism for participation in a two-sided model of the MSSP, ACOs must select from one or more types of repayment arrangements: (1) funds placed in escrow; (2) a line of credit; and (3) a letter of credit that the Medicare program could draw upon; or (4) a surety bond. For Track 2 and Track 3, the repayment mechanism must be equal to at least 1 percent of the total per capita Medicare Parts A and B FFS expenditures for the ACOs’ assigned

beneficiaries. CMS states that program stakeholders have continued to identify the repayment mechanism requirement as a potential barrier for some ACOs to enter into performance-based risk tracks, such as small, physician-only and rural ACOs that may lack access to capital. CMS provides more flexibility under its Track 1+ model, which uses a bifurcated approach. ACOs without an IPPS hospital, cancer center, or rural hospital with more than 100 beds as a participant, for example, could be subject to the revenue-based sharing limit, where the repayment mechanism is the lower of the 1 percent of total per capita Medicare Parts A and B FFS expenditures, or 2 percent of the ACO participants' total Medicare Parts A and B FFS revenue. In addition, ACOs must replenish within 90 days any funds used to repay any portion of shared losses owed to CMS. The repayment mechanism must remain in effect for 24 months following the end of the agreement period to ensure that funds are available to repay any portion of shared losses owed to CMS.

Consistent with its approach used under the Track 1+ Model, CMS believes the amount of the repayment mechanism should be potentially lower for BASIC track ACOs compared to the repayment mechanism amounts required for ACOs in Track 2 or the ENHANCED track.

Therefore, CMS finalizes, with modifications, its proposed provisions at §425.204(f)(4) to specify the methodologies and data used in calculating the repayment mechanism amounts for BASIC track, Track 2, and ENHANCED track ACOs. CMS finalizes the following:

- **ACO in Track 2** (§425.204(f)(4)(i)): Repayment mechanism amount must be equal to at least 1 percent of the total per capita Medicare Parts A and B FFS expenditures used to calculate the benchmark for the applicable agreement periods, as estimated by CMS at the time of the application. Based on comments received, CMS finalized a modification for Track 2 – it had proposed using the most recent calendar year for which 12 months of data are available – and instead is using expenditures calculated at the time of the application. CMS states that as it is retiring Track 2 as a participation option, the proposed policy would have been irrelevant.
- **ACO for a BASIC or ENHANCED Track** (§425.204(f)(4)(ii)): Repayment mechanism amount must be equal to the lesser of (i) 1 percent of the total per capita Medicare Parts A and B FFS expenditures for its assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available; or (ii) 2 percent of the total Medicare Parts A and B FFS revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available. In the final rule, based on comments received, CMS extended the flexibility proposed for the BASIC track to ACOs participating in the ENHANCED track, and believes that this will reduce the burden associated with establishing a repayment mechanism on lower-revenue ACOs. Several commenters believed that the proposed repayment mechanism amounts were too high, but CMS disagreed and believes the proposed levels were necessary to protect the Medicare Trust Funds and believes that the “lesser of” approach helps to mitigate this issue for rural ACOs or ACOs that otherwise face funding constraints.

CMS also finalizes §425.204(f)(4)(iii) to state that, for agreement periods beginning on or after

July 1, 2019, CMS recalculates the ACO's repayment mechanism amount before the second and each subsequent performance year in the agreement period based on the certified ACO participant list for the relevant performance year. If the recalculated repayment mechanism amount exceeds the existing repayment mechanism amount by at least 50 percent or \$1,000,000, whichever is the lesser value, CMS notifies the ACO in writing that the amount of its repayment mechanism must be increased to the recalculated repayment mechanism amount. Within 90 days after receipt of such written notice from CMS, the ACO must submit for CMS' approval documentation that the amount of its repayment mechanism has been increased to the amount specified by CMS. CMS modified its proposal based on feedback from commenters. It was persuaded by commenters' suggestions to increase the thresholds that would trigger reimbursement for an ACO to increase to increase the dollar amount of its repayment mechanism arrangement. Its revised amounts (up from 10 percent or \$100,000) is based on its analysis that shows that only ACOs with the largest changes in their estimated repayment mechanisms (the top 5 to 10 percent of ACOs) would need to increase their repayment mechanism amounts.

CMS also finalizes §425.204(f)(4)(iv) to state that, in the case of an ACO that has submitted a request to renew its participation agreement and wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period, the amount of the repayment mechanism must be equal to the greater of the following: (A) the amount calculated by CMS in accordance with §425.204(f)(4)(ii) of this section; or (B) the repayment mechanism amount that the ACO was required to maintain during the last performance year of the participation agreement it seeks to renew.

d. Regarding Submission of Repayment Mechanism Documentation

CMS finalizes its proposal, without modification, to amend the regulations to provide that an ACO entering an agreement period in Levels C, D, or E of the BASIC track's glide path must demonstrate the adequacy of its repayment mechanism prior to the start of its agreement period and at such other times as requested by CMS. In addition, CMS finalizes its proposal that an ACO entering an agreement period in Level A or Level B of the BASIC track's glide path must demonstrate the adequacy of its repayment mechanism prior to the start of any performance year in which it either elects to participate in, or is automatically transitioned to a two-sided model (Level C, Level D, or Level E) of the BASIC track's glide path, and at such other times as requested by CMS. CMS did not receive any comments on its proposal.

e. Repayment Mechanism Duration

CMS finalizes with modification its proposed provisions regarding the duration of the repayment mechanism at §425.204(f)(6).

CMS finalizes at §425.204(f)(6) to state that with limited exceptions, a repayment mechanism must be in effect for the duration of an ACO's participation under a two-sided model plus 12 months after the conclusion of the agreement period. CMS modified its policy from the proposed rule – it had proposed a 24-month tail period—based on comments received. It did not receive any

comments in support of its proposal and ACOs were concerned about the potential financial burden, particularly on small and low revenue ACOs.

For an ACO that is establishing a new repayment mechanism, CMS finalizes at §425.204(f)(6)(i) to state that for an ACO to meet this requirement, the repayment mechanism must satisfy one of the following criteria: (A) the repayment mechanism covers the entire duration of the ACO's participation under a two-sided model plus 12 months following the conclusion of the agreement period; or (B) the repayment mechanism covers a term of at least the first two performance years in which the ACO is participating under a two-sided model and provides for automatic, annual 12-month extensions of the repayment mechanism such that the repayment mechanism will eventually remain in effect through the duration of the agreement period plus 12 months following the conclusion of the agreement period.

For a renewing ACO that wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period, CMS finalizes at §425.204(f)(6)(ii) to state that the existing repayment mechanism must be amended to meet one of the following criteria (A) the duration of the existing repayment mechanism is extended by an amount of time that covers the duration of the new agreement period plus 12 months following the conclusion of the new agreement period; or (B) the duration of the existing repayment mechanism is extended, if necessary, to cover a term of at least the first two performance years of the new agreement period and provides for automatic, annual 12-month extensions of the repayment mechanism such that the repayment mechanism will eventually remain in effect through the duration of the new agreement period plus 12 months following the conclusion of the new agreement period.

CMS also finalizes at §425.204(f)(6)(iii) to state that, CMS may require an ACO to extend the duration of its repayment mechanism beyond the 12-month tail period, if necessary, to ensure that the ACO fully repays CMS any shared losses for each of the performance years of the agreement period.

At §425.204(f)(6)(iv), CMS states that a repayment mechanism may be terminated at the earliest of the following conditions: (A) the ACO has fully repaid CMS any shared losses owed for each of the performance years of the agreement period under a two-sided model; (B) CMS has exhausted the amount reserved by the ACO's repayment mechanism and the arrangement does not need to be maintained to support the ACO's participation under the MSSP; or (C) CMS determines that the ACO does not owe any shared losses under the MSSP for any of the performance years of the agreement period.

Based on these finalized provisions, if CMS notifies a renewing ACO that its repayment mechanism amount will be higher for the new agreement period, the ACO may either (i) establish a second repayment mechanism arrangement in the higher amount under one of the options set forth in §425.204(f)(6)(i); or (ii) increase the amount of its existing repayment mechanism to the higher amount and amend the existing repayment mechanism arrangement under one of the options set forth in §425.204(f)(6)(ii). On the other hand, if CMS notifies a renewing ACO that the repayment mechanism amount for its new agreement period is equal to or lower than its existing repayment mechanism amount, the ACO may choose to amend its existing repayment mechanism under one of the options set forth in §425.204(f)(6)(i) instead of obtaining a second

repayment mechanism for the new agreement period. However, in that case, the ACO would be required to maintain the repayment mechanism at the existing higher amount.

Commenters also expressed concern about the ability of an ACO to obtain a repayment mechanism that would cover a 5-year agreement period, plus its proposed 24-month tail period (shortened to 12 months in final rule). CMS replied that it believed that ACOs would be able to work with financial institutions to establish repayment mechanisms that would cover the duration of the agreement period plus a 12-month tail period. CMS also modified its policy to provide the option to permit ACOs to establish a repayment mechanism that covers at least the first two performance years under which an ACO is participating in a two-sided risk model and provides for automatic, 12-month extensions of the repayment mechanism that cover the duration of the agreement plus the 12-month tail period.

f. Institutions Issuing Repayment Mechanism Arrangements

CMS finalizes its proposal to revise §425.204(f)(2) to specify that an ACO that will participate in a two-sided model must establish one or more of the following repayment mechanisms to demonstrate its ability to repay shared losses: an escrow account with an insured institution, obtaining a surety bond from a company included on the U.S. Department of Treasury's List of Certified Companies, or establishing a line of credit (as evidenced by a letter of credit that the Medicare program can draw upon) at an insured institution. CMS anticipates updating the Repayment Mechanism Arrangements Guidance to specify the types of institutions that would meet these new requirements. For example, in the case of funds placed in escrow and letters of credit, the repayment mechanism could be issued by an institution insured by either the Federal Deposit Insurance Corporation or the National Credit Union Share Insurance Fund.

Commenters were generally supportive and appreciative of CMS' proposals to expand the list of institutions with which an ACO may establish a repayment mechanism. Other expressed the belief that ACOs need additional repayment mechanisms citing insurance or reinsurance coverage as a potential repayment mechanism. CMS notes in its response that it had originally allowed reinsurance in the early years of the program, but eliminated this option in the June 2015 final rule (See 80 FR 32783-32784) as the terms of reinsurance policies could vary greatly and proved difficult for CMS to effectively evaluate.

g. Advance Notice for and Payment Consequences of Termination

Termination policies for MSSP are described in §§425.18 and 425.220. CMS has the authority to terminate the participation agreement with an ACO when the ACO fails to comply with any of the requirements. An ACO may also voluntarily terminate its participation agreement. The ACO must provide at least 60 days advance written notice to CMS and its ACO participants of its decision to terminate the participation agreement and the effective date of the termination. An ACO may still share in savings for a performance year if it voluntarily terminates with an effective date of December 31st of the performance year, if it meets all other requirements. The current regulations do not impose any liability for shared losses on two-sided model ACOs that terminate from the program prior to December 31 of a given performance year.

These policies have raised concerns for both stakeholders and CMS. Stakeholders have raised concerns that the 60-day notification period is too long and it hampers ACO's ability to make timely and informed decisions. CMS acknowledges that a key factor is the timing of when program reports (with information on the ACO's assigned beneficiaries population, and expenditure and utilization trends) are available. On the other hand, CMS is concerned that shortening the notice period from 60 days may increase gaming among risk-bearing ACOs facing losses.

After consideration of comments, CMS finalizes its proposals for advance notice for and payment consequences of termination, with modifications to reflect a new date of applicability.

- CMS revises §425.220 to reduce the minimum notification period from 60 to 30 days. Reducing the notice requirement to 30 days would typically allow ACOs considering a year-end termination to base their decision on three quarters of feedback reports instead of two, given current report production schedules.
- CMS sets June 30 as a deadline for effective date of termination to withdraw without financial risk (not liable for any portion of any shared losses determined for the performance year). For ACOs that voluntarily terminate after the June 30 deadline, CMS pro-rates the shared-loss amount by the number of months during the year in which the ACO was in the program. Thus, an ACO with an effective date of any time in July will be liable for 7/12 of any shared losses determined.
- CMS pro-rates shared losses for ACOs in two-sided models that are involuntarily terminated by CMS for any portion of the performance year during which the termination becomes effective.
- CMS finalizes its proposal that ACOs that start a 12-month performance year on January 1, 2019, that subsequently terminate their participation agreement with effective date of termination of June 30, 2019, and then enter a new agreement period beginning on July 1, 2019, would be eligible for pro-rated shared savings or accountable for pro-rated shared losses for the first 6 months of 2019.
- CMS modifies its proposed applicability date on the payment consequences of early termination. The finalized policy will be effective for performance years beginning on or after July 1, 2019 instead of performance years beginning on January 1, 2019.
- CMS also makes technical changes to revise the regulations at §425.22 to streamline and reorganize the provisions in paragraph (b).

CMS received limited comments on this issue. Several commenters agreed that an ACO that voluntarily terminates from the program should be held responsible for repayment of pro-rated shared losses based on the date of termination. They did not believe, however, that an ACO that is involuntarily terminated by CMS should be held responsible for losses. CMS disagrees and believes that it would be unfair to treat any such ACO more favorably with respect to the payment consequences of early termination.

6. Participation Options for Agreement Periods Beginning in 2019

CMS finalizes its proposal to offer a July 1, 2019 start date as the initial opportunity for ACOs to enter an agreement period under the BASIC track or the ENHANCED track. CMS anticipates that the application cycle for the July 1, 2019 start date would begin in early 2019. Thus, CMS is forgoing the application cycle that would otherwise would take place during calendar year 2018 for January 1, 2019 start date for new MSSP agreements. CMS finalizes its proposal that the July 1, 2019 start date as a one-time opportunity and thereafter CMS would resume its typical process of offering an annual application cycle that allows for review and approval of applications in advance of a January 1 agreement start date.

Given the calendar year basis for performance years under the current regulations, CMS considers how to address (1) the possible 6-month lapse in participation that could result for ACOs that entered a first or second 3-year agreement period beginning on January 1, 2016, due to the lack of availability of an application cycle for a January 1, 2019 start date, and (2) the July 1 start date for agreement periods starting in 2019.

