

Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success Summary of Proposed Rule.**TABLE OF CONTENTS**

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I. Introduction and Background

On August 9, 2018, the Centers for Medicare & Medicaid Services (CMS) placed on public display a proposed rule that would redesign the participation options available under the Medicare Shared Savings Program (MSSP) to encourage Accountable Care Organizations (ACOs) to transition to two-sided risk models.¹ Two-sided risk models are ones which ACOs share in savings and are also accountable for repaying any shared losses. Under the MSSP, providers of services and suppliers that participate in an ACO continue to receive traditional fee- for-service (FFS) payments under Parts A and B, but the ACO can receive a shared savings payment if it meets specified quality and savings requirements. CMS notes that of the 561 ACOs that participate in MSSP, the vast majority (82 percent) continue to operate under a one-sided, shared savings-only model (Track 1). There is limited participation in its traditional two-sided risk models (Track 2 and Track 3). The Innovation Center designed an additional option (Track 1+ Model) that is a lower-risk two-sided model that shows more promise. CMS states that the one-sided risk models are not producing desired results, increasing Medicare spending in some cases, encouraging consolidation in the marketplace, and reducing competition and choice for Medicare FFS beneficiaries. CMS believes a new approach is needed to create a better pathway for ACOs to more rapidly transition to performance-based risk. This proposed rule was published in the August 17, 2018 issue of the *Federal Register* (83 FR 41786-41951).

Of special note, the proposed rule would redesign the MSSP's performance-based risk tracks. CMS proposes to retire Track 1 and Track 2, and retain Track 3; Track 3 would be renamed as the ENHANCED track. CMS also proposes to create a new BASIC track, in which participants could begin participation in a one-sided risk model and phase-in risk over the course of a single agreement (referred to as a glide path). CMS also proposes refining its benchmarking methodology (spending is compared to this benchmark to determine ACO savings or losses). In particular, CMS proposes to accelerate the use of regional FFS expenditures in establishing benchmarks, but modify the maximum weight in calculating the regional adjustment, lengthen agreement periods to at least 5 years (instead of the current 3 years), and modify how trend factors are calculated. CMS also implements provisions of the Bipartisan Budget Act (BBA) of 2018 that would allow, for example, ACOs under two-sided risk models to provide incentive payments to assigned beneficiaries who receive qualifying primary care services. CMS is also proposing to allow broader access to its program's existing SNF 3-day waiver for ACOs under performance-based risk. Other modifications includes changes to its claims-based assignment methodology, the process for beneficiaries to voluntarily align to an ACO, and a proposed extension of its extreme and uncontrollable circumstances policy.

As noted in more detail in section III of this summary, CMS estimates that changes being proposed would result in average estimated federal savings of \$2.24 billion from 2019 through 2028 or about \$200 million per year. CMS anticipates an overall drop in expected participation as the number of risk-free years available to new ACOs would be reduced from 6 years to 2 years in the BASIC track, but expects increased continued participation from existing ACOs.

¹The 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.

The public comment period on the proposed rule will close on October 8, 2018. Although all issues addressed in the proposed rule are subject to comment, this summary uses bold to highlight CMS requests for specific comments on selected issues and questions.

CMS has also made available several data sources to facilitate analysis of the proposed modifications to the MSSP and its potential impacts on individual ACOs in various markets. See https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/SSPACO/SSP_Benchmark_Rebasing.html. The standard analytical files incorporate factors based on regional FFS expenditures (available for 2014, 2015, and 2016) that tabulate:

- aggregate expenditure and risk score data for assignable beneficiaries by county
- the number of beneficiaries assigned to ACOs, by county.

CMS also created standard analytical files that include ACO-specific annual data on financial and quality performance, person years and demographic characteristics of assigned beneficiaries, aggregate expenditure and utilization, and participant composition of the ACO. The files cover years 2013 through 2016. See <https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/SSPACO/index.html>

In the brief Collection of Information Requirements section of the proposed rule, CMS notes that section 3022 of the Affordable Care Act (ACA) specifies that MSSP-related information collection requirements need not be reviewed by the Office of Management and Budget (OMB).

II. Provisions of the Proposed Regulations

A. Redesigning Participation Options to Facilitate Performance-Based Risk

1. Proposals for Modified Participation Options under 5-year Agreement Periods

With respect to its proposals for modified participation options, CMS states that it considered a number of factors in light of the program's financial results and stakeholders' feedback on program design. First, CMS believes that the current design (allowing up to 6 years of participation in a one-sided model) lacks 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 is encouraged by ACO participation in the Track 1+ Model (55 participants began in 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 is concerned that it does 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 is concerned that differences in performance 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 believes that it could reduce and eliminate

redundancy by permitting choices of risk level and assignment methodology within an ACO’s agreement period. Fifth, CMS believes 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, CMS proposes 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 proposes to require ACOs to enter into one of two tracks for agreement periods beginning on July 1, 2019 and in subsequent years. For those agreement periods beginning on July 1, 2019, the length of the agreement would be 5 years and 6 months, and in subsequent years, the length of the agreement would be 5 years. CMS uses its authority under section 1899(i)(3) of the Social Security Act (or the “Act”) that allows it to add a track as long as it improves the quality and efficiency of items and services provided to Medicare beneficiaries without additional program expenditures.

CMS summarizes the major proposed revisions to its regulations with respect to the BASIC and ENHANCED Tracks. These proposed revisions are discussed in more detail in other sections of the proposed rule and this summary, but summarized in the table below. With respect to the new names, CMS states 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.

Proposal	Regulations Cite
Add a new provision to the MSSP regulations to establish the BASIC track requirements	§425.605
Modify regulations to designate Track 3 as the ENHANCED track. All regulatory references to the ENHANCED track would be deemed to include Track 3.	§425.600 and §425.610
Make changes to the “agreement period” and other related changes to specify the term of these modified agreement periods.	§425.20, §425.200, §425.200(b)
Modify the reference to a 3-year agreement period in the calculation of the quality improvement reward as part of determining the ACO’s quality score. The comparison year for the performance in the first year of the new agreement period would be the last year in the previous agreement period.	§425.502(e)(4)(v)
Allow ACOs annually to elect the beneficiary assignment methodology (preliminary prospective assignment with retrospective reconciliation, or prospective assignment) to apply for each remaining performance year within their agreement period	§425.226
Allow eligible ACOs in the BASIC track’s glide path the option to elect entry into a higher level of risk and potential reward under the BASIC track for each performance year	§425.226
Discontinue Track 1 as a participation option. Amend regulations to limit the availability of Track 1 to agreement periods beginning before July 1, 2019.	§425.600
Discontinue Track 2 as a participation option. Amend regulations to limit the availability of Track 2 to agreement periods beginning before July 1, 2019.	§425.600
Discontinue the deferred renewal option, which allowed ACOs in Track 1 in their first agreement period to defer renewal for a second agreement period in a two-sided risk model by 1 year. Available only to those Track 1 ACOs that began a first agreement period in 2014 and 2015 and have renewed their participation agreement under this option.	§425.200(e) and §425.200(b)(3)
Discontinue the “sit-out” period. ACOs that have already been approved to defer renewal under this participation option (ACOs with 2015 start dates that deferred entering a second agreement period until January 1, 2019) would have the option of terminating their participation agreement for their second agreement period for Track 2 and Track 3 and applying to enter the BASIC track and the highest level of risk and potential reward (Level E) or the Enhanced Track.	§425.222(a)
One-time exception allowing that, for performance year 2020, an ACO may remain in the same level of the BASIC track’s glide path that it entered for the performance year beginning on July 1, 2019 (6-month period), and then in subsequent years would automatically advance to the next level of the glide path.	§425.600

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

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

Within the BASIC track, CMS proposes a 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 would 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 at the same level of BASIC track glide path at which the ACO entered for the 6-month period. In subsequent years, these ACOs would automatically advance to the next level.

With respect to participation options within the BASIC track, ACOs new to the program would 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 their participation in one-sided risk). CMS also proposes to allow 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 under CMS' proposal. For ACO participants with recent prior experience in a Track 1 ACO, Level E must be entered into no later than the fourth performance year. Special rules apply for low revenue ACOs that have experience in ACO initiatives and would otherwise be required to be at Level E of the BASIC track.

CMS proposes that savings would be calculated based on the same methodology used to determine shared savings under the program's existing tracks. The maximum amount of potential reward under the BASIC track would be the same as the upside of Track 1 and the Track 1+ Model. 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 2 (reproduced below).

TABLE 2—COMPARISON OF RISK AND REWARD UNDER BASIC TRACK AND ENHANCED TRACK

	BASIC Track's Glide Path				ENHANCED Track (Current Track 3)
	Level A & Level B (one-sided model)	Level C (risk/reward)	Level D (risk/reward)	Level E (risk/reward)	
Shared Savings (once Minimum Savings Rate (MSR) met or exceeded)	1 st dollar savings at a rate of up to 25% based on quality performance; not to exceed 10% of updated benchmark	1 st dollar savings at a rate of up to 30% based on quality performance, not to exceed 10% of updated benchmark	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	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 Minimum Loss Ratio (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)	Yes	Yes	Yes	Yes	Yes

	BASIC Track's Glide Path				ENHANCED Track (Current Track 3)
	Level A & Level B (one-sided model)	Level C (risk/reward)	Level D (risk/reward)	Level E (risk/reward)	
Annual election to enter higher risk? (see section II.A.4.b)	Yes	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 (CEHRT); 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. BASIC track Level E 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 proposed rule. CMS will make a final determination based on the policies adopted in the final rule.

CMS proposes to codify these policies a new section of the MSSP regulations governing the BASIC track at §425.605. **CMS seeks comment on these proposals.**

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 proposes an approach where it would 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 proposed phase-in schedule (described in Table 2 above) 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 4 in the proposed 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 proposed 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 4 – Hypothetical Example of Loss Sharing Limit Amounts for ACO in Basic Track Level E

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

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 IME, DSH, and uncompensated care payments. Its approach to determining a revenue-based loss sharing limit is total revenue uncapped by truncation, as CMS believes this best represent the ACO's capacity to bear performance-based risk.

3. Permitting Annual Participation Elections

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

CMS proposes 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. ACO's, for example, could skip a level, but could not go 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 proposes to add a new section of the MSSP regulations at §425.226 to govern annual participation elections. Specifically, CMS proposes to allow an ACO in the BASIC track's glide path to annually elect to accept higher levels of performance-based risk, available within the glide path, within its current agreement period. CMS makes several other related proposals:

- 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 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 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.

CMS gives an example, that if 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 also clarifies that the proposal to allow ACOs to elect to transition to higher 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.

b. Permitting Annual Election of Beneficiary Assignment Methodology

As background, Section 1899(c)(1) of the Act, as amended by section 50331 of the Bipartisan Budget Act 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.² 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.

In this proposed rule, CMS proposes to allow all ACOs with a choice of prospective assignment for agreement periods beginning July 1, 2019 and in subsequent years. CMS does not believe the statute requires that it must continue to specify the applicable beneficiary assignment methodology for each track of the MSSP. CMS proposes to 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

² 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 years, whereas limited adjustments are done for the prospective approach.

application). CMS also proposes that ACOs be allowed to switch their selection of beneficiary assignment methodology on an annual basis or retain the same beneficiary assignment methodology.

CMS proposes that, in addition to choosing the track to which it is applying, an ACO would 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 would 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, CMS proposes that 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 would 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 proposes to codify these policies in a new section of the MSSP regulation at §425.226.

CMS proposes that the form and manner of the annual selection and its timeframe will be as determined by CMS. In addition, CMS proposes that an ACO executive who has the authority to legally bind the ACO must certify the selection of beneficiary assignment methodology for the ACO. CMS also proposes conforming changes its regulations that currently identify assignment methodologies according to program track. Proposes to revise §§425.400 and 425.401 (assignment of beneficiaries), §425.702 (aggregate reports) and § 25.704 (beneficiary- identifiable claims data). CMS clarifies that this proposal would have no effect on the voluntary alignment process under §425.402(e). This voluntary alignment process would occur regardless of the ACO's track or claims-based beneficiary assignment methodology.

With respect to an ACO historical benchmark, CMS proposes to adjust this benchmark to reflect the ACO's election of a different assignment methodology (in §425.601). CMS notes, however, that any adjustment to the benchmark to account for a change in the ACO's beneficiary assignment methodology would not alter the timing of benchmark rebasing under §425.601; the historical benchmark would not be rebased as a result of a change in the ACO's beneficiary assignment methodology.

CMS seeks comment on these proposals.

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

In this section, CMS describes considerations related to, and proposed 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 Shared Savings Program and performance-based risk Medicare ACO initiatives, and prior performance in the Shared Savings Program.

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.

CMS proposes to use a 25 percent threshold 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 proposes to add new definitions at § 425.20 for "low revenue ACO," and "high 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 25 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 25 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 notes that it considered alternative thresholds for determining low revenue and high revenue ACOs. For example, CMS considered setting the threshold as low as 15 or 20 percent and as high as 30 percent. **CMS is seeking comment on alternative thresholds for defining "low revenue ACO" and "high revenue ACO".**

With respect to ACOs with a participation agreement start date of July 1, 2019, CMS proposes to determine whether the ACO is low revenue or high revenue using expenditure data from the most recent calendar year for which 12 months of data are available. CMS also notes that it might be difficult for an applicant to know whether they would be identified as low revenue or high revenue ACO, but that CMS would provide this information before the ACO would be required to execute a participation agreement. CMS also considered a longer look back period of data than 12 months, such as multiple years of revenue and expenditure data, but decided this would make the calculation overly complex. **CMS seeks comment on the alternative of using multiple years of data in determining whether an ACO is a low revenue ACO or a high revenue ACO.**

CMS establishes proposals 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 states that it is 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 protect against these circumstances, CMS proposes to monitor low revenue ACOs experienced with performance-based risk Medicare ACO initiatives participating in the BASIC track, to determine if they continue to meet the definition of low revenue ACO. 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 proposes 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. CMS proposes to revise § 425.600 to include these requirements to account for changes in ACO participant revenue during an agreement period.

CMS also considered two alternatives to the proposed claims-based approach to differentiating low revenue versus high revenue ACOs. One alternative, CMS discussed would be to differentiate ACOs based directly on ACO participant composition using Medicare provider enrollment data and certain other data. A second alternative CMS considered would be to distinguish between ACOs based on their size of their assigned population (that is, small versus large ACOs). **CMS seeks comment on these alternatives.**

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

CMS proposes to differentiate between low revenue ACOs and high revenue ACOs with respect to the continued availability of the BASIC track as a participation option. CMS proposes to limit high revenue ACOs to, at most, a single agreement period under the BASIC track prior to transitioning to participation under the ENHANCED track. In contrast, CMS proposes to limit low revenue ACOs to, at most, two agreement periods under the BASIC track. These agreements would not need to be sequential, so that under this proposal an ACO could transition to the ENHANCED track after one agreement under the BASIC track and then return back to the BASIC track.

CMS proposes to specify these proposed requirements for low revenue ACOs and high revenue ACOs in revision to § 425.600.

CMS also considered and seeks comment on an approach that would allow low revenue ACOs to gradually transition from the BASIC track's Level E up to the level of risk and potential reward under the ENHANCED track. For example, CMS seeks comment on whether it would be helpful to devise a glide path that would be available to low revenue ACOs entering the ENHANCED track. CMS also considered, and seeks comment on, whether such a glide path under the ENHANCED track should be available to all ACOs. As another alternative, CMS considered allowing low revenue ACOs to continue to participate in the BASIC track under Level E for longer periods of time, such as a third or subsequent agreement period. As an alternative to the proposed approach for allowing low revenue ACOs to participate in the BASIC track in any two agreement periods (non-sequentially), CMS seeks comment on an approach that would require participation in the BASIC track to occur over two consecutive agreement periods before the ACO enters the ENHANCED track.

c. Allowing greater potential for reward for lower revenue ACOs

CMS describes and seeks comment on several approaches to allowing for potentially greater access to shared savings for low revenue ACOs compared to high revenue ACOs, but did not make any specific proposals.

