DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 425

[CMS–1701–F2 and CMS–1702–F]

RINs 0938–AT45 and 0938–AT51

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

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rules.

SUMMARY: Under the Medicare Shared Savings Program (Shared Savings Program), providers of services and suppliers that participate in an Accountable Care Organization (ACO) continue to receive traditional Medicare fee-for-service (FFS) payments under Parts A and B, but the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements. The policies included in this final rule provide a new direction for the Shared Savings Program by establishing pathways to success through redesigning the participation options available under the program to encourage ACOs to transition to two-sided models (in which they may share in savings and are accountable for repaying shared losses). These policies are designed to increase savings for the Trust Funds and mitigate losses, reduce gaming opportunities, and promote regulatory flexibility and free-market principles. This final rule also provides new tools to support coordination of care across settings and strengthen beneficiary engagement; and ensure rigorous benchmarking.

In this final rule, we also respond to public comments we received on the extreme and uncontrollable circumstances policies for the Shared Savings Program that were used to assess the quality and financial performance of ACOs that were subject to extreme and uncontrollable events, such as Hurricanes Harvey, Irma, and Maria, and the California wildfires, in performance year 2017, including the applicable quality data reporting period for performance year 2017.

DATES: *Effective Date:* This rule is effective February 14, 2019.

Applicability Dates: In the **SUPPLEMENTARY INFORMATION** section of this final rule, we provide a table (Table 1) which lists key changes in this final rule that have an applicability date other than the effective date of this final rule.

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SUPPLEMENTARY INFORMATION: Table 1 lists key changes that have an applicability date other than 60 days after the date of publication of this final rule. By indicating that a provision is 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.

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TABLE 1—APPLICABILITY DATES OF SELECT PROVISIONS OF THE FINAL RULE

Preamble Section	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 year beginning on July 1, 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 year beginning on July 1, 2019, and subsequent years.
II.A.6.c.(2).	Annual recalculation of repayment mechanism amounts.	Agreement periods starting on or after July 1, 2019.

Preamble Section	Section Title/Description	Applicability Date
II.A.6.d.	Payment consequences of early termination for ACOs under performance-based risk.	Performance year beginning on July 1, 2019, and subsequent years.
II.A.7.	Participation options for agreement periods beginning in 2019	One-time, July 1, 2019 agreement start date; 6-month first performance year from July 1, 2019, through December 31, 2019.
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.

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I. Executive Summary and Background

A. Executive Summary

1. Purpose

In August 2018 we issued a proposed rule, titled ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success'' (hereinafter referred to as the ''August 2018 proposed rule''), which appeared in the **Federal Register** on August 17, 2018 (83 FR 41786). On November 1, 2018, we issued a final rule, titled ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program—Accountable Care Organizations—Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act'' (hereinafter referred to as the ''November 2018 final rule''), that appeared in the **Federal Register** on November 23, 2018 (83 FR 59452). In the November 2018 final rule, we finalized certain policies from the August 2018 proposed rule in order to ensure continuity of participation, and finalize time-sensitive program policy changes for currently participating ACOs. We also finalized provisions to streamline the ACO core quality measure set to reduce burden and encourage better outcomes, which we proposed in the proposed rule for the CY 2019 PFS, entitled Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program; Proposed Rule (83 FR 35704). This final rule addresses the remaining policies from the August 2018 proposed rule that were not addressed in the November 2018 final rule.

Since the Medicare Shared Savings Program (Shared Savings Program) was established in 2012, CMS has continued to monitor and evaluate program results to look for additional ways to streamline program operations, reduce burden, and facilitate transition to risk that promote a competitive and accountable marketplace, while improving the quality of care for Medicare beneficiaries. This final rule makes changes to the regulations for the Shared Savings Program that were promulgated through rulemaking between 2011 and 2017, and are codified in 42 CFR part 425. The changes in this final rule are based on the additional program experience we have gained and on lessons learned from testing of Medicare ACO initiatives by the Center for Medicare and Medicaid Innovation (Innovation Center). As we implement these changes, we will continue to monitor the program's ability to reduce healthcare spending and improve care quality, including whether the program provides beneficiaries with the value and choice demonstrated by other Medicare options such as Medicare Advantage (MA), and will use the results of this monitoring to inform future development of the program. This rule also finalizes changes to address new requirements of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) (herein referred to as the Bipartisan Budget Act).

In December 2017, we issued an interim final rule with comment period, titled ''Medicare Shared Savings Program: Extreme and Uncontrollable Circumstances Policies for Performance Year 2017'' (hereinafter referred to as the ''December 2017 interim final rule with comment period''), which appeared in the **Federal Register** on December 26, 2017 (82 FR 60912). The December 2017 interim final rule with comment period established policies for assessing the financial and quality performance of Shared Savings Program ACOs that were affected by extreme and uncontrollable circumstances during performance year 2017, including the applicable quality reporting period for performance year 2017. This final rule includes an analysis of and responses to comments received on the December 2017 interim final rule with comment period.

Section 1899 of the Social Security Act (the Act) established the Medicare Shared Savings Program, which promotes accountability for a patient population, fosters coordination of items and services under Medicare Parts A and B, encourages investment in infrastructure and redesigned care processes for high quality and efficient health care service delivery, and promotes higher value care. The Shared Savings Program is a voluntary program that encourages groups of doctors, hospitals, and other health care providers to come together as an ACO to lower growth in expenditures and improve quality. An ACO agrees to be held accountable for the quality, cost, and experience of care of an assigned Medicare FFS beneficiary population. ACOs that successfully meet quality and savings requirements share a percentage of the achieved savings with Medicare.

Shared Savings Program ACOs are an important innovation for moving CMS' payment systems away from paying for volume and towards paying for value and outcomes because ACOs are held accountable for spending in relation to a historical benchmark and for quality performance, including performance on outcome and patient experience measures. The program began in 2012, and as of January 2018, 561 ACOs were participating in the program and serving over 10.5 million Medicare FFS beneficiaries. (See the Medicare Shared Savings Program website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/* for information about the program, the program's statutory authority, regulations and guidance, the program's application process, participating ACOs, and program performance data.)

The Shared Savings Program currently includes three financial models that allow ACOs to select an

arrangement that makes the most sense for their organization. The vast majority of Shared Savings Program ACOs, 82 percent in 2018,[1] have chosen to enter and maximize the allowed time under a one-sided, shared savings-only model (Track 1), under which eligible ACOs receive a share of any savings under their benchmark, but are not required to pay back a share of spending over the benchmark. In comparison, there is relatively low participation in the program's two-sided, shared savings and shared losses models, under which eligible ACOs share in a larger portion of any savings under their benchmark, but are required to share losses if spending exceeds the benchmark. Participation in Track 2 (introduced at the start of the program in 2012) has slowly declined in recent years, particularly following the availability of Track 3 (beginning in 2016), although participation in Track 3, the program's highest-risk track, remains modest.

Recently, the Innovation Center designed an additional option available to eligible Track 1 ACOs, referred to as the Track 1+ Model, to facilitate ACOs' transition to performance-based risk. The Track 1+ Model is a time-limited model that began on January 1, 2018, and is based on Shared Savings Program Track 1, but tests a payment design that incorporates more limited downside risk, as compared to Track 2 and Track 3. Our early experience with the design of the Track 1+ Model demonstrates that the availability of a lower-risk, two-sided model is an effective way to encourage Track 1 ACOs (including ACOs within a current agreement period, initial program entrants, and renewing ACOs) to progress more rapidly to performance-based risk. Fifty-five ACOs entered into Track 1+ Model agreements effective on January 1, 2018, the first time the model was offered. These ACOs represent our largest cohort of performance-based risk ACOs to date.

ACOs in two-sided models have shown significant savings to the Medicare program while advancing the quality of care furnished to FFS beneficiaries; but, the majority of ACOs have yet to assume any performance-based risk although they have the ability to benefit from waivers of certain federal requirements in connection with their participation in the Shared Savings Program. Even more concerning is the finding that for performance years beginning in 2012 through 2016, one-sided model ACOs, which are not accountable for sharing in losses, actually increased Medicare spending relative to their benchmarks under the program's financial methodology. Further, the presence of an ''upside-only'' track may be encouraging consolidation in the marketplace, reducing competition and choice for Medicare FFS beneficiaries. While we understand that systems need time to adjust, Medicare cannot afford to continue with models that are not producing desired results.

Our results to date have shown that ACOs in two-sided models perform better over time than one-sided model ACOs, low revenue ACOs, which are typically physician-led, perform better than high revenue ACOs, which often include hospitals, and the longer ACOs are in the program the better they do at achieving the program goals of lowering growth in expenditures and improving quality. For example, in performance year 2016, about 68 percent of Shared Savings Program ACOs in two-sided models (15 of 22 ACOs) shared savings compared to 29 percent of Track 1 ACOs; 41 percent of low revenue ACOs shared savings compared to 23 percent of high revenue ACOs; and 42 percent of April and July 2012 starters shared savings, compared to 36 percent of 2013 and 2014 starters, 26 percent of 2015 starters, and 18 percent of 2016 starters. Shortly after the August 2018 proposed rule was announced, CMS made publicly available performance year 2017 results that showed similarities to 2016. In performance year 2017, 51 percent of Shared Savings Program ACOs in two-sided models (20 of 39 ACOs) shared savings compared to 33 percent of Track 1 ACOs; 44 percent of low revenue ACOs shared savings compared to 28 percent of high revenue ACOs; and 51 percent of April and July 2012 starters shared savings, compared to 43 percent of 2013 and 2014 starters, 28 percent of 2015 and 2016 starters, and 21 percent of 2017 starters.

In the August 2018 proposed rule, we explained our belief that additional policy changes to the Shared Savings Program and its financial models are required to support the move to value, achieve savings for the Medicare program, and promote a competitive and accountable healthcare marketplace. Accordingly, we proposed to redesign the Shared Savings Program to provide pathways to success in the future through a combination of policy changes, informed by the following guiding principles:

- Accountability—Increase savings for the Medicare Trust Funds, mitigate losses by accelerating the move to two-sided risk by ACOs, and ensure rigorous benchmarking.
- Competition—Promote free-market principles by encouraging the development of physician-only and rural ACOs in order to provide a pathway for physicians to stay independent, thereby preserving beneficiary choice.
- Engagement—Promote regulatory flexibility to allow ACOs to innovate and be successful in coordinating care, improving quality, and engaging with and incentivizing beneficiaries to achieve and maintain good health.
- Integrity—Reduce opportunities for gaming.
- Quality—Improve quality of care for patients with an emphasis on promoting interoperability and the sharing of healthcare data between providers, focusing on meaningful quality measures, and combatting opioid addiction.

In the August 2018 proposed rule, we explained that the need for a new approach or pathway to transition Track 1 ACOs to performance-based risk is particularly relevant at this time, given the current stage of participation for the initial entrants to the Shared Savings Program under the program's current design. The program's initial entrants are nearing the end of the time allowed under Track 1 (a maximum of two, 3-year agreement periods). Among the program's initial entrants (ACOs that first entered the program in 2012 and 2013), there are 82 ACOs that would be required to renew their participation agreements to enter a third agreement period beginning in 2019, and they face transitioning from a one-sided model to a two-sided model with significant levels of risk that some are not prepared to accept. Another 114 ACOs that have renewed for a second agreement period under a one-sided model, including 59 ACOs that started in 2014 and 55 ACOs that started in 2015, will face a similar transition to a two-sided model with significant levels of risk in 2020 and 2021, respectively. The transition to performance-based risk remains a pressing concern for ACOs, as evidenced by a recent survey of the 82 ACOs that would be required to move to a two-sided payment model in their third agreement period beginning in 2019. The survey results, based on a 43 percent response rate, indicate that these Track 1 ACOs are reluctant to move to two-sided risk under the current design of the program. See National Association of ACOs, Press Release (May 2018), available at *https://www.naacos.com/press-release-may-2-2018.*

In the August 2018 proposed rule, we explained our belief that the long term success and sustainability of the Shared Savings Program is affected by a combination of key program factors: The savings and losses potential of the

[1] See, for example, Medicare Shared Savings Program Fast Facts (January 2018), available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/SSP-2018-Fast-Facts.pdf.*

program established through the design of the program's tracks; the methodology for setting and resetting the benchmark, which is the basis for determining shared savings and shared losses; the length of the agreement period, which determines the amount of time an ACO remains under a financial model; and the frequency of benchmark rebasing. In the proposed rule, we carefully considered each of these factors and proposed a framework that we believed, on balance, would create sufficient incentives for participation in a voluntary program, while also achieving program goals to increase quality of care for Medicare beneficiaries and reduce expenditure growth to protect the Trust Funds.

In order to achieve these program goals and preserve the long term success and sustainability of the program, we explained the need to create a pathway for ACOs to more rapidly transition to performance-based risk. ACOs and other program stakeholders have urged CMS to smooth the transition to risk by providing more time to gain experience with risk and more incremental levels of risk. Through the proposed program redesign, we aimed to create a pathway for success that facilitates ACOs' transition to performance-based risk more quickly and makes this transition smooth by phasing-in risk more gradually. Through the creation of a new BASIC track, we proposed to allow ACOs to gain experience with more modest levels of performance-based risk on their way to accepting greater levels of performance-based risk over time (as the proposed BASIC track's maximum level of risk is similar to that of the Track 1+ Model, and substantially less than the proposed ENHANCED track). As stakeholders have suggested, we proposed to provide flexibility to allow ACOs that are ready to accelerate their move to higher risk within agreement periods, and enable such ACOs to participate in Advanced APMs for purposes of the Quality Payment Program. We proposed to streamline the program and simplify the participation options by retiring Track 1 and Track 2. We proposed to retain Track 3, which we would rename as the ENHANCED track, to encourage ACOs that are able to accept higher levels of potential risk and reward to drive the most significant systematic change in providers' and suppliers' behavior. We proposed to further strengthen the program by establishing policies to deter gaming by limiting more experienced ACOs to higher-risk participation options; more rigorously screening for good standing among ACOs seeking to renew their participation in the program or re-enter the program after termination or expiration of their previous agreement; identifying ACOs re-forming under new legal entities as re-entering ACOs if greater than 50 percent of their ACO participants have recent prior participation in the same ACO in order to hold these ACOs accountable for their ACO participants' experience with the program; and holding ACOs in two-sided models accountable for partial-year losses if either the ACO or CMS terminates the agreement before the end of the performance year.

Under the proposed redesign of the program, our policies would recognize the relationship between the ACO's degree of control over total Medicare Parts A and B FFS expenditures for its assigned beneficiaries and its readiness to accept higher or lower degrees of performance-based risk. Comparisons of ACO participants' total Medicare Parts A and B FFS revenue to a factor based on total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries would be used in determining the maximum amount of losses (loss sharing limit) under the BASIC track, the estimated amount of repayment mechanism arrangements for BASIC track ACOs (required for ACOs entering or continuing their participation in a two-sided model to assure CMS of the ACO's ability to repay shared losses), and in determining participation options for ACOs. Using revenue-based loss sharing limits and repayment mechanism amounts for eligible BASIC track ACOs would help to ensure that low revenue ACOs have a meaningful pathway to participate in a two-sided model that may be more consistent with their capacity to assume risk. By basing participation options on the ACO's degree of control over total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, low revenue ACOs, which tend to be smaller and have less capital, would be able to continue in the program longer under lower levels of risk; whereas high revenue ACOs, which tend to include institutional providers and are typically larger and better capitalized, would be required to move more quickly to higher levels of performance-based risk in the ENHANCED track, because they should be able to exert more influence, direction, and coordination over the full continuum of care. By requiring high revenue ACOs to enter higher levels of performance-based risk under the ENHANCED track after no more than one agreement period under the BASIC track, we aimed to drive more meaningful systematic change in these ACOs, which have greater potential to control their assigned beneficiaries' Medicare Parts A and B FFS expenditures by coordinating care across care settings, and thus to achieve significant change in spending. Further, allowing low revenue ACOs a longer period of participation under the lower level of performance-based risk in the BASIC track, while challenging high revenue ACOs to more quickly move to higher levels of performance-based risk, could give rise to more innovative arrangements for lowering growth in expenditures and improving quality, particularly among low revenue ACOs that tend to be composed of independent physician practices.

The program's benchmarking methodology, a complex calculation that incorporates the ACO's risk-adjusted historical expenditures and reflects either national or regional spending trends, is a central feature of the program's financial models. We proposed to continue to refine the benchmarking approach based on our experience using factors based on regional FFS expenditures in resetting the benchmark in an ACO's second or subsequent agreement period, and to address ACOs' persistent concerns over the risk adjustment methodology. Through the proposed redesign of the program, we would provide for more accurate benchmarks for ACOs that are protective of the Trust Funds by ensuring that ACOs do not unduly benefit from any one aspect of the benchmark calculations, while also helping to ensure the program continues to remain attractive to ACOs, especially those caring for the most complex and highest risk patients who could benefit from high-quality, coordinated care from an ACO.

We proposed to accelerate the use of factors based on regional FFS expenditures in establishing the benchmark by applying this methodology in setting an ACO's benchmark beginning with its first agreement period. This would allow the benchmark to be a more accurate representation of the ACO's costs in relation to its localized market (or regional service area), and could strengthen the incentives of the program to drive meaningful change by ACOs. Further, allowing agreement periods of at least 5 years, as opposed to the current 3-year agreement periods, would provide greater predictability for benchmarks by reducing the frequency of benchmark rebasing, and therefore provide greater opportunity for ACOs to achieve savings against these benchmarks. In combination, these

policies would protect the Trust Funds, provide more accurate and predictable benchmarks, and reduce selection costs, while creating incentives for ACOs to transition to performance-based risk.

The existing regional adjustment under § 425.603(c) can provide overly inflated benchmarks for ACOs that are relatively low spending compared to their region, while ACOs with higher spending compared to their region may find little value in remaining in the program when faced with a significantly reduced benchmark. To address this dynamic, we proposed to reduce the maximum weight used in calculating the regional adjustment, and cap the adjustment amount for all agreement periods, so as not to excessively reward or punish an ACO based on where the ACO is located. This would make the benchmark more achievable for ACOs that care for medically complex patients and are high spending compared to their region, thereby encouraging their continued participation, while at the same time preventing windfall shared savings payments for ACOs that have relatively low spending levels relative to their region.

We also sought to provide more sustainable trend factors for ACOs with high penetration in markets with lower spending growth compared to the nation, and less favorable trend factors for ACOs with high penetration in markets with higher spending growth compared to the nation. This approach would have little impact on ACOs with relatively low to medium penetration in counties in their regional service area.

ACOs and other program stakeholders have continued to express concerns that the program's methodology for risk adjusting the benchmark for each performance year does not adequately account for changes in acuity and health status of patients over time. We proposed to modify the current approach to risk adjustment to allow changes in health status to be more fully recognized during the agreement period, providing further incentives for continued participation by ACOs faced with higher spending due to the changing health status of their population.

ACOs and other program stakeholders have urged CMS to allow additional flexibility of program and payment policies to enable ACOs to engage beneficiaries and provide the care for beneficiaries in the most appropriate care setting. It is also critical that patients have the tools to be more engaged with their doctors in order to play a more active role in their care coordination and the quality of care they receive, and that ACOs empower and incentivize beneficiaries to achieve good health. The Bipartisan Budget Act allows for certain new flexibilities for Shared Savings Program ACOs to support these aims, including new beneficiary incentive programs, telehealth services furnished in accordance with section 1899(l) of the Act, and a choice of beneficiary assignment methodology. We proposed to establish policies in accordance with the new law in these areas. For example, in accordance with section 1899(m)(1)(A) of the Act (as added by section 50341 of the Bipartisan Budget Act), we would allow certain ACOs under two-sided risk to establish CMS-approved beneficiary incentive programs, through which an ACO would provide incentive payments to assigned beneficiaries who receive qualifying primary care services. We proposed to establish policies to govern telehealth services furnished in accordance with 1899(l) of the Act by physicians and practitioners in eligible two-sided model ACOs. We also proposed to allow broader access to the program's existing SNF 3-day rule waiver for ACOs under performance-based risk.

Lastly, we sought comment on how Medicare ACOs and the sponsors of stand-alone Part D prescription drug plans (PDPs) could be encouraged to collaborate in order to improve the coordination of pharmacy care for Medicare FFS beneficiaries.

2. Summary of the Major Provisions

This final rule restructures the participation options for ACOs applying to participate in the program in 2019 by discontinuing Track 1 (one-sided shared savings-only model), and Track 2 (two-sided shared savings and shared losses model) while maintaining Track 3 (renamed the ENHANCED track) and offering a new BASIC track. Under the approach we are adopting in this final rule, the program's two tracks are: (1) A BASIC track, offering a glide path from a one-sided model for eligible ACOs to progressively higher increments of risk and potential reward within a single agreement period; and (2) an ENHANCED track based on the existing Track 3 (two-sided model), for ACOs that take on the highest level of risk and potential reward. As part of this approach we are replacing the current 3-year agreement period structure with an agreement period of at least 5 years, allowing eligible BASIC track ACOs greater flexibility to select their level of risk within an agreement period in the glide path, and allowing all BASIC track and ENHANCED track ACOs the flexibility to change their selection of beneficiary assignment methodology prior to the start of each performance year, consistent with the requirement under the Bipartisan Budget Act to provide ACOs with a choice of prospective assignment. We are finalizing Level A and B of the BASIC track as one-sided models with a maximum shared savings rate of 40 percent, not to exceed 10 percent of updated benchmark; Level C of the BASIC track with a maximum shared savings rate of 50 percent not to exceed 10 percent of updated benchmark, and loss sharing rate of 30 percent, not to exceed 2 percent of ACO participant revenue capped at 1 percent of updated benchmark; Level D of the BASIC track with a maximum shared savings rate of 50 percent, not to exceed 10 percent of updated benchmark, and loss sharing rate of 30 percent, not to exceed 4 percent of ACO participant revenue capped at 2 percent of updated benchmark; Level E of the BASIC track with a maximum shared savings rate of 50 percent, not to exceed 10 percent of updated benchmark, and loss sharing rate of 30 percent, not to exceed the percentage of revenue specified in the revenue-based nominal amount standard under the Quality Payment Program (for example, 8 percent in 2019–2020), capped at the amount that is 1 percentage point higher than the percentage of the updated benchmark specified in the expenditure-based nominal amount standard under the Quality Payment Program (for example, 4 percent in 2019–2020); and the ENHANCED track with a maximum shared savings rate of 75 percent, not to exceed 20 percent of updated benchmark, and loss sharing rate determined based on the inverse of the final sharing rate, but not less than 40 percent (that is, between 40–75 percent), not to exceed 15 percent of updated benchmark. Additionally, new, low revenue ACOs will have the option to participate under one-sided risk for 3 years and in exchange will be required to move to Level E of the BASIC track for the final 2 years of their 5-year agreement period.

To provide ACOs time to consider the new participation options and prepare for program changes, make investments and other business decisions about participation, obtain buy-in from their governing bodies and executives, and to complete and submit a Shared Savings Program application for a performance year beginning in 2019, we will offer a July 1, 2019 start date for the first agreement period under the new participation options. This midyear start in 2019 will also allow both new

applicants and ACOs currently participating in the program an opportunity to make any changes to the structure and composition of their ACO as may be necessary to comply with the new program requirements for the ACO's preferred participation option. ACOs entering a new agreement period on July 1, 2019, will have the opportunity to participate in the program under an agreement period spanning 5 years and 6 months, with a 6-month first performance year.

We are finalizing modifications to the repayment mechanism arrangement requirements, which help ensure that an ACO can repay losses for which it may be liable. Our modifications include: (1) Adding a provision to align repayment mechanism requirements across all ACOs in two-sided models under the BASIC track and ENHANCED track to allow a repayment mechanism equal to 2 percent of the ACO participants' total Medicare Parts A and B FFS revenue up to 1 percent of total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries; (2) adding a provision to permit recalculation of the estimated amount of the repayment mechanism each performance year to account for changes in ACO participant composition; (3) specifying the required duration of repayment mechanism arrangements and the options available to ACOs for fulfilling this requirement; (4) adding a provision to allow a renewing ACO the flexibility to maintain a single, existing repayment mechanism arrangement to support its ability to repay shared losses in the new agreement period so long as the term of the arrangement is extended and the repayment mechanism amount is modified to cover any increase to the repayment mechanism amount during the new agreement period; and (5) establishing requirements regarding the issuing institutions for a repayment mechanism arrangement.

This final rule establishes regulations in accordance with the Bipartisan Budget Act on coverage for telehealth services furnished on or after January 1, 2020, by physicians and other practitioners participating in an ACO under performance-based risk that has selected prospective assignment. This policy allows for payment for telehealth services furnished to prospectively assigned beneficiaries receiving telehealth services in non-rural areas, and allow beneficiaries to receive certain telehealth services at their home, to support care coordination across settings. The final rule also provides for limited waivers of the originating site and geographic requirements to allow for payment for otherwise covered telehealth services provided to beneficiaries who are no longer prospectively assigned to an applicable ACO (and therefore no longer eligible for payment for these services under section 1899(l) of the Act) during a 90-day grace period. In addition, ACO participants are prohibited, under certain circumstances, from charging beneficiaries for telehealth services, where CMS does not pay for those telehealth services under section 1899(l) of the Act solely because the beneficiary was never prospectively assigned to the applicable ACO or was prospectively assigned, but the 90-day grace period has lapsed.

We are finalizing the policy to allow eligible ACOs under performance-based risk under either prospective assignment or preliminary prospective assignment with retrospective reconciliation to use the program's existing SNF 3-day rule waiver. We also are amending the existing SNF 3-day rule waiver to allow critical access hospitals (CAHs) and other small, rural hospitals operating under a swing bed agreement to be eligible to partner with eligible ACOs as SNF affiliates for purposes of the SNF 3-day rule waiver.

We are finalizing policies to expand the role of choice and incentives in engaging beneficiaries in their health care. First, we are establishing regulations in accordance with section 1899(m)(1)(A) of the Act, as added by section 50341 of the Bipartisan Budget Act, to permit ACOs under certain two-sided models to operate CMS-approved beneficiary incentive programs. The beneficiary incentive programs will encourage beneficiaries assigned to certain ACOs to obtain medically necessary primary care services while requiring such ACOs to comply with program integrity and other requirements, as the Secretary determines necessary. Any ACO that operates a CMS-approved beneficiary incentive program will be required to ensure that certain information about its beneficiary incentive program is made available to CMS and the public on its public reporting web page. Second, to empower beneficiary choice and further program transparency, we are revising policies related to beneficiary notifications. For example, we are requiring that ACOs notify Medicare FFS beneficiaries about voluntary alignment in the written notifications they must provide to beneficiaries. An ACO or its ACO participants will be required to provide each beneficiary with such notification prior to or at the beneficiary's first primary care visit of each performance year. In addition, such information must be posted in an ACO participant's facility and available upon request (as currently required). Additionally, any ACO that operates a beneficiary incentive program must also notify its beneficiaries of the availability of the program.

We are finalizing new policies for determining the participation options for ACOs based on the degree to which ACOs control total Medicare Parts A and B FFS expenditures for their assigned beneficiaries (low revenue ACO versus high revenue ACO), and the experience of the ACO's legal entity and ACO participants with the Shared Savings Program and performance-based risk Medicare ACO initiatives.

We also are revising the criteria for evaluating the eligibility of ACOs seeking to renew their participation in the program for a subsequent agreement period and ACOs applying to re-enter the program after termination or expiration of the ACO's previous agreement, based on the ACO's prior participation in the Shared Savings Program. We also will identify new ACOs as re-entering ACOs if greater than 50 percent of their ACO participants have recent prior participation in the same ACO in order to hold these ACO accountable for their ACO participants' experience with the program. We will use the same criteria to review applications from renewing and re-entering ACOs to more consistently consider ACOs' prior experience in the Shared Savings Program. We will also modify existing review criteria, such as the ACO's history of meeting the quality performance standard and the ACO's timely repayment of shared losses to ensure applicability to ACOs with an agreement period that is not less than 5 years. We will also strengthen the program's requirements for monitoring ACOs within an agreement period for poor financial performance to ensure that ACOs with poor financial performance are not allowed to continue their participation in the program, or to re-enter the program without addressing the deficiencies that resulted in termination.

We are updating program policies related to termination of ACOs' participation in the program. We are reducing the amount of notice an ACO must provide CMS of its decision to voluntarily terminate. We also address the timing of an ACO's re-entry into the program after termination. Specifically, we are modifying current requirements that prevent an ACO from terminating its participation agreement and quickly re-entering the program to allow the flexibility for an ACO in a current 3-year agreement period to terminate its

participation agreement and immediately enter a new agreement period of not less than 5 years under one of the redesigned participation options. We are also finalizing policies that will prevent ACOs from taking advantage of this flexibility to avoid transitioning to risk by repeatedly participating in the BASIC track's glide path for a short time, terminating, and then entering a one-sided model in a future agreement period under the BASIC track. Specifically, we will restrict eligibility for the BASIC track's glide path to ACOs inexperienced with performance-based risk Medicare ACO initiatives, and we define performance-based risk Medicare ACO initiative to include all levels of the BASIC track's glide path. We also will differentiate between initial entrants (ACOs entering the program for the first time), ''re-entering ACOs'' (ACOs re-entering after a break in participation following termination or expiration of a prior participation agreement, and new ACOs identified as re-entering ACOs because greater than 50 percent of their ACO participants have recent prior participation in the same ACO), and ''renewing ACOs'' (ACOs that participate continuously in the program, without interruption, including ACOs that choose to renew early by terminating their current agreement and immediately entering a new agreement period). This differentiation is relevant for determining the agreement period the ACO is entering for purposes of applying policies that phase-in over time (benchmarking methodology and quality performance standards) and for determining whether an ACO can extend the use of its existing repayment mechanism when it enters a new agreement period.

Further, we will impose payment consequences for early termination by holding ACOs in two-sided models liable for pro-rated shared losses. This approach will apply to ACOs that voluntarily terminate their participation more than midway through a 12-month performance year and all ACOs that are involuntarily terminated by CMS. ACOs will continue to be ineligible to share in savings for a performance year if the effective date of their termination from the program is prior to the last calendar day of the performance year; however, we will allow an exception for ACOs that are participating in the program as of January 1, 2019, that terminate their agreement with an effective date of June 30, 2019, and enter a new agreement period under the BASIC track or ENHANCED track beginning July 1, 2019. Under this exception, an ACO would be eligible for pro-rated shared savings or liable for pro-rated shared losses. In these cases, we will perform separate reconciliations to determine shared savings and shared losses for the ACO's first 6 months of participation in 2019 and for the ACO's 6-month performance year from July 1, 2019, to December 31, 2019, under the subsequent participation agreement.

To strengthen ACO financial incentives for continued program participation and improve the sustainability of the program, we are finalizing changes to the methodology for establishing, adjusting, updating and resetting benchmarks for agreement periods beginning on July 1, 2019, and in subsequent years, to include the following:

- Application of factors based on regional FFS expenditures to establish, adjust, and update the ACO's benchmark beginning in an ACO's first agreement period, to move benchmarks away from being based solely on the ACO's historical costs and allow them to better reflect costs in the ACO's region.
- Mitigating the risk that an excessive positive or negative regional adjustment will be used to establish and reset the benchmark by—
  - ++ Reducing the maximum weight used in calculating the regional adjustment from 70 percent to 50 percent;
  - ++ Modifying the phase in schedule for applying increased weights in calculating the regional adjustment for ACOs with spending above their region; and
  - ++ Capping the amount of the adjustment based on a percentage of national FFS expenditures.
- Calculating growth rates used in trending expenditures to establish the benchmark and in updating the benchmark each performance year as a blend of regional and national expenditure growth rates with increasing weight placed on the national component of the blend as the ACO's penetration in its region increases.
- Better accounting for certain health status changes by using full CMS-Hierarchical Condition Category (HCC) risk scores to adjust the benchmark each performance year, although restricting the upward effects of these adjustments to positive 3 percent over the agreement period.

We also discuss comments received in response to our request for comment on approaches for encouraging Medicare ACOs to collaborate with the sponsors of stand-alone Part D PDPs (Part D sponsors) to improve the coordination of pharmacy care for Medicare FFS beneficiaries to reduce the risk of adverse events and improve medication adherence. In particular, we sought comment to understand how Medicare ACOs, and 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 to achieve better health outcomes, what clinical and pharmacy data may be necessary to support improved coordination of pharmacy care for Medicare FFS beneficiaries, and approaches to structuring financial arrangements to reward ACOs and Part D sponsors for improved health outcomes and lower growth in expenditures for Medicare FFS beneficiaries.

Lastly, in the December 2017 interim final rule with comment period we established policies for assessing the financial and quality performance of Shared Savings Program ACOs that were affected by extreme and uncontrollable circumstances during performance year 2017, including the applicable quality reporting period for performance year 2017. These policies were used to assess quality and financial performance during performance year 2017 for ACOs subject to extreme and uncontrollable events, such as Hurricanes Harvey, Irma, and Maria, and the California wildfires, during performance year 2017, including the applicable quality data reporting period for the performance year. In this final rule, we provide an analysis of and responses to the public comments we received in response to the December 2017 interim final rule with comment period.

3. Summary of Costs and Benefits

As detailed in section V. of this final rule, the faster transition from one-sided model agreements to performance-based risk arrangements, tempered by the option for eligible ACOs of a gentler exposure to downside risk calculated as a percentage of ACO participants' total Medicare Parts A and B FFS revenue and capped at a percentage of the ACO's benchmark, can affect broader participation in performance-based risk in the Shared Savings Program and reduce overall claims costs. A second key driver of estimated net savings is the reduction in shared savings payments from the limitation on the amount of the regional adjustment to the ACO's historical benchmark. Such reduction in overall shared savings payments is projected to result despite the benefit of higher net adjustments expected for a larger number of ACOs from the use of a simpler HCC risk adjustment methodology, the blending of national and regional expenditure growth rates for certain benchmark calculations, and longer (at least 5 years, instead of 3-year) agreement periods that allow ACOs a longer horizon from which to benefit from efficiency gains before benchmark rebasing. Overall, the decreases in claims costs and shared

saving payments to ACOs are projected to result in $2.9 billion in federal savings over 10 years.

B. Statutory and Regulatory Background

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted, followed by enactment of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) on March 30, 2010, which amended certain provisions of Public Law 111–148.

Section 3022 of the Affordable Care Act amended Title XVIII of the Act (42 U.S.C. 1395 *et seq.*) by adding section 1899 to the Act to establish the Shared Savings Program to facilitate coordination and cooperation among health care providers to improve the quality of care for Medicare FFS beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. See 42 U.S.C. 1395jjj.

The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule'')). We viewed this final rule as a starting point for the program, and because of the scope and scale of the program and our limited experience with shared savings initiatives under FFS Medicare, we built a great deal of flexibility into the program rules.

Through subsequent rulemaking, we have revisited and amended Shared Savings Program policies in light of the additional experience we gained during the initial years of program implementation as well as from testing through the Pioneer ACO Model, the Next Generation ACO Model, and other initiatives conducted by the Center for Medicare and Medicaid Innovation (Innovation Center) under section 1115A of the Act. A major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule (80 FR 32692) (hereinafter referred to as the ''June 2015 final rule'')). A final rule addressing changes related to the program's financial benchmark methodology appeared in the June 10, 2016 **Federal Register** (Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule'')). We have also made use of the annual CY Physician Fee Schedule (PFS) rules to address updates to the Shared Savings Program quality measures, scoring, and quality performance standard, the program's beneficiary assignment methodology and certain other issues.[2]

Policies applicable to Shared Savings Program ACOs have continued to evolve based on changes in the law. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the Quality Payment Program (Pub. L. 114–10). In the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008), CMS established regulations for the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs) and related policies applicable to eligible clinicians who participate in the Shared Savings Program.

The requirements for assignment of Medicare FFS beneficiaries to ACOs participating under the program were amended by the 21st Century Cures Act (Pub. L. 114–255). Accordingly, we revised the program's regulations in the CY 2018 PFS final rule to reflect these new requirements.

On February 9, 2018, the Bipartisan Budget Act of 2018 was enacted (Pub. L. 115–123), amending section 1899 of the Act to provide for the following: Expanded use of telehealth services by physicians or practitioners participating in an applicable ACO to a prospectively assigned beneficiary, greater flexibility in the assignment of Medicare FFS beneficiaries to ACOs by allowing ACOs in tracks under retrospective beneficiary assignment a choice of prospective assignment for the agreement period, permitting Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider and requiring that such beneficiaries be notified of the ability to make and change such identification, and mandating that any such voluntary identification will supersede claims-based assignment, and allowing ACOs under certain two-sided models to establish CMS-approved beneficiary incentive programs.

In the November 2018 final rule, we finalized a subset of the provisions proposed in the August 2018 proposed rule and the CY 2019 PFS proposed rule as follows:

- Offering existing ACOs whose participation agreements expire on December 31, 2018, the opportunity to elect a voluntary 6-month extension of their current agreement period, and the methodology for determining financial and quality performance for the 6-month performance year from January 1, 2019, through June 30, 2019.
- Allowing beneficiaries greater flexibility in selecting their primary care provider and in the use of that selection for purposes of assigning the beneficiary to an ACO, if the clinician they align with is participating in an ACO, as provided for in the Bipartisan Budget Act.
- Revising the definition of primary care services used in beneficiary assignment.
- Providing relief for ACOs and their clinicians impacted by extreme and uncontrollable circumstances in performance year 2018 and subsequent years.
- Reducing the Shared Savings Program core quality measure set by eight measures; and promoting interoperability among ACO providers/suppliers by adding a new CEHRT threshold criterion to determine ACOs' eligibility for program participation and retiring the current Shared Savings Program quality measure on the percentage of eligible clinicians using CEHRT.

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

In the August 17, 2018 **Federal Register** (83 FR 41786), we published a proposed rule titled ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success''. The proposed rule would provide a new direction for the Shared Savings Program by establishing pathways to success through redesigning the participation options available under the program to encourage ACOs to transition to two-sided models (in which they may share

[2] See for example, Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014; Final Rule (78 FR 74230, Dec. 10, 2013). Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2015; Final Rule (79 FR 67548, Nov. 13, 2014). Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2016; Final Rule (80 FR 70886, Nov. 16, 2015). Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2017; Final Rule (81 FR 80170, Nov. 15, 2016). Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2018; Final Rule (82 FR 52976, Nov. 15, 2017). Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program—Accountable Care Organizations—Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act'' (83 FR 59452, Nov. 23, 2018).

in savings and are accountable for repaying shared losses). These policies are designed to increase savings for the Trust Funds and mitigate losses, reduce gaming opportunities, and promote regulatory flexibility and free-market principles. The rule would also provide new tools to support coordination of care across settings and strengthen beneficiary engagement; ensure rigorous benchmarking; promote interoperable electronic health record technology among ACO providers/suppliers; and improve information sharing on opioid use to combat opioid addiction.

We received 469 timely pieces of correspondence in response to the proposed rule. Stakeholders offered comments that addressed both high level issues related to the Shared Savings Program as well as our specific proposals and requests for comments. We extend our deep appreciation to the public for their interest in the program and the many comments that were made in response to our proposed policies. In some instances, the public comments offered were outside the scope of the proposed rule and will not be addressed in this final rule.

As summarized in section I.B of this final rule, in the November 2018 final rule, we addressed a subset of changes to the Shared Savings Program proposed in the August 2018 proposed rule. In the following sections of this final rule, we summarize and respond to public comments on the following proposed policies and discuss our final policies after taking into consideration the public comments we received on the August 2018 proposed rule.

A. Redesigning Participation Options To Facilitate Transition to Performance-Based Risk

In this section, we discuss a series of interrelated proposals around transition to risk, including: (1) Length of time an ACO may remain under a one-sided model; (2) the levels of risk and reward under the program's participation options; (3) the duration of the ACO's agreement period; and (4) the degree of flexibility ACOs have to choose their beneficiary assignment methodology and also to select their level of risk within an agreement period.

1. Background on Shared Savings Program Participation Options

In this section, we review the statutory and regulatory background for the program's participation options by track and the length of the ACO's agreement period for participation in the program, and also provide an overview of current ACO participation in the program for performance year 2018.

a. Background on Development of Track 1, Track 2 and Track 3

Section 1899(d) of the Act establishes the general requirements for shared savings payments to participating ACOs. Specifically, section 1899(d)(1)(A) of the Act specifies that providers of services and suppliers participating in an ACO will continue to receive payments under the original Medicare FFS program under Parts A and B in the same manner as would otherwise be made, and that an ACO is eligible to receive payment for a portion of savings generated for Medicare provided that the ACO meets both the quality performance standards established by the Secretary and achieves savings against its historical benchmark based on average per capita Medicare FFS expenditures during the 3 years preceding the start of the agreement period. Additionally, section 1899(i) of the Act authorizes the Secretary to use other payment models rather than the one-sided model described in section 1899(d) of the Act, as long as the Secretary determines that the other payment model will improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures.

In the November 2011 final rule establishing the Shared Savings Program (76 FR 67909), we created two tracks from which ACOs could choose to participate: The one-sided model (Track 1) that is based on the statutory payment methodology under section 1899(d) of the Act, and a two-sided model (Track 2) that is also based on the payment methodology under section 1899(d) of the Act, but incorporates performance-based risk using the authority under section 1899(i)(3) of the Act to use other payment models. Under the one-sided model, ACOs can qualify to share in savings but are not responsible for losses. Under a two-sided model, ACOs can qualify to share in savings with an increased sharing rate, but must also take on risk for sharing in losses. ACOs entering the program or renewing their agreement may elect to enter a two-sided model. Once an ACO has elected to participate under a two-sided model, the ACO cannot go into Track 1 for subsequent agreement periods (see § 425.600).

In the initial rulemaking for the program, we considered several approaches to designing the program's participation options, principally: (1) Base the program on a two-sided model, thereby requiring all participants to accept risk from the first program year; (2) allow applicants to choose between program tracks, either a one-sided model or two-sided model, for the duration of the agreement; or (3) allow a choice of tracks, but require ACOs electing the one-sided model to transition to the two-sided model during their initial agreement period (see, for example, 76 FR 19618). We proposed a design for Track 1 whereby ACOs would enter a 3-year agreement period under the one-sided model and would automatically transition to the two-sided model (under Track 2) in the third year of their initial agreement period. Thereafter, those ACOs that wished to continue participating in the Shared Savings Program would only have the option of participating under performance-based risk (see 76 FR 19618). We explained that this approach would have the advantage of providing an entry point for organizations with less experience with risk models, such as some physician-driven organizations or smaller ACOs, to gain experience with population management before transitioning to a risk-based model while also providing an opportunity for more experienced ACOs that are ready to share in losses to enter a sharing arrangement that provides the potential for greater reward in exchange for assuming greater potential responsibility. A few commenters favored this proposed approach, indicating the importance of performance-based risk in the health care delivery system transformation necessary to achieve the program's aims and for ''good stewardship'' of Medicare Trust Fund dollars. However, most commenters expressed concerns about requiring ACOs to quickly accept performance-based risk. Therefore, we finalized a policy where an ACO could remain under the one-sided model for the duration of its first agreement period (see 76 FR 67904 through 67909).

In earlier rulemaking, we explained that offering multiple tracks with differing degrees of risk across the Shared Savings Program tracks would create an ''on-ramp'' for the program to attract both providers and suppliers that are new to value-based purchasing, as well as more experienced entities that are ready to share performance-based risk. We stated that a one-sided model would have the potential to attract a large number of participants to the program and introduce value-based purchasing broadly to providers and suppliers, many of whom may never have participated in a value-based purchasing initiative before (see, for example, 76 FR 67904 through 67909).

Another reason we included the option for a one-sided track with no

downside risk was that this model would be accessible to and attract small, rural, safety net, and/or physician-only ACOs (see 80 FR 32759). Commenters identified groups that may be especially challenged by the upfront costs of ACO formation and operations, including: Private primary care practitioners, small to medium sized physician practices, small ACOs, safety net providers (that is, Rural Health Clinics (RHCs), CAHs, Federally Qualified Health Centers (FQHCs), community-funded safety net clinics), and other rural providers (that is, Method II CAHs, rural prospective payment system hospitals designated as rural referral centers, sole community hospitals, Medicare dependent hospitals, or rural primary care providers) (see 76 FR 67834 through 67835). Further, commenters also indicated that ACOs that are composed of small- and medium-sized physician practices, loosely formed physician networks, safety net providers, and small and/or rural ACOs would be encouraged to participate in the program based on the availability of a one-sided model (see, for example, 76 FR 67906). Commenters also expressed concerns about requiring ACOs that may lack experience with care management or managing performance-based risk to quickly transition to performance-based risk. Some commenters suggested that small, rural and physician-only ACOs be exempt from downside risk (see, for example, 76 FR 67906).

In establishing the program's initial two track approach, we acknowledged that ACOs new to the accountable care model—and particularly small, rural, safety net, and physician-only ACOs—would benefit from additional time under the one-sided model before being required to accept risk (76 FR 67907). However, we also noted that although a one-sided model could provide incentives for participants to improve quality, it might not be sufficient incentive for participants to improve the efficiency and cost of health care delivery (76 FR 67904 and 80 FR 32759). We explained that payment models where ACOs bear a degree of financial risk have the potential to induce more meaningful systematic change in providers' and suppliers' behavior (see, for example, 76 FR 67907). We also explained that performance-based risk options could have the advantage of providing more experienced ACOs an opportunity to enter a sharing arrangement with the potential for greater reward in exchange for assuming greater potential responsibility (see, for example, 76 FR 67907).

We note that in earlier rulemaking we have used several terms to refer to participation options in the Shared Savings Program under which an ACO is potentially liable to share in losses with Medicare. In the initial rulemaking for the program, we defined ''two-sided model'' to mean a model under which the ACO may share savings with the Medicare program, if it meets the requirements for doing so, and is also liable for sharing any losses incurred (§ 425.20). We have also used the term ''performance-based risk'' to refer to the type of risk an ACO participating in a two-sided model undertakes. As we explained in the November 2011 final rule (76 FR 67945), in a two-sided model under the Shared Savings Program, the Medicare program retains the insurance risk and responsibility for paying claims for the services furnished to Medicare beneficiaries. It is only shared savings payments (and shared losses in a two-sided model) that will be contingent upon ACO performance. The agreement to share risk against the benchmark would be solely between the Medicare program and the ACO. As a result, we have tended to use the terms ''two-sided model'' and ''performance-based risk'' interchangeably, considering them to be synonymous when describing payment models offered under the Shared Savings Program and Medicare ACO initiatives more broadly.

In the June 2015 final rule, we modified the existing policies to allow eligible Track 1 ACOs to renew for a second agreement period under the one-sided model, and to require that they enter a performance-based risk track in order to remain in the program for a third or subsequent agreement period. We explained the rationale for these policies in the prior rulemaking and we refer readers to the December 2014 proposed rule and June 2015 final rule for more detailed discussion. (See, for example, 79 FR 72804, and 80 FR 32760 through 32761.) In developing these policies, we considered, but did not finalize, approaches to make Track 1 less attractive for continued participation, in order to support progression to risk, including offering a reduced sharing rate to ACOs remaining under the one-sided model for a second agreement period.[3] We also modified the two-sided performance-based risk track (Track 2) and began to offer an alternative two-sided performance-based risk track (Track 3) for agreement periods beginning on or after January 1, 2016 (80 FR 32771 through 32781). Compared to Track 2, which uses the same preliminary prospective beneficiary assignment methodology with retrospective reconciliation as Track 1, Track 3 includes prospective beneficiary assignment and a higher sharing rate for shared savings as well as the potential for greater liability for shared losses. Further, we established a SNF 3-day rule waiver (discussed further in section II.B.2.a. of this final rule), for use by eligible Track 3 ACOs.

The Innovation Center has tested progressively higher levels of risk for more experienced ACOs through the Pioneer ACO Model (concluded December 31, 2016) and the Next Generation ACO Model (ongoing).[4] Lessons learned from the Pioneer ACO Model were important considerations in the development of Track 3, which incorporates several features of the Pioneer ACO Model, including prospective beneficiary assignment, higher levels of risk and reward (compared to Track 2), and the availability of a SNF-3-day rule waiver. Since Track 3 was introduced as a participation option under the Shared Savings Program, we have seen a growing interest, with 16 Track 3 ACOs completing PY 2016 and 38 Track 3 ACOs participating in PY 2018. The continued increase in the number of ACOs participating in Track 3, a higher proportion of which have achieved shared savings compared to Track 1 ACOs, suggests that the track offers a pathway to improve care for beneficiaries at a level of risk and reward sufficient to induce ACOs to improve their financial performance.

[3] See 79 FR 72805 (discussing proposal to reduce the sharing rate by 10 percentage points for ACOs in a second agreement period under Track 1 to make staying in the one-sided model less attractive than moving forward along the risk continuum); 80 FR 32766 (In response to our proposal in the December 2014 proposed rule to offer a 40 percent sharing rate to ACOs that remained in Track 1 for a second agreement period, several commenters recommended dropping the sharing rate under the one-sided model even further to encourage ACOs to more quickly accept performance-based risk, for example to 20 percent, 25 percent or 30 percent under the second agreement period, or making a 5 percentage point reduction for each year under the second agreement period).