CMS considered using an interim payment calculation approach that it had developed for the first two cohorts of ACOs, but believes that this would introduce further complexity into program calculations. Instead, CMS finalizes its proposal 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 6-month period of participation during 2019. The following opportunities for ACOs are available, based on their agreement period start date:

- ACOs entering an agreement period beginning on July 1, 2019, will be in a participation agreement for a term of 5 years and 6 months, of which the first performance year would be defined as 6 months (July 1, 2019 through December 31, 2019), and the 5 remaining performance years of the agreement period would each consist of a 12-month calendar year.
- An existing ACO that wants to quickly move to a new participation agreement under the BASIC track or the ENHANCED track could voluntarily terminate its participation agreement with an effective date of termination of June 30, 2019, and apply to enter a new agreement period with a July 1, 2019 start date to continue its participation in the program. This includes 2017 starters, 2018 starters, and 2015 starters that deferred renewal by 1 year, and entered into a second agreement period under Track 2 or Track 3 beginning on January 1, 2019.
- CMS clarifies that early renewal is voluntary and does not include a 6-month extension from January 1, 2019, through June 30, 2019, which was finalized in the November 2018 final rule and is limited to ACOs that entered a first or second agreement period beginning on January 1, 2016, that would have otherwise expired on December 31, 2018.

CMS makes some technical modifications to align its policies to its regulations to define agreement period, term of the participation agreement, and definition of performance year.

While some commenters supported the proposed approach of a July 1, 2019 agreement start date, many others urged CMS to implement the redesigned participation options under the BASIC track and the ENHANCED track for agreement periods beginning on January 1, 2020 and in subsequent years. Many of these commenters suggested allowing ACOs whose agreement expire on December 31, 2019, a 12-month extension instead of a 6-month extension. Commenters were also concerned about rapid implementation and CMS' ability to manage this process, as well as ACOs having sufficient time to prepare and successfully implement any changes adopted in the final rule. CMS replies that it believes the mid-year start date allows for continuity in participation by ACOs whose agreement periods expire December 31, 2018. In fact, based on the policies adopted in the November 2018 final rule (83 FR 59942 through 58846) 90 percent of eligible ACOs, whose agreements would otherwise expire on December 31, 2018, elected to voluntarily extend their agreements for the 6-month performance year from January 1, 2019, through June 30, 2019. In general, CMS states its belief that it is important not to delay implementation of the redesigned participation options, as it believes these changes are necessary to more aggressively pursue the program's goals of lowering growth in Medicare FFS expenditures and improving quality of care for Medicare beneficiaries.

a. Methodology for Determining Financial and Quality Performance for the 6-month Performance Year During 2019

In this section, CMS describes the methodology for determining financial and quality performance for the 6-month performance year from July 1, 2019 through December 31, 2019. CMS also finalizes an approach for determining performance during the period from January 1, 2019, through June 30, 2019, for ACOs that begin a 12-month performance year on January 1, 2019, and terminate their participation agreement with an effective date of termination of June 30, 2019, in order to enter a new agreement period starting on July 1, 2019. In the November 2018 final rule (83 FR 59946 through 59951), CMS adopted its proposed approach to determine an ACO's performance for the 6-month performance year from January 1, 2019, through June 30, 2019.

The general approach CMS will take is to first reconcile the ACO based on its performance during the entire 12-month calendar year, and then pro-rate the calendar year shared savings or shared losses to reflect the ACO's participation in that 6-month period.

In this final rule, CMS finalizes policies that address the following issues for the 6-month performance year from July 1, 2019 through December 31, 2019: 1) the ACO participant list that will be used to determine beneficiary assignment; (2) the approach to assigning beneficiaries; (3) the quality reporting period; (4) the benchmark year assignment methodology and the methodology for calculating, adjusting and updating the ACO's historical benchmark; and (5) the methodology for determining shared savings and shared losses. CMS specifies these policies for reconciling the 6-month periods in paragraphs (b) and (c) of a new section of the regulations at §425.609.

These policies, and their resolution from the proposed rule, are briefly described below in the following table:

Policies	6-month performance year (or performance period) from July 1, 2019 through December 31, 2019
ACO participant list that will be used to determine beneficiary assignment	CMS will use the ACO participant list beginning July 1, 2019 to determine beneficiary assignment.
Approach to assigning beneficiaries for ACOs that select a prospective beneficiary assignment methodology	Prospective beneficiary assignment window: October 1, 2017 through September 30, 2018. This is a modification to its proposal to use an assignment window of the most recent 12 months of data available.
Quality reporting period	CMS will use the quality performance for the 2019 reporting period to determine the ACO's quality performance score.
Benchmark year assignment methodology and the methodology for calculating, adjusting and updating the ACO's historical benchmark	<p>CMS will calculate the benchmark and assigned beneficiary expenditures as though the performance year were the entire calendar year.</p> <p>The ACO's historical benchmark would be determined according to the methodology applicable to the ACO based on its agreement period beginning on July 1, 2019.</p>
Methodology for determining shared savings and shared losses	<p>CMS would pro-rate any shared savings amount, or any shared loss amount, by multiplying by one-half (fraction of the calendar year covered by the 6-month performance year or period).</p> <p>Steps are described in detail in final rule.</p>

Note: CMS makes a distinction in discussing these 6-month intervals, by using two references: “6-month performance year” and “performance period.” For an ACO starting a 12-month performance year on January 1, 2019, that terminates its participation agreement by June 30, 2019, and enters a new agreement period beginning on July 1, 2019, CMS refers to the 6-month period from January 1, 2019 through June 30, 2019, as a “performance period.” Otherwise, its referred to as “6-month performance year.”

Several commenters expressed concerns that under the proposed approach that ACOs participating in the performance year from July 1, 2019 through December 31, 2019, would also be accountable for their financial performance during the first 6 months of CY 2019. Commenters also indicated that ACOs would not have program reports or sufficient data to affect care for their assigned beneficiaries. CMS notes, to address this concern, that it will provide aggregate and beneficiary-level data, shortly after ACOs begin the agreement period. CMS continues to believe that basing performance on a 12-month calendar year aligns with its current approach and is the best approach to determining financial and quality performance. This approach also aligns with the approach CMS finalized for the 6-month performance year from January 1, 2019, through June 30, 2019.

Many commenters also expressed concern about the potential burden on ACOs of managing and implementing the necessary modifications to maintain two separate ACO participant lists, and potentially two different assignment windows. CMS agrees with commenters that for the purpose of determining prospective assignment for the 6-month performance year from July 1, 2019, through December 31, 2019, it is preferable to use an offset assignment window from October 1,

2017, through September 30, 2018, rather than a later assignment window, as it originally proposed. CMS believes that maintaining the same prospective assignment window for both 6-month performance years during CY 2019 has a number of advantages, but that participant list differences could still result even with the same assignment window.

- b. Applicability of program policies to ACOs participating in a 6-month performance year or performance period in 2019

In the August 2018 proposed rule, CMS proposed that, unless otherwise stated, the general program requirements under 42 CFR part 425 that are applicable to an ACO under the ACO's chosen participation track and based on the ACO's agreement start date would be applicable to an ACO participating in a 6-month performance period. In the November 2018 MSSP final rule, CMS finalized this approach with respect to ACOs participating in the 6-month performance year from January 1, 2019, through June 30, 2019. In this rule, CMS finalizes this approach with respect to ACOs participating the 6-month performance year from July 1, 2019, through December 31, 2019, and the 6-month performance period from January 1, 2019, through June 30, 2019.

In this section, CMS describes the program participation options that are affected by its decision to forgo an application cycle in calendar year 2018 for a January 1, 2019 start date, and offer instead an application cycle in calendar year 2019 for a July 1, 2019 start date.

(1) Application cycle for use of a SNF 3-day Rule Waiver Beginning July 1, 2019

CMS notes that in light of its decision to forgo an application cycle in calendar year 2018 for a start date of January 1, 2019, the July 1, 2019 start date would be the next opportunity for eligible ACOs to apply for initial use of a SNF 3-day waiver. This would extend to ACOs within existing agreement periods in Track 3 and the Track 1+ Model. CMS received generally supportive comments on this approach, and CMS finalized its proposed policy without modification.

(2) Annual Certifications and ACO Participant List Modifications

As background, at the end of each performance year, ACOs complete an annual certification process. At the same time as this annual certification process, CMS also requires ACOs to review, certify and electronically sign official program documents to support the ACO's participation in the upcoming performance year. CMS stated in the August 2018 proposed rule (83 FR 41855), and reiterated in the November 2018 final rule (83 FR 59951 and 59952), that requirements for this annual certification, and other certifications that occur on an annual basis, continue to apply to all currently participating ACOs in advance of the performance year beginning on January 1, 2019.

In accordance with §425.118., ACO has to meet certain requirements:

- Each ACO is required to certify its list of ACO participant TINs before the start of its agreement period, before the start of every performance year thereafter, and at such other times as specified by CMS.

- A request to add ACO participants must be submitted prior to the start of the performance year in which these additions would become effective. In order to remove an ACO participant, an ACO must notify CMS no later than 30 days after termination of an ACO participant's agreement, and the entity is deleted from the ACO participant list effective as of the termination date of the ACO participant agreement.
- Absent unusual circumstances, the ACO participant list that was certified prior to the start of the performance year is used for the duration of the performance year. An ACO's certified ACO participant list for a performance year is used to determine beneficiary assignment for the performance year and therefore also the ACO's quality reporting samples and financial performance.⁶

These policies apply for ACOs participating in a 6-month performance year consistent with the terms of the existing regulations.

CMS also notes that ACOs that started a first or second agreement period on January 1, 2016, that extend their agreement period for a 6-month performance year beginning on January 1, 2019, will have the opportunity during 2018 to make changes to their ACO participant list to be effective for the 6-month performance year from January 1, 2019, through June 30, 2019. If these ACOs elect to continue their participation in the program for a new agreement period starting on July 1, 2019, they would have an opportunity to submit a new ACO participant list as part of their renewal application for the July 1, 2019 start date.

CMS makes the following observations regarding ACO participants that submit claims for services that are used in beneficiary assignment, and that are participating in a MSSP ACO for a 12-month performance year during 2019 (such as a 2017 starter, 2018 starter, or 2015 starter that deferred renewal until 2019).

- If the ACO remains in the program under its current agreement past June 30, 2019, these ACO participants would not be eligible to be included on the ACO participant list of another ACO applying to enter a new agreement period under the program beginning on July 1, 2019. An ACO participant in these circumstances could be added to the ACO participant list of a July 1, 2019 starter effective for the performance year beginning on January 1, 2020, if it is no longer participating in the other MSSP ACO and is not participating in another initiative identified in §425.114(a).
- If an ACO starting a 12-month performance year on January 1, 2019, terminates its participation agreement with an effective date of termination of June 30, 2019, the effective end date of the ACO participants' participation would also be June 30, 2019. Such ACOs that elect to enter a new agreement period beginning on July 1, 2019, can make ACO participant list changes that would be applicable for their new agreement period. This means that the ACO participants of the terminating ACO could choose to be

⁶ . See also MSSP ACO Participant List and Participant Agreement Guidance (July 2018, version 5), available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharesavingsprogram/Downloads/ACO-Participant-List-Agreement.pdf>.

added to the ACO participant list of another July 1, 2019 starter, effective for the performance year beginning July 1, 2019.

Some commenters urged CMS to provide ACOs with opportunities to add and delete ACO participants throughout the performance years (or performance period) during 2019 and to clarify when such opportunities would be available. In response, CMS states that it does not believe it is operationally feasible to allow, as the commenters suggest, ACOs within a 12-month performance year beginning on January 1, 2019, to make ACO participant list changes effective for the second half of the year, unless the ACO is an early renewal ACO that elects to voluntarily terminate its existing participation agreement, effective June 30, 2019, and enter a new agreement period starting on July 1, 2019.

(3) Repayment Mechanism Requirements

Consistent with the final policy described in section II.A.6.c. of this final rule, an ACO that is currently participating under a two-sided model and enters a new agreement period beginning on July 1, 2019 will be permitted to use its existing repayment mechanism. An ACO choosing this option would be required to either extend the term of the existing repayment mechanism such that it is in effect until 12 months following the end of the new agreement period or extend the term of the existing repayment mechanism, if necessary, such that it covers the first two performance years of the new agreement period and provides for automatic, annual 12-month extensions of the repayment mechanism, which will result in the repayment mechanism remaining in effect until 12 months following the conclusion of the agreement period.

CMS also finalizes a policy, that, for agreement periods beginning on or after July 1, 2019, it will recalculate the estimated amount of the ACO's repayment mechanism arrangement before the second and each subsequent performance year in which the ACO is under a two-sided model in the BASIC track or ENHANCED track. For example, for an ACO with a July 1, 2019 agreement start date, CMS will recalculate the amount of the ACO's repayment mechanism, in accordance with its final regulation at §425.204(f)(4), before the start of performance year 2020. If the recalculated repayment mechanism amount exceeds the existing repayment mechanism amount by at least 50 percent or \$1,000,000, whichever is the lesser value, CMS would require the ACO to increase its repayment mechanism amount, consistent with the approach described in section II.A.6.c. of this final rule and §425.204(f)(4)(iii). Depending on how much the recalculated amount exceeds the existing repayment mechanism amount by at least 50 percent or \$1 million, CMS will require the ACO to increase its repayment mechanism amount, consistent with its approach described previously.

(4) Quality Reporting and Quality Measure Sampling

In order to determine an ACO's quality performance during either 6-month performance year during 2019, CMS finalizes its proposal to use the ACO's quality performance for the 2019 reporting period as determined under §425.502. The approach CMS finalized in the November 2018 final rule, for determining an ACO's quality performance for the 6-month performance year from January 1, 2019, through June 30, 2019, using the ACO's quality performance for the 12-

month CY 2019 (2019 reporting period) as determined under §425.502, will apply to determine quality performance for the performance period from January 1, 2019, through June 30, 2019, for ACOs that elect to voluntarily terminate their existing participation agreement, effective June 30, 2019, and enter a new agreement period starting on July 1, 2019.

CMS believes the following considerations support this approach as it aligns with the program's existing quality measurement approach, and aligns with the proposed use of 12 months of expenditure data (for calendar year 2019) in determining the ACO's financial performance. Also, this approach would continue to align the program's quality reporting period with policies under the Quality Payment Program.

CMS is also finalizing its proposal that the ACO participant list finalized for the first performance year of the ACO's agreement period beginning on July 1, 2019, is used to determine the quality reporting samples for the 2019 reporting year for the following ACOs that also participate in a performance year or performance period from January 1, 2019, through June 30, 2019: (1) an ACO that extends its participation agreement for a 6-month performance year from January 1, 2019, through June 30, 2019, and enters a new agreement period beginning on July 1, 2019; and (2) an ACO that participates in the program for the first 6 months of a 12-month performance year during 2019, but elects to voluntarily terminate its existing participation agreement effective June 30, 2019, and enters a new agreement period starting on July 1, 2019. This policy will be specified in revisions to §425.609(b)(2).

CMS also finalizes its proposal to include a provision at §425.609(c)(2), to specify that for purposes of the 6-month performance year from July 1, 2019, through December 31, 2019, the ACO participant list finalized for the first performance year of the ACO's agreement period beginning on July 1, 2019, is used to determine the quality reporting samples for the 2019 reporting year for all ACOs.