One approach CMS considered would be to allow for a lower MSR for low revenue ACOs in the basic track. As an alternative, to provide a greater incentive for low revenue ACOs, CMS considered applying a lower MSR during the one-sided model years (Level A and B) for low revenue ACOs that have at least 5,000 assigned beneficiaries for the performance year. For example, CMS considered a policy under which it would apply an MSR that is a fixed 1 percent, a fixed 2 percent, or effectively removing the threshold by setting the MSR at zero percent.

However, CMS would apply a variable MSR based on the ACO's number of assigned beneficiaries in the event the ACO's population falls below 5,000 assigned beneficiaries for the performance year, consistent with its proposals.

Another approach CMS considered is to allow for a relatively higher final sharing rate under the first four levels of the BASIC track's glide path for low revenue ACOs. For example, rather than the proposed approach under which the final sharing rate would phase in from a maximum of 25 percent in Level A to a maximum of 50 percent in Level E, CMS could allow a maximum 50 percent sharing rate based on quality performance to be available at all levels within the BASIC track's glide path for low revenue ACOs.

CMS seeks comment on these considerations. It notes that it will carefully consider the comments received regarding these options during the development of the final rule, and may consider adopting one or more of these options in the final rule.

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

In this section, CMS describes proposed 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 proposes to define 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.

Proposed 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.

Proposed 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 Shared Savings Program and is applying to participate in the program and more than 50 percent of its ACO participants were included on the ACO participant list 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 proposed definition of re-

entering ACO. For example, if the ACO was 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 was 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.

CMS also briefly discusses other alternatives it considered to identify prior participation other than the overall percentage of ACO participants that previously participated in the same ACOs, including using the percentage of ACO participants weighted by the paid claim amounts, the percentage of individual practitioners (NPIs) that had reassigned their billing rights to ACO participants, or the percentage of assigned beneficiaries the new legal entity has in common with the assigned beneficiaries of a previously participating ACO. CMS concluded that these options would be less transparent to ACOs and more operationally complex to compute.

CMS seeks comment on these proposed definitions and on the alternatives considered.

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

CMS believes that it would be useful to revise its regulations to more clearly set forth the eligibility requirements and application procedures for renewing ACOs and re-entering ACOs. CMS proposes to revise §4245.22 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 proposes to revise §425.224 to address general application requirements and procedures for all re-entering ACOs and all renewing ACOs. These proposals are discussed in more detail below. In revising §425.222, CMS removes the required “sit-out” period for terminated ACOs, as it believes this policy would restrict the ability of ACOs in current agreement periods to transition to the proposed participation options under new agreements. CMS notes that if left unchanged, the “sit-out” policy would prevent existing, eligible Track 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 would also allow ACOs that deferred renewal in a second agreement to more quickly transition to the proposed BASIC track or ENHANCED track. CMS notes that ACOs doing this should ensure that there is not a gap in time when it concludes an agreement and when it begins the new agreement period.

In revising §425.224, CMS proposes to make certain policies applicable to both renewing ACOs and re-entering ACOs to incorporate other technical changes. One of the primary changes includes adding a proposed 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. 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 under its proposal.

CMS also modifies 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., the proposed 5 years instead of 3), and to prevent ACOs with a history of poor performance from participating in the program. These are summarized in the table below.

§425.224(b)(1)(iv)	Proposes to add criteria for evaluating ACOs that entered into a participation agreement for a period longer than 3 years by considering whether the ACO was terminated for failing to meet the quality performance standard or failed to meet the quality performance standard for 2 or more performance years (regardless of whether the years were consecutive).
§425.224(b)(1)(v)	Revises the criterion governing the evaluation of whether an ACO under a two-sided model repaid shared losses owed to the program that were generated during the first 2 years of the previous agreement period to instead consider whether the ACO failed to repay shared losses in full within 90 days for any performance year of the ACO's previous agreement period. This provision would be relevant to all renewing and re-entering ACOs that may have unpaid shared losses as well as re-entering ACOs that may have been terminated for non-compliance with the repayment requirement.
§425.224(b)	Adds a financial performance review criterion to allow CMS to evaluate whether the ACO generated losses that were "negative outside corridor" for 2 performance years of the ACO's previous agreement period. CMS defines an ACO as "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.
§425.224(b)	Adds a review criterion which would allow CMS to consider whether an ACO corrected its deficiencies that caused it to fail its quality performance standards, fail to timely repay shared losses, or any other factors that may have caused the program to be terminated from the MSSP. CMS also proposes that ACOs demonstrate that it has processes in place to ensure that it remains in compliance.

CMS proposes 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 proposed financial performance review criterion would 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 ACO to participate in the program based on the past performance of this other entity.

f. Proposed Evaluation Criteria for Determining Participation Options.

CMS expresses 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 believes that some restrictions are needed to prevent all current and previously participation 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 has similar concerns about new ACOs identified as re-entering ACOs. CMS prefers an approach that would help ensure that ACOs, whether they are initial applicants to the program, renewing ACOs or re-entering ACOs, would be treated comparably.

Thus, CMS proposes 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 proposes definitions of how it defines "experience" 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	Proposed 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 proposed ENHANCED track, and the proposed 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>

Term	Proposed definition
	(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.
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> <ol style="list-style-type: none"> <li data-bbox="589 439 1372 572">(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. <li data-bbox="589 608 1372 775">(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.

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. It would determine it cumulatively based on percentage of ACO participants in any performance-based risk Medicare ACO initiative in each 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 would 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 would 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 (notes based on its data for these applicants that the maximum percentage observed was 30 percent), and would not be overly restrictive.

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.

In consideration of these issues, CMS proposes that ACOs that previously participated in Track 1 of the Shared Savings Program 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 also considered an alternative where one-sided models of the BASIC track's glide path would be unavailable to current or previously participating Track 1 ACOs and new ACOs identified as re-entering ACOs because of their ACO participants' prior participation in a Track 1 ACO. It notes that some of these ACOs may have already had 6-7 performance years in a one-sided model and should have already been taking steps to enter performance-based risk. CMS produces three tables in this section (reproduced below) that explains how the proposed regional adjustment weights would apply and the participation options available:

- Table 5- Examples of Phase-In of Proposed Regional Adjustment Weights Based on Agreement Start Date and Applicant Type
- Table 6 – Participation Options for Low Revenue ACOs Based on Applicant Type and Experience with Risk
- Table 7 – Participation Options for High Revenue ACOs Based on Applicant Type and Experience with Risk

These new proposed provisions for the selection of risk model are at §425.600. CMS also proposes to discontinue 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.

CMS seeks comment on the proposals described in this section and the alternatives considered

Table 5—Examples of Phase-In of Proposed Regional Adjustment Weights Based on Agreement Start Date and Applicant Type

Applicant Type	First time regional adjustment used: 35 percent or 25 percent (if spending above region)	Second time regional adjustment used: 50 percent or 35 percent (if spending above region)	Third and subsequent time regional adjustment used: 50 percent weight
<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 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 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	Applicable to third agreement period starting on July 1, 2019	Applicable to fourth agreement period starting in 2025 and all subsequent agreement periods
Re-entering ACO with initial start date in 2014 whose agreement expired December 31, 2016 (did not renew) and <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 and all subsequent agreement periods
<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	Applicable to second agreement period starting on July 1, 2019 (ACO considered to be reentering a second agreement period)	Applicable to third agreement period starting in 2025	Applicable to fourth agreement period starting in 2030 and all subsequent agreement periods

Table 6—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	Yes	Yes	First agreement period
New legal entity	Experienced	No	Yes	Yes	First agreement period
Re-entering ACO	Inexperienced - former Track 1 ACOs or new ACOs identified as re-entering ACOs because more than 50 percent of their ACO participants have recent prior experience in a Track 1 ACO	Yes - glide path Levels B through E	Yes	Yes	Either: (1) the next consecutive agreement period if the ACO's prior agreement expired; (2) the same agreement period in which the ACO was participating at the time of termination; or (3) applicable agreement period for new ACO identified as re-entering because of ACO participants' experience in the same ACO
Re-entering ACO	Experienced - including former Track 1 ACOs that deferred renewal under a two-sided model	No	Yes	Yes	Either: (1) the next consecutive agreement period if the ACO's prior agreement expired; (2) the same agreement period in which the ACO was participating at the time of termination; or (3) applicable agreement period for

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

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

Table

7 –

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 for new ACO identified as re-entering because of ACO participants' experience in the same ACO

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

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.

g. Monitoring for Financial Performance

CMS notes 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 proposes to modify §425.316 to add a provision for monitoring ACO financial performance. Specifically, CMS proposes 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.³ If the ACO is negative outside corridor for a performance year, CMS proposes that it 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 proposes that it may immediately or with advance notice terminate the ACO's participation agreement under §425.218.

CMS proposes that financial performance monitoring would be applicable for performance years beginning in 2019 and subsequent years. Specifically, CMS would apply this proposed approach for monitoring financial performance results for performance years beginning on January 1, 2019, and July 1, 2019, and for subsequent performance years. CMS notes that financial and quality performance results are typically made available to ACOs in the summer following the conclusion of the calendar year performance year.

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 is 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 is

³ For purposes of this proposed rule, an ACO is considered to have shared savings when its benchmark minus performance year expenditures are greater than or equal to the MSR. An ACO is "positive within corridor" when its benchmark minus performance year expenditures are greater than zero, but less than the MSR. An ACO is "negative within corridor" when its benchmark minus performance year expenditures are less than zero, but greater than the negative MSR for ACOs in a one-sided model or the MLR for ACOs in a two-sided model. An ACO is "negative outside corridor" when its benchmark minus performance year expenditures are less than or equal to the negative MSR for ACOs in a one-sided model or the MLR for ACOs in a two-sided model.

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 proposed financial monitoring approach would be effective in removing ACOs with a history of poor financial performance.

CMS seeks comment on its proposals and related considerations.

5. Requirements for ACO participation in Two-sided Models

In this section, CMS address 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 Ratio (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

CMS proposes that ACOs under the BASIC track would have the same MSR/MLR options as are currently available to ACOs under one-sided and two-sided models of the MSSP, as applicable to the model under which the ACO is participating. ACOs in a one-sided model of the BASIC track glide path would have a variable MSR based on the ACO's number of assigned beneficiaries and those in the two-sided models of the BASIC track would have the same options as currently available to ACOs in a two-sided model (i.e., choose among several options, such as symmetrical MSR/MLR in a 0.5 percent increment between 0.5 to 2.0 percent). CMS notes that providing the same MSR/MLR options for BASIC track ACOs under two-sided risk as ENHANCED track is consistent with its current policy, reduced complexity for CMS' operations, and established more equal footing between the risk models.

CMS also proposes to include a policy in the proposed new section of the regulations at §425.605(b)(2) to allow ACOs under the BASIC track's glide path in Level A or Level B to choose the MSR/MLR to be applied before the start of their first performance year in a two-sided model. This selection would 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 elects to more quickly transition to a two-sided model within the glide path (Level C, D, or E).

b. Proposals for 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 8 in the proposed 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.

Table 8 – Determination of MSR by Number of Assigned 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 proposes 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. This approach would begin with performance years starting in 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 would revert 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 proposes to 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 starting on January 1, 2019, and any remaining years of the current agreement period for ACOs under Track 1. CMS also makes some technical changes to reorganize the provisions at §425.110.

CMS seeks comment on these proposals and specifically on the proposed MSR ranges for ACOs with fewer than 5,000 assigned beneficiaries, including the application of a MSR/MLR in excess of 12 percent, in the case of ACOs that have failed to meet the requirement to maintain a population of at least 5,000 assigned beneficiaries and have very small population sizes. CMS also seeks comments on whether the proposed approach could improve accountability of ACOs.

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 proposes to amend §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 proposes the following for these tracks:

- **ACO in Track 2 or the ENHANCED track:** Repayment mechanism amount must be equal to at least 1 percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available.
- **ACO in BASIC Track:** 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.

CMS also proposes that for ACOs with a participant agreement start date of July 1, 2019, it will calculate the repayment mechanism amount using expenditure data from the most recent calendar year for which 12 months of data are available.

CMS generally does not revise the estimated repayment mechanism amount for an ACO during its agreement period, but believes that it may be appropriate to address changes in the ACO's composition over the course of an agreement period. Thus, CMS proposes to 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. If CMS determines the estimated amount of the ACO's repayment mechanism has increased, it may require the ACO to demonstrate the repayment mechanism arrangement covers at least an amount equal to this higher amount.

CMS proposes to make this determination as part of the ACO's annual certification process (in which it finalizes changes to its ACO participant list). If the amount has increased substantially (at least 10 percent or \$100,000, whichever is the lesser value), CMS would notify the ACO in writing and require the ACO to submit documentation for CMS approval to document that the funding for its repayment mechanism has been increased to reflect the recalculated amount. This determination would need to be made within 90 days. CMS clarifies that if the estimated amount decreases as a result of the ACO's change in composition, it will not permit the ACO to decrease the amount of the repayment mechanism.

CMS seeks comments on whether a higher value or lower charge in the repayment mechanism estimate should trigger the ACO's obligation to increase its repayment mechanism amount.

CMS also makes additional revisions for renewing ACOs, which would otherwise have to maintain two separate repayment mechanisms for overlapping periods of time. CMS proposes at §425.204(f)(3)(iv) that a renewing ACO can use its existing repayment mechanism to demonstrate that it has the ability to repay losses that may be incurred for performance years in the next agreement period, as long as the ACO submits documentation that the term of the repayment mechanism has been extended and the amount of the repayment mechanism has been updated, if necessary. CMS also proposes that if an ACO wishes to use its existing repayment mechanism to demonstrate its ability to repay losses in the next agreement period, the amount of the existing repayment mechanism must be equal to the greater of the following: (1) the amount calculated by CMS in accordance with the benchmark-based methodology or revenue-based methodology, as applicable by track or (2) the repayment mechanism amount that the ACO was required to maintain during the last performance year of its current agreement.

CMS proposes to consolidate at § 425.204(f)(4) all of its proposed policies, procedures, and requirements related to the amount of an ACO's repayment mechanism, including provisions regarding the calculation and recalculation of repayment mechanism amounts.

d. Proposals Regarding Submission of Repayment Mechanism Documentation

CMS proposes 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 proposes 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 seeks comment on these proposals.

e. Proposal for Repayment Mechanism Duration

CMS codifies in regulation a general rule (which it has been following under current requirements) at §425.204(f)(6) that a repayment mechanism must be in effect for the duration of the ACO's participation in a two-sided model plus 24 months after the conclusion of the agreement period. CMS proposes some exceptions to this general rule. CMS proposes that it may require an ACO to extend the duration of its repayment mechanism beyond the 24-month tail period if necessary to ensure that the ACO will repay CMS. In addition, CMS believes the duration requirement should account for the special circumstances of renewing ACOs. To the extent that the renewing ACO chooses to extend its current agreement, CMS proposes that the term of the existing repayment mechanism must be extended in these cases and that it must periodically be extended thereafter upon notice from CMS.

CMS recognizes that it may be difficult for ACOs that are completing the term of their current agreement period to extend an existing agreement by 7 years (the full 5-year agreement plus 24 months). CMS is considering whether it would be sufficient to permit an extension for the first 2 or 3 years and have another extension to cover the remaining period. **CMS solicits comments on whether it should require a longer or shorter extension. CMS also seeks comment on whether this approach should also apply to an ACO entering two-sided risk for the first time.**

With respect to terminating the repayment mechanism, CMS proposes that the repayment mechanism may be terminated at the earliest of the following conditions:

- 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;
- 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 Shared Savings Program; or
- CMS determines that the ACO does not owe any shared losses under the Shared Savings Program for any of the performance years of the agreement period.