[4] See Pioneer ACO Model website, *https://innovation.cms.gov/initiatives/Pioneer-aco-model/* (the Pioneer ACO Model ''was designed for health care organizations and providers that were already experienced in coordinating care for patients across care settings''); see also CMS Press Release, New Participants Join Several CMS Alternative Payment Models (January 18, 2017), available at *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-01-18.html* (the ''Next Generation ACO Model was designed to test whether strong financial incentives for ACOs can improve health outcomes and reduce expenditures for Medicare fee-for-service beneficiaries. Provider groups in this model assume higher levels of financial risk and reward than are available under the Shared Savings Program.'').

For example, for performance year 2016, about 56 percent of Track 3 ACOs (9 of 16 ACOs) achieved shared savings compared to 29 percent of Track 1 ACOs (119 of 410 ACOs). See 2016 Shared Savings Program Accountable Care Organization Public Use File, available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/SSPACO/index.html.*

Further, the Innovation Center has tested two models for providing up-front funding to eligible small, rural, or physician-only Shared Savings Program ACOs. Initially, CMS offered the Advance Payment ACO Model, beginning in 2012 and concluding December 31, 2015. See *https://innovation.cms.gov/initiatives/Advance-Payment-ACO-Model/.* The ACO Investment Model (AIM), which began in 2015, builds on the experience with the Advance Payment ACO Model. The AIM is ongoing, with 45 participating ACOs. See *https://innovation.cms.gov/initiatives/ACO-Investment-Model/.*

In the June 2016 final rule, to further encourage ACOs to transition to performance-based risk, we finalized a participation option for eligible Track 1 ACOs to defer by one year their entrance into a second agreement period under a two-sided model (Track 2 or Track 3) by extending their first agreement period under Track 1 for a fourth performance year (§ 425.200(e); 81 FR 37994 through 37997). Under this deferred renewal option, we defer resetting the benchmark as specified at § 425.603 until the beginning of the ACO's second agreement period. This participation option became available to ACOs seeking to enter their second agreement period beginning in 2017 and in subsequent years. However, only a small number of ACOs have made use of this option.

In prior rulemaking for the Shared Savings Program, we have indicated that we would continue to evaluate the appropriateness and effectiveness of our incentives to encourage ACOs to transition to a performance-based risk track and, as necessary, might revisit alternative participation options through future notice and comment rulemaking (81 FR 37995 through 37996). We stated that it is timely to reconsider the participation options available under the program in light of the financial and quality results for the first four performance years under the program, participation trends by ACOs, and feedback from ACOs and other program stakeholders' about factors that encourage transition to risk. Therefore, we issued the August 2018 proposed rule.

b. Background on Factors Affecting Transition to Performance-Based Risk

Based on comments submitted by ACOs and other program stakeholders in response to earlier rulemaking and our experience with implementing the Shared Savings Program, a combination of factors affect ACOs' transition to performance-based risk.[5] These factors include the following:

(1) Length of time allowed under a one-sided model and availability of options to transition from a one-sided model to a two-sided model within an ACO's agreement period. (Discussed in detail within this section. See also discussion of related background in section II.A.1.a. of this final rule.)

(2) An ACO's level of experience with the accountable care model and the Shared Savings Program.[6]

(3) Choice of methodology used to assign beneficiaries to ACOs, which determines the beneficiary population for which the ACO is accountable for both the quality and cost of care. (Background on choice of assignment methodology is discussed within this section; see also section II.A.4. of this final rule.) Specifically, the assignment methodology is used to determine the populations that are the basis for determining the ACO's historical benchmark and the population assigned to the ACO each performance year, which is the basis for determining whether the ACO will share in savings or losses for that performance year.

(4) Availability of program and payment flexibilities to ACOs participating under performance-based risk to support beneficiary engagement and the ACO's care coordination activities (see discussion in sections II.B. and II.C. of this final rule).

(5) Financial burden on ACOs in meeting program requirements to enter into two-sided models, specifically the requirement to establish an adequate repayment mechanism (see discussion in section II.A.6.c. of this final rule).

(6) Value proposition of the program's financial model under one-sided and two-sided models.

The value proposition of the program's financial models raises a number of key considerations that pertain to an ACO's transition to risk. One consideration is the level of potential reward under the one-sided model in relation to the levels of potential risk and reward under a two-sided model. A second consideration is the availability of asymmetrical levels of risk and reward, such as in the Medicare ACO Track 1+ Model (Track 1+ Model), where, for certain eligible ACOs, the level of risk is determined based on a percentage of ACO participants' total Medicare Parts A and B FFS revenue, not to exceed a percentage of the ACO's benchmark (determined based on historical expenditures for its assigned population). A third consideration is the interactions between the ACO's participation in a two-sided model of the Shared Savings Program and incentives available under other CMS value-based payment initiatives; in particular, eligible clinicians participating in an ACO under a two-sided model of the Shared Savings Program may qualify to receive an APM incentive payment under the Quality Payment Program for sufficient participation in an Advanced APM. Lastly, the value proposition of the program is informed by the methodology for setting and resetting the benchmark, which is the basis for determining shared savings and shared losses, and the length of agreement period, which determines the amount of time an ACO remains under a financial model and the frequency of benchmark rebasing. See discussion in sections II.D. (benchmarking) and II.A.1.c. (length of agreement period) of this final rule.

Currently, the design of the program locks in the ACO's choice of financial model, which also determines the applicable beneficiary assignment methodology, for the duration of the ACO's 3-year agreement period. For an ACO's initial or subsequent agreement period in the Shared Savings Program, an ACO applies to participate in a particular financial model (or ''track'') of the program as specified under § 425.600(a). If the ACO's application is accepted, the ACO must remain under that financial model for the duration of its 3-year agreement period. Beneficiary assignment and the level of performance-based risk (if applicable) are determined consistently for all ACOs participating in a particular track. Under Track 1 and Track 2, we assign

[5] See, for example, 80 FR 32761 (summarizing comments suggesting a combination of factors could make the program more attractive and encourage ACOs to transition to risk, such as: The level of risk and reward offered under the program's financial models, tools to enable ACOs to more effectively control and manage their patient populations, opportunity for ACOs to gain experience with the program under the one-sided model under the same rules that would be applied under a two-sided model, including the assignment methodology, allowing ACOs to move to two-sided risk within an agreement period, and allowing for longer agreement periods).

[6] See discussion in section II.A.1.a of this final rule. See also 81 FR 37996 (summarizing comments suggesting that if a Track 1 ACO is uncertain about its ability to successfully manage financial risk, the ACO would more likely simply choose to continue under Track 1 for a second agreement period.)

beneficiaries using preliminary prospective assignment with retrospective reconciliation (§ 425.400(a)(2)). Under Track 3, we prospectively assign beneficiaries (§ 425.400(a)(3)).

As described in earlier rulemaking, commenters have urged that we offer greater flexibility for ACOs in their choice of assignment methodology.[7] In the June 2015 final rule, we acknowledged there is additional complexity and administrative burden to implementing an approach under which ACOs in any track may choose either prospective assignment or preliminary prospective assignment with retrospective reconciliation, with an opportunity to switch their selection on an annual basis. At that time, we declined to implement prospective assignment in Track 1 and Track 2, and we also declined to give ACOs in Track 3 a choice of either prospective assignment or preliminary prospective assignment with retrospective reconciliation. Further, we explained that implementing prospective assignment only in a two-sided model track may encourage Track 1 ACOs that prefer this assignment methodology, and the other features of Track 3, to more quickly transition to performance-based risk (80 FR 32773).

We also have considered alternative approaches to allow ACOs greater flexibility in the timing of their transition to performance-based risk, including within an ACO's agreement period. For example, as described in earlier rulemaking, commenters suggested approaches that would allow less than two 3-year agreement periods under Track 1.[8] Some commenters recommended that CMS allow ACOs to ''move up'' the risk tracks (that is, move from Track 1 to Track 2 or Track 3, or move from Track 2 to Track 3) between performance years without being required to wait for the start of a new agreement period, to provide more flexibility for ACOs prepared to accept performance-based risk, or a higher level of performance-based risk. These commenters suggested that allowing an ACO to accept varying degrees of risk within an agreement period would position the ACO to best balance its exposure to and tolerance for financial risk and would create a true glide path for participating healthcare providers (81 FR 37995 through 37996).

Transition to performance-based risk has taken on greater significance with the introduction of the Quality Payment Program. Under the CY 2017 Quality Payment Program final rule with comment period,[9] ACO initiatives that require ACOs to bear risk for monetary losses of more than a nominal amount, and that meet additional criteria, can qualify as Advanced APMs beginning in performance year 2017. Eligible clinicians who sufficiently participate in Advanced APMs such that they are Qualifying APM Participants (QPs) for a performance year receive APM Incentive Payments in the corresponding payment year between 2019 through 2024, and then higher fee schedule updates starting in 2026. Track 2 and Track 3 of the Shared Savings Program, and the Track 1+ Model, are currently Advanced APMs under the Quality Payment Program.

ACOs and other program stakeholders continue to express a variety of concerns about the transition to risk under Track 2 and Track 3. For example, as described in the CY 2017 Quality Payment Program final rule with comment period (see, for example, 81 FR 77421 through 77422), commenters suggested a new Shared Savings Program track as a meaningful middle path between Track 1 and Track 2 (''Track 1.5''), that meets the Advanced APM generally applicable nominal amount standard, to create an option for ACOs with relatively low revenue or small numbers of participating eligible clinicians to participate in an Advanced APM without accepting the higher degrees of risk involved in Track 2 and Track 3. Commenters suggested this track would be a viable on-ramp for ACOs to assume greater amounts of risk in the future. Commenters' suggestions for Track 1.5 included prospective beneficiary assignment, asymmetric levels of risk and reward, and payment rule waivers, such as the SNF 3-day rule waiver available to ACOs participating in Shared Savings Program Track 3.[10] Another key component of commenters' suggestions was to allow Track 1 ACOs to transition to Track 1.5 within their current agreement periods.[11] These commenters' suggestions were considered in developing the Track 1+ Model, which began on January 1, 2018. This Model, which is being tested by the Innovation Center, includes a two-sided payment model that incorporates the upside of Track 1 with more limited downside risk than is currently present in Track 2 or Track 3 of the Shared Savings Program. The Track 1+ Model is currently an Advanced APM under the Quality Payment Program.

The Track 1+ Model is designed to encourage ACOs, especially those made up of small physician practices, to advance to performance-based risk. ACOs that include hospitals, including small rural hospitals, are also allowed to participate. See CMS Fact Sheet, New Accountable Care Organization Model Opportunity: Medicare ACO Track 1+ Model, Updated July 2017 (herein Track 1+ Model Fact Sheet), available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/New-Accountable-Care-Organization-Model-Opportunity-Fact-Sheet.pdf.* In performance year 2018, 55 ACOs began in the Track 1+ Model, demonstrating strong interest in this financial model design. The availability of the Track 1+ Model increased the number of ACOs participating under a two-sided risk model in connection with their participation in the Shared Savings Program to approximately 18 percent, with approximately 22.7 percent of assigned beneficiaries receiving care through an ACO in a two-sided model. Of the 55 Track 1+ Model ACOs, based on the ACOs' self-reported composition: 58.2 percent attested to the presence of

[7] See, for example, 76 FR 67864 (summarizing comments suggesting allowing ACOs a choice of prospective or retrospective assignment); 80 FR 32772 through 32774 (In response to our proposal to use a prospective assignment methodology in Track 3, many commenters generally encouraged CMS to extend the option for prospective assignment beyond Track 3 to Track 1 and Track 2. Other commenters saw the value in retaining both assignment methodologies, and encouraged CMS to allow all ACOs, regardless of track, a choice of prospective or retrospective assignment. Several commenters suggested CMS allow ACOs a choice of retrospective or prospective assignment annually, within the ACO's 3-year agreement period).

[8] See, for example, 76 FR 67907 through 67909 (discussing comments suggesting ACOs be allowed 3, 4, 5, or 6 years under Track 1 prior to transitioning to a performance-based risk track).

[9] See Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models final rule with comment period, 81 FR 77008 (Nov. 4, 2016), herein referred to as the CY 2017 Quality Payment Program final rule with comment period.

[10] See CY 2017 Quality Payment Program final rule with comment period for summary of comments and responses. Individual comments are available at *https://www.regulations.gov,* search on file code CMS–5517–P, docket ID CMS–2016–0060 (*https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&dct=PS&D=CMS-2016-0060*). See for example, Letter from Clif Gaus, NAACOS to Andrew Slavitt, Acting Administrator, Centers for Medicare & Medicaid Services, regarding CMS–5517–P (June 27, 2016); Letter from Tonya K. Wells, Trinity Health to Slavitt regarding CMS–5517–P (June 27, 2016); Letter from Joseph Bisordi, M.D., Ochsner Health System to Slavitt regarding CMS–5517–P (June 27, 2016); Letter from Kevin Bogari, Lancaster General Health Community Care Collaborative to Slavitt regarding CMS–5517–P (June 27, 2016).

[11] See 81 FR 77421 (describing comments suggesting CMS adopt a Track 1.5 and also suggesting that Track 1 ACOs should be permitted to move into this suggested Track 1.5 before the end of their current agreement period).

an ownership or operational interest by an inpatient prospective payment system (IPPS) hospital, cancer center or rural hospital with more than 100 beds among their ACO participants, and therefore these ACOs were under a benchmark-based loss sharing limit; and 41.8 percent attested to the absence of such ownership or operational interests by these institutional providers among their ACO participants (likely ACOs composed of independent physician practices and/or ACOs that include small rural hospitals), which qualified these ACOs for generally lower levels of risk under the Track 1+ Model's revenue-based loss sharing limit.

c. Background on Length of Agreement Period

Section 1899(b)(2)(B) of the Act requires participating ACOs to enter into an agreement with CMS to participate in the program for not less than a 3-year period referred to as the agreement period. Further, section 1899(d)(1)(B)(ii) of the Act requires us to reset the benchmark at the start of each agreement period. In initial rulemaking for the program, we limited participation agreements to 3-year periods (see 76 FR 19544, and 76 FR 67807). We have considered the length of the ACO's agreement period in the context of the amount of time an ACO may remain in a one-sided model and also the frequency with which we reset (or rebase) the ACO's historical benchmark. For example, in the June 2015 final rule, we discussed commenters' suggestions that we extend the agreement period from the current 3 years to a 5-year agreement period, for all tracks, including not only the initial agreement period, but all subsequent agreement periods.[12] These commenters explained that extending the length of the agreement period would make the program more attractive by increasing program stability and providing ACOs with the necessary time to achieve the desired quality and financial outcomes. We declined to adopt these suggestions, believing at that time it was more appropriate to maintain a 3-year agreement period to provide continuity with the initial design of the program. At that time we did not find it necessary to extend agreement periods past 3 years to address the renewal of initial program entrants, particularly in light of the policies we finalized in the June 2015 final rule allowing Track 1 ACOs to apply to continue under the one-sided model for a second 3-year agreement period and modifying the benchmark rebasing methodology. However, we explained that longer agreement periods could increase the likelihood that ACOs would build on the success or continue the failure of their current agreement period. For this reason we noted that rebasing every 3 years, at the start of each 3-year agreement period, is important to protect both the Trust Funds and ACOs. See 80 FR 32763. See also 81 FR 37957 (noting commenters' suggestions that we eliminate rebasing or reducing the frequency of rebasing).

d. Background on Shared Savings Program Participation

There remains a high degree of interest in participation in the Shared Savings Program. Although most ACOs continue to participate in the program's one-sided model (Track 1), ACOs have demonstrated significant interest in the Track 1+ Model. Table 2 summarizes the total number of ACOs that are participating in the Shared Savings Program, including those also participating in the Track 1+ Model, for performance year 2018 with the total number of assigned beneficiaries by track.[13] Of the 561 ACOs participating in the program as of January 1, 2018, 55 were in the Track 1+ Model, 8 were in Track 2, 38 were in Track 3, and 460 were in Track 1. As of performance year 2018, there are over 20,000 ACO participant Taxpayer Identification Numbers (TINs) that include 377,515 clinicians (physicians, physician assistants, nurse practitioners and clinical nurse specialists) some of whom are in small and solo practices. About half of ACOs are provider networks, and 66 ACOs include rural providers. See Medicare Shared Savings Program Fast Facts (January 2018) available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/SSP-2018-Fast-Facts.pdf.*

Based on the program's existing requirements, ACOs can participate in Track 1 for a maximum of two agreement periods. There are a growing number of ACOs that have entered into their second agreement period, and, starting in 2019, many that will begin a third agreement period and will be required to enter a risk-based track.

The progression by some ACOs to performance-based risk within the Shared Savings Program remains relatively slow, with approximately 82 percent of ACOs participating in Track 1 in 2018, 43 percent (196 of 460) of which are within a second agreement period in Track 1.

TABLE 2—ACOs BY TRACK AND NUMBER OF ASSIGNED BENEFICIARIES FOR PERFORMANCE YEAR 2018

Track	Number of ACOs	Number of Assigned Beneficiaries
Track 1	460	8,147,234
Track 1+ Model	55	1,212,417
Track 2	8	122,995
Track 3	38	993,533
Total	**561**	**10,476,179**

[12] See 80 FR 32763. See also 80 FR 32761 (discussing several commenters' recommendation to move to 5 or 6 year agreements for ACOs and the suggestion that ACOs have the opportunity to move to a performance-based risk model during their first agreement period, for example, after their first 3 years under the one-sided model. A commenter suggested encouraging ACOs to transition to two-sided risk by offering lower loss sharing rates for ACOs that move from Track 1 to the two-sided model during the course of an agreement period, and phasing-in loss sharing rates for these ACOs (for example, 15 percent in year 1, 30 percent in year 2, 60 percent in year 3). Another commenter suggested that CMS allow all ACOs (regardless of track) the option to increase their level of risk annually during the agreement period.)

[13] See Performance Year 2018 Medicare Shared Savings Program Accountable Care Organizations available at *Data.CMS.gov, https://data.cms.gov/Special-Programs-Initiatives-Medicare-Shared-Saving/Performance-Year-2018-Medicare-Shared-Savings-Prog/28n4-k8qs/data.*

However, the recent addition of the Track 1+ Model provided a significant boost in Shared Savings Program ACOs taking on performance-based risk, with over half of the 101 ACOs participating in the Shared Savings Program and taking on performance-based risk opting for the Track 1+ Model in 2018. The lower level of risk offered under the Track 1+ Model has been positively received by the industry and provided a pathway to risk for many ACOs.

2. Modified Participation Options Under 5-Year Agreement Periods

As described in the August 2018 proposed rule (83 FR 41797 through 41801), in developing the proposed policies described in this section, we considered a number of factors related to the program's current participation options in light of the program's financial results and stakeholders' feedback on program design, including the following.

First, we considered the program's existing policy allowing ACOs up to 6 years of participation in a one-sided model. We have found that the policy has shown limited success in encouraging ACOs to advance to performance-based risk. By the fifth year of implementing the program, only about 18 percent of the program's participating ACOs are under a two-sided model, over half of which are participating in the Track 1+ Model (see Table 2).

As discussed in detail in the August 2018 proposed rule (see 83 FR 41916 through 41918), our experience with the program indicates that ACOs in two-sided models generally perform better than ACOs that participate under a one-sided model. For example, for performance year 2016, about 68 percent of Shared Savings Program ACOs in two-sided models (15 of 22 ACOs) shared savings compared to 29 percent of Track 1 ACOs. For performance year 2015, prior to the first year of Track 3, one of the three remaining Track 2 ACOs shared savings, while about 30 percent of Track 1 ACOs (118 of 389 ACOs) shared savings. For performance year 2014, two of the three remaining Track 2 ACOs shared savings while about 25 percent of Track 1 ACOs (84 of 330 ACOs) shared savings. In the program's first year, concluding December 31, 2013, 40 percent of Track 2 ACOs (2 of 5 ACOs) compared to 23 percent of Track 1 ACOs (50 of 215 ACOs) shared savings. See Shared Savings Program Accountable Care Organization Public Use Files, available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/SSPACO/index.html.* These observations, in combination with participation trends that show most ACOs prefer to remain in Track 1 for a second 3-year agreement period, suggests that a requirement for ACOs to more rapidly transition to performance-based risk could be effective in creating incentives for ACOs to more quickly meet the program's goals.

The program's current design lacks a sufficiently incremental progression to performance-based risk, the need for which is evidenced by robust participation in the new Track 1+ Model. A significant issue that contributes to some ACOs' reluctance to participate in Track 2 or Track 3 is that the magnitude of potential losses is very high compared to the ACO's degree of control over the total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, particularly when its ACO participants have relatively low total Medicare Parts A and B FFS revenue. We are encouraged by the interest in the Track 1+ Model as indicated by the 55 Shared Savings Program ACOs participating in the Model for the performance year beginning on January 1, 2018; the largest group of Shared Savings Program ACOs to enter into performance-based risk for a given performance year to date. Based on the number of ACOs participating in the Track 1+ Model for performance year 2018, a lower risk option appears to be important for Track 1 ACOs with experience in the program seeking to transition to performance-based risk, as well as ACOs seeking to enter an initial agreement period in the program under a lower risk model.

Interest in the Track 1+ Model suggests that the opportunity to participate in an Advanced APM while accepting more moderate levels of risk (compared to Track 2 and Track 3) is an important financial model design for ACOs. Allowing more manageable levels of risk within the Shared Savings Program is an important pathway for helping organizations to gain experience with managing risk as well as participating in Advanced APMs under the Quality Payment Program. The high uptake we have observed with the Track 1+ Model also suggests that the current design of Track 1 may be unnecessarily generous since the Track 1+ Model has the same level of upside as Track 1 but under which ACOs must also assume performance-based risk.

Second, under the program's current design, CMS lacks adequate tools to properly address ACOs with patterns of negative financial performance. Track 1 ACOs are not liable for repaying any portion of their losses to CMS, and therefore may have potentially weaker incentives to improve quality and reduce growth in FFS expenditures within the accountable care model. These ACOs may take advantage of the potential benefits of continued program participation (including the receipt of program data and the opportunity to enter into certain contracting arrangements with ACO participants and ACO providers/suppliers in connection with their participation in the Shared Savings Program), without providing a meaningful benefit to the Medicare program. ACOs under two-sided models may similarly benefit from program participation and seek to continue their participation despite owing shared losses.

Third, differences in performance of ACOs indicate a pattern where low revenue ACOs outperformed high revenue ACOs. As discussed in the August 2018 proposed rule (see 83 FR 41916 through 41918), we have observed a pattern of performance, across tracks and performance years, where low revenue ACOs show better average results compared to high revenue ACOs. We explained that high revenue ACOs, which typically include hospitals, have a greater opportunity to control assigned beneficiaries' total Medicare Parts A and B FFS expenditures, as they coordinate a larger portion of the assigned beneficiaries' care across care settings, and have the potential to perform better than what has been demonstrated in performance trends from 2012 through 2016. We concluded that the trends in performance by high revenue ACOs in relation to their expected capacity to control growth in expenditures are indications that these ACOs' performance would improve through greater incentives, principally a requirement to take on higher levels of performance-based risk, and thus drive change in FFS utilization for their Medicare FFS populations. This conclusion is further supported by our initial experience with the Track 1+ Model, for which our preliminary findings support the conclusion that the degree of control an ACO has over expenditures for its assigned beneficiaries is an indication of the level of performance-based risk an ACO is prepared to accept and manage, where control is determined by the relationship between ACO participants' total Medicare Parts A and B FFS revenue and the total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries. Our experience with the Track 1+ Model has also shown that ACO participants' total Medicare

Parts A and B FFS revenue as a percentage of the total Medicare Parts A and B FFS expenditures of the assigned beneficiaries can serve as a proxy for ACO composition (that is, whether the ACO includes one or more institutional providers as an ACO participant, and therefore is likely to control a greater share of Medicare Parts A and B FFS expenditures and to have greater ability to coordinate care across settings for its assigned beneficiaries).

Fourth, permitting choice of level of risk and assignment methodology within an ACO's agreement period would create redundancy in some participation options, and eliminating this redundancy would allow CMS to streamline the number of tracks offered while allowing ACOs greater flexibility to design their participation to meet the needs of their organizations. ACOs and stakeholders have indicated a strong preference for maintaining an option to select preliminary prospective assignment with retrospective reconciliation as an alternative to prospective assignment for ACOs under performance-based risk within the Shared Savings Program. We considered what would occur if we retained Track 2 in addition to the ENHANCED track and offered a choice of prospective assignment and preliminary prospective assignment (see section II.A.4.c. of this final rule) for both tracks. We stated that ACOs prepared to accept higher levels of benchmark-based risk would be more likely to enter the ENHANCED track (which allows the greatest risk and potential reward). This is suggested by participation statistics, where 8 ACOs are participating in Track 2 compared to the 38 ACOs participating in Track 3 as of January 1, 2018. We noted that for agreement periods beginning in 2018, only 2 ACOs entered Track 2, both of which had deferred renewal in 2017, while 4 ACOs entered Track 3 (for their first or second agreement period). ACOs may be continuing to pick Track 2 because of the preliminary prospective assignment methodology, and we would expect participation in Track 2 to decline further if we finalize the proposal to allow a choice of assignment methodology in the ENHANCED track, since we would expect ACOs ready for higher risk (that is, a level of risk that is higher than the highest level of risk and potential reward under the proposed BASIC track) to prefer the ENHANCED track over Track 2.

Fifth, longer agreement periods could improve program incentives and support ACOs' transition into performance-based risk when coupled with changes to improve the accuracy of the program's benchmarking methodology. Extending agreement periods for more than 3 years could provide more certainty over benchmarks and in turn give ACOs a greater chance to succeed in the program by allowing them more time to understand their performance, gain experience and implement redesigned care processes before rebasing of the ACO's historical benchmark. Shared Savings Program results show that ACOs tend to perform better the longer they remain in the program. Further, under longer agreement periods, historical benchmarks would become more predictable, since the benchmark would continue to be based on the expenditures for beneficiaries who would have been assigned to the ACO in the 3 most recent years prior to the start of the ACO's agreement period (see §§ 425.602(a) and 425.603(c)) and the benchmark would be risk adjusted and updated each performance year relative to benchmark year 3. However, a number of factors can affect the amount of the benchmark, and therefore its predictability, during the agreement period regardless of whether the agreement period spans 3 or 5 years, including: Adjustments to the benchmark during the ACO's agreement period resulting from changes in the ACO's certified ACO participant list and regulatory changes to the assignment methodology; as well as variation in the benchmark value that occurs each performance year as a result of annual risk adjustment to the ACO's benchmark (§§ 425.602(a)(9) and 425.603(c)(10)) and annual benchmark updates (§§ 425.602(b) and 425.603(d)). We explained that the proposed approach to incorporating factors based on regional FFS expenditures in establishing, adjusting and updating the benchmark beginning with the ACO's first agreement period (discussed in section II.D. of this final rule) would result in more accurate benchmarks. This improved accuracy of benchmarks would mitigate the impact of the more generous updated benchmarks that could result in the later years of longer agreement periods.

In summary, taking these factors into consideration, we proposed 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.

We proposed to require ACOs to enter one of two tracks for agreement periods beginning on July 1, 2019, and in subsequent years (as described in section II.A.7. of this final rule): Either the ENHANCED track, which would be based on Track 3 as currently designed and implemented under § 425.610, or the new BASIC track, which would offer eligible ACOs a glide path from a one-sided model to incrementally higher performance-based risk. (We referred to this participation option for eligible ACOs entering the BASIC track as the BASIC track's glide path, or simply the glide path.)

We proposed to add a new provision to the Shared Savings Program regulations at § 425.605 to establish the requirements for this BASIC track. The BASIC track would offer lower levels of risk compared to the levels of risk currently offered in Track 2 and Track 3, and the same maximum level of risk as offered under the Track 1+ Model. Compared to the design of Track 1, this glide path approach, which requires assumption of gently increasing levels of risk and potential reward beginning no later than an ACO's fourth performance year under the BASIC track for agreement periods starting on July 1, 2019 or third performance year under the BASIC track for agreement periods starting in 2020 and all subsequent years, could provide stronger incentives for ACOs to improve their performance.

For agreement periods beginning on July 1, 2019, and in subsequent years, we proposed to modify the regulations at §§ 425.600 and 425.610 to designate Track 3 as the ENHANCED track. We proposed that all references to the ENHANCED track in the program's regulations would be deemed to include Track 3. We explained that we intend references to the ENHANCED track to apply to Track 3 ACOs, unless otherwise noted.

We explained that as part of the redesign of the program's participation options, it is timely to provide the program's tracks with more descriptive and meaningful names. ''Enhanced'' is indicative of the increased levels of risk and potential reward available to ACOs under the current design of Track 3, the new tools and flexibilities available to performance-based risk ACOs, and the relative incentives for ACOs under this

financial model designed to improve the quality of care for their assigned beneficiaries (for example, through the availability of the highest sharing rates based on quality performance under the program) and their potential to drive towards reduced costs for Medicare FFS beneficiaries and therefore increased savings for the Medicare Trust Funds. In contrast, ''basic'' suggests a foundational level, which is reflected in the opportunity under the BASIC track to provide a starting point for ACOs on a pathway to success from a one-sided shared savings model to two-sided risk.

We proposed that for agreement periods beginning on July 1, 2019, the length of the agreement would be 5 years and 6 months. For agreement periods beginning on January 1, 2020, and in subsequent years, the length of the agreement would be 5 years.

In the November 2018 final rule (83 FR 59946) we finalized a revision to the definition of ''agreement period'' to broadly mean the term of the participation agreement. For consistency, we also revised the heading in § 425.200(b) from ''term of the participation agreement'' to ''agreement period,'' based on the modification to the definition of ''agreement period'' in § 425.20.

In the August 2018 proposed rule (83 FR 41799), we proposed to specify the term of participation agreements beginning on July 1, 2019 and in subsequent years in revisions to § 425.200, which currently specifies the term of the participation agreement for each agreement start date since the beginning of the program.

In the August 2018 proposed rule (83 FR 41800), we also proposed to revise § 425.502(e)(4)(v), specifying calculation of the quality improvement reward as part of determining the ACO's quality score, which includes language based on 3-year agreement periods. Through these revisions, we would specify that the comparison for performance in the first year of the new agreement period would be the last year in the previous agreement period, rather than the third year of the previous agreement period.

The regulation on renewal of participation agreements (§ 425.224(b)) includes criteria regarding an ACO's quality performance and repayment of shared losses that focus on specific years in the ACO's prior 3-year agreement period. We discussed proposals to revise these evaluation criteria to be more relevant to assessing prior participation of ACOs under an agreement period of at least 5 years, among other factors (83 FR 41823 through 41825).

For ACOs entering agreement periods beginning on July 1, 2019, and in subsequent years, we proposed to 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. See discussion in section II.A.4.c. of this final rule.

For ACOs entering agreement periods beginning on July 1, 2019, and in subsequent years, we proposed to 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 within their agreement period. See the discussion in section II.A.4.b. of this final rule.

We proposed to discontinue Track 1 as a participation option for the reasons described elsewhere in this section. We proposed to amend § 425.600 to limit availability of Track 1 to agreement periods beginning before July 1, 2019.

We proposed to discontinue Track 2 as a participation option. We proposed to amend § 425.600 to limit availability of Track 2 to agreement periods beginning before July 1, 2019. We based these proposals on the following considerations.

For one, the proposal to allow ACOs to select their assignment methodology (section II.A.4.c. of this final rule) and the availability of the proposed BASIC track with relatively low levels of risk compared to the ENHANCED track would ensure the continued availability of a participation option with moderate levels of risk and potential reward in combination with the optional availability of the preliminary prospective beneficiary assignment in the absence of Track 2. We explained that maintaining Track 2 as a participation option between the lower risk of the proposed BASIC track and the higher risk of the ENHANCED track would create redundancy in participation options, while removing Track 2 would offer an opportunity to streamline the tracks offered.

Although Track 2 was the initial two-sided model of the Shared Savings Program, the statistics on Shared Savings Program participation by track (and in the Track 1+ Model) summarized in Table 2 show few ACOs entering and completing their risk bearing agreement period under Track 2 in recent years, and suggest that ACOs prefer either a lower level of risk and potential reward under the Track 1+ Model or a higher level of risk and potential reward under Track 3 than the Track 2 level of risk and potential reward.

Further, under the proposed modifications to the regulations (see section II.A.5.c. of this final rule), Track 2 ACOs prepared to take on higher risk would have the option to elect to enter the ENHANCED track by completing their agreement period in Track 2 and applying to renew for a subsequent agreement period under the ENHANCED track or by voluntarily terminating their current 3-year agreement and entering a new agreement period under the ENHANCED track, without waiting until the expiration of their current 3-year agreement period. Certain Track 2 ACOs that may not be prepared for the higher level of risk under the ENHANCED track could instead elect to enter the proposed BASIC track at the highest level of risk and potential reward, under the same circumstances.

We proposed to discontinue the policy that allows Track 1 ACOs in their first agreement period to defer renewal for a second agreement period in a two-sided model by 1 year, to remain in their current agreement period for a fourth performance year, and to also defer benchmark rebasing. We proposed to amend § 425.200(e) to discontinue the deferred renewal option, so that it would be available to only those Track 1 ACOs that began a first agreement period in 2014 or 2015 and have already renewed their participation agreement under the deferred renewal option, and therefore this option would not be available to Track 1 ACOs seeking to renew for a second agreement period beginning on July 1, 2019, or in subsequent years. We proposed to amend § 425.200(b)(3) to specify that the extension of a first agreement period in Track 1 under the deferred renewal option is available only for ACOs that began a first agreement period in 2014 or 2015 and therefore deferred renewal in 2017 or 2018 (respectively). We considered the following issues in developing this proposal.

For one, continued availability of this option is inconsistent with our proposed redesign of the program, which encourages rapid transition to performance-based risk and requires ACOs on the BASIC track's glide path to enter performance-based risk within their first agreement period under the BASIC track.

Deferral of benchmark rebasing was likely a factor in some ACOs' decisions to defer renewal, particularly for ACOs concerned about the effects of the rebasing methodology on their benchmark. Under the proposal to extend the length of agreement periods

from 3 years to not less than 5 years, benchmark rebasing would be delayed by 2 years (relative to a 3-year agreement), rather than 1 year, as provided under the current deferred renewal policy.

Eliminating the deferred renewal option would streamline the program's participation options and operations. Very few ACOs have elected the deferred renewal participation option, with only 8 ACOs that began participating in the program in either 2014 or 2015 renewing their Shared Savings Program agreement under this option to defer entry into a second agreement period under performance-based risk until 2018 or 2019, respectively. We stated that the very low uptake of this option demonstrates that it is not effective at facilitating ACOs' transition to performance-based risk. The proposed timing of applicability would prevent ACOs from electing to defer renewal in 2019 for a second agreement period beginning in 2020.

Further, as discussed in section II.A.5.c. of this final rule, we proposed to discontinue the ''sit-out'' period under § 425.222(a), which is cross-referenced in the regulation at § 425.200(e) establishing the deferred renewal option. Under the proposed modifications to § 425.222(a), ACOs that have already been approved to defer renewal until 2019 under this participation option (ACOs with 2015 start dates in the Shared Savings Program that deferred entering a second agreement period under two-sided risk until January 1, 2019), would have the option of terminating their participation agreement for their second agreement period under Track 2 or Track 3 and applying to enter the BASIC track at the highest level of risk and potential reward (Level E), or the ENHANCED track, for a new agreement period.

We proposed to modify the Shared Savings Program participation options to offer a new performance-based risk track using the Secretary's authority under section 1899(i)(3) of the Act. In the August 2018 proposed rule, we explained use of our authority under section 1899(i)(3) of the Act (83 FR 41801). In order to add the BASIC track, we must determine that it will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without additional program expenditures. Consistent with our earlier discussions of the use of this authority to establish the current two-sided models in the Shared Savings Program (see 76 FR 67904 and 80 FR 32771), we explained that the BASIC track would provide an additional opportunity for organizations to enter a risk-sharing arrangement and accept greater responsibility for beneficiary care. We explained that the proposed restructuring of participation options, more generally, would help ACOs transition to performance-based risk more quickly than under the program's current design. Under the proposed program redesign we would eliminate Track 1 (under which a one-sided model currently is available for up to 6 years), offering instead a glide path with up to 2 performance years under a one-sided model (three, for ACOs that enter the glide path on July 1, 2019), followed by the incremental phase-in of risk and increasing potential for reward over the remaining 3 performance years of the agreement period. We proposed that ACOs that previously participated in Track 1, 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, entering the BASIC track's glide path would be eligible for a single performance year under a one-sided model (two, for ACOs that enter the glide path on July 1, 2019). We proposed a one-time exception to be specified in revisions to § 425.600, under which 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 on July 1, 2019. For performance year 2020, the 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). The ACO would be automatically advanced to the next level of the BASIC track's glide path at the start of performance year 2021 and all subsequent performance years of the agreement period, unless the ACO elects to advance to a higher level of risk and potential reward under the glide path more quickly, as proposed in section II.A.4.b. of this final rule. The glide path concludes with the ACO entering a level of potential reward that is the same as is currently available under Track 1, with a level of risk that is similar to the lesser of either the revenue-based or benchmark-based loss sharing limit under the Track 1+ Model.

Further, we realized that a significant incentive for ACOs to transition more quickly to the highest level of risk and reward under the BASIC track would be the opportunity to participate in an Advanced APM for purposes of the Quality Payment Program. Under the BASIC track's Level E, an ACO's eligible clinicians would have the opportunity to receive APM Incentive Payments and ultimately higher fee schedule updates starting in 2026, in the payment year corresponding to each performance year in which they attain QP status.

We explained in the Regulatory Impact Analysis section of the proposed rule (83 FR 41927) that the proposed BASIC track is expected to increase participation in performance-based risk by ACOs that may not otherwise take on the higher exposure to risk required in the ENHANCED track (or in the current Track 2). Such added participation in performance-based risk is expected to include a significant number of low revenue ACOs, including physician-led ACOs. These ACOs have shown stronger performance in the first years of the program despite mainly opting to participate in Track 1. Furthermore, the option for BASIC track ACOs to progress gradually toward risk within a single agreement period or accelerate more quickly to the BASIC track's Level E is expected to further expand eventual participation in performance-based risk by ACOs that would otherwise hesitate to immediately transition to this level of risk because of uncertainty related to benchmark rebasing.

Therefore, adding the BASIC track as a participation option under the Shared Savings Program would not likely result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology in section 1899(d). Further, we expected that adding the BASIC track would continue to lead to improvement in the quality of care furnished to Medicare FFS beneficiaries because participating ACOs would have an incentive to perform well on the quality measures in order to maximize the shared savings they may receive and minimize any shared losses they must pay.

The proposed rule included other policy proposals that require that we reassess the policies adopted under the authority of section 1899(i)(3) of the Act to ensure that they comply with the requirements under section 1899(i)(3)(B) of the Act. As described in the August 2018 proposed rule (83 FR 41927), the elimination of Track 2 as an on-going participation option, the addition of the BASIC track, the benchmarking changes (see section II.D. of this final rule), and the proposal to determine shared savings and shared losses for the 6-month performance years starting on January 1, 2019, and July 1, 2019, using expenditures for the entire CY 2019 and then pro-rating these amounts to reflect the shorter performance year (see section II.A.7. of this final rule, as well as the November 2018 final rule), require the use of our authority under

section 1899(i) of the Act. These proposed changes to our payment methodology would not be expected to result in a situation in which all policies adopted under the authority of section 1899(i) of the Act, when taken together, result in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act. We noted that we would continue to reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model established under section 1899(i)(3) of the Act no longer meets this requirement, we would undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

As discussed in the Regulatory Impact Analysis section of this final rule (see section V), we believe the BASIC track meets the requirements for use of our authority under section 1899(i)(3) of the Act. The considerations we previously described, as included in the August 2018 proposed rule and the November 2018 final rule (83 FR 59949), were relevant in making this determination. Specifically, we do not believe that the BASIC track, as finalized in this section of this final rule, will result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology in section 1899(d), and adding the BASIC track would continue to lead to improvement in the quality of care furnished to Medicare FFS beneficiaries.

Comment: We received feedback from several commenters that favored the proposed Shared Savings Program two track redesign and the incremental transition to two-sided risk, including effectively consolidating Track 1 and the Track 1+ Model into the single BASIC track and the preservation of Track 3 in the ENHANCED track. Generally, commenters supported the overall framework and supported CMS' proposal to pursue a tiered approach to introducing downside financial risk for ACOs. One commenter in support of the proposal noted that the renamed tracks are ''more descriptive'' than the current ones and applauded the permanent inclusion of the Track 1+ Model (described as Level E of the BASIC track). One commenter stated that the approach would strike an appropriate balance between encouraging the transition to performance-based risk while not creating an undue burden on clinicians and ACOs as they make this transition. Another commenter believed that the new transition from one-sided to two-sided risk within the BASIC track would reward participants for providing beneficiaries with good care while holding ACOs accountable for potential losses. Another commenter believed that the proposed rule would provide an opportunity to make changes to the Medicare program that advance high-quality, affordable, and value-based care to improve patient outcomes and reduce costs.

One commenter strongly supported and shared CMS' goal of strengthening the Shared Savings Program to make it successful for patients, providers, and Medicare over the long-term so that Medicare beneficiaries can benefit from the advantage of high-quality, cost-efficient, and highly coordinated care. Another commenter urged CMS to continue providing a variety of ways to participate in the Shared Savings Program, including different tracks and levels of risk. The commenter stated that each organization is unique and will follow its own path to gain experience in redesigning care processes, learning where to appropriately direct resources so that its patients can receive patient-centered, team-based, and integrated healthcare, while at the same time, providing system savings to programs, patients and healthcare professionals.

However, many commenters disagreed with the more aggressive transition of ACOs to performance-based risk under the proposed program redesign. Some commenters cautioned that although the requirement that all ACOs undertake two-sided risk at some point during their participation agreement may improve the performance of the ACOs that continue to participate in the Shared Savings Program, it may also reduce ACO participation in the program. Several commenters expressed concern that the change in program requirements may cause ACOs to end their participation with the Shared Savings Program and create a barrier to entry for ACOs to join the program.

One commenter recommended that CMS carefully monitor Shared Savings Program participation and change course if participation falls precipitously. Several commenters expressed concern that the rapid assumption of significant levels of risk by ACOs would discourage new participants and impede current ACOs' ability to make patient-centered infrastructure investments that are necessary for successful participation. Another commenter believed that reducing the amount of time permitted in upside only programs is ill advised and jeopardizes ACOs' continued participation.

Response: We appreciate the support of some commenters favoring the Shared Savings Program redesign and the more rapid transition from one-sided to two-sided risk. We continue to believe that the proposed policies for the new BASIC track and the ENHANCED track generally strike an appropriate balance between risk and reward, appropriately distinguish available participation options by ACO and ACO participant characteristics, and will be effective in creating incentives for better coordinating care and assisting ACOs with the transition to risk. We continue to believe that models under which ACOs bear a degree of financial risk hold greater potential than one-sided models to induce more meaningful systematic change, promote accountability for a patient population and coordination of patient medical care, and encourage investment in redesigned care processes.

In response to commenters' concerns about the potential impact of the proposed redesign on program participation, we note the discussion in the Regulatory Impact Analysis (section V of this final rule), where we describe that potentially fewer new ACOs may enter the program, although ACOs within current agreement periods may be more likely to continue their participation. However, in general, we believe that the benefits associated with making the BASIC track's glide path available to eligible ACOs, including the incremental increase in risk and reward, outweigh the risk of reduced ACO participation. With respect to the concerns about reduced ACO participation in the program, the potential effects of the proposed policies regarding the required transition to a two-sided model on participation decisions must be viewed together with other proposed program design elements that factor into participation decisions, including the methodology used to set and reset the ACO's historical benchmark; the approach used to calculate the ACO's shared savings and/or shared losses; the level of performance-based risk for ACOs; availability of the SNF 3-Day Rule Waiver, expanded coverage of telehealth services under section 1899(l) of the Act and Beneficiary Incentive Program; and the choice of methodologies for assigning beneficiaries to the ACO.

Further, we believe that offering a glide path to transition ACOs to a two-

sided model through progressive levels of increasing risk and potential reward is responsive to commenters' requests for additional program options for ACOs, including those less experienced with performance-based risk in an accountable care model. We believe that the addition of the new BASIC track, including a glide path with multiple levels of risk and potential reward, will help ACOs inexperienced with performance-based risk Medicare ACO initiatives to match their infrastructure and organizational readiness to an available participation option to support their achievement of the program's goals of better care for individuals, better health for populations, and lower growth in Medicare Parts A and B expenditures.

Further, as described elsewhere in this final rule, in response to commenters' suggestions, we are finalizing several modifications to our proposals to further smooth ACOs' transitions to performance-based risk. For example, as described in section II.A.5.c. of this final rule, we are finalizing a policy modification to allow additional flexibility for new ACO legal entities that qualify as low revenue ACOs and inexperienced with performance-based risk Medicare ACO initiatives, to participate for up to 3 performance years under a one-sided model (4 performance years in the case of ACOs entering an agreement period beginning on July 1, 2019) of the BASIC track's glide path before transitioning to Level E (the highest level of risk and potential reward under the BASIC track). We believe that this option may address some commenters' concerns. For instance, this option could be an attractive alternative to new ACOs that are inexperienced with the Shared Savings Program, by providing an additional year for the ACO to earn shared savings payments and make patient-centered infrastructure investments that would support their successful participation under a two-sided model. Additionally, as described in section II.A.6.c. of this final rule, we are finalizing modifications to the approach for determining repayment mechanism arrangement amounts to potentially reduce the burden of these arrangements for both lower-revenue and higher-revenue ACOs participating in the ENHANCED track.

We will continue to monitor program participation and consider further refinements to the program's participation options as we gain experience with implementing the redesigned program.

Comment: As we summarize and respond to elsewhere in this section of this final rule, some commenters expressed concerns about the high level of risk under the ENHANCED track, and suggested that CMS allow for additional participation options that would smooth the transition from level of risk and potential reward within Level E of the BASIC track to the ENHANCED track. Some of these comments included suggestions for alternative designs of the ENHANCED track. Several commenters offered suggestions for how to modify the design of the financial model of, or participation options under, the ENHANCED track. A few commenters suggested that CMS should increase the shared savings rate to 80 percent for each performance year under the ENHANCED track (the same as the Next Generation ACO Model) and increase the performance payment limits over the agreement period.

Response: We continue to believe it is important to maintain a participation option with the level of risk and potential reward as currently available under Track 3, proposed to be the ENHANCED track under the redesign of the program's participation options. We believe that the opportunity for greater shared savings as compared to Level E of the BASIC track will encourage ACOs to undertake greater performance-based risk under the ENHANCED track, as well as provide a suitable participation option for ACOs more experienced with the accountable care model.

Further, the design of the ENHANCED track offers symmetrical levels of risk and reward. To maintain this overall design, to increase the level of reward for the ENHANCED track (as suggested by one commenter), we would likewise need to consider increasing the level of risk as well. In light of commenters' concerns about the level of risk in the design of this track, we are concerned about changing the design of the ENHANCED track to include even higher levels of risk and potential reward.

Comment: Several commenters recommended that the ENHANCED track should include a revenue-based loss sharing limit. One commenter recommended that CMS should incorporate a revenue-based loss sharing limit into the ENHANCED track, similar to the BASIC track design. A few commenters suggested that CMS apply a loss sharing limit that is the lesser of 20 percent of the ACO participant's revenue or 10 percent of updated benchmark for the ENHANCED track.

Response: We decline at this time to adopt the commenters' suggestion to include an opportunity for ENHANCED track ACOs to qualify for a revenue-based loss sharing limit. The loss sharing limit under the ENHANCED track will remain 15 percent of the ACO's updated benchmark. We continue to believe that ACOs participating under higher levels of risk and reward can drive more meaningful systematic change in the behavior of providers and suppliers towards meeting the program's goals. As we describe elsewhere in this final rule, we continue to believe that all ACOs should transition to the level of risk and reward under the ENHANCED track. Therefore, we do not believe it is necessary to decrease the overall downside risk in the ENHANCED track or develop a financial model within the ENHANCED track, similar to the design of the two-sided models of the BASIC track. Thus, we decline to apply the revenue-based loss sharing limit to the ENHANCED track, which would potentially provide a relatively lower level of risk and weaken the incentives of the track's financial model. We note that, as discussed in section II.A.6.c. of this final rule, we are modifying the methodology for calculating repayment mechanism amounts for ENHANCED track ACOs, so that lower-revenue ACOs may be eligible for potentially lower repayment mechanism amounts under a revenue-based calculation. We believe this approach may assist ACOs by potentially reducing the financial burden of setting aside capital to establish a repayment mechanism before transitioning to greater risk under the ENHANCED track.