Several commenters mistakenly believed that ACOs participating in both the 6-month performance year (or performance period) from January 1, 2019, through June 30, 2019, and the 6-month performance year from July 1, 2019, through December 31, 2019, would be required to report quality data twice for CY 2019. CMS replies that ACOs will only have to report quality data once for CY 2019.

(5) Applicability of Extreme and Uncontrollable Circumstances Policies

CMS proposed (in section II.E.4 of the proposed rule) to extend the policies for addressing the impact of extreme and uncontrollable circumstances on ACO financial and quality performance results for performance year 2017 to performance year 2018 and subsequent years. In the November 2018 final rule (83 FR 59968 through 59979), CMS extended the policies for addressing the impact of extreme and uncontrollable circumstances on financial and quality performance that it had previously adopted for performance year 2017 to performance year 2018 and subsequent years. CMS also finalizes its proposal to extend the application of these policies

to ACOs participating in a 6-month performance year from July 1, 2019 through December 31, 2019.

(6) Payment and Recoupment for 6-month Performance Years

CMS finalizes the proposed policies on payment and recoupment for the 6-month performance year from July 1, 2019, through December 31, 2019, and the performance period from January 1, 2019, through June 30, 2019, for ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019. These policies will be specified in modifications to §425.609(e). These policies are consistent with the program's existing policies for notification to ACOs about payment and recoupment for 12-month performance years, and for the 6-month performance year from January 1, 2019, through June 30, 2019, as finalized in the November 2018 final rule. These policies also take into account that some ACOs may participate in both 6-month performance years (or performance period) and will be reconciled for their financial and quality performance for both periods.

CMS will provide separate reconciliation reports for each 6-month performance year, and it will pay shared savings or recoup shared losses separately for each 6-month performance year. CMS anticipates that financial performance reports for both of these 6-month performance years would be available in Summer 2020, similar to the expected timeframe for issuing financial performance reports for the 12-month 2019 performance year (and for 12-month performance years generally).

CMS states that there is a possibility that an ACO could be eligible for shared savings for one 6-month performance year and liable for shared losses for the other 6-month performance year. Although the same 12-month period will be used to determine performance, the outcome for each partial calendar year performance year could be different because of differences in the ACO's assigned population (for example, resulting from potentially different ACO participant lists and the use of different assignment methodologies), different benchmark amounts resulting from the different benchmarking methodologies applicable to each agreement period, and/or differences in the ACO's track of participation.

CMS finalizes its proposals to conduct reconciliation for each 6-month performance year at the same time. After reconciliation for both 6-month performance years is complete, CMS will furnish notice of shared savings or shared losses due for each performance year at the same time, either in a single notice or two separate notices. For ACOs that have mixed results for the two 6-month performance years of 2019, being eligible for a shared savings payment for one performance year and owing shared losses for the other performance year, CMS will reduce the shared savings payment for one 6-month performance year by the amount of any shared losses owed for the other 6-month performance year.

CMS notes that it is finalizing its proposed policies with a change in the enumeration scheme. Specifically, CMS places the general provisions regarding notification to ACOs of shared savings and losses at §425.609(e)(1), and places the policies addressing ACOs with mixed results for the two 6-month performance periods at §425.609(e)(2).

(7) Automatic Transition of ACOs under the BASIC Track's Glide Path

CMS finalizes, as proposed, a one-time exception to be specified in §425.600, whereby the automatic advancement policy would not apply to the second performance year for an ACO entering the BASIC track's glide path for an agreement period beginning July 1, 2019.

(8) Interactions with the Quality Payment Program

CMS states that it took into consideration how the July 1, 2019 start date could interact with other Medicare initiatives, particularly the Quality Payment Program timelines relating to participation in APMs. CMS believes that its July 1, 2019 start date for the new participation options under the MSSP would align with Quality Payment Program rules and requirements for participation in Advanced APMs.

Based on comments received, CMS provides clarification about whether an ACO's participation in Level E of the BASIC track or the ENHANCED track for the 6-month performance year from July 1, 2019, through December 31, 2019, would allow its eligible clinicians to potentially attain QP status and earn an APM Incentive Payment, as well as be excluded from the MIPS reporting requirements and payment adjustment for performance year 2019. An eligible clinician participating in an Advanced APM who is determined to be a QP based on any of the three snapshot dates for QP determinations will receive the full APM Incentive Payment in the corresponding payment year. Eligible clinicians in ACOs that elect to participate in Level E of the BASIC track or the ENHANCED track for the 6-month performance year from July 1, 2019, through December 31, 2019, may earn the APM Incentive Payment and be excluded from the MIPS reporting requirements and payment adjustment for 2019 if they meet the requisite QP payment amount (50 percent) or patient count (35 percent) thresholds on the third QP snapshot (August 31, 2019) during the QP performance period. When conducting QP determinations for the third snapshot (August 31, 2019) for ACOs that elect to participate in Level E of the BASIC track or the ENHANCED track for the 6-month performance year from July 1, 2019, through December 31, 2019, CMS will continue to use the entire QP performance period (that is, January 1, 2019, through August 31, 2019) rather than conducting QP determinations from July 1, 2019, through August 31, 2019.

CMS also provides clarification on what happens to an eligible clinician's QP status if they are participating in an ACO that is in a track that meets the Advanced APM criteria for the 6-month performance year from July 1, 2019, through December 31, 2019, and either voluntarily terminates or is involuntarily terminated on or before August 31, 2019. If their ACO terminates or is involuntarily terminated on or before August 31, 2019, then eligible clinicians will lose the opportunity to attain QP status as a result of the termination. In addition, the eligible clinicians would not be scored under MIPS using the APM Scoring Standard because they would not be captured as participants in a MIPS APM on one of the four snapshots used to determine APM participation. If the ACO is in an active agreement period on August 31, 2019, then eligible clinicians who are determined to be QPs based on the third QP snapshot will maintain their QP status and be considered MIPS APM participants, even if the ACO's agreement is terminated after that date.

(9) Sharing CY 2019 Aggregate Data with ACOs in 6-month Performance Year from January 2019 through June 2019

Under the program's current regulations in §425.702, CMS shares aggregate data with ACOs during the agreement period. This includes providing data at the beginning of each performance year and quarterly during the agreement period.

CMS finalizes its proposal that for ACOs in a 6-month performance year from January 2019 through June 2019, CMS proposes to continue to deliver aggregate reports for all four quarters of calendar year 2019 based on the ACO participant list in effect for the first 6 months of the year. CMS believes this approach will allow it to maintain transparency by providing ACOs with data that relates to the entire period for which the expenditures for the beneficiaries who are assigned to the ACO for the 6-month performance year (or performance period) would be compared to the ACO's benchmark (before pro-rating any shared savings or shared losses to reflect the length of the performance year). This will also maintain consistency with the reports delivered to ACOs that participate in a 12-month performance year 2019. CMS specifies this policy in revisions to §425.702.

CMS also extends this provision to ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019 (§425.609(b)).

(10) Technical or Conforming Changes to Allow for 6-month Performance Years

CMS make a number of technical or conforming changes to allow for 6-month performance year (detailed on pages FR 67966-67967).

B. Fee-For-Service Beneficiary Enhancements

1. Skilled Nursing Facility 3-Day Rule Waiver

CMS states that savings to the Medicare program from the MSSP ACOs might be increased further by providing additional tools and flexibility for care coordination to ACOs on two-sided MSSP risk tracks. Waiver of the requirement for a 3-day acute inpatient stay prior to a Medicare-covered skilled nursing facility (SNF) admission allows for SNF admission earlier during a course of treatment, when appropriate, and potentially hastens a beneficiary's ultimate return to the community. The waiver has been limited to ACOs on two-sided risk tracks that utilize prospective beneficiary assignment, and admissions to swing beds for SNF services have been excluded. In the August 2018 MSSP proposed rule, CMS proposed to expand the applicability of the SNF 3-day rule waiver by increasing the numbers of ACOs and SNF service providers eligible to participate (see summary section B.1.e below for Final Actions)

a. Extension to ACOs Using Preliminary Prospective Beneficiary Assignment

CMS proposed to make ACOs on two-sided risk tracks that utilize preliminary prospective with retrospective reconciliation beneficiary assignment eligible to apply for the SNF 3-day rule waiver. The waiver would apply for all beneficiaries who have been identified as preliminarily prospectively assigned to the ACO on any one of the ACO's assignment lists (initial or quarterly), for SNF services during a performance year provided after the beneficiary first appeared on one of that year's lists. The beneficiary would remain eligible to receive SNF services under the waiver for the remainder of the performance year, unless he or she is no longer eligible for assignment to the ACO because he or she is no longer enrolled in both Part A and Part B or has enrolled in a Medicare group health plan.⁷ CMS notes that the comprehensive revisions proposed to the MSSP ACO track participation options allow risk-bearing ACOs to elect either prospective assignment or preliminary prospective assignment with retrospective reconciliation and to change their elections at the start of each performance year.

Most commenters were supportive of the proposal. One concern was expressed that errors involving cost-sharing and benefit availability could be increased if ACOs using preliminary prospective with retrospective reconciliation beneficiary assignment could apply for the waiver. Some commenters asserted that the SNF 3-day rule waiver should be available to ACOs on one-sided risk tracks (shared savings only); CMS declines, stating that the waiver is not a necessary incentive to participation in one-sided models. Other commenters suggested CMS drop the exclusion from the waiver of beneficiaries already residing in SNFs or other long-term care facilities. CMS declines, citing potential for abuse by long-term care facilities who receive a higher payment rate for covered SNF services.

b. Extension to Providers Furnishing SNF Services through Swing Bed Arrangements

Second, CMS proposed to allow add swing bed operators (critical access hospitals and small rural hospitals) as providers eligible to partner with ACOs as SNF affiliates for waiver purposes. CMS further proposed that the requirement for an eligible SNF affiliate to have a CMS 5-Star Quality Rating System overall rating of 3 stars or greater would not apply to providers who are not included in the rating system, such as CAHs and other hospitals operating swing beds.

A few commenters opposed the proposal to include swing bed operators as eligible SNF affiliates, categorizing the proposal as an unfair trade practice for these SNF services providers versus traditional SNFs. Others suggested that there should be a hardship exception process to identify those swing bed operators appropriate to serve as SNF affiliates. CMS states that allowing swing bed operators to provide SNF services under the SNF 3-day rule waiver would be beneficial for beneficiaries whose ACOs include rural or underserved areas. CMS further notes that the limited options for post-acute care in rural areas are sufficient justification for expanding the SNF 3-day rule waiver without a hardship exception process. Another commenter suggested that quality of care provided by swing bed SNF affiliates of ACOs be continuously monitored. CMS responds

⁷ A waiver-eligible beneficiary residing outside the U.S. during a performance year would technically remain eligible to receive SNF services furnished in accordance with the waiver, but SNF services furnished to the beneficiary outside the U.S. would not be covered.

that swing bed operators must be in substantial compliance with the special requirements specified at §482.58(b) and that excepting swing bed arrangement providers from the star rating requirement supports care coordination for beneficiaries residing in rural areas. Other commenters suggested dropping the overall star rating requirement altogether for SNF affiliates of ACOs, whether traditional SNF or swing bed operators, as the rating is too difficult to attain, limiting effective use of the waiver. CMS declines to remove the star rating requirement, stating that the rating offers some evidence to beneficiaries of quality of care.

c. Implementation Timeline.

CMS notes that proposing revisions to the SNF 3-day rule waiver for MSSP ACOs concomitantly with proposals to comprehensively revise ACO track participation options potentially interferes with the normal performance year timelines for ACOs to apply for and start using the waiver. CMS, therefore, proposed that the revisions to the SNF 3-day rule waiver regulations would become applicable beginning with waivers approved by CMS for performance years beginning on July 1, 2019 and subsequently, aligning with the new track options timeline. CMS further proposed that ACOs already having approved SNF 3-day rule waivers could modify their SNF affiliate lists for the performance year beginning January 1, 2019, but also that they could not add a swing bed SNF affiliate until the July 1, 2019 change request review cycle.

No comments specific to the proposed timeline were reviewed. One commenter opposed any further modifications of the SNF 3-day rule waiver until CMS has collected and analyzed data examining the impact of the waiver to date on patient outcomes. CMS responds that waiver use is being monitored, that beneficiaries have not complained about adverse impacts of the waiver, and that instances of waiver misuse have not been observed. CMS plans continued monitoring.

d. Other Comments

MSSP regulations require that an ACO physician evaluate and approve each beneficiary for SNF admission within 3 days prior to the admission. Some commenters requested regulatory revisions to enable other qualified clinicians to perform the pre-admission evaluation. CMS responds that revisions are unnecessary, as a qualified non-physician practitioner could directly evaluate the beneficiary within the required timeframe and make a recommendation for SNF admission. That evaluation and recommendation could then be reviewed and approved by a physician who has been involved in the care of the beneficiary. Another commenter recommended that CMS require interoperability between the EHRs of SNF affiliates and their ACO partners. CMS declines to do so, concerned about unintended consequences since ACOs can partner with multiple SNF affiliates and the SNFs can affiliate with multiple ACOs.

e. Final Actions

CMS finalizes the proposed revisions to the SNF 3-day rule waiver without modifications. Expanding waiver eligibility to include ACOs bearing two-sided risk and who use preliminary prospective with retrospective reconciliation beneficiary assignment, including swing bed operators as SNF affiliates, and revisions to the 3-star overall minimum rating requirement are

addressed at §425.612(a)(1). CMS also finalizes a new provision at §425.612(a)(1)(vi) to allow ACOs participating in performance-based risk within the newly finalized BASIC track or ACOs participating in Track 3 or the newly finalized ENHANCED track to request to use the SNF 3-day rule waiver.

2. Billing and Payment for Telehealth Services

In the August 2018 MSSP proposed rule CMS proposed several revisions to telehealth service regulations consistent with provisions of the BBA of 2018. The revisions would apply whenever approved telehealth services are furnished and billed through the ACO's TIN, during performance year 2020 or subsequent years, by physicians and practitioners participating in performance-based, risk-bearing, MSSP ACOs to which beneficiaries are prospectively assigned. In such cases, the limitations on originating site and geographic location would be waived so that payment could be made for telehealth services originating in the beneficiary's home (in addition to currently allowed sites) and from geographic locations that would otherwise be prohibited (e.g., an urban site in an urban metropolitan statistical area (MSA)). The usual facility fee would not be paid to the originating site when services originate from a beneficiary's home, and no payment for the service itself would be made if the service is not appropriate for delivery in the home (e.g., emergency department telehealth consultation). Specifically, CMS proposed that ACO participants must not submit claims for services designated as inpatient only as a telehealth service originating from a beneficiary's home (e.g., HCPCS codes G0406-G0408 and G0425-G0427).