CMS seeks comments on whether the provisions proposed at § 425.204(f)(6) are adequate to protect the financial integrity of the Shared Savings Program, to provide greater certainty to ACOs and financial institutions, and to facilitate the establishment of repayment mechanism arrangements.

f. Proposals Regarding Institutions Issuing Repayment Mechanism Arrangements

CMS proposes additional requirements related to the financial institutions through which ACOs establish their repayment mechanism arrangements that would be applicable to all ACOs participating in a performance-based risk track. CMS is proposing to expand the repayment mechanism arrangements. Specifically, CMS proposes to revise §425.204(f)(2) to specify the following requirements about the institution issuing the repayment mechanism arrangement: an ACO may demonstrate its ability to repay shared losses by placing funds in escrow 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.

CMS invites comments on these proposed requirements for ACOs regarding the issuing institution for repayment mechanism arrangements.

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. CMS makes the following proposals to address these issues:

- CMS proposes to revise §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 proposes 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 proposes to pro-rate 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 would be liable for 7/12 of any shared losses determined.
- CMS also proposes to pro-rate 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 considered, but did not propose, allowing ACOs voluntarily terminating after June 30 but before December 31 an opportunity to share in a portion of any shared savings earned. CMS decided to limit the proposed changes to shared losses.
- CMS also proposes technical changes to revise the regulations at §425.22 to streamline and reorganize the provisions in paragraph (b).

CMS seeks comment on these proposals and the alternative policies discussed.

6. Participation Options for Agreement Periods Beginning in 2019

CMS proposes 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 proposes 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 proposes to use an approach that would maintain financial reconciliation and quality performance determinations based on a 12-month calendar year period, but would prorate shared savings/shared losses for each potential 6-month period of participation during 2019. CMS proposes the following opportunities for ACOs, based on their agreement period start date:

- ACOs entering an agreement period beginning on July 1, 2019, would 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.
- ACOs that entered a first or second agreement period with a start date of January 1, 2016, may elect to extend their agreement period for an optional fourth performance year, defined as the 6-month period from January 1, 2019 through June 30, 2019. This election to extend the agreement period is voluntary and an ACO could therefore conclude its participation in the program with the expiration of its current agreement period on December 31, 2018.
- 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 makes some technical modifications to align its proposed policies to its regulations to define agreement period, term of the participation agreement, and definition of performance year. CMS also considered other alternatives including an agreement period that would have been 4 years and 6 months, or foregoing an application cycle for a 2019 start date altogether and allowing ACOs to enter agreement periods for the BASIC track and ENHANCED track for the first time beginning in January 1, 2020. **CMS seeks comment on these proposals and the related considerations, as well as alternatives considered.**

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

In this section, CMS describes the proposed methodology for determining financial and quality performance for the two 6-month performance years during calendar year 2019: the 6-month performance year from January 1, 2019, to June 30, 2019; and the 6-month performance year from July 1, 2019, to December 31, 2019. These proposals are included in a new section of the regulations at §425.609. The general approach CMS proposes would first reconcile the ACO based on its performance year 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.

CMS presents proposed policies that address the following issues for these two 6-month time periods: 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 proposes to specify these policies for reconciling the 6-month periods in paragraph (b) and of a new section of the regulations at § 425.609.

These proposed policies are briefly described below in the following table:

Proposed Policies	6-month performance years from January 1, 2019 through June 30, 2019	6-month performance year (or performance period) from January 1, 2019 through June 30, 2019
ACO participant list that will be used to determine beneficiary assignment	Proposes to use the ACO participants list beginning January 1, 2019 to determine beneficiary assignment. ACOs would be able to make changes to their ACO participant list in advance of the performance year beginning January 1, 2019.	Proposes to use the ACO participants list beginning July 1, 2019 to determine beneficiary assignment.
Approach to assigning beneficiaries	<p>Proposes to consider the allowed charges for primary care services furnished to a beneficiary during a 12-month assignment window – with a 3-month claims run-out.</p> <p>Assignment window: calendar year 2019</p> <p>Prospective beneficiary assignment window: October 1, 2017 through September 30, 2018.</p>	<p>Proposes to consider the allowed charges for primary care services furnished to a beneficiary during a 12-month assignment window – with a 3-month claims run-out.</p> <p>Assignment window: calendar year 2019</p> <p>Prospective beneficiary assignment window: April 20, 2018 through March 31, 2019.</p>
Quality reporting period	Proposes to use the quality performance for the 2019 reporting period.	Proposes to use the quality performance for the 2019 reporting period.
Benchmark year assignment methodology and the methodology for calculating, adjusting and updating the ACO's historical benchmark	<p>Proposes to 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 ACOs based on its agreement period in the program.</p>	<p>Proposes to 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 ACOs based on its agreement period in the program.</p>
Methodology for determining shared savings and shared losses	CMS would pro-rate any shared savings amount, or any shared losses amount, by multiplying by one-half (fraction of the calendar	CMS would pro-rate any shared savings amount, or any shared losses amount, by multiplying by one-half (fraction of the calendar

Proposed Policies	6-month performance years from January 1, 2019 through June 30, 2019	6-month performance year (or performance period) from January 1, 2019 through June 30, 2019
	<p>year covered by the 6-month performance year or period.</p> <p>Steps are described in detail in proposed rule.</p>	<p>year covered by the 6-month performance year or period.</p> <p>Steps are described in detail in proposed 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.”

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

CMS proposes 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. 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.

c. Annual Certifications and ACO Participant List Modifications

With respect to annual certification and ACO participant list, CMS makes several proposals:

- In the case of ACOs that participate for a portion of calendar year 2019 under one agreement and enter a new agreement period starting on July 1, 2019, these ACOs would need to complete another certification as part of completing the requirements to enter a new agreement period beginning on July 1, 2019, which would be applicable for the duration of their first performance year under the new agreement period, spanning July 1, 2019 to December 31, 2019.
- 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, would 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, to 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.
- An ACO that enters a new agreement period beginning on July 1, 2019, would submit and certify its ACO participant list for the agreement period beginning on July 1, 2019,

according to the requirements in § 425.118(a). The ACO's approved ACO participant list would remain in effect for the full performance year from July 1, 2019, to December 31, 2019. These ACOs would have the opportunity to add or delete ACO participants prior to the start of the next performance year. Any additions to the ACO participant list that are approved by CMS would become effective at the start of performance year 2020.

CMS makes the following observations regarding ACO participants that submit claims for services that are used assignment, and that are participating in a Shared Savings Program 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 Shared Savings Program 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 added to the ACO participant list of another July 1, 2019 starter, effective for the performance year beginning July 1, 2019.

d. Repayment Mechanism Requirements

CMS states that ACOs must demonstrate that they have in place an adequate repayment mechanism prior to entering a two-sided model. The repayment mechanism must be in effect for the duration of an ACO's participation in a two-sided model and for 24 months following the conclusion of the agreement period. CMS proposes that, for agreement periods beginning on or after July 1, 2019, it would recalculate the amount of the ACO's repayment mechanism before the second and each subsequent performance year in the agreement period, based on the ACO's certified ACO participant list for the relevant performance year. Depending on how much the recalculated amount exceeds the existing repayment mechanism amount, CMS would require the ACO to increase its repayment mechanism amount, consistent with its proposed approach described previously.

e. Proposals for Quality Reporting and Quality Measure Sampling

In order to determine an ACO's quality performance during either 6-month performance year during 2019, CMS proposes to use the ACO's quality performance for the 2019 reporting period as determined under § 425.502.

CMS believes the following considerations support this proposed 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.

The ACO participant list is used to determine beneficiary assignment for purposes of generating the quality reporting samples. The samples for claims-based measures are typically determined based on the assignment list for calendar year quarter 4. The sample for quality measures reported through the CMS web interface is typically determined based on the beneficiary assignment list for calendar year quarter 3. The CAHPS for ACOs survey sample is typically determined based on the beneficiary assignment list for calendar year quarter 2. For purposes of determining the quality reporting samples for the 2019 reporting period, CMS proposes to use the ACO's most recent certified ACO participant list available at the time the quality reporting samples are generated, and the assignment methodology most recently applicable to the ACO for a 2019 performance year.

CMS proposes to specify the ACO participant lists that would be used in determining the quality reporting samples for measuring quality performance for the 6-month performance years in a new section of the regulations at §425.609. CMS provides additional detail on its approach to determine the ACO participant list, assignment methodology and assignment window that would be used to generate the quality reporting samples for measuring quality performance of ACOs participating in a 6-month performance year (or performance period) during 2019 in the proposed rule (FR 41849-41859)

f. Proposals for Applicability of Extreme and Uncontrollable Circumstances Policies

CMS proposes (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.

g. Proposals for Payment and Recoupment for 6-month Performance Years

CMS proposes to provide separate reconciliation reports for each 6-month performance year, and it would 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 proposes to apply the same policies regarding notification of shared savings payment and shared losses, and the timing of repayment of shared losses, to ACOs in 6-month performance years that apply under its current regulations to ACOs in 12-month performance years. CMS proposes to specify in a new regulation at §425.609 that CMS would notify the ACO of shared savings or shared losses for each reconciliation, consistent with the notification requirements specified in §425.604(f), proposed §425.605(e), §425.606(h), and §425.610(h). Specifically, CMS proposes to (1) notify an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due; (2) provide written notification to an ACO of the amount of shared losses, if any, that it must repay to the program; (3) require that, if an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

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 would 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 proposes to conduct reconciliation for each 6-month performance year at the same time. After reconciliation for both 6-month performance years is complete, CMS would 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 proposes to 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 proposes to specify these policies on payment and recoupment for ACOs in 6-month performance years within calendar year 2019 in a new section of the regulations at §425.609(e).

h. Proposals for Automatic Transition of ACOs under the BASIC Track's Glide Path

CMS proposes 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.

Interactions with the Quality Payment Program

CMS states that it took into consideration how the proposed 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 proposed July 1, 2019 start date for the proposed new participation options under the Shared Savings Program would align with Quality Payment Program rules and requirements for participation in Advanced APMs.

- i. Proposals for 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. 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 proposed approach would 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 prorating any shared savings or shared losses to reflect the length of the performance year), and maintain consistency with the reports delivered to ACOs that participate in a 12 month performance year 2019. CMS proposes to specify this policy in revisions to §425.702.

- j. Proposals for 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 41859-41860).

B. Fee-For-Service Beneficiary Enhancements

1. Shared Savings Program Skilled Nursing Facility 3-Day Rule Waiver (§425.612)

Current Applicability. CMS states that Shared Savings Program ACOs bearing performance- based financial risk (subject to shared losses and receiving shared savings), such as Track 3 ACOs, have generally achieved greater Medicare program savings than ACOs under one-sided (shared savings only) risk tracks (e.g., Track 1). CMS believes that even greater savings might be achieved if performance- based risk bearing ACOs were given increased flexibility that could enhance more coordinated care. In the June 2015 Shared Savings Program final rule, CMS made available the Skilled Nursing Facility (SNF) 3-day rule waiver to enhance care coordination between ACOs and their SNF affiliates, beginning with the 2017 performance year. Features of the waiver currently include:

- The SNF 3-day rule waiver must be requested by the ACO.
- The waiver is available only to Shared Savings Program ACOs bearing two-sided risk and to which beneficiaries are prospectively assigned (Track 3 ACOs).⁴
- The SNF must be an eligible SNF affiliate of the ACO and have a rating of 3 stars or greater under the CMS 5-star Quality Rating System.

⁴ Waiver eligibility was later extended to the Innovation Center's Track 1+ model's ACOs. The Track 1+ model has elements in common with several Shared Savings Program tracks but is separate from the Program.

- A 90-day grace period applies.
 - To compensate for potential operational delays in communicating beneficiary assignment status changes that would cancel a beneficiary’s SNF 3-day rule waiver eligibility (under the Shared Saving Program) for the remainder of the performance year that is already underway (e.g., Medicare Advantage plan enrollment), a SNF stay beginning within 90 days of a beneficiary’s loss of 3-day SNF rule waiver eligibility remains covered for payment by CMS.
- The waiver is not applicable to SNF care furnished under swing bed arrangements.

Proposed Expanded Applicability. At the inception of the SNF 3-day rule waiver, CMS believed that only ACOs using prospective beneficiary assignment could confidently identify waiver- applicable beneficiaries prior to the start of a waiver-eligible SNF stay. CMS now believes that Shared Savings Program ACOs using the preliminary prospective (with retrospective reconciliation) assignment methodology could identify waiver-applicable beneficiaries in advance with substantial certainty. For this reason and to support care coordination flexibility for a larger pool of ACOs, CMS proposes to expand access to the SNF 3-day rule waiver to ACOs under Shared Savings Program tracks in which ACOs bear two-sided risk and in which beneficiary assignment is preliminarily prospective. Currently, only Track 2 ACOs meet these criteria. However, as described elsewhere in the rule, CMS proposes to discontinue Track 2 and to establish several new Shared Savings Program track participation options that would satisfy the SNF 3-day waiver criteria. Concomitantly, CMS is proposing to allow ACOs to move back and forth annually between the prospective and preliminary prospective assignment options.

To facilitate clear identification by Shared Savings Program ACOs using preliminary prospective assignment of beneficiaries to whom the SNF 3-day waiver would become applicable, CMS plans to provide and maintain a cumulative assignment list to be shared with each ACO choosing preliminary prospective assignment. The cumulative list would begin on January 1 of each performance year (populated with assigned beneficiaries from the prior year) and would be updated quarterly by adding beneficiaries who have received at least one primary care service through the ACO. Waiver applicability would be established for a performance year the first time a beneficiary is listed, even though the beneficiary might not appear on any of that ACO’s subsequent quarterly list updates or might not be finally assigned to the ACO during retrospective reconciliation for that year. Once listed, a beneficiary’s waiver applicability would continue for the remainder of the ongoing performance year unless the individual is no longer a FFS beneficiary (e.g., enrolls in a Medicare Advantage plan).⁵ The waiver would apply only to payment for SNF services furnished after the beneficiary is first listed; as usual, a provider or supplier would be expected to confirm beneficiary coverage prior to furnishing care. CMS acknowledges that its proposed approach could result in covered SNF stays for beneficiaries who were later discovered not to have been eligible for the waiver, but CMS would not claw back those payments. Since the beneficiary would thereby be protected from financial liability for the SNF stay under such circumstances, CMS does not believe a 90-day grace period to be necessary in conjunction with expanding the SNF 3-day rule waiver to ACOs using preliminary

⁵ Also, a waiver-eligible beneficiary who resides 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.

prospective beneficiary assignment. Finally, CMS adds that if a beneficiary is admitted to a SNF prior to an ACO's termination date, and all requirements of the SNF 3-day rule waiver are met, the SNF services furnished without a prior 3-day stay would be covered under the SNF 3- day rule waiver.

Swing Bed Applicability. SNF services are sometimes furnished at Critical Access Hospitals (CAHs) and certain small, rural hospitals under swing bed arrangements between those hospitals and CMS. Swing beds currently are not waiver-eligible because Shared Savings Program regulations do not define swing beds as eligible SNFs and because hospitals operating swing beds do not participate in the CMS 5-star Quality Rating System (so cannot achieve the minimum 3-star rating required for waiver applicability). Most swing beds are located in rural areas, and rural health stakeholders have urged CMS to extend the SNF 3-day rule waiver to swing beds as an adjunct to supporting access to value-based care coordination for beneficiaries living in rural areas. CMS agrees and proposes to extend the waiver by revising the regulations at §425.612 to allow application of the waiver to SNF services furnished under swing bed arrangements when those services fall under a written agreement between the swing bed operator and a waiver-eligible ACO. CMS clarifies that the 5-star rating system requirement applies only to those providers eligible for inclusion in the rating system, but notes that the agency will monitor the quality of care furnished to beneficiaries under swing bed arrangements.