Comment: Some commenters supported the consideration of allowing a participation option that would provide a gentler transition from the level of risk and potential reward under the BASIC track's Level E and the level of risk and potential reward under the ENHANCED track, which we described and sought comment on in section II.A.5.b. of the August 2018 proposed rule (83 FR 41818). Several commenters expressed concern about the steep increase in risk between the BASIC track's Level E and the ENHANCED track. Several commenters called attention to the difference between the maximum amount of loss liability under the BASIC track's Level E (4 percent of the ACO's updated historical benchmark) and the ENHANCED track (15 percent of the ACO's updated historical benchmark). Several commenters indicated the likelihood of decreasing participation from low revenue ACOs if they are required to take on the level of two-sided risk in the ENHANCED track. One commenter stated that this significant increase in risk may present a barrier to successful

participation by smaller and less experienced ACOs. One commenter, concerned about the increase in risk between Level E of the BASIC track and the ENHANCED track, indicated that differences in exposure to loss liability and the repayment mechanism requirements between these tracks are unbalanced. One commenter, comparing the ENHANCED track to the Pioneer ACO model, cautioned CMS that we should expect attrition from the ENHANCED track based on the Pioneer ACO model experience.

Several commenters suggested alternatives to ease the transition into risk from BASIC Level E to the ENHANCED track. Commenters suggested alternative participation options to create a series of gradual increases in both risk and reward, rather than a few inflection points to significantly different levels of risk. For example, creating a glide path to the highest risk level within the ENHANCED track or offer an additional track to help bridge the gap between the BASIC track and ENHANCED track that offers more options for gradual risk increases between Level E of the BASIC track and the ENHANCED track. Commenters' specific suggestions included the following:

- Establishing a glide path from Level E of the BASIC track to the ENHANCED track based on the design of Track 2. One commenter suggested that CMS create a ''BASIC Level E+'' alternative that mimics the maximum shared savings and loss rates of the current Track 2. It would have an up to 60 percent maximum shared savings rate and a loss sharing rate that is not less than 40 percent but would not exceed 60 percent and would qualify as an Advanced APM.
- Installing Track 2 as a three year glide path for all ACO entities within the ENHANCED track.
- Creating a voluntary intermediate track with a loss sharing limit of 8 percent of the ACO's updated benchmark and shared savings rate of 65 percent.
- Phasing-in the loss sharing limits within the ENHANCED track incrementally. One commenter suggested that the loss sharing limits be phased-in at 7 percent of benchmark in year 1, 10 percent in year 2, and then 15 percent in years 3, 4, and 5. Another commenter suggested a slower phase-in of the loss sharing limit, with a more incremental increase in the percentage each performance year.

One commenter encouraged CMS to continue to assess the ability of low revenue ACOs to assume higher levels of downside risk. According to the commenter, CMS should also evaluate the success rates of low revenue ACOs that move to the ENHANCED track and monitor the number of ACOs that return to the BASIC track, particularly due to inability to assume higher levels of risk.

Response: We continue to believe that the transition to risk from Level E of the BASIC track to the ENHANCED track best supports achieving our goal of driving more meaningful systematic change in providers' and suppliers' behavior towards achieving the program's goals. Allowing more manageable levels of risk within the BASIC track's glide path within the Shared Savings Program is an important pathway for helping organizations gain experience with managing risk as well as participating in Advanced APMs under the Quality Payment Program. We also recognize that it may be more difficult for low revenue ACOs to transition to higher levels of risk and potential reward and are therefore allowing eligible low revenue ACOs the opportunity to participate in the BASIC track for up to two agreement periods before advancing to the ENHANCED track (as discussed in section II.A.5.b.(2) of this final rule). As discussed in section II.A.6.c of this final rule, we are modifying our approach to determining the amount of the repayment mechanism for ENHANCED track ACOs, to allow for potentially lower estimated amounts for lower-revenue ACOs, to support their transition to the ENHANCED track. Although the financial model of the ENHANCED track will remain the same as the design of Track 3, the modified repayment mechanism arrangement estimation approach may reduce the financial burden on ACOs of establishing these arrangements, for example in setting aside capital, when transitioning to greater risk.

One purpose of the proposed redesign is to streamline participation options under the Shared Savings Program. At this time, and considering the factors we described in this response as well as previous comment responses in this section, we decline to establish additional participation options that would include a bridge or intermediate track between Level E of the BASIC track and the ENHANCED track. Specifically, we decline the suggestion to modify the design of the ENHANCED track at this time to more closely resemble the design of Track 2, with a phase-in of the loss sharing limits over a single agreement period (as suggested by one commenter). As explained elsewhere in this final rule we are finalizing our proposal to discontinue Track 2, in part reflective of the reduced rates of participation in this track, and the availability of the BASIC track with relatively lower levels of risk and reward that, for ACOs eligible for the glide path, gradually increase over the term of the agreement period.

As suggested by the commenter, we agree with the need to continue to monitor the redesigned participation options, including with respect to low revenue ACOs that move to the ENHANCED track as well as performance by high revenue ACOs under the ENHANCED track. We note that as described in section II.A.5.c of this final rule, we are finalizing a policy to monitor ACOs for composition changes during their agreement period that would affect their participation options.

Comment: Many commenters opposed the proposal to discontinue Track 1 or an equivalent option that would allow for ACOs to participate for an entire agreement period, or up to 6 performance years (to match the two 3-year agreement periods that are currently allowed), under a one-sided model. Many of these commenters believed that the current Track 1 is the only viable opportunity for rural ACOs to participate in a Medicare value-based payment model. The comments stated that although there are other options for health care providers to work together to address the cost and quality of care, collaborating in a Shared Savings Program ACO remains the most viable option for ACO participants, specifically independent rural healthcare organizations. One commenter stated that as a non-profit, low revenue ACO, they may be forced out of the Shared Savings Program because they lack the capital required for the repayment mechanism. Another commenter strongly opposed the elimination of Track 1 and urged its retention for physician-led organizations. The commenter proposed that if CMS chose to retain Track 1, it would recommend modifications to increase net savings for Medicare, such as terminating ACOs that have not achieved savings over several years, reducing shared savings payments for ACOs that fail to meet quality performance standards, or allowing ACOs to be accountable only for the spending they control versus the total cost of care.

A few commenters asserted that CMS does not have authority under section 1899(i) of the Act to discontinue Track 1 and replace it with the BASIC track. These commenters noted that section 1899(i)(2)(B) of the Act says that ''payments to an ACO for items and services . . . for beneficiaries for a year . . . shall be established in a manner that does not result in spending more for such ACO for such beneficiaries than would otherwise be expended for such ACO for such beneficiaries for such year

if the model were not implemented.'' As a result, the commenters contend that the statute is not referring to a measure of overall program spending, but to the change in spending for each individual ACO.

Further, these commenters noted that the current Track 1 model meets the statutory requirements for determining shared savings payments under section 1899(d) of the Act. Section 1899(i) of the Act permits CMS to use partial capitation or other payment models instead of the shared savings approach under section 1899(d). However, one of the requirements for both of these other payment models is that spending cannot be more for such an ACO than would otherwise be expended for such ACO if the model were not implemented. In the proposed BASIC track and ENHANCED track, if Medicare spending exceeds an ACO's benchmark, the ACO would be required to repay a portion of the difference but not the full amount. Because the ACO would not be required to repay the full increase, these commenters assert that Medicare would spend more for that ACO than it would otherwise have spent and, as a result, the two-sided payment model under the proposed BASIC track and ENHANCED track does not satisfy the statutory requirement in section 1899(i) of the Act.

Response: After evaluating commenters' concerns related to discontinuing Track 1, and as further detailed in section II.A.5 of this final rule, we are modifying our proposals and are finalizing an approach that would allow new legal entities that are low revenue ACOs and inexperienced with performance-based risk Medicare ACO initiatives the option to elect an additional year in a one-sided model of the BASIC track's glide path, for a total of 3 performance years in a one-sided model (or 4 performance years in the case of ACOs entering an agreement period beginning on July 1, 2019). The ACO would enter the glide path at Level A, and automatically advance to Level B. Prior to the automatic advancement of the ACO to Level C, an eligible ACO may elect to remain in Level B for another performance year, and then be automatically advanced to Level E for the remaining two years. As we discuss in section II.A.3 of this final rule, we are also modifying our proposals regarding the design of the BASIC track's glide path in order to increase the final shared savings rate to 40 percent for one-sided levels (Levels A and B) and allow for a 50 percent shared savings rate for two-sided levels (Levels C, D, and E) to further incentivize ACOs to move to risk while also providing the opportunity for ACOs to share in a greater percentage of savings to support their ongoing operating costs.

We believe this approach will allow for a smoother progression to two-sided risk within the BASIC track's glide path, particularly for new legal entities that are low revenue ACOs and inexperienced with the Shared Savings Program and other Medicare ACO initiatives. We also note that, under the policies we are adopting in this final rule, eligible ACOs will have the opportunity to participate for up to 3 performance years (or 4 performance years in the case of ACOs entering an agreement period beginning on July 1, 2019) under a one-sided model of approximately the same design as is currently offered in Track 1. This approach allows an ACO to benefit from the stability and predictability of their benchmark when moving to two-sided risk within the same agreement period.

However, we disagree with commenters on the need to allow ACOs to continue under a one-sided model for longer periods of time. For example, allowing ACOs to continue under a one-sided model for up to 6 performance years (as with the program's current design). We believe that such an approach would, at best, maintain the status quo of the program, and therefore continue a pattern where ACOs are allowed to remain under the one-sided model without strong incentives to become accountable for the cost and quality of care for their assigned populations.

Finally, we disagree with the commenters' assertions that CMS does not have authority to discontinue Track 1 and replace it with the BASIC track, which includes a glide path beginning with a one-sided model that offers the opportunity to earn shared savings determined under section 1899(d) of the Act. Section 1899(i)(3) of the Act authorizes the Secretary to use other payment models rather than the one-sided model described in section 1899(d) of the Act, as long as the Secretary determines that the other payment model will improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures. As we described in the August 2018 proposed rule and restate in this final rule, we believe that the requirements for use of our authority under section 1899(i)(3) are met with respect to establishing the new BASIC track, as well as the other policies we proposed and are finalizing that require use of this authority. In particular, we note that the Regulatory Impact Analysis in Section V of this final rule includes a description of the comparison that was conducted between the projected impact of the payment methodology that incorporates all program elements implemented using our authority under section 1899(i)(3) of the Act, versus a hypothetical baseline payment methodology that excludes the elements that require section 1899(i)(3) authority. As detailed in that section, the analysis estimates approximately $4 billion greater average net program savings under the alternative payment model that includes all policies that require the authority of section 1899(i)(3) of the Act than would be expected under the hypothetical baseline in total over the 2019 to 2028 projection period. The alternative payment model, as finalized in this rule, is projected to result in greater savings via a combination of reduced Medicare Parts A and B FFS expenditures and reduced net payments to ACOs.

Comment: Some commenters agreed with discontinuing the deferred renewal option for Track 1 ACOs that is available under the current regulations. However, most commenters disagreed with CMS' decision to discontinue the current policy to allow Track 1 ACOs in their first agreement period to defer renewal for a second agreement period prior to taking on risk in a two-sided model.

Response: As we previously explained, very few ACOs have elected the deferred renewal participation option, and we have concluded that the deferred renewal policy has shown limited success in encouraging ACOs to advance to performance-based risk. As we explained in the proposed rule, and reiterated in this section of this final rule, we continue to believe that the deferred renewal option would be inconsistent with our proposed redesign of the program that would transition ACOs from a one-sided model to two-sided models within one agreement period under the BASIC track's glide path. Further, extending the length of the agreement period from 3 years to 5 years, as we are finalizing in this final rule, creates another redundancy with the deferred renewal option which allows ACOs to defer benchmark rebasing by 1 year. We are finalizing as proposed our policy to discontinue the availability of the deferred renewal option for Track 1 ACOs applying to enter a second agreement period in the Shared Savings Program under a two-sided model.

Comment: Generally, most commenters favored the proposal to move from three to five year agreement periods. Most commenters believed that

the five year agreement periods would be beneficial due to the amount of time it takes for ACOs to operationalize changes to support improved performance in the program. Other commenters stated that the change would advance greater predictability for providers and health systems that are making investments and other system changes to support participation. One commenter noted that a three year agreement period has been insufficient in terms of enabling participants to implement reforms to care delivery and workflow. Many other commenters agreed and believed that the five year agreement periods would help with program predictability and increase stability. A few commenters stated that historical benchmarks would become more predictable, since the benchmark would continue to be based on the expenditures for beneficiaries who would have been assigned to the ACO in the three most recent years prior to the start of the ACO's agreement period. Other commenters believed that the longer agreement periods would provide a meaningful length of time to measure ACO successes and challenges. Further, one of the commenters contended that as the Shared Savings Program matures, it will be important to evaluate and measure ACO performance and the 5-year agreement period will allow for a more robust evaluation of financial performance.

However, some commenters disagreed with the change in the length of the agreement period. Several commenters asserted that the greatest factor undermining stability within the Shared Savings Program is CMS' changes to policy repeatedly within and between agreement periods, and these commenters expressed that moving to a 5-year agreement period would expose participants to extra potential change within a single agreement period. One of these commenters stated that this kind of instability can only be mitigated via shorter agreement periods. Another commenter stated that it would support the change from three- to five-years if CMS minimized year-over-year policy changes. One commenter stated that ACOs who began participating in the Shared Savings Program in 2012/2013 were either sheltered from consequences or put at a significant disadvantage. The commenter stated that early adopters were put at a competitive disadvantage when the regional benchmarking formulas were introduced for later entrants, and cited the uncertainty inherent in the potential for future changes in the regulatory landscape. The commenter further contended that these ACOs also had the ability to remain under one-sided risk for an extended period of time, which the commenter believed sheltered these ACOs from consequences of two-sided risk. The commenter proposed that CMS either shorten the agreement period or provide for annual updates and renewals, similar to the Medicare Advantage regulations. Another commenter stated that, although they accept CMS' decision to extend the agreement period from three to five years to promote stability, the commenter was also critical of the fact that CMS regularly changes, rewrites, or clarifies the Shared Savings Program rules, creating instability in the program.

Other commenters urged CMS to reconsider the change to a 5-year agreement period due to their concern that the length of the agreement period in relation to CMS' proposed risk ratio cap is too long to properly reflect changes in the attributes of the assigned beneficiary population. Another commenter was concerned about procuring a repayment mechanism for the 5-year agreement period plus the additional 24 month tail period. Specifically, the commenter contended that the extended duration of the participation agreement might limit the availability of the surety bond as a repayment mechanism option.

Finally, several commenters recommended that CMS extend the agreement period to 7 years. Once commenter was concerned that the proposed rule, with its new and shorter transition to shared losses, could lead to even greater pressure on providers to respond to the program's financial incentives to reduce spending on services. The commenter further contended that these pressures, in turn, may lead to greater risk that patient access to greater innovations and technologies will be compromised, especially when these are more expensive than the standard of care embedded in benchmarks.

Response: We appreciate the general support for moving from three to five year agreement periods. During previous rulemaking in 2011, we received a large number of comments surrounding the length of the agreement period that specifically requested that it be extended to five years. As part of reevaluating the program requirements, we believe that it may benefit ACOs to extend the 3-year agreement period to five years so they will have more predictable benchmarks and therefore a greater opportunity for return on investment through achieving shared savings with the longer agreement period. We also believe that extending the agreement period to five years allows ACOs to gradually transition to risk and establish an operational structure to support quality reporting and other Shared Savings Program requirements, and provides adequate time for data evaluation during the early part of the agreement period. Further, we recognize that the longer the agreement period, the greater an ACO's chance to build on the success or continue the failure of its current agreement. CMS' PY 2016 results show that ACOs produce a higher level of net savings and more optimal financial performance results the longer they have been in the Shared Savings Program and with additional participation experience (83 FR 41917). We also understand commenters' concern that CMS policy may evolve during the five year agreement period. However, we will continue to evaluate the effectiveness of Shared Savings Program policies and make adjustments, as necessary, to further promote accountability for a patient population, foster the coordination of Medicare Parts A and B items and services, and encourage high quality and efficient service delivery.

We reviewed quality and financial results to date in developing these policy proposals to refine the program. We continue to review ACO quality and financial results to ensure that the program is providing as much value as possible, is responsive to stakeholders' feedback, and is meeting its objectives of improving care coordination for beneficiaries and lowering growth in Medicare expenditures. We also make available, to researchers and other external parties, public use files and research identifiable files with program data, to promote program transparency and to allow researchers and others to evaluate and comment on program results.

We appreciate the comments related to the proposed symmetrical 3 percent cap on CMS–HCC risk scores in relation to the proposal for 5-year agreement periods. In developing our proposed policies, we considered alternate levels for the cap or allowing full CMS–HCC risk adjustment with no cap at all. However, we were concerned that a lower cap would not offer ACOs enough protection against greater health status changes relative to our current approach. At the same time, we were concerned that adopting a higher cap, or allowing for full, uncapped risk adjustment would not provide sufficient protection against potential coding initiatives. Our choice of 3 percent as the preferred level for the cap was

influenced by program experience as described in more detail in section II.D.2.b of the August 2018 proposed rule.

We appreciate the concerns raised regarding the availability of repayment mechanism arrangements and, in particular, the availability of surety bonds. As we explain in section II.A.6 of this final rule, based on our experience, we believe ACOs will be able to work with financial institutions to establish the required arrangement to cover the full 5-year agreement period and tail period plus the 12-month tail period we are finalizing. However, as described in section II.A.6 of this final rule, we are also permitting ACOs to satisfy the repayment mechanism duration requirement by establishing a repayment mechanism that has a term that covers at least the first two performance years that an ACO is participating under a two-sided model and provides for automatic, annual 12 month extensions of the repayment mechanism such that the repayment mechanism will eventually remain in effect for the duration of the agreement period plus 12 months following the conclusion of the agreement period. We believe that these changes will reduce the burden of establishing a repayment mechanism that satisfies the duration requirement. We will monitor the use of repayment mechanisms and may revisit the issue in future rulemaking if we determine that the ability of an ACO to establish an adequate repayment mechanism that meets the duration requirement is constrained by the availability or cost of repayment mechanism options. Furthermore, we note that nothing in our program rules prohibits an ACO from establishing multiple repayment mechanisms, as long as the total of the repayment mechanisms meets the repayment mechanism amount provided by CMS.

Finally, we appreciate the suggestion for a 7-year agreement period but due to potential financial and administrative burdens on ACOs, including procuring a repayment mechanism for a longer period of time, we are declining to extend the agreement period to that span at this time.

Comment: One commenter suggested that current ACOs participating in Track 3 should be provided reward options for undertaking risk such as the ability to participate in the BASIC track, extension of their current agreement period, and reduction of the new agreement period to three years for the first renewal period under the new participation options for current Track 3 ACOs.

Response: We decline the commenter's suggestions to allow current Track 3 ACOs the option to choose alternative participation options, including participation under an initial 3-year agreement period rather than a 5-year agreement period under the ENHANCED track. As described elsewhere in this section of this final rule, we are finalizing an approach to require all ACOs entering agreement periods beginning July 1, 2019 and subsequent years to participate under agreement periods of at least 5 years. We note that, in the November 2018 final rule, we finalized a policy which allows all ACOs whose agreement periods expire on December 31, 2018 to elect a voluntary 6-month extension of their current agreement period, which includes current Track 3 ACOs with participation agreements expiring on that date. In addition, we note that eligible low revenue ACOs that are determined to be experienced with performance-based risk Medicare ACO initiatives may participate for an agreement period under Level E of the BASIC track, including such qualifying ACOs that currently are participating under Track 3. As described in section II.A.5. of this final rule, low revenue ACOs may participate in the BASIC track for up to two agreement periods, which are not required to be sequential. For example, this would allow low revenue ACOs that transition to the ENHANCED track after a single agreement period under the BASIC track the opportunity to return to the BASIC track if the ENHANCED track initially proves to involve too high a level of performance-based risk.

Comment: One commenter sought clarification as to the interaction between the Bundled Payments for Care Improvement Advanced (BPCI Advanced) model and the proposed redesigned Shared Savings Program participation options. Specifically, the commenter stated that given its financial and operational investment that they recently made to participate in the BPCI Advanced model, providers need to understand explicitly how CMS intends to handle the interaction of the two programs as the commenter makes its business decision regarding participation in the Shared Savings Program for the next agreement period.

Response: Entities may concurrently participate in BPCI Advanced and the Shared Savings Program. The interactions between the Shared Savings Program assigned beneficiaries and episodes that are initiated under the BPCI Advanced model are governed by the model participation agreement. The current BPCI Advanced participation agreement addresses financial reconciliation and indicates that clinical episodes may not be initiated for beneficiaries assigned to a Shared Savings Program ACO in Track 3, but can be initiated for beneficiaries assigned to a Shared Savings Program ACO in Track 1, the Track 1+ Model or Track 2. We will continue to work with our colleagues in the Innovation Center to address interactions between models and Shared Savings Program ACOs, including the interaction between BPCI Advanced and the BASIC track and ENHANCED track, and provide such information in future guidance. We work to align and create synergies between the Shared Savings Program and the payment and service delivery models tested by the Innovation Center. We have policies in place to take into account overlap between the Shared Savings Program and Innovation Center models, which are designed to test new payment and service delivery models to reduce expenditures and preserve or enhance quality of care, whenever possible. We continue to monitor these policies and make refinements as we gain experience and lessons learned from these interactions. When new models are announced, we encourage ACOs and their leaders to engage in dialogue with the Innovation Center and Shared Savings Program staff to inform their decision-making regarding the participation options.

Comment: Several commenters suggested CMS consider how to align the design parameters across Medicare ACO initiatives in redesigning the Shared Savings Program. One commenter explained that inconsistency across different Medicare ACO initiatives presents challenges for organizations that want to progress from one initiative to the next, as well for organizations that have participants in different Medicare ACO models at the same time. Another commenter specifically suggested that CMS continue to identify areas such as with beneficiary attribution and payment methodologies to create consistency across different Medicare ACO initiatives and even more broadly across CMS' delivery system reform portfolio. One commenter specifically suggested that CMS incorporate several elements of the Next Generation ACO Model into the Shared Savings Program such as the choice of allowing participation by TINs or NPIs (as opposed to Shared Savings Program's current requirement for participation by all NPIs enrolled in an ACO participant TIN), infrastructure payments, prepayment of shared savings and primary capitation, which were

suggestions echoed by other commenters.

Response: We appreciate commenters' support for and interest in CMS' Medicare ACO initiatives, more generally. We note that the Innovation Center's time-limited Medicare ACO models, including the Next Generation ACO Model, are designed to test alternative payment and service delivery models. Lessons learned from these initiatives may be used to inform the development of future policies under the Shared Savings Program, which is a permanent program established under the authority of section 1899 of the Act. We also believe the alternative designs of these ACO models provide important pathways for ACOs to select to participate under a Medicare ACO model that may be more in line with their organizational preferences and experience with the accountable care model or the needs of the populations they serve. CMS provides education and outreach to explain the designs of ACO models, and requirements for participation in these initiatives, to support ACOs' compliance with initiative requirements and their success in achieving the goals of these initiatives. Some changes suggested by commenters were not contemplated in the August 2018 proposed rule. We decline to undertake these additional policy modifications at this time. Specifically, we decline to redefine ACO participants to allow participation by some but not all NPIs that have reassigned their billing rights to a TIN, allow for infrastructure payments or prepayment of shared savings as part of the national program, or to create a capitated payment model.

Comment: Several commenters encouraged CMS to take steps towards aligning the Shared Savings Program with Medicare Advantage as part of the redesign of the Shared Savings Program. One commenter stated that Medicare Advantage plans are rewarded with higher benchmarks for higher quality, which puts Shared Savings Program ACOs at a financial disadvantage. Other commenters suggested that CMS incorporate into the Shared Savings Program aspects of Medicare Advantage such as utilization management and more extensive beneficiary incentive payments (such as under the Innovation Center's Medicare Advantage Value-Based Insurance Design model). One commenter suggested that Shared Savings Program ACOs need to be more clearly defined as an alternative to both traditional FFS Medicare and Medicare Advantage. Another commenter suggested that there may not be a need for the Shared Savings Program in light of the availability of Medicare Advantage and other value-based payment initiatives such as the Innovation Center's Comprehensive Primary Care Plus (CPC+) Model.

Response: Elsewhere in this final rule, we discuss commenters' specific suggestions for bringing greater alignment between the design of the Shared Savings Program and Medicare Advantage, such as the modifications to the Shared Savings Program's methodology to annually risk adjust the historical benchmark (see section II.D of this final rule). In section II.C.2. of this final rule, we also address commenters' suggestions that CMS align its proposed beneficiary incentive program policies with MA.

Although we frequently relied on our experience in other Medicare programs, including MA, to help develop the original framework for the Shared Savings Program and will continue to explore opportunities to align the requirements of the Shared Savings Program and Medicare Advantage, we believe that the Shared Savings Program offers an alternative to both volume-based payments under traditional Medicare FFS and Medicare Advantage. Under the Shared Savings Program, the providers and suppliers that form an ACO agree to become accountable for the quality, cost, and overall care of the Medicare FFS beneficiaries assigned to the ACO. Shared Savings Program ACOs only share in savings if they meet both the quality performance standards and generate shareable savings. Medicare FFS beneficiaries assigned to Shared Savings Program ACOs retain all rights and benefits under traditional Medicare, including the right to see any physician of their choosing, and they do not enroll in the Shared Savings Program.

Further, we will continue to offer the Shared Savings Program, as required by law, and decline the commenters' suggestion that CMS discontinue the program.

Final Action: We are finalizing our proposed policies to redesign the program's participation options by discontinuing Track 1, Track 2, and the deferred renewal option under §§ 425.200(b)(3), and 425.200(e). We are also finalizing our policy to offer two tracks that eligible ACOs would enter into for an agreement period of at least 5 years:

- BASIC track, added as a new provision at § 425.605, which includes 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 (as described in section II.A.3. of this final rule). We are finalizing our proposal in § 425.600(a)(4) for eligible ACOs to elect to operate under the BASIC track.

  Under the BASIC track's glide path, the level of risk and potential reward phases in over the course of the agreement period in the following order:

  ++ *Level A.* The ACO operates under a one-sided model as described under § 425.605(d)(1)(i).

  ++ *Level B.* The ACO operates under a one-sided model as described under § 425.605(d)(1)(ii).

  ++ *Level C.* The ACO operates under a two-sided model as described under § 425.605(d)(1)(iii).

  ++ *Level D.* The ACO operates under a two-sided model as described under § 425.605(d)(1)(iv).

  ++ *Level E.* The ACO operates under a two-sided model as described under § 425.605(d)(1)(v).

- ENHANCED track as currently designed and implemented under §§ 425.600(a)(3), 425.610, based on the program's existing Track 3.

Additionally, we are finalizing changes to § 425.200 to specify that ACOs will agree to participate for a period of not less than 5 years for agreement periods beginning on July 1, 2019 and in subsequent years. Lastly, we are finalizing revisions to § 425.502(e)(4)(v), specifying calculation of the quality improvement reward as part of determining the ACO's quality score, which previously included language based on 3-year agreements.

3. Creating a BASIC Track With Glide Path to Performance-Based Risk

a. Overview

We proposed that the BASIC track would be available as a participation option for agreement periods beginning on July 1, 2019 and in subsequent years. Special considerations and proposals with respect to the midyear start of the first BASIC track performance year and the limitation of this first performance year to a 6-month period are discussed in section II.A.7. of this final rule and, as needed, throughout this preamble.

In general, we proposed to model the BASIC track on the current provisions governing Shared Savings Program ACOs under 42 CFR part 425, including the general eligibility requirements (subpart B), application procedures (subpart C), program requirements and beneficiary protections (subpart D), beneficiary assignment methodology (subpart E), quality performance standards (subpart F), data sharing opportunities and requirements (subpart H), and benchmarking methodology (which as discussed in section II.D. of this final rule, we proposed to specify in a new section of the regulations at

§ 425.601). Further, we proposed that the policies on reopening determinations of shared savings and shared losses to correct financial reconciliation calculations (§ 425.315), the preclusion of administrative and judicial review (§ 425.800), and the reconsideration process (subpart I) would apply to ACOs participating in the BASIC track in the same manner as for all other Shared Savings Program ACOs. Therefore, we proposed to amend certain existing regulations to incorporate references to the BASIC track and the proposed new regulation at § 425.605. This includes amendments to §§ 425.100, 425.315, 425.600, and 425.800. As part of the revisions to § 425.800, we proposed to clarify that the preclusion of administrative and judicial review with respect to certain financial calculations applies only to the extent that a specific calculation is performed in accordance with section 1899(d) of the Act.

As discussed in section II.A.4.c. of this final rule, we proposed that ACOs in the BASIC track would have an opportunity to annually elect their choice of beneficiary assignment methodology. As discussed in section II.B. of this final rule, we proposed to make the SNF 3-day rule waiver available to ACOs in the BASIC track under two-sided risk. If these ACOs select prospective beneficiary assignment, their physicians and practitioners billing under ACO participant TINs would also have the opportunity to provide telehealth services under section 1899(l) of the Act, starting in 2020. As described in section II.C. of this final rule, BASIC track ACOs under two-sided risk (Levels C, D, or E) would be allowed to apply for and, if approved, establish a CMS-approved beneficiary incentive program to provide incentive payments to eligible beneficiaries for qualifying services.

We proposed that, unless otherwise indicated, all current policies that apply to ACOs under a two-sided model would apply also to ACOs participating under risk within the BASIC track. This includes the selection of a Minimum Savings Rate (MSR)/Minimum Loss Rate (MLR) consistent with the options available under the ENHANCED track, as specified in § 425.610(b)(1) (with related proposals discussed in section II.A.6.b. of this final rule), and the requirement to establish and maintain an adequate repayment mechanism under § 425.204(f) (with related proposals discussed in section II.A.6.c. of this final rule). ACOs participating under the one-sided models of the BASIC track's glide path (Level A and Level B), would be required to select a MSR/MLR and establish an adequate repayment mechanism prior to their first performance year in performance-based risk. Additionally, the same policies regarding notification of savings and losses and the timing of repayment of any shared losses that apply to ACOs in the ENHANCED track (see § 425.610(h)) would apply to ACOs in two-sided risk models under the BASIC track, including the requirement that an ACO must make payment in full to CMS within 90 days of receipt of notification of shared losses.

As described in section II.E.4. of the August 2018 proposed rule, we proposed to extend the policies for addressing the impact of extreme and uncontrollable circumstances on ACO quality and financial performance, as established for performance year 2017 to performance year 2018 and subsequent years. We finalized this proposal in the November 2018 final rule (83 FR 59968 through 59979) to ensure that relief is available for ACOs affected by the recent hurricanes in North Carolina and Florida and other disasters during 2018. In the August 2018 proposed rule, we proposed that these policies would also apply to BASIC track ACOs. Section 425.502(f) specifies the approach to calculating an ACO's quality performance score for all affected ACOs. Further, we proposed that the policies regarding the calculation of shared losses for ACOs under a two-sided risk model that are affected by extreme and uncontrollable circumstances (see § 425.610(i)) would also apply to BASIC track ACOs under performance-based risk.

Final Action: There were no comments directed specifically at our proposal to model the BASIC track on the current provisions governing Shared Savings Program ACOs under 42 CFR part 425, including the general eligibility requirements (subpart B), application procedures (subpart C), program requirements and beneficiary protections (subpart D), beneficiary assignment methodology (subpart E), quality performance standards (subpart F), data sharing opportunities and requirements (subpart H), and benchmarking methodology (subpart G). We are finalizing our proposals to model the BASIC track on the existing provisions governing other tracks of the Shared Savings Program. Elsewhere in this final rule we describe in detail our final policies for the other proposed revisions to the program's regulations to establish the BASIC track.

We did not receive any comments specifically addressing our proposal to extend the policies on extreme and uncontrollable circumstances to ACOs participating in the BASIC track. We are finalizing without modification our proposal to specify the policies regarding extreme and uncontrollable circumstances for the BASIC track in a new provision at § 425.605(f). We are also finalizing without modification our proposal to apply § 425.502(f) in calculating the quality performance score of BASIC track ACOs affected by extreme and uncontrollable circumstances.

Additionally, we received no comments on our proposal to apply policies on reopening determinations of shared savings or shared losses to correct financial reconciliation calculations (§ 425.315) to ACOs in the BASIC track. Further, no comments addressed our proposal to apply the policies on the preclusion of administrative and judicial review (§ 425.800), and the reconsideration process (subpart I) to ACOs in the BASIC track. *We* are finalizing these policies as proposed and accordingly we are amending §§ 425.315, and 425.800 to incorporate references to the new provision for the BASIC track at § 425.605. We also received no comments addressing our proposal to revise § 425.100, which includes a general description of ACOs that are eligible to receive payments for shared savings or that must share losses under the program, to incorporate references to the new provision for the BASIC track at § 425.605, and we are finalizing the revisions as proposed.

b. Phase-In of Performance-Based Risk in the BASIC Track

(1) Background on Levels of Risk and Reward

To qualify for shared savings, an ACO must have savings equal to or above its MSR, meet the minimum quality performance standards established under § 425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program (§§ 425.604(a)(7), (b) and (c), 425.606(a)(7), (b) and (c), 425.610(a)(7), (b) and (c)). If an ACO qualifies for savings by meeting or exceeding its MSR, then the final sharing rate (based on quality performance) is applied to the ACO's savings on a first dollar basis, to determine the amount of shared savings up to the performance payment limit (§§ 425.604(d) and (e), 425.606(d) and (e), 425.610(d) and (e)).

Under the current program regulations, an ACO that meets all of the requirements for receiving shared savings under the one-sided model can qualify to receive a shared savings

payment of up to 50 percent of all savings under its updated benchmark, as determined on the basis of its quality performance, not to exceed 10 percent of its updated benchmark. A Track 2 ACO can potentially receive a shared savings payment of up to 60 percent of all savings under its updated benchmark, not to exceed 15 percent of its updated benchmark. A Track 3 ACO can potentially receive a shared savings payment of up to 75 percent of all savings under its updated benchmark, not to exceed 20 percent of its updated benchmark. The higher sharing rates and performance payment limits under Track 2 and Track 3 were established as incentives for ACOs to accept greater financial risk for their assigned beneficiaries in exchange for potentially higher financial rewards. (See 76 FR 67929 through 67930, 67934 through 67936; 80 FR 32778 through 32779.)

Under the current two-sided models of the Shared Savings Program, an ACO is responsible for sharing losses with the Medicare program when the ACO's average per capita Medicare expenditures for the performance year are above its updated benchmark costs for the year by at least the MLR established for the ACO (§§ 425.606(b)(3), 425.610(b)(3)). For an ACO that is required to share losses with the Medicare program for expenditures over its updated benchmark, the shared loss rate (also referred to as the loss sharing rate) is determined based on the inverse of its final sharing rate, but may not be less than 40 percent. The loss sharing rate is applied to an ACO's losses on a first dollar basis, to determine the amount of shared losses up to the loss recoupment limit (also referred to as the loss sharing limit) (§§ 425.606(f) and (g), 425.610(f) and (g)).

In earlier rulemaking, we discussed considerations related to establishing the loss sharing rate and loss sharing limit for Track 2 and Track 3. See 76 FR 67937 (discussing shared loss rate and loss sharing limit for Track 2) and 80 FR 32778 through 32779 (including discussion of shared loss rate and loss sharing limit for Track 3). Under Track 2 and Track 3, the loss sharing rate is determined as 1 minus the ACO's final sharing rate based on quality performance, up to a maximum of 60 percent or 75 percent, respectively (except that the loss sharing rate may not be less than 40 percent for Track 3). This creates symmetry between the sharing rates for savings and losses. The 40 percent floor on the loss sharing rate under both Track 2 and Track 3 ensures comparability in the minimum level of performance-based risk that ACOs accept under these tracks. The higher ceiling on the loss sharing rate under Track 3 reflects the greater risk Track 3 ACOs accept in exchange for the possibility of greater reward compared to Track 2.

Under Track 2, the limit on the amount of shared losses phases in over 3 years starting at 5 percent of the ACO's updated historical benchmark in the first performance year of participation in Track 2, 7.5 percent in year 2, and 10 percent in year 3 and any subsequent year. Under Track 3, the loss sharing limit is 15 percent of the ACO's updated historical benchmark, with no phase-in. Losses in excess of the annual limit would not be shared.

The level of risk under both Track 2 and Track 3 exceeds the Advanced APM generally applicable nominal amount standard under § 414.1415(c)(3)(i)(B) (set at 3 percent of the expected expenditures for which an APM Entity is responsible under the APM). CMS has determined that Track 2 and Track 3 meet the Advanced APM criteria under the Quality Payment Program, and are therefore Advanced APMs. Eligible clinicians that sufficiently participate in Advanced APMs such that they are QPs for a performance year receive APM Incentive Payments in the corresponding payment year between 2019 through 2024, and then higher fee schedule updates starting in 2026.

The Track 1+ Model is testing whether combining the upside sharing parameters of the popular Track 1 with limited downside risk sufficient for the model to qualify as an Advanced APM will encourage more ACOs to advance to performance-based risk. The Track 1+ Model has reduced risk in two main ways relative to Track 2 and Track 3. First, losses under the Track 1+ Model are shared at a flat 30 percent loss sharing rate, which is 10 percentage points lower than the minimum quality-adjusted loss sharing rate used in both Track 2 and Track 3. Second, a bifurcated approach is used to set the loss sharing limit for a Track 1+ Model ACO, depending on the ownership and operational interests of its ACO participants, as identified by TINs and CMS Certification Numbers (CCNs).

The applicable loss sharing limit under the Track 1+ Model is determined based on whether the ACO includes an ACO participant (TIN/CCN) that is an IPPS hospital, cancer center or a rural hospital with more than 100 beds, or that is owned or operated, in whole or in part, by such a hospital or by an organization that owns or operates such a hospital. If at least one of these criteria is met, then a potentially higher level of performance-based risk applies, and the loss sharing limit is set at 4 percent of the ACO's updated historical benchmark (described herein as the benchmark-based loss sharing limit). For the Track 1+ Model, this is a lower level of risk than is required under either Track 2 or Track 3, and greater than the Advanced APM generally applicable nominal amount standard under § 414.1415(c)(3)(i)(B) for 2018, 2019 and 2020. If none of these criteria is met, as may be the case with some ACOs composed of independent physician practices and/or ACOs that include small rural hospitals, then a potentially lower level of performance-based risk applies, and the loss sharing limit is determined as a percentage of the total Medicare Parts A and B FFS revenue of the ACO participants (described herein as the revenue-based loss sharing limit). For Track 1+ Model ACOs under a revenue-based loss sharing limit, in performance years 2018, 2019 and 2020, total liability for shared losses is limited to 8 percent of total Medicare Parts A and B FFS revenue of the ACO participants. If the loss sharing limit, as a percentage of the ACO participants' total Medicare Parts A and B FFS revenue, exceeds the amount that is 4 percent of the ACO's updated historical benchmark, then the loss sharing limit is capped and set at 4 percent of the updated historical benchmark. For performance years 2018 through 2020, this level of performance-based risk qualifies the Track 1+ Model as an Advanced APM under § 414.1415(c)(3)(i)(A). In subsequent years of the Track 1+ Model, if the relevant percentage specified in the Quality Payment Program regulations changes, the Track 1+ Model ACO would be required to take on a level of risk consistent with the percentage required in § 414.1415(c)(3)(i)(A) for an APM to qualify as an Advanced APM.

The loss sharing limit under this bifurcated structure is determined by CMS near the start of an ACO's agreement period under the Track 1+ Model (based on the ACO's application to the Track 1+ Model), and re-determined annually based on an annual certification process prior to the start of each performance year under the Track 1+ Model. The Track 1+ Model ACO's loss sharing limit could be adjusted up or down on this basis. See Track 1+ Model Fact Sheet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/New-Accountable-Care-Organization-Model-Opportunity-Fact-Sheet.pdf* for more detail.

Since the start of the Shared Savings Program, we have heard a variety of concerns and suggestions from ACOs

and other program stakeholders about the transition from a one-sided model to performance-based risk (see discussion in section II.A.1. of this final rule). Through rulemaking, we developed a one-sided shared savings only model and extended the allowable time in this track to support ACOs' readiness to take on performance-based risk. As a result, the vast majority of Shared Savings Program ACOs have chosen to enter and remain in the one-sided model. Our early experience with the design of the Track 1+ Model demonstrates that the availability of a lower-risk, two-sided model is effective to encourage a large cohort of ACOs to rapidly progress to performance-based risk.

(2) Levels of Risk and Reward in the BASIC Track's Glide Path

In general, we proposed the following participation options within the BASIC track.

First, we proposed the BASIC track's glide path as an incremental approach to higher levels of risk and potential reward. The glide path includes 5 levels: A one-sided model available only for the first 2 consecutive performance years of a 5-year agreement period (Level A and B), each year of which is identified as a separate level; and three levels of progressively higher risk and potential reward in performance years 3 through 5 of the agreement period (Level C, D, and E). ACOs would be automatically advanced at the start of each participation year along the progression of risk/reward levels, over the course of a 5-year agreement period, until they reach the track's maximum level of risk/reward (designed to be the same as the level of risk and potential reward as under the Track 1+ Model). 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. Such an ACO would enter the BASIC track for its first performance year of July 1, 2019 through December 31, 2019, at its chosen level of the glide path. For performance year 2020, the ACO may remain in the same level of the BASIC track's glide path that it entered for the performance year (or 6-month performance period) beginning July 1, 2019. The ACO would be automatically advanced to the next level of the BASIC track's glide path at the start of performance year 2021 and all subsequent performance years of the agreement period (see section II.A.7. of this final rule).

We proposed that the participation options in the BASIC track's glide path would depend on an ACO's experience with the Shared Savings Program, as described in section II.A.5.c. of this final rule. ACOs eligible for the BASIC track's glide path that are new to the program would have the flexibility to enter the glide path at any one of the five levels. However, ACOs that previously participated in Track 1, or a new ACO identified as a re-entering ACO because more than 50 percent of its ACO participants have recent prior experience in a Track 1 ACO, would be ineligible to enter the glide path at Level A, thereby limiting their opportunity to participate in a one-sided model of the glide path. We also proposed ACOs would be automatically transitioned to progressively higher levels of risk and potential reward (if higher levels are available) within the remaining years of the agreement period. We proposed to allow ACOs in the BASIC track's glide path to more rapidly transition to higher levels of risk and potential reward within the glide path during the agreement period. As described in section II.A.4.b. of this final rule, ACOs in the BASIC track may annually elect to take on higher risk and potential reward within their current agreement period, to more rapidly progress along the glide path.

Second, we proposed the BASIC track's highest level of risk and potential reward (Level E) may be elected for any performance year by ACOs that enter the BASIC track's glide path, but it will be required no later than the ACO's fifth performance year of the glide path (sixth performance year for eligible ACOs starting participation in Level A of the BASIC track on July 1, 2019). ACOs in the BASIC track's glide path that previously participated in Track 1, 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, would be eligible to begin in Level B, and therefore would be required to participate in Level E no later than the ACO's fourth performance year of the glide path (fifth performance year for ACOs starting participation in the BASIC track on July 1, 2019). The level of risk/reward under Level E of the BASIC track is also required for low revenue ACOs eligible to enter an agreement period under the BASIC track that are determined to be experienced with performance-based risk Medicare ACO initiatives (discussed in section II.A.5. of this final rule).

We explained that designing a glide path to performance-based risk that concludes with the level of risk and potential reward offered under the Track 1+ Model balances ACOs' interest in remaining under lower-risk options with our goal of more rapidly transitioning ACOs to performance-based risk. The BASIC track's glide path offers a pathway through which ACOs inexperienced with performance-based risk Medicare ACO initiatives can participate under a one-sided model before entering relatively low levels of risk and asymmetrical potential reward for several years, concluding with the lowest level of risk and potential reward available under a current Medicare ACO initiative. As we stated in the August 2018 proposed rule (83 FR 41804), we believe the opportunity for eligible ACOs to participate in a one-sided model for up to 2 years (3 performance years, in the case of an ACO entering at Level A of the BASIC track's glide path on July 1, 2019) could offer new ACOs a chance to become experienced with the accountable care model and program requirements before taking on risk. The proposed approach also recognizes that ACOs that gained experience with the program's requirements during prior participation under Track 1, would need less additional time under a one-sided model before making the transition to performance-based risk. However, we also stated that the glide path should provide strong incentives for ACOs to quickly move along the progression towards higher performance-based risk, and therefore preferred an approach that significantly limits the amount of potential shared savings in the one-sided model years of the BASIC track's glide path, while offering incrementally higher potential reward in relation to each level of higher risk. Under this approach ACOs would have reduced incentive to enter or remain in the one-sided model of the BASIC track's glide path if they are prepared to take on risk, and we would anticipate that these ACOs would seek to accept greater performance-based risk in exchange for the chance to earn greater reward.

As described in detail in this section, we proposed a similar asymmetrical two-sided risk design for the BASIC track as is available under the Track 1+ Model, with key distinguishing features based on early lessons learned from the Track 1+ Model. Unless indicated otherwise, we proposed that savings would be calculated based on the same methodology used to determine shared savings under the program's existing tracks (see § 425.604). 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. The methodology for determining shared losses would be a bifurcated approach similar to the approach used under the Track 1+

Model, as discussed in more detail elsewhere in this section. In all years under performance-based risk, we proposed to apply asymmetrical levels of risk and reward, where the maximum potential reward would be greater than the maximum level of performance-based risk.

For the BASIC track's glide path, we proposed the phase-in schedule of levels of risk/reward by year would be as follows. This progression assumes an ACO enters the BASIC track's glide path under a one-sided model for 2 years and follows the automatic progression of the glide path through each of the 5 years of its agreement period.

• Level A and Level B: Eligible ACOs entering the BASIC track would have the option of being under a one-sided model for up to 2 consecutive performance years (3 consecutive performance years for ACOs that enter the BASIC track's glide path on July 1, 2019). As described elsewhere in this final rule, ACOs that previously participated in Track 1, 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, would be ineligible to enter the glide path under Level A, although they could enter under Level B. Under this proposed one-sided model, a final sharing rate not to exceed 25 percent based on quality performance would apply to first dollar shared savings for ACOs that meet or exceed their MSR. This sharing rate is one-half of the maximum sharing rate of 50 percent currently available under Track 1. Savings would be shared at this rate not to exceed 10 percent of the ACO's updated benchmark, consistent with the current policy for Track 1. For subsequent years, ACOs that wished to continue participating in the Shared Savings Program would be required to participate under performance-based risk.

• Level C risk/reward:

++ Shared Savings: A final sharing rate not to exceed 30 percent based on quality performance would apply to first dollar shared savings for ACOs that meet or exceed their MSR, not to exceed 10 percent of the ACO's updated historical benchmark.

++ Shared Losses: A loss sharing rate of 30 percent regardless of the quality performance of the ACO would apply to first dollar shared losses for ACOs with losses meeting or exceeding their MLR, not to exceed 2 percent of total Medicare Parts A and B FFS revenue for ACO participants. 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 1 percent of the ACO's updated historical benchmark, then the loss sharing limit would be capped and set at 1 percent of the ACO's updated historical benchmark for the applicable performance year. This level of risk is not sufficient to meet the generally applicable nominal amount standard for Advanced APMs under the Quality Payment Program specified in § 414.1415(c)(3)(i).

• Level D risk/reward:

++ Shared Savings: A final sharing rate not to exceed 40 percent based on quality performance would apply to first dollar shared savings for ACOs that meet or exceed their MSR, not to exceed 10 percent of the ACO's updated historical benchmark.

++ Shared Losses: A loss sharing rate of 30 percent regardless of the quality performance of the ACO would apply to first dollar shared losses for ACOs with losses meeting or exceeding their MLR, not to exceed 4 percent of total Medicare Parts A and B FFS revenue for ACO participants. 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 2 percent of the ACO's updated historical benchmark, then the loss sharing limit would be capped and set at 2 percent of the ACO's updated historical benchmark for the applicable performance year. This level of risk is not sufficient to meet the generally applicable nominal amount standard for Advanced APMs under the Quality Payment Program specified in § 414.1415(c)(3)(i).

• Level E risk/reward: The ACO would be under the highest level of risk and potential reward for this track, which is the same level of risk and potential reward being tested in the Track 1+ Model. Further, ACOs that are eligible to enter the BASIC track, but that are ineligible to enter the glide path (as discussed in section II.A.5. of this final rule) would enter and remain under Level E risk/reward for the duration of their BASIC track agreement period.

++ Shared Savings: A final sharing rate not to exceed 50 percent based on quality performance would apply to first dollar shared savings for ACOs that meet or exceed their MSR, not to exceed 10 percent of the ACO's updated historical benchmark. This is the same level of potential reward currently available under Track 1 and the Track 1+ Model.