CMS also proposed regulatory changes to protect beneficiaries from potential liability related to expanded telehealth services provided by MSSP ACOs. Specifically, CMS proposed to establish a 90-day grace period after any change in a beneficiary's telehealth eligibility, during which payment would be made for expanded telehealth services. Further, should otherwise covered telehealth services be furnished to an FFS beneficiary who is not prospectively assigned to the billing ACO and the associated claims are denied by Medicare, CMS proposed the following:

- The ACO participant must not charge the beneficiary for the expenses incurred for such services;
- The ACO participant must return to the beneficiary any monies collected for such services; and
- The ACO may be subject to compliance actions (e.g., corrective action plan submission).

Commenters were generally supportive of the telehealth services expansion proposals. Some requested CMS to clarify whether telehealth services could be provided by Federally Qualified Health Centers (FQHCs). CMS responds that FQHCs may serve as originating but not distant sites. CMS was asked to provide a real time beneficiary benefit eligibility system for physician offices, but responds that ACOs are not prohibited from creating such systems for their own use. An ACO commented that some rural populations lack access to technology required for telehealth service implementation, limiting utility of the proposed waivers. CMS responds that beneficiaries without access to technology for home telehealth service origination remain eligible to receive telehealth services using other originating sites (e.g., FQHC). Commenters encouraged CMS to

expand telehealth service waivers to ACOs electing preliminary prospective beneficiary assignment with retrospective reconciliation or even to ACOs on one-sided risk tracks (shared savings only). CMS declines to invoke waiver authority to go beyond the specific expansion of telehealth services specified by Congress through the BBA of 2018. A request was made to advance the start date for telehealth service expansion to July 1, 2019, rather than January 1, 2020. CMS declines to use waiver authority to change the start date from performance year 2020 as specified in the BBA of 2018. CMS was asked to clarify telehealth services inappropriate for furnishing in the home setting and to define “inappropriate use” of telehealth services. CMS reiterates that inpatient hospital telehealth services are not appropriate for delivery to the home setting (e.g., G codes 0406 through 0408) and notes that ACO providers/suppliers who furnish telehealth services must comply with all applicable MSSP and FFS regulations. Commenters asked that telepsychiatry and emergency medicine services be added to the approved telehealth service list. CMS recommends that commenters submit such requests through the usual process during as part of physician fee schedule rulemaking. Some commenters described the need to review beneficiary assignment lists before furnishing telehealth services to beneficiaries as burdensome to which CMS responds that ACOs are not required to provide telehealth services. A commenter suggested that ACOs should be required to publicly report their delivery of telehealth services on their websites; CMS notes proposing public reporting by ACOs of their usage of payment waivers.

CMS concludes by finalizing as proposed the changes for services provided by ACOs on two-sided risk tracks using prospective beneficiary assignment, and finalizing modifications at §425.308(b)(6) requiring public reporting by ACOs about their usage of payment waivers. (§425.308(b)(6) for public reporting, §425.613 for other revisions)

C. Providing Tools to Strengthen Beneficiary Engagement

1. Beneficiary Incentives

a. Background and Overview

MSSP ACOs have been permitted to offer in-kind beneficiary engagement incentives since the program’s inception. However, navigating complex regulatory definitions and apprehension about potential violations of the Federal anti-kickback statute and the Beneficiary Inducements Civil Monetary Penalties (CMP) law have limited in-kind incentive offerings by ACOs. Usage is further discouraged by the requirement for determination of incentive propriety on a case-by-case basis.⁸ The BBA of 2018 allows MSSP ACOs who bear two-sided risk to establish incentive payment programs for assigned beneficiaries receiving qualifying primary care services and CMS proposed implementing regulations in the August 2018 MSSP proposed rule.

b. Comments and Actions Concerning Regulations Proposed for Implementing Beneficiary Incentive Payment Programs by MSSP ACOs

⁸ Permissible incentives are described in the Office of the Inspector General’s (OIG) final rule “Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements” (see 81 FR 88368-88409).

ACO Eligibility. CMS proposed that Track 2 ACOs, ENHANCED track ACOs (which includes the current Track 3), and BASIC ACOs in glide path Levels C, D, and E would be eligible to establish beneficiary incentive programs.⁹ Commenters supported expanding eligibility to other ACO models. CMS responds that eligibility is defined in statute and does not include one-sided risk models. CMS finalizes the proposal without modification. (§425.304(c)(1))

Program Initiation and Cycle Duration. Guided by BBA of 2018 provisions, CMS proposed an initial beneficiary incentive payment program start date of July 1, 2019; later program start dates will be limited to January 1, 2020, and annually thereafter. The July 1, 2019, start date matches the effective date for the newly finalized MSSP ACO track participation options (described previously) and it will allow ACOs with differing initial performance years (12 versus 18 months) to ultimately be synchronized onto a single, calendar year-based, annual certification cycle.¹⁰ CMS considered deferring the initial start date to January 1, 2020, for all incentive program applicants, but rejected this option to avoid introducing unnecessary delay of incentive program availability. Each incentive program would be required to operate its program throughout its first cycle (12 or 18 months, depending upon start date), absent involuntary termination by CMS. CMS does not identify any comments received specific to the above proposals and finalizes them without change. (§425.304(c)(3))

Application Process and Subsequent Program Certification. CMS proposed that the application to establish an incentive payment program would be in a form and manner specified by CMS, and to accept incentive program applications during the July 1, 2019 MSSP application cycle or a future annual cycle. In addition, an ACO that is mid-agreement would be allowed to apply to establish a beneficiary incentive program during the application cycle prior to the performance year in which the ACO would begin implementing its incentive program.¹¹ An ACO whose incentive program application is approved would be required to begin operating its program at the start of the performance year immediately following approval. An ACO operating an approved program would be allowed to continue to do so after its initial incentive program period (whether 12 or 18 months) for any consecutive performance year if the ACO complies with CMS' certification requirements. CMS proposed to require the ACO to certify its intent (in a form and manner and by a deadline specified by CMS) to operate its approved incentive program for the entire upcoming performance year and to certify that the program still meets all applicable requirements. CMS considered but did not propose to require an ACO with an approved incentive program to notify CMS of any modification to its program prior to implementing the modification.

⁹ ACO models eligible to have incentive payment programs are specified in Section 1899(m)(2)(B) of the Act; all include two-sided risk bearing. The statutory language did not include the two-sided risk-bearing Track 1+ model. Level E of the BASIC track closely resembles the Track 1+ model.

¹⁰ An ACO starting a program on July 1, 2019, must commit to an initial 18-month term and a program beginning on January 1, 2020, must commit to an initial 12-month term; both program sets will have subsequent 12-month terms.

¹¹ This would pertain to two-sided risk track ACOs that defer starting their incentive programs during their first MSSP participation years and to ACOs who are preparing to transition from one-sided to two-sided risk tracks.

CMS does not identify any comments received specific to the application process and finalizes the relevant proposals without change. (§425.304(c)(2)). Commenters agreed with CMS' initial decision not to require an ACO to notify CMS of any modification to its program prior to implementation. CMS responded, however, by reconsidering this proposal and goes on to finalize the requirement as an important contribution to program integrity. Review of proposed "material changes" will be promptly completed.¹² (§425.304(c)(2)(iii))

Beneficiary Eligibility for Incentive Payment. Consistent with BBA of 2018 language, CMS proposed that an FFS beneficiary is eligible to receive an incentive payment from an ACO operating an approved beneficiary incentive program if the beneficiary is assigned to the ACO either through preliminary prospective assignment with retrospective reconciliation or assigned prospectively (Track 2; Levels C, D, or E of the BASIC track; or the ENHANCED track). A commenter asked whether a beneficiary can receive more than one incentive payment per year, whether a beneficiary can deny receipt of an incentive payment, and what an ACO would need to do if a beneficiary denied an incentive payment. CMS clarifies that a payment must be made to a beneficiary for each and every qualifying service the beneficiary receives, so that a beneficiary may receive multiple payments each year. CMS does not anticipate beneficiary denial of payment but will provide sub-regulatory guidance to ACOs for handling this scenario.

CMS finalizes beneficiary eligibility for incentive payment regardless of ACO assignment methodology as proposed. (§425.304(c)(3)(ii))

Qualifying Services. CMS proposed to mirror BBA of 2018 language defining a qualifying primary care service (one for which the beneficiary would become eligible for an incentive payment upon receiving) as follows:

- a primary care service (as described in §425.20) to which coinsurance applies under Part B,¹³ and
- a service furnished through an ACO by a an ACO professional with a primary care specialty designation (included in §425.20); or an ACO professional who is a physician assistant, nurse practitioner, or certified nurse specialist; or an FQHC or RHC.

Some commenters recommended expansion of qualifying services to include annual wellness visits, while others suggested that each ACO be allowed to choose its qualifying services. CMS declines to make changes due to constraints of the statutory language and existing regulatory language, but states that expanding the primary care service definition at §425.20 could be considered in future rulemaking. CMS finalizes as proposed the description of services that may qualify for an incentive payment to a beneficiary. (§425.304(c)(3)(iii))

Payment Amount and Timing. As directed by BBA of 2018, CMS proposed to require that the incentive payment would be in an amount of up to \$20, and that the amount would be updated

¹² CMS plans to provide guidance on what constitutes a "material change". CMS anticipates requiring 30-days advance notice of a change and reaching a decision about the change during that review period.

¹³ Qualifying primary care services include office, nursing facility, home, and domiciliary visits along with transitional and chronic care management services.

annually using the CPI-U.¹⁴ The payment amount would be identical for each FFS beneficiary and would bear no relation to any other health insurance policy or plan in which the beneficiary is enrolled. Cash payments would not be permitted because they could not be readily monitored for uniform payment amounts or traced for accuracy and timeliness, and would thereby introduce significant potential for fraud and abuse. Instead, CMS proposed to require that payments be made as traceable cash equivalents (e.g., instruments convertible to cash or accepted widely on the same basis as cash) and all payments must have the same monetary value regardless of payment type. CMS also proposed that the incentive payment type could vary both within and across ACOs according to beneficiary preferences (e.g., an ACO could offer both prepaid debit cards and checks). Finally, CMS proposed to require that an incentive payment be made for each qualifying service and that each payment be made within 30 days of service delivery.

Some commenters stated that a \$20 payment would be insufficient to incentivize beneficiaries to receive qualifying services. Suggestions were offered that transportation costs should be separately reimbursable, and that ACOs should be allowed to share savings with beneficiaries as well as to provide a higher percentage of savings to high-risk patients. Concern was raised that a one-size-fits-all incentive does not allow ACOs to adjust payments to reflect their operating environments (e.g., vary payment amount by region). Other commenters recommended that ACOs be allowed the option of making payments only to higher-risk patients to maximize the impact of available incentive funds. A request also was made to lengthen the required payment window from 30 to 45 days. CMS responds that transportation vouchers already are separately permissible under existing incentive regulations. CMS notes that the incentive payment maximum amount is stipulated in statute along with the requirements that payment amounts be uniform across beneficiaries and be made within a 30-day window. CMS adds that a uniform payment amount mitigates the potential for incentive payment program abuse. CMS finalizes without changes the proposals for incentive program payment amount and timing. (§425.304(c)(3)(iv))

Payment Distribution Process. CMS proposed that incentive payments would be made only by the ACO legal entity directly to the eligible beneficiary rather than by a participant or a provider/supplier, but sought comment on this issue. Commenters argued for allowing payment distribution by ACO participants or provider/suppliers at the point of care since savings and losses are shared across the ACO and to avoid inappropriate use of incentive payments as ACO beneficiary recruiting tools. Another recommendation offered was that CMS allow each ACO to choose its own incentive payment distribution method. CMS responds by interpreting statutory language to restrict incentive payment distribution to beneficiaries to be done only by ACO legal entities.¹⁵ CMS asserts that ACO legal entities are better equipped to handle incentive payment program documentation requirements, including payment tracking and record retention, than are most ACO participants. CMS notes that record-keeping could increase ACO participant costs. CMS finalizes the proposed requirement that incentive payments will be distributed to beneficiaries by ACOs rather than their participants or providers/suppliers. (§425.304(c)(3)(iv))

¹⁴ The updated maximum payment would be rounded to the nearest whole dollar to avoid frequent minor changes.

¹⁵ CMS cites sections 1899(m)(1)(A) and 1899(m)(2)(D) of the Act.

Incentive Payment Program Funding. CMS proposed to require each ACO to fully fund all of its beneficiary incentive program operational costs; acceptance or utilization of funds from an outside entity would be prohibited (e.g., insurance or pharmaceutical company). CMS proposed that no separate payment would be made by CMS to the ACO to fund the operational costs or the payments themselves. CMS proposed to allow the ACO to utilize its shared savings for funding the incentive payment program (and to fund approved in-kind incentives). Finally, the ACO would not be permitted to shift any incentive program costs to another Federal health care program.

Commenters expressed concerns about the staff demands, operational costs, and regulatory burden imposed by implementing and operating an approved incentive payment program. Some asserted that costs could be higher for ACOs serving high-risk beneficiaries whose care involves furnishing more qualifying visits. CMS responds that operating incentive payment programs is optional for ACOs and views the option as a potentially valuable beneficiary engagement and care management tool. CMS cautions that each ACO should consider carefully the potential operational and financial impacts before applying to establish an incentive payment program, since the ACO would be required to implement the program if approved, beginning with the next performance year. Commenters disagreed that ACOs should be required to fully fund their incentive payment programs and be prohibited from using external funding sources. Recommendations included allowing external funding with appropriate safeguards against undue influence, and program funding in full by CMS or in part by fully reimbursing the ACO (including co-insurance amounts) for all qualifying services furnished to beneficiaries under an approved incentive program. CMS emphasizes that operating an incentive program is optional. CMS states that external funding is not readily trackable so that undue influence by such funders on the ACO is not readily mitigated by safeguards. CMS asserts that statutory language precludes separate funding for incentive programs by CMS. CMS ends by noting that an ACO opting not to establish a payment incentive program may still offer approved in-kind incentives.

CMS finalizes as proposed that ACOs must fully fund their incentive payment programs without using funds from external sources. (§425.304(c)(4)(ii))

Beneficiary Notification about Incentive Payment Programs. CMS proposed to prohibit the advertisement of a beneficiary incentive program. CMS also solicited comments on other actions under consideration concerning beneficiary notification about incentive payments:

- modifying existing beneficiary notification requirements (see §425.312(a)) to include incentive program availability information;
- requiring ACOs to inform their beneficiaries about their approved incentive programs using CMS-approved outreach materials; and,
- specifying how and when an ACO might otherwise notify its beneficiaries that its beneficiary incentive program is available, without inappropriately steering beneficiaries.