Future Applicability. CMS proposes that new Shared Savings Program ACO tracks that include performance-based financial risk bearing (BASIC tracks Levels C, D, and E along with the ENHANCED track) would be eligible for the SNF 3-day rule waiver if their implementing regulations are finalized. CMS does not propose to revise the regulations to make Track 2 ACOs waiver-eligible, having proposed to phase out this track. CMS notes that existing Track 2 ACOs that choose to terminate their current participation agreements and to reapply under the BASIC tracks Levels C, D, and E or the ENHANCED track would be eligible to apply for the SNF 3-day rule waiver.

Implementation Timeline. CMS attempts to relieve burden and limit confusion by proposing 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 subsequent performance years, coinciding with the proposed changes to track participation options. This proposed timeline would apply to Shared Savings Program ACOs that start new participation agreement periods under the proposed participation options on July 1, 2019, and those ACOs applying for waivers during the terms of existing agreements. (CMS is forgoing the previously planned Shared Savings Program ACO application cycle having a January 1, 2019 start date.) Finally, CMS proposes that ACOs having approved SNF 3-day rule waivers could modify their SNF affiliate lists for the performance year beginning January 1, 2019, but they could not add a swing-bed SNF affiliate until the July 1, 2019 change request review cycle.

CMS invites comments on the proposals to revise the SNF 3-day rule waiver as part of incentivizing Shared Savings Program ACOs to increase quality and decrease costs under performance-based risk arrangements, as well as comments on related issues.

2. Billing and Payment for Telehealth Services

CMS believes that telehealth services may be used by ACOs to enhance care coordination across settings. Currently telehealth services coverage by the Medicare program is limited in several ways including:

- By service type.
 - The service furnished must appear on Medicare's telehealth-approved list⁶; and
- By beneficiary location, termed the "originating site".
 - Sites are limited to certain facility types (e.g., practitioner office⁷) and geographic areas (e.g., a county that is not in a metropolitan statistical area (MSA)⁸).

Proposed Policy. CMS proposes regulatory changes for when 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 Shared Savings Program ACOs to which beneficiaries are prospectively assigned. In such cases, consistent with the BBA of 2018, the limitations on originating site and geographic location would not apply for payment purposes. As a result, payment could be made for telehealth services originating in the beneficiary's home (in addition to currently allowed sites⁹) and from geographic locations that would otherwise be prohibited (e.g., an urban site in an urban MSA). The BBA of 2018 also directs that the usual facility fee would not be paid to the originating site when services originate from a beneficiary's home, and that 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 proposes 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-G04270).

ACO Applicability. CMS states that the proposed expanded telehealth policy would apply to ACOs entering both the proposed BASIC track (at Levels C, D, and E) and ENHANCED track if proposals to create those tracks are finalized, as long as those ACOs continue to elect prospective beneficiary assignment. (Elsewhere in the rule, CMS proposes to allow those ACOs to annually choose either prospective or preliminarily prospective assignment.) CMS also states that the proposed expanded telehealth policy would apply to Track 3 ACOs and Track 1+ Model ACOs. The expanded policy would cease to apply to an ACO (and its clinicians) whose Shared Savings Program participation agreement has expired.

Potential Beneficiary Liability. CMS proposes regulatory changes to protect beneficiaries from potential liability related to expanded telehealth services provided by Shared Savings Program ACOs. To compensate for potential operational delays in communicating beneficiary

⁶The list is available at <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.html>.

⁷Also included for 2018 are rural health centers, federally qualified health centers, hospitals, hospital-based or CAH-based renal dialysis centers (including satellites), SNFs, and community mental health centers.

⁸Other applicable locations include a health professional shortage area that is either outside of a Metropolitan Statistical Area (MSA) or within a rural census tract of an MSA, or a location included as a participant in a Federal telemedicine demonstration project.

⁹The originating site must comply with applicable state licensing requirements.

assignment status changes to ACOs that would cancel the applicability to a FFS beneficiary of the expanded telehealth services (under the Shared Savings Program) for the remainder of the performance year already underway (e.g., Medicare Advantage plan enrollment), CMS proposes to establish a 90-day grace period after the beneficiary's status change during which payment would be made for expanded telehealth services (as is already done under the Next Generation ACO model). CMS also is concerned that beneficiaries might be held liable by ACOs or their participant clinicians when otherwise covered telehealth services are furnished to a FFS beneficiary who is not prospectively assigned to the billing ACO and the associated claims are denied by Medicare. Such a scenario, described at length in the rule, could arise from ACO process failures (e.g., the ACO and/or the clinician failed to verify that the beneficiary was prospectively assigned to their ACO prior to furnishing the service) or even represent intentionally inappropriate billing. In the event the described scenario leads to claim rejection and potential beneficiary liability for the telehealth services, CMS proposes 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., required corrective action plan).

CMS does not make any proposals concerning expanded coverage of services delivered through asynchronous telehealth technologies at this time because it is awaiting results of testing a related waiver under the Next Generation ACO model.

CMS invites comments on the proposals described above for implementing the expanded telehealth services of section 1899(l) of the Act, as added by the Bipartisan Budget Act, and related issues.

CMS summarizes the proposed SNF 3-day rule waiver and telehealth services expansion in Table 9 in the rule, reproduced below

TABLE 9—AVAILABILITY OF PROPOSED PAYMENT AND PROGRAM POLICIES

Policy	Policy Description	Track 1 (One-sided model; Propose to discontinue)	Track 2 (Two-sided model; Propose to discontinue)	Track 1+ Model (Two-sided model)	BASIC track (Proposed new track)	ENHANCED track (Proposed; current track 3 financial model)
Telehealth services furnished in accordance with §1899(1) of the act	Removes geographic limitations and allows the beneficiary's home to serve as originating site for prospectively assigned beneficiaries	N/A (because this is a one-sided model under preliminary prospective assignment) years.	N/A (because under preliminary prospective assignment)	Proposed requirements for performance year 2020 and onward (prospective assignment) ¹	Proposed requirements for performance year 2020 and onward, applicable for performance years under a two-sided model (prospective assignment)	Proposed requirements for performance year 2020 and onward (prospective assignment)
SNF 3-Day Rule Waiver²	Waives the requirement for a 3-day inpatient stay prior to admission to a SNF affiliate	N/A (unavailable under current policy)	N/A (unavailable under current policy)	Current policy (prospective assignment)	Proposed for performance years beginning on July 1, 2019 and subsequent years, eligible for performance years under a two-sided model (prospective or preliminary prospective assignment)	Proposed for performance years beginning on July 1, 2019 and subsequent years (prospective or preliminary prospective assignment)

¹ An amendment to the Track 1+ Model Participation Agreement would be required to apply the proposed policies regarding the use of telehealth services under §1899(1) to Track 1+ Model ACOs as described in section II.F of this proposed rule.

² As discussed in section II.A.7.c and II.F of this proposed rule, Track 3 ACOs and Track 1+ Model ACOs participating in a performance year beginning on January 1, 2019, may apply for a SNF 3-day rule waiver effective on July 1, 2019. We expect this application cycle would coincide with the application cycle for new agreement periods beginning on July 1, 2019.

C. Providing Tools to Strengthen Beneficiary Engagement

1. Beneficiary Incentives: Background and Overview

CMS notes that existing regulations (see §425.304) already allow Shared Savings Program ACOs to provide in-kind items or services as incentives to beneficiaries. The incentives must be connected to the beneficiary's care, and be either preventive care items and services or advance a clinical goal of the beneficiary (e.g., medication adherence).¹⁰ A wide range of incentives may be offered (e.g., meal plan vouchers for malnourished beneficiaries, gift cards for blood pressure monitors for beneficiaries with hypertension), and the incentives may be offered on a targeted basis to beneficiaries most likely to achieve the incentive's intended goal. CMS notes that ACOs offering incentives must comply with all applicable laws (including the Federal anti-kickback statute and the Beneficiary Inducements Civil Monetary Penalties (CMP) provisions). Incentive propriety is judged on a case-by-case basis.¹¹ The BBA of 2018 enables Shared Savings Program ACOs who bear two-sided risk to establish incentive programs for assigned beneficiaries receiving qualifying primary care services to encourage FFS beneficiaries to obtain medically necessary primary care services. CMS proposes to add implementing regulations at §425.304 that would allow eligible Shared Savings Program ACOs to establish beneficiary incentive programs as directed in the BBA of 2018.

2. Regulations Proposed for Implementing BBA Beneficiary Incentive Program Provisions

ACO Eligibility. The BBA provides that ACOs in Shared Savings Program tracks bearing two- sided risk may establish beneficiary incentive programs. CMS reviews the various references in the Act to risk-bearing tracks in the context of the current Program tracks (e.g., Track 2) and the participation option proposals described elsewhere in the rule (e.g., the ENHANCED track).

CMS proposes 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.

Program Initiation and Cycle Duration. The BBA provides for incentive program implementation no earlier than January 1, 2019, and no later than January 1, 2020. The statute also directs that an ACO's approved incentive program must be conducted for not less than one year (unless terminated earlier by the Secretary). CMS proposes July 1, 2019 as the start date and explains in detail how this approach would allow ACOs with differing initial performance years (12 versus 18 months) to ultimately be synchronized onto a single calendar year incentive program certification cycle when the proposed participation option changes (described elsewhere).

¹⁰ The items or services may be provided by the ACO itself, or by ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities.

¹¹ Permissible incentives are more fully described in the final rule published by the Office of the Inspector General (OIG) entitled "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).

in the rule) are fully implemented (if finalized).¹² CMS considered an alternative proposal for a start date of January 1, 2020 for all incentive programs.

Application Process and Subsequent Program Certification. The BBA is largely silent on the application criteria and process, other than specifying that only two-sided risk ACOs can apply. CMS proposes that the application to establish an incentive program would be in a form and manner specified by CMS and would be distinct from that for joining the Shared Savings Program. CMS further proposes to accept incentive program applications during the July 1, 2019 Shared Savings Program 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. This would pertain to two-sided risk track ACOs that defer starting their incentive programs during their first Shared Savings Program years and to ACOs who are preparing to transition from one-sided risk tracks to two-sided risk tracks. An ACO whose incentive program 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 (12 or 18 months) for any consecutive performance year if the ACO complies with CMS' certification requirements. CMS proposes 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 certify that the program still meets all applicable requirements. Finally, CMS proposes that failure to certify annually as described could lead to incentive program termination.

CMS seeks comment as to whether an ACO operating an approved beneficiary incentive program should be required to notify CMS of any planned program modifications prior to their implementation.

Eligibility for Incentive Payment. The BBA directs and CMS proposes to require that an ACO operating an approved incentive program will make payments to all FFS beneficiaries eligible to receive payments, irrespective of the methodology by which a beneficiary is assigned to the ACO (e.g., prospective, preliminary prospective, or voluntary alignment).

Qualifying Services. CMS proposes to implement the BBA by requiring that a beneficiary would become eligible for payment upon receiving a qualifying primary care service from an ACO professional with a primary care designation, or a FQHC or RHC, which is furnished through an ACO operating an approved incentive program. CMS proposes to adopt the definition of primary care services at §425.20 as well as the definition of primary care designation at §425.20 (or successor regulations).¹³ A co-insurance payment must be required.

¹² An ACO starting a program on July 1, 2019, will have an initial 18 month term and subsequent 12 month terms; a program that begins on January 1 of a performance year will have initial and subsequent 12 month terms.

¹³ Qualifying primary care services include office, nursing facility, home, domiciliary, transitional and chronic care management, the Welcome to Medicare and annual wellness visits, and FQHC and RHC services, furnished through the ACO by a primary care physician (MD/DO), physician assistant, nurse practitioner, or clinical nurse specialist.

Payment Amount and Timing. The BBA directs and CMS proposes to require that the incentive payment would be in an amount of up to \$20; the payment amount would be updated 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. CMS proposes that the incentive payment type could vary both within and across ACOs according to beneficiary preferences (e.g., an ACO could offer both gift cards and checks), but the monetary value of incentive payments of each type would be required to be the same. CMS proposes, as directed by the BBA, to require that an incentive payment be made for each qualifying service and that each payment be made within 30 days of service delivery.

Payment Distribution Method. Based upon the BBA, CMS proposes that incentive payments would be made by the ACO legal entity directly to the eligible beneficiary rather than by a participant or a provider/supplier. **CMS seeks comment on other potential methods for incentive payment distribution.**

Program Integrity, Recordkeeping, and Incentive Program Funding. The BBA provides discretion to the Secretary to establish program integrity requirements for the incentive program, and CMS proposes to prohibit incentive payments distribution in the form of cash. Cash payments 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. CMS proposes to require that payments be made as cash equivalents (e.g., instruments convertible to cash or accepted widely on the same basis as cash such as prepaid debit cards or vouchers).

With regards to incentive program recordkeeping, CMS builds upon BBA provisions and proposes to require that approved programs must maintain records that include for each payment the following: beneficiary identifying information, payment type and amount, qualifying service date and HCPCS code billed, qualifying service provider/supplier identifying information, and date of incentive payment. CMS proposes 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.

The ACO would also be required to update its compliance plan once regulations related to beneficiary incentive programs are finalized. CMS additionally proposes 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 proposes that no separate payment would be made by CMS to the ACO to fund the operational costs or the payments themselves, but the ACO would be permitted to utilize its shared savings for funding purposes. Finally, the ACO would not be permitted to shift any incentive program costs to another Federal health care program.

CMS seeks comment on all of the proposed program integrity requirements, especially as to whether external funding of incentive program costs should be prohibited.

Benchmarking and Taxation Impacts. As directed by the BBA, CMS proposes that incentive payments would be disregarded in calculated ACO benchmarks, estimated average per capita Medicare expenditures, and shared savings and losses. CMS also proposes that incentive

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

payments to beneficiaries would be treated as exempt for purposes of income tax laws or laws governing qualification for Federal or State assistance programs.

Termination. The BBA 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 proposes to terminate an ACO's approved incentive program for failure to comply with proposals finalized for inclusion at §425.304 (Beneficiary Incentives) in whole or in part, or for any of the grounds for termination of the ACO itself (see §425.218). **CMS solicits comments on whether it also would be appropriate for the Secretary to terminate a beneficiary incentive program in other circumstances, or whether an ACO should have the ability to terminate its beneficiary incentive program early (e.g., after less than a year of operation).**

Should an ACO desire to reestablish an incentive program after its termination, the ACO would be required to submit a new application for incentive program approval. Finally CMS proposes to incorporate the BBA provision that does not allow for administrative or judicial review of an incentive program's termination.

Program Evaluation and Compliance Monitoring. The BBA 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. CMS notes that current regulations regarding compliance monitoring already allow the agency to employ multiple monitoring methods for assessing compliance with Shared Savings Program eligibility and program requirements by ACOs, ACO participants, and ACO providers/suppliers; CMS would extend such monitoring to include beneficiary incentive programs if the incentive programs are finalized.

Beneficiary notification and Public Reporting. CMS proposes to prohibit the advertisement of a beneficiary incentive program but is also considering requiring ACOs to inform their beneficiaries about their approved incentive programs using CMS-approved outreach materials. Any beneficiary notifications about incentive payments would be subject to recordkeeping in accordance with §425.314. **CMS solicits comments on:**

- **Whether existing beneficiary notifications (see §425.312(a)) should include incentive program availability information and, if so, whether CMS should supply template language.**
- **How and when an ACO might otherwise notify its beneficiaries that its beneficiary incentive program is available, without inappropriately steering beneficiaries.**
- **Whether it would be appropriate to impose restrictions regarding advertising of a beneficiary incentive program.**

To operationalize BBA provisions about public reporting of beneficiary incentive program information, CMS proposes to revise the program's public reporting requirements. Any ACO operating an approved incentive program would be required to publicly report certain incentive payment information on the ACO's public reporting web page. Specifically, the ACO would be required to publicly report for each performance year:

- The total number of beneficiaries who receive an incentive payment,
- The total number of incentive payments furnished,
- The HCPCS codes associated with any qualifying payment for which an incentive payment was furnished,

- The total value of all incentive payments furnished, and
- The total of each type of incentive payment furnished (e.g., check or debit card).