++ Shared Losses: A loss sharing rate of 30 percent regardless of the quality performance of the ACO would apply to first dollar shared losses for ACOs with losses meeting or exceeding their MLR. The percentage of ACO participants' total Medicare Parts A and B FFS revenue used to determine the revenue-based loss sharing limit would be set for each performance year consistent with the generally applicable nominal amount standard for an Advanced APM under § 414.1415(c)(3)(i)(A) to allow eligible clinicians participating in a BASIC track ACO subject to this level of risk the opportunity to earn the APM incentive payment and ultimately higher fee schedule updates starting in 2026, in the payment year corresponding to each performance year in which they attain QP status. For example, for performance years 2019 and 2020, this would be 8 percent. However, if the loss sharing limit, as a percentage of the ACO participants' total Medicare Parts A and B FFS revenue exceeds the expenditure-based nominal amount standard, as a percentage of the ACO's updated historical benchmark, then the loss sharing limit would be capped at 1 percentage point higher than the expenditure-based nominal amount standard specified under § 414.1415(c)(3)(i)(B), which is calculated as a percentage of the ACO's updated historical benchmark. For example, for performance years 2019 and 2020, the expenditure-based nominal amount standard is 3 percent; therefore, the loss sharing limit for Level E of the BASIC track in these same years would be 4 percent of the ACO's updated historical benchmark. The proposed BASIC track at Level E risk/reward would meet all of the Advanced APM criteria and would be an Advanced APM. (See Table 3 and related notes for additional information and an overview of the Advanced APM criteria.)

This approach initially maintains consistency between the level of risk and potential reward offered under Level E of the BASIC track and the popular Track 1+ Model. This proposed approach to determining the maximum amount of shared losses under Level E of the BASIC track strikes a balance between (1) placing ACOs under a higher level of risk to recognize the greater potential reward under this financial model and the additional tools and flexibilities available to BASIC track ACOs under performance-based risk and (2) establishing an approach to help ensure the maximum level of risk under the BASIC track remains moderate. Specifically, this proposed approach differentiates the level of risk and potential reward under Level E compared to Levels C and D of the BASIC track, by requiring greater risk in

exchange for the greatest potential reward under the BASIC track, while still offering more manageable levels of benchmark-based risk than currently offered under Track 2 (in which the loss sharing limit phase-in begins at 5 percent of the ACO's updated benchmark) and Track 3 (15 percent of the ACO's updated benchmark). Further, this approach recognizes that eligible ACOs in Level E have the opportunity to earn the greatest share of savings under the BASIC track, and should therefore be accountable for a higher level of losses, particularly in light of their access to tools for care coordination and beneficiary engagement, including the ability of participating physicians and practitioners to furnish telehealth services in accordance with 1899(l) of the Act, the SNF 3-day rule waiver (as discussed in section II.B. of this final rule), and the opportunity to implement a CMS-approved beneficiary incentive program (as discussed in section II.C. of this final rule).

We proposed that ACOs entering the BASIC track's glide path would be automatically advanced along the progression of risk/reward levels, at the start of each performance year over the course of the agreement period (except at the start of performance year 2020 for ACOs that start in the BASIC track on July 1, 2019), until they reach the track's maximum level of risk and potential reward. As discussed in section II.A.4.b. of this final rule, BASIC track ACOs in the glide path would also be permitted to elect to advance more quickly to higher levels of risk and potential reward within their agreement period. The longest possible glide path would be 5 performance years for eligible new ACOs entering the BASIC track (6 performance years for ACOs beginning their participation in the BASIC track on July 1, 2019). The maximum allowed time in Levels A, B, C and D of the glide path would be one performance year (with the exception that ACOs beginning their participation in the BASIC track on July 1, 2019, would have the option to remain at their chosen level of risk and potential reward for their first 2 performance years in the BASIC track). Once the highest level of risk and potential reward is reached on the glide path (Level E), ACOs would be required to remain under the maximum level of risk/reward for all subsequent years of participation in the BASIC track, which includes all years of a subsequent agreement period under the BASIC track for eligible ACOs. Further, an ACO within the BASIC track's glide path could not elect to return to lower levels of risk and potential reward, or to the one-sided model, within an agreement period under the glide path.

To participate under performance-based risk in the BASIC track, an ACO would be required to establish a repayment mechanism and select a MSR/MLR to be applicable for the years of the agreement period under a two-sided model (as discussed in section II.A.6. of this final rule). We proposed that an ACO that is unable to meet the program requirements for accepting performance-based risk would not be eligible to enter into a two-sided model under the BASIC track. If an ACO enters the BASIC track's glide path in a one-sided model and is unable to meet the requirements to participate under performance-based risk prior to being automatically transitioned to a performance year under risk, CMS would terminate the ACO's agreement under § 425.218. For example, if an ACO is participating in the glide path in Level B and is unable to establish an adequate repayment mechanism before the start of its performance year under Level C, the ACO would not be permitted to continue its participation in the program.

In section II.A.5.c. of this final rule, we describe our proposed requirements for determining an ACO's eligibility for participation options in the BASIC track and ENHANCED track based on a combination of factors: ACO participants' Medicare FFS revenue (low revenue ACOs versus high revenue ACOs) and the experience of the ACO legal entity and its ACO participants with performance-based risk Medicare ACO initiatives. Tables 7 and 8 summarize the participation options available to ACOs under the BASIC track and ENHANCED track. As with current program policy, an ACO would apply to enter an agreement period under a specific track. If the ACO's application is accepted, the ACO would remain under that track for the duration of its agreement period.

We proposed to codify these policies in a new section of the Shared Savings Program regulations governing the BASIC track, at § 425.605. We sought comment on these proposals.

Further, in section II.A.5.b.(3) of the August 2018 proposed rule (83 FR 41819 through 41820), we described and sought comment on several approaches to allowing for potentially greater access to shared savings for low revenue ACOs compared to high revenue ACOs. We explained that low revenue ACOs (identified as proposed using a threshold of 25 percent of Medicare Parts A and B FFS expenditures for assigned beneficiaries), which may tend to be small, physician-only and rural ACOs, are likely less capitalized organizations and may be relatively risk-averse. These ACOs may be encouraged to participate and remain in the program under performance-based risk based on the availability of additional incentives, such as the opportunity to earn a greater share of savings. Therefore, we considered allowing 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, we 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.

Comment: Generally, many commenters understood and agreed with the need to introduce the BASIC track's five level glide path (with the two year limit in a one-sided model and automatic advancement to incremental risk each of the remaining 3 years) as an incremental approach to higher levels of risk and reward. A few commenters appreciated CMS' effort to simplify the participation options and establish a clear streamlined glide path to risk-bearing models. They agreed that 2017 Shared Savings Program results confirm that ACO performance improves with longer participation in the program, and encouraged CMS to provide accurate and timely reporting and carefully monitor these efforts to support their continued growth and improvement. Another noted that the proposed approach provided a clear and consistent pathway for participants and prospective enrollees to understand their journey to risk. One commenter noted that CMS' redesign of the program and addition of the new BASIC track is an approach that factors in ACOs' revenue and experience and will provide greater stability and predictability and help more health care providers benefit from qualifying as participating in Advanced APMs under the Quality Payment Program. One commenter was encouraged to see that through this rule, CMS is advancing opportunities in two-sided risk ACOs because it has seen firsthand the type of care transformation that is possible when organizations participate in performance-based risk to improve population health. The commenter was also pleased with CMS' commitment to waiving and modifying certain burdensome program rules for

organizations that are engaged in increasing levels of financial risk. Another commenter generally agreed with CMS' redesign proposal, noting that, although it may reduce the number of ACOs in the program, those that remain would be more likely to control expenditures for the Medicare program and make real efforts to improve care. The commenter added that the goal of the Shared Savings Program should be to create the conditions that will reward efficient ACOs that can create real value for the Medicare program, its beneficiaries, and the taxpayers, not to maximize the number of ACOs. Another commenter noted CMS likely moderated any concerns of ACOs leaving the program by incorporating other policy changes and flexibilities in the proposed rule, such as refining the benchmarking methodology, allowing for risk adjustment each performance year, adjusting patient attribution methodology, and establishing flexibility for low revenue ACOs.

However, a majority of commenters were opposed to limiting the amount of time an ACO can participate under a one-sided model from six to two years (because, for example, it dramatically decreases the time in which an ACO can build capital reserves for a repayment mechanism) and provided suggestions for CMS to adopt a more gradual approach to risk. Many commenters did not want us to discontinue Track 1 (as detailed in section II.A.2 of this final rule) and would prefer that we provide for an upside-only track. Some commenters expressed that it makes sense to push hospital-led ACOs into risk, but stated that there is no compelling case that risk is necessary for physician-led ACOs. One commenter, a physician-led ACO, added that requiring it to automatically advance to performance-based risk would cause it to face the prospect of bankrupting its organization. We received numerous comments from rural ACOs to extend the allotted time period in which a rural ACO can participate in an upside-only arrangement in the BASIC track. Some of those commenters noted that certain ACO participants, such as FQHCs, RHCs, and CAHs, provide care to some of the most underserved communities and require additional time and investments to prepare for two-sided risk arrangements.

Most commenters provided recommendations for CMS to extend the time any ACO can participate in a one-sided model to three years, as opposed to two, stating that it takes longer than two participation years to implement meaningful changes in a healthcare delivery model and among healthcare provider and patient populations. Other commenters believe that the progression to two-sided risk is far too aggressive and will deter participation. These commenters usually suggested allowing for 4 or 5 performance years (or a full agreement period) under a one-sided model. Some commenters suggested that rural ACOs should be allowed at least two, 5-year agreement periods under a one-sided model.

Response: We appreciate the comments, but we continue to believe that the proposed transition to two-sided risk under the design of the BASIC track's glide path will promote a competitive and accountable marketplace, while improving the quality of care for Medicare beneficiaries.

We disagree with commenters' suggestions to allow all ACOs or select ACOs (for example, based on their geographic location, historical cost or provider composition) to remain under the one-sided model for an extended time or even indefinitely. We believe such a policy design would, at best, maintain the status quo of the program, and therefore continue a pattern where ACOs are allowed to remain under the one-sided model for a significant number of years without strong incentives to become accountable for the cost and quality of care for their assigned populations. As described in the Regulatory Impact Analysis (see section V of this final rule), our results have shown that ACOs in two-sided models perform better over time than one-sided model ACOs. At the same time, while some ACOs have taken on significant downside risk and shown significant savings to the Medicare program while advancing quality, a majority of ACOs—while having the ability to benefit from waivers of certain federal rules and requirements—have yet to move to any downside risk. Generally, these ACOs are increasing Medicare spending compared to their benchmarks, and the presence of an ''upside-only'' track may be encouraging consolidation in the marketplace, reducing competition and beneficiary choice. The combination of six years of upside-only risk and the ability to benefit from significant waivers available in the program may also be leading to the formation of one-sided ACOs that are not making serious efforts to improve quality and reduce spending, potentially crowding out formation of more effective ACOs. Thus, we continue to believe that Medicare FFS beneficiaries and the Trust Funds would be better protected by the progression of eligible ACOs from a one-sided model to two-sided models within the span of a five-year agreement period under the BASIC track's glide path.

However, we understand that this requirement may pose an additional financial burden, particularly for rural or physician-led ACOs, many of which would be considered low revenue ACOs under the proposed rule. We also continue to believe that the move to two-sided risk will encourage low revenue ACOs, typically small, rural and physician-only ACOs, to more aggressively pursue the program's goals of improving quality of care, and lowering growth in expenditures, for Medicare FFS beneficiaries. Therefore, as discussed in greater detail in section II.A.5.c of this final rule, we are finalizing an approach that will permit ACO legal entities without prior experience in the Shared Savings Program that are identified as low revenue ACOs and inexperienced with performance-based risk Medicare ACO initiatives to stay in a one-sided model of the BASIC track's glide path for an additional performance year. Under this approach eligible ACOs will have the opportunity to participate for up to 3 performance years (or 4 performance years in the case of ACOs entering an agreement period beginning on July 1, 2019) under a one-sided model of the BASIC track's glide path before automatically advancing to Level E of the BASIC track for the remaining performance years of their agreement period. We believe that this option, in part, addresses commenters' concerns and suggestions for a relatively gentler glide path to two-sided risk for small, rural and physician-only ACOs that are likely to qualify as low revenue ACOs, and supports continued participation of these ACOs in the Shared Savings Program. For instance, we believe that this option provides an opportunity for new, low revenue ACOs to become more experienced with the Shared Savings Program's requirements and the accountable care model, and to potentially realize savings, to support their participation in performance-based risk. In light of this additional flexibility that we are making available for new legal entities that qualify as low revenue ACOs inexperienced with performance-based risk Medicare ACO initiatives, we decline to adopt any other alternatives suggested by commenters that would allow for lower risk participation options for rural or physician-led ACOs.

Comment: We received numerous comments concerning our proposal to set the final sharing rate for the one-sided model not to exceed 25 percent based on quality performance that applies to first dollar shared savings for

ACOs that meet or exceed their MSR. One commenter stated that although a 25 percent sharing rate under Levels A and B of the BASIC track is not worth the ACO's continued participation in the program, the commenter contended that it is the right thing to do in order to continue to innovate primary care in the medical community.

Most commenters had concerns about reducing the shared savings rate from 50 percent (as currently available under Track 1) to 25 percent for ACOs in Levels A and B of the BASIC track, asserting that doing so would deter new entrants from applying to the Shared Savings Program and undermine the business case to join the Shared Savings Program. Some contended that, due to the sizeable investment that ACOs make (for example, one ACO reportedly spent almost $2 million a year, on average, including investments made in health information technology, population health management and ACO administration), it is imperative that the opportunity for return on investment is realistic enough for the business model to be attractive, retain current ACO participants, and bring in new ACOs. One commenter stated that the reduction in sharing rates would result in challenges with provider/supplier buy-in, which has been crucial to the success of the commenter's ACOs. The commenter further contended that many physicians value the Shared Savings Program's emphasis on quality of care as a result of collaborative efforts across practices. Another commenter stated that the impact of increased financial pressure will cause ACOs to inappropriately focus on reducing costs over achieving high-quality outcomes, and consequently put beneficiaries' access to medical care at risk. One commenter contended there is a low likelihood that a newly formed ACO will achieve shared savings in the early years of its operations.

Some commenters noted that clinicians and physician-led practices seeking to start or join an ACO must make significant practice changes and investments to position themselves for success in the program. One commenter noted that for independent physicians, the potential reward for making these changes must be high enough to justify initial infrastructure costs, as well as ongoing investments in staff and other resources needed for population health management and that the proposed 25 percent savings rate would deter these participants and ACOs from joining the Shared Savings Program. Some commenters explained a reduction in potential savings will greatly impact low revenue, physician-led ACOs, and could end up forcing these ACOs from the program.

Most commenters proposed an increased maximum shared savings rate under Levels A and B of the BASIC track ranging from 40 to 80 percent, with a majority requesting a 50 percent shared savings rate. One of these commenters also suggested an incremental upwards adjustment of the shared savings rate up to 10 percentage points (from 50 percent) based on quality to emphasize and reward above average quality performance or improvement. Some commenters recommended that CMS offer a higher sharing rate to support ACOs, especially physician-led and low revenue ACOs with more limited capital reserves. Some commenters suggested that CMS provide higher sharing rates for all levels of the BASIC track's glide path, for instance beginning at 50 percent (Level A and B), progressing to 55 percent for Levels C and D, and reaching 60 percent in Level E.

We also received numerous comments from rural ACOs stating that rural ACOs lack the resources to take on risk (including capital reserves necessary for required repayment mechanisms) and that the proposed 25 percent final sharing rate under Levels A and B of the BASIC track is not worth the risk of joining the program and will drive most of these ACOs from the program. Many noted that they operate on tight budgets and with limited human and capital resources while providing care for a sicker and older Medicare population than urban providers. Thus, they assert that CMS should create a glide path specifically for rural ACOs. One commenter noted that rural ACOs predominantly made up of Critical Access Hospitals (CAHs) are not in a position to take on downside risk given the inherent volatility in cost-based reimbursement, and the proposal would force these rural ACOs to exit the Shared Savings Program, resulting in these ACOs no longer having access to useful information such as beneficiary-level claims data and reducing the value of significant investments these ACOs have made (to date) to redesign rural healthcare delivery. Thus, the commenter asserted that CMS' proposal failed to provide a viable alternative for APM participation for rural ACOs.

Instead, these commenters proposed several alternatives for CMS to provide an exception specifically for rural ACOs to receive an increased final sharing rate under the BASIC track. One commenter was generally supportive of the proposed BASIC track, but proposed that CMS provide a no-downside risk option for rural providers due to their cost of operations. Additionally, many commenters requested that CMS develop a third Track for rural ACOs. Similarly, another commenter believed that CMS should develop a more gradual pathway to increased levels of financial risk for low revenue ACOs, specifically those composed of FQHCs. Several commenters suggested that CMS should consider all rural ACOs to be low revenue ACOs and maintain the 50 percent shared savings rate for them each year under the BASIC track. Another commenter proposed that ACOs comprised solely of safety net providers should be allowed to participate in Level A of the BASIC track with 50 percent shared savings indefinitely as long as they improve quality and do not increase costs.

One commenter, representing the perspective of a hospital-based ACO, explained it had grave concerns about allowing higher shared savings rates (such as 50 percent) for only low revenue ACOs for all years in the BASIC track (an approach we sought comment on in the August 2018 proposed rule), viewing this approach as giving low revenue ACOs a competitive advantage over high revenue ACOs. This commenter indicated that this approach would discourage high revenue ACOs, which the commenter argued are best situated to achieve savings for Medicare.

Response: We appreciate the wide range of comments requesting or suggesting adjustments to specific policies so that an ACO could share in a higher level of savings than what was proposed for the BASIC track's glide path: 25 percent sharing rate for Levels A and B, 30 percent sharing rate for Level C, 40 percent sharing rate for Level D, and 50 percent sharing rate for Level E. Initially, we decided to propose a 25 percent sharing rate under Levels A and B of the BASIC track because the 25 percent sharing rate is one-half of the maximum sharing rate of 50 percent currently available under Track 1. As an ACO transitioned to performance-based risk, and then continued to undertake greater risk by advancing through the glide path, the sharing rate would incrementally increase to 50 percent under Level E. However, generally, we are persuaded by the expressed views that the reward-to-risk ratio for participating in the program as proposed is generally unattractive to ACOs, and agree with commenters that an alternative policy featuring more generous sharing rates would attract and sustain broader participation in the Shared Savings Program. We believe that increasing the maximum sharing rates will strike a better balance between robust participation and incentivizing

the move to two-sided risk. We decided to increase the maximum sharing rate to 50 percent for Levels C through E of the BASIC track to correspond with the gradual increase in risk as the ACO advances on the glide path. We understand the commenters' concerns that the reduction in the maximum sharing rate could pose a financial hardship for ACOs by reducing shared savings payments that could support operational costs, and thus, the policy could be a potential barrier to the formation of and continued success of ACOs. We agree that financial rewards must be sufficient to offset provider risks and startup-costs, particularly for low revenue ACOs (which tend to be small, rural and physician-only ACOs). We also agree with commenters that the same shared savings rates should apply consistently across ACOs participating in a particular level of the BASIC track's glide path, rather than differentiating the shared savings rates based on the distinction between low revenue ACOs and high revenue ACOs. Therefore, we also decline to apply different shared savings rates to ACOs within the same Level of the BASIC track's glide path, based on other factors, such as composition, as suggested by some commenters.

Thus, we are modifying our proposal and finalizing higher maximum sharing rates for ACOs participating in the BASIC track as a means of encouraging participation in the program and potentially providing greater resources to ACOs to support their transition to performance-based risk. We are finalizing an approach to allow for a maximum shared savings rate of 40 percent for Levels A and B and 50 percent for Levels C, D, and E.

Comment: We received a few comments opposing our proposal to automatically transition ACOs to progressively higher levels of risk and potential reward (if higher levels are available) within the remaining years of the agreement period under the BASIC track's glide path. One commenter urged CMS to consider allowing high performing ACOs more than a year in limited risk tracks, such as Levels C and D of the BASIC track, and that CMS could outline parameters for successful ACOs to continue in a particular level prior to automatic advancing to another level, such as achieving shared savings or meeting quality goals.

Response: As stated in the November 2011 final rule (76 FR 19534), we continue to believe that the Shared Savings Program should provide an entry point for all willing organizations that wish to move in a direction of providing value-driven healthcare. We also continue to believe in the importance of encouraging ACOs to progress to greater performance-based risk to drive quality improvement and efficiency in care delivery. Doing otherwise could encourage ACOs to remain under a one-sided model, or under comparatively low levels of performance-based risk, without strong incentives to become accountable for the cost and quality of care for their assigned populations. We also note that some commenters (as summarized elsewhere in this final rule) agreed with CMS' emphasis on the importance of two-sided risk as a driver of more meaningful change. For this reason, we decline the commenters' suggestion to forgo the automatic advancement policy to progress eligible ACOs through the levels of risk and potential reward of the BASIC track's glide path, or to create a policy where we evaluate and determine whether each individual ACO will be required to enter higher levels of performance-based risk. We are finalizing our proposed approach to require automatic advancement along the BASIC track's glide path, although we note we are finalizing a modification to allow new legal entities that are low revenue ACOs and inexperienced with performance-based risk Medicare ACO initiatives the option to forgo automatic advancement to Level C to remain in Level B for an additional performance year, and then be automatically advanced to Level E.

Comment: Generally, most commenters supported the design of Levels C and D of the BASIC track, stating that they would create new opportunities for ACOs to experiment with downside risk. One commenter believed that the creation of Levels C and D of the BASIC track would empower healthcare providers to move to risk and create a ladder for ACOs to becoming an Advanced APM. However, as previously summarized in this section of the final rule, several commenters expressed concern about the proposed 30 percent shared savings rate in Level C of the BASIC track and 40 percent shared savings rate in Level D of the BASIC track and offered a variety of alternative maximum shared savings rates that they believed would incentivize ACOs to remain in the program and take on risk. Other commenters suggested additional changes to the design of Levels C and D. For example, one commenter recommended that Levels C and D of the BASIC track should include a shared savings rate of 80 percent balanced by an increase in shared risk levels to meet Advanced APM criteria. Another commenter suggested that advancement on the glide path should be optional, Levels C and D of the BASIC track could include a 50 percent shared savings rate, and if providers do not transition to greater risk within a set time period, the shared savings rate would decrease to 25 percent savings rate or lower.

Response: As we previously discussed in this section of this final rule, after considering the commenters' suggestions for adjusting the shared savings rates for ACOs participating in Levels A through D of the BASIC track, we are modifying our proposal to allow for first dollar savings at a rate of up to 50 percent based on quality performance, not to exceed 10 percent of updated benchmark, for all ACOs participating in Level C and Level D of the BASIC track. Therefore, we decline to adopt the commenters' alternative suggestions. Namely, we decline to establish additional levels within the BASIC track's glide path (other than Level E) that qualify as an Advanced APM. We believe that ACOs that are ready for higher levels of risk and reward should transition more rapidly to Level E of the BASIC track, or to the ENHANCED track, which qualify as Advanced APMs. Further, we decline to establish a policy that would allow ACOs to forgo the transition to higher levels of risk and potential reward in exchange for incrementally decreasing shared savings rates. We believe this could create a circumstance where poorly performing ACOs seek to continue their participation under relatively lower risk while taking advantage of other aspects of program participation. We believe that a policy to forgo the transition to higher levels of risk would effectively maintain the status quo of the program and would eliminate any incentive for many ACOs to transition to meaningful levels of performance-based risk.

Comment: Many commenters supported the permanent inclusion of the Track 1+ Model equivalent, Level E of the BASIC track, in the Shared Savings Program. A commenter stated that it is an important option for ACOs assuming downside financial risk and allows loss sharing limits similar to those for Advanced APMs in the Quality Payment Program. A few commenters were concerned about the level of risk and shared savings rates associated with Level E of the BASIC track. Commenters recommended a variety of shared savings rates for Level E, ranging from 55 to 100 percent. For example, several commenters proposed that CMS change the final shared savings rate to 60 percent with a goal of 75 percent shared savings based on quality performance

and other program criteria. Another commenter recommended that CMS set the maximum shared savings rate at 100 percent, particularly as the Next Generation ACO Model sunsets.

Response: We thank commenters for their support of the proposal to offer the level of risk and potential reward under the proposed Level E of the BASIC track, which is the same as level of risk and potential reward under the popular Track 1+ Model and would meet all of the Advanced APM criteria to be an Advanced APM under the Quality Payment Program. We believe there is sufficient reward in Level E as proposed, since in addition to the shared savings potential of this financial model, an ACO's eligible clinicians may be eligible for incentive payments under the Quality Payment Program because of the ACO's participation in an Advanced APM. Therefore, we decline to increase the 50 percent shared savings rate under Level E of the BASIC track based on commenters' suggestions. We believe that allowing more manageable levels of risk and moderate levels of potential reward under Level E within the Shared Savings Program will be an important pathway for helping organizations gain experience with performance-based risk while participating in Advanced APMs for purposes of the Quality Payment Program.

Comment: Several commenters suggested that the level of risk associated with Level E of the BASIC track should be the nominal risk standard under MACRA and consistent with Quality Payment Program standards. The commenters suggested that CMS decrease the benchmark-based level of risk under Level E to be the expenditure-based nominal amount standard rather than the proposal to set the level of maximum losses as 1 percentage point higher than the expenditure-based nominal amount standard. For example, to reduce the percentage from 4 percent of updated benchmark (proposed approach) to 3 percent. One commenter stated that setting the benchmark-based level of risk at 4 percent rather than 3 percent would disproportionately affect ACOs with hospital participants and subject them to additional risk. A few other commenters noted that CMS did not provide a rationale for setting the benchmark-based loss limit at the nominal standard plus one percentage point. One commenter suggested that aligning the loss sharing limit with the MACRA standard would create alignment between the Quality Payment Program and Shared Savings Program. Finally, one commenter noted that, to enable participation and set ACOs up for success, CMS should rely on a revenue-based risk structure and that any expenditure-based nominal risk amount should be kept low to avoid placing physician-led and low revenue ACOs at a disadvantage.

Response: After reviewing the commenter's concerns, we decline to align the benchmark-based loss sharing limit for Level E with the expenditure-based nominal amount standard for APM models established under the Quality Payment Program. As we explained in the August 2018 proposed rule, our proposal maintains consistency between the level of risk and potential reward offered under Level E and the Track 1+ Model (83 FR 41805). We believe the level of risk and potential reward proposed in Level E, which would provide more limited downside risk than is currently present in Tracks 2 and 3, offers ACOs the opportunity to participate and gain experience with more limited performance-based risk. Our experience, with 55 ACOs choosing to participate the first year the Track 1+ Model was available, suggests that this approach will encourage ACOs, especially small, rural and physician-only ACOs, to advance to performance-based risk and provide a viable on-ramp for ACOs to assume greater amounts of risk in the future.

Comment: A majority of commenters supported CMS' proposal to use a revenue-based approach to calculate ACO loss sharing limits and the proposal to cap and set the loss sharing limits at a percentage of an ACO's updated historical benchmark. One commenter commended CMS for recognizing that ACOs differ significantly in their ability to accept financial risk and for including limits on downside risk based on a percentage of the ACO participants' revenue, not just as a percentage of Medicare spending.

Response: We thank commenters for their support of the proposal to offer a relatively lower level of performance-based risk under the BASIC track, calculated as a percentage of ACO participants' total Medicare Parts A and B FFS revenue not to exceed an amount that is a percentage of the ACO's updated historical benchmark.

Comment: Some commenters encouraged CMS to retain use of quality scores in the shared loss methodology calculation as a part of the BASIC track. These commenters believe that improved quality for Medicare beneficiaries has always been a cornerstone of the program and should continue to be a vital part of both shared savings and shared losses calculations. Another commenter was concerned that CMS' decision not to apply quality measure performance to the loss rate under the BASIC track sends the wrong message to providers about the importance of quality measurement and performance. The commenter believes that CMS should apply a sliding scale quality measure adjustment to the loss rate to minimize the repayment by ACOs that are able to achieve high-quality outcomes.

Response: We are declining to include quality scoring in the loss calculation methodology for the two-sided models under the BASIC track. Under the Track 1+ Model, we established a fixed 30 percent loss sharing rate, which is lower than the loss sharing rate, based on quality performance, under Track 2 and the ENHANCED track, which is at least 40 percent. We designed the BASIC track's glide path to gradually introduce ACOs to greater risk and reward and all ACOs are eventually expected to move to the ENHANCED track where the loss sharing rate will include adjustments for quality performance. Quality performance is important to the program and the design of the financial model is not meant in any way to compromise the goal of improving quality, which is integrally related to the potential upside in all levels of the BASIC track. We believe that the lower, fixed loss sharing rate provides a more manageable level of risk for ACOs transitioning to risk in the BASIC track.

Final Action: After considering the comments we received, we are finalizing with modifications our proposal to codify policies in a new section of the Shared Savings Program regulations governing the BASIC track, at § 425.605. Specifically, we are finalizing the BASIC track's glide path with five levels. For each PY starting after January 1, 2020, ACOs in the glide path will be automatically progressed to the next level of the glide path. ACOs eligible for the glide path that have not participated in the Shared Savings Program previously, and that are not regarded as re-entering ACOs related to the prior participation of their ACO participants, can enter the glide path at any Level. ACOs that previously participated in Track 1, or a new ACO identified as a re-entering ACO because more than 50 percent of its ACO participants have recent prior experience in a Track 1 ACO, would be ineligible to enter the glide path at Level A but would be eligible to begin in Level B.

We are modifying our proposed maximum shared savings rates and are finalizing shared savings rates of 40 percent for Levels A and B and 50

percent for Levels C, D, and E of the BASIC track. We are finalizing as proposed the methodology for determining shared losses for Levels C, D, and E, as follows:

- Level C: A loss sharing rate of 30 percent regardless of the quality performance of the ACO would apply to first dollar shared losses for ACOs with losses meeting or exceeding their MLR, not to exceed 2 percent of total Medicare Parts A and B FFS revenue for ACO participants. 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 1 percent of the ACO's updated historical benchmark, then the loss sharing limit would be capped and set at 1 percent of the ACO's updated historical benchmark for the applicable performance year. This level of risk is not sufficient to meet the generally applicable nominal amount standard for Advanced APMs under the Quality Payment Program specified in § 414.1415(c)(3)(i).
- Level D: A loss sharing rate of 30 percent regardless of the quality performance of the ACO would apply to first dollar shared losses for ACOs with losses meeting or exceeding their MLR, not to exceed 4 percent of total Medicare Parts A and B FFS revenue for ACO participants. 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 2 percent of the ACO's updated historical benchmark, then the loss sharing limit would be capped and set at 2 percent of the ACO's updated historical benchmark for the applicable performance year. This level of risk is not sufficient to meet the generally applicable nominal amount standard for Advanced APMs under the Quality Payment Program specified in § 414.1415(c)(3)(i).
- Level E: A loss sharing rate of 30 percent regardless of the quality performance of the ACO would apply to first dollar shared losses for ACOs with losses meeting or exceeding their MLR. The percentage of ACO participants' total Medicare Parts A and B FFS revenue used to determine the revenue-based loss sharing limit would be set for each performance year consistent with the generally applicable nominal amount standard for an Advanced APM under § 414.1415(c)(3)(i)(A). The ACO's revenue-based loss sharing limit would not exceed its benchmark-based loss sharing limit, but would be capped at that amount.

Finally, if an ACO enters the BASIC track's glide path in a one-sided model and is unable to meet the requirements to participate under performance-based risk prior to being automatically transitioned to a performance year under risk, CMS would terminate the ACO's agreement under § 425.218.

The financial model of the BASIC track is summarized in Table 3, which also includes a summary of the design of the ENHANCED track (for comparison).

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

	BASIC Track's Glide Path				ENHANCED Track (Track 3)
	Level A & Level B (one-sided model)	**Level C (risk/reward)**	**Level D (risk/reward)**	**Level E (risk/reward)**	
Shared Savings (once MSR met or exceeded)	1st dollar savings at a rate of up to 40% based on quality performance; not to exceed 10% of updated benchmark	1st dollar savings at a rate of up to 50% based on quality performance, not to exceed 10% of updated benchmark	1st dollar savings at a rate of up to 50% based on quality performance, not to exceed 10% of updated benchmark	1st dollar savings at a rate of up to 50% based on quality performance, not to exceed 10% of updated benchmark	No change. 1st dollar savings at a rate of up to 75% based on quality performance, not to exceed 20% of updated benchmark
Shared Losses (once MLR met or exceeded)	N/A	1st dollar losses at a rate of 30%, not to exceed 2% of ACO participant revenue capped at 1% of updated benchmark	1st dollar losses at a rate of 30%, not to exceed 4% of ACO participant revenue capped at 2% of updated benchmark	1st dollar losses at a rate of 30%, not to exceed 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. 1st dollar losses at a rate of 1 minus final sharing rate (between 40% - 75%), not to exceed 15% of updated benchmark
Annual choice of beneficiary assignment methodology? (see section II.A.4.c. of this final rule)	Yes	Yes	Yes	Yes	Yes
Annual election to enter higher risk? [3] (see section II.A.4.b. of this final rule, and section	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

	BASIC Track's Glide Path				ENHANCED Track (Track 3)
	Level A & Level B (one-sided model)	Level C (risk/reward)	Level D (risk/reward)	Level E (risk/reward)	
II.A.5.c of this final rule)					
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/Resource-Library/Comprehensive-List-of-APMs.pdf.

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

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

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(3) Calculation of Loss Sharing Limit

As described in the August 2018 proposed rule, under the Track 1+ Model, either a revenue-based or a benchmark-based loss sharing limit is applied based on the Track 1+ Model ACO's self-reported composition of ACO participants as identified by TINs and CCNs, and the ownership of and operational interests in those ACO participants. We noted our concerns about use of self-reported information for purposes of determining the loss sharing limit in the context of the permanent, national program. The purpose of capturing information on the types of entities that are Track 1+ Model ACO participants and the ownership and operational interests of those ACO participants, as reported by ACOs applying to or participating in the Track 1+ Model, is to differentiate between those ACOs that are eligible for the lower level of risk potentially available under the revenue-based loss sharing limit and those that are subject to the benchmark-based loss sharing limit. For purposes of our proposal to establish the BASIC track in the permanent program, we reconsidered this method of identifying which ACOs are eligible for the revenue-based or benchmark-based loss sharing limits. One concern regarding the Track 1+ Model approach is the burden imposed on ACOs and CMS resulting from reliance on self-reported information. Under the Track 1+ Model, ACOs must collect information about their ACO participant composition and about ownership and operational interests from ACO participants, and potentially others in the TINs' and CCNs' ownership and operational chains, and assess this information to accurately answer questions as required by CMS.[14] These questions are complex and ACOs' ability to respond accurately could vary. Self-reported information is also more complex for CMS to audit. As a result, the use of ACOs' self-reported information in the permanent program could become burdensome for CMS to validate and monitor to ensure program integrity.

We proposed that a simpler approach that achieves similar results to the use of self-reported information would be to consider the total Medicare Parts A and B FFS revenue of ACO participants (TINs and CCNs) based on claims data, without directly considering their ownership and operational interests (or those of related entities), based on our

[14] See Medicare Shared Savings Program, Medicare ACO Track 1+ Model, and SNF 3-Day Rule Waiver, 2018 Application Reference Manual, version #3, July 2017 (herein 2018 Application Reference Manual), available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/MSSP-Reference-Table.pdf* (see ''Appendix F. Application Reference Table—For Medicare ACO Track 1+ Model Applicants'', including definitions for institutional providers and ownership and operational interests for the purpose of the Track 1+ Model).

experience with the initial application cycle for the Track 1+ Model. As part of the application cycle for the 2018 performance year under the Track 1+ Model, CMS gained experience with calculating estimates of ACO participant revenue to compare with estimates of ACO benchmark expenditures, for purposes of determining the repayment mechanism amounts for the Track 1+ Model (as described in section II.A.6.c. of this final rule). The methodology for determining repayment mechanism amounts follows a similar bifurcated approach to the one used to determine the applicable loss sharing limit under the Track 1+ Model. Specifically, for ACOs eligible for a revenue-based loss sharing limit, when the specified percentage of estimated total Medicare Parts A and B FFS revenue for ACO participants exceeds a specified percentage of estimated historical benchmark expenditures, the benchmark-based methodology is applied to determine the ACO's loss sharing limit, which serves to cap the revenue-based amount (see Track 1+ Model Fact Sheet for a brief description of the repayment mechanism estimation methodology). Based on our calculations of repayment mechanism amounts for Track 1+ Model ACOs, we observed a high correlation between the loss sharing limits determined using an ACO's self-reported composition, and its ACO participants' total Medicare Parts A and B FFS revenue. For ACOs that reported including an ACO participant that was an IPPS hospital, cancer center or rural hospital with more than 100 beds, or that was owned or operated by, in whole or in part, such a hospital or by an organization that owns or operates such a hospital, the estimated total Medicare Parts A and B FFS revenue for the ACO participants tended to exceed an estimate of the ACO's historical benchmark expenditures for assigned beneficiaries. For ACOs that reported that they did not include an ACO participant that met these ownership and operational criteria, the estimated total Medicare Parts A and B FFS revenue for the ACO participants tended to be less than an estimate of the ACO's historical benchmark expenditures.

We recognized that this analysis was informed by the definitions for ownership and operational interests, and the definitions for IPPS hospital, cancer center and rural hospital with 100 or more beds, used in the Track 1+ Model. However, we stated that these observations from the Track 1+ Model supported a more generalizable principle about the extent to which ACOs can control total Medicare Parts A and B FFS expenditures for their assigned beneficiaries, and therefore their readiness to take on lower or higher levels of performance-based risk.

In the proposed rule and in this final rule, we use the phrases ''ACO participants' total Medicare Parts A and B FFS revenue'' and ''total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries'' in the discussion of certain proposed policies. For brevity, we sometimes use shorter phrases instead. For instance, we may refer to ACO participant Medicare FFS revenue, or expenditures for the ACO's assigned beneficiaries.

Based on our experience with the Track 1+ Model, we proposed an approach under which the loss sharing limit for BASIC track ACOs would be determined as a percentage of ACO participants' total Medicare Parts A and B FFS revenue that is capped at a percentage of the ACO's updated historical benchmark expenditures when the amount that is a certain percentage of ACO participant FFS revenue (depending on the BASIC track risk/reward level) exceeds the specified percentage of the ACO's updated historical benchmark expenditures for the relevant BASIC track risk/reward level. Under our proposed approach, we would not directly consider the types of entities included as ACO participants or ownership and operational interests in ACO participants in determining the loss sharing limit that would apply to ACOs under Levels C, D, and E of the BASIC track. We stated our belief that ACOs whose ACO participants have greater total Medicare Parts A and B FFS revenue relative to the ACO's benchmark are better financially prepared to move to greater levels of risk. Accordingly, this comparison of revenue to benchmark would provide a more accurate method for determining an ACO's preparedness to take on additional risk than an ACO's self-reported information regarding the composition of its ACO participants and any ownership and operational interests in those ACO participants.

We explained that ACOs that include a hospital billing through an ACO participant TIN are generally more capable of accepting higher risk given their control over a generally larger amount of their assigned beneficiaries' total Medicare Parts A and B FFS expenditures relative to their ACO participants' total Medicare Parts A and B FFS revenue. As a result, our proposed approach would tend to place ACOs that include hospitals under a benchmark-based loss sharing limit because their ACO participants typically have higher total Medicare Parts A and B FFS revenue compared to the ACO's benchmark. Less often, the ACO participants in an ACO that includes a hospital billing through an ACO participant TIN have low total Medicare Part A and B FFS revenue compared to the ACO's benchmark. Under a claims-based approach to determining the ACO's loss sharing limit, ACOs with hospitals billing through ACO participant TINs and relatively low ACO participant FFS revenue would be under a revenue-based loss sharing limit.

To illustrate, Table 4 compares two approaches to determining loss liability: A claims-based approach (proposed approach) and self-reported composition (approach used for the Track 1+ Model). The table summarizes information regarding ACO participant composition reported by the Track 1+ Model applicants for performance year 2018 and identifies the percentages of applicants whose self-reported composition would have placed the ACO under a revenue-based loss sharing limit or a benchmark-based loss sharing limit. The table then indicates the outcomes of a claims-based analysis applied to this same cohort of applicants. This analysis indicates the proposed claims-based method produces a comparable result to the self-reported composition method. Further, this analysis suggests that under a claims-based method, ACOs that include institutional providers with relatively low Medicare Parts A and B FFS revenue would be placed under a revenue-based loss sharing limit, which may be more consistent with their capacity to assume risk than an approach that considers only the inclusion of certain institutional providers among the ACO participants and their providers/suppliers (TINs and CCNs).

TABLE 4—DETERMINATION OF LOSS SHARING LIMIT BY SELF-REPORTED COMPOSITION VERSUS CLAIMS-BASED APPROACH FOR TRACK 1+ MODEL APPLICANTS

Approach to Determining Loss Liability	Revenue-based Loss-Sharing Limit	Benchmark-based Loss-Sharing Limit
Use of applicants' self-reported composition (Track 1+ Model approach)	34%	66%
Use of claims: percentage of ACO participant revenue compared to percentage of ACO benchmark	38%	62%

Using ACO participant Medicare FFS revenue to determine the ACO's loss sharing limit balances several concerns. For one, it allows CMS to make a claims-based determination about the ACO's loss limit instead of depending on self-reported information from ACOs. This approach would also alleviate the burden on ACOs of gathering information from ACO participants about their ownership and operational interests and reporting that information to CMS, and would address CMS' concerns about the complexity of auditing the information reported by ACOs.

We proposed to establish the revenue-based loss sharing limit as the default for ACOs in the BASIC track and to phase-in the percentage of ACO participants' total Medicare Parts A and B FFS revenue. However, if the amount that is the applicable percentage of ACO participants' total Medicare Parts A and B FFS revenue exceeds the amount that is the applicable percentage of the ACO's updated benchmark based on the previously described phase-in schedule, then the ACO's loss sharing limit would be capped and set at this percentage of the ACO's updated historical benchmark. We sought comment on this proposal.

We considered issues related to the generally applicable nominal amount standard for Advanced APMs in our development of the revenue-based loss sharing limit under Level E of the proposed BASIC track. Under § 414.1415(c)(3)(i)(A), the revenue-based nominal amount standard is set at 8 percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers in a participating APM Entity for QP Performance Periods 2017, 2018, 2019, and 2020. We proposed that, for the BASIC track, the percentage of ACO participants' FFS revenue used to determine the revenue-based loss sharing limit for the highest level of risk (Level E) would be set for each performance year consistent with the generally applicable nominal amount standard for an Advanced APM under § 414.1415(c)(3)(i)(A), to allow eligible clinicians participating in a BASIC track ACO subject to the revenue-based loss sharing limit the opportunity to earn the Advanced APM incentive payment when the ACO is participating under Level E. For example, for performance years 2019 and 2020, this would be 8 percent of ACO participants' total Medicare Parts A and B FFS revenue that would be capped and set at 4 percent of the updated benchmark. As a result, the proposed BASIC track at Level E risk/reward would meet all of the criteria and be an Advanced APM.

Further, in the CY 2018 Quality Payment Program final rule with comment period, we revised § 414.1415(c)(3)(i)(A) to more clearly indicate that the revenue-based nominal amount standard is determined as a percentage of the revenue of all providers and suppliers in the participating APM Entity (see 82 FR 53836 through 53838). Under the Shared Savings Program, ACOs are composed of one or more ACO participant TINs, which include all providers and suppliers that bill Medicare for items and services that are participating in the ACO. See definitions at § 425.20. In accordance with § 425.116(a)(3), ACO participants must agree to ensure that each provider/supplier that bills through the TIN of the ACO participant agrees to participate in the Shared Savings Program and comply with all applicable requirements. Because all providers/suppliers billing through an ACO participant TIN must agree to participate in the program, for purposes of calculating ACO revenue under the nominal amount standard for Shared Savings Program ACOs, the FFS revenue of the ACO participant TINs is equivalent to the FFS revenue for all providers/suppliers participating in the ACO. Therefore, we intend to perform these revenue calculations at the ACO participant level.

We proposed to calculate the loss sharing limit for BASIC track ACOs in generally the same manner that is used under the Track 1+ Model. However, as discussed elsewhere in this section, we would not rely on an ACO's self-reported composition as used in the Track 1+ Model to determine if the ACO is subject to a revenue-based or benchmark-based loss sharing limit. Instead, we 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 section II.A.3.b.(2). of this final rule) to this total Medicare Parts A and B FFS revenue for ACO participants to derive the revenue-based loss sharing limit.
- Use the applicable percentage of the ACO's updated benchmark, instead of the revenue-based loss sharing limit, if the loss sharing limit as a percentage of total Medicare Parts A and B FFS revenue for ACO participants exceeds the amount that is the specified percentage of the ACO's updated historical benchmark, based on the phase-in schedule. In that case, the loss sharing limit is capped and set at the applicable percentage of the ACO's updated historical benchmark for the applicable performance year.

To illustrate, Table 5 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 Level E of the BASIC track for the performance years beginning on July 1, 2019, and January 1, 2020, based on the percentages of revenue and ACO benchmark expenditures specified in generally applicable nominal amount standards in the Quality Payment Program regulations. 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. If in this scenario the ACO's revenue would have been greater, and the revenue-based loss sharing limit exceeded the benchmark-based loss sharing limit amount, the loss sharing limit would be capped and set at the benchmark-based loss sharing limit amount (in this example $3,736,453).

TABLE 5—HYPOTHETICAL EXAMPLE OF LOSS SHARING LIMIT AMOUNTS FOR ACO IN LEVEL E OF THE BASIC TRACK

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

More specifically, ACO participants' total Medicare Parts A and B FFS revenue would be calculated as the sum of Medicare paid amounts on all non-denied claims associated with TINs on the ACO's certified ACO participant list, or the CCNs enrolled under an ACO participant TIN as identified in the Provider Enrollment, Chain, and Ownership System (PECOS), for all claim types used in program expenditure calculations that have dates of service during the performance year, using 3 months of claims run out. ACO participant Medicare FFS revenue would not be limited to claims associated with the ACO's assigned beneficiaries, and would instead be based on the claims for all Medicare FFS beneficiaries furnished services by the ACO participant. Further, in calculating ACO participant Medicare FFS revenue, we would not truncate a beneficiary's total annual FFS expenditures or adjust to remove indirect medical education (IME), disproportionate share hospital (DSH), or uncompensated care payments or to add back in reductions made for sequestration. ACO participant Medicare FFS revenue would include any payment adjustments reflected in the claim payment amounts (for example, under MIPS or Hospital Value Based Purchasing Program) and would also include individually identifiable final payments made under a demonstration, pilot, or time-limited program, and would be determined using the same completion factor used for annual expenditure calculations.

This approach to calculating ACO participant Medicare FFS revenue is different from our approach to calculating benchmark and performance year expenditures for assigned beneficiaries, which we truncate at the 99th percentile of national Medicare FFS expenditures for assignable beneficiaries, and from which we exclude IME, DSH and uncompensated care payments (see subpart G of the program's regulations). We truncate expenditures to minimize variation from catastrophically large claims. We note that truncation occurs based on an assigned beneficiary's total annual Parts A and B FFS expenditures, and is not apportioned based on services furnished by ACO participant TINs. See Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (May 2018, version 6) available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/program-guidance-and-specifications.html* (herein Shared Savings and Losses and Assignment Methodology Specifications, version 6). As discussed in earlier rulemaking, we exclude IME, DSH and uncompensated care payments from ACOs' assigned beneficiary expenditure calculations because we do not wish to incentivize ACOs to avoid the types of providers that receive these payments, and for other reasons described in earlier rulemaking (see 76 FR 67919 through 67922, and 80 FR 32796 through 32799). But to accurately determine ACO participants' revenue for purposes of determining a revenue-based loss sharing limit, we would include total revenue uncapped by truncation and to include IME, DSH and uncompensated care payments. These payments represent resources available to ACO participants to support their operations and offset their costs and potential shared losses, thereby increasing the ACO's capacity to bear performance-based risk, which should be reflected in the ACO's loss sharing limit. Excluding such payments could undercount revenue and also could be challenging to implement, particularly truncation, since it likely would require apportioning responsibility for large claims among the ACO participants and non-ACO participants from which the beneficiary may have received the services resulting in the large claims.

Currently, for Track 2 and Track 3 ACOs, the loss sharing limit (as a percentage of the ACO's updated benchmark) is determined each performance year, at the time of financial reconciliation. Consistent with this approach, we would determine the loss sharing limit for BASIC track ACOs annually, at the time of financial reconciliation for each performance year. Further, under the existing policies for the Shared Savings Program, we adjust the historical benchmark annually for changes in the ACO's certified ACO participant list. See §§ 425.602(a)(8) and 425.603(b), (c)(8). See also the Shared Savings and Losses and Assignment Methodology Specifications, version 6. Similarly, the annual determination of a BASIC track ACO's loss sharing limit would reflect changes in ACO composition based on changes to the ACO's certified ACO participant list.

We proposed to codify these policies in a new section of the Shared Savings Program regulations governing the BASIC track, at § 425.605. We sought comment on these proposals.