An ACO commenter recommended that marketing and outreach about incentive payments should be permitted, while most commenters supported the prohibition on advertising. Support for mandatory beneficiary notification about program availability was mixed. Concerns expressed

included: 1) beneficiary notification could be perceived as advertising; 2) ACOs without incentive programs should not be required to incur the costs of providing incentive program notices; and 3) template language could enhance program integrity but should be tested for accuracy, neutrality, and clarity. CMS responds by stating that existing regulations would be modified to address beneficiary notification about incentive payment programs and that template language would be developed by CMS for distribution by ACOs at or before the first primary care visit of the performance year. CMS notes the value of the proposed advertising ban in limiting incentive payment fraud and abuse, but adds that the standardized mandatory incentive program notification would be exempt from the prohibition on marketing by MSSP ACOs. CMS states that further guidance would be provided to ACOs and that focus group testing will be incorporated into template language development.

CMS finalizes the proposed ban on advertising of incentive payment programs, finalizes a requirement for mandatory beneficiary notification about such programs, and exempts the mandatory notification from the advertising prohibition. (§425.304(c)(4)(iii) and (c)(4)(iv)) CMS notes that beneficiary notifications must be maintained and available for inspection in accordance with §425.314 (Audits and record retention).

Public Reporting. To operationalize BBA provisions about public reporting of beneficiary incentive payment program information, CMS proposed to revise the existing MSSP reporting requirements at §425.308. ACOs operating approved incentive programs would be required to inform their beneficiaries about their programs using CMS-approved outreach materials. CMS further proposed that those ACOs would be required to publicly report for each performance year the following information on the ACO's public reporting web page:

- total number of beneficiaries who receive an incentive payment,
- total number of incentive payments furnished,
- HCPCS codes associated with any qualifying payment for which an incentive payment was furnished,
- total value of all incentive payments furnished, and
- total of each type of incentive payment furnished (e.g., check or debit card).

CMS does not discuss any comments on the proposed revisions and finalizes the changes as proposed. (§425.308(b)(7))

Program Integrity: In General. CMS notes that BBA of 2018 provided wide discretion to the Secretary to establish program integrity requirements for the incentive payment program. Commenters expressed program integrity concerns about beneficiary incentive programs in general. They encouraged CMS to implement safeguards against patient “cherry picking” and “lemon dropping” and to establish processes for monitoring and auditing incentive programs. Another requested clarification as to whether payments made under an approved incentive program could implicate federal fraud and abuse laws (e.g., anti-kickback statute, CMP provisions).

CMS notes that existing regulations about compliance monitoring already allow the agency to employ multiple methods for assessing compliance with other MSSP program requirements (e.g., beneficiary eligibility); CMS will simply broaden that ongoing monitoring to include beneficiary incentive programs. CMS further notes that multiple safeguards concerning incentive programs are addressed in this rule (e.g., record-keeping and retention, prohibition of incentive program advertising). CMS clarifies that illegal remuneration under the anti-kickback statute does not include incentive payments made in accordance with the requirements of section 1899(m) of the Act. CMS further cites section 1128(A)(i)(6)(B) of the Act, which provides that a practice permissible under the anti-kickback statute is also excepted from the beneficiary inducements CMP. CMS concludes by noting that BBA of 2018 requires the Secretary to evaluate the impact of the ACO Beneficiary Incentive Program on Medicare spending and beneficiary outcomes and submit a report to Congress by October 1, 2023.

Program Integrity: Record-keeping. Building on BBA provisions, CMS proposed to require each approved incentive payment program to maintain records that include the following information for each payment: beneficiary identifying information, payment type and amount, qualifying service date and HCPCS code billed, qualifying service's provider/supplier identifying information, and date of incentive payment. CMS further proposed that an ACO making payments would be required to maintain and to make available all records for audit or other compliance review for 10 years. Finally, the ACO would be required to update its compliance plan to address beneficiary incentive payment program requirements.

Commenters offered conflicting feedback. Some supported the proposed data collection and suggested that ACOs be able to share the information publicly as a resource for beneficiaries. Others opposed the record retention requirements as an unfunded mandate that would increase operational costs and regulatory burden and would discourage incentive program development by ACOs. Commenters suggested that burden could be reduced by eliminating requirements for public reporting about incentive payment programs or using claims and other currently available data sources rather than requiring new data collection by ACOs. CMS responds that the importance of ACO accountability for incentive payment programs outweighs concerns about potential burden of data collection and that claims data provide insufficient information.

CMS finalizes the record-keeping requirements for beneficiary incentive payment programs as proposed. (§425.304(c)(4)(i))

Program Integrity: Termination. CMS notes that BBA of 2018 provides the Secretary with discretion to terminate an ACO's beneficiary incentive program at any time for any reason deemed appropriate by the Secretary. CMS proposed to terminate an ACO's approved incentive program for failure to comply in whole or in part with any of the proposals finalized for inclusion at §425.304 (Beneficiary Incentives) or for any of the grounds for termination of the ACO itself (see §425.218(b)). CMS also proposed to incorporate statutory language that does not allow for administrative or judicial review of an incentive program's termination; an ACO wishing to reestablish an incentive program after termination would be required to submit a new, complete application for approval.

Commenters suggested that CMS promulgate clear incentive payment program compliance standards such as inappropriate use of the program to improperly influence beneficiaries. Commenters further recommended that beneficiaries, other ACOs, and the public be notified in advance of any program termination planned by CMS for noncompliance and be allowed to comment before termination is completed. CMS responds that guidance will be issued about bases for involuntary termination of a previously approved incentive payment program. CMS agrees that beneficiaries assigned to an ACO whose incentive program is to be terminated should be notified of the termination. CMS disagrees that notification should be in advance and that input from beneficiaries or others should be allowed prior to termination for noncompliance.

CMS finalizes as proposed, at §425.304(c)(7), that an ACO may be required to terminate its beneficiary incentive program at any time for either failure to comply with the requirements set forth in §425.304 (Beneficiary Incentives) or any of the grounds for ACO termination set forth in §425.218(b).

Benchmarking and Taxation Impacts. As directed by the BBA, CMS proposed that incentive payments would be disregarded in calculated ACO benchmarks, estimated average per capita Medicare expenditures, and shared savings and losses. CMS also proposed that incentive payments to beneficiaries would be treated as exempt for purposes of income tax laws or laws governing qualification for Federal or State assistance programs.

Commenters suggested that CMS positively adjust an ACO's performance year financial results using incentive payment program expenses to account for the program's operational costs, or that CMS consider the costs of establishing an incentive payment program when rebasing an ACO's benchmark. CMS states that these and similar adjustments for incentive payment program costs are precluded by statutory language (section 1899(m)(2)(F) of the Act). CMS discusses no comments about impacts of incentive program payments on beneficiary tax liability or assistance program eligibility.

CMS finalizes as proposed that CMS will disregard incentive payments made by an ACO in calculating an ACO's benchmarks, estimated average per capita Medicare expenditures, and shared savings and losses. (§425.304(c)(5)). CMS also finalizes the exemption of incentive payments from tax and federal assistance program qualification as proposed. (§425.304(c)(6))

Other Comments. Several comments contained suggestions that CMS judged to be out-of-scope relative to the focus of this rule on implementing the incentive payment program provisions of the BBA of 2018 (e.g., co-payment waivers for certain services, incorporation of elements from the Medicare Advantage Value-Based Insurance Design model). CMS states that these suggestions will be considered during future rulemaking.

Clarifications of existing rules. CMS proposed adding clarifying text to (renumbered) §425.304(b)(3) to specify that in-kind items or services provided to an MSSP ACO beneficiary must not include Medicare-covered items or services. CMS further emphasized that provision of in-kind items and services is available to all Medicare FFS beneficiaries and is not limited solely to beneficiaries assigned to an ACO nor contingent upon the existence of an approved beneficiary

incentive program at an ACO (though still subject to all applicable laws. CMS also proposed several technical changes related to the proposed incentive program regulations of §425.304. CMS received no comments addressing the proposed changes and finalizes them without modification. (§425.304)

2. Beneficiary Notifications

a. Background

In the August 2018 MSSP proposed rule, CMS revisited MSSP beneficiary notification requirements because of concerns that information about the MSSP and its ACOs is difficult for beneficiaries to assimilate. Currently, ACO participants are required to display posters in their facilities and to make a written notice (i.e., the Beneficiary Information Notice) available upon request in areas where primary care services are delivered. CMS provides templates for the posters and notices, including language about voluntary ACO alignment and declining claims data sharing with the ACO.¹⁶ The template also highlights FFS beneficiary freedom to choose providers without restrictions. Additional information sources available to beneficiaries include the Medicare & You handbook, 1-800-MEDICARE, and MyMedicare.gov.

b. Proposed Revisions and Final Actions

CMS sought to make the Beneficiary Information Notice a more comprehensive resource about MSSP ACOs and to expand methods for making the Notice readily available at the point of care, while minimizing adding to provider burden. CMS proposed to require that starting July 1, 2019, the Beneficiary Information Notice be provided by an ACO participant during a beneficiary's first primary care visit of each performance year. The Notice must inform the beneficiary that the ACO providers/suppliers are participating in the MSSP and that the beneficiary has the opportunity to decline claims data sharing. Further, the Notice must inform the beneficiary of his or her ability to identify (and to change the identification) of a primary care provider for purposes of voluntary alignment. CMS proposed that providing the Notice in this manner would be additive to current poster and written notice requirements and would incorporate template language from CMS. CMS also proposed regulation text to clarify that beneficiary notification obligations are applicable to all FFS beneficiaries, not solely those assigned to an ACO. Finally, CMS proposed technical changes to the title and structure of §425.312 (e.g., to be retitled Beneficiary notifications).

Most commenters were opposed to one or more of the proposed changes. Many cited added operational and cost burden from disrupted workflow, reduced efficiency, and increased supply costs. Some noted that similar requirements had been adopted previously into the MSSP and then deleted, primarily due to beneficiary confusion that was created. Commenters asserted that ACOs and their participants should be able to provide notifications; notice dissemination outside of the point of care and separate from the first primary care visit of the performance year should be permitted; multiple methods of notice dissemination should be allowed (e.g., electronic mail,

¹⁶ Voluntary alignment is triggered when a beneficiary designates an ACO professional as his or her primary clinician through MyMedicare.gov. Declining claims data sharing is done through 1-800-MEDICARE.

facsimile transmission, hard copy) and method choice should be left to ACO discretion; and template language should be simplified and tested using beneficiary focus groups or developed individually by ACOs based upon guidance from CMS. Multiple commenters were concerned that revised notification content would lead to widespread beneficiary confusion and that expanded content would overwhelm beneficiaries and not be retained for future use.

CMS responds by restating the need for revisions to current notification policies, but also adopts modifications to the proposed changes:

- Separating the content into general and incentive program notifications;¹⁷
 - CMS will issue subregulatory guidance about the two notifications, and
 - CMS will provide two notification templates.
- Allowing both notices to be provided by ACOs themselves and by their participants;
- Permitting both notices to be provided at the first primary care service visit of a performance year or at some point earlier in that performance year; and
- Allowing both notices to be disseminated by electronic transmission or mailed hard copy.

CMS still encourages ACOs to have their ACO participants provide notifications at the point of care and declines to allow notification using non-written methods (e.g., telephone recordings). CMS states that beneficiary focus group input into template language will be sought and invites ACOs to provide comments on the templates developed, but declines to allow ACOs to develop their own templates to ensure consistent information is provided program-wide. ACOs would still be required to display posters and to provide standardized written notifications upon request.

CMS finalizes the proposed beneficiary notification regulations with modifications as described above. (§425.312(a) and (b))

3. Beneficiary Opt-In Assignment Methodology

In the August 2018 MSSP proposed rule, in response to recurring comments from several stakeholders, CMS discussed at length (83 FR 41876-41883) options for developing a methodology to assign beneficiaries to ACOs where the beneficiary directly opts in to the ACO (the opt-in methodology). Both pure opt-in and hybrid options were explored, the latter including voluntary alignment and modified claims-based assignment along with direct opting in to ACOs by beneficiaries. CMS did not make any proposals nor outline definitive next steps towards adopting an opt-in methodology but did invite comments on a wide range of related issues. In this final rule, CMS repeats most of the material from the proposed rule, divided into five parts: process issues, ACO marketing, beneficiary communications, system infrastructure to support communication of beneficiary opt in choices, and balancing being responsive to stakeholder requests with conforming to existing statutory and program requirements.

¹⁷ The general notification would inform beneficiaries that they are receiving care through an MSSP ACO and may decline claims data sharing with the ACO. Beginning July 1, 2019, the process for designating a primary clinician (and thereby triggering voluntary ACO alignment) will also be described (and how to change the designation).

Most commenters did not support the opt-in assignment methodology concept as a replacement for or as a supplement to the current claims-based methodology with supplementation by voluntary alignment. Concerns expressed included the following:

- MSSP ACOs lack the infrastructure and staff resources available to health plans that currently use an opt-in methodology successfully.
- The opt-in and hybrid assignment methodologies as discussed would not mitigate beneficiary churn. Beneficiaries would be confused, and few who were not already assigned through claims or by voluntary alignment would choose to opt into an ACO.
- Benchmark setting and other ACO operational processes would become inordinately complicated, difficult, and costly.
- Using a threshold of seven primary service claims for beneficiary assignment to an ACO as described for the hybrid methodology would significantly skew the MSSP population towards high-risk beneficiaries, increasing operational costs and necessitating changes to shared savings and loss rates.
- Administrative burden would grow markedly, especially for ACOs composed of independent physicians, and would discourage continued physician participation.
- ACOs should focus their efforts on recruiting the right doctors and other providers to improve the health of their patients, not recruiting patients to opt-in to the ACO.

Some commenters supported the consideration of opt-in assignment options under the MSSP, believing that effects of opt-in assignment include the following:

- Increasing patient-centeredness of the assignment process,
- Empowering beneficiary engagement in their healthcare decisions,
- Allowing ACOs to raise their public profiles by marketing their quality statistics, and
- Driving further demand for coordinated, value-based care for FFS beneficiaries.

Other commenters supported variations of the hybrid assignment approach such as focusing on patients with chronic conditions, using plurality of primary care services furnished rather than number of claims for those services for modified claims-based assignment, and setting geographic limits for beneficiary assignment. Multiple commenters recommended further research and testing before implementing an opt-in or hybrid assignment methodology (e.g., small-scale testing in several regions). Some commenters noted the importance of beneficiary outreach and education about any opt-in assignment process chosen for implementation and that CMS develop informational materials. Others remarked upon the overlap of opt-in assignment processes with elements of managed care plans like Medicare Advantage (MA) and asserted that beneficiaries would be confused by the overlap with MA. Concerns were raised that opt-in assignment would increase ACO administrative costs. Lastly, commenters recommended allowing beneficiaries to opt-in by telephone, hard copy mail, and in-person at the point of care.