CMS invites comments on whether information about a beneficiary incentive program should be publicly reported by the ACO or simply reported to CMS annually or upon request.

Clarifications of existing rules. CMS describes revisions to existing regulatory text at renumbered §425.304(b)(3) to specify that in-kind items or services provided to a Shared Savings Program ACO beneficiary must not include Medicare-covered items or services. CMS emphasizes 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 details numerous regulatory text changes related to the proposed incentive program regulations.

TABLE 10—ABILITY OF ACOs TO ESTABLISH A PROPOSED BENEFICIARY INCENTIVE PROGRAM BY TRACK

Policy	Policy Description	Track 1 (One-Sided model; Propose to discontinue)	Track 2 (Two-Sided model; Propose to discontinue)	Track 1+ Model (Two-sided model)	BASIC track (Proposed new track)	ENHANCED track (Proposed; current track 3 financial model)
Beneficiary Incentive Program	Requires ACOs that establish a beneficiary incentive program to provide an incentive payment to each assigned beneficiary (prospective or preliminary prospective) for each qualifying service received	N/A	Proposed beginning July 1, 2019 and for subsequent performance years (prospective prospective assignment)	N/A	Proposed beginning July 1, 2019 and for subsequent performance years for ACOs in Levels C, D or E (prospective or preliminary prospective assignment)	Proposed beginning July 1, 2019 and for subsequent performance years (prospective or preliminary prospective assignment)

3. Empowering Beneficiary Choice: Beneficiary Notifications

In the rule, CMS revisits current Shared Savings Program beneficiary notification requirements. CMS notes that from its inception, the Shared Savings Program has required its ACOs to communicate regularly and transparently with beneficiaries, including informing them that their care is being furnished under a shared savings payment model. CMS reviews in detail the evolution of the Program's beneficiary notification requirements, intended to balance provider burden with beneficiary access to and comprehension of pertinent information. Currently ACOs must post informational signs in ACO facilities and primary care service delivery settings (e.g., practitioner offices), and they must provide upon request a written Beneficiary Information Notice. Both the posters and the Information Notice incorporate template language created by CMS. CMS describes the multiple other sources through which beneficiaries may obtain information about Shared Savings Program ACOs including the Medicare & You handbook, 1-800-MEDICARE, and MyMedicare.gov.

CMS is concerned that information about the Shared Savings Program and its ACOs is difficult for beneficiaries to assimilate because the information is spread across several sources. CMS states its intention to make the Information Notice a comprehensive resource about the Program and to expand methods for making the Notice readily available at the point of care. The BBA of 2018 directs CMS to inform beneficiaries about their option to designate a primary clinician to coordinate their care¹⁵; CMS hopes to increase beneficiary awareness of their option through the expanded Information Notice. CMS also plans to use the Notice to remind ACO beneficiaries of their options to decline (or accept) sharing of their health data between CMS and their ACO in beneficiary-identifiable formats.

CMS proposes to require additional content for beneficiary notices starting July 1, 2019, with a special focus on identifying a primary clinician and thus triggering voluntary alignment of the beneficiary to the ACO. CMS also proposes to require that information about primary clinician choice and voluntary alignment be given to beneficiaries at their first primary care visit of each performance year (regardless of performance year length). This notification would be additive to current posted sign and written Beneficiary Information Notice requirements and would incorporate template language from CMS.

CMS poses multiple requests for comments addressing diverse topics:

- Alternative means of dissemination of the beneficiary notice, including the frequency with which and by whom the notice should be furnished (e.g., whether a beneficiary should receive the written notice at the beneficiary's first primary care visit of the performance year, or during the beneficiary's first visit of the performance year with any ACO participant);
- Alternative media for disseminating the beneficiary notice that may be less burdensome on ACOs, such as dissemination via email;

¹⁵ Designating a primary clinician triggers voluntary alignment of the beneficiary with the clinician's ACO as described more fully later in the rule and in this summary.

- **Requiring the template notice to include other information outlining ACO activities that may be related to or affect a Medicare FFS beneficiary (e.g., quality improvement);**
- **The timing of providing the proposed annual notice to the beneficiary, particularly what would constitute the appropriate point of care for the beneficiary to receive the notice; and**
- **Whether an ACO that elects prospective assignment should be required to disseminate the beneficiary notice at the point of care only to beneficiaries who are prospectively assigned to the ACO, rather than to all Medicare FFS beneficiaries.**

4. Empowering Beneficiary Choice: Opt-In Assignment Methodology

In response to recurring comments from several stakeholders, CMS explores at length options for developing a methodology to assign beneficiaries to Shared Savings Program ACOs where the beneficiary directly opts in to the ACO (the opt-in methodology). CMS notes that under the current claims-based assignment methodology, beneficiaries – arguably – already opt in to assignment to an ACO by freely choosing to seek primary care through that ACO. CMS does not make any proposals nor outline definitive next steps to adopt an opt-in methodology but does invite comments on a range of related issues.

Stakeholders supporting an opt-in methodology contend that this approach:

- Promotes beneficiary free choice,
- Enhances an ACO's ability to effectively manage a beneficiary's care since the patient has directly chosen the ACO and is likely to be engaged, and
- Makes the assignment methodology more patient-centered, strengthening beneficiary empowerment in health care decision-making.

CMS believes that potentially positive aspects of adopting an opt-in methodology include:

- Allowing ACOs to better target their care coordination efforts on beneficiaries for whose care the ACOs will be held accountable, and
- Providing a stronger economic incentive for ACOs to compete against one another and against other providers, as successful ACOs presumably could attract more beneficiaries and increase their shared savings.

CMS mentions having recently implemented a voluntary alignment process for beneficiaries, to which refinements are proposed elsewhere in the rule. Voluntary alignment resembles an opt-in methodology with the beneficiary directly opting in to care by a primary clinician but only indirectly opting in to the clinician's ACO. Opt-in assignment, as now being considered by CMS, is based instead upon direct beneficiary opt-in to the ACO. CMS notes that voluntary alignment first became available in 2017, allowing beneficiaries to align themselves for performance year 2018. CMS reports the following data for the first year of voluntary alignment: 4,314 beneficiaries voluntarily aligned to 339 ACOs, and 338 beneficiaries were assigned to an ACO based solely on their voluntary alignment. Ninety-two percent of the

beneficiaries who voluntarily aligned were already assigned to the same ACO under the claims- based assignment algorithm.

CMS divides its opt-in assignment methodology discussion 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.

Process issues. CMS describes multiple, time-sensitive tasks that ACOs would be required to perform under an opt-in assignment methodology (e.g., beneficiary notification, reporting opt-in data to CMS). CMS notes that the Shared Savings Program opt-in process could borrow some elements from the MA enrollment process. Similarities between opt-in assignment and MA plan enrollment would necessitate distinct processes and timelines to minimize beneficiary confusion. CMS would need to determine whether any limitations would be required on opt-in frequency and timing. CMS comments that ACOs might need to acquire new IT systems and hire additional personnel to collect, track, monitor, and transmit to CMS large volumes of beneficiary data. CMS points out that changes in an ACO's participants or providers/suppliers might cause a beneficiary who had opted in to withdraw (opt out) from assignment to the ACO. Having smooth processes for keeping beneficiaries informed about the ACO's composition changes and about the option to withdraw would be essential for ACOs as they seek to manage beneficiary satisfaction and to limit potential beneficiary churn.

ACO Marketing. CMS remarks upon the guidelines and requirements that apply to MA plan enrollment and anticipates creating similar boundaries for Shared Savings Program ACOs with respect to any beneficiary opt-in assignment methodology that might be adopted. ACOs would be expected to provide complete and accurate information to inform beneficiary opt-in decision- making. ACOs would also be expected not to market selectively or discriminate based upon beneficiary health status, or otherwise attempt to improperly influence opt-in choices made by beneficiaries. CMS states that it would require ACOs to track beneficiaries notified about opt-in opportunities and their responses. ACOs, ACO participants, ACO providers/suppliers and all other associates already must agree to inspections, audits, or other investigations by CMS to monitor ACO compliance with Program requirements, and CMS would extend its compliance monitoring to include ACO marketing guidelines.

Balancing Requests and Requirements. CMS discusses how it might approach balancing being responsive to stakeholder requests with conforming to existing statutory and program requirements while implementing an opt-in based assignment methodology.

(a) Minimum Beneficiary Number. ACOs are required to have at least 5,000 assigned beneficiaries when applying to the Shared Savings Program and throughout their agreement periods, and this requirement would not change under opt-in assignment. CMS raises concerns that if opting in were the sole assignment method, ACOs – particularly new, smaller, or rural ones – could find it difficult to initially meet or to maintain the 5,000-beneficiary minimum.

MSR and MLR rates would increase if an ACO's population shrank under opt-in assignment; smaller overall beneficiary populations also could complicate ACO efforts to aggressively

manage care for high-risk patient subsets while continuing to manage the health of their entire population.

(b) Primary Care Service Requirement. Under an opt-in methodology, a beneficiary could opt in to an ACO without ever having received a primary care service from that ACO's clinicians, causing the ACO to be accountable for the cost and quality of the beneficiary's care despite not having provided that care. Further, the statute requires that beneficiary assignment to an ACO be based upon beneficiary use of primary care services furnished by that ACO to the beneficiary. One option would be for CMS to retain a requirement that at least one primary care service from an ACO primary care professional (or other designated specialty ACO professional as defined at §425.402) would be necessary before beneficiary opt in was allowed.

(c) Historical Benchmark Adjustment. CMS provides several examples of how assignment based solely on an opt-in methodology would be likely to impact negatively the suitability and reliability of historical benchmark calculations made using opt-in beneficiary data. For example, the disconnect between beneficiaries opting in to assignment to an ACO for a performance year and the beneficiaries assigned to the ACO on the basis of claims for the historical year will likely be quite large. CMS notes past difficulties in attempting a somewhat similar benchmark adjustment for the Pioneer ACO Model.

Hybrid Methodology. Having analyzed applying a pure opt-in beneficiary assignment methodology to the Shared Savings Program and having elucidated the associated challenges, CMS turns to describing what it terms a "hybrid" methodology that the agency is considering implementing. CMS believes that the hybrid approach could address some stakeholder concerns (e.g., patient-centeredness) while taking into consideration the Program's regulatory infrastructure.

CMS first describes a bifurcated system that allows an ACO to elect either an opt-in or existing methodological approach to assignment. An ACO applying to enter or renew participation in the Shared Savings Program could elect to apply the opt-in beneficiary assignment methodology for the length of its agreement period, though it would not be required to do so.

- The "existing assignment methodology" (i.e., claims-based plus voluntary alignment) would be used to determine if the ACO is eligible for the Program (e.g., meet the minimum of 5,000 assigned beneficiaries in each of the three prior years), as the ACO applicant would not have had the opportunity to gain assigned beneficiaries through opting in.
- For each application submission, an ACO could instead not elect the opt-in methodology, and assignment to the ACO would follow the existing assignment methodology.

CMS is also considering discontinuing the existing assignment methodology and replacing it with a hybrid methodology that includes beneficiary opt-in, modified claims-based assignment, and voluntary alignment. Given concerns identified previously about a pure opt-in assignment approach, CMS finds value in first accruing experience with opt-in assignment as a voluntary participation option rather than mandating its use by all ACOs. For an ACO choosing opt-in

assignment, CMS would assign beneficiaries to the ACO using a hybrid approach that would be based on beneficiaries opting in supplemented by voluntary alignment and modified claims- based assignment. A beneficiary would be considered prospectively assigned to an ACO that chooses opt-in assignment if he or she opted into or aligned voluntarily with that ACO. Assignment of any other beneficiaries to that ACO would be made only if the beneficiary received the plurality of his or her primary care services from the ACO and received at least seven primary care services from one or more ACO professionals in the ACO during the applicable assignment window (i.e., modified claims-based assignment). If the beneficiary received the plurality of his or her primary care services but less than six services through the ACO, the beneficiary would not be assigned to that ACO. (The seven services threshold is based on data from an integrated health system that participated in a prior demonstration project.) The ACO choosing the opt-in methodology could also choose either prospective or preliminary prospective claims-based assignment (to be used when needed to assign beneficiaries under the hybrid model) at the beginning of its agreement period and could change its election annually.

Also, for ACOs that choose the opt-in methodology, CMS would create an election period each year during which beneficiaries could opt in to those ACOs (i.e., the first calendar year quarter of the ACO's first performance year, then the first 3 calendar year quarters of the year preceding the performance year). No floor or minimum number of opt-in beneficiaries would be required. The opt-in ACO's Shared Savings Program beneficiary minimum (5,000) could include opt-in, claims-based, and/or voluntary alignment beneficiaries. If the minimum was not met, the ACO could face pre-termination, and the ACO's MSR/MLR would be reset at a level consistent with the total number of beneficiaries in the ACO. CMS considered an alternative approach under which an opt-in assignment ACO would be required to maintain a minimum number of assigned beneficiaries in each performance year. CMS also considered requiring an incremental increase in opt-in beneficiaries during each performance year for an ACO electing opt-in beneficiary assignment. Under opt-in assignment, beneficiaries could select from all opt-in ACOs without geographic restrictions. **CMS seeks comment as to whether geographic restrictions would be appropriate.**

A hybrid assignment approach could necessitate changes in the revised benchmarking methodology proposed elsewhere in the rule (e.g., to account for health status differences between opt-in and claims-based beneficiaries). CMS analyses suggest that opt-in beneficiaries and voluntarily-aligned beneficiaries resemble beneficiaries for whom claims-based assignments are made and who receive six or fewer primary care services per year. CMS would not alter its approach to benchmark year beneficiary assignment for ACOs electing opt-in assignment but would change its approach to annual risk adjustment of historical benchmark expenditures. Risk adjustment would still begin with categorizing beneficiaries by enrollment type (e.g., ESRD) but the populations assigned to benchmark year (BY) 3 and the applicable performance year (PY) would be further stratified. The PY population would be divided into modified claims-based beneficiaries receiving seven or more primary care services per year and who have not opted in versus beneficiaries who opt in plus those who voluntarily align. The BY3 population would be divided into modified claims-based beneficiaries receiving seven or more primary care services per year versus those receiving six or fewer services. To adjust the historical benchmark expenditures for the population with seven or more primary care services in the benchmark

period, CMS would apply risk ratios comparing the risk scores of the BY3 population with seven or more primary care services to the PY population with seven or more primary care services.

CMS would apply risk ratios comparing the risk scores of the BY3 population with six or fewer primary care services and the risk scores of the performance year opt-in or voluntarily-aligned population to adjust the historical benchmark expenditures for the population with six or fewer primary care services in the benchmark period.

CMS performs benchmark rebasing at the start of each new agreement period. Under the hybrid methodology, CMS would include in the benchmark year's assigned population those beneficiaries who were opted in to the ACO in a prior performance year that equates to a benchmark year for the ACO's new agreement period. Although health status may change over time as an opt-in beneficiary ages, CMS would account for this by using full CMS-HCC risk scores when risk adjusting the rebased historical benchmark. CMS notes considering an alternative approach under which CMS could determine the assigned population for the ACO's rebased benchmark using the program's existing assignment methodology and incorporating opt-in assigned beneficiaries into the benchmark population. In risk adjusting the rebased benchmark each performance year, the BY3 population would be stratified into two groups by numbers of primary care services received (six or fewer versus seven and greater). The performance year population would be stratified into two categories: (1) beneficiaries who are assigned using the modified claims-based assignment methodology, who received seven or more primary care services from ACO professionals, and who have not also opted in to assignment to the ACO; and (2) beneficiaries who opt in and beneficiaries who voluntarily align. Risk ratios would then be applied.