Comment: A few commenters had suggestions as to whether certain payments or expenditures should be included in an ACO's benchmark. One commenter recommended that CMS exclude payments from the CPC+ Model

in their entirety from the benchmark and expenditures on both a retrospective and prospective basis. The commenter further recommended that CMS update the historical benchmark to remove CPC+ Model payments from the calculation of ACOs' expenditures as non-claims based payments. Another commenter recommended that CMS exclude MIPS bonuses from the determination of ACO expenditures because MIPS bonuses are projected to rise in future program years, which may penalize ACOs in comparison to their historical benchmark, and result in lower shared savings or higher shared losses. The commenter questioned CMS' treatment of these payments, stating that CMS currently excludes Advanced APM incentive payments from ACO expenditures and recommended that CMS do the same for MIPS expenditures.

Response: First, section 1833(z)(1)(C) of the Act provides that incentive payments made to a Qualifying APM Participant (QP) should not be taken into account for purposes of determining actual expenditures under an alternative payment model and for purposes of determining or rebasing any benchmarks used under the alternative payment model. Thus, we will not include the Advanced APM incentive payments in calculation of the ACOs expenditures. Second, the total per capita expenditures for an ACO's assigned beneficiary population reflect services that are furnished by ACO providers/suppliers and also by providers and suppliers outside the ACO. As a result, the ACO only supplies a fraction of the services represented in the total per capita expenditures for the ACO's assigned beneficiaries. Therefore, the net effect of MIPS adjustments on ACO expenditures for the ACO's assigned beneficiary population, would be variable and often small and would depend on the mix of adjustments affecting the amount of payment for services supplied to ACO assigned beneficiaries by all MIP eligible clinicians, not just services that were supplied by ACO providers/suppliers. Third, the Shared Savings Program regulations provide that individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program will be included in the calculation of Medicare Part A and Part B expenditures for the ACO's assigned beneficiary population for purposes of establishing the historical benchmark and determining performance year expenditures. CPC+ Model payments are individually beneficiary identifiable final payments made under such a model, and therefore are included in the ACO's expenditures for purposes of establishing the financial benchmark and calculating performance year expenditures. The CPC+ Model payments and other non-claims based payments typically represent a small amount of expenditures for a small number of ACO assigned beneficiaries, so the impact of final non-claims based payments on an ACO's historical benchmark or performance year expenditures is likely to be minimal.

Comment: Several commenters expressed concern about the approach to calculating revenue used in determining the loss sharing limits under the BASIC track. These commenters explained that CMS proposed to include hospital add-on payments such as Indirect Medical Education (IME), Disproportionate Share Hospital (DSH), and uncompensated care payments when calculating an ACO's ACO participant revenue for purposes of determining the loss sharing limit. These commenters pointed out that CMS will exclude these payments when calculating assigned beneficiary expenditures for determining benchmark and performance year expenditures. These commenters urged CMS to exclude add-on payments in determining an ACO's ACO participant revenue as well, suggesting that the proposed approach could penalize ACOs with ACO participants that treat vulnerable populations, including teaching hospitals and those that treat the uninsured population.

Response: We discuss related considerations in our discussion of the determination of whether an ACO qualifies as a low revenue ACO or a high revenue ACO in section II.A.5.b. of this final rule. To accurately determine ACO participants' revenue for purposes of determining a revenue-based loss sharing limit, we explain that it is important to include total revenue uncapped by truncation and to include IME, DSH and uncompensated care payments. As noted earlier in this section and discussed in greater detail in section II.A.5.b, this approach to calculating ACO participant Medicare FFS revenue is different from our approach to calculating benchmark and performance year expenditures for assigned beneficiaries, which we truncate at the 99th percentile of national Medicare FFS expenditures for assignable beneficiaries, and from which we exclude IME, DSH and uncompensated care payments (see subpart G of the program's regulations). IME, DSH, uncompensated care payments represent resources available to ACO participants to support their operations and offset their costs and potential shared losses, thereby increasing the ACO's capacity to bear performance-based risk, which we believe should be reflected in the ACO's loss sharing limit. Excluding such payments could undercount revenue and also could be challenging to implement, particularly truncation, since it likely would require apportioning responsibility for large claims among the ACO participants and non-ACO participants from which the beneficiary may have received the services resulting in the large claims. We therefore decline to modify our approach to determining ACO participant's total Medicare Parts A and B FFS revenue to include IME, DSH and uncompensated care payments, or to cap claim payment amounts through truncation.

For similar reasons, we also decline at this time to make other technical adjustments to calculations of revenue to exclude any other payment adjustments reflected in the claim payment amounts, such as payments under MIPS or the Hospital Value Based Purchasing Program.

Final Action: We are finalizing the approach to calculating ACO participants' Medicare FFS revenue used in the determination of the loss sharing limits under the BASIC track as proposed.

4. Permitting Annual Participation Elections

a. Overview

Background on our consideration of and stakeholders' interest in allowing ACOs the flexibility to elect different participation options within their current agreement period is described in section II.A.1. of this final rule. In the August 2018 proposed rule (83 FR 41810 through 41813), we proposed policies to allow ACOs in the BASIC track's glide path to annually elect to take on higher risk and to allow ACOs in the BASIC track and ENHANCED track to annually elect their choice of beneficiary assignment methodology (either preliminary prospective assignment with retrospective reconciliation or prospective assignment).

b. Permitting Election of Differing Levels of Risk Within the BASIC Track's Glide Path

In the August 2018 proposed rule (83 FR 41810 through 41813), we proposed to incorporate additional flexibility in participation options by allowing ACOs

that enter an agreement period under the BASIC track's glide path an annual opportunity to elect to enter higher levels of performance-based risk within the BASIC track within their agreement period. This flexibility would be important for ACOs entering the glide path under either the one-sided model (Level A or Level B) or the lowest level of risk (Level C) that may seek to transition more quickly to higher levels of risk and potential reward. (We note that an ACO entering the glide path at Level D would be automatically transitioned to Level E in the following year, and an ACO that enters the glide path at Level E must remain at this level for the duration of its agreement period and any subsequent agreement period under the BASIC track, if eligible.)

In developing the proposed policy, we considered that an ACO under performance-based risk has the potential to induce more meaningful systematic change in providers' and suppliers' behavior. We also considered that an ACO's readiness for greater performance-based risk may vary depending on a variety of factors, including the ACO's experience with the program (for example, in relation to its elected beneficiary assignment methodology, composition of ACO participants, and benchmark value) and its ability to coordinate care and carry out other interventions to improve quality and financial performance. Lastly, we considered that an ACO may seek to more quickly take advantage of the features of higher levels of risk and potential reward within the BASIC track's glide path, including: Potential for greater shared savings; increased ability for participating physicians and practitioners to furnish telehealth services as provided under section 1899(l) of the Act, use of a SNF 3-day rule waiver, and the opportunity to establish a CMS-approved beneficiary incentive program (described in sections II.B and II.C. of this final rule); and the opportunity to participate in an Advanced APM under the Quality Payment Program after progressing to Level E of the BASIC track's glide path.

We explained that restricting ACOs from moving from the BASIC track to the ENHANCED track within their current agreement period would protect the Trust Funds. This would guard against selective participation in a financial model with the highest potential level of reward while the ACO remains subject to a benchmark against which it is very confident of its ability to generate shared savings. However, under the proposal to eliminate the sit-out period for re-entry into the program after termination (see discussion in section II.A.5.c. of this final rule), an ACO (such as a BASIC track ACO) may terminate its participation agreement and quickly enter a new agreement period under a different track, if eligible (such as the ENHANCED track).

We proposed to add a new section of the Shared Savings Program regulations at § 425.226 to govern annual participation elections. Specifically, we proposed 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. We proposed that 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. We also proposed that 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. We proposed that 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 MSR/MLR that will apply for the remainder of their agreement period under performance-based risk. (See section II.A.6. of this final rule for a detailed discussion of these requirements.) We proposed that 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. We envisioned that the timing of an ACO's election would generally follow the timing of the Shared Savings Program's application cycle.

The ACO's participation in the newly selected level of risk and potential reward, if approved, would be effective at the start of the next performance year. In subsequent years, the ACO may again choose to elect a still higher level of risk and potential reward (if a higher risk/reward option is available within the glide path). Otherwise, the automatic transition to higher levels of risk and potential reward in subsequent years would continue to apply to the remaining years of the ACO's agreement period in the glide path. We also proposed related changes to § 425.600 to reflect the opportunity for ACOs in the BASIC track's glide path to transition to higher risk and potential reward during an agreement period.

For example, 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. We note that ACOs starting in the BASIC track's glide path for an agreement period beginning on July 1, 2019, could elect to enter a higher level of risk/reward within the BASIC track in advance of the performance year beginning on January 1, 2020.

In general, we wish to clarify 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 would not alter the timing of benchmark rebasing under the proposed new section of the regulations at § 425.601. For example, if an ACO participating in the BASIC track's glide path transitions to a higher level of risk and potential reward during its agreement period, the ACO's historical benchmark would not be rebased as a result of this change. We 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 the benchmarking methodology under the proposed new provision at § 425.601.

Comment: Overall, commenters supported CMS' proposal to permit an annual opportunity to elect to enter higher levels of performance-based risk, if available, within the BASIC track within an ACO's agreement period. One commenter suggested this is a good policy for CMS because it allows CMS to achieve its goal of shifting more ACOs into higher levels of risk. The commenter also suggested it is a good policy for ACOs because it gives them greater flexibility. Some commenters proposed allowing an ACO that elected to advance to a higher level early to remain at the higher level until it reaches the PY when it would have automatically advanced to the next successive level, absent the ACO's election to advance more quickly than the glide path required. A few commenters supported the proposal to allow annual election of risk and skipping to higher levels, but encouraged CMS to allow ACOs to glide backward and select a lower level of risk if they jumped ahead and their losses exceeded their MLR for the level they skipped or if the ACO found that it was not ready to bear risk. Commenters suggested this added flexibility would encourage ACOs to experiment with risk as commenters suggested that CMS intended.

Response: We appreciate the commenters' suggestions related to options for ACOs to elect varying levels of risk along the glide path. As we have discussed in this final rule, we believe there are incentives for increased efficiency when ACOs are in a two-sided risk track. Our goal continues to be to advance ACOs to taking on higher levels of risk. Our experience with the Track 1+ Model has shown that ACOs are willing to accept the amount of risk in Level E of the BASIC track. ACOs should evaluate whether they are able to undertake greater risk before electing to move to a higher level of risk and ensure that the ACO has the operational capabilities in place to assume higher risk. Therefore, we decline to adopt these suggestions and are finalizing the glide path that transitions ACOs to higher levels of risk throughout the agreement period.

Comment: Several commenters suggested that ACOs be allowed to move from the BASIC track to the ENHANCED track within their agreement period. One commenter proposed that CMS allow ACOs to jump BASIC levels to the ENHANCED track without an application process, asserting that this policy would create unnecessary administrative burden. Another commenter recommended removal of restrictions preventing ACOs that begin at the BASIC track's Level E from moving up to the ENHANCED track without an interruption to their existing participation agreement or the redetermination of benchmarks. The commenter explained its preference that all levels of gainsharing and risk assumption be on a single platform to facilitate the continuous movement to higher levels of risk and potential reward. One commenter seemed to suggest an alternative approach to allow low revenue ACOs and high revenue ACOs to transition from the BASIC track to the ENHANCED track within a single agreement period, and then potentially return to the BASIC track if they discovered that they were unprepared to take on the higher level of risk.

Response: As noted in the preamble, we continue to believe it is protective of the Trust funds to restrict ACOs from moving from the BASIC track to the ENHANCED track within the ACO's current agreement period. This would guard against selective participation in a financial model with the highest potential level of reward while the ACO remains subject to a benchmark against which it is very confident of its ability to generate savings. We decline at this time to accept commenters' suggestions to allow the flexibility for ACOs to move between the levels of risk and reward under the ENHANCED track and the BASIC track within a single agreement period. ACOs seeking to make this transition could elect to terminate their participation agreement under the BASIC track and ''renew early'' to enter the ENHANCED (see discussion in section II.A.5.c of this final rule), for example, which would result in rebasing of the ACO's historical benchmark.

We did not receive any comments on our proposals requiring: (1) Annual election of the change in the ACO's level of risk and potential reward in the form and manner, and according to the timeframe, established by CMS; (2) certification by an ACO executive who has the authority to legally bind the ACO of any election to enter a higher level of risk and potential reward within the agreement period; (3) the ACO to 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 MSR/MLR that will apply for the remainder of the ACO's agreement period under performance-based risk; or (4) the ACO to 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, if available (generally following the timing of the Shared Savings Program's application cycle).

Final Action: After considering the comments concerning the annual election of differing levels of risk along the BASIC track's glide path, we are finalizing the policies as proposed. Specifically, we are finalizing policies 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. If an ACO decides to elect a higher level of performance-based risk during their agreement period, it will make the election in the form and manner specified by CMS. Additionally, we are finalizing the requirement that ACOs 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 MSR/MLR that will apply for the remainder of their agreement period under performance-based risk. Accordingly, we are finalizing as proposed the new § 425.226 and related changes at § 425.600.

c. Permitting Annual Election of Beneficiary Assignment Methodology

Section 1899(c)(1) of the Act, as amended by section 50331 of the Bipartisan Budget Act, 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 FQHC or RHC. The provisions of section 1899(c) of the Act govern beneficiary assignment under all tracks of the Shared Savings Program. Although, to date, we have designated which beneficiary assignment methodology will apply for each track of the Shared Savings Program, section 1899(c) of the Act (including as amended by the Bipartisan Budget Act) does not expressly require that the beneficiary assignment methodology be determined by track.

Under the Shared Savings Program regulations, we have established two claims-based beneficiary assignment methods (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 (discussed in section II.E.2. of the August 2018 proposed rule) that applies to all program tracks and is used to supplement claims-based assignment. The regulations governing the assignment methodology under the Shared Savings Program are in 42 CFR part 425, subpart E. In the November 2011 final rule, we adopted a claims-based hybrid approach (called preliminary prospective assignment with retrospective reconciliation) for assigning beneficiaries to an ACO (76 FR 67851 through 67870), which is currently applicable to ACOs participating under Track 1 or Track 2 of the Shared Savings Program (except for Track 1 ACOs that are also participating in the Track 1+ Model for which we use a prospective assignment methodology in accordance with our authority under section 1115A of the Act). Under this approach, beneficiaries are preliminarily assigned to an ACO, based on a two-step assignment methodology, at the beginning of a performance year and quarterly thereafter during the performance year, but final beneficiary assignment is determined after the performance year based on where beneficiaries chose to receive the plurality of their primary care services during the performance year. Subsequently, in the June 2015

final rule, we implemented an option for ACOs to participate in a new performance-based risk track, Track 3 (80 FR 32771 through 32781). Under Track 3, beneficiaries are prospectively assigned to an ACO at the beginning of the performance year using the same two-step methodology used in the preliminary prospective assignment approach, based on where the beneficiaries have chosen to receive the plurality of their primary care services during a 12-month assignment window offset from the calendar year that reflects the most recent 12 months for which data are available prior to the start of the performance year. The ACO is held accountable for beneficiaries who are prospectively assigned to it for the performance year. Under limited circumstances, a beneficiary may be excluded from the prospective assignment list, such as if the beneficiary enrolls in MA during the performance year or no longer lives in the United States or U.S. territories and possessions (as determined based on the most recent available data in our beneficiary records regarding residency at the end of the performance year).

Finally, in the CY 2017 PFS final rule (81 FR 80501 through 80510), we augmented the claims-based beneficiary assignment methodology by finalizing a policy under which beneficiaries, beginning in 2017 for assignment for performance year 2018, 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. Notwithstanding the assignment methodology in § 425.402(b), beneficiaries who designate an ACO professional whose services are used in assignment as responsible for their overall care will be prospectively assigned to the ACO in which that ACO professional participates, provided the beneficiary meets the eligibility criteria established at § 425.401(a) and is not excluded from assignment by the criteria in § 425.401(b), and has had at least one primary care service during the assignment window with an ACO professional in the ACO who is a primary care physician or a physician with one of the primary specialty designations included in § 425.402(c). Such beneficiaries will be added prospectively to the ACO's list of assigned beneficiaries for the subsequent performance year. See section V.B.2.b. of the November 2018 final rule for a discussion of the new provisions regarding voluntary alignment added to section 1899(c) of the Act by section 50331 of the Bipartisan Budget Act, and our related proposed regulatory changes.

Section 50331 of the Bipartisan Budget Act specifies 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. The Bipartisan Budget Act incorporates this requirement as a new provision at section 1899(c)(2)(A) of the Act.

In the August 2018 proposed rule (83 FR 41811 through 41813), we proposed to implement this provision of the Bipartisan Budget Act to provide all ACOs with a choice of prospective assignment for agreement periods beginning on July 1, 2019, and in subsequent years. We also proposed to incorporate additional flexibility into the beneficiary assignment methodology consistent with the Secretary's authority under section 1899(c)(1) of the Act to determine an appropriate beneficiary assignment methodology. We do not believe that section 1899(c) of the Act, as amended by the Bipartisan Budget Act, requires that we must continue to specify the applicable beneficiary assignment methodology for each track of the Shared Savings Program. Although section 1899(c)(2)(A) of the Act now provides that ACOs must be permitted to choose prospective assignment for each agreement period, we do not believe this requirement limits our discretion to allow ACOs the additional flexibility to change beneficiary assignment methodologies more frequently during an agreement period. As summarized in section II.A.1. of this final rule and as described in detail in earlier rulemaking, commenters have urged us to allow greater flexibility for ACOs to select their assignment methodology. Accordingly, we proposed an approach that separates the choice of beneficiary assignment methodology from the choice of participation track (financial model), and that allows ACOs to make an annual election of assignment methodology. Such an approach would afford greater flexibility for ACOs to choose between assignment methodologies for each year of the agreement period, without regard to their participation track. Consistent with the requirements of the Bipartisan Budget Act, we will offer all Shared Savings Program ACOs the opportunity to select their assignment methodology annually, starting with agreement periods beginning on July 1, 2019.

As an approach to meeting the requirements of the Bipartisan Budget Act while building on them to offer greater flexibility, we proposed to offer ACOs entering agreement periods in the BASIC track or ENHANCED track, beginning on July 1, 2019 and in subsequent years, the option to choose either prospective assignment or preliminary prospective assignment with retrospective reconciliation, prior to the start of their agreement period (at the time of application). We also proposed to provide an opportunity for ACOs to switch their selection of beneficiary assignment methodology on an annual basis. As we explained in the August 2018 proposed rule, under this approach, in addition to the requirement under the Bipartisan Budget Act that ACOs be permitted to change from retrospective assignment to prospective assignment, an ACO would have the added flexibility to change from prospective assignment to preliminary prospective assignment with retrospective reconciliation. As an additional flexibility that further builds on the Bipartisan Budget Act, ACOs would be allowed to retain the same beneficiary assignment methodology for an entire agreement period or to change the methodology annually. An individual ACO's preferred choice of beneficiary assignment methodology may vary depending on the ACO's experience with the two assignment methodologies used under the Shared Savings Program. Therefore, this proposed approach implements the requirements of the Bipartisan Budget Act and will also be responsive to stakeholders' suggestions that we allow additional flexibility around choice of beneficiary assignment methodology to facilitate ACOs' transition to performance-based risk (as discussed earlier in this section). Further, allowing this additional flexibility for choice of beneficiary assignment methodology within the proposed BASIC track and ENHANCED track would enable ACOs to select a combination of participation options that would overlap with certain features of Track 2, and thus lessen the need to maintain Track 2 as a separate participation option. Accordingly, as discussed in section II.A.2. of this final rule, we proposed to discontinue Track 2. Finally, we believed it would be appropriate and reasonable to start offering the choice of beneficiary assignment to ACOs in the BASIC track or ENHANCED track for agreement periods beginning on July 1, 2019, and

in subsequent years, in order to align with the availability of these two tracks under the proposed redesign of the Shared Savings Program.

In the August 2018 proposed rule, we proposed 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 Shared Savings Program 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. We also proposed 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. For example, if an ACO selects preliminary prospective assignment with retrospective reconciliation at the time of its application to the program for an agreement period beginning on July 1, 2019, this methodology would apply in the ACO's first performance year (6-month performance year from July 1, 2019, through December 31, 2019) and all subsequent performance years of its agreement period, unless the ACO selects prospective assignment in advance of the start of performance year 2020, 2021, 2022, 2023, or 2024. To continue this example, during its first performance year, the ACO would have the option to select prospective assignment to be applicable beginning with performance year 2020. If selected, this assignment methodology would continue to apply unless the ACO again selects a different methodology.

We proposed to incorporate the requirements governing the ACO's initial selection of beneficiary assignment methodology and the annual opportunity for an ACO to notify CMS that it wishes to change its beneficiary assignment methodology within its current agreement period, in a new section of the Shared Savings Program regulations at § 425.226 along with the other annual elections described elsewhere in this final rule. We proposed that the initial selection of, and any annual selection for a change in, beneficiary assignment methodology must be made in the form and manner, and according to the timeframe, established by CMS. We also proposed that an ACO executive who has the authority to legally bind the ACO must certify the selection of beneficiary assignment methodology for the ACO. We envision that the timing of this opportunity for an ACO to change assignment methodology would generally follow the Shared Savings Program's application cycle. For consistency, we also proposed to make conforming changes to regulations that currently identify assignment methodologies according to program track. Specifically, we proposed to revise §§ 425.400 and 425.401 (assignment of beneficiaries), § 425.702 (aggregate reports) and § 425.704 (beneficiary-identifiable claims data) to reference either preliminary prospective assignment with retrospective reconciliation or prospective assignment instead of referencing the track to which a particular assignment methodology applies (currently Track 1 and Track 2, or Track 3, respectively).

We clarified that this proposal would have no effect on the voluntary alignment process under § 425.402(e). Because beneficiaries may voluntarily align with an ACO through their designation of a ''primary clinician,'' and eligible beneficiaries will be prospectively assigned to that ACO regardless of the ACO's track or claims-based beneficiary assignment methodology, an ACO's choice of claims-based assignment methodology under this proposal would not alter the voluntary alignment process.

As part of the proposed approach to allow ACOs to elect to change their assignment methodology within their agreement period, we also proposed to adjust the ACO's historical benchmark to reflect the ACO's election of a different assignment methodology. Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established. This provision specifies that the Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per beneficiary expenditures for Parts A and B services for Medicare FFS beneficiaries assigned to the ACO. Such benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate.

As we explained in earlier rulemaking, we currently use differing assignment windows to determine beneficiary assignment for the benchmark years and performance years, according to the ACO's track and the beneficiary assignment methodology used under that track. The assignment window for ACOs under prospective assignment is a 12-month period off-set from the calendar year, while for ACOs under preliminary prospective assignment with retrospective reconciliation, the assignment window is the 12-month period based on the calendar year (see 80 FR 32699, and 80 FR 32775 through 32776). However, for all ACOs, the claims used to determine the per capita expenditures for a benchmark or performance year are the claims for services furnished to assigned beneficiaries from January 1 through December 31 of the calendar year that corresponds to the applicable benchmark or performance year (see for example, 79 FR 72812 through 72813, see also 80 FR 32776 through 32777). We explained that this approach removes actuarial bias between the benchmarking and performance years for assignment and financial calculations, since the same method would be used to determine assignment and the financial calculations for each benchmark and performance year. Further, basing the financial calculations on the calendar year would be necessary to align with actuarial analyses with respect to risk score calculations and other data inputs based on national FFS expenditures used in program financial calculations, which are determined on a calendar year basis (79 FR 72813). To maintain symmetry between the benchmark and performance year calculations it would be necessary to adjust the benchmark for ACOs that change beneficiary assignment methodology within their current agreement period to reflect changes in beneficiary characteristics due to the change in beneficiary assignment methodology, as provided in section 1899(d)(1)(B)(ii) of the Act. For example, if an ACO were to elect to change its applicable beneficiary assignment methodology during its initial agreement period from preliminary prospective assignment with retrospective reconciliation to prospective assignment, we would adjust the ACO's historical benchmark for the current agreement period to reflect the expenditures of beneficiaries that would have been assigned to the ACO during the benchmark period using the prospective assignment methodology, instead of the expenditures of the beneficiaries assigned under the preliminary prospective assignment methodology that were used to establish the benchmark at the start of the agreement period. Therefore, we proposed to

specify in the proposed new section of the regulations at § 425.601 that would govern establishing, adjusting, and updating the benchmark for all agreement periods beginning on July 1, 2019, and in subsequent years, that we will adjust an ACO's historical benchmark to reflect a change in the ACO's beneficiary assignment methodology within an agreement period. However, 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.

We sought comment on these proposals.

Comment: Generally, commenters were supportive of the proposal implementing section 1899(c)(2)(A) of the Act, as added by the Bipartisan Budget Act, to allow all ACOs a choice of prospective assignment for agreement periods beginning on July 1, 2019, and in subsequent performance years. They also supported CMS' proposal to exercise its discretion to separate the choice of assignment methodology from the choice of participation track (financial model) and provide ACOs with additional flexibility to change beneficiary assignment methodologies annually. Commenters praised these proposals and provided various rationale for their support, stating that the annual choice of assignment methodology for all ACOs:

- Removes challenges caused by uncertainty of preliminary prospective beneficiary assignment with retrospective reconciliation, for ACOs that would be newly free to select prospective assignment.
- Offers some much-needed stability and allows for the appropriate allocation of ACOs' finite resources, for ACOs that would be newly free to select prospective assignment.
- Assists ACOs in planning and designing care management strategies.
- Assists ACOs that, for care-driven reasons, may find it difficult to adopt one methodology versus another.
- Provides ACOs with more flexibility to manage their patient populations based on their unique circumstances, care model, and ability to taken on risk for the total cost of care.
- Equals the playing field between different types of ACOs.
- Serves to increase ACO entity interest and participation in the program. One commenter that generally supported the proposal additionally suggested that CMS should provide accurate and timely reporting (for example, year-to-year performance comparisons based on the selected assignment methodology) so ACOs can analyze trends and results in a timely manner and be in a position to make an annual determination.

A few commenters offered alternatives to CMS' proposal. One commenter encouraged CMS to develop an approach that offers only preliminary prospective assignment with retrospective reconciliation so providers can target high-risk patients for care management throughout the program period. The commenter asserted that this would improve accuracy at the end of the year because ACOs would likely be held accountable for the patients they coordinated care for during the performance year. One ACO commenter supported the annual option of prospective or preliminary prospective assignment and requested that the option chosen have no effect on the shared savings rate for ENHANCED track ACOs (a maximum of 75 percent). One commenter recommended that the choice of assignment only be exercised once during the term of the participation agreement to prevent ongoing gaming of the system by switching attribution models based upon financial arbitrage rather than focusing on care redesign. Finally, a commenter was concerned about the effect of late reporting on the selection of assignment methodology.

Response: CMS appreciates the enthusiasm of the commenters and the overwhelming support received. In this final rule, and consistent with Section 1899(c)(2)(a) of the Act, we are providing ACOs flexibility in their choice of beneficiary assignment methodology. We agree that timely reporting and data collection are crucial for ACOs to make an informed assignment selection; and under § 425.702, we provide ACOs with aggregate quarterly reports that identify prospective and preliminary prospective assigned beneficiaries as well as utilization and expenditure data. Under § 425.704, we provide ACOs with monthly claim and claim line feed files. We provide the aggregate reports and monthly claim and claim line feed files to provide ACOs with data to aid them in making informed decisions regarding their participation in the program. We believe this information will may help them determine the assignment methodology that best suits their ACO and ACO participants. We confirm that an ACO's annual beneficiary assignment election has no effect on the maximum 75 percent shared savings rate for ENHANCED track ACOs. We disagree with one of the commenter's assertion that the election should only occur once during the contract term to prevent gaming by switching attribution models based on financial arbitrage. We believe the flexibility will allow ACOs to determine the best assignment methodology for their unique organizational structure. We do not believe that allowing ACOs to change their assignment methodology on an annual basis provides a gaming opportunity; we will continue to determine assignment based upon where beneficiaries receive the plurality of their primary care services and whether beneficiaries have designated an ACO professional as their primary clinician, responsible for their overall care, and hold ACOs accountable for the resulting assigned beneficiary population. Although we recognize that, for some ACOs, there may be some financial impact, since the choice of assignment may change the ACO's historical benchmark and subsequently impact expenditure calculations, we believe that the program-wide impact will be minimal. Thus, we are finalizing as proposed the opportunity for ACOs to select the applicable assignment methodology annually.

Comment: Several commenters sought clarification on CMS' proposal and recommended that CMS clarify the following:

- What the process will be for assignment and what communications would be involved;
- When would the ACOs election of beneficiary assignment methodology occur and the process for the election to be made (would this occur during the annual certification process or as a separate process);
- Is the ACO required to make an election every year or would they continue in the same methodology unless they make a proactive selection each year;
- How the preliminary prospective with retrospective reconciliation versus prospective methodology would impact shared savings and shared losses calculations;
- Whether there will be full disclosure to beneficiaries upon assignment to an ACO and expectations as to the network of providers;
- Whether assigned beneficiaries can receive care outside of an ACO at any given time; and
- Process for beneficiaries to opt-out of assignment.

Response: CMS plans to align the annual selection of an assignment methodology (preliminary prospective with retrospective reconciliation or prospective assignment) with the application cycle. During this period, an ACO may either retain or change its current assignment selection that would become effective at the beginning of the next performance year. We are planning on automating the assignment methodology selection and will provide

further clarification in sub-regulatory guidance on the assignment selection process. As proposed, ACOs may select the assignment methodology that CMS employs for assignment of beneficiaries, ACOs are not required to make an election each year. CMS is establishing a system and process so that we can quickly and accurately execute ACOs' assignment methodology changes. We want to emphasize that the term ''assignment'' for purposes of the Shared Savings Program in no way implies any limits, restrictions, or diminishment of the rights of Medicare FFS beneficiaries to exercise freedom of choice in the physicians and other health care practitioners from whom they receive covered services, nor will the policy allowing ACOs to annually choose an assignment methodology have any effect on the voluntary alignment process under § 425.402(e).

Concerning the impact of an ACO changing their assignment methodology during an agreement period, we note the program's calculations for establishing historical benchmarks and performance year reconciliation are performed consistently across all ACOs participating in the Shared Savings Program. We do not modify our benchmark year or performance year calculations based upon the assignment methodology.

In addition, as explained in section II.C.3.a, we are modifying our proposed revisions to the current beneficiary notice requirements at § 425.312 to require each ACO or its ACO participants to provide each beneficiary with a standardized written notice that explains that the ACO's providers/suppliers are participating in the Shared Savings Program. The ACO or its ACO participant would be required to provide this notice prior to or at the beneficiary's first primary care visit of each performance year in the form and manner that we specify in subregulatory guidance. We anticipate that the template notice will explain what an ACO provider or supplier's participation in an ACO means for the beneficiary's care and that the beneficiary has the right to receive care from any provider or supplier that accepts Medicare. ACOs and ACO participants may also provide additional information that they have determined to be useful when notifying beneficiaries about their participation in an ACO, consistent with the marketing requirements at § 425.310.

The Shared Savings Program voluntary alignment methodology (§ 425.402(e)) allows beneficiaries to designate their primary clinician on *MyMedicare.gov*. Under the revisions to the voluntary alignment methodology that were finalized in the November 2018 final rule (83 FR 59960), if a beneficiary selects an ACO professional as their primary clinician, the beneficiary will be prospectively assigned to the ACO, unless the beneficiary has been aligned to an entity participating in a model tested or expanded under section 1115A of the Act under which claims-based assignment is based solely on claims for services other than primary care services and for which there has been a determination by the Secretary that waiver of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model. If a beneficiary determines that he/she does not want to be assigned to an ACO, the beneficiary may log into *MyMedicare.gov* and designate a clinician that is not participating in an ACO as their primary clinician. Beneficiaries assigned to an ACO remain free to seek services wherever they choose, and assignment results only from a beneficiary's exercise of that free choice by seeking and receiving services from ACO participants or by selecting a primary clinician who is participating in the ACO on *MyMedicare.gov.*

Comment: One commenter agreed with CMS' proposal for all agreement periods beginning on July 1, 2019, and in subsequent performance years, to adjust the ACO's historical benchmark to reflect a change in the ACO's beneficiary assignment methodology within the agreement period. However, the commenter sought further clarification on how an ACO would determine what impacts an assignment methodology change would have on its performance.

Response: We note that under our proposed approach of allowing choice of beneficiary assignment methodology, the populations used to determine benchmark and performance year assignment would vary based on the ACO's assignment methodology selection, however the benchmark calculations and calculations for determining savings and losses would be the same. Additionally, we provide ACOs with aggregate reports (see § 425.702) to help them trend their performance year over year. When looking at a similar length of time (for example, 12 months) ACOs can compare their performance from one year to the next. We believe there are other changes ACOs voluntarily make from year to year that may pose greater difficulty in terms of comparing ACO performance between performance years, such as annual changes to the ACO participant list.

Final Action: After considering the comments concerning our proposals to allow ACOs to annually elect their beneficiary assignment methodology, we are finalizing the proposal as proposed. Specifically, we will offer ACOs entering agreement periods in the BASIC track or ENHANCED track, beginning July 1, 2019 and in subsequent years, the option to choose either prospective assignment or preliminary prospective assignment with retrospective reconciliation, prior to the start of their agreement period (at the time of application). We will also provide an opportunity for ACOs to switch their selection of beneficiary assignment methodology on an annual basis. We are finalizing as proposed the new section at § 425.226. Additionally, we are finalizing as proposed the conforming changes at §§ 425.400 and 425.401 (assignment of beneficiaries), § 425.702 (aggregate reports) and § 425.704 (beneficiary-identifiable claims data) to reference either preliminary prospective assignment with retrospective reconciliation or prospective assignment instead of referencing the track to which a particular assignment methodology applies.

5. Determining Participation Options Based on Medicare FFS Revenue and Prior Participation

a. Overview

In the August 2018 proposed rule (83 FR 41813 through 41836), we described 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 ACOs 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. Based on operational experience and considerations related to our proposal to extend the length of an agreement period under the program from 3 to not less than 5 years for agreement periods beginning on July 1, 2019 and in subsequent years, we identified the following programmatic areas for further policy development.

First, differentiating between ACOs based on their degree of control over total Medicare Parts A and B FFS expenditures for their assigned beneficiaries would allow us to transition high revenue ACOs more

quickly to higher levels of performance-based risk under the ENHANCED track, rather than remaining in a lower level of risk under the BASIC track. We stated our aim to drive more meaningful systematic change in high revenue ACOs which have greater potential to control total Medicare Parts A and B FFS expenditures for their assigned beneficiaries and in turn the potential to drive significant change in spending and coordination of care for assigned beneficiaries across care settings. We also aimed to encourage continued participation by low revenue ACOs, which control a smaller proportion of total Medicare Parts A and B FFS expenditures for their assigned beneficiaries, and thus may be encouraged to continue participation in the program by having additional time under the BASIC track's revenue-based loss sharing limits (capped at a percentage of benchmark) before transitioning to the ENHANCED track.

Second, differentiating between ACOs that are experienced and inexperienced with performance-based risk Medicare ACO initiatives to determine their eligibility for participation options would allow us to prevent experienced ACOs from taking advantage of options designed for inexperienced ACOs, namely lower levels of performance-based risk.

Third, it would be timely to clarify the differences between ACOs applying to renew their participation agreements and ACOs applying to re-enter the program after a break in participation, and to identify new ACOs as re-entering ACOs if greater than 50 percent of their ACO participants have recent prior participation in the same ACO in order to hold these ACOs accountable for their ACO participants' experience with the program. We stated our aim to provide a more consistent evaluation of these ACOs' prior performance in the Shared Savings Program at the time of reapplication. We also aimed to update policies to identify the agreement period an ACO is entering into for purposes of benchmark calculations and quality performance requirements that phase-in as the ACO gains experience in the program, as appropriate for renewing ACOs, re-entering ACOs, and new program entrants.

Fourth, and lastly, we believed it would be appropriate to modify the evaluation criteria for prior quality performance to be relevant to ACOs' participation in longer agreement periods and introduce a monitoring approach for and evaluation criterion related to financial performance to prevent underperforming ACOs from remaining in the program.

b. Differentiating Between Low Revenue ACOs and High Revenue ACOs

In section II.A.5.b of the August 2018 proposed rule (83 FR 41814 through 41820), we proposed to differentiate between the participation options available to low revenue ACOs and high revenue ACOs, through the following: (1) Proposals for defining ''low revenue ACO'' and ''high revenue ACO'' relative to a threshold of ACO participants' total Medicare Parts A and B FFS revenue compared to total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries for the same 12 month period; and (2) proposals for establishing distinct participation options for low revenue ACOs and high revenue ACOs, with the availability of multiple agreement periods under the BASIC track as the primary distinction. We also considered approaches to allow greater potential for reward for low revenue ACOs, such as by reducing the MSR ACOs must meet to share in savings during one-sided model years of the BASIC track's glide path, or allowing higher sharing rates based on quality performance during the first 4 years in the glide path.

In this section of this final rule we summarize and respond to comments on the proposed approach to differentiating between low revenue ACOs and high revenue ACOs. We summarize and respond to comments on the proposed MSR for ACOs in one-sided model years of the BASIC track's glide path in section II.A.6.b of this final rule, including comments on our consideration of applying a different MSR to low revenue ACOs. We summarize and respond to comments on the sharing rate based on quality performance in the BASIC track's glide path in section II.A.3. of this final rule, including comments on our consideration of applying a different sharing rate to low revenue ACOs.

(1) Identifying Low Revenue ACOs and High Revenue ACOs

As discussed in the August 2018 proposed rule (83 FR 41814 through 41817), to define low revenue ACOs and high revenue ACOs for purposes of determining ACO participation options, we considered the relationship between an ACO's degree of control over the Medicare Parts A and B FFS expenditures for its assigned beneficiaries and its readiness to accept higher or lower degrees of performance-based risk. We explained 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. Thus, high revenue ACOs, which typically include a hospital billing through an ACO participant TIN, are generally more capable of accepting higher risk, given their control over a generally larger amount of their assigned beneficiaries' total Medicare Parts A and B FFS expenditures. In contrast, lower risk options could be more suitable for low revenue ACOs, which have control over a smaller amount of their assigned beneficiaries' total Medicare Parts A and B FFS expenditures.

In the Regulatory Impact Analysis of the August 2018 proposed rule (see 83 FR 41917), we described an approach for differentiating low revenue ACOs versus high revenue ACOs that reflects the amount of control ACOs have over total Medicare Parts A and B FFS expenditures for their assigned beneficiaries. Under this analysis, an ACO was identified as low revenue if its ACO participants' total Medicare Parts A and B FFS revenue for assigned beneficiaries was less than 10 percent of the ACO's assigned beneficiary population's total Medicare Parts A and B FFS expenditures. In contrast, an ACO was identified as high revenue if its ACO participants' total Medicare Parts A and B FFS revenue for assigned beneficiaries was at least 10 percent of the ACO's assigned beneficiary population's total Medicare Parts A and B FFS expenditures. As further explained in the Regulatory Impact Analysis of the August 2018 proposed rule (83 FR 41917), nationally, evaluation and management spending accounts for about 10 percent of total Parts A and B per capita spending. Because beneficiary assignment principally is based on allowed charges for primary care services, which are highly correlated with evaluation and management spending, we concluded that identifying low revenue ACOs by applying a 10 percent limit on the ACO participants' Medicare FFS revenue for assigned beneficiaries in relation to total Medicare Parts A and B expenditures for these beneficiaries would be likely to capture all ACOs that were solely comprised of ACO providers/suppliers billing for Medicare PFS services, and generally exclude ACOs with ACO providers/suppliers that bill for inpatient or other institutional services for their assigned beneficiaries. We considered this approach as an option for distinguishing between low revenue ACOs and high revenue ACOs.

However, we explained our concern that this approach does not sufficiently account for ACO participants' total

Medicare Parts A and B FFS revenue (as opposed to their revenue for assigned beneficiaries), and therefore could misrepresent the ACO's overall risk bearing potential, which would diverge from other aspects of the proposed design of the BASIC track. We believed it would be important to consider ACO participants' total Medicare Parts A and B FFS revenue for all FFS beneficiaries, not just assigned beneficiaries, as a factor in assessing an ACO's readiness to accept performance-based risk. The total Medicare Parts A and B FFS revenue of the ACO participants could be indicative of whether the ACO participants, and therefore potentially the ACO, are more or less capitalized. For example, ACO participants with high levels of total Medicare Parts A and B FFS revenue are presumed to be better capitalized, and may be better positioned to contribute to repayment of any shared losses owed by the ACO. Further, the proposed methodologies for determining the loss sharing limit under the BASIC track (see section II.A.3. of the August 2018 proposed rule (83 FR 41801 through 41810)) and the estimated repayment mechanism values for BASIC track ACOs (see section II.A.6.c. of the August 2018 proposed rule (83 FR 41840 through 41842)), included a comparison of a specified percentage of ACO participants' total Medicare Parts A and B FFS revenue for all Medicare FFS beneficiaries to a percentage of the ACO's updated historical benchmark expenditures for its assigned beneficiary population.

Accordingly, we proposed that if ACO participants' total Medicare Parts A and B FFS revenue exceeds a specified threshold of total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, the ACO would be considered a high revenue ACO, while ACOs with a percentage less than the threshold amount would be considered a low revenue ACO. In determining the appropriate threshold, we considered our claims-based analysis comparing estimated revenue and benchmark values for Track 1+ Model applicants (see 83 FR 41807 through 41808). We believed setting the threshold at 25 percent would tend to categorize ACOs that include institutional providers as ACO participants or as ACO providers/suppliers billing through the TIN of an ACO participant, as high revenue because their ACO participants' total Medicare Parts A and B FFS revenue would likely significantly exceed 25 percent of total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries. Among Track 1+ Model ACOs that self-reported as eligible for the Model's benchmark-based loss sharing limit because of the presence of an ownership or operational interest by an IPPS hospital, cancer center or rural hospital with more than 100 beds among their ACO participants, we compared estimated total Medicare Parts A and B FFS revenue for ACO participants to estimated total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries. We found that self-reported composition and high revenue determinations made using the 25 percent threshold were in agreement for 96 percent of ACOs. For two ACOs, the proposed approach would have categorized the ACOs as low revenue ACOs and therefore allowed for a potentially lower loss sharing limit than the self-reported method.

We believed small, physician-only and rural ACOs would tend to be categorized as low revenue ACOs because their ACO participants' total Medicare Parts A and B FFS revenue would likely be significantly less than total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries. Among Track 1+ Model ACOs that self-reported to be eligible for the Model's revenue-based loss sharing limit because of the absence of an ownership or operational interest by the previously described institutional providers among their ACO participants, we compared estimated total Medicare Parts A and B FFS revenue for ACO participants to estimated total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries. We found the self-reported composition and low revenue determinations made using the 25 percent threshold were in agreement for 88 percent of ACOs. The proposed approach would move ACOs with higher revenue to a higher loss sharing limit, while continuing to categorize low revenue ACOs, which are often composed of small physician practices, rural providers, and those serving underserved areas, as eligible for potentially lower loss sharing limits. Further, based on initial modeling with performance year 2016 program data, ACOs for which the total Medicare Parts A and B FFS revenue of their ACO participants was less than 25 percent of the total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries tended to have either no or almost no inpatient revenue and generally showed stronger than average financial results compared to higher revenue ACOs.

We believed these observations were generalizable and suggested our proposal to use ACO participants' total Medicare Parts A and B FFS revenue to classify ACOs would serve as a proxy for ACO participant composition. The proposed approach generally would categorize ACOs that include hospitals, health systems or other providers and suppliers that furnish Part A services as ACO participants or ACO providers/suppliers as high revenue ACOs, while categorizing ACOs with ACO participants and ACO providers/suppliers that mostly furnish Part B services as low revenue ACOs. Accordingly, we proposed to use a 25 percent threshold to determine low revenue ACOs versus high revenue ACOs by comparing 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. Consistent with this proposal, we also proposed to add new definitions at § 425.20 for ''low revenue ACO,'' and ''high revenue ACO.''

We proposed to define ''high revenue ACO'' to mean an ACO whose 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, is at least 25 percent of the total 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.

We proposed to define ''low revenue ACO'' to mean an ACO whose 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, is less than 25 percent of the total 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.

We also considered using a lower or higher percentage as the threshold for determining low revenue ACOs and high revenue ACOs. Specifically, we considered instead setting the threshold for ACO participant revenue lower, for example at 15 percent or 20 percent of total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries. However, we were concerned a lower threshold could categorize ACOs with more moderate revenue as high revenue ACOs, for example because of the presence of multi-specialty physician practices or certain rural or safety net providers (such as CAHs, FQHCs and RHCs). Categorizing these moderate revenue ACOs as high revenue ACOs, could require ACOs that have a smaller degree

of control over the expenditures of their assigned beneficiaries, and ACOs that are not as adequately capitalized, to participate in a level of performance-based risk that the ACO would not be prepared to manage. We also considered setting the threshold higher, for example at 30 percent. We noted our concern that a higher threshold could inappropriately categorize ACOs as low revenue when their ACO participants have substantial total Medicare Parts A and B FFS revenue and therefore an increased ability to influence expenditures for their assigned beneficiaries and also greater access to capital to support participation under higher levels of performance-based risk. We sought comment on these alternative thresholds for defining ''low revenue ACO'' and ''high revenue ACO.''

The proposed 12-month comparison period for determining whether an ACO is a low revenue ACO or high revenue ACO was consistent with the proposed 12 month period for determining repayment mechanism amounts (as described in section II.A.6.c. of the August 2018 proposed rule (83 FR 41840 through 41842)). We explained that this approach could allow us to use the same sources of revenue and expenditure data during the program's annual application cycle to estimate the ACO's repayment mechanism amount and to determine the ACO's participation options according to whether the ACO is categorized as a low revenue ACO or high revenue ACO. Additionally, for ACOs with a participant agreement start date of July 1, 2019, we also proposed to determine whether the ACO is a low revenue ACO or high revenue ACO using expenditure data from the most recent calendar year for which 12 months of data are available.

We noted that under this proposed approach to using claims data to determine participation options, it would be difficult for ACOs to determine at the time of application submission whether they would be identified as a low revenue ACO or high revenue ACO. We explained that after an ACO's application is submitted and before the ACO would be required to execute a participation agreement, we would determine how the ACO participants' total Medicare Parts A and B FFS revenue for the applicable calendar year compare to total Medicare Parts A and B FFS expenditures for the ACO's assigned Medicare beneficiaries in the same calendar year, provide feedback and then notify the applicant of our determination of its status as a low revenue ACO or high revenue ACO.

We also considered using a longer look back period, for example, using multiple years of revenue and expenditure data to identify low revenue ACOs and high revenue ACOs. For example, instead of using a single year of data, we considered instead using 2 years of data (such as the 2 most recent calendar years for which 12 months of data are available). In evaluating ACOs applying to enter a new agreement period in the Shared Savings Program, the 2 most recent calendar years for which 12 months of data are available would align with the ACOs' first and second benchmark years. While this approach could allow us to take into account changes in the ACO's composition over multiple years, it could also make the policy more complex because it could require determinations for each of the 2 calendar years and procedures to decide how to categorize ACOs if there were different determinations for each year, for example, as a result of changes in ACO participants. We sought 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.

ACO participant list changes during the agreement period could affect the categorization of ACOs, particularly for ACOs close to the threshold percentage. We considered that an ACO may change its composition of ACO participants each performance year, as well as experience changes in the providers/suppliers billing through ACO participants, during the course of its agreement period. Any approach under which we would apply different policies to ACOs based on a determination of ACO participant revenue would need to recognize the potential for an ACO to add or remove ACO participants, and for the providers/suppliers billing through ACO participants to change, which could affect whether an ACO meets the definition of a low revenue ACO or high revenue ACO. We explained our concern about the possibility that an ACO may be eligible to continue for a second agreement period in the BASIC track because of a determination that it is a low revenue ACO at the time of application, and then quickly thereafter seek to add higher-revenue ACO participants, thereby avoiding the requirement under our proposed participation options to participate under the ENHANCED track.

To protect against these circumstances, we proposed 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. This is because high revenue ACOs experienced with performance-based risk Medicare ACO initiatives are restricted to participation in the ENHANCED track only. We proposed to monitor these low revenue ACOs for changes in the revenue of ACO participants and assigned beneficiary expenditures that would cause an ACO to be considered a high revenue ACO and ineligible for participation in the BASIC track. We are less concerned about the circumstance where an ACO inexperienced with performance-based risk Medicare ACO initiatives enters an agreement period under the BASIC track and becomes a high revenue ACO during the course of its agreement because inexperienced, high revenue ACOs are also eligible for a single agreement period of participation in the BASIC track.

We proposed the following approach to ensuring continued compliance of ACOs with the proposed eligibility requirements for participation in the BASIC track, for an ACO that was accepted into the BASIC track's Level E because the ACO was experienced with performance-based risk Medicare ACO initiatives and determined to be low revenue at the time of application. If, during the agreement period, the ACO meets the definition of a high revenue ACO, we proposed 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. We proposed 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, we 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, if the ACO participants' total Medicare Parts A and B FFS revenue has increased in relation to total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, 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. We proposed to revise § 425.600 to include these requirements to account for changes in ACO participant revenue during an agreement period.