CMS concludes the discussion of opt-in assignment methodologies potentially applicable to MSSP ACOs by stating that no methodology would be finalized in this final rule. CMS plans to collaborate with the Innovation Center to develop a model testing opt-in assignment for MSSP ACOs that may be proposed through future rulemaking.

D. Benchmarking Methodology Refinements

1. Risk Adjustment Methodology for Adjusting Historical Benchmarks each Performance Year

When establishing the historical benchmark, CMS currently uses the CMS-HCC prospective risk adjustment model to calculate beneficiary risk scores to adjust for changes in the health status of the population assigned to the ACO. To account for changes in beneficiary health status between the historical benchmark period and the performance year, CMS performs risk adjustment using a methodology that differentiates between newly assigned and continuously assigned beneficiaries. Commenters have raised concern over the years that the current approach does not adequately adjust for changes in health status between the benchmark and performance years. For example, continuously assigned beneficiaries could have had acute events, such as a heart attack or stroke, that is not appropriately adjusted for in this methodology. This has the result of making it harder for ACOs to realize savings as the benchmark wouldn't accurately reflect the cost of treating these patients.

CMS expressed concern in the August 2018 proposed rule about the provider coding initiatives that increase coding intensity so as to maximize their performance year risk scores. At the same time, CMS acknowledged concerns that the current approach is difficult to understand, resulting in ACOs being unable to predict how their financial performance may be affected by risk adjustment. To balance these concerns, CMS proposed an alternative approach.

After consideration of comments, CMS finalizes its proposal, with modifications, to change the program's risk adjustment methodology to use the CMS-HCC prospective risk score to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries, subject to a cap of positive 3 percent for the agreement periods, for agreement periods beginning on July 1, 2019, and in subsequent years. This cap will reflect the maximum increase in risk scores allowed between BY3 and any performance year in the agreement period. CMS did not finalize its proposal to apply a 3 percent cap on negative risk score changes. This approach will eliminate the distinction between newly and continuously assigned beneficiaries. Consistent with current policy, risk adjustment calculations will be carried out separately for each of the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible), and CMS-HCC prospective risk scores for each enrollment type would be renormalized to the national assignable beneficiary population for that enrollment type before the cap is applied. CMS will apply this approach for ACOs participating under the BASIC track (§425.605(a)) and the ENHANCED track (§425.610(a)).

Many of the stakeholders applauded CMS' risk adjustment proposal to apply its approach to all assigned beneficiaries and thus eliminate the distinction between newly and continuously assigned beneficiaries. MedPAC, on the other hand, encouraged CMS to continue to distinguish between these two groups and modify the current methodology to adjust benchmarks based only on demographic factors for continuously assigned beneficiaries and based on CMS-HCC scores for newly assigned beneficiaries. In response, CMS acknowledges commenters' support and states that its changes should provide a less complex and more transparent risk adjustment approach. CMS disagreed with the suggestions made by MedPAC and did not believe their

proposed solution for continuously assigned beneficiaries would be sufficient and could create windfall gains for an ACO if their CMS-HCC risk scores decrease more (or increase less) between the benchmark period and the performance year than the national average.

With respect to the proposed symmetrical 3 percent cap on changes in risk scores, commenters were mostly opposed. CMS states that commenters representing academic and research institutions, physician associations, health care alliances and task forces, and individual ACOs, expressed concern that the proposed symmetrical cap on risk score changes may have unintended consequences by introducing incentives for ACO to engage in favorable risk selection; that is, to avoid sicker beneficiaries or to seek out healthier beneficiaries. Some of these commenters recommended that, at a minimum, CMS eliminate the proposed downside cap. In response to these concerns, CMS finalizes its proposal to cap positive risk scores at 3 percent, but does not finalize its proposal to limit negative risk score changes. CMS shares their concern that this could result in ACOs seeking to attract low-cost beneficiaries or avoid high cost beneficiaries, which would be detrimental to medically complex patients, who may miss the opportunity to receive better coordinated care through an ACO.

2. Use of Regional Factors when Establishing and Resetting ACO's Benchmarks

As background, CMS calculates an ACO's historical benchmark based on expenditures for beneficiaries that would have been assigned to the ACO in each of the 3 calendar years prior to the start of the agreement period. For those ACOs continuing into a second or subsequent agreement period, the benchmark is based on the 3 calendar years of the previous agreement period. In the 2016 final rule (81 FR 37953 through 37991), CMS finalized application of a regional adjustment to the rebased historical benchmark for ACOs entering a second or subsequent agreement period in 2017 or later years. This percentage is phased-in over time, and ultimately reaches 70 percent.

a. Applying Regional Expenditures in Determining the Benchmark for an ACO's First Agreement Period

In the August 2018 proposed rule, CMS observed that its experience in incorporating regional expenditures into the calculation of ACOs historical benchmarks has been positive and has led to more accurate benchmarks than those computed solely using national factors. CMS believed that introducing regional expenditures into the benchmarking methodology for ACOs in the first agreement period would improve the accuracy of the benchmarks, and provide a more consistent and simpler methodology that is more predictable for ACOs.

CMS finalizes its proposal to incorporate regional expenditures into the benchmarking methodology for ACOs in a first agreement period for all ACOs entering the program beginning on July 1, 2019 and in subsequent years. This benchmarking methodology will apply for all agreement periods. The weights applied to the benchmark years, however, will continue to differ for the first agreement period compared with the second or subsequent agreement period. Specifically, CMS will continue to use weights of 10 percent, 30 percent, and 60 percent to weight the 3 benchmark years, respectively, when calculating the historical benchmark for an

ACO in its first agreement period, rather than the equal weights that are used in resetting the benchmark for ACOs entering a second or subsequent agreement period.

CMS adds a new provision at §425.601 that describes how it will establish, adjust, update and reset historical benchmarks using factors based on regional FFS expenditures for all ACOs for agreement periods beginning on July 1, 2019 and in subsequent years.

The majority of comments CMS received on its proposal to incorporate regional expenditures in an ACO's first agreement period were generally supportive of their incorporation into the benchmark methodology for various reasons. These included, for example, that it could improve incentives for participation by low-cost ACOs, provide predictability and simplicity for ACOs, and would prove particularly important given the longer five-year agreement periods. Other commenters continued to express concerns about the implications of incorporating regionally-adjusted benchmarks too quickly for areas with high-spending health care providers, as well as incorporating regional factors into benchmarks for rural and low-spending growth areas, such as many areas in the state of California. CMS appreciates the concern raised about incorporating regional adjusted benchmarks too quickly and is reducing the weight that is applied to the regional adjustment in the first period (described in the next section) to improve the business case for more higher-cost ACOs to participate in the program. With respect to concerns about rural areas, CMS was unconvinced and believes that the impact of the regional adjustment will be small. Likewise, while CMS acknowledges that ACOs in lower-spending growth areas may be disadvantaged in the first agreement period, the national-regional blend should help these ACOs in subsequent agreement periods in which they would have been subject to purely regional trends under current policy.

b. Modifying the Regional Adjustment

CMS expresses concern in the August 2018 proposed rule about weighting the regional adjustment too heavily in the calculation of the ACO's benchmark. In the June 2016 rule, CMS adopted a policy under which the maximum weight to be applied to the adjustment would be 70 percent. In particular, CMS expressed concern that as the weight applied to the regional adjustment increases, the benchmarks with the lower spending relative to their region will become overly inflated to the point where the ACO will need to do little to generate savings. Likewise, CMS was concerned that regional adjustment could reduce benchmarks for ACOs with higher spending compared to their region to the point where these ACOs would find little value in continuing in the program, as it would be difficult for them to succeed.

To mitigate these potential unintended effects, CMS proposed policies that would limit the magnitude of the adjustment by reducing the weight that is applied to the adjustment and imposing an absolute dollar limit on the adjustment.

CMS finalizes its proposal, with modifications, to amend the schedule of weights used to phase in the regional adjustment. For ACOs with historical spending lower than its region, the weight would range from 35 percent for the first time the regional adjustment is applied to a maximum of 50 percent for the second or subsequent agreement period. This is unchanged from the proposed

rule. If the ACO’s historical spending is higher than its region, the regional adjustment would range from 15 percent the first time the regional adjustment is applied to a maximum of 50 percent for the fourth or subsequent years. CMS modified its proposal to allow a more gradual increase of weights for ACOs where its historical spending is higher than that of its region. The schedule for the level of regional adjustment is summarized below.

Schedule for Level of Regional Adjustment		
Timing when subject to regional adjustment	ACO’s historical spending is lower than its region	ACO’s historical spending is higher than its region
First agreement period	Weight of 35 percent	Weight of 15 percent
Second agreement period	Weight of 50 percent	Weight of 25 percent
Third agreement period	Weight of 50 percent	Weight of 35 percent
Fourth or subsequent agreement period	Weight of 50 percent	Weight of 50 percent

CMS clarifies that for renewing or re-entering ACOs that previously received a rebased historical benchmark under the current methodology, CMS will consider the agreement period the ACO is entering upon renewal or re-entry in combination with the weight previously applied. It provided the following examples:

- An ACO that was subject to a weight of 35 or 25 percent in its second agreement period in the MSSP (first agreement period subject to a regional adjustment) under the current benchmarking methodology that enters its third agreement period in the program (second agreement period subject to a regional adjustment) would be subject to a weight of 50 or 25 percent.
- If the same ACO terminated during its second agreement period and subsequently re-enters the program, the ACO would face a weight of 35 or 15 percent until the start of its next agreement period.
- For a new ACO identified as a re-entering ACO because greater than 50 percent of its ACO participants have recent prior participation in the same ACO, CMS will consider the weight most recently applied to calculate the regional adjustment to the benchmark for the ACO in which the majority of the new ACO’s participants were participating previously.

CMS also finalizes its proposal to cap the regional adjustment amount using a flat dollar amount equal to 5 percent of the national per capita expenditures for Parts A and B services under the original Medicare FFS program in BY3 for assignable beneficiaries identified for the 12-month calendar year corresponding to BY3 using data from the CMS OACT. The cap will be calculated and applied by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) and will apply for both positive and negative adjustments. CMS believes capping the amount of regional adjustment at this level will continue to provide meaningful reward for ACOs that are efficient relative to their region, while reducing potential windfall gains for the ACOs with lower relative costs.

Table 13 in the final rule (reproduced below) provides an illustrative example of how the final adjustment will be determined. In this example, the ACO’s positive adjustment for ESRD will be constrained by the cap because the uncapped adjustment exceeds 5 percent of the national assignable FFS expenditure for the ESRD population.

Table 13 – Hypothetical Data on Application of Cap to Regional Adjustment Amount				
Medicare Enrollment Type	Uncapped Adjustment	National Assignable FFS Expenditure	5 percent of National Assignable FFS Expenditure	Final Adjustment
ESRD	\$4,214	\$81,384	\$4,069	\$4,069
Disabled	-\$600	\$11,128	\$556	-\$556
Aged/dual eligible	\$788	\$16,571	\$829	\$788
Aged/non-dual eligible	-\$367	\$9,942	\$497	-\$367

Nearly all of commenters addressing this issue opposed reducing the maximum weight on the regional adjustment from 70 percent to 50 percent. Reasons for opposition included that it was premature (i.e. the existing policy was finalized only two years ago), and likely to reduce recruitment and retention of high value and experienced ACOs. Likewise, a number of commenters suggested alternative phase-in or schedules for the weights applied to the regional adjustment. MedPAC, for instance, suggested that the share of the benchmark attributed to regional costs should start low and be refined as program results are evaluated over time. CMS, in response, continues to believe that reducing the maximum weight of the regional adjustment from 70 percent to 50 percent is appropriate to promote continuous improvement and prevent potential windfall gains to lower cost ACOs. However, CMS was convinced that applying the regional adjustment weights too quickly may not sufficiently improve incentives for ACOs that are high cost relative to their region to enter or remain in the program. Specifically, CMS modifies its proposal for ACOs with historical spending higher than that of its region to 15 percent as the initial adjustment, 25 percent for the second agreement period, 35 percent for the third agreement period, and 50 percent for the fourth or subsequent agreement period.

With respect to the proposed 5 percent symmetrical cap on the regional adjustment, commenters had mixed reactions with the majority requesting that CMS impose a higher cap or no cap at all. CMS, however, states that it continues to believe that the symmetrical 5 percent cap on the regional adjustment will protect the Medicare Trust Fund from excessive positive adjustments and will improve incentives for participation among higher-cost ACOs, particularly in combination with the modified schedule of weights.

c. Modifying the Methodology for Calculating Growth Rates Used in Establishing, Resetting, and Updating the Benchmark

CMS reiterates its belief that using regional expenditures to trend forward BY1 and BY2 to BY3 in the calculation of the historical benchmark and to update the benchmark to the performance years produces more accurate benchmarks. Stakeholders have raised concerns in the past that the use of regional trend or update factors may affect ACO's incentives to reduce spending growth, particularly in circumstances where an ACO serves a high proportion of beneficiaries in select counties making up its regional service area. One option recommended by many stakeholders would be to exclude an ACO's own assigned beneficiaries from the population used to compute regional expenditures. CMS rejected this option in the June 2016 final rule because of potential bias due to the potential for small sample sizes and differences in the spending and utilization patterns between ACO-assigned and non-assigned beneficiaries.

To address these concerns, CMS finalizes its proposal to use what it refers to as a national-regional blend or a blend of national and regional growth rates to trend forward BY1 and BY2 to BY3 when establishing or resetting an ACO's historical benchmark. CMS will also use this approach to update the historical benchmark to the performance year – this would be calendar year 2019 for ACOs within the 6-month performance period from July 1, 2019 to December 31, 2019.

To calculate the national-regional blend, CMS will 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. This is computed by taking a weighted average of county-level shares. The weight assigned to the regional component will be equal to 1 minus the national weight. As an ACO's penetration in its region increases, a higher weight will be placed on the national component of the national-regional blend and a lower weight on the regional component, reducing the extent to which the trend factors reflect the ACO's own expenditure history. The national and regional components are defined as follows:

- The national component of the national-regional blend will be trend factors computed for each Medicare enrollment type using per capita FFS expenditures for the national assignable beneficiary population. Consistent with its current approach, the per capita FFS expenditures used in these calculations would not be explicitly risk-adjusted.
- The regional component of the national-regional blend will be trend factors computed for each Medicare enrollment type based on the weighted average of risk-adjusted county FFS expenditures for assignable beneficiaries, including assigned beneficiaries, in the ACO's regional service area. These trend factors would be computed in the same manner as the regional trend factors used to trend benchmark year expenditures for ACOs that enter a second or subsequent agreement period in 2017 or later years under the current regulations.