CMS also is considering whether a modified approach to capping CMS-HCC risk scores different from that proposed elsewhere in the rule (i.e., the 3 percent symmetrical cap) would be needed for ACOs choosing opt-in assignment: for PY1, the cap would not be applied while an asymmetrical cap could be used for subsequent performance years (increases in risk scores would be capped but decreases would not). CMS believes that this modification would discourage ACOs from trying to enroll only healthy beneficiaries. Beneficiaries assigned using modified claims and those voluntarily aligned would be subject to the three percent cap. Caps are not applied during rebasing of an ACO's historical benchmark. CMS notes that data are insufficient to fully model the impact of the proposed benchmark adjustments and any behavioral responses.

When establishing an opt-in methodology (hybrid or otherwise), CMS would also plan to establish program integrity requirements similar to those with respect to voluntary alignment. ACOs, their participants, their providers/suppliers and other associates would be prohibited from

1) offering gifts or other remuneration to beneficiaries as inducements to influence opt-in decisions, and 2) directly or indirectly committing any act or omission, or adopting any policy that coerces or otherwise influences a beneficiary's opt-in decision. CMS concludes with a reminder that beneficiaries who opt in to assignment would retain their right to seek care from any Medicare-enrolled provider or supplier of their choosing (including from outside the ACO).

CMS concludes the discussion of potential ways to incorporate elements of an opt-in methodology into the structure of the Shared Savings Program (e.g., by adopting a hybrid methodology) by posing a series of questions/topics upon which comments are being sought. The questions/ topics posed are as follows:

- **Whether CMS should offer ACOs an opportunity to voluntarily choose an alternative beneficiary assignment methodology under which an ACO could elect to have beneficiaries assigned to the ACO based on a beneficiary opt-in methodology supplemented by voluntary alignment and a modified claims-based assignment methodology.**
- **Whether it would be appropriate to establish a minimum threshold number of primary care services, such as seven primary care services, for purposes of using claims to assign beneficiaries to ACOs electing an opt-in based assignment methodology (enabling these ACOs to focus their care coordination efforts on those beneficiaries who have either opted in to assignment to or voluntarily aligned with the ACO, or who are receiving a high number of primary care services from the ACO, and may have complex conditions requiring a significant amount of care coordination).**
- **Whether the minimum threshold for use in determining modified claims-based assignment should be set higher or lower than seven services.**
- **What might be an appropriate methodology for establishing and adjusting an ACO's historical benchmark under an opt-in based assignment methodology.**
- **How to treat opt-in beneficiaries when rebasing the historical benchmark for renewing ACOs.**
- **What other considerations might be relevant to adopting a methodology under which beneficiaries may opt in to assignment to an ACO, including ways to minimize burden on beneficiaries, ACOs, ACO participants, and ACO providers/suppliers and avoid beneficiary confusion.**
- **Whether the existing assignment methodology under subpart E should be discontinued and instead make beneficiary assignment to all ACOs using a hybrid assignment methodology, which would incorporate opt-in-based assignment and the modified claims-based assignment methodology, as well as voluntary alignment.**

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

CMS proposes to change the program's risk adjustment methodology to use CMS-HCC prospective risk score to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries, subject to a symmetrical cap of positive or negative 3 percent for the agreement period, for agreement periods beginning on July 1, 2019, and in subsequent years.

This approach would eliminate the distinction between newly and continuously assigned beneficiaries. With respect to the cap, the risk ratios applied to historical benchmark expenditures to capture changes in health status between benchmark year 3 (BY3) and the performance year would never fall below 0.970 nor be higher than 1.030 for any performance year over the course of the agreement period. Consistent with current policy, risk adjustment calculations would 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 proposes to apply this approach for ACOs participating under the proposed BASIC track and the proposed ENHANCED track.

Table 11 in the proposed rule (reproduced here) provides an illustrative example of how the cap would be applied to the risk ratio used to adjust historical benchmark expenditures to reflect changes in health status between BY3 and the performance year. In this example, the decrease in the disabled risk score and the increase in the aged/dual risk score would both be subject to the positive or negative 3 percent cap. Changes in the ESRD and aged/non-dual risk scores would not be affected by the cap.

TABLE 11—HYPOTHETICAL DATA ON APPLICATION OF AGREEMENT PERIOD CAP ON PY TO BY3 RISK RATIO

Medicare Enrollment Type	BY3 Renormalized CMS-HCC Risk Score	PY Renormalized CMS-HCC Risk Score	Risk Ratio before Applying Cap	Final Risk Ratio
ESRD	1.031	1.054	1.022	1.022
Disabled	1.123	1.074	0.956	0.970
Aged/dual eligible	0.987	1.046	1.060	1.030
Aged/non-dual eligible	1.025	1.001	0.977	0.977

When CMS modeled this approach, it found that among the 239 ACOs that received a demographic risk adjustment for their continuously assigned population, 86 percent would have received a larger positive adjustment to their benchmark had this policy been in place. CMS believes this approach could help reduce the incentive for ACOs to avoid complex patients and perhaps lead to more ACOs willing to accept higher levels of performance-based risk. It also believes that the use of a symmetrical cap (of 3 percent) would allow ACOs to more easily predict their performance. CMS considered alternative levels of the cap, but believed that this level is appropriate and has been tested in the Next Generation ACO model. CMS had concerns that a lower cap would not offer ACOs enough meaningful protection and that too high of a cap would not protect against potential coding initiatives.

CMS seeks comment on its proposal, including the level of the cap.

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 would be 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. Proposals to Apply Regional Expenditures in Determining the Benchmark for an ACO's First Agreement Period

CMS observes 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. As recommended by some commenters, CMS agrees 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 proposes 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 would apply for all agreement periods. The weights applied to the benchmark years, however, would continue to differ for the first agreement period compared with the second or subsequent agreement period. Specifically, CMS would 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 proposes to add a new provision at §425.601 that will describe 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.

b. Proposals for Modifying the Regional Adjustment

CMS expresses concern 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 expresses 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 is 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 proposes 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.

First, CMS proposes 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 third or subsequent time. If the ACO's historical spending is higher than its region, the regional adjustment would range from 25 percent the first time the regional adjustment is applied to a maximum of 50 percent for the third or subsequent years. 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 time	Weight of 35 percent	Weight of 25 percent
Second time	Weight of 50 percent	Weight of 35 percent
Third or subsequent time	Weight of 50 percent	Weight of 50 percent

CMS clarifies two points related to the proposed schedule of weights. First, CMS would use the same set of weights as was used for the first performance year in the agreement period in calculating an adjusted benchmark for an ACO that makes changes to its ACO participant list or assignment methodology for the second or subsequent performance year. CMS also clarifies what regional adjustment weight would apply for renewing or re-entering ACOs. For example, if an ACO had terminated during its second agreement period (under the current benchmarking methodology) and subsequently re-enters the program, the ACO would continue to face a weight of 35 or 25 percent until the start of the subsequent agreement period.

CMS also proposes 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 would be calculated and applied by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) and would apply for both positive and negative adjustments. CMS believes capping the amount of regional adjustment at this level would continue to provide meaningful reward for ACOs that are efficient relative to their region, while reducing potential windfall gains for the ACOs with the lowest relative costs.

Table 12 in the proposed rule (reproduced below) provides an illustrative example of how the final adjustment would be determined. In this example, the ACO's positive adjustment for ESRD would be constrained by the cap because the uncapped adjustment exceeds 5 percent of the national assignable FFS expenditure for the ESRD population.

Table 12 – 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

CMS also considered an alternative approach under which the cap would be applied at the aggregate level rather than at the Medicare enrollment type level. In this case, CMS would have a single aggregate regional adjustment rather than four adjustments by Medicare enrollment type. CMS favors imposing separate caps by Medicare enrollment type because it aligns with its current benchmark calculations.

CMS seeks comment on its proposals, as well as the alternative capping methodology considered. CMS is also seeking comment on the proposed timeline for application of these proposals.

c. Proposals for 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 proposes 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 would 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 would calculate a weighted average of national FFS and regional trend factors, where the weight assigned to the national component would represent the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO. The weight assigned to the regional component would be equal to 1 minus the national weight. As an ACO's penetration in its region increases, a higher weight would 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 component are defined as follows:

- The national component of the national-regional blend would 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 would 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 enrollment 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 inputs into the following formula:

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 would receive a higher weight than the national component and that the overall impact of this proposed policy on benchmarks would be small.

CMS also discusses two other alternatives: (1) an approach that would incorporate national trends at the county level instead of at the regional service area level (national-county blend); and (2) an approach that would simply replace regional trend and update factors with national factors for ACOs above a certain threshold of penetration in their regional service area. CMS has concerns about calculating trends at the county level rather than at the regional level, as it states that results would be less accurate and less transparent to ACOs. With respect to the threshold option, CMS is concerned that this approach would treat ACOs just below the threshold and just above the threshold very differently, even though they may be similarly influencing expenditure trends.

The proposed blended trend and update factors would apply to all agreement periods starting on July 1, 2019 or in subsequent years, regardless of whether it is an ACO's first, second, or subsequent agreement period. CMS includes these new proposed provisions at §425.601, which would govern the determination of historical benchmarks for all ACOs. CMS also makes several technical changes to incorporate references to benchmarking rebasing policies (FR 41894).

CMS seek comment on these proposals, as well as the alternatives considered, including incorporating national trends at the county rather than regional level or using national trend factors for ACOs with penetration in their regional service area exceeding a certain threshold.

E. Updating Program Policies

1. Beneficiary Voluntary Alignment to an ACO (§425.402(e))

Most beneficiaries are assigned annually to an ACO based upon their receipt of primary care services from one or more ACO professionals and/or practitioners of certain designated specialties within that ACO.¹⁶ Alternatively, an ACO-eligible beneficiary¹⁷ may voluntarily align with an ACO by selecting a “primary physician” from those same specialties through MyMedicare.gov. Voluntary alignment supersedes all other ACO assignment methodologies. The Bipartisan Budget Act (BBA) of 2018, however, contains provisions impacting voluntary alignment that CMS now addresses with a series of proposals for performance year 2019 and subsequent performance years.

- A beneficiary would be voluntarily aligned to an ACO by designating a “primary clinician” from that ACO regardless of the physician’s specialty.
- A beneficiary who designates a primary clinician would not be assigned to an ACO (by another methodology) whose professionals do not include that primary clinician.
- A beneficiary would be able to voluntarily align even without receiving any services (including primary care) from a professional within the primary clinician’s ACO during the 12-month assignment window.
- A beneficiary who designates an ACO professional as their primary clinician would remain voluntarily aligned to the ACO in which that clinician participates until such time as the beneficiary changes their primary clinician designation or the ACO’s (initial and any subsequent) Shared Savings Program agreement period ends, even if the beneficiary seeks some or all of their care outside of the ACO (see exception below).
- ACO participants would be required to notify their Medicare Fee-for-Service (FFS) beneficiaries of the option (and the related process) to designate a primary clinician using a CMS-developed template notice; the notice would encourage beneficiaries to periodically check their designations and to update when appropriate (e.g., relocation to a new area).

CMS proposes to create an exception to voluntary alignment using the Innovation Center’s section 1115(A) waiver authority. Voluntary alignment would be overridden when:

- A beneficiary is assigned to an Innovation Center model participant;
- The model’s claims-based assignment is based solely on services other than primary care; and
- The Secretary has determined that the waiver of voluntary alignment is necessary solely for purposes of testing the Innovation Center model.

¹⁶The designated specialties are specified at §425.402(a) and (c). Included are 5 primary care specialties and 19 other specialties as well as nurse practitioners, physician assistants, and clinical nurse specialists.

¹⁷See §425.401 (a); for example, criteria include living within the United States or its territories or possessions.

CMS discusses the rationale for this exception using the Comprehensive ESRD Care Model as an example; the exception falls under the provision that the waiver of voluntary alignment is necessary solely for purposes of testing the Innovation Center model. To communicate with beneficiaries the Innovation Center would notify the affected beneficiaries of their assignments to the model; CMS would post a list of models for which the exception applies on the Shared Savings Program's website; and CMS would share related information with 1-800-MEDICARE. ACO beneficiary assignment reports would also contain information about any voluntary alignment overrides.

CMS seeks comments on the proposed changes in voluntary alignment including using Innovation Center waiver authority to create an exception to voluntary alignment. CMS also invites comments on increasing beneficiary awareness about voluntary alignment and improving the associated electronic primary physician designation process.

2. Primary Care Services Definition (§425.400(c))

As part of implementing ACO beneficiary assignment provisions of the 21st Century Cures Act and BBA 2018 for performance years 2019 and thereafter, CMS proposes to update their definition of primary care services. The most recent revisions were included in the CY 2018 PFS final rule (e.g., adding behavioral health integration services). The proposed update includes adding some existing Current Procedural Terminology (CPT) codes and Healthcare Common Procedure Coding System (HCPCS) G-codes, adding some recently proposed G-codes (if finalized), and refining the identification of primary care services performed in nursing facilities. CMS discusses the existing services and proposed additions in varying degrees of detail and references discussions in prior rules.

Existing CPT and HCPCS G-codes proposed for addition to the definition of primary care services used in ACO beneficiary assignment:

- (1) Advance care planning services (CPT codes 99497 and 99498; See 80 FR 70955-70959)
- (2) Administration of health risk assessment services (CPT codes 96160 and 96161; See 81 FR 80330-80331)
- (3) Prolonged evaluation and management or psychotherapy service(s) beyond the typical service time of the primary procedure (CPT codes 99354 and 99355¹⁸; See CMS MLN Matters <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm5972.pdf>)
- (4) Annual depression screening service (HCPCS code G0444; See <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm7633.pdf>).
- (5) Alcohol misuse screening service (HCPCS code G0442; see reference for item (4))
- (6) Alcohol misuse counseling service (HCPCS code G0443; see reference for item (4))

¹⁸ When either CPT code 99354 or 99355 is billed in conjunction with base code(s) for pscyhotherapy services, the claims for codes 99354 or 99355 would not be included for us in determining beneficiary assignemnt

New HCPCS G-codes proposed for addition to the definition of primary care services used in ACO beneficiary assignment, (if finalized for addition to the CY 2019 PFS¹⁹):

- (1) Complexity/additional resource costs inherent in primary care office visits (GPC1X)
- (2) Complexity inherent in office visits for certain specialties (GCG0X)²⁰
- (3) Prolonged evaluation and management or psychotherapy services (additional 30 minutes) (GPRO1)²¹

G-codes included in primary care services for removal and replacement by CPT codes:

Remove Behavioral health integrations services (HPCPS codes G0502, G0503, G0504 and G0507)

Replace with Behavioral health integration services (CPT codes 99492, 99493, 99494 and 99484, respectively)

CMS concludes by proposing to more accurately identify nursing facility evaluation and management (E/M) services (CPT codes 99304 – 99318) when delivered within skilled nursing facilities (SNFs; Place of Service (POS) code 31). CMS believes that these services when furnished in SNFs represent short-term, rehabilitation-related services, rather than ongoing primary care services; CMS views that only primary care services should be used for ACO beneficiary claims-based assignment. Rather than identifying short-term use of codes 99304 – 99318 by their submission as professional claims that include POS 31, CMS instead proposes to identify short-term (non-primary care use) of codes 99304 – 99318 through SNF facility claims for the same dates of service as the associated professional claims. CMS agrees with stakeholders that the proposed method would more completely and accurately capture those shorter-term SNF E/M services that are not appropriate for use in ACO beneficiary assignment.

CMS seeks comments on the proposed additions to the primary care services list used in the assignment of beneficiaries to ACOs and on the process proposed for more accurate identification of nursing facility E/M services. CMS also invites comments about other potential revisions to the primary care services list for making beneficiary assignments.