We also considered two alternatives to the proposed claims-based approach to differentiating low revenue ACOs versus high revenue ACOs, which, as discussed, can also serve as a proxy for ACO participant composition. One alternative would be to differentiate ACOs based directly on ACO participant composition using Medicare provider enrollment data and certain other data. Under this option we could define ''physician-led ACO'' and ''hospital-based ACO'' based on an ACO's composition of ACO participant TINs, including any CCNs identified as billing through an ACO participant TIN, as determined using Medicare enrollment data and cost report data for rural hospitals. A second alternative to the claims-based approach to distinguishing between ACOs based on their revenue would be to differentiate between ACOs based on the size of their assigned population (that is, small versus large ACOs). First, we considered differentiating between physician-led and hospital-based ACOs by ACO composition, determined based on the presence or absence of certain institutional providers as ACO participants. We considered an approach that deviates from the Track 1+ Model design to determining ACO composition for the purposes of identifying whether the ACO is eligible to participate under a benchmark-based or a revenue-based loss sharing limit by using Medicare enrollment data and certain other data to determine ACO composition rather than relying on ACOs' self-reported information, and by using a different approach to identifying institutional providers than applies under the Track 1+ Model.

Under this alternative approach, we could define a hospital-based ACO as an ACO that includes a hospital or cancer center, but excluding an ACO whose only hospital ACO participants are rural hospitals. As used in this definition, a hospital could be defined according to § 425.20. As defined under § 425.20, ''hospital'' means a hospital as defined in section 1886(d)(1)(B) of the Act. A cancer center could be defined as a prospective payment system-exempt cancer hospital as defined under section 1886(d)(1)(B)(v) of the Act (see CMS website on PPS-exempt cancer hospitals, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/PPS_Exc_Cancer_Hospasp.html*). Rural hospital could be a hospital defined according to § 425.20 that meets both of the following requirements: (1) The hospital is classified as being in a rural area for purposes of the CMS area wage index (as determined in accordance with section 1886(d)(2)(d) or section 1886(d)(8)(E) of the Act); and (2) The hospital reports total revenue of less than $30 million a year. We could determine total revenue based on the most recently available hospital 2552–10 cost report form or any successor form. In contrast, we could define physician-led ACO as an ACO that does not include a hospital or cancer center, except for a hospital that is a rural hospital (as we previously described). Physician-led ACOs therefore could also include certain hospitals that are not cancer centers, such as CAHs.

Under this alternative approach to differentiating between ACOs we would identify hospitals and cancer centers in our Medicare provider enrollment files based on their Medicare enrolled TINs and/or CCNs. We would include any CCNs identified as billing through an ACO participant TIN, as determined using PECOS enrollment data and claims data. We believe this alternative approach would provide increased transparency to ACOs because ACOs could work with their ACO participants to identify all facilities enrolled under their TINs to tentatively determine the composition of their ACO, and thus, the available participation options under the Shared Savings Program. However, this alternative approach to categorizing ACOs deviates from the proposed claims-based approaches to determining loss sharing limits and the repayment mechanism estimate amounts for ACOs in the BASIC track using ACO participant Medicare FFS revenue and expenditures for the ACO's assigned beneficiaries.

Second, we also considered differentiating between ACOs based on the size of their assigned beneficiary population, as small versus large ACOs. Under this approach, we could determine an ACO's participation options based on the size of its assigned population. We recognize that an approach that distinguishes between ACOs based on population size would require that we set a threshold for determining small versus large ACOs as well as to determine the assignment data to use in making this determination (such as the assignment data used in determining an ACO's eligibility to participate in the program under the requirement that the ACO have at least 5,000 assigned beneficiaries under § 425.110). For instance, we considered whether an ACO with fewer than 10,000 assigned beneficiaries could be defined as a small ACO whereas an ACO with 10,000 or more assigned beneficiaries could be defined as a large ACO. However, we currently have low revenue ACOs participating in the program that have well over 10,000 assigned beneficiaries, as well as high revenue ACOs that have fewer than 10,000 assigned beneficiaries. We believed a revenue-based approach would be a more accurate means to measure the degree of control that ACOs have over total Medicare Parts A and B FFS expenditures for their assigned beneficiaries compared to an approach that only considers the size of the ACO's assigned population.

We sought comment on the proposed definitions of ''low revenue ACO'' and ''high revenue ACO''. We also sought comment on the alternatives considered. Specifically, we sought comment on the alternative of defining hospital-based ACO and physician-led ACO based on an ACO's composition of ACO participant TINs, including any CCNs identified as billing through an ACO participant TIN, as determined using Medicare enrollment data and cost report data for rural hospitals. In addition, we sought comment on the second alternative of differentiating between ACOs based on the size of their assigned population (that is, small versus large ACOs).

Comment: A few commenters generally supported the proposed use of a distinction between low revenue ACOs and high revenue ACOs for determining ACO participation options. One commenter explained its belief that small ACOs in rural areas face challenges that large health systems do not. A few commenters supported the distinction between low and high revenue ACOs for determining ACO participation options but suggested alternative approaches to implementing this policy as further described in this section of this final rule. One commenter explained that there is intuitive logic in the idea that risk tolerance should be commensurate with organization size or financial wherewithal.

Response: We appreciate the support of the commenters who generally favored the proposed approach and our related considerations.

Comment: Many commenters expressed concerns about the proposed approach to identifying low revenue ACOs versus high revenue ACOs. A few commenters requested that CMS not finalize the distinction to avoid creating new blunt tools to define and categorize ACOs. Another commenter explained that the proposed rule states that the

low revenue ACO versus high revenue ACO distinction is intended to measure differences in the ability of the ACO to control total spending, but the commenter believed the discussion suggested that the real goal is to identify which ACO participants have more financial resources and are less likely to be bankrupted by repaying losses to CMS.

Response: We thank commenters for their careful consideration of the proposed approach to identifying ACOs as low revenue ACOs versus high revenue ACOs, and the related considerations discussed in section II.A.5.b.(2) of this final rule for distinguishing participation options of ACOs (in part) based on this determination.

We continue to believe that the total Medicare Parts A and B FFS revenue of the ACO participants could be indicative of whether the ACO participants, and therefore potentially the ACO, are more or less capitalized and thus able to accept higher levels of performance based risk. We also believe that these higher levels of performance-based risk for these organizations can act as a stronger catalyst for them to redesign care, in conjunction with the new tools and flexibilities for risk based ACOs and achieve program goals more quickly. For example, ACO participants with high levels of total Medicare Parts A and B FFS revenue are presumed to be better capitalized, and may be better positioned to contribute to repayment of any shared losses owed by the ACO. To this extent we agree with the commenter that indicated that one goal of the proposed approach is to place better capitalized ACOs under participation options that are commensurate with their ability to take on greater risk because they have the capacity to repay losses (if owed).

We disagree with commenters' suggestions that we remain neutral to whether an ACO has low revenue or high revenue in determining program participation options. We continue to believe that all ACOs should eventually participate under the program's highest level of risk and potential reward, in the ENHANCED track, which could drive ACOs to more aggressively pursue the program's goals of improving quality of care and lowering growth in FFS expenditures for their assigned beneficiary populations. For the reasons we have previously described in the August 2018 proposed rule and as restated in this final rule, we also continue to believe that low revenue ACOs should be allowed additional time to prepare to take on the higher levels of performance-based risk required under the ENHANCED track. Therefore we continue to believe it is necessary to distinguish participation options based on ACO participants' Medicare FFS revenue (among other factors as described elsewhere in this final rule).

Comment: Some commenters, including MedPAC, viewed favoring low revenue ACOs over high revenue ACOs (or physician-only ACOs over ACOs that include hospitals) as unnecessary. MedPAC pointed out that the maximum risk under two-sided models of the proposed BASIC track already accounts for the ACO participants' revenue, with low revenue or small ACOs having relatively limited maximum risk in some cases compared to high revenue ACOs. MedPAC explained that the automatic transition to two-sided risk in the glide path will ensure that high revenue ACOs transition to performance-based risk to prevent them from further increasing spending and that low revenue ACOs that expect to achieve savings should be willing to move into Level E in the glide path, which has minimal risk and potentially greater reward.

Response: We agree with MedPAC that under the BASIC track's two-sided models, where we determine the maximum loss liability based on the higher of a percentage of ACO participants' Medicare FFS revenue or a percentage of the ACO's updated benchmark, high revenue ACOs will be at proportionally greater risk than low revenue ACOs. We disagree, however, with commenters' suggestions that the same participation options and therefore the same progression to higher levels of performance-based risk should be made available to all ACOs. We continue to believe that low revenue ACOs should be allowed additional time to prepare to take on the higher levels of performance-based risk required under the ENHANCED track and that high revenue ACOs should be given stronger incentives over time to continue to transform care. Therefore, we continue to believe it is necessary to distinguish participation options based on ACO participants' Medicare FFS revenue (among other factors, as described elsewhere in this final rule), and disagree with commenters who argued that identifying ACOs as low revenue ACOs versus high revenue ACOs is unnecessary.

Comment: Some commenters viewed the distinction between low revenue ACOs and high revenue ACOs as arbitrary or unfounded. Some commenters did not accept CMS' position that a greater level of control over assigned beneficiaries' total Part A and Part B spending (''low revenue ACOs'' versus ''high revenue ACOs'') necessarily should lead to better performance or readiness to accept performance-based risk. Several commenters described the concept that high revenue ACOs have a higher degree of control over Part A and B expenditures and that they have more control over the full continuum as a ''fallacy'' and ''fundamentally flawed''.

MedPAC explained that physician-only ACOs have, in effect, a larger incentive to reduce hospital-provided services than ACOs in which hospitals are also participating, because reduced expenditures for costly hospital services represent forgone revenue for the hospital. Similarly, another commenter explained that physician-led or physician-dominated ACOs, particularly those led or dominated by primary care physicians, can succeed in an ACO by providing more services themselves, and thereby enhancing their own FFS revenue along the way, and then cutting back on referrals, admissions, testing, and other services that result in expenditures and correspondingly involve revenues to some entity that is not part of the ACO. On the other hand, an ACO led by a hospital or created as part of an integrated system must cut its own FFS revenues at multiple levels to succeed. According to this commenter, in principle, the latter type of ACO has more ''control'' over total spending, but ''control'' means intentionally cutting back on Medicare volumes and revenues within its own network of providers and suppliers. One commenter explained that the larger the organization, the more time and effort it takes to gain collaboration and navigate various systems, to achieve consensus and implement changes. One commenter pointed to the discussion in the proposed rule to suggest the opposite point, that the ACOs that have been relatively more successful so far have been the smaller, physician-led ACOs that have demonstrated strong financial performance despite having relatively less ''control'' over total Part A and Part B spending (83 FR 41819).

Another commenter disagreed with CMS that hospitals can innately influence Medicare FFS costs, and instead expressed that only experienced ACO entities can exert this level of control because they will have already developed preferred post-acute care networks, educated them on cost and readmissions reduction, and included them as ACO participants in order to exert meaningful control over total beneficiary cost of care.

Response: We do not believe the proposed approach to distinguishing

low revenue ACOs versus high revenue ACOs is arbitrary or unfounded, and it is informed by our early experience with the Track 1+ Model as a means to differentiate the ability of ACOs to bear higher degrees of performance-based risk. More specifically as we explained in the August 2018 proposed rule and reiterate in this final rule, our experience with the Track 1+ Model demonstrates that ACO participants' Medicare FFS revenue can serve as a proxy for self-reported composition. In particular, higher Medicare FFS revenue among ACO participants in relation to the ACO's benchmark expenditures tends to be indicative of the presence of institutional providers in the ACO. We continue to believe in the validity of the proposed approach as a means to identify ACOs that are likely prepared to participate in greater levels of risk after gaining experience with more modest levels of risk and to mitigate the burden on ACOs (as compared to the Track 1+ Model) by not requiring ACOs to self-report data about the ownership and operational interests of their ACO participants, which, in addition, is difficult for CMS to independently validate.

We disagree with commenters who suggest that ACO providers/suppliers that bill for and receive payment for a proportionally greater amount of the ACO's assigned beneficiaries' Part A and B Medicare FFS expenditures and that have agreed to become accountable for the total cost and quality of care they provide these beneficiaries, are unable to effectively manage these costs in proportion to their control over a relatively larger or smaller proportion of assigned beneficiaries' expenditures.

Commenters provided examples of approaches ACOs may use to lower FFS expenditures for their assigned beneficiaries, such as coordinating post-acute care to avoid unnecessary readmissions, or focusing on the provision of primary care services to avoid the need for more costly specialty and facility-based services. We note that primary care providers have a central role in the Shared Savings Program, for instance as evidenced by the use of primary care services provided by ACO participants as the basis for beneficiary assignment. In focusing on primary care, ACOs may seek to reduce avoidable services by and consequently payments to acute-care facilities (for example) under FFS Medicare.

We also acknowledge that ACOs are composed differently and take a variety of organizational forms, as is permitted under section 1899(b)(1) of the Act and through the program's regulations, at § 425.102, describing the ACO participants or combinations of ACO participants eligible to form an ACO. Based on our observations, successful ACOs typically achieve lower growth in expenditures across all claim types. We also acknowledge that the ability of an ACO to succeed may be specific to its composition, governance and leadership, factors specific to its market circumstances and the populations it serves, as well as the ACO's individualized approach to meeting the program's goals.

Further, we note the following in response to the commenter's suggestion that there is an inconsistency between our belief that low revenue ACOs have less control over assigned beneficiaries expenditures, and therefore may be less capable of taking on higher levels of two-sided-risk, and our findings based on program performance results that low revenue ACOs have been relatively more successful so far compared to high revenue ACOs. The levels of risk and reward for each track of the Shared Savings Program ultimately are set based on the ACO's benchmark. However, a comparison of the ACO's benchmark-based risk and reward in relation to the total Medicare Parts A and B FFS revenue of the ACO participants highlights that ACOs with lower ACO participant total Medicare Parts A and B FFS revenue have the potential to incur both losses and savings that are a greater percentage of such revenue than ACOs that are higher revenue. For example, consider a low revenue ACO that has ACO participant total Medicare Parts A and B FFS revenue of $2,000,000 and benchmark expenditures of $100,000,000, so the total Medicare Parts A and B FFS revenue of the ACO participants would be 2 percent of the ACO's benchmark expenditures. If this low-revenue ACO then achieved savings of 3 percent of its benchmark ($3,000,000), and shared at a rate of 50 percent, the ACO would earn $1,500,000 in shared savings. This shared savings amount would represent 75 percent of the total Medicare Parts A and B FFS revenues of the ACO participants, providing a large incentive for this ACO to continue to improve the quality of care and control costs for beneficiaries. Next, consider a high revenue ACO that has ACO participant total Medicare Parts A and B FFS revenue of $200,000,000 but has the same benchmark as the low revenue ACO of $100,000,000. The total Medicare Parts A and B FFS revenue of the ACO participants in the ACO would be 200 percent of the ACO's benchmark expenditures. If this high revenue ACO then achieved the same savings of 3 percent of its benchmark ($3,000,000), and shared at a rate of 50 percent, the ACO would earn the same $1,500,000 in shared savings. This shared savings amount would only represent 0.75 percent of the total Medicare Parts A and B FFS revenues of the ACO participants, providing a much smaller incentive for this ACO to improve care and control costs for beneficiaries. We therefore believe that identifying ACOs as high revenue ACOs and low revenue ACOs is an appropriate method to identify which ACOs are more likely to demonstrate improved performance under greater levels of risk and reward. Our historical results show that these relatively greater incentives (for lower revenue ACOs, as shown in the first example) may have influenced and supported the better performance of low revenue ACOs compared to high revenue ACOs.

Comment: A few commenters offered an alternative suggestion for making adjustments in financial rewards and penalties that would directly measure the degree of control that ACOs have over total Medicare Parts A and B FFS expenditures for their assigned beneficiaries, instead of using proxies that the commenters viewed as problematic, such as the proportion of ACO participant revenues to expenditures for assigned beneficiaries. These commenters suggested this could be done by dividing services or spending into several categories reflecting the relative levels of control that ACO participants would be expected to have over services, and then assigning different levels of reward potential (and risk) to each. These categories could include spending for: Services delivered by ACO participants; services ordered by ACO participants; services resulting from potentially avoidable complications of services delivered or ordered by ACO participants; and all other services.

One commenter suggested that CMS also distinguish between health systems that are for-profit and not-for-profit, because not-for-profit entities on average provide more uncompensated care than for-profit entities.

Response: We prefer our proposed approach to distinguishing ACOs based on a comparison of estimated total Medicare Parts A and B FFS revenue for ACO participants to estimated total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries because it is simpler, allows for greater transparency, and is easier to validate. We decline to adopt the alternative methodologies suggested by commenters. For instance, we decline to increase the complexity of the

approach to distinguishing the degree of control ACO participants have over expenditures of the ACO's assigned beneficiaries by dividing services or spending into several categories (such as services delivered by ACO participants, services ordered by ACO participants, services resulting from potentially avoidable complications of services delivered or ordered by ACO participants, and all other services), and then assigning different levels of reward potential (and risk) to each because the Shared Savings Program is a population-based model and ACOs are accountable for the total cost of care rather than more segmented expenditure components as currently exist under other parts of the Medicare FFS program. We also decline to adopt an approach that only considers the ACO's tax status, or corporate structure, such as based on whether the ACO is for-profit, or not-for-profit, since ACOs must be governed by their ACO participants (according to § 425.106(c)(3)) and the ACO legal entity may have a different tax or corporate structure than its ACO participants, and tax status or corporate structure is not indicative of an organization's ability to take on risk.

Comment: One commenter suggested that the proposed approach may not take into account recent, major changes to the program's benchmarking methodology that could drastically alter the current discrepancy in performance between low revenue ACOs and high revenue ACOs. This commenter suggested that CMS should not rush with multiple major changes to the program simultaneously and should instead wait to see if adjustments to benchmarking, risk adjustment, and other design elements help to address other discrepancies, including the pattern of high revenue ACOs not performing as well as low revenue ACOs.

Response: We disagree with the commenter's suggestion that we delay implementing the proposed changes to the program's design to allow for additional experience with the program. We believe the proposed changes, which were based on program results and our experience in implementing program policies and the Track 1+ Model, are necessary to drive Medicare FFS providers and suppliers towards a system of value-based payment instead of volume-based payment and that these policies work in combination to help transition health care providers more quickly, but still incrementally, to value-based care. As we explained in the August 2018 proposed rule (83 FR 41787), and have reiterated in this final rule, while we understand that systems need time to adjust, Medicare cannot afford to continue with models that are not producing desired results. We also note that many ACOs currently participating in Track 1 are near the end of their second agreement period and thus have had 5 or 6 years of experience in the program entirely under the one-sided model, and should be capable and ready to transition to performance-based risk. Further, we do not have reason to believe that the benchmarking changes that we are adopting in this final rule (discussed in section II.D. of this final rule) would necessarily lead to improved performance for high revenue ACOs versus low revenue ACOs, and therefore we do not anticipate that these changes alone would eliminate or reduce the differential performance patterns we have seen in the past.

Comment: A few commenters suggested that CMS should create a level competitive playing field and let those that perform best succeed most, and find approaches that are not based on an ACO's composition to eliminate poor performers. One commenter suggested that CMS ensure that its methodology rewards ACOs that do a better job of controlling spending instead of emphasizing revenue. Several commenters suggested (as an alternative to distinguishing low revenue ACOs and high revenue ACOs) that CMS improve the program's methodology to accurately reward performance for improving quality and reducing costs, and offer resources and assistance to all ACOs. One commenter stated that the program should be about raising the bar for everyone and not disadvantaging one provider group over another with respect to their ACO participation.

One commenter recommended that CMS should focus on addressing a smaller group of ACOs with poor performance rather than implementing the broader proposed changes to differentiate participation options for all ACOs. The commenter stated that in the performance year 2017 program data, eight ACOs with costs exceeding benchmarks by more than $20 million were responsible for $251 million of the losses under the Shared Savings Program. According to the commenter, 5 percent of Shared Savings Program ACOs were responsible for 42 percent of the negative impact on the program.

Response: We believe that the program's design already includes significant financial incentives for ACOs, ACO participants, and ACO providers/suppliers, to enter the program and continue their participation in the program, as well as to meet the program's goals of lowering growth in Medicare FFS expenditures and improving quality of care for their assigned Medicare FFS beneficiaries so that ACOs may share in savings with Medicare. We believe that the level of participation and interest in the program are evidence of the value healthcare providers see in forming ACOs and participating in the Shared Savings Program.

Further, we disagree with commenters suggesting that participation option requirements should be focused on select, poorly performing ACOs, such as ACOs with proportionally large shared losses. We believe such an option would be too narrow to adequately incentivize the majority of ACOs, and we continue to believe that a broader redesign of program participation options is warranted, and greater gains in improving quality and reducing costs would be seen from our proposed participation options, as opposed to maintaining the status quo or creating policies targeted at only a few ACOs in the program. We also believe these revised program policies should be applied program-wide, to further drive improved performance for all participating ACOs. As discussed in section II.A.5.d of this final rule, we are finalizing our proposal to monitor ACO financial performance and to potentially terminate ACOs demonstrating significant losses (negative outside corridor) for two performance years. We believe that this policy will identify ACOs that are repeatedly large outliers in terms of financial losses, which may be unable to meet program goals and objectives.

Comment: Several commenters expressed that the proposed approach overlooks the original intention of the Shared Savings Program to foster collaboration between providers (specifically between physicians and hospitals) and would prove detrimental to program goals. A few commenters stated that healthcare transformation can only successfully occur when there is coordination across the continuum of care.

Some commenters argued that the proposed approach would set up a system that disadvantages hospital-based ACOs and could therefore limit the types of innovations needed to build a high performing healthcare system for the range of communities across the nation. These commenters tended to suggest that the best way to drive high quality care for patients is to create incentives that drive all the providers in a system to collaborate, to innovate and deliver high quality, cost effective healthcare.

One commenter, discussing the proposal to make the Shared Savings Program more accessible to low revenue and inexperienced ACOs, suggested that CMS consider policies that generate more accessible opportunities for practices and organizations to begin moving along the path to outcome-based payment. The commenter cautioned that a narrow program that accelerates progress for some, but leaves many behind, will not meet our national ambitions to transform to a high-value, outcome-based healthcare delivery system.

One commenter explained that new incentives to work harder through greater financial risk in two-sided risk models are also incentives to leave the program and revert back to FFS payment, a consideration echoed in other comments.

Response: We believe that the proposed approach to redesigning the program's participation options, and the approach as finalized in this final rule, will further the fulfillment of the program's goals of improving quality of care and lowering growth in Medicare FFS expenditures for beneficiaries. We believe that rapid transition to the new participation options will drive more meaningful systematic change in ACOs, which have the potential to control their assigned beneficiaries' Medicare Parts A and B FFS expenditures by coordinating care across care settings, and thus to achieve significant change in spending. We also believe that these policies will promote free-market principles which may lead to further innovation within markets and potentially greater success in achieving the program's goals. The new tools and flexibilities afforded to ACOs participating under performance-based risk, such as the expanded ability of their clinicians to furnish covered telehealth services under section 1899(l) of the Act and to strengthen beneficiary engagement through new beneficiary incentive programs, in conjunction with revised benchmarking and risk adjustment policies, will enable these ACOs to be successful.

We also note that based on our observations, successful ACOs typically achieve lower growth in expenditures across all claim types, and we believe this is a reflection of the collaborative relationships that exist within ACOs (between ACO providers/suppliers), and collaborations between ACOs and non-ACO providers and suppliers and other entities. We believe that hospitals will remain essential ACO participants in many cases, and non-ACO participant partners in others, as they are key collaborators in meeting the program's goals of lowering growth in Medicare Parts A and B FFS expenditures, and improving the quality of care, for the ACO's assigned beneficiary population.

The Shared Savings Program was established as, and remains, a voluntary program for providers and suppliers to become accountable for the quality and cost of care for an assigned population of Medicare FFS beneficiaries. We have aligned incentives between the Shared Savings Program and other CMS initiatives to provide beneficiaries value-based care. For example, program participation has taken on greater significance since the establishment of the Quality Payment Program. Our continued alignment with the Quality Payment Program provides a low burden way for clinicians to participate in both programs, including allowing eligible clinicians in ACOs that are participating in a track of the Shared Savings Program that is an Advanced Alternative Payment Model (APM) to qualify for APM incentive payments. We acknowledge that Medicare is only one payer, but effective collaborations between providers and suppliers are necessary to provide high-quality, value-based care across the healthcare system, and the APM track of the Quality Payment Program will account for participation in both Advanced APMs and in Other Payer Advanced APMs with payers other than Medicare through the All-Payer Combination Option beginning in performance year 2019.

Comment: One commenter explained that the disproportionate emphasis on ACOs reducing costs overshadows the equally important goal of quality improvement, which benefits patients and the Medicare program generally.

Response: In response to the concern that the proposed redesign of the program is disproportionately focused on lowering growth in expenditures, and not sufficiently focused on quality of care, we note that improved quality of care for patients was one of the five principles guiding our proposed redesign of the Shared Savings Program, and we disagree with the commenters' assertion that this goal has been overshadowed by a focus on lowering growth in expenditures. We also note that we recently finalized policies in the November 2018 final rule to make the quality measure set more outcome oriented, while also reducing reporting burden on ACOs and their participating ACO providers/suppliers.

Comment: One commenter pointed out the added complexity proposed for determining participation options for ACOs under the program redesign, with CMS evaluating whether ACOs are new, renewing or re-entering, experienced or inexperienced with performance-based risk, and high revenue or low revenue. The commenter suggested that eliminating the high revenue ACO versus low revenue ACO distinction would help minimize some of the complexity and would remove a significant amount of work required by CMS and ACOs to model, predict, and determine if the ACO would be a high revenue ACO or a low revenue ACO. Some commenters opposed to the concept of distinguishing between ACOs according to the proposed low revenue ACO and high revenue ACO definitions viewed the distinction as confusing.

Response: We believe that ACOs should be able to surmise if they are likely to be determined low revenue ACOs or high revenue ACOs, based on their composition. ACOs with a large hospital or other institutional provider will likely be determined to be high revenue ACOs. We plan to provide feedback to ACOs during the application process, and as part of program monitoring of low revenue ACOs experienced with performance-based risk Medicare ACO initiatives that are in an agreement period under Level E of the BASIC track (discussed elsewhere in this section of this final rule) regarding their status as a low revenue ACO or high revenue ACO. More generally, we anticipate providing information annually to ACOs within their agreement period, particularly as part of the ACO participant list change request review cycles, about their ACO participants' Medicare FFS revenue so they will have information about the composition of their ACO and the Medicare FFS revenue of their ACO participants to support their ongoing participation in the program. As discussed in greater detail elsewhere in this preamble, we believe that considering whether an ACO is a low revenue ACO or high revenue ACO is an important and necessary policy for determining ACO participation options within the program redesign.

Comment: A few commenters supported CMS' proposed definitions for low revenue ACO and high revenue ACO. A few commenters indicated their preference for the proposed use of Medicare claims data to make the low revenue ACO versus high revenue ACO determination, rather than the alternative sources of data discussed in the proposed rule. For instance, one commenter explained that a claims-based approach would provide a more accurate method for determining an ACO's preparedness to take on additional risk rather than an ACO's self-reported information regarding the

composition of its ACO participants and any ownership and operational interests in those ACO participants. Another commenter shared CMS' belief that a revenue-based approach would be a more accurate means to measure the degree of control that ACOs have over total Medicare Parts A and B FFS expenditures for their assigned beneficiaries compared to approaches that consider the size of the ACO's assigned population or the inclusion of a hospital or cancer center in the ACO.

However, other commenters suggested a variety of alternatives. Some commenters suggested alternative approaches to identifying low revenue ACOs and high revenue ACOs using alternative sources of data instead of or in addition to ACO participant Medicare Parts A and B FFS revenue.

More generally, some commenters believe the proposed approach could result in ACOs gaming the revenue determinations by manipulating their ACO participant lists. For instance, a high revenue ACO could be encouraged to selectively redefine its component TINs to meet the definition of a low revenue ACO, such as by restructuring to exclude acute care facilities. Other commenters suggested low revenue, or physician-led ACOs may avoid including these facilities as ACO participants. Several commenters indicated that use of FFS revenue as a proxy for composition could lead to ACOs appearing to be low revenue when in fact they have hospitals or health systems in their ownership and operational chain, and suggested CMS use other data to make these determinations. One commenter explained that the proposed approach could lead an ACO to split its network of physicians, which it considers a suboptimal outcome and counter to the organization's long-standing collaborative approach. This commenter also noted that there are non-trivial costs to setting up a new physician network and ACO entity.

A few commenters suggested that CMS apply the Track 1+ Model policy requiring ACO attestation regarding the ownership interests of and in its ACO participants in determining participation options under the Shared Savings Program. One commenter preferred the Track 1+ Model approach to the proposed distinction between low revenue ACOs and high revenue ACOs. Another commenter suggested we apply the Track 1+ Model approach in addition to the proposed approach to determining low revenue ACOs and high revenue ACOs. However, several commenters preferred CMS forgo self-reporting requirements as exist, for example, under the Track 1+ Model.

One commenter suggested that CMS use additional data on full organizational structure (such as such as IRS filings and PECOS data) to determine organization-wide revenue for physician groups responsible for the bulk of the ACO's assigned population. Under this alternative, the commenter suggested that CMS consider ACOs with physician groups that are part of a large health system, or large physician groups with market power (such as those that are very specialty-heavy or have substantial market share) to be high revenue ACOs. This commenter also expressed concern that the proposed approach to determining low revenue ACOs and high revenue ACOs could discourage partnerships between physician groups and hospitals through means other than mergers and acquisitions. To address this circumstance, the commenter suggested that ACOs should be regarded as low revenue if their ACO participant lists include independent physician groups and hospitals, to avoid disrupting these partnerships. This commenter argued that under this alternative approach, consolidation in provider markets would be discouraged because it would lead to more downside risk in available Shared Savings Program participation options, while partnerships or preferred networks that can support competition and do not cause commercial mark-ups would not be discouraged.

However, somewhat contrary to this suggestion, a few commenters explained their belief that it is valuable for physician-led ACOs to be able to recruit and include specialty physicians to further redesign health care delivery. According to these commenters, simply because a physician-led ACO contracts with specialty practices does not ensure the ACO is more capable of taking on ENHANCED track level of risk.

One commenter seemed to suggest we go further than the Track 1+ Model approach, which requires ACOs to report to CMS certain ownership and operational interests in ACO participants, by counting revenue received by entities that have ownership and operational interests in ACO participants and not just revenue received by providers and suppliers that bill through the TINs included on the ACO's participant list. This commenter explained that failing to count revenue earned by entities with an ownership or operational relationship to ACO participants would allow many ACOs that are affiliated with a hospital to access participation options that are intended for physician-only ACOs through manipulation of their ACO participant list. However, seemingly contrary to this suggestion, another commenter explained that some ACOs have shareholders that are large hospital systems but own only a small portion of the ACO and do not provide a substantial amount of funding to the ACO. This commenter (an ACO), explained that it would have to close its doors if all income for the other entities with ownership interests in ACO participants (such as a large hospital system) was considered when setting the ACO's amount of loss liability.

Several commenters suggested that we consider ACO participant composition in making the low revenue ACO versus high revenue ACO determination. One commenter suggested that CMS identify ACOs that include hospitals as ACO participants, and designate those ACOs as ''high revenue''. Some commenters suggested that rural ACOs be considered low revenue ACOs. In particular, some commenters suggested rural ACOs that meet ACO Investment Model (AIM) eligibility criteria should be considered low revenue ACOs.

One commenter recommended that CMS consider more than two revenue definitions or categories, suggesting that the proposed distinction may be too stark. The commenter suggested that CMS use multiple criteria, such as using self-reported composition, ACO composition as determined by CMS according to the alternative approach considered for distinguishing hospital-based and physician-led ACOs, and size of an ACO's assigned beneficiary population, in differentiating low revenue ACOs and high revenue ACOs.

A few commenters stated that CMS is unable to truly identify whether an ACO is well capitalized and should not create distinctions based on assumptions about capital, indicating that CMS is unable to identify if an ACO is well capitalized through sources outside of Medicare revenue (such as insurer- or investor-backed ACOs). A few commenters explained, for example, the proposed approach would not capture private investments in ACOs, noting that insurers and venture capital funds have invested heavily in some ACOs, often physician-led ACOs.

One commenter encouraged CMS to leverage public use data to calculate an ACO's revenue in an effort to make the ACO's revenue determination transparent, citing as an example the ''Medicare Provider Utilization and Payment'' data available through *https://data.cms.gov.*

Response: We appreciate the support of some commenters for CMS' proposed definitions for low revenue ACO and

high revenue ACO, and commenters' careful consideration of the options we considered, as well as their alternative suggestions.

We note that commenters offered opposing positions on some of the suggested alternative approaches. For instance, comments reflect differing views on the approach used under the Track 1+ Model to determine whether ACOs are under a revenue-based or benchmark-based loss sharing limit, with some supporting and others opposing the Track 1+ Model approach. One commenter seemed to mistakenly believe that under the Track 1+ Model, we consider the revenue earned by health care providers with an ownership or operational interest in an ACO participant. However, to clarify, under the design of the Track 1+ Model, ACOs are required to collect, assess, and report to CMS information on the ownership and operational interests of their ACO participants, which in turn is used to determine the ACO's participation options under the Track 1+ Model. As we described in the August 2018 proposed rule, we believe this approach adds complexity for ACOs and is also more complex for CMS to validate and audit. As a result, we explained that the use of ACOs' self-reported information in the permanent program could become burdensome for CMS to validate and monitor to ensure program integrity (83 FR 41807). Therefore, we agree with commenters that we should forgo use of similar self-reporting requirements in determining low revenue ACOs and high revenue ACOs under the Shared Savings Program.

We continue to believe, based on our experience with the Track 1+ Model, that ACO participants' Medicare Part A and B FFS revenue serves as an effective and accurate proxy for self-reported composition. Based on our experience with the initial application cycle for the Track 1+ Model, we believe a simpler approach that achieves similar results to the use of self-reported information would be to consider the total Medicare Parts A and B FFS revenue of ACO participants (TINs and CCNs) based on claims data, without directly considering their ownership and operational interests (or those of related entities). We believe that the use of Medicare Parts A and B FFS claims data for ACO participants provides an accurate estimate of their Medicare revenue and potential ability to cover losses that are proportional to their Medicare revenue. It also avoids additional burden for ACOs to collect and submit revenue data to CMS and for CMS to establish additional collection and validation processes.

Further, we continue to believe that ACOs whose ACO participants have greater total Medicare Parts A and B FFS revenue relative to the ACO's benchmark are better financially prepared to move to greater levels of risk (83 FR 41807). Accordingly, this comparison of revenue to benchmark would provide a more accurate method for determining an ACO's preparedness to take on additional risk than an ACO's self-reported information regarding the composition of its ACO participants and any ownership and operational interests in those ACO participants.

Commenters also offered differing perspectives on use of ACO participant composition to determine ACO participation options. However, as we explained in the August 2018 proposed rule, we continue to believe that a claims-based approach to determining low revenue ACOs and high revenue ACOs would better align with the claims-based approaches to determining loss sharing limits (discussed in section II.A.3 of this final rule) and the repayment mechanism estimate amounts for ACOs (as discussed in section II.A.6 of this final rule) providing more consistent feedback and program transparency and reducing complexity from multiple but slightly different calculations.

We also decline to adopt commenters' alternative suggestions to use multiple sources of data to determine participation options, which could add further complexity to our approach. Some comments indicated concerns that under the proposed approach CMS would not be able to effectively identify well capitalized ACOs. However, we believe that ACO participant revenue coupled with establishing a repayment mechanism to cover potential losses provide sufficient assurances and proxies for demonstrating capitalization and ability to invest in care coordination and cover potential losses. We believe it would place additional burden on ACOs and add complexity to the approach to consider how well capitalized ACOs are through their composition or private investments, for example. We have not routinely required that ACOs disclose statements about their financial status, or the financial status of their ACO participants or ACO providers/suppliers, in determining their eligibility to enter or continue their participation in the program, or a particular participation option in the program.

Further, with respect to the comment suggesting that we base participation options on ACO organizational formations or provider/supplier relationships that the commenter considered beneficial to health care markets, we believe our approach to defining low revenue ACOs and high revenue ACOs, and to determining participation options based on the distinction between these two categories of ACOs, promotes innovative arrangements between physicians and hospitals while providing an alternative for physicians to stay independent and work collaboratively with other providers and suppliers.

We also decline to use the publicly available sources of revenue data described by one commenter. We believe use of existing sources of program data for the revenue calculations will allow for greater consistency across the program's calculations, and timely feedback to ACOs, including through information shared during the application cycle and through program reports.

Lastly, we appreciate commenters' concerns about the possibility that existing ACOs may bifurcate their ACO participant lists to form new ACOs that may satisfy the definition of a low revenue ACO and therefore be eligible to participate under potentially lower levels of performance-based risk. We note that ACOs are accountable for total Medicare Parts A and B FFS expenditures for their assigned beneficiaries. To the extent that ACOs modify their ACO participant lists to remove higher-revenue providers and suppliers, such as institutional providers, the ACO remains accountable for the total cost of care received by its assigned beneficiaries, including services received from non-ACO providers and suppliers. The requirement that ACOs agree to be accountable for the quality and cost of all care furnished to their assigned beneficiaries, including services furnished by providers and suppliers that are not participating in the ACO, reduces our concern about ACOs manipulating their ACO participant lists to take advantage of potentially lower-risk participation options.

As one commenter points out, there could be costs associated with setting up a new legal entity and new Medicare-enrolled TINs, and this could be a deterrent to engaging in these practices to avoid the intended applicability of program requirements. We also believe several other policies we are finalizing in this final rule will help protect against ACOs gaming determinations for program participation options through modifications to their ACO participant

lists, specifically: (1) The approach we are finalizing to monitor for changes in revenue that cause ACOs identified as low revenue, and experienced with performance-based risk Medicare ACO initiatives to become considered high revenue and therefore no longer be eligible for participation in the BASIC track, as described elsewhere in this section of this final rule; and (2) the approach we are finalizing to identify re-entering ACOs, based on the prior participation of their ACO participants, as described in section II.A.5.c. of this final rule, will help ensure that ACOs are held accountable for their ACO participants' prior program experience.

Comment: One commenter suggested that CMS should provide ACOs with the ability to select only the highest performing providers and suppliers by allowing ACOs to select their participants by NPI rather than solely at the TIN level. The commenter explained that this approach could help enable ACOs to have greater control over managing costs for their assigned beneficiaries. According to this commenter, under this approach to allowing participation by individual NPIs, rather than the all NPIs that reassigned their billings rights to the ACO participant TIN (as currently required), ACOs would have the flexibility to build a high performing network of providers who will deliver the most efficient and highest quality care. In turn, the commenter stated that these high performing networks would incentivize providers that want to join or remain in an ACO to focus more on reducing unnecessary costs and maintaining high quality, and incentivize ACOs to more closely evaluate providers in their network based on sophisticated data analytics.

Response: In the August 2018 proposed rule, we did not contemplate changes to the current definition of ''ACO participant'' under § 425.20 which means an entity identified by a Medicare-enrolled billing TIN through which one or more ACO providers/suppliers bill Medicare, that alone or together with one or more other ACO participants compose an ACO, and that is included on the list of ACO participants that is required under § 425.118. We also did not contemplate changes to the underlying methodology used to assign beneficiaries to ACOs based on ACO participant TINs.

We continue to believe that ACOs have the potential to transform the quality and cost of care more broadly for the Medicare FFS beneficiaries who receive care from ACO participants. We believe that defining ACO participants to include all NPIs that have reassigned their billing rights to the TIN is a means to allowing the ACO's redesigned care processes to more broadly reach all Medicare FFS beneficiaries that may receive care from ACO participants, including those that may not meet the program's assignment criteria, and provides incentives for lower performing providers within an ACO participant TIN to improve. We also have concerns about ACOs selecting only the highest performing providers within a practice to be part of the ACO while less efficient and effective providers are not part of the ACO, because this structure could have negative implications for patients seen by the ACO participant and for the Medicare Trust Funds. Moreover, an approach allowing for participation by individual NPIs, rather than all NPIs that reassigned their billings rights to ACO participant TINs, could further opportunities for ACOs to game participation determinations by including only the most efficient and effective clinicians in the ACO, while less efficient and effective clinicians are excluded from the ACO. Therefore, we believe that maintaining the definition of ACO participant at the TIN level continues to be an effective approach in achieving the program's goals of improved care, and reduced expenditures, for Medicare FFS beneficiaries more broadly.

Comment: Some commenters addressed the threshold percentage to differentiate low revenue ACO and high revenue ACO, proposed at 25 percent. Commenters offered a variety of alternative suggestions for the threshold percentage.

A few commenters argued that the proposed 25 percent threshold, and the alternative consideration for a 30 percent threshold, would incorrectly deem moderate revenue ACOs, especially rural ACOs or urban ACOs that serve surrounding rural areas, to be high revenue ACOs. These commenters suggested that CMS either exempt rural ACOs from the revenue designation or raise the threshold for determining low revenue ACOs such as to 60 percent.

One commenter explained their belief that rural and small providers do not fit squarely within the low revenue ACO category. The commenter asserted that a revenue-based distinction could ultimately lead to rural providers, small providers, and many ACOs with mixed FFS and cost-based revenue (including both urban and rural provider/suppliers) being categorized as high revenue ACOs contrary to the intended purpose of the policy.

Another commenter questioned how a rural ACO with 25 small rural hospitals would be classified under this approach, but did not offer details that would inform how this composition might affect ACO participants' Medicare FFS Parts A and B revenue, or total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries.

One commenter recommended that CMS begin with a 30 percent threshold to account for ACOs with physician groups with a comparatively larger number of specialists as ACO participants, in addition to considering other metrics in distinguishing low revenue ACOs and high revenue ACOs, and/or develop more granular methods than the two proposed revenue-based categories to ascertain ACO risk tolerance. Another commenter generally urged CMS to establish pathways for specialists to meaningfully engage in the Shared Savings Program.

One commenter recommended that CMS increase the threshold of ACO participant revenue as a percentage of benchmark from 25 percent to 40 percent or greater for this and any future standards in which CMS seeks to distinguish small and large health systems.

One commenter disagreed that the proposed 25 percent threshold corresponds to the ACO's ability to control costs, since it does not account for a number of factors beyond the control of ACOs that could artificially inflate this number. This concern was reflected in other comments. For example, a few commenters expressed concern generally over the ability of ACOs to control costs and provide value in the Medicare FFS environment, pointing to factors including beneficiaries' freedom of choice of providers under FFS Medicare, and the absence of protection from the cost of Part B drugs and/or new technologies, and CAH costs as examples.

One commenter suggested CMS use a lower threshold, as a means to deter gaming, such as 15 percent. This commenter pointed to the use of a 10 percent threshold approach as described in the Regulatory Impact Analysis of the August 2018 proposed rule (83 FR 41917).

Response: We agree with commenters' concerns that ACOs that include small, rural hospitals may not be identified as low revenue ACOs under the proposed 25 percent threshold, and we agree with commenters suggesting that the threshold be raised to allow additional ACOs with small hospitals and clinics, including small rural hospitals, as ACO participants to qualify as low revenue ACOs. Therefore, to help ensure more ACOs under these circumstances may

be considered low revenue ACOs, we believe it would be appropriate to increase the threshold used in determining low revenue ACOs and high revenue ACOs to 35 percent. ACOs with small hospitals as ACO participants, including small rural hospitals, may not control a large enough portion of assigned beneficiary expenditures or be financially prepared to take on greater risk. Increasing the threshold used to determine low revenue ACOs versus high revenue ACOs would provide these ACOs with the opportunity to remain under the BASIC track at lower levels of performance-based risk, for a longer period of time. This would allow such ACOs to gain experience in a lower level of risk in the program before being required to move to the ENHANCED track.

Based on modeling using the most recently available expenditure and revenue data and ACO assignment data, we are increasing the threshold from 25 percent to 35 percent. Modeling shows increasing the threshold would allow more ACOs with small hospitals as ACO participants, including small rural hospitals, to be considered low revenue ACOs, while continuing to ensure that ACOs with large institutional providers are considered high revenue ACOs. The increased threshold would increase the number of low revenue ACOs by 31 ACOs, a 13 percent increase from the number of ACOs that would be included in the 25 percent threshold, based on our modeling with data used for performance year 2018. A 35 percent threshold balances concerns by recognizing additional ACOs with small institutional providers or clinics as low revenue ACOs, while helping to ensure ACOs with higher revenue continue to have the strongest incentives to improve quality of care for Medicare FFS beneficiaries and reduce expenditure growth to protect the Trust Funds.

We decline the commenter's suggestion to use a much lower threshold in identifying low revenue ACOs, such as 15 percent. The commenter pointed to the use of a 10 percent threshold in distinguishing low revenue ACOs from high revenue ACOs in the August 2018 proposed rule's Regulatory Impact Analysis. As we explained in the August 2018 proposed rule (83 FR 41814) and reiterated in this section of this final rule, under this analysis, an ACO was identified as low revenue if its ACO participants' total Medicare Parts A and B FFS revenue for assigned beneficiaries was less than 10 percent of the ACO's assigned beneficiary population's total Medicare Parts A and B FFS expenditures. We continue to have concerns that this approach does not sufficiently account for ACO participants' total Medicare Parts A and B FFS revenue (as opposed to their revenue for assigned beneficiaries), and therefore could misrepresent the ACO's overall risk bearing potential, which would diverge from other aspects of the design of the BASIC track as finalized (see section II.A.3 of this final rule).

Comment: Several commenters expressed concern about the approach to calculating revenue used in the definitions of low revenue ACOs and high revenue ACOs. These commenters explain that CMS proposes to include hospital add-on payments such as Indirect Medical Education (IME), Disproportionate Share Hospital (DSH), and uncompensated care payments when calculating an ACO's revenue. These commenters point out that CMS will exclude these payments when calculating assigned beneficiary expenditures for determining benchmark and performance year expenditures. These commenters urged CMS to exclude add-on payments in determining an ACO's revenue, suggesting that this approach could penalize ACOs that treat vulnerable populations, including teaching hospitals or those that treat the uninsured population.

One commenter requested that CMS modify the proposed approach to identifying high revenue ACOs to ensure ACOs that are appropriately engaging, and incentivizing hospital engagement, in value-based care delivery are not penalized for their success.

Response: We discuss related considerations in our discussion of the calculation of ACO participants' total Medicare Parts A and B FFS revenue for determining the loss sharing limits under the BASIC track in the August 2018 proposed rule (83 FR 41809 through 41810) and in section II.A.3 of this final rule. To accurately determine ACO participants' revenue for purposes of determining a revenue-based loss sharing limit, we explain our belief that it is important to include total revenue uncapped by truncation and to include IME, DSH and uncompensated care payments. We noted that this approach to calculating ACO participant Medicare FFS revenue is different from our approach to calculating benchmark and performance year expenditures for assigned beneficiaries, which we truncate at the 99th percentile of national Medicare FFS expenditures for assignable beneficiaries, and from which we exclude IME, DSH and uncompensated care payments (see subpart G of the program's regulations). We explained that IME, DSH, uncompensated care payments represent resources available to ACO participants to support their operations and offset their costs and potential shared losses, thereby increasing the ACO's capacity to bear performance-based risk, which we believe should be reflected in the ACO's loss sharing limit. Excluding such payments could undercount revenue and also could be challenging to implement, particularly truncation, since it likely would require apportioning responsibility for large claims among the ACO participants and non-ACO participants from which the beneficiary may have received the services resulting in the large claims. We therefore decline to modify our approach to determining ACO participant's total Medicare Parts A and B FFS revenue to include IME, DSH and uncompensated care payments, or to cap claim payment amounts through truncation.

For similar reasons, we also decline at this time to make other technical adjustments to calculations of revenue to exclude any other payment adjustments reflected in the claim payment amounts, such as payments under MIPS or the Hospital Value Based Purchasing Program.

Comment: Several commenters suggested that CMS should take into consideration the impact of extreme and uncontrollable circumstances when determining participation options based on Medicare FFS revenue.

Response: At this time, we decline to modify our approach to determining ACO participants' total Medicare Parts A and B FFS revenue, and will not exclude Medicare Parts A and B FFS revenue earned during a disaster period, nor will we make other adjustments to the calculation of ACO participants' Medicare Parts A and B FFS revenue to address extreme and uncontrollable circumstances because we do not have a reliable means for estimating what the ACO participants' Medicare Parts A and B FFS revenues would have been in the absence of the event.

We will continue to monitor the impact of extreme and uncontrollable circumstances on ACOs, particularly as we gain experience with the disaster-relief policies we have finalized for performance year 2017 and subsequent performance years. As part of this monitoring, we will consider whether any changes to our policy for determining low revenue ACOs and high revenue ACOs may be necessary to account for the effects of extreme and uncontrollable circumstances. Any such

changes would be made through notice and comment rulemaking.