CMS provides an example to illustrate how the regional component of the blended trend factor would be calculated for one of the Medicare enrollment types (aged/non-dual eligible enrolment status). The example assumes two counties (County A and B) with 11,000 assigned beneficiaries in total across these counties.

- 10,000 assignable aged/non-dual beneficiaries residing in County A in BY3, 9,000 assigned to the ACO in that year
- 12,000 assignable aged/non-dual beneficiaries residing in County B in BY3, 2,000 assigned to the ACO in that year.

These data are entered into the following formulas:

National component of the blended trend factor = [(Assigned Beneficiaries in County A/Assignable Beneficiaries in County A) x (Assigned Beneficiaries in County A/Total Assigned Beneficiaries)] + [(Assigned Beneficiaries in County B/Assignable Beneficiaries in County B) x (Assigned Beneficiaries in County B/Total Assigned Beneficiaries)]

or $[(9,000/10,000) \times (9,000/11,000)] + [(2,000/12,000) \times (2,000/11,000)] = 0.767$ or 76.7 percent.

Regional component of the blended trend factor = (1-National Component of the Blended Trend Factor)

or $(1-0.767) = 0.233$ or 23.3 percent.

CMS notes that most ACOs currently do not have significant penetration in their regional service areas, and that for most ACOs the regional component will receive a higher weight than the national component and that the overall impact of this policy on benchmarks will be small.

The 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. CMS includes these new provisions at §425.601, which govern the determination of historical benchmarks for all ACOs. CMS also makes several technical changes to incorporate references to benchmarking rebasing policies (FR 68030), which it finalizes, as proposed.

Commenters had mixed views on the use of blended regional and national trend factors when calculating the historical benchmark. Many appeared to agree with the concept, but had specific suggestions on the calculation, such as excluding ACO assigned beneficiaries from the regional component of the blend. A larger number of commenters recommended using purely regional trend factors based on a regional population that excludes ACO and assigned beneficiaries to trend and update benchmarks instead of a blend. CMS agrees with commenters that using a blend would help to address concerns about ACOs with high penetration driving the trends in their region and finalizes this proposal. It continues to believe that removing assigned beneficiaries could lead to biased calculations and would be overly complex. Several commenters did not agree with its proposal for weighting the regional and national components of the growth rate with some suggesting that CMS use a multilevel statistical modeling approach rather than the "arbitrary"

weighting scheme CMS proposed. CMS disagrees and believes its approach is reasonable and more transparent than an approach that relies on statistical modeling. CMS also notes that it anticipates that for a majority of ACOs, this approach should provide a higher weight for regional factors.

E. Updating Program Policies

1. Background

In the August 2018 MSSP proposed rule, CMS proposed updates to policies concerning:

- voluntary alignment,
- the definition of primary care used for beneficiary claims-based assignment purposes,
- mitigating quality and financial performance impacts on ACOs affected by extreme and uncontrollable circumstances for performance years 2018 and subsequently, and
- promoting healthcare system interoperability through use of Certified Electronic Health Record Technology (CEHRT) by ACOs.

CMS also discussed the application of the Meaningful Measures initiative to the ACO quality program and the potential uses of combined ACO and Medicare Part D data as part of the national Opioid Misuse Strategy, inviting comments on both topics. CMS took final actions on the proposed policy updates and reviewed comments received on discussion items in the November 2018 MSSP final rule (83 FR 59959 through 59988).

2. Coordination of Pharmacy Care for ACO Beneficiaries

In the August 2018 MSSP proposed rule, CMS also invited recommendations on how to foster collaboration between MSSP ACOs and independent Part D plan sponsors to better coordinate pharmacy care for Medicare FFS beneficiaries. CMS asserted that collaboration could lead to:

- improved (and clinically appropriate) formulary compliance by clinicians,
- enhanced delivery of pharmacist counseling services to patients,
- expanded implementation of medication therapy management,
- increased medication adherence and better outcomes for patients with chronic conditions,
- lower drug costs through increased generic drug prescribing, and
- reduced medication-related errors through better communication between prescribers and pharmacists.

In this final rule, CMS reviews the input received in response to the August 2018 solicitation. Commenters were supportive of encouraging ACO and Part D plan sponsor collaboration and the related potential for better outcomes and offered some specific suggestions.

- CMS should offer financial incentives for ACOs and plan sponsors to collaborate.
- ACOs and plan sponsors should increase their use of enabling technologies such as secure data access portals to allow more timely sharing of claims data.

- CMS should consider developing a voluntary demonstration in which MSSP ACOs are held accountable for some or all Part D costs.
- CMS should foster collaboration between ACOs and community pharmacies in underserved areas.

Some commenters raised concerns including variability across Part D plans in beneficiary eligibility for medication therapy management services; the need for more details about support from CMS to promote information sharing; and, whether ACOs and plan sponsors have sufficient financial resources to fund the operational costs of their collaboration. CMS concludes without making proposals and states that the feedback received will be incorporated into future planning.

F. Applicability of Proposed Policies to Track 1+ Model ACOs

1. Background

The Track 1+ model was established by the Innovation Center as an ACO option for bearing two-sided risk at a lower potential loss level than MSSP Tracks 2 and 3.¹⁸ The model also qualifies as an Advanced APM. Track 1+ participants execute with CMS both a Track 1+ Model agreement and an MSSP ACO agreement, some provisions of the latter are superseded by Innovation Center-issued waivers contained in the Track 1+ Model agreement. ACOs approved by CMS for Track 1+ participation began operations on January 1, 2018. Included in this group were 20 ACOs completing MSSP Track 1 agreements who started new 3-year Track 1+ agreements and 35 ACOs who converted their remaining Track 1 agreement periods to be completed instead under Track 1+ terms. Level E of the BASIC track, as finalized in the November 2018 MSSP final rule, closely resembles the Track 1+ model. Coincident with establishing Level E, CMS did not offer a Track 1+ application cycle for 2019 and will not offer a cycle for 2020, so that the Track 1+ model will end with performance year 2020. Existing Track 1+ ACOs would be able to complete their current agreement periods under the Track 1+ model; alternatively, they could terminate their Track 1+ agreements and apply to enter new MSSP ACO Level E agreements.¹⁹

2. Applying Specific Proposed Policy Changes to Track 1+ Model ACOs

In the November 2018 MSSP final rule, CMS described the applicability to Track 1+ model ACOs of several specific policies finalized in that rule (83 FR 59988 through 59990) dealing with the following: revised voluntary alignment process, revised definition of primary care services used for beneficiary assignment purposes, discontinuation of quality measure ACO-11 related to CEHRT usage by ACO participants, addition of a requirement for annual certification about CEHRT usage by ACO participants, and extreme and uncontrollable circumstances affecting ACOs in performance year 2018 and subsequent years. Additional applicable proposals finalized in the November 2018 MSSP final rule will be implemented through amendments to the Track 1+

¹⁸ Track 1+ is a time-limited Innovation Center model, not a track within the MSSP. Losses under the Track 1+ model are shared at a flat 30 percent loss sharing rate, i.e., 10 percentage points lower than the minimum quality-adjusted loss sharing rates used in Tracks 2 and 3.

¹⁹ Low revenue, former Track 1+ model ACOs will be allowed two agreement periods at Level E while high revenue former Track 1+ model ACOs will be limited to a single period at Level E.

Model Participation Agreement. These amendments address the following topics: setting a threshold for CEHRT usage by Track 1+ model ACO participants that satisfies the criterion to qualify as an Advanced APM and specific requirements for Track 1+ model ACOs who elect to extend their MSSP participation agreement for the 6-month performance year from January 1, 2019 through June 30, 2019 (repayment mechanism duration, shared savings eligibility requirements, and calculation of financial performance).

In this final rule section, CMS highlights the policies finalized in earlier sections of this rule and described earlier in this summary that apply to Track 1+ model ACOs. These policies address repayment arrangement mechanisms and beneficiary notification about voluntary alignment option availability. CMS notes that existing Track 1+ model ACO repayment arrangements will meet the revised requirements and that the ACOs will be able to extend their arrangement mechanism to their next agreement period. Additional finalized policies that will be implemented through amendments to the Track 1+ Model Participation Agreement address the following: monitoring for poor financial performance, consequences of poor financial performance, MSR/MLR revision for ACOs with smaller populations, payment consequences of early termination by risk-bearing ACOs, and waived telehealth service requirements.

III. Provisions of the December 2017 Interim Final Rule with Comment Period and Analysis of and Response to Public Comments

A Background and Regulation History

CMS published this final rule (CMS-1702-F) in the December 31, 2018 issue of the *Federal Register*, along with the MSSP December final rule summarized above (CMS-1701-F2).²⁰ In this final rule, CMS completes the regulatory process to provide relief for ACOs affected by extreme and uncontrollable circumstances during performance year 2017.

CMS reviews the evolution of MSSP policies applicable to ACOs and their clinicians affected by extreme and uncontrollable circumstances (e.g., natural disasters such as Hurricane Harvey and Northern California wildfires of 2017).

- The initial extreme and uncontrollable circumstances policies for clinicians participating in the Quality Payment Program (QPP) were issued in November 2017 as an interim final rule with comment period (IFC) applicable for QPP performance year 2017 (82 FR 53895-53900). Some MSSP ACO professionals are considered eligible professionals under the QPP (physicians, nurse practitioners, clinical nurse specialists, physicians' assistants, and certified registered nurse anesthetists). Depending on their ACOs' tracks, they may be subject to the MIPS Alternative Payment Model (APM) scoring standard (e.g., Track 1) or become Advanced APM Qualifying Participants (e.g., Track 3 ACOs).
- The initial extreme and uncontrollable circumstances policies for MSSP ACOs were issued in December 2017 as an IFC applicable for MSSP performance year 2017 and its

²⁰ This final rule appears at 83 FR 68033-68082 and the MSSP December 2018 final rule at 83 FR 67816-68033.

associated quality reporting period (82 FR 60912-60919).²¹ Some provisions were intentionally aligned with those of the November 2017 QPP IFC, and comments were solicited to guide future permanent policy development.

- Policies for MSSP performance year 2018 and subsequent years were proposed in the August 2018 MSSP Pathways to Success proposed rule (83 FR 41900-41906).
- Policies for MSSP performance year 2018 and subsequent years were finalized in the November 2018 MSSP Pathways to Success final rule (83 FR 59968-59979). Included were CMS' responses to comments received on the August 2018 proposed rule.

B. December 2017 MSSP IFC Comments and Final Actions

Overview. In this final rule, CMS completes the extreme and uncontrollable circumstances regulation history by responding to comments received on the December 2017 MSSP IFC, and finalizes the policies established for MSSP performance year 2017.²² CMS also shares some experiences acquired from applying the policies in 2017. Most of the policies finalized in the December 2017 MSSP IFC were retained as the basis for the policies for 2018 and future years (already finalized), including the criteria for events that automatically trigger the policies and the calculations used to adjust quality scoring and to mitigate shared losses for affected ACOs.²³

Comments: General and Quality Scoring. Commenters generally supported development of policies to manage the impacts of extreme and uncontrollable circumstances on affected ACOs.²⁴ Several supported aligning with extreme and uncontrollable circumstances policies of the QPP, but urged that CMS modify MSSP policies as needed should disasters be found to have differing implications for the QPP and the MSSP. CMS reiterates that events that automatically trigger extreme and uncontrollable circumstances policy application will be reviewed by CMS on a case-by-case basis to confirm applicability to the MSSP. Commenters also generally supported the 20 percent threshold calculation to identify ACOs in affected areas that would be eligible for quality scoring adjustment, though recommended reassessing the threshold as CMS gains experience with applying the policy. Others suggested a threshold based on the percentage of billing NPIs of an ACO that are located in affected areas and some requested a hardship request process for ACOs in affected areas that do not meet the threshold for scoring adjustment. CMS responds that the 20 percent threshold is based upon the number of beneficiaries typically needed for complete quality data collection and reporting by an ACO of minimum size (i.e., 5000 beneficiaries). CMS states that this threshold offers consistency and predictability, and proved to be operationally feasible when applied for performance year 2017; over 40 percent of eligible ACOs were able to report sufficient data to achieve a quality score above the policy's default minimum score, the national overall mean score of all ACOs. CMS further states that the suggestion for a threshold criterion based upon billing NPIs would be operationally more complex and less transparent.

²¹ The reporting period for performance year 2017 was January 1, 2018-March 16, 2018. The extreme and uncontrollable circumstances policy applies to the performance year and its associated quality reporting period, unless the reporting period is extended by CMS for that performance year.

²² The comment period closed February 20, 2018.

²³ Trigger criteria are a Federal Emergency Management Agency (FEMA) major disaster or a public health emergency declared by the Secretary; CMS reviews each triggering event to confirm MSSP policy applicability.

²⁴ FEMA determines affected geographic areas at the county level and the involved time periods are those for which the Secretary has declared public health emergencies.

CMS observes that an automatic policy triggering process was intentionally selected rather than a case-by-case hardship exemption process.²⁵

Commenters also varied in their support for the national mean score as the default minimum score. While some agreed, others expressed concerns about effects on bonus point eligibility, quality benchmarks, and asked that an ACO's prior year quality score be used if higher than the national mean. CMS responds that bonus point eligibility has been clarified in the November 2018 MSSP final rule (explained below). CMS also responds that quality benchmarks are calculated using actual MSSP ACO and all other available and applicable Medicare FFS data, and thereby not affected by substituting national mean scores for adjustment to individual ACO quality scores for a single performance year. CMS further responds that the typical year-to-year variability of an ACO's quality score invalidates the suggested usage of the preceding year's score. Clarification was sought as to whether an ACO could opt in or opt out of the scoring adjustment policy for performance year 2019; CMS reiterates that quality scoring adjustment policy is automatically triggered and therefore participation is not optional. A commenter expressed concern that an affected ACO's missing quality data would be sufficient to trigger the Quality Measures Validation audit process. CMS answers that affected ACOs were excluded from the validation audit sample and would be treated similarly in future years.