3. Extreme and Uncontrollable Circumstances (§425.502 and §425.609 for quality scoring; §§425.605, 425.606, 425.609 and 425.610 for shared loss mitigation)

Background. CMS reviews the many factors (e.g., beneficiary displacement, cost volatility) that could negatively impact the quality and cost performances of ACOs that experience extreme and uncontrollable circumstances (“extreme circumstances”; e.g., 2017 hurricanes and wildfires).

CMS notes having issued an interim final rule with comment period (IFC) in December, 2017 (82 FR 60912), in which policies were adopted to address quality performance scoring and

¹⁹ See 83 FR 35841 through 35844

²⁰ Included specialties are endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or interventional pain management-centered care

²¹ If HCPCS code GPRO1 were billed in conjunction with base code(s) for psychotherapy services, the claims for code GPTO1 would not be included for us in determining beneficiary assignment.

shared loss determinations for Shared Savings Program ACOs experiencing extreme circumstances in 2017. Building upon policies from the IFC, commenter responses to the IFC, and experience gained with IFC implementation for 2017, CMS now proposes policies to manage the effects of disasters on the performances of risk bearing ACOs for performance years 2018 and subsequent years.

Applying Trigger Criteria. For performance year 2018 and later years, CMS proposes to continue using the criteria defined in the IFC as automatic triggering events for the Shared Savings Program's extreme circumstances policy.²² The policy's trigger criteria would continue to be aligned with those applicable to MIPS-eligible clinicians as adopted under the Quality Payment Program (QPP).²³ Once triggered, the extreme circumstances policy would apply to any Shared Savings Program ACO within an affected area if CMS determines that 20 percent or more of an ACO's assigned beneficiaries resided in the affected area and/or the ACO's legal entity was located in the affected area (affected areas are identified at the county level).²⁴ The 20 percent threshold reflects the minimum number of beneficiaries needed for quality reporting by an ACO of minimum required size (5000 beneficiaries). Given operational timelines for various beneficiary assignment list releases, CMS proposes to use the list from which the Web Interface reporting sample is generated as the basis upon which to calculate the 20 percent threshold for applying the extreme circumstances policy. Relatedly, CMS proposes that discretion to determine the time period during which an extreme and uncontrollable circumstance occurred, the percentage of the ACO's assigned beneficiaries residing in the affected areas, and the location of the ACO legal entity, would remain solely with CMS.

ACO Quality Performance Scoring. CMS proposes to apply the following for a performance year in which an ACO is affected by extreme and uncontrollable circumstances:

- Set the ACO's minimum quality score to the mean Shared Savings Program score;
- Use the higher of the mean Shared Savings Program score or the ACO's own score if the ACO is able to completely report all quality measures;
 - If the mean Shared Savings Program score is used, the ACO would not be eligible for bonus points for quality improvement;
 - If the ACO's own score is used, the ACO would be eligible for bonus points for quality improvement; and
- For an ACO receiving the mean Shared Savings Program score during a year, calculate quality improvement for the first post-disaster year by comparing the most recently available ACO-specific, pre-disaster, quality score to the ACO-specific score for the year immediately following the disaster.

²² The extreme and uncontrollable circumstances policy once triggered also applies to the reporting period for the associated performance year, unless the reporting period is extended by CMS for that year.

²³ A Federal Emergency Management Agency (FEMA) major disaster or a public health emergency declared by the Secretary may trigger application of the extreme and uncontrollable circumstances policy, subject to review on a case-by-case basis by CMS.

²⁴ Location of an ACO's legal entity is determined based on the address on file for the ACO in CMS's ACO application and management system.

If proposals in this rule regarding ACO participant agreement start dates are finalized, some ACOs will have 6-month performance periods during 2019. CMS proposes that an ACO with a 6-month reporting period and that is affected by extreme circumstances occurring anytime in 2019 will have its quality scoring based upon all 12 months of 2019 data and will have its assigned beneficiaries identified using the 2019 Web Interface-derived beneficiary assignment list. CMS would then use the higher of the mean Shared Savings Program score or the ACO- specific score as described above.

MIPS APM Scoring Standard. If the proposed BASIC and ENHANCED Shared Savings Program tracks are finalized, CMS anticipates that those tracks will be considered MIPS APMs and the QPP's APM scoring standard would apply to each ACO and their clinicians. Should an ACO be found to be affected by extreme circumstances and cannot report quality performance data for a year, it will receive the mean Shared Savings Program ACO quality score,, and the MIPS quality category performance score would be reweighted to zero for its MIPS-eligible clinicians (for the MIPS-eligible clinicians, revised MIPS category score weights would be assigned: 75 percent for the Promoting Interoperability category and 25 percent for the Improvement Activities category). If the ACO is able to report all quality measures, clinicians would receive the higher of the Shared Savings Program mean quality score or their own ACO's quality score and there would be no MIPS performance category reweighting, (See § 414.137).

Mitigating Shared Losses. Under the Shared Savings Program IFC, CMS established a policy for 2017 that an ACO experiencing extreme and uncontrollable circumstances would have their shared losses, if any, for that year reduced as follows:

$$\begin{aligned} \text{Reduction} = & \text{ Shared Losses} \times (\text{affected months} / \text{total performance year months}) \\ & \times (\text{affected assigned ACO beneficiaries} / \text{total ACO assigned beneficiaries}). \end{aligned}$$

The assigned beneficiary numbers are based upon the 2017 final assignment list. CMS describes a sample calculation for an ACO owing \$100,000 in shared losses experiencing extreme circumstances for 3 months and having 25 percent of assigned beneficiaries residing in affected areas: Reduction = \$100,000 x 0.25 (from 3/12 months) x 0.25 (from 25 percent of beneficiaries affected) = \$6,250. Shared losses owed to CMS would be \$100,000 - \$6,250 = \$93,750.

CMS proposes to extend this reduction calculation formula for performance years 2018 and subsequent years. CMS asserts that this approach appropriately balances the need to hold ACOs accountable for the months in which they did not experience extreme circumstances with the need to offer relief for months in which the ACOs were negatively impacted. For ACOs with a 6-month reporting period who are also affected by extreme circumstances during CY 2019, CMS proposes to: 1) determine shared losses for the ACO over the full calendar year; 2) adjust the ACO's losses for extreme and uncontrollable circumstances as described above; and 3) multiply the remaining shared losses by the portion of the year in which the ACO participated (e.g., multiply shared loss by 0.5 for a 6-month period). (CMS provides a sample calculation for this scenario.) CMS also proposes to apply this approach for affected ACOs that would be liable for a prorated share of losses using full year assigned beneficiary expenditures (e.g., involuntary

termination during CY 2019, as discussed at section II.A.6 of the rule). The extreme circumstances adjustment would be made prior to proration.

CMS notes that the proposed risk mitigation policies would change the payment methodology for 2018 after the year has started, which constitutes a retroactive change in regulation or subregulatory guidance. However, CMS cites section 1871(e)(1)(A)(ii) of the Act, asserting that it would be contrary to the public interest not to propose a mechanism to recognize the potential impacts on ACOs that experience extreme and uncontrollable circumstances in CY 2018. CMS further notes that the proposed policies would not change the Advanced APM status of qualifying ACOs (e.g., Shared Savings Program Tracks 2, 3, and 1+) nor prevent clinicians in those tracks from becoming Advanced APM Qualifying Participants (QPs). Finally, CMS emphasizes that all ACOs would continue to be entitled to any shared savings they achieve, though an ACO's savings could be affected if its quality score was changed by the extreme circumstances policy.

Historical Benchmark Calculations for Affected ACOs. CMS believes that the impacts of extreme and uncontrollable circumstances on expenditures for assigned beneficiaries used to determine an ACO's historical benchmark are unpredictable. CMS invited comments on this topic in the 2017 Shared Savings program IFC. Expenditure increases would later result in higher historical benchmarks for affected years while expenditure decreases would produce lower benchmarks. In considering options to manage possible benchmark effects of extreme circumstances, CMS examined the potential effects of the proposed regional benchmarking factors (See Section II.D.3 of the rule). After conducting a preliminary analysis of data for ACOs in areas affected by extreme circumstances in 2017, CMS concludes that the proposed regional factors would inherently adjust for year-to-year expenditure variations such as might occur related to extreme circumstances and their aftermath. In general, expenditures trends during performance years with disasters fell below projections for affected areas then began to increase after the disaster period ended. (See Section II.E.4.b.3 of the rule for a full discussion of CMS' analysis and reasoning.)

CMS considered whether an adjustment other than regional benchmarking factors was needed to account for expenditure variations. CMS describes an approach to adjust the historical benchmark by reducing the weight of expenditures for disaster area beneficiaries, so that the relative weight of beneficiary expenditures from outside of the disaster area would be increased. This adjustment would be projected to proportionally increase the historical benchmark for an ACO with decreased expenditures while proportionally decreasing the historical benchmark for an ACO with increased expenditures. The portion of expenditures for impacted assigned beneficiaries would be removed from the historical benchmark year(s). CMS believes that a minim threshold of affected beneficiaries would need to be set to avoid frequent but minor adjustments (e.g., 50 percent) and voices concerns about the accuracy of this alternative approach versus the effects that would result from the proposed regional benchmarking factors.

CMS concludes by inviting comments about 1) the necessity to adjust the historical benchmarks for extreme circumstances and appropriate methods to do so, including for benchmark years prior to 2019; 2) the proposals offered for quality and financial

performance adjustments during extreme circumstances; and 3) other effects of extreme circumstances and how they might be addressed.

4. Program Data and Quality Measures

CMS seeks wide-ranging input in the context of two initiatives: 1) Meaningful Measures, designed to achieve a parsimonious set of high-value, outcomes-based measures for beneficiaries across all parts of the Medicare program; and 2) the Opioid Misuse Strategy, describing and organizing the many actions underway targeting the national opioid misuse epidemic.

Meaningful Measures. CMS offers highlights of the Shared Savings Program quality reporting plan since its inception, the most recent being the inclusion of a set of ACO-targeted measure recommendations from the multi-stakeholder, multi-payer Core Quality Measures Collaborative (see 81 FR 80484-80489). CMS notes that more than half of the current 31 Shared Savings Program quality measures are outcomes-based, including patient-reported and intermediate outcomes as well as outcomes reflecting care coordination and effective communication (e.g., CAHPS for ACOs Survey²⁵; hemoglobin A1c control for diabetics; and unplanned readmissions, respectively). CMS characterizes ACO measures that align with other Medicare program initiatives and measures of other payers as high priority measures for reporting under the ACO quality programs. **CMS seeks comments, including new and more meaningful measures, particularly those that would advance ACO quality reporting by setting higher standards.**

Medicare Program Data and the Opioid Misuse Strategy. CMS notes that the Medicare program has become the largest payer for prescription opioids in the United States, and that opioid misuse and abuse increase adverse beneficiary events both from intrinsic opioid drug effects and opioid interactions with the several other medications typically taken by most beneficiaries. Consistent with the Opioid Misuse Strategy, CMS is 1) focusing on identifying relevant interventions applicable to ACOs (and the entire Medicare program) that could be developed through sharing of Part D data with ACOs; and 2) considering adding new ACO quality measures targeting appropriate opioid use.

CMS notes that ACOs currently receive Part D prescription drug event data as part of their monthly claims reports from CMS. CMS provides results of Part D data event analyses that show the following:

- Roughly 70 percent of Shared Savings Program ACO-assigned beneficiaries had continuous Part D coverage;
- Approximately 35 percent of ACO beneficiaries with continuous coverage had at least one opioid prescription, and the rates across ACOs ranged from 10-60 percent; and
- Opioid prescriptions filled per month per assigned beneficiary with continuous coverage varied substantially across ACOs (mean of 2.1 and a range of 0.3-4.5).

²⁵ The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for ACOs includes items like Health Status & Functional Status, Shared Decision-Making, and Access to Specialists, reflected in measures ACO 1-7.

CMS seeks suggestions for other aggregate opioid use data that would be helpful if provided to ACOs to prevent misuse and to coordinate care for misuse (e.g., frequency of concomitant use of opioids and benzodiazepines). CMS also invites comments on opioid- related measures for addition to the ACO quality measure set, especially measures for which data are readily available (including from Part D) and that align with other opioid- related measures. CMS notes the following measures to be already under consideration:

- NQF #2940 Use of Opioids at High Dosage in Persons Without Cancer;
- NQF #2950 Use of Opioids from Multiple Providers in Persons Without Cancer; and
- NQF #2951 Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer.

5. Promoting Interoperability through the ACO CEHRT Usage Requirement
(§§414.1415, 425.20, 425.204, 425.302, and 425.506)

CMS provides highlights of legislation and prior rules that focus on interoperable access, exchange, and use of health information (e.g., 21st Century Cures Act). Shared Savings Program ACOs already are required by the Act to promote the use of enabling technologies (e.g. electronic health records) for care coordination. Since 2012, ACOs have reported measure

ACO-11 Use of Certified Electronic Health Record Technology (CEHRT), allowing tracking of CEHRT usage by ACO clinicians. All ACO MIPS-eligible clinicians must submit data into the Promoting Interoperability (formerly Advancing Care Information) QPP performance category. Shared Savings Program ACOs that are also Advanced APMs (e.g., Track 3 ACOs) receive rewards or are penalized depending upon their CEHRT usage levels. CMS further points out that non-ACO APMs must also demonstrate substantial CEHRT usage to satisfy one of the criteria that APMs are required to meet under the QPP to qualify as Advanced APMs. CMS adds that the CY 2019 PFS proposed rule calls for required CEHRT usage by Advanced APM professionals to increase for performance year 2019 (and subsequent years) to 75 percent from 50 percent. Against that background, to further increase Shared Savings Program and QPP alignment, CMS proposes the following changes for ACOs beginning January 1, 2019:

- To be eligible to participate in the Shared Savings Program, an ACO would have to demonstrate a specified level of CEHRT usage.
- To be eligible to participate in an ACO track that also meets the Advanced APM financial criterion (a specified level of two-sided risk), an ACO would have to certify a CEHRT usage level that meets or exceeds the level that is required to qualify as an Advanced APM under the QPP.
- To be eligible to participate in an ACO track that does not meet the Advanced APM financial criterion, an ACO still would be required to certify annually that at least 50 percent of the ACO's eligible clinicians use CEHRT.
 - This requirement is consistent with CEHRT usage as mandated for other Innovation Center models and tracks that are not Advanced APMs under the QPP (e.g., the one- sided risk track of the Oncology Care Model).
- To apply the QPP definition of CEHRT for purposes of the Shared Savings Program to ACOs that are also Advanced APMs, including future updates to the definition (e.g., increasing CEHRT levels for 2019).

- CMS considered requiring the new higher level for all ACOs.
- To retire the ACO-11 quality measure from the Shared Savings Program measure set if the new CEHRT eligibility requirements are finalized as proposed.
 - There would be no impact on any related provisions of the MIPS Promoting Interoperability performance category standards.
 - CMS would remove the existing separate reward/penalty criterion for ACO CEHRT use as being no longer necessary once the QPP and ACO requirements are aligned.
- To update the definition of CEHRT to reflect the other proposed changes and to incorporate the definition of “eligible clinician” into the Shared Savings Program.

CMS states that average Shared Savings Program ACO-11 performance is well over 50 percent already. **CMS seeks comments on the proposed CEHRT usage changes and their start date, as well as whether all ACOs (not just those in Advanced APM tracks) should be required to meet a CEHRT standard greater than 50 percent. CMS solicits comments about removing measure ACO-11 from the Shared Savings Program and removing the separate ACO penalty/reward criterion regarding CEHRT use.**

6. Pharmacy Care Coordination: Comment Requests

CMS seeks comments on how Medicare ACOs, specifically Shared Savings Program ACOs, and Part D sponsors could work together and be encouraged to improve the coordination of pharmacy care for Medicare FFS beneficiaries.