Comment: A few commenters explained that rural hospitals and physician practices have demonstrably smaller net operating profit margins than urban hospitals, and commenters suggested that the proposed approach to differentiating participation options based on ACO participants' Medicare FFS revenue should consider ACO participants' fixed costs and operating margins.

Response: We currently do not consider operating costs in program calculations for benchmark and performance year expenditures since we determine benchmark and performance year expenditures based on Medicare Parts A and B FFS expenditures, according to the statutory requirements for the Shared Savings Program under section 1899(d)(1)(B) of the Act. We decline to consider operating costs in determining whether an ACO qualifies as a low revenue ACO or high revenue ACO. We believe that doing so would add a degree of variability and also unpredictably to the revenue calculations. We also believe it would be burdensome for ACOs to track operating costs of individual ACO participants, report this information to CMS, and for CMS to validate the data for use in calculations.

Comment: One commenter requested that CMS provide clarification around the data that will be used for the ACO participant revenue calculations. The commenter noted that the proposed rule states that the most recently available 12 months of data will be used, but it is unclear what time period that would be. This commenter also responded to the discussion in the proposed rule on CMS' consideration of an alternative approach where we would use multiple years of data to make the determination of whether an ACO is a low revenue ACO or high revenue ACO. This commenter preferred the proposed approach, to have the calculations based on one year of data, and did not consider use of multiple years of data in the revenue determination to be beneficial.

Response: We appreciate the commenter's support for the proposed look back period in the definition of low revenue ACO and high revenue ACO. To clarify, we proposed that we would make the determination based on ACO participant Medicare Parts A and B FFS revenue and total Medicare Parts A and B FFS expenditures for the most recent calendar year for which 12 months of data are available. As an example, the annual application cycle for a January 1st agreement period start date typically spans the Summer–Fall of the prior calendar year. For example, for ACOs applying for the agreement start date of January 1, 2020, we would anticipate the application cycle to occur during CY 2019. Therefore, we would make the low revenue ACO versus high revenue ACO determination for ACOs applying for a new agreement period beginning January 1, 2020 based on the 12 months of data from January 1, 2018, through December 31, 2018.

We also proposed that for ACOs applying for an agreement start date of July 1, 2019, we would determine whether the ACO is a low revenue ACO or high revenue ACO using data from the most recent calendar year for which 12 months of data are available. We anticipate the application cycle for the July 1, 2019 agreement start date to occur in Winter–Spring of 2019. Therefore, for ACOs applying for the agreement start date of July 1, 2019, we would make the low revenue ACO and high revenue ACO determination based on the 12 months of data from January 1, 2018, through December 31, 2018.

Comment: Several commenters addressed CMS' proposal 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, and to take compliance action if the ACO meets the definition of a high revenue ACO during the agreement period. Under the proposed approach, high revenue ACOs experienced with performance-based risk Medicare ACO initiatives would be restricted to participation under the ENHANCED track.

One commenter expressed significant reservations about the proposal to annually monitor low revenue ACOs to determine if, during the course of the performance year, the ACO became a high revenue ACO, and in turn requiring an ACO that becomes high revenue to move to the ENHANCED track. The commenter encouraged CMS not to finalize this approach as proposed. This commenter stated that many low revenue ACOs may be looking to partner with high revenue entities, such as IPPS hospitals, in order to have greater control over total Medicare Parts A and B FFS expenditures for their assigned beneficiaries. The commenter disagreed that this partnership automatically makes the low revenue ACO's experience commensurate to that of a high revenue ACO, experienced with performance-based risk Medicare ACO initiatives. The commenter explained that entities with significant Medicare FFS revenues that are inexperienced with Medicare performance-based risk ACO initiatives may seek out experienced, low revenue ACOs to join as an ACO participant, to capitalize upon the ACO entity's experience with success in performance-based risk. The commenter argued that an experienced, low revenue ACO with a newly added, inexperienced ACO participant, is not equivalent to a high revenue ACO that is experienced with performance-based risk Medicare ACO initiatives, even if the addition of the ACO participant causes the ACO to meet the proposed definition of a high revenue ACO, and therefore should not be aggressively accelerated to program's maximum downside risk under the ENHANCED track. Instead, the commenter encouraged CMS to allow these ACOs to continue their BASIC track participation until the end of their participation agreement.

One commenter described that CMS would have to consistently monitor to ensure ACO participant changes did not alter an ACO's status as a low revenue ACO or high revenue ACO and for those that did, CMS would have to issue correction notices and require corrective action plans. The commenter described this as operationally difficult and creating more unnecessary complication and burden on both ACOs and CMS.

A few commenters explained that an ACO's qualification as a low revenue ACO or high revenue ACO would also change over time as ACO participant composition changes, adding more complexity and making long-term planning very difficult. These commenters were concerned that uncertainty would be further compounded by the timing of our determination of whether ACOs qualify as a low revenue ACO or high revenue ACO.

Response: We considered commenters' suggestions that we not require ACOs that transition from low revenue ACO to high revenue ACO status during the course of an ACO's agreement period in Level E of the BASIC track to transition to the ENHANCED track. We also considered commenters' concerns (described elsewhere in this section of this final rule) that the proposed approach to distinguishing participation options for low revenue ACOs and high revenue ACOs could result in ACOs gaming the revenue determinations by manipulating their ACO participant lists. We remain concerned about the possibility that an ACO identified as experienced with performance-based risk Medicare ACO initiatives, and participating in an agreement period

under Level E of the BASIC track because it is also determined to be a low revenue ACO at the start of its agreement period, could become a high revenue ACO during the course of its agreement period. We believe that absent a structured approach to monitoring and addressing changes in composition, ACOs entering the BASIC track initially appearing to be low revenue ACOs could dramatically change their composition to take advantage of this lower-risk participation option in a manner that the program redesign does not contemplate.

At this time, we believe it would be appropriate to finalize the proposal to monitor for revenue changes in ACOs that entered an agreement period under Level E of the BASIC track because they are low revenue and experienced with performance-based risk Medicare ACO initiatives, for example as a result of changes in ACO participant composition. Further, under this approach, such an ACO that becomes high revenue during its agreement period under Level E of the BASIC track would be required to take corrective action to remedy the issue, such as removing an ACO participant from its ACO participant list, so that the ACO could meet the definition of low revenue ACO. If corrective action is not taken, CMS would terminate the ACO's participation agreement under § 425.218.

If an ACO is required to terminate its participation, it may apply to enter a new agreement period under the ENHANCED track. As a consequence of entering a new agreement period, the ACO's benchmark will be calculated based on the 3 most recent years prior to the ACO's agreement start date, using the ACO participant list the ACO finalizes as being applicable for the new agreement period.

We note that ACOs participating in the program may submit change requests in accordance with program procedures to indicate additions, updates, and deletions to their existing ACO participant lists. As part of the ACO participant change request process, we anticipate providing ACOs with information so that they are informed about the potential impact of ACO participant list changes on their compliance with program requirements, including how these changes may affect whether the ACO is considered a low revenue ACO or high revenue ACO, under the criteria for determining ACO participation options we are establishing with this final rule.

Although we are finalizing the proposal, we do find the commenters' concerns about the possible effects of applying this policy to be compelling. In particular, after further consideration, we believe that the low revenue ACO/high revenue ACO determination could be affected by changes in the ACO participant list for the ACO, or changes in ACO providers/suppliers, that are made in the course of program participation, where the changes are not motivated by the ACO's desire to avoid program requirements regarding participation options. For example, any addition or removal of an ACO participant, or change in ACO providers/suppliers, could affect the basis for the low revenue ACO/high revenue ACO determination: ACO participants' total Medicare Parts A and B FFS revenue, and total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries for the relevant period. In particular, ACOs close to the threshold percentage that are initially identified as low revenue ACOs could, during the course of their agreement period, become high revenue ACOs due to only a slight increase in ACO participant revenue. We note that under our proposed approach, which we are finalizing, we may be required to terminate ACOs from an agreement period in the BASIC track because of changes in ACO participants' total Medicare Parts A and B FFS revenue, and/or total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, that result in small percentage changes that put the ACO over the threshold for the definition of high revenue ACO, and which could not be easily remedied by the ACO.

Therefore, we plan to closely monitor the effects of this policy. In particular we plan to monitor the magnitude by which ACOs exceed the 35 percent threshold to become a high revenue ACO during an agreement period, and the ease or difficulty with which ACOs can remedy these circumstances to return to being low revenue ACOs (if desired by the ACO). If this policy results in ACOs being required to transition to the ENHANCED track, we will monitor to determine if these ACOs elect to renew early (to avoid a break in program participation), or terminate their participation, and if so whether they apply to re-enter the program later. We may revisit this policy in future rulemaking based on our lessons learned.

Comment: A few commenters indicated that ACOs may be challenged to anticipate CMS' determination of whether they are low revenue ACOs or high revenue ACOs, and will depend on these determinations to make business decisions on program participation. One commenter explained that ACOs may not have the data necessary to determine whether they are low revenue ACOs or high revenue ACOs without receiving additional data from CMS. A few commenters pointed to the need for CMS to provide revenue determinations early in the application process, so that ACOs know in advance what category they fall into. Several commenters suggested that CMS provide ample time for ACOs to make participation decisions based on its determination of whether an ACO is a low revenue ACO or high revenue ACO, including to allow ACOs to make any changes and execute a coordinated transition into their desired participation option (if a choice is available).

A few commenters suggested that CMS provide more detailed processes and timelines governing its assessment of and determination of ACOs as low revenue ACOs or high revenue ACOs (including how it will monitor ACOs) which it believes will help to protect against the potential for ACO gaming whereby ACOs use creative business organization strategies to ensure that they are able to remain in the low revenue ACO designation. A few commenters urged that CMS keep the process simple, straightforward, and transparent. One commenter suggested that CMS announce to ACOs a date by which it will complete its assessment of all ACOs regarding their categorization as a low revenue ACO or high revenue ACO. One commenter suggested the following approach for a typical application cycle, in advance of a January 1 start date: CMS should provide an option for an ACO to file a request by May for a determination of low revenue ACO/high revenue ACO status with receipt of the determination no later than June. Thus, when the ACO files its application in July, the ACO will be fully aware of its status and to be ready to meet the necessary requirements.

Response: We appreciate the commenters' concern and we anticipate providing timely feedback to ACOs throughout program application cycles, on whether the ACO is likely to be determined to be a low revenue ACO or high revenue ACO (among other factors), in order to ensure ACOs have the information they need to make decisions about program participation and to take action to align with program requirements. We announce application cycle dates in advance, through the Shared Savings Program website, and through various other methods available, including webinars, FAQs and a weekly newsletter. The program's application cycle typically includes

multiple opportunities for CMS to review the ACO's application, and provide the applicant feedback and the opportunity to correct deficiencies. We encourage ACOs and the public to monitor the Shared Savings Program website for related announcements.

We decline commenter's suggestions to make final determination of whether an ACO is a low revenue ACO or high revenue ACO in advance of the application submission date. ACOs submit their ACO participant list as part of the application submission process, and have opportunities to make changes or corrections to their ACO participant list during the application review period. As a result, the determination of whether an ACO is a low revenue ACO or high revenue ACO could change.

Final Action: After consideration of the public comments received, we are finalizing, with modifications, the proposed approach to identifying low revenue ACOs and high revenues ACOs for the purposes of determining ACO participation options in the Shared Savings Program. We are finalizing the addition of new definitions at § 425.20 for ''low revenue ACO,'' and ''high revenue ACO.''

We define ''high revenue ACO'' to mean an ACO whose 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, is at least 35 percent of the total 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.

We define ''low revenue ACO'' to mean an ACO whose 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, is less than 35 percent of the total 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.

In § 425.600(e) we are finalizing our approach to ensuring continued compliance of ACOs with the eligibility requirements for participation in the BASIC track, for an ACO that is accepted into the BASIC track's Level E because the ACO was experienced with performance-based risk Medicare ACO initiatives and determined to be low revenue at the time of application. If, during the agreement period, the ACO meets the definition of a high revenue ACO, the ACO will be permitted to complete the remainder of its current performance year under the BASIC track, but will 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. We will 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, we 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 will be required to remedy the issue. For example, if the ACO participants' total Medicare Parts A and B FFS revenue has increased in relation to total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, 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 will terminate the ACO's participation under § 425.218.

(2) Restricting ACOs' Participation in the BASIC Track Prior To Transitioning to Participation in the ENHANCED Track

As discussed in section II.A.5.c. of the August 2018 proposed rule (83 FR 41820 through 41836), we proposed to use factors based on ACOs' experience with performance-based risk to determine their eligibility for the BASIC track's glide path, or to limit their participation options to either the highest level of risk and potential reward under the BASIC track (Level E) or the ENHANCED track. As discussed in section II.A.5.b.(2) of the August 2018 proposed rule (83 FR 41817 through 41819), we also proposed to differentiate between low revenue ACOs and high revenue ACOs with respect to the continued availability of the BASIC track as a participation option. This approach would allow low revenue ACOs, new to performance-based risk arrangements, additional time under the BASIC track's revenue-based loss sharing limits, while requiring high revenue ACOs to more rapidly transition to the ENHANCED track under which they would assume relatively higher, benchmark-based risk. We explained our belief that all ACOs should ultimately transition to the ENHANCED track, the highest level of risk and potential reward under the program, which could drive ACOs to more aggressively pursue the program's goals of improving quality of care and lowering growth in FFS expenditures for their assigned beneficiary populations.

We considered that some low revenue ACOs may need additional time to prepare to take on the higher levels of performance-based risk required under the ENHANCED track. Low revenue ACOs, which could include small, physician-only and rural ACOs, may be encouraged to enter and remain in the program based on the availability of lower-risk options. For example, small, physician-only and rural ACOs may have limited experience submitting quality measures or managing patient care under two-sided risk arrangements, which could deter their participation in higher-risk options. ACOs and other program stakeholders have suggested that the relatively lower levels of risk available under the Track 1+ Model (an equivalent level of risk and potential reward to the payment model available under Level E of the BASIC track) encourages transition to risk by providing a more manageable level of two-sided risk for small, physician-only, and rural ACOs, compared to the levels of risk and potential reward currently available under Track 2 and Track 3, and that would be offered under the proposed ENHANCED track.

We also considered that, without limiting high revenue ACOs to a single agreement period under the BASIC track, they could seek to remain under a relatively low level of performance-based risk for a longer period of time, and thereby curtail their incentive to drive more meaningful and systematic changes to improve quality of care and lower growth in FFS expenditures for their assigned beneficiary populations. Further, high revenue ACOs, whose composition likely includes institutional providers, particularly hospitals and health systems, are expected generally to have greater opportunity to coordinate care for assigned beneficiaries across care settings among their ACO participants than low revenue ACOs. One approach to ensure high revenue ACOs accept a level of risk commensurate with their degree of control over total Medicare Parts A and B FFS expenditures for their assigned beneficiaries, and to further encourage these ACOs to more aggressively pursue the program's goals, is to require these ACOs to transition to higher levels of risk and potential reward.

We proposed 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. We explained our belief that an approach that allows high

revenue ACOs that are inexperienced with the accountable care model the opportunity to become experienced with program participation within the BASIC track's glide path prior to undertaking the higher levels of risk and potential reward in the ENHANCED track offers an appropriate balance between allowing ACOs time to become experienced with performance-based risk and protecting the Medicare Trust Funds. This approach recognizes that high revenue ACOs control a relatively large share of assigned beneficiaries' total Medicare Parts A and B FFS expenditures and generally are positioned to coordinate care for beneficiaries across care settings, and is protective of the Medicare Trust Funds by requiring high revenue ACOs to more quickly transition to higher levels of performance-based risk.

In contrast, we proposed to limit low revenue ACOs to, at most, two agreement periods under the BASIC track. These agreement periods would not be required to be sequential, which would allow low revenue ACOs that transition to the ENHANCED track after a single agreement period under the BASIC track the opportunity to return to the BASIC track if the ENHANCED track initially proves too high of risk. An experienced ACO may also seek to participate in a lower level of risk if, for example, it makes changes to its composition to include ACO providers/suppliers that are less experienced with the accountable care model and the program's requirements. Once an ACO has participated under the BASIC track's glide path (if eligible), a subsequent agreement period under the BASIC track would be required to be at the highest level of risk and potential reward (Level E), according to the proposed approach to identifying ACOs experienced with performance-based Medicare ACO initiatives (see section II.A.5.c. of this final rule).

Therefore, we proposed that in order for an ACO to be eligible to participate in the BASIC track for a second agreement period, the ACO must meet the requirements for participation in the BASIC track as described in this final rule (as determined based on whether an ACO is a low revenue ACO versus high revenue ACO and inexperienced with performance-based risk Medicare ACO initiatives versus experienced with performance-based risk Medicare ACO initiatives) and either of the following: (1) The ACO is the same legal entity as a current or previous ACO that previously entered into a participation agreement for participation in the BASIC track only one time; or (2) for a new ACO identified as a re-entering ACO because at least 50 percent of its ACO participants have recent prior participation in the same ACO, the ACO in which the majority of the new ACO's participants were participating previously entered into a participation agreement for participation in the BASIC track only one time.

Several examples illustrate this proposed approach. First, for an ACO legal entity with previous participation in the program, we would consider the ACO's current and prior participation in the program. For example, if a low revenue ACO enters the program in the BASIC track's glide path, and remains an eligible, low revenue ACO, it would be permitted to renew in Level E of the BASIC track for a second agreement period. Continuing this example, for the ACO to continue its participation in the program for a third or subsequent agreement period, it would need to renew its participation agreement under the ENHANCED track. As another example, a low revenue ACO that enters the program in the BASIC track's glide path could participate for a second agreement under the ENHANCED track, and enter a third agreement period under Level E of the BASIC track before being required to participate in the ENHANCED track for its fourth and any subsequent agreement period.

Second, for ACOs identified as re-entering ACOs because greater than 50 percent of their ACO participants have recent prior participation in the same ACO, we would determine the eligibility of the ACO to participate in the BASIC track based on the prior participation of this other entity. For example, if ACO A is identified as a re-entering ACO because more than 50 percent of its ACO participants previously participated in ACO B during the relevant look back period, we would consider ACO B's prior participation in the BASIC track in determining the eligibility of ACO A to enter a new participation agreement in the program under the BASIC track. For example, if ACO B had previously participated in two different agreement periods under the BASIC track, regardless of whether ACO B completed these agreement periods, ACO A would be ineligible to enter the program for a new agreement period under the BASIC track and would be limited to participating in the ENHANCED track. Changing the circumstances of this example, if ACO B had previously participated under the BASIC track during a single agreement period, ACO A may be eligible to participate in the BASIC track under Level E, the track's highest level of risk and potential reward, but would be ineligible to enter the BASIC track's glide path because ACO A would have been identified as experienced with performance-based risk Medicare ACO initiatives (as proposed).

We recognized that the difference in the level of risk and potential reward under the BASIC track, Level E compared to the payment model under the ENHANCED track could be substantial for low revenue ACOs. Therefore, we also considered and sought 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, we sought comment on whether it would be helpful to devise a glide path that would be available to low revenue ACOs entering the ENHANCED track. We also considered, and sought comment on, whether such a glide path under the ENHANCED track should be available to all ACOs. As another alternative, we 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. However, we indicated our concern that without a time limitation on participation in the BASIC track, ACOs may not prepare to take on the highest level of risk that could drive the most meaningful change in providers' and suppliers' behavior toward achieving the program's goals.

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), we sought 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. This approach would prevent low revenue ACOs that entered the ENHANCED track from participating in a subsequent agreement period under the BASIC track. That is, it would prevent an ACO from moving from a higher level of risk to a lower level of risk. However, given changes in ACO composition, among other potential factors, we indicated our belief that it is important to offer low revenue ACOs some flexibility in their choice of level of risk from one agreement period to the next.

We proposed to specify these proposed requirements for low revenue ACOs and high revenue ACOs in revisions to § 425.600, along with other proposed requirements for determining participation options based on the experience of the ACO and its ACO participants, as discussed in section

II.A.5.c. of this final rule. We proposed to use our determination of whether an ACO is a low revenue ACO or high revenue ACO in combination with our determination of whether the ACO is experienced or inexperienced with performance-based risk (which we proposed to determine based on the experience of both the ACO legal entity and the ACO participant TINs with performance-based risk), in determining the participation options available to the ACO. We sought comment on these proposals.

More generally, we noted that the proposed approach to redesigning the program's participation options maintains flexibility for ACOs to elect to enter higher levels of risk and potential reward more quickly than is required under the proposed participation options. Any ACO may choose to apply to enter the program under or renew its participation in the ENHANCED track. Further, ACOs eligible to enter the BASIC track's glide path may choose to enter at the highest level of risk and potential reward under the BASIC track (Level E), or advance to that level more quickly than is provided for under the automatic advancement along the glide path.

Comment: A few commenters agreed with the proposed approach to allow low revenue (typically physician-led) ACOs up to two agreement periods under the BASIC, while requiring high revenue ACOs (the typically better-resourced, hospital-based entities) to move more quickly to the ENHANCED track. Another commenter explained that the required move to downside risk is appropriate for urban health care systems that have the scale and resources to absorb a bad year. Several commenters favored the proposed approach for requiring more rapid transition to higher risk by high revenue ACOs. A few commenters urged CMS to encourage more low revenue ACO participation, and to increase financial alignment with value for high revenue ACOs. More generally, a few commenters supported the overall framework for the proposed redesign of the Shared Savings Program, including the proposed transition from one-sided to two-sided models.

Many commenters expressed concerns about the proposed approach to restricting the amount of time ACOs may participate in the BASIC track prior to participation in the ENHANCED track. Some commenters suggested that all ACOs should be allowed to remain in the BASIC track in Level E, or a track that meets the nominal risk requirements under the Quality Payment Program, finding the level of risk offered under the ENHANCED track to be unbearable.

One commenter, MedPAC, suggested CMS consider allowing all ACOs to operate in the BASIC track for two agreement periods, suggesting that it has enough downside risk to encourage ACOs to control costs, and the modest level of risk in the model may be more palatable to a wider range of ACOs. However, we note that MedPAC also suggested that because the ENHANCED track has stronger incentives for cost control, an argument can be made that all ACOs should move to the ENHANCED track after one 5-year agreement period in the BASIC track.

Some commenters specifically opposed limiting high revenue ACOs to one agreement period in the BASIC track. Given that high revenue ACOs are responsible for a greater share of healthcare spending than low revenue ACOs, one commenter agreed that it is reasonable to ask high revenue ACOs to assume greater levels of risk and/or at a faster pace than low revenue ACOs. But this commenter also suggested that CMS should also take into account that larger systems must invest in change across a much broader delivery ''footprint'' and so may require additional investments over multiple years to make transformative system changes, and also need a longer time to recoup investments (such as in the form of shared savings). This commenter suggested that high revenue ACOs be allowed to remain in Level E of the BASIC track for a second agreement period.

Some commenters suggested alternatives for distinguishing ACOs:

- One commenter suggested that instead of distinguishing low revenue ACOs and high revenue ACOs for purposes of determining the ACO's participation option by track, that the distinction be used to determine the sharing rate or MSR applied to the ACO within the BASIC track's glide path. This commenter supported the alternative consideration to provide low revenue ACOs (particularly small, rural and physician-led ACOs) either a lower MSR or higher shared savings rate.
- One commenter suggested that CMS consider a combination of other program policies to drive ACO performance, rather than the proposed approach to transition ACOs to performance-based risk, which could include: (1) Dropping ACOs from the program if they have not achieved savings after several years; (2) Reducing shared savings payments to ACOs that incur large losses before generating savings; and (3) Allowing ACOs to take accountability for the specific types of spending they are capable of controlling, rather than total Medicare spending.
- One commenter suggests that the potential to share in savings is a sufficient motivation for ACOs, as opposed to performance-based risk.
- Several commenters believe that both CMS and other researchers have significantly overstated the degree to which the performance of hospital-based ACOs differs from that of physician-led ACOs. These commenters urged CMS not move forward with the proposed approach, and to instead seek ways to support these ACOs, rather than make it harder for them to achieve savings.

Response: We appreciate commenters' support for the proposed approach to limiting ACOs' participation in the BASIC track, and requiring all ACOs to eventually transition to the ENHANCED track. Specifically, we appreciate commenters' support for the proposed approach to limiting high revenue ACOs to a single agreement period in the BASIC track (if eligible based on a determination that they are inexperienced with performance-based risk Medicare ACO initiatives), while limiting low revenue ACOs to a maximum of two agreement periods in the BASIC track (with ACOs inexperienced with performance-based risk Medicare ACO initiatives being eligible to participate under a single agreement period in the BASIC track's glide path and a single agreement period in Level E of the BASIC track).

We recognize that many commenters expressed concern about this approach, although at this time we decline to adopt commenters' suggestions that we allow some or all ACOs additional agreement periods under the BASIC track compared to the proposed approach, or to not require that ACOs ultimately transition to the ENHANCED track. As supported by some commenters, we continue to believe that requiring ACOs to transition to the ENHANCED track, with the highest level of risk and potential reward under the program, could drive ACOs to more aggressively pursue the program's goals of improving quality of care and lowering growth in FFS expenditures for their assigned beneficiary populations.

We also note that under the longer, 5-year agreement periods we are finalizing in this final rule (see section II.A.2), the timeline for entering higher levels of benchmark-based risk remains relatively consistent with the program's current requirements. Under the program's current requirements, ACOs must transition to a two-sided model by the start of their third 3-year agreement period, allowing for not more than 6 performance years under a one-sided model before being required to enter either Track 2 or Track 3. A gentler pathway between the existing Track 1 and the levels of risk and reward under

the program's current two-sided models has been a long standing request from ACOs and other program stakeholders, as described in section II.A.1 of this final rule and as reflected in some comments on the proposed program redesign. The proposed approach allows a gentler progression to two-sided risk, including a progression over a 5-year agreement period for all ACOs inexperienced with performance-based risk Medicare ACO initiatives, and a progression over two, 5-year agreement periods for low revenue ACOs. We note that this timeline is further extended for ACOs entering an agreement period beginning on July 1, 2019, since this mid-year start includes an additional 6-month performance year, resulting in an agreement period of 5.5 years.

We also note also that early entrants into the Shared Savings Program have been able to participate under a one-sided model for up to 6 performance years, and we anticipate that eligible ACOs will continue their participation in the BASIC track's glide path to extend their transition to benchmark-based risk under the ENHANCED track for at least another 5 years.

We also believe the proposed approach offers the right combination of a slower transition to the ENHANCED track for low revenue ACOs, and more rapid progression for high revenue ACOs. We therefore decline the commenter's suggestion that we require all ACOs to transition to the ENHANCED track after one 5-year agreement period in the BASIC track.

We also decline to accept the commenters' alternative suggestions. We are not adopting an approach to distinguish the sharing rates or the MSR applied to ACOs within the BASIC track's glide path, as described in sections II.A.3 and II.A.6. of this final rule, since ACOs may elect their MSR and MLR under performance-based risk. Therefore we decline to use the low revenue ACO and high revenue ACO distinctions to determine the financial model features applied to ACOs within the BASIC track's glide path. This approach would also not achieve our goal of requiring ACOs to progress to the ENHANCED track over time.

Some suggested alternative approaches, to distinguish ACOs based on their financial performance, were beyond the scope of the proposed rule, such as reducing ACOs' shared savings payments if they incurred large losses in prior years, or allowing ACOs to become accountable for specific types of spending instead of total Medicare spending. We believe the latter approach, to segment accountability for beneficiaries' healthcare costs, would not achieve a key aim of the program, which is for ACOs to become accountable for total Medicare Parts A and B FFS expenditures for their assigned beneficiaries, and could reinforce existing incentives that lead to fragmented care. Further, we appreciated the suggestion that we remove ACOs with poor financial performance, which seems similar to our proposed approach to monitoring and termination for poor financial performance as discussed in section II.A.5.d of this final rule.

We also disagree with the commenter's suggestion that shared savings potential alone is a sufficient motivator for ACOs to drive the most meaningful systematic change in the healthcare system. We believe that greater risk with the possibility of greater reward under two-sided models is a pathway for ACOs to transform their care delivery by lowering growth in expenditures while ensuring they provide coordinated, high quality care for their Medicare FFS populations. For this reason we also decline commenters' suggestions that we forgo the proposed approach and instead seek other ways to support high revenue ACOs' achievement of the program's goals.

Comment: A few commenters explained that the challenge of being forced into risk is of great importance to ACOs of all sizes, composition, and ownership. Some commenters warned that requiring ACOs to take on high levels of risk before they are ready will result in program attrition. One commenter explained that regardless of structure, significant investments are needed in population health platforms and care process changes for ACOs to bear risk. Several commenters point to a variety of factors, other than ACO composition, related to an ACO's readiness to take on performance-based risk. One commenter explained that the financial position and backing of a particular ACO as well as the ability to assume risk depends on a variety of factors, such as local market dynamics, culture, leadership, financial status, previous program success, and the resources required to address social determinants of health that influence care and outcomes for patients. Another commenter described an organization's ability to bear risk as having many inputs, including payer mix. Another commenter explained that each ACO is unique and faces different circumstances that determine its ability to take on higher levels of risk.

Response: As we have previously described in responding to comments in this section of this final rule, the current structure of the Shared Savings Program requires ACO's eventual transition to performance-based risk while also affording ACOs and their provider/suppliers the flexibility to redesign care to address the unique needs of their population and community. While we appreciate that the circumstance of each ACO may be unique, as commenters point out, we also believe that the program's requirements are clear about the expectation that ACOs enter performance-based risk over the course of their participation in the program, should they choose to continue their participation over of multiple agreement periods. We believe the proposed approach, including a glide path within the BASIC track from a one-sided model through progressively higher levels of performance-based risk offers a gentler and more manageable approach for ACOs to become experienced with two-sided models before undertaking more significant levels of risk and potential reward.

Comment: Commenters described a variety of reasons why high revenue ACOs would benefit from additional time under lower-risk participation options. As echoed in other comments, one commenter explained that the proposed rule would force hospital-centric ACOs to take on additional risk too quickly, when these ACOs need additional time to adjust their cost structures and change operating models.

Another commenter described its concerns that, in the current environment, if CMS pushes to drive losses more quickly to hospitals, it will be increasingly difficult for hospital systems to invest dollars back into population health management activities, which is necessary for long term success of ACO to meet the aims of the Shared Savings Program.

A few commenters explained that hospital-based, high revenue ACOs, face greater challenges in taking on performance-based risk because they tend to be less cohesive groups, which have invested heavily in developing the infrastructure in both technology platforms and care management to help their ACOs eventually succeed.

However, another commenter explained that hospitals and health systems are best equipped to lead other providers in moving toward downside risk because they have provided—and continue to provide—significant infrastructure support related to health information technology, regulatory compliance and other administrative functions that are key to successful APM implementation.

A few commenters explained that larger systems often already operate at greater efficiency before entering the

program, and as a result may often have less spending to trim, which is a commonly cited concern regarding historical benchmarks. Requiring transition to higher levels of performance-based risk may limit participation by these providers in the program.

Response: We appreciate the commenters' explanations of the challenges some high revenue ACOs may face in taking on performance-based risk under the proposed redesign of the Shared Savings Program. We are not persuaded, however, by the suggested reasons to permit high revenue ACOs additional time under the BASIC track, when we believe they have the capacity to drive more meaningful, systematic change in achieving the program's goals by participating under higher levels of performance-based risk.

As we have described elsewhere in this final rule, we have observed that low revenue ACOs, which include small, physician-only and rural ACOs, show better average results compared to high revenue ACOs, which typically include hospitals (see section V of this final rule). Given the potential for high revenue ACOs to lower growth in Medicare Parts A and B FFS expenditures, we believe it is critical to ensure they remain accountable for the quality of care, and expenditures, for their assigned beneficiaries. We believe that an outcome of this approach to program redesign may be new, innovative and more aggressive approaches to reaching the program's goals of improving quality of care and lowering growth in Medicare FFS expenditures for beneficiaries.

Regarding the commenter's concern about the participation of already efficient high revenue ACOs, we note that (as described in section II.D. of this final rule) we are finalizing additional modifications to the program's methodology for establishing, updating and adjusting the ACO's historical benchmark to improve incentives and to increase the accuracy of the benchmark by incorporating regional factors in an ACO's first agreement period and better capturing changes in beneficiary health status. The BASIC track's glide path, coupled with longer agreement periods and benchmark improvements, including regional adjustments for efficiency starting in the first agreement period, as well as new risk adjustment coding intensity adjustments, should help ACOs transition to performance-based risk.

Comment: Some commenters stated that requiring hospital-based ACOs to take on more risk sooner will cause these ACOs to cease participation, or discourage ACO formation.

A few commenters expressed concern that the proposed approach would make participation more challenging for ACOs that would be high volume, such as those with hospital participants, and would thereby marginalize these participants and result in reduced participation by hospital-based ACOs. These commenters explained that this could lead to their departure and would squander the significant investments they have made in care coordination and data-sharing before they were able to pay off for the Medicare program and its beneficiaries.

Several commenters explained that keeping hospitals in the Shared Savings Program is critical to reducing total cost of care. One commenter suggested the high revenue ACO distinction would discourage participation by the ACOs that can best coordinate acute and ambulatory care and are more likely to generate substantial savings to the Medicare program over the long-term.

A few commenters stated that the proposed approach would disadvantage ACOs that treat complex patients that have higher expenditures, while other commenters indicated that the proposed approach would penalize high revenue ACOs for the size of their patient populations and their volume of services.

Response: We believe a combination of the policy changes being established with this final rule can help ACOs transform care and mitigate to some extent commenters' concerns around the populations served by high revenue ACOs and other challenges faced by these organizations. For example, as discussed in section II.D. of this final rule, the potentially smaller regional adjustments for ACOs caring for complex patients (where the ACOs' expenditures may be higher than expenditures in the ACO's regional service area) will provide more time for these ACOs to bring their costs in line with their region. In addition, these ACOs will benefit from the modified approach to risk adjustment using full CMS–HCC scores with a 3 percent cap on growth for the agreement period, which may more accurately capture the conditions of their patients and account for the health status changes in an ACO's performance year assigned beneficiary population. Further, eligible ACOs will have new tools to support care coordination, such as through expanded coverage of telehealth services and a SNF 3-day rule waiver (see section II.B. of this final rule), and beneficiary engagement such as through the opportunity for eligible ACOs to implement Beneficiary Incentive Programs (see section II.C. of this final rule). Eligible clinicians in high revenue ACOs may also be eligible to receive QP status and benefit from incentive payments under the Quality Payment Program for participation in an Advanced APM under the ENHANCED track or Level E of the BASIC track (if eligible). High revenue ACOs (and ACOs more generally) could find their participation in a financial model that is an Advanced APM to be a factor to their advantage in attracting and retaining participation of ACO participants and ACO providers/suppliers. The longer agreement periods will provide more time for ACOs to become successful and transform care and benefit from their success, which we believe will be especially important to high revenue ACOs (including most hospital-based ACOs), which we expect generally will have more potential savings to achieve. We also note that while only a small number of ACOs have owed shared losses, we have observed that one high revenue ACO that incurred shared losses, which was a hospital-based ACO, continues to participate and work toward transforming care. This suggests that even ACOs that have incurred shared losses still can provide a catalyst for making health systems and provider networks more efficient and effective.

Comment: One commenter disagreed with the need to push high revenue ACOs to accept greater amounts of risk, pointing to the relative newness of the Shared Savings Program and the other Medicare payment reforms that have occurred in recent years. According to this commenter, these initiatives are straining already limited resources in hospitals and making it more challenging to keep up with the extremely rapid pace of payment reforms being pursued by CMS.

Response: As we explained in the August 2018 proposed rule, our proposed redesign of the Shared Savings Program was informed by our initial years of experience with the program, including performance results. However, we do not agree with the commenter's suggestion that we potentially delay changes to further the achievement of the program's goals in light of other payment reforms implemented by the agency. Hospitals have been at the forefront of value-based purchasing and we believe the principles and lessons learned from quality improvement and efficiency measures can help inform their success under larger population-based, value-based programs.

Comment: Some commenters urged CMS to allow even greater flexibility to

small, rural, or physician-only ACOs, low revenue ACOs, and ACOs that include safety net providers, to prepare for the transition to performance-based risk. Commenters explained that these ACOs face challenges in that they lack the financial reserves or the financial backing to move into performance-based risk. One commenter explained: Small and rural ACOs have achieved excellent clinical quality scores above national averages even as they beat their spending benchmarks, however, the natural year-to-year variation in performance and risk of paying back shared losses even in a single year is too much uncertainty for providers that live on the margins. Several commenters described the level of risk in the ENHANCED track as being too high for low revenue ACOs. One commenter described the distance in risk and downside loss between the BASIC track's Level E and the ENHANCED track as ''abysmal,'' and undertaking this level of performance-based risk may be ''financially suicidal'' for a low revenue ACO.

Response: We appreciate commenters' concerns about the obstacles low revenue ACOs face in transitioning to performance-based risk given their potentially more limited financial reserves, particularly the challenges faced by small, rural and physician-only ACOs, and especially ACOs new to the Shared Savings Program and the accountable care model. We believe these concerns further support our proposed approach to providing low revenue ACOs additional time to prepare to take on the higher levels of performance-based risk required under the ENHANCED track, by allowing eligible low revenue ACOs up to two, 5-year agreement periods for a total of 10 years under the BASIC track (or 10.5 years in the case of an ACO with an agreement period beginning on July 1, 2019).

We also believe that a combination of policy modifications reflected in our final policies within this final rule address commenters' concerns and suggestions for a relatively gentler glide path to two-sided risk for small, rural and physician-only ACOs, and support continued participation of these ACOs in the Shared Savings Program. For one, as discussed in section II.A.5.b.(1) of this final rule, we are finalizing our proposed definitions of low revenue ACOs and high revenue ACOs with a modification to increase the threshold percentage used in making these determinations (from 25 percent to 35 percent) so that more ACOs would be considered low revenue ACOs. Second, we are finalizing higher sharing rates under BASIC track (as described in section II.A.3 of this final rule) which we believe will allow ACOs eligible for shared savings access to additional financial resources to support their operational costs and their participation in performance-based risk (such as supporting these ACOs in establishing their repayment mechanism arrangements). Third, as described in section II.A.5.c of this final rule, we are finalizing a policy modification to allow additional flexibility for new legal entities, that are low revenue ACOs and inexperienced with performance-based risk Medicare ACO initiatives, to participate for up to 3 performance years (or 4 performance years in the case of ACOs entering an agreement period beginning on July 1, 2019) under a one-sided model of the BASIC track's glide path before transitioning to Level E (the highest level of risk and potential reward under the BASIC track). Fourth, and lastly, as described in section II.A.6.c of this final rule, we are modifying our proposed approach for determining repayment mechanism arrangement amounts to reduce the burden of these arrangements on all ACOs participating in the ENHANCED track. Under the modified approach, the repayment mechanism amount for such ACOs must be equal to the lesser of the following: 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; or 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.

We decline commenters' suggestions that certain ACOs be exempt from transitioning to performance-based risk (generally) or higher levels of risk and potential reward. As we explain elsewhere in this section of this final rule, we believe the progression to performance-based risk is critical to driving the most meaningful change in providers' and suppliers' behavior toward achieving the program's goals, and that participation in two-sided models, and ultimately the ENHANCED track, should be the goal for all Shared Savings Program ACOs. Therefore, at this time, we also decline to establish a separate track with alternative participation options targeted specifically at particular subsets of ACOs, including those that typically may be low revenue ACOs.

Comment: A few commenters supported the ability of low revenue ACOs to transition from the BASIC track to the ENHANCED track after a single agreement period under the BASIC track, while retaining the opportunity to return to the BASIC track. One commenter explained its belief that this approach creates a ''safety net'' that will encourage ACOs that believe they are ready to bear a significant amount of risk to test their capabilities in the ENHANCED track as opposed to taking advantage of both agreement periods in the BASIC track (sequentially).

Response: We appreciate commenters' support for our proposal to allow low revenue ACOs to participate in the BASIC track in any two agreement periods (including non-sequentially).

Final Action: After considering the comments we received, we are finalizing our proposed policies for restricting ACOs' participation in the BASIC track prior to transitioning to participation in the ENHANCED track. High revenue ACOs will be limited to, at most, a single agreement period under the BASIC track prior to transitioning to participation under the ENHANCED track. Low revenue ACOs will be limited to, at most, two agreement periods for a total of 10 years under the BASIC track (or 10.5 years in the case of an ACO that participates in an agreement period that begins on July 1, 2019, which spans a total of 5.5 years). These agreement periods do not need to be sequential. We are specifying these requirements for low revenue ACOs and high revenue ACOs in revisions to § 425.600, along with other requirements we are finalizing for determining participation options based on the experience of the ACO and its ACO participants with performance-based risk Medicare ACO initiatives, as discussed in section II.A.5.c. of this final rule.

c. Determining Participation Options Based on Prior Participation of ACO Legal Entity and ACO Participants

(1) Overview

In this section of the final rule we describe policies for determining ACO participation options based on prior participation of the ACO legal entity and ACO participants. In section II.A.5.c of the August 2018 proposed rule (83 FR 41820 through 41834), we proposed modifications to the regulations to address the following:

- Allowing flexibility for ACOs currently within a 3-year agreement period under the Shared Savings Program to transition quickly to a new agreement period that is not less than 5 years under the BASIC track or ENHANCED track.
- Establishing definitions to more clearly differentiate ACOs applying to renew for a second or subsequent agreement period and

ACOs applying to re-enter the program after their previous Shared Savings Program participation agreement expired or was terminated resulting in a break in participation, and to identify new ACOs as re-entering ACOs if greater than 50 percent of their ACO participants have recent prior participation in the same ACO in order to hold these ACO accountable for their ACO participants' experience with the program.

- Revising the criteria for evaluating an ACO's prior participation in the Shared Savings Program to determine the eligibility of ACOs seeking to renew its participation in the program for a subsequent agreement period, ACOs applying to re-enter the program after termination or expiration, and ACOs that are identified as re-entering ACOs based on their ACO participants' recent experience with 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 that of its ACO participants) and on whether the ACO is a low revenue ACO or high revenue ACO.
- Establishing policies that more clearly differentiate the participation options, and the applicability of program requirements that phase-in over time based on the ACO's and ACO participants' prior experience in the Shared Savings Program or with other Medicare ACO initiatives.

We summarized the regulatory background for the proposed policies, which included multiple sections of the program's regulations, as developed over several rulemaking cycles.

(2) Background on Re-Entry Into the Program After Termination

In the initial rulemaking for the program, we specified criteria for terminated ACOs seeking to re-enter the program in § 425.222 (see 76 FR 67960 through 67961). In the June 2015 final rule, we revised this section to address eligibility for continued participation in Track 1 by previously terminated ACOs (80 FR 32767 through 32769). Currently, this section prohibits ACOs re-entering the program after termination from participating in the one-sided model beyond a second agreement period and from moving back to the one-sided model after participating in a two-sided model. This section also specifies that terminated ACOs may not re-enter the program until after the date on which their original agreement period would have ended if the ACO had not been terminated (the ''sit-out'' period). This policy was designed to restrict re-entry into the program by ACOs that voluntarily terminate their participation agreement, or have been terminated for failing to meet program integrity or other requirements (see 76 FR 67960 and 67961). Under the current regulations, we only consider whether an ACO applying to the program is the same legal entity as a previously terminated ACO, as identified by TIN (see definition of ACO under § 425.20), for purposes of determining whether the appropriate ''sit-out'' period of § 425.222(a) has been observed and the ACO's eligibility to participate under the one-sided model. Section 425.222 also provides criteria to determine the applicable agreement period when a previously terminated ACO re-enters the program. We explained the rationale for these policies in prior rulemaking and refer readers to the November 2011 and June 2015 final rules for more detailed discussions.

Additionally, under § 425.204(b), the ACO must disclose to CMS whether the ACO or any of its ACO participants or ACO providers/suppliers have participated in the Shared Savings Program under the same or a different name, or are related to or have an affiliation with another Shared Savings Program ACO. The ACO must specify whether the related participation agreement is currently active or has been terminated. If it has been terminated, the ACO must specify whether the termination was voluntary or involuntary. If the ACO, ACO participant, or ACO provider/supplier was previously terminated from the Shared Savings Program, the ACO must identify the cause of termination and what safeguards are now in place to enable the ACO, ACO participant, or ACO provider/supplier to participate in the program for the full term of the participation agreement (§ 425.204(b)(3)).

The agreement period in which an ACO is placed upon re-entry into the program has ramifications not only for its risk track participation options, but also for the benchmarking methodology that is applied and the quality performance standard against which the ACO will be assessed. ACOs in a second or subsequent agreement period receive a rebased benchmark as currently specified under § 425.603. For ACOs that renew for a second or subsequent agreement period beginning in 2017 and subsequent years, the rebased benchmark incorporates regional expenditure factors, including a regional adjustment. The weight applied in calculating the regional adjustment depends in part on the agreement period for which the benchmark is being determined (see § 425.603(c)), with relatively higher weights applied over time. Further, for an ACO's first agreement period, the benchmark expenditures are weighted 10 percent in benchmark year 1, 30 percent in benchmark year 2, and 60 percent in benchmark year 3 (see § 425.602(a)(7)). In contrast, for an ACO's second or subsequent agreement period we equally weight each year of the benchmark (§ 425.603). With respect to quality performance, the quality performance standard for ACOs in the first performance year of their first agreement period is set at the level of complete and accurate reporting of all quality measures. Pay-for-performance is phased in over the remaining years of the first agreement period, and continues to apply in all subsequent performance years (see § 425.502(a)).

We explained our belief that the regulations as currently written create flexibilities that allow more experienced ACOs to take advantage of the opportunity to re-form and re-enter the program under Track 1 or to re-enter the program sooner or in a different agreement period than otherwise permissible. In particular, terminated ACOs may re-form as a different legal entity and apply to enter the program as a new organization to extend their time in Track 1 or enter Track 1 after participating in a two-sided model. These ACOs would effectively circumvent the requisite ''sit-out'' period (the remainder of the term of an ACO's previous agreement period), benchmark rebasing, including the application of equal weights to the benchmark years and the higher weighted regional adjustment that applies in later agreement periods, or the pay-for-performance quality performance standard that is phased in over an ACO's first agreement period in the program.

(3) Background on Renewal for Uninterrupted Program Participation

In the June 2015 final rule, we established criteria in § 425.224 applicable to ACOs seeking to renew their agreements, including requirements for renewal application procedures and factors CMS uses to determine whether to renew a participation agreement (see 80 FR 32729 through 32730). Under our current policies, we consider a renewing ACO to be an organization that continues its participation in the program for a consecutive agreement period, without interruption resulting from termination of the participation agreement by CMS or by the ACO (see §§ 425.218 and 425.220). Therefore, to be considered for timely renewal, an ACO within its third performance year of an agreement period is required to meet the application requirements, including submission of a renewal application, by the deadline specified by CMS, during the program's typical annual application process. If the ACO's

renewal application is approved by CMS, the ACO would have the opportunity to enter into a new participation agreement with CMS for the agreement period beginning on the first day of the next performance year (typically January 1 of the following year), and thereby to continue its participation in the program without interruption.

In evaluating the application of a renewing ACO, CMS considers the ACO's history of compliance with program requirements generally, whether the ACO has established that it is in compliance with the eligibility and other requirements of the Shared Savings Program, including the ability to repay shared losses, if applicable, and whether it has a history of meeting the quality performance standard in its previous agreement period, as well as whether the ACO satisfies the criteria for operating under the selected risk track, including whether the ACO has repaid shared losses generated during the prior agreement period.

Under § 425.600(c), an ACO experiencing a net loss during a previous agreement period may reapply to participate under the conditions in § 425.202(a), except the ACO must also identify in its application the cause(s) for the net loss and specify what safeguards are in place to enable the ACO to potentially achieve savings in its next agreement period. In the initial rulemaking establishing the Shared Savings Program, we proposed, but did not finalize, a requirement that would prevent an ACO from reapplying to participate in the Shared Savings Program if it previously experienced a net loss during its first agreement period. We explained that this proposed policy would ensure that under-performing organizations would not get a second chance (see 76 FR 19562, 19623). However, we were persuaded by commenters' suggestions that barring ACOs that demonstrate a net loss from continuing in the program could serve as a disincentive for ACO formation, given the anticipated high startup and operational costs of ACOs (see 76 FR 67908 and 67909). We finalized the provision at § 425.600(c) that would allow for continued participation by ACOs despite their experience of a net loss.

(4) Streamlining Regulations

As described in the August 2018 proposed rule (83 FR 41821 through 41825), we proposed to modify the requirements for ACOs applying to renew their participation in the program (§ 425.224) and re-enter the program after termination (§ 425.222) or expiration of their participation agreement by both eliminating regulations that would restrict our ability to ensure that ACOs quickly migrate to the redesigned tracks of the program and strengthening our policies for determining the eligibility of ACOs to renew their participation in the program (to promote consecutive and uninterrupted participation in the program) or to re-enter the program after a break in participation. We also sought to establish criteria to identify as re-entering ACOs new ACOs for which greater than 50 percent of ACO participants have recent prior participation in the same ACO, and to hold these ACO accountable for their ACO participants' experience in the program.