Mitigating Shared Losses and Other Financial Issues. Commenters supported the necessity for policies to mitigate shared losses for ACOs bearing two-sided risk that are affected by disasters. Some offered suggestions including statistical validation by comparing performances of affected Track 2 and Track 3 ACOs to performance year 2017 benchmarks, prolonging the time period for which an ACO is considered affected, waiving of all shared losses, and allowing temporary conversion to one-sided models for affected performance years. CMS notes that mitigation applies to all two-sided ACOs in affected areas that experience shared losses. CMS also responds that experience gained with mitigating shared losses for performance year 2017 supports the calculation established in the December 2017 MSSP IFC that takes into account the percentage of an ACO's assigned beneficiaries residing in affected areas and the duration of the disaster declaration. All 11 ACOs with shared losses in affected areas received adjustments to their shared losses ranging from \$980 to over \$400,000. CMS, therefore, declines the suggestions as too broad in scope, too variable, too complex, or unnecessary. Commenters expressed concern for financial impacts from extreme and uncontrollable circumstances on shared savings and on models in one-sided risk tracks. CMS notes having considered removing claims from all affected beneficiaries from shared savings and shared loss calculations for ACOs in all tracks but found no reliable and operationally feasible method for identifying those claims. CMS further notes that shared savings can be increased under two-sided tracks when quality scores for affected ACOs are raised higher by use of the national mean score, since higher quality scores can increase the sharing rate. Some commenters raised concerns about accounting for extreme and uncontrollable circumstances when setting ACO historical financial benchmarks. CMS notes having declined in the MSSP December 2017 IFC to make benchmark methodology changes for performance year 2017 but would propose adjustments as experience with disasters impacts warrants (see Policy

²⁵ An ACO whose legal entity is located in a county declared involved in a disaster is considered to be affected for purposes of quality scoring adjustments and the 20 percent beneficiary threshold does not apply. The entity's location is determined using the address on file for the ACO in CMS's ACO application and management system.

Modifications below). Concern also was raised about ACOs whose populations fall below the statutory minimum of 5,000 assigned beneficiaries as a result of extreme and uncontrollable circumstances (e.g., related to out-migration) and could face involuntary termination. CMS declines to allow extended time for population recovery prior to or during future performance years, observing that added recovery time would not guarantee that the ACO's assigned beneficiary population would sufficiently increase to the minimum required. (CMS notes that such ACOs, if terminated, would be allowed to reapply without a "sit-out" period according to provisions finalized in this final rule, once their populations increased to meet the requirement.)

Interactions Between the MSSP and the QPP. CMS explained in the December 2017 MSSP IFC that MIPS eligible clinicians in ACOs that do not completely report quality data for 2017, and therefore receive the mean ACO quality score, would receive a score of zero percent in the MIPS quality performance category. However, these same clinicians would receive a score of 100 percent in the improvement activities (IAs) performance category, which would be enough for them to receive a 2017 MIPS final score above the performance threshold. This would result in at least a slight positive MIPS payment adjustment in 2019. If the ACO participants were able to report advancing care information (ACI, since renamed Promoting Interoperability), those clinicians would further increase their final scores under MIPS. Several commenters objected strongly to this approach, particularly for future performance years when the MIPS performance threshold will increase and negative payment adjustments become more likely. Suggestions included setting the total MIPS scores of affected clinicians equal to the threshold score for the performance year, redistributing MIPS performance category weights to make the threshold score more attainable by clinicians in affected areas and automatically assigning a neutral payment adjustment to clinicians in a MIPS APM ACO that is unable to report data due to extreme and uncontrollable circumstances. CMS responds that the low MIPS threshold score for QPP performance year 2017 enabled ACO clinicians in affected areas to meet the threshold due to the full ACI score automatically awarded to MSSP ACOs and declines to make further MIPS APM scoring standard adjustments. CMS agrees that a different approach would be appropriate for future performance years (see Policy Modifications below).

Final Action for Performance Year 2017. After considering all comments, CMS finalizes without changes all of the policies for managing extreme and uncontrollable circumstances as established in the December 2017 MSSP IFC.

Policy Modifications for 2018. CMS retained most of the December 2017 MSSP IFC's policies as part of the extreme and uncontrollable circumstances policies for performance year 2018 and subsequent years. Several modifications were made and were finalized in the November 2018 MSSP final rule, listed below.

- An affected ACO's final assigned beneficiary list for performance year 2017 was used for calculation of the 20 percent threshold for applying quality scoring adjustments. Starting with 2018, the ACO's assignment list for the Web Interface data reporting sample will be used for the 20 percent threshold calculation; the list is typically available in the third quarter of the performance year.
- Bonus points are not awarded to ACOs whose quality score is reset to the national mean. Starting with 2018, bonus point eligibility resumes with the next performance year for

which those ACOs successfully report quality data. The comparison baseline year will be the most recent year (before the disaster) in which the ACO reported quality data.

- MIPS eligible clinicians in ACOs that do not completely report quality data for 2018 or subsequent years will continue to receive a MIPS quality category score of zero percent. The clinicians also will continue to receive a score of 100 percent in the improvement activities (IAs) performance category. If the affected clinicians cannot be scored for Promoting Interoperability, and thereby can only be scored in one category (IAs), they would receive a total MIPS score equal to the MIPS performance threshold for that year.
- CMS expects that regional trend factors incorporated into historical benchmark setting for all MSSP ACOs as finalized in this December 2018 MSSP final rule will compensate for annual performance variability due to extreme and uncontrollable circumstances and declines to make additional benchmark methodology adjustments. However, CMS will monitor this issue and propose adjustments as appropriate through future rulemaking.
- CMS clarified how extreme and uncontrollable circumstances spanning two performance years will be managed. CMS will treat the portion of each year falling within the declared disaster period as if it were a separate event. Quality scoring adjustment and shared loss decreases will be calculated separately for each year involved.

IV. Regulatory Impact

A. Statement of Need

CMS states that this final rule is necessary to propose payment and policy changes to the MSSP established under section 1899 of the Act. The MSSP promotes accountability for a patient population, coordinates items and services under parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery.

CMS highlights reasons for why it believes the final rule is necessary. ACOs in two-sided models have shown significant savings to the Medicare program and are advancing quality, but the vast majority of ACOs in the program remain under a one-sided model. Some of these ACOs are generating losses and therefore increasing Medicare spending. This final rule redesigns the participation options, including the payment models, to encourage ACOs to transition to performance-based risk. Other key changes are necessary to implement new requirements by the BBA of 2018.

B. Overall Impact

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity).²⁶ A regulatory impact analysis (RIA) must be prepared

²⁶ Impact assessments of this rule are required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security

for major rules with economically significant effects (\$100 million or more in any 1 year). CMS estimates that this rulemaking is "economically significant" as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, CMS prepared a Regulatory Impact Analysis to present the costs and benefits of the rulemaking.

C. Anticipated Effects

1. Effects on the Medicare Program

CMS notes that the MSSP is a voluntary program operating since 2012 involving a mix of financial incentives for quality of care and efficiency gains within FFS Medicare. As a result, the changes to the MSSP finalized in this rule could result in a range of possible outcomes. CMS finalized additions to or changes in policy that are intended to better encourage ACO participation in performance based risk-based models and generate savings to the Medicare program by including, among others, (1) discontinuing Track 1 and Track 2, and offering instead the BASIC track (including the glide path for eligible ACOs) and ENHANCED track (formerly known as Track 3), (2) changes to the benchmarks to better incorporate regional expenditures, while also limiting this adjustment to positive or negative 5 percent of the national per capita spending amount, and (3) changes intended to promote participation by low revenue ACOs. This final rule also includes changes that CMS states improves the business case for certain ACOs to renew or join the program. These changes include, for example, higher shared savings rates in certain years of the BASIC track, and the option for new low revenue ACOs to participate in 3 risk-free years under the BASIC track before moving to the risk-bearing BASIC level E for the last 2 years of their first agreement period. These changes, in total, are estimated to increase participation by existing and new ACOs and thereby increase the projected savings.

As shown in Table 17 of the final rule (reproduced below), CMS estimates that the policies finalized would result in approximately \$2.9 billion (roughly \$500 million greater than in the proposed rule) in lower overall federal spending over 10 years from 2019 through 2028.²⁷ The 10th and 90th percentiles from the range of projected 10-year impacts range from -\$5.14 billion in lower spending to -\$0.068 billion in lower spending, respectively. CMS states that the relatively small increases in spending in years 2019 through 2021 (+\$250 million) are largely driven by expectations for more favorable risk adjustment to ACO's updated benchmarks and a temporary delay in migration of certain ACOs to performance-based risk. Savings under CMS' model grow significantly in the out years as CMS anticipates existing ACOs eventually transitioning to a higher level of risk and expected savings from capping the regional adjustment to the benchmark. CMS expects a drop in ACO participation as the program will be less likely to attract new ACOs in future years as the number of risk-free years available to attract new ACOs would be reduced from 6 years (two, 3-year agreement periods) to up to 3 years for low revenue ACOs or 2 years for high revenue ACOs in the BASIC track.

Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

²⁷CMS uses a stochastic or simulation model to estimate the impact of the policies in the final rule.

Table 17—10-Year Estimated Impact of Final Rule on ACO Participation, Spending on Parts A and B Claims, ACO Shared Savings Net of Losses and Net Federal Impact (Impact on claims, ACO shared savings, Advanced APM incentive payments, and net federal spending are expressed in \$ millions)

Performance Year	ACO Participation	Claims	ACO Net Earnings	Federal Impact Before APM Incentives	Advanced APM Incentives to QPs	Net Federal Impact
2019	-3	50	80	130	0	130
2020	10	30	50	90	0	90
2021	12	-20	60	40	-10	30
2022	43	-30	-150	-180	80	-100
2023	58	-130	-240	-380	130	-250
2024	39	-190	-210	-400	210	-190
2025	-19	-210	-350	-570	0	-570
2026	-36	-240	-460	-700	30	-670
2027	-36	-170	-560	-720	20	-700
2028	-36	-50	-650	-700	20	-680
10-Year Total		-950	-2,430	-3,390	490	-2,900
Low (10 th percentile)		-3,080	-4,700	-5,610	180	-5,140
High (90 th percentile)		1,000	30	-1,110	800	-680

CMS notes that secondary impacts are not included in the analysis. To the extent that the MSSP will result in net savings or costs to Part B of Medicare, revenues from Part B beneficiary premiums would also be correspondingly lower or higher. In addition, because Medicare Advantage (MA) payment rates depend on the level of spending within traditional FFS Medicare, savings or costs arising from the MSSP would result in corresponding adjustments to MA payment rates.

2. Effects on Beneficiaries

CMS notes that for all ACOs that participated during performance year 2016 that had four or more years of experience in the program, average quality performance improved by 15 percent across the 25 measures used over a three-year period. CMS believes that the changes made in this final rule will provide additional incentive for ACOs to improve care management efforts and maintain program participation. Beneficiaries will also benefit, for example, from expanded use of telehealth services and waiver of the SNF 3-day rule, as more ACOs transition to performance-based risk. Moreover, beneficiaries will benefit from a reduction of Part B premium payments, an estimated savings of \$380 million over the 10-year projection period through 2028.

3. Effect on Providers and Suppliers

CMS notes that it believes the contemporaneous growth of ACO agreements with other payers is sufficiently mature that it would not be materially affected by changes in this final rule to the MSSP. CMS acknowledges that the elimination of Track 1 may ultimately reduce the overall

number of ACOs participating in the program, but that it might also create opportunities for more effective ACOs to step-in and serve these beneficiaries. Other changes (e.g., longer five-year agreement periods, gradual exposure to risk in the BASIC track) are expected to increase the number of existing and new ACOs that transition to performance-based risk. CMS also believes that changes to the methodology for making regional adjustments should broaden the mix of ACOs with plausible business cases without creating excessive residual windfall payments to ACOs with very low baseline costs. Other improvements that CMS cites that will provide ACOs with stronger business cases for participating in the program include transition to full HCC risk adjustment (with caps), and blending national with regional trends for ACO benchmark calculations.

4. Effect on Small Entities

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. Most physician practices, hospitals and other providers are small entities. CMS determined that this final rule will have a significant impact on a substantial number of small entities and states that it presented detailed analysis of these impacts, including costs and benefits to small entities and alternative policy considerations throughout the regulatory impact analysis. CMS states that its policies included in the final rule, such as the policy to allow low revenue ACOs to participate under one-sided risk for up to 3 performance years in the BASIC track (4 performance years if beginning their first agreement period on July 1, 2019).in exchange for moving to Level E (the highest level of risk and reward) for the last two performance years, may encourage participation by small entities. Total expected incentive payments to Qualifying APM participants are expected to increase by \$490 million over the 2019 to 2028 period and thus also increase the average small entity's earnings from such incentives. CMS also cites that extending the agreement period to five years also provides greater certainty to ACOs, including small entities.

5. Effect on Small Rural Hospitals

Section 1102(b) of the Act requires CMS to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, CMS defines a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds CMS believes changes made in this final rule provide a gentler pathway to performance-based risk for small, rural and physician-only ACOs. These include revising the schedule of weights to better recognize the variation that exists across regions, incorporation of the full HCC risk adjustment approach, and allowing legal entities without prior experience an additional year under a one-sided risk model under the BASIC track's glide path prior to transitioning to Level E.

6. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2018, that is

approximately \$150 million. This final rule does not include any mandate that would result in spending by state, local or tribal governments, in the aggregate, or by the private sector in the amount of \$150 million in any 1 year. CMS also notes that participation in this program is voluntary.

7. Regulatory Review Cost Estimation and Other Impacts

CMS estimates that the total cost of reviewing this final rule is approximately \$542,000 for the 561 ACOs. This assumes 9 hours to review half of the final rule at a cost of \$107.38 per hour.

With respect to other impacts, CMS estimates that extending the agreement period to 5 years would reduce certain administrative costs incurred by ACOs. CMS estimates this amount to be \$10,760 per ACO (one-tenth of its initial start-up costs for administrative processes) and that in total this would reduce ACO administrative burden by \$6 million over 10 years.

D. Alternatives Considered

In addition to estimating the difference between impacts at baseline and adoption of changes finalized in this rule, the stochastic model was also adapted to isolate marginal impacts for several alternative scenarios related to individual proposals within the overall set of changes to the program. CMS examined two primary alternatives.

In one alternative scenario, CMS removed the cap of positive or negative 5 percent of national average per capita FFS expenditures for assignable beneficiaries. Removing this cap would increase the cost for the final rule by roughly \$4.4 billion such that the estimated \$2.9 billion savings relative to current regulations would instead be projected as a \$1.5 billion cost.

In another alternative scenario, CMS pushes back the first agreement periods under the proposed new participation options and all other applicable proposed changes to a January 1, 2020 start date. CMS estimates that this would have likely marginally increased spending on claims through a combination of factors.

E. Accounting Statement and Table

As required by OMB Circular A-4 under Executive Order 12866, in Table 18, CMS prepared an accounting statement. For CYs 2019-2028, net federal monetary transfers was -263.6 million annually (reflecting a reduction in federal net cost), calculated at a discount rate of 3 percent.²⁸ These estimates are based on policies in the final rule as compared to baseline.

²⁸ The accounting statement does not show shared savings payments to ACOs net of shared loss payments from ACOs, and incentive payments made under the Quality Payment Program.