CMS believes that collaboration between ACOs and Part D stand-alone prescription drug plan (PDP) sponsors could lead to improved (and clinically appropriate) formulary compliance by clinicians, enhanced delivery of pharmacist counseling services to patients, and more widespread implementation of medication therapy management. Increased medication adherence by patients with chronic conditions may improve outcomes; increased generic drug prescribing might lower costs for beneficiaries and Medicare; and increased communication between prescribers and pharmacists could reduce medication-related errors.

CMS seeks comments on ways to support innovative business arrangements to financially reward plan sponsors for related better beneficiary outcomes.

CMS notes that all arrangements would need to comply with all applicable laws and regulations. CMS indicates that ACOs already are given some prescription drug event data routinely by CMS, and believes that increased, HIPAA-compliant data sharing between ACOs and plan sponsors could facilitate care coordination.

CMS requests information about existing ACO partnerships with plan sponsors, barriers to partnership formation encountered, and ways for CMS to assist in reducing barriers and enabling data-sharing.

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

1. Overview

The Track 1+ model was established by the Innovation Center to offer an ACO option for bearing two-sided risk at a lower potential loss level than required by Shared Savings Program Tracks 2 and 3.²⁶ The model was also designed to meet criteria to qualify as an Advanced APM. ACOs approved by CMS for participation executed Track 1+ model-specific agreements and began operations on January 1, 2018. First round participants include 55 ACOs from Track 1: 20 who began new 3-year agreements and 35 who converted their remaining Track 1 agreement periods to be completed instead under Track 1+ terms.

2. Future Track 1+ Model Application Cycles

The Track 1+ model was designed with application cycles for new or renewed participation agreements to occur in 2018, 2019, and 2020. Cycles were to be aligned with those of the Shared Savings Program, and the 2018 Track 1+ application cycle has closed. Concomitantly with the proposed restructuring of the Shared Savings Program's tracks (described previously in section II.A.7 of the rule), CMS has not offered an application cycle for Track 1+ participation to begin on January 1, 2019, as the proposed Shared Savings Program BASIC track Level E replicates many of the elements of the Innovation Center's Track 1+ model. If the proposed Shared Savings Program track changes are finalized, CMS would not offer an application cycle for Track 1+ participation to begin on January 1, 2020. Existing Track 1+ ACOs would be able to complete their existing agreement periods under the Track 1+ model; alternatively, they could terminate their Track 1+ agreements and apply to enter new Shared Savings Program agreements under the BASIC track Level E or the ENHANCED track.²⁷ CMS believes that coexistence of the Track 1+ model and BASIC track Level E would be unnecessarily redundant. CMS states that BASIC track Level E incorporates lessons learned from its experiences to date with Track 1+ (e.g., repayment arrangement mechanism structure).

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

Under Track 1+ agreements, the requirements of the Shared Savings Program under 42 CFR part 425 apply unless specifically stated otherwise. CMS notes also that 1) Track 1+ ACOs are subject to all applicable regulatory changes unless otherwise specified through rulemaking or amendment to the Track 1+ Model Participation Agreement,²⁸ and 2) the Track 1+ Model Participation Agreement permits CMS and the ACO to amend the agreement at any time by mutual written agreement. CMS discusses selected proposals of the rule that would apply to

²⁶ The Track 1+ model builds on elements of the Shared Savings Program, including Tracks 2 and 3 of the Program. However, Track 1+ is a time-limited Innovation Center model, not a track within the Shared Savings Program.

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.

²⁷ The new agreement's track option selection would depend upon whether the ACO meets criteria as a low-revenue or high-revenue organization, as previously described in Section II.A.5 of the rule.

²⁸ Some elements of the Track 1+ model agreement were taken from Shared Savings Program Track 2 or Track 3. Regulations (and changes thereto) applicable to those elements also apply to the Track 1+ model.

Track 1+ model ACOs if finalized, including proposals that would require amending ACO participation agreements. CMS provides a more extensive applicable policy list in Table 13 of the rule, reproduced at the end of this section.

Repayment Mechanism Requirements. The proposed changes at §425.204(f)(4) that address calculating the repayment mechanism amount would apply with the effective date of the final rule. No other changes to the repayment mechanism arrangements would be required. CMS would permit those Track 1+ ACOs seeking to renew their agreements through participation in one of the proposed Shared Savings Program two-sided risk tracks, to continue to use their existing repayment mechanism arrangements, as long as arrangement amounts and duration are updated as specified by CMS.

Beneficiary Voluntary Alignment. Proposals regarding notification of beneficiaries about their options for voluntary alignment, including a standardized written notice provided at the first primary care visit of each performance year, would apply beginning July 1, 2019, and for subsequent performance years (Section II.C.3.a.2 of the rule). Other revisions regarding voluntary alignment (e.g., allowing the voluntarily designated “primary clinician” to be of any specialty) would be applicable beginning January 1, 2019, and for subsequent performance years (Section II.E.2 of the rule).

Primary Care Services and Beneficiary Assignment. Proposed revisions to the definition of primary care services (e.g., addition of behavioral health integration services) as used for the purpose of claims-based beneficiary assignment would apply to performance years beginning January 1, 2019, and subsequent years (Section II.E.3.b of the rule).

ACO-11 Measure Retirement. The ACO-11 measure concerning ACO practitioner use of CEHRT would be retired. The ACO would be required to attest during application and at each annual certification that a specified percentage of the ACO’s MIPS-eligible clinicians are using CEHRT to document and communicate clinical care (Section II.E.6 of the rule).

CMS further states their desire to apply the following proposed policies (if finalized) to Track 1+ ACOs. To do so, however, the Track 1+ Model Participation Agreement between CMS and each ACO would require amendment.

Financial Performance for All Track 1+ ACOs. Proposed policies regarding monitoring for and consequences of poor financial performance (section II.A.5.d); revising the MSR/MLR to address small population sizes (section II.A.6.b.3); and payment consequences of early termination for ACOs under performance-based risk (section II.A.6.d) would be applicable for performance years beginning in 2019 and later.

Financial Performance for Selected Track 1+ ACOs (ACOs that started a first or second Shared Savings Program participation agreement on January 1, 2016, and entered the Track 1+ Model on January 1, 2018, and that elect to extend their Shared Savings Program participation agreement for the 6-month performance year from January 1, 2019 through June 30, 2019). The ACO would be required to extend its repayment mechanism to end 24 months after the end of the agreement period (June 30, 2021) (Section II.A.7 of the rule). Performance for the 6-month

period from January 1, 2019 through June 30, 2019, would be determined using the approach proposed at new §425.609(b) and applying the shared loss calculation methodology as specified in the Track 1+ Model Participation Agreement (Section II.A.6.c of the rule). CMS would continue to share aggregate report data for the entirety of calendar year 2019 with each ACO (Section II.A.7.c of the rule).

CEHRT Use and Advanced APM Status. ACOs would be required to certify annually that the percentage of their MIPS-eligible clinicians participating in the ACO that use CEHRT (to document and communicate clinical care) meets or exceeds the higher of 50 percent or the threshold established under §414.1415(a)(1)(i) to qualify as an Advanced APM (section II.E.6 of the rule).

Extreme and uncontrollable circumstances. Shared losses for performance year 2018 and subsequent years for Track 1+ ACOs located in areas affected by extreme and uncontrollable circumstances would be determined as outlined in the policies proposed in sections II.E.4 and II.A.7.c.5 of the rule.

Telehealth. The BBA of 2018 allows ACOs that meet certain criteria to expand their use of telehealth services. The beneficiary's home may serve as an originating site and the usual geographic limitations are eliminated. Track 1+ ACOs meet the telehealth expansion criteria, and CMS proposes to apply a uniform set of related regulations to Track 1+ ACOs as well as across all Shared Savings Program ACOs beginning with performance year 2020 (section II.B.2.b of the rule).

NOTE: Table 13 from the rule will follow here without changes other than formatting

G. Summary of Timing of Proposed Applicability

CMS provides a summary of policies and their applicability dates in Table 13 (reproduced below from the rule). When a provision is described as applicable to a performance year (PY) or agreement period, activities related to implementation of the policy may precede the start of the performance year or agreement period.

Table 13 – Applicability Dates of Select Provisions of the Finale Rule

Preamble	Section Title/Description	Applicability Date
II.A.2.	Availability of an additional participation option under a new BASIC track (including glide path) under an agreement period of at least 5 years ; Availability of Track 3 as the ENHANCED track under an agreement period of at least 5 years.	Agreement periods starting on or after July 1, 2019.
II.A.2.	Discontinuing Track 1 and Track 2.	No longer available for applicants for agreement periods starting in 2019 and subsequent years.
II.A.2.	Discontinuing deferred renewal option.	No longer available for renewal applicants for agreement periods starting in 2019 and subsequent years.
II.A.4.b.	Permitting annual election of differing levels of risk and potential reward within the BASIC track's glide path.	Performance year beginning on July 1, 2019, and subsequent years for eligible ACOs.
II.A.4.c.	Permitting annual election of beneficiary assignment methodology for ACOs in BASIC track or ENHANCED track.	Performance year beginning on July 1, 2019, and subsequent years.
II.A.5.c.	Evaluation criteria for determining participation options based on ACO participants' Medicare FFS revenue, ACO legal entity and ACO participant experience with performance-based risk Medicare ACO initiatives, and prior performance (if applicable).	Agreement periods starting on or after July 1, 2019.
II.A.5.d.2.	Monitoring for financial performance.	Performance years beginning in 2019 and subsequent years.

II.A.6.b.2.	Timing of election of MSR/MLR.	Agreement periods starting on or after July 1, 2019.
II.A.6.b.3.	Modifying the MSR/MLR to address small population sizes.	Performance years beginning in 2019 and subsequent years.
II.A.6.c.3.	Annual recalculation of repayment mechanism amounts.	Agreement periods starting on or after July 1, 2019.
II.A.6.d.	Payment consequences of early termination for ACOs under performance-based risk.	Performance years beginning in 2019 and subsequent years.
II.A.7	Participation options for agreement periods beginning in 2019	January 1, 2019 effective date for extension of existing agreement period for a 6-month fourth performance year, if elected by ACOs that started a first or second agreement period on January 1, 2016. One-time, July 1, 2019 agreement start date; 6- month first performance year.
II.B.2.a.	Availability of the SNF 3-day rule waiver for eligible ACOs under performance-based risk under either prospective assignment or preliminary prospective assignment.	July 1, 2019 and subsequent performance years, for eligible ACOs applying for, or currently approved for, a SNF 3-day rule waiver. Not available to Track 2 ACOs.
II.B.2.a.	Eligible CAHs and hospitals operating under a swing-bed agreements permitted to partner with eligible ACOs as SNF affiliates.	July 1, 2019, and subsequent performance years.
II.B.2.b	Telehealth services furnished under section 1899(l).	Performance year 2020 and subsequent years for services furnished by physicians and practitioners billing through the TIN of an ACO participant in an applicable ACO.
II.C.2	Implementation of approved beneficiary incentive programs.	July 1, 2019, and subsequent performance years
II.C.3.a.2.	New content and timing for beneficiary notifications.	Performance year beginning on July 1, 2019, and subsequent years.

II.D.2.b.	Benchmarking Methodology Refinements: Risk adjustment methodology for adjusting historical benchmark each performance year.	Agreement periods starting on or after July 1, 2019.
II.D.3.b.	Benchmarking Methodology Refinements: Application of regional factors to determine the benchmark for an ACO's first agreement period.	Agreement periods starting on or after July 1, 2019.
II.D.3.c.	Benchmarking Methodology Refinements: Modifying the regional adjustment.	Agreement periods starting on or after July 1, 2019.
II.D.3.d.	Benchmarking Methodology Refinements: Modifying the methodology for calculating growth rates used in establishing, resetting, and updating the benchmark.	Agreement periods starting on or after July 1, 2019.
II.E.2	Modifications to voluntary alignment requirements.	Performance years beginning in 2019 and subsequent years.
II.E.3	Revisions to the definition of primary care services used in beneficiary assignment.	Performance years beginning in 2019 and subsequent years.
II.E.4	Extreme and uncontrollable circumstances policies for the Shared Savings Program.	Performance year 2018 and subsequent years.
II.E.6	Addition of an interoperability criterion (use of CEHRT) to determine eligibility for program participation.	Performance years beginning in 2019 and subsequent years.
II.E.6	Discontinued use of quality measure ACO-11.	Performance years beginning in 2019 and subsequent years.

III. Regulatory Impact

A. Statement of Need

CMS states that this proposed 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 proposed 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 proposed rule would redesign 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).²⁹ A regulatory impact analysis (RIA) must be prepared 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 being proposed to the MSSP could result in a range of possible outcomes. CMS proposes additions to or changes in policy that are intended to better encourage ACO participation in performance based risk-based models and generated savings to the Medicare

²⁹ Impacts 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 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)).

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.

As shown in Table 17 of the proposed rule (reproduced below), CMS estimates that changes being proposed would result in approximately \$2.24 billion in lower overall federal spending over 10 years from 2019 through 2028.³⁰ The 10th and 90th percentile from the range of projected 10-year impacts range from -\$4.43 billion in lower spending to \$0.09 billion in higher spending, respectively. CMS states that the relatively small increases in spending in years 2019 through 2021 (+\$310 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 in

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 2 years in the BASIC track (less attractive because of a lower 25 percent maximum sharing rate for these years).

Table 17—10-Year Estimated Impact of Proposed 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	-20	60	60	120	0	120
2020	-33	80	40	120	0	120
2021	-49	50	20	70	0	70
2022	-29	20	-150	-130	70	-60
2023	-17	-40	-200	-240	130	-110
2024	-21	-110	-160	-280	220	-60
2025	-90	-160	-290	-450	0	-450
2026	-109	-190	-400	-590	30	-560
2027	-107	-150	-500	-650	0	-650
2028	-109	-80	-570	-650	-10	-660
10-Year Total		-510	-2,170	-2,680	440	-2,240
Low (10 th percentile)		-2,140	-4,310	-4,840	110	-4,430
High (90 th percentile)		1,040	270	-440	740	90

³⁰CMS uses a stochastic or simulation model to estimate the impact of the proposed policies.

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 proposed changes would provide additional incentive for ACOs to improve care management efforts and maintain program participation. Beneficiaries could 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 would benefit from a reduction of Part B premium payments, estimated savings of \$310 million over the 10-year projection period through 2028.

3. Effect on Providers and Suppliers

CMS notes that it believes the contemptuous growth of ACO agreements with other payers is sufficiently mature that it would not be materially affected by the proposed changes to the MSSP. **CMS seeks comment on this issue if stakeholder disagree.** CMS acknowledges that the proposed changes ultimately may 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 CMS proposes (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 proposed changes to the methodology for making regional adjustments should broaden the mix of ACOs with plausible business cases without creating excessive residual windfalls payment to ACOs with very low baseline cost. Other improvements that CMS cite 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 proposed 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 proposed rule, such as the proposal to allow low revenue ACOs up to 2

agreement periods in the BASIC track may encourage participation by small entities. Total expected incentive payments to Qualifying APM participants are expected to increase by \$440 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 seeks comments from small rural hospitals on the proposed changes with special focus on the impact of the proposed changes to the adjustment to the benchmark to reflect regional FFS expenditures.**

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 proposed 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 proposed regulation is approximately \$361,500 for the 561 ACOs. This assumes 6 hours to review half of the proposed rule at a cost of \$107.39 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 ACOs (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 assuming all proposed changes are adopted, the stochastic model was also adapted to isolate marginal impacts for several alternative scenarios related to individual proposals within the overall set of proposed 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 proposed rule by roughly \$5 billion such that the estimate \$2.24 billion savings relative to current regulations would instead be projected as a \$2.75 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 a relatively small impact – reduces overall Federal spending by an additional \$100 million relative to the estimated \$2.24 billion reduction in spending estimates for the proposal to offer a July 1, 2019 start date.

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 -199.8 million annually (reflecting a reduction in federal net cost), calculated at a discount rate of 3 percent.³¹ These estimates are based on estimates of provisions of the proposed rule as compared to baseline.

³¹ 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.