(a) Defining Renewing and Re-Entering ACOs

We proposed to define a renewing ACO and an ACO re-entering after termination or expiration of its participation agreement (83 FR 41821 through 41823). Under the program's regulations, there is currently no definition of a renewing ACO, and based on our operational experience, this has caused some confusion among applicants. For example, there is confusion as to whether an ACO that has terminated from the program would be considered a first time applicant into the program or a renewing ACO. The definition of these terms is also important for identifying the agreement period that an ACO is applying to enter, which is relevant to determining the applicability of certain factors used in calculating the ACO's benchmark that phase-in over the span of multiple agreement periods as well as the phase-in of pay-for-performance under the program's quality performance standards. We explained that having definitions that clearly distinguish renewing ACOs from ACOs that are applying to re-enter the program after a termination, or other break in participation will help us more easily differentiate between these organizations in our regulations and other programmatic material. We proposed to define renewing ACO and re-entering ACO in new definitions in § 425.20.

We proposed to define renewing ACO to mean 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. This proposed definition is consistent with current program policies for ACOs applying to timely renew their agreement under § 425.224 to continue participation following the expiration of their participation agreement. This proposed definition would include a new policy that would consider an ACO to be renewing in the circumstance where the ACO voluntarily terminates its current participation agreement and enters a new agreement period under the BASIC track or ENHANCED track, beginning immediately after the termination date of its previous agreement period thereby avoiding an interruption in participation. We would consider these ACOs to have effectively renewed their participation early. This part of the definition is consistent with the proposal to discontinue use of the ''sit-out'' period after termination under § 425.222(a).

We considered two possible scenarios in which an ACO might seek to re-enter the program. In one case, a re-entering ACO would be a previously participating ACO, identified by a TIN (see definition of ACO under § 425.20), that applies to re-enter the program after its prior participation agreement expired without having been renewed, or after the ACO was terminated under § 425.218 or § 425.220 and did not immediately enter a new agreement period (that is, an ACO with prior participation in the program that does not meet the proposed definition of renewing ACO). In this case, it is clear that the ACO is a previous participant in the program. In the other scenario, an entity applies under a TIN that is not previously associated with a Shared Savings Program ACO, but the entity is composed of ACO participants that previously participated together in the same Shared Savings Program ACO in a previous performance year. Under the current regulations, there is no mechanism in place to prevent a terminated ACO from re-forming under a different TIN and applying to re-enter the program, or for a new legal entity to be formed from ACO participants in a currently participating ACO. Doing so could allow an ACO to avoid accountability for the experience and prior participation of its ACO participants, and to avoid the application of policies that phase-in over time (the application of equal weights to the benchmark years and the higher weighted regional adjustment that applies in later agreement periods,

or the pay-for-performance quality performance standard that is phased in over an ACO's first agreement period in the program). We explained our concern that, under the current regulations, Track 1 ACOs would be able to re-form to take advantage of the BASIC track's glide path, which, as proposed, would allow for 2 years under a one-sided model for new ACOs only (2.5 performance years in the case of an agreement period starting July 1, 2019). We therefore described our interest in adopting an approach to better identify prior participation and to specify participation options and program requirements applicable to re-entering ACOs.

We proposed to define ''re-entering ACO'' to mean 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.

We noted that a number of proposed policies depend on the prior participation of an ACO or the experience of its ACO participants, including: (1) Using the ACO's and its ACO participants' experience or inexperience with performance-based risk Medicare ACO initiatives to determine the participation options available to the ACO (proposed in § 425.600(d)); (2) identifying ACOs experienced with Track 1 to determine the amount of time an ACO may participate under a one-sided model of the BASIC track's glide path (proposed in § 425.600(d)); (3) determining how many agreement periods an ACO has participated under the BASIC track as eligible ACOs are allowed a maximum of two agreement periods under the BASIC track (proposed in § 425.600(d)); (4) assessing the eligibility of the ACO to participate in the program (proposed revisions to § 425.224); and (5) determining the applicability of program requirements that phase-in over multiple agreement periods (proposed in § 425.600(f)). The proposed revisions to the regulations to establish these requirements would apply directly to an ACO that is the same legal entity as a previously participating ACO. We also discuss throughout the preamble how these requirements would apply to new ACOs that are identified as re-entering ACOs because greater than 50 percent of their ACO participants have recent prior participation in the same ACO.

Several examples illustrate the application of the proposed definition of re-entering ACO. For example, if ACO A is applying to the program for an agreement period beginning on July 1, 2019, and ACO A is the same legal entity as an ACO whose previous participation agreement expired without having been renewed (that is, ACO A has the same TIN as the previously participating ACO) we would treat ACO A as the previously participating ACO, regardless of what share of ACO A's ACO participants previously participated in the ACO. As another example, if ACO A, applying for a July 1, 2019 start date, were a different legal entity (identified by a different TIN) from any ACO that previously participated in the Shared Savings Program, we would also treat ACO A as if it were an ACO that previously participated in the program (ACO B) if more than 50 percent of ACO A's ACO participants participated in ACO B in any of the 5 most recent performance years (that is, performance year 2015, 2016, 2017, 2018, or the 6-month performance year from January 1, 2019 through June 30, 2019), even though ACO A and ACO B are not the same legal entity.

We explained that looking at the experience of the ACO participants, in addition to the ACO legal entity, would be a more robust check on prior participation. It would also help to ensure that ACOs re-entering the program are treated comparably regardless of whether they are returning as the same legal entity or have re-formed as a new entity. With ACOs allowed to make changes to their certified ACO participant list for each performance year, we have observed that many ACOs make changes to their ACO participants over time. For example, among ACOs that participated in the Shared Savings Program as the same legal entity in both PY 2014 and PY 2017, only around 60 percent of PY 2017 ACO participants had also participated in the same ACO in PY 2014, on average. For this reason, the ACO legal entity alone does not always capture the ACO's experience in the program and therefore it is also important to look at the experience of ACO participants.

We chose to propose a 5 performance year look back period for determining prior participation by ACO participants as it would align with the look back period for determining whether an ACO is experienced or inexperienced with performance-based risk Medicare ACO initiatives as discussed elsewhere in this section of this final rule. We clarified that the threshold for prior participation by ACO participants is not cumulative when determining whether an ACO is a re-entering ACO. For example, assume 22 percent of applicant ACO A's ACO participants participated in ACO C in the prior 5 performance years, 30 percent participated in ACO D, and the remaining 48 percent did not participate in any ACO during this period. ACO A would not be considered a re-entering ACO (assuming that ACO A is a new legal entity), because more than 50 percent of its ACO participants did not participate in the same ACO during the 5-year look back period. Although unlikely, we recognized the possibility that an ACO could quickly re-form multiple times and therefore more than 50 percent of its ACO participants may have been included on the ACO participant list of more than one ACO in the 5 performance year look back period. In these cases, the most recent experience of the ACO participants in the new ACO would be most relevant to determining the applicability of policies to the re-entering ACO. We therefore proposed that the ACO in which more than 50 percent of the ACO participants most recently participated would be used in identifying the participation options available to the new ACO.

We opted to propose a threshold of greater than 50 percent because it would identify ACOs with significant participant overlap and would allow us to more clearly identify a single, Shared Savings Program ACO in which at least the majority of ACO participants recently participated. We also considered whether to use a higher or lower percentage threshold. A lower threshold, such as 20, 30 or 40 percent, would further complicate the analysis for identifying the ACO or ACOs in which the ACO participants previously participated, and the ACO whose prior performance should be evaluated in determining the eligibility of the applicant ACO. On the other hand, using a higher percentage for the threshold would identify fewer ACOs that significantly resemble ACOs with

experience participating in the Shared Savings Program.

We considered alternate approaches to identifying prior participation other than the overall percentage of ACO participants that previously participated in the same ACO, 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. While these alternative approaches have merit, we concluded that they would be less transparent to ACOs than using a straight percentage of TINs, as well as more operationally complex to compute.

We sought comment on these proposed definitions and on the alternatives considered.

Comment: Some commenters expressed concern that the distinctions for determining participation options, including evaluating whether ACOs are new, renewing, or re-entering, add complexity to the program. A few commenters opposed the approach to identifying re-entering ACOs, and suggested CMS forgo the policy.

Response: We acknowledge that the approach to identifying re-entering ACOs and renewing ACOs will add some complexity to program policies and certain operational processes, such that it requires (for example) that we establish procedures to identify new legal entities that are re-entering ACOs because more than 50 percent of their ACO participants were included on the ACO participant list of the same ACO in any of the 5 most recent performance years prior to the agreement start date, as well as to process requests for ACOs seeking to renew early. However, we believe these definitions for ''renewing ACO'' and ''re-entering ACO'' are timely with the redesign of the program's participation options and provide needed clarification to the program's regulations, as well as an opportunity to more consistently evaluate eligibility for program participation by ACOs whose legal entity, or a significant portion of the ACO participants, has previous experience in the Shared Savings Program.

We believe that the proposed definitions for renewing ACOs and re-entering ACOs, and related changes to the program's regulations for identifying participation options for these organizations, bolster program integrity. As we discussed in the August 2018 proposed rule (see for example, 83 FR 41822) and as we reiterated in this section of this final rule, we believe that the program's regulations as currently written create flexibilities that allow more experienced ACOs to potentially re-form and re-enter the program under participation options they find advantageous, such as avoiding the transition to performance-based risk, or avoiding the application of policies that phase-in over time (the application of equal weights to the benchmark years and the higher weighted regional adjustment that applies in later agreement periods, or the pay-for-performance quality performance standard that is phased in over an ACO's first agreement period in the program). We also explained that establishing definitions for ''renewing ACO'' and ''re-entering ACO'' will help us more easily differentiate between these organizations in our regulations and other programmatic material (83 FR 41821). Further, the removal of the sit-out period after termination and the allowance for an early renewal option under the definition of ''renewing ACO'' allows an important flexibility for ACOs to more readily move to new participation options under the program redesign without a break in their program participation.

Comment: We received few comments on the proposed definition of ''renewing ACO.'' Several commenters specifically supported the proposed definition of renewing ACO. Several commenters expressed support for the early renewal policy. However, a few comments indicated some confusion over the early renewal policies.

Response: We thank the commenters for their support of the proposed definition of ''renewing ACO''. We are finalizing this definition as proposed. We respond further in this section and in section II.A.7 of this final rule to those commenters who expressed confusion regarding the early renewal policy.

Comment: One commenter stated that it is unclear that the opportunity to terminate early and begin a new 5-year agreement is open to all ACOs, and pointed out that reference is made to Track 2 ACOs having this opportunity (83 FR 41800). This commenter requested that CMS clarify in the final rule that all ACOs regardless of their agreement period start year are offered the opportunity to transition to the BASIC track or ENHANCED track.

Response: To clarify, the proposed definition of renewing ACO, in combination with our proposal to discontinue use of the ''sit-out'' period after termination under § 425.222(a), would create the flexibility for any ACO within an agreement period to voluntarily terminate its current participation agreement and (if eligible) enter a new agreement period under the BASIC track or ENHANCED track, beginning at the start of the next performance year after the termination date of its previous agreement period, as early as July 1, 2019, thereby avoiding an interruption in participation. We would consider these ACOs to have effectively renewed their participation early. We note that we would assess the eligibility of the ACO to renew early under the revised evaluation criteria we are finalizing under amendments to § 425.224 as described in section II.A.5.c.(5). of this final rule.

Comment: One commenter, an existing ACO, expressed support for the early renewal option, and requested the opportunity to early renew as quickly as possible and with as little disruption as possible. This commenter seemed to favor benchmark rebasing at the start of the ACO's new agreement period. The commenter specifically suggested that CMS account for non-claims based payments consistently across benchmark and performance year expenditures. This commenter recommended that CMS provide an exception to enable Track 2 and Track 3 ACOs with physicians participating in the CPC+ Model to enter a new agreement period under the ENHANCED track as soon as is practicable to enable rebasing of the benchmark, ideally on July 1, 2019.

Response: We are finalizing policies in this final rule to allow for a July 1, 2019 agreement start date as the next available start date in the Shared Savings Program. We are also finalizing our proposed approach to remove the ''sit-out'' period after termination and the proposed definition of ''renewing ACO'' to include the early renewal option. As we previously explained in responding to comments in this section of this final rule, early renewal would be an option for all ACOs within a current agreement period within the Shared Savings Program. Therefore, the first opportunity for ACOs to renew early will be available for ACOs that start a 12-month performance year on January 1, 2019. These ACOs may terminate their participation agreements with an effective date of termination of June 30, 2019, and enter a new agreement period beginning on July 1, 2019.

We also explained in the August 2018 proposed rule (83 FR 41831) that early renewal results in rebasing of the ACO's historical benchmark. In section II.D. of this final rule we finalize the methodology for establishing, adjusting and updating the ACO's historical

benchmark for agreement periods beginning on July 1, 2019 and in subsequent years, and specify these policies in a new section of the regulations at § 425.601. We note that under this methodology, in calculating benchmark year expenditures we include individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program. Similarly, under the methodology for calculating performance year expenditures, we also take into consideration individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program. (See § 425.605(a)(5)(ii) on the calculation of shared savings and losses under the BASIC track, § 425.610(a)(6)(ii)(B) on calculation of shared savings and losses under the ENHANCED track.) We note that these expenditures are included in the calculations for the relevant year they are made.

The CPC+ Model began in 2017. Final CPC+ Model payments were included in expenditures for ACOs' assigned beneficiaries for performance year and benchmark year 2017, and similarly will be included in expenditures for subsequent years the model is available. If an ACO seeks to early renew for a new agreement period beginning on July 1, 2019, the historical benchmark years for the ACO's new agreement period will be 2016, 2017 and 2018. Therefore, if applicable, final CPC+ Model payments would be included in benchmark year expenditures for 2017 and 2018, and would be included in expenditures for each of the performance years in which they are made during the agreement period.

Comment: A few commenters supported the proposed approach to identifying re-entering ACOs including the proposal to identify new legal entities as re-entering ACOs if more than 50 percent of its ACO participants were included on the ACO participant list of the same ACO in any of the 5 most recent performance years prior to the agreement start date. One commenter supporting the proposed approach, recognized the opportunity for ACOs to reorganize or otherwise terminate and re-enter to secure participation in the Shared Savings Program under better terms as program rules or market conditions change. Some commenters generally supported a policy for determining whether an ACO is a re-entering ACO, but suggested alternative approaches. One commenter explained that the policy for identifying re-entering ACOs would be especially important if CMS finalized the proposed program redesign, as the commenter expected that the redesigned program would experience considerable churn or turnover in ACO participation, and the commenter suggested that CMS ensure that ACOs not be precluded from re-entering the program with ACO participants that previously had participated in a different ACO.

Several commenters suggested alternative approaches to identifying re-entering ACOs. One commenter suggested that CMS weight ACO participant TINs by their number of years in the program, to ensure that ACO participants with limited experience in the Shared Savings Program do not tip the scales for a new legal entity to be identified as a re-entering ACO.

One commenter expressed concern that the approach could ultimately limit participation by ACOs that are high revenue and new legal entities but composed of previous ACO participants in a Track 1 ACO. The commenter explained the proposed approach could expose newly formed ACO entities to a more aggressive glide path and drive very inexperienced ACOs, particularly high revenue ACOs, to accept higher levels of risk more quickly than they are actually prepared to handle. The commenter alternatively seemed to recommend that CMS identify re-entering ACOs based on whether both criteria (instead of either criterion) included in the proposed definition are met: (1) The ACO is the same legal entity as an ACO that previously participated in the program, and (2) more than 50 percent of its ACO participants were included on the ACO participant list of the same ACO in any of the 5 most recent performance years prior to the agreement start date.

Some commenters suggested that CMS should monitor the impact of the policies for identifying re-entering ACOs and ACOs that are experienced with performance-based risk Medicare ACO initiatives, as well as to create an appeals process for these determinations. They recommended using a threshold of 50 percent for both of these determinations (rather than using the proposed 40 percent threshold for determining ACOs experienced with performance-based risk Medicare ACO initiatives) and also setting an additional criterion that would allow an ACO determined to be a re-entering ACO or experienced performance-based risk Medicare ACO initiatives to appeal the determination if less than 30 percent of the ACO participants in the ACO were previously part of the same legal entity.

Response: We appreciate commenters' support of the proposed definition of re-entering ACO. In response to the commenter's suggestion that ACOs not be precluded from re-entering the program with ACO participants that previously had participated in a different ACO, we note that the proposed definition of a re-entering ACO would allow us to hold ACOs accountable for the experience of their legal entity and ACO participants, and ensure they are participating in the program under participation options and program policies that are reflective of this experience.

We decline to adopt the commenter's alternative suggestion to weight ACO participants by their number of years in the program, when identifying new legal entities as re-entering ACOs based on the prior participation in the Shared Savings Program by their ACO participants. We believe this approach may make it more challenging for applicants to anticipate whether their composition could result in a determination by CMS that they are a re-entering ACO. We are also concerned that such a weighting approach, which would allow ACOs to avoid being considered re-entering ACOs based on the duration of prior participation by ACO participants, could further encourage ACOs that are re-forming and re-entering the Shared Savings Program to manipulate their ACO participant lists to avoid accountability for their experience with the program.

Under the proposed definition of a re-entering ACO and under our proposals for determining participation options, which we are finalizing as discussed in section II.A.5.c.(5) of this final rule, new legal entities identified as re-entering ACOs that are high revenue ACOs, and inexperienced with performance-based risk Medicare ACO initiatives, would be eligible for participation under the BASIC track's glide path. However, as noted by the commenter, if the re-entering ACO is identified as having previously participated in Track 1, the ACO would be restricted to entering the glide path at Level B, therefore having relatively less time under a one-sided model compared to new legal entities that are eligible to enter the glide path at Level A. We believe that holding ACOs accountable for the previous experience of the ACO legal entity and its ACO participants in the Shared Savings Program, and Medicare ACO initiatives more broadly, and protecting the Trust Funds from ACOs that terminate from the program and re-enter the program in an effort to take advantage of program policies designed for ACOs inexperienced with accountable care models in FFS Medicare, outweigh the commenter's

concern that this approach could expose a new legal entity to higher levels of risk and potential reward than the ACO can manage. We would identify the ACO's participation options at the time of its application to the program, and the applicant would have the opportunity to determine whether to enter an agreement period in the Shared Savings Program under a participation option for which it is eligible.

We decline to adopt an approach that would only recognize ACOs as re-entering if they are identified as both the same legal entity as a former program participant, and if a majority of ACO participants previously participated in the same legal entity. We believe this approach would be too narrow and not identify some re-entering ACOs that are the same legal entity as an ACO whose participation agreement was terminated or whose participation agreement expired without having been renewed. These ACO legal entities would have previous experience with the Shared Savings Program and should not be allowed to take advantage of policies aimed at organizations new to the program's requirements or the accountable care model more generally.

We believe that some commenters recommending modifications to the process for determining re-entering ACOs and ACOs that are experienced with performance-based risk may have had confusion around our proposed policies. (We respond to the commenters' suggestions about the alternative approach to identifying ACOs experienced with performance-based risk Medicare ACO initiatives elsewhere in this section of this final rule.) We would like to clarify that the policy that we proposed, and are finalizing in this final rule, for determining new legal entities to be re-entering ACOs requires that more than 50 percent of an applicant's ACO participants have participated together as part of the same legal entity in any of the 5 most recent performance years prior to the agreement start date. Thus, all ACOs determined to be a re-entering ACO under this policy would automatically exceed the commenters' recommended secondary threshold of 30 percent to trigger eligibility for an appeal process. By contrast, the approach that we have proposed and are finalizing for determining ACOs experienced with performance-based risk Medicare ACO initiatives requires that, cumulatively, at least 40 percent of an applicant's ACO participants have participated in a performance-based risk Medicare ACO initiative in any of the 5 most recent performance years prior to the agreement start date, and does not require the ACO participants to have to participated together in the same legal entity. That being said, we decline to adopt an approach for determining re-entering ACOs such as recommended by the commenters that would require a multi-step process. That is, an initial determination for whether an ACO is a re-entering ACO, a secondary test to identify whether the ACO is eligible to request an appeal, and finally an appeal process for the final determination. We believe such an approach would add complexity as well as uncertainty as ACOs would need to request an appeal and await a final determination. Additionally, we currently have an established process for ACOs to request reconsiderations, as specified in subpart I of the program's regulations.

We also decline to adopt a lower percentage threshold as part of identifying new legal entities as re-entering ACOs, for the reasons we previously described in the August 2018 proposed rule and reiterated in this final rule. In particular, using a lower threshold for determining re-entering ACOs would further complicate the analysis for identifying the ACO or ACOs in which the ACO participants previously participated, and the ACO whose prior performance should be evaluated in determining the eligibility of the applicant ACO and for determining the applicability of program policies that phase-in over time.

More generally, we agree with commenters suggesting that we evaluate and monitor the policy once implemented.

Comment: One commenter supported a 5-year look back period in the definition of re-entering ACO, particularly in light of the proposal to allow for agreement periods of at least 5 years.

The commenter also supported the clarification that the 50 percent threshold would not be cumulative based on experience in any ACO over the past five years, but rather, based on 50 percent or more participants most recently participating in the same ACO. The commenter agreed this would serve CMS' goal of identifying ACOs with significant participant overlap (as described in the August 2018 proposed rule) while minimizing complexity that could easily arise from using other methods and therefore improve transparency.

Response: We thank the commenters for their support of the proposed 5-year look back period in the definition of ''re-entering ACO'', and support for an approach under which the threshold for prior participation by ACO participants is not cumulative.

Comment: One commenter disagreed with the idea that ACOs would invest substantial upfront start-up costs and undergo a major organizational shift or undergo the burdensome process of dissolving and re-forming under a different legal entity, much less voluntarily subject itself to shared losses, simply to ''game'' the system. The commenter asserted that the number of ACOs that drop out of the program after sustaining losses proves that waivers for certain service billing requirements or fraud and abuse restrictions are not enough to warrant continued participation in the program without the prospect of earning shared savings.

Response: We disagree with the commenter and continue to believe that there is clear value in program participation for ACOs that are not earning shared savings, as evidenced by the continued participation of ACOs that have not shared in the savings (such as ACOs that generate savings below their MSR), or ACOs that remain in the program despite generating the equivalent of losses, or even after sharing in losses. ACOs can be the catalyst for changing a health care system or provider network, and can provide a vehicle for transforming care in a community. However, we have concerns about the motivation of ACOs that continue their participation in the program despite poor performance. Under the program's current requirements, ACOs may continue their participation in the program despite poor financial performance, and we believe that the choice of many to do so indicates they may be able to take advantage of other program features, such as the ability to benefit from waivers of certain federal requirements in connection with their participation in the Shared Savings Program, and lack a genuine motivation to achieve the program's goals. With the more rapid transition to performance-based risk under the redesign of the program's participation options we are finalizing in this final rule, we believe that it is increasingly important for program integrity purposes that we protect against ACOs seeking to game program participation options including by re-forming and re-entering the program in an effort to take advantage of the BASIC track's glide path.

Final Action: After consideration of public comments, we are finalizing as proposed to define renewing ACO and re-entering ACO in new definitions in § 425.20.

We are finalizing our proposal to define renewing ACO to mean 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.

We are finalizing our proposal to define ''re-entering ACO'' to mean 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.

(b) Eligibility Requirements and Application Procedures for Renewing and Re-Entering ACOs

In the August 2018 proposed rule (83 FR 41823), we proposed to revise our regulations to clearly set forth the eligibility requirements and application procedures for renewing ACOs and re-entering ACOs. Therefore, we proposed to revise § 425.222 to address limitations on the ability of re-entering ACOs to participate in the Shared Savings Program for agreement periods beginning before July 1, 2019. In addition, we proposed to revise § 425.224 to address general application requirements and procedures for all re-entering ACOs and all renewing ACOs.

In revising § 425.222 (which consists of paragraphs (a) through (c)), we considered that removing the required ''sit-out'' period for terminated ACOs under § 425.222(a) would facilitate transition of ACOs within current 3-year agreement periods to new agreements under the participation options in the proposed rule. As discussed elsewhere in this section, we proposed to retain policies similar to those under § 425.222(b) for evaluating the eligibility of ACOs to participate in the program after termination. Further, instead of the approach used for determining participation options for ACOs that re-enter the program after termination described in § 425.222(c), our proposed approach to making these determinations is described in detail in section II.A.5.c.(5). of this final rule.

The ''sit-out'' period policy restricts the ability of ACOs in current agreement periods to transition to the proposed participation options under new agreements. For example, if left unchanged, the ''sit-out'' period would prevent existing, eligible Track 1 ACOs from quickly entering an agreement period under the proposed BASIC track and existing Track 2 ACOs from quickly entering a new agreement period under either the BASIC track at the highest level of risk (Level E), if available to the ACO, or the ENHANCED track. Participating under Levels C, D, or E of the BASIC track or under the ENHANCED track could allow eligible physicians and practitioners billing under ACO participant TINs in these ACOs to provide telehealth services under section 1899(l) of the Act (discussed in section II.B.2.b. of this final rule), the ACO could apply for a SNF 3-day rule waiver (as proposed in section II.B.2.a. of this final rule), and the ACO could elect to offer incentive payments to beneficiaries under a CMS-approved beneficiary incentive program (as proposed in section II.C.2. of this final rule).

The ''sit-out'' period also applies to ACOs that deferred renewal in a second agreement period under performance-based risk as specified in § 425.200(e)(2)(ii), a participation option we proposed to discontinue (as described in section II.A.2. of this final rule). Therefore, by eliminating the ''sit-out'' period, ACOs that deferred renewal may more quickly transition to the BASIC track (Level E), if available to the ACO, or the ENHANCED track. An ACO that deferred renewal and is currently participating in Track 2 or Track 3 may terminate its current agreement to enter a new agreement period under the BASIC track (Level E), if eligible, or the ENHANCED track. Similarly, an ACO that deferred renewal and is currently participating in Track 1 for a fourth performance year may terminate its current agreement and the participation agreement for its second agreement period under Track 2 or Track 3 that it deferred for 1 year. In either case, the ACO may immediately apply to re-enter the BASIC track (Level E), if eligible, or the ENHANCED track without having to wait until the date on which the term of its second agreement would have expired if the ACO had not terminated.

We noted that, to avoid interruption in program participation, an ACO that seeks to terminate its current agreement and enter a new agreement in the BASIC track or ENHANCED track beginning the next performance year should ensure that there is no gap in time between when it concludes its current agreement period and when it begins the new agreement period so that all related program requirements and policies would continue to apply. For an ACO that is completing a 12 month performance year and is applying to enter a new agreement period beginning January 1 of the following year, the effective termination date of its current agreement should be the last calendar day of its current performance year, to avoid an interruption in the ACO's program participation. For instance, for a 2018 starter ACO applying to enter a new agreement beginning on January 1, 2020, the effective termination date of its current agreement should be December 31, 2019. For an ACO that starts a 12-month performance year on January 1, 2019, that is applying to enter a new agreement period beginning on July 1, 2019 (as discussed in section II.A.7. of this final rule), the effective termination date of its current agreement should be June 30, 2019.

We proposed to amend § 425.224 to make certain policies applicable to both renewing ACOs and re-entering ACOs and to incorporate certain other technical changes, as follows:

(1) Revisions to refer to the ACO's ''application'' more generally, instead of specifically referring to a ''renewal request,'' so that the requirements would apply to both renewing ACOs and re-entering ACOs.

(2) Addition of a requirement, consistent with the current provision at § 425.222(c)(3), for ACOs previously in a two-sided model to reapply to participate in a two-sided model. We further proposed that a renewing or re-entering ACO that was previously under a one-sided model of the BASIC track's glide path may only reapply for participation in a two-sided model for consistency with our proposal to include the BASIC track within the definition of a performance-based risk Medicare ACO initiative. As proposed, this included a new ACO identified as a re-entering ACO because greater than 50 percent of its ACO participants have recent prior participation in the same ACO that was previously under a two-sided model or a one-sided model of the

BASIC track's glide path (Level A or Level B).

(3) Revision to § 425.224(b)(1)(iv) (as redesignated from § 425.224(b)(1)(iii)) to cross reference the requirement that an ACO establish an adequate repayment mechanism under § 425.204(f), to clarify our intended meaning with respect to the current requirement that an ACO demonstrate its ability to repay losses.

(4) Modifications to the 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 (under the proposed approach allowing for agreement periods of at least 5 years rather than 3-year agreements), and to prevent ACOs with a history of poor performance from participating in the program. As described in detail, as follows, we addressed: (1) Whether the ACO has a history of compliance with the program's quality performance standard; (2) whether an ACO under a two-sided model repaid shared losses owed to the program; (3) the ACO's history of financial performance; and (4) whether the ACO has demonstrated in its application that it has corrected the deficiencies that caused it to perform poorly or to be terminated.

First, we proposed modifications to the criterion governing our evaluation of whether the ACO has a history of compliance with the program's quality performance standard. We proposed to revise the existing provision at § 425.224(b)(1)(iv), which specifies that we evaluate whether the ACO met the quality performance standard during at least 1 of the first 2 years of the previous agreement period, to clarify that this criterion is used in evaluating ACOs that entered into a participation agreement for a 3-year period. We proposed 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 under § 425.316(c)(2) for failing to meet the quality performance standard or whether the ACO failed to meet the quality performance standard for 2 or more performance years of the previous agreement period, regardless of whether the years were consecutive.

In proposing this approach, we considered that the current policy is specified for ACOs with 3-year agreements. With the proposal to shift to agreement periods of not less than 5 years, additional years of performance data would be available at the time of an ACO's application to renew its agreement, and may also be available for evaluating ACOs re-entering after termination (depending on the timing of their termination) or the expiration of their prior agreement, as well as being available to evaluate new ACOs identified as re-entering ACOs because greater than 50 percent of their ACO participants have recent prior participation in the same ACO.

Further, under the program's monitoring requirements at § 425.316(c), ACOs with 2 consecutive years of failure to meet the program's quality performance standard will be terminated. However, we noted our concern about a circumstance where an ACO that fails to meet the quality performance standard for multiple, non-consecutive years may remain in the program by seeking to renew its participation for a subsequent agreement period, seeking to re-enter the program after termination or expiration of its prior agreement, or by re-forming to enter under a new legal entity (identified as a re-entering ACO based on the experience of its ACO participants).

Second, we proposed to revise 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 (§ 425.224(b)(1)(v)), to instead consider whether the ACO failed to repay shared losses in full within 90 days in accordance with subpart G of the regulations for any performance year of the ACO's previous agreement period. As described in section II.A.7. of this final rule, CY 2019 will include two, 6-month performance years. In the November 2018 final rule (83 FR 59942 through 59946) we finalized the option for ACOs that started a first or second agreement period on January 1, 2016, to elect an extension of their agreement period by 6 months from January 1, 2019 through June 30, 2019. In this final rule we are finalizing an agreement period start date of July 1, 2019, which includes a 6-month first performance year from July 1, 2019, through December 31, 2019. We will reconcile these ACOs, and ACOs that start a 12-month performance year on January 1, 2019, and terminate their participation agreement with an effective date of termination of June 30, 2019, and enter a new agreement period beginning on July 1, 2019, separately for the 6-month periods from January 1, 2019, through June 30, 2019, and from July 1, 2019, through December 31, 2019, as described in section II.A.7. of this final rule. In evaluating this proposed criterion on repayment of losses, we would consider whether the ACO timely repaid any shared losses for these 6-month performance years, or the 6-month performance period for ACOs that elect to voluntarily terminate their existing participation agreement, effective June 30, 2019, and enter a new agreement period starting on July 1, 2019, which we will determine according to the methodology specified under a new section of the regulations at § 425.609.

The current policy regarding repayment of shared losses is specified for ACOs with 3-year agreements. With the proposal to shift to agreement periods of at least 5 years, we considered it would be appropriate to broaden our evaluation of the ACO's timely repayment of shared losses beyond the first 2 years of the ACO's prior agreement period. For instance, without modification, this criterion could have little relevance when evaluating the eligibility of ACOs in the proposed BASIC track's glide path that elect to participate under a one-sided model for their first 2 performance years (or 3 performance years for ACOs that start an agreement period in the proposed BASIC track's glide path on July 1, 2019).

We noted that timely repayment of shared losses is required under subpart G of the regulations (§§ 425.606(h)(3) and 425.610(h)(3)), and non-compliance with this requirement may be the basis for pre-termination actions or termination under §§ 425.216 and 425.218. We explained that a provision that permits us to consider more broadly whether an ACO failed to timely repay shared losses for any performance year in the previous agreement period would be relevant to all renewing and re-entering ACOs that may have unpaid shared losses, as well as all re-entering ACOs that may have been terminated for non-compliance with the repayment requirement. This includes ACOs that have participated under Track 2, Track 3, and ACOs that would participate under the BASIC track or ENHANCED track for a new agreement period. For ACOs that have participated in two-sided models authorized under section 1115A of the Act, including the Track 1+ Model, we also proposed to consider whether an ACO failed to repay shared losses for any performance year under the terms of the ACO's participation agreement for such model.

Third, we proposed to add a financial performance review criterion to § 425.224(b) to allow us to evaluate whether the ACO generated losses that were negative outside corridor for 2 performance years of the ACO's previous agreement period. We

proposed to use this criterion to evaluate the eligibility of ACOs to enter agreement periods beginning on July 1, 2019 and in subsequent years. For purposes of this proposal, 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. This proposed approach relates to our proposal to monitor for financial performance as described in section II.A.5.d. of this final rule.

Lastly, we proposed to add a review criterion to § 425.224(b), which would allow us to consider whether the ACO has demonstrated in its application that it has corrected the deficiencies that caused it to fail to meet the quality performance standard for 2 or more years, fail to timely repay shared losses, or to generate losses outside its negative corridor for 2 years, or any other factors that may have caused the ACO to be terminated from the Shared Savings Program. We proposed to require that the ACO also demonstrate it has processes in place to ensure that it will remain in compliance with the terms of the new participation agreement.

We proposed 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. We believe the proposed financial performance review criterion would be more effective in identifying ACOs with a pattern of poor financial performance. An approach that accounts for financial performance year after year allows ACOs to understand if their performance is triggering a compliance concern and take action to remedy their performance during the remainder of their agreement period. Further, an approach that only considers net losses across performance years may not identify as problematic an ACO that generates losses in multiple years which in aggregate are canceled out by a single year with large savings. Although uncommon, such a pattern of performance, where an ACO's results change rapidly and dramatically, is concerning and warrants consideration in evaluating the ACO's suitability to continue its participation in the program.

This proposed requirement is similar to the current provision at § 425.222(b), which specifies that a previously terminated ACO must demonstrate that it has corrected deficiencies that caused it to be terminated from the program and has processes in place to ensure that it will remain in compliance with the terms of its new participation agreement. We proposed to discontinue use of § 425.222. We explained that adding a similar requirement to § 425.224 would allow us to more consistently apply policies to renewing and re-entering ACOs. Further, applying this requirement to both re-entering and renewing ACOs would safeguard the program against organizations that have not met the program's goals or complied with program requirements and that may not be qualified to participate in the program, and therefore this approach would be protective of the program, the Trust Funds, and Medicare FFS beneficiaries.

For ACOs identified as re-entering ACOs because greater than 50 percent of their ACO participants have recent prior participation in the same ACO, we would determine the eligibility of the ACO to participate in the program based on the past performance of this other entity. For example, if ACO A is identified as a re-entering ACO because more than 50 percent of its ACO participants previously participated in ACO B during the relevant look back period, we would consider ACO B's financial performance, quality performance, and compliance with other program requirements in determining the eligibility of ACO A to enter a new participation agreement in the program.

Comment: We received few comments directly addressing the proposal to remove the ''sit-out'' period after termination. Generally, the comments we received were supportive of the proposal to modify current restrictions that prevent an ACO from terminating its participation agreement and re-entering the program before the existing agreement period would have ended. Commenters explained that this ''sit-out'' period is unnecessary and shuts healthcare providers out of participating in an essential CMS value-based program. Commenters also supported eliminating this restriction to allow the flexibility for an ACO in a current 3-year agreement period to terminate its participation agreement and then enter a new 5-year agreement period under one of the proposed redesigned participation options. One commenter explained that maintaining the sit-out period after termination could diminish participation in the program and restrict the ability of ACOs in current agreement periods to transition to the proposed participation options under new agreements.

Response: We appreciate commenters' support of the proposal to remove the required ''sit-out'' period for terminated ACOs under § 425.222(a). In particular, we appreciate commenters' support of this approach which will facilitate transition of ACOs to new agreements under the participation options established in this final rule, including the transition of ACOs currently in 3-year agreement periods to new agreement periods of at least 5-years through the early renewal process described in section II.A.5.c.(4).(a). of this final rule.

Comment: One commenter recommended that CMS take into account the impact of extreme and uncontrollable circumstances on ACOs when applying the prior participation criteria.

Response: We appreciate the commenter's suggestion that we take into account the impact of extreme and uncontrollable circumstances when evaluating the eligibility of ACOs to renew their participation in or re-enter the Shared Savings Program. We note that, under our proposed evaluation criteria, we would also consider whether the ACO has demonstrated in its application that it has corrected the deficiencies that caused it to perform poorly or to be terminated. We believe that this provides a means for ACOs to explain the particular circumstances that affected their results during their prior participation, including the impact of extreme and uncontrollable circumstances, and for CMS to consider this information in evaluating the eligibility of ACOs to renew their participation in or re-enter the Shared Savings Program. We will also continue to monitor the impact of extreme and uncontrollable circumstances on ACOs, particularly as we gain experience with the disaster-relief policies we have finalized for performance year 2017 and subsequent performance years, including adjusting quality performance scores for affected ACOs, and mitigating shared losses for ACOs under two-sided models, and will consider whether any changes to our eligibility criteria may be necessary to account for the effects of extreme and uncontrollable circumstances. Any such changes would be made through notice and comment rulemaking.

Comment: Another commenter suggested we streamline the renewal process for ACOs that have demonstrated positive performance results, such as requiring that they complete a brief form with minimal information required.

Response: In the CY 2018 PFS final rule (82 FR 53217 through 53222), we

modified the program's application to reduce burden on all applicants. These changes included revisions to § 425.204 to remove the requirements for ACOs to submit certain documents and narratives as part of its Shared Savings Program application. We believe these requirements have streamlined the application process. As described in section II.A.5.c.(5).(d) of this final rule, we are discontinuing use of condensed Shared Savings Program applications by former Physician Group Practice (PGP) demonstration sites and former Pioneer ACOs. We explain our belief that it is no longer necessary to permit these entities to use condensed application forms. For similar reasons, we therefore also decline to allow alternative applications for other categories of ACOs.

Comment: One commenter suggested that CMS revisit the evaluation criterion for prior quality performance relevant to ACOs' participation in longer agreement periods in future rulemaking as it becomes implemented and applicable to ACOs over time.

Response: We appreciate the commenter's suggestion to consider our experience with the evaluation criterion for poor quality performance in light of longer agreement periods (not less than 5-years) finalized in this final rule. As with other program policies, we may revisit this approach based on lessons learned, in future rulemaking.

Final Action: After consideration of public comments, we are finalizing as proposed to revise § 425.222 to remove the required ''sit-out'' period for terminated ACOs under § 425.222(a) to facilitate transition of ACOs to new agreements under the participation options established in this final rule. We are retaining policies similar to those under § 425.222(b) for evaluating the eligibility of ACOs to participate in the program after termination in modifications to § 425.224. Instead of the approach used for determining participation options for ACOs that re-enter the program after termination described in § 425.222(c), we will make these determinations consistent with our final policies described in section II.A.5.c.(5) of this final rule.

We received no comments directly addressing the proposals to revise § 425.224 to make certain policies applicable to both renewing ACOs and re-entering ACOs and to incorporate certain other technical changes, as described in this section of this final rule. We are finalizing as proposed amendments to § 425.224 to include the following changes:

- Revisions to refer to the ACO's ''application'' more generally, instead of specifically referring to a ''renewal request,'' so that the requirements would apply to both renewing ACOs and re-entering ACOs.
- Addition of a requirement, consistent with the current provision at § 425.222(c)(3), for ACOs previously in a two-sided model to reapply to participate in a two-sided model. We are finalizing an approach for determining participation options under which a renewing or re-entering ACO that was previously under a one-sided model of the BASIC track's glide path may only reapply for participation in a two-sided model for consistency with our final policy to include the BASIC track within the definition of a performance-based risk Medicare ACO initiative (described in section II.A.5.c.(5) of this final rule). This includes a new ACO identified as a re-entering ACO because greater than 50 percent of its ACO participants have recent prior participation in the same ACO that was previously under a two-sided model or a one-sided model of the BASIC track's glide path (Level A or Level B).
- Revision to § 425.224(b)(1)(iv) (as redesignated from § 425.224(b)(1)(iii)) to cross reference the requirement that an ACO establish an adequate repayment mechanism under § 425.204(f), to clarify our intended meaning with respect to the current requirement that an ACO demonstrate its ability to repay losses.
- Modifications to the 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 (under the proposed approach allowing for agreement periods of at least 5 years rather than 3-year agreements), and to prevent ACOs with a history of poor performance from participating in the program. The criteria include: (1) Whether the ACO has a history of compliance with the program's quality performance standard; (2) the ACO's history of financial performance; (3) whether an ACO under a two-sided model repaid shared losses owed to the program; and (4) whether the ACO has demonstrated in its application that it has corrected the deficiencies that caused it to perform poorly or to be terminated.

In light of these other final policies, we are also finalizing our proposal to discontinue use of the requirement at § 425.600(c), under which an ACO with net losses during a previous agreement period must identify in its application the causes for the net loss and specify what safeguards are in place to enable it to potentially achieve savings in its next agreement period.

(5) Proposed Evaluation Criteria for Determining Participation Options

(a) Background

As we explained in section II.A.5.c.(5) of the August 2018 proposed rule (83 FR 41825 through 41834), we have a number of concerns 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 and its ACO participants with the Shared Savings Program and other performance-based risk Medicare ACO initiatives.

First, as the program matures and ACOs become more prevalent throughout the country, and as an increasing number of ACO participants become experienced in different Medicare ACO initiatives with differing levels of risk, the regulations as currently written create flexibilities that would allow more experienced ACOs to take advantage of the opportunity to participate under the proposed BASIC track's glide path.

There are many Medicare ACO initiatives in which organizations may gain experience, specifically: Shared Savings Program Track 1, Track 2 and Track 3, as well as the proposed BASIC track and ENHANCED track, and the Track 1+ Model, Pioneer ACO Model, Next Generation ACO Model, and the Comprehensive End-Stage Renal Disease (ESRD) Care (CEC) Model. All but Shared Savings Program Track 1 ACOs and non-Large Dialysis Organization (LDO) End-Stage Renal Disease Care Organizations (ESCOs) participating in the one-sided model track of the CEC Model participate in a degree of performance-based risk within an ACO's agreement period in the applicable program or model.

We proposed to discontinue application of the policies in § 425.222(a). As a result of this change, we would allow ACOs currently participating in Track 1, Track 2, Track 3, or the Track 1+ Model, to choose whether to finish their current agreement or to terminate and apply to immediately enter a new agreement period through an early renewal. We explained our concern that removing the existing safeguard under § 425.222(a) without putting in place other policies that assess an ACO's experience with performance-based risk would enable ACOs to participate in the BASIC track's glide path in Level A and Level B, under a one-sided model, terminate, and enter a one-sided model of the glide path again.

We also stated our concern that existing and former Track 1 ACOs would have the opportunity to gain additional time under a one-sided model of the BASIC track's glide path before accepting performance-based risk. Under the current regulations, Track 1 ACOs are limited to two

agreement periods under a one-sided model before transitioning to a two-sided model beginning with their third agreement period (see § 425.600(b)). Without some restriction, Track 1 ACOs that would otherwise be required to assume performance-based risk at the start of their third agreement period in the program could end up continuing to participate under a one-sided model (BASIC track's Levels A and B) for 2 additional performance years, or 3 additional performance years in the case of ACOs that enter the BASIC track's glide path for an agreement period of 5 years and 6 months beginning July 1, 2019, under the participation options as proposed. We explained our belief that the performance-based risk models within the BASIC track's glide path would offer former Track 1 ACOs an opportunity to continue participation within the program under relatively low levels of two-sided risk and that these ACOs have sufficient experience with the program to begin the gradual transition to performance-based risk. Therefore some restriction would be needed to prevent all current and previously participating Track 1 ACOs from taking advantage of additional time under a one-sided model in the BASIC track's glide path and instead to encourage their more rapid progression to performance-based risk. For similar reasons we also believed it would be important to prevent new ACOs identified as re-entering ACOs because greater than 50 percent of their ACO participants have recent prior participation in a Track 1 ACO from also taking advantage of additional time under a one-sided model in the BASIC track's glide path. This restriction would help to ensure that ACOs do not re-form as new legal entities to maximize the time allowed under a one-sided model.

We also considered that currently § 425.202(b) of the program's regulations addresses application requirements for organizations that were previous participants in the PGP demonstration, which concluded in December 2012 with the completion of the PGP Transition Demonstration, and the Pioneer ACO Model, which concluded in December 2016, as described elsewhere in this section. We proposed to eliminate these provisions, while at the same time proposing criteria for identifying ACOs and ACO participants with previous experience in Medicare ACO initiatives as part of a broader approach to determining available participation options for applicants.

Second, using prior participation by ACO participant TINs in Medicare ACO initiatives along with the prior participation of the ACO legal entity would allow us to gauge the ACO's experience, given the observed churn in ACO participants over time and our experience with determining eligibility to participate in the Track 1+ Model. ACOs are allowed to make changes to their certified ACO participant list for each performance year, and we have observed that, each year, about 80 percent of ACOs make ACO participant list changes. We also considered CMS' recent experience with determining the eligibility of ACOs to participate in the Track 1+ Model. The Track 1+ Model is designed to encourage more group practices, especially small practices, to advance to performance-based risk. As such, it does not allow participation by current or former Shared Savings Program Track 2 or Track 3 ACOs, Pioneer ACOs, or Next Generation ACOs. As outlined in the Track 1+ Model Fact Sheet, the same legal entity that participated in any of these performance-based risk ACO initiatives cannot participate in the Track 1+ Model. Furthermore, an ACO would not be eligible to participate in the Track 1+ Model if 40 percent or more of its ACO participants had participation agreements with an ACO that was participating in one of these performance-based risk ACO initiatives in the most recent prior performance year.

Third, any approach to determining participation options relative to the experience of ACOs and ACO participants must also factor in the differentiation between low revenue ACOs and high revenue ACOs, as previously discussed in this section.

Fourth, and lastly, we explained that the experience of ACOs and their ACO participants in Medicare ACO initiatives should be considered in determining which track (BASIC track or ENHANCED track) the ACO is eligible to enter as well as the applicability of policies that phase-in over time, namely the equal weighting of benchmark year expenditures, the policy of adjusting the benchmark based on regional FFS expenditures (which, for example, applies different weights in calculating the regional adjustment depending upon the ACO's agreement period in the program) and the phase-in of pay-for-performance under the program's quality performance standards.

Although § 425.222(c) specifies whether a former one-sided model ACO can be considered to be entering its first or second agreement period under Track 1 if it is re-entering the program after termination, the current regulations do not otherwise address how we should determine the applicable agreement period for a previously participating ACO after termination or expiration of its previous participation agreement.

(b) Approach to Determining ACOs' Participation Options

In the August 2018 proposed rule we stated our preference for an approach that would help to ensure that ACOs, whether they are initial applicants to the program, renewing ACOs or re-entering ACOs, would be treated comparably (83 FR 41826). Any approach should also ensure eligibility for participation options reflects the ACO's and ACO participants' experience with the program and other Medicare ACO initiatives and be transparent. Therefore, we proposed 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.

As a factor in determining an ACO's participation options, we proposed to establish requirements for evaluating whether an ACO is inexperienced with performance-based risk Medicare ACO initiatives such that the ACO would be eligible to enter into an agreement period under the BASIC track's glide path or whether the ACO is experienced with performance-based risk Medicare ACO initiatives and therefore limited to participating under the higher-risk tracks of the Shared Savings Program (either an agreement period under the maximum level of risk and potential reward for the BASIC track (Level E), or the ENHANCED track).

To determine whether an ACO is inexperienced with performance-based risk Medicare ACO initiatives, we proposed that both of the following requirements would need to be met: (1) The ACO legal entity has not participated in any performance-based risk Medicare ACO initiative (for example, the ACO is a new legal entity identified as an initial applicant or the same legal entity as a current or previously participating Track 1 ACO); and (2) CMS determines that less than 40 percent of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative in each of the 5 most recent performance years prior to the agreement start date.

We proposed that CMS would determine that an ACO is experienced

with performance-based risk Medicare ACO initiatives if either of the following criteria are met: (1) The ACO is the same legal entity as a current or previous participant in a performance-based risk Medicare ACO initiative; or (2) CMS determines that 40 percent or more of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative in any of the 5 most recent performance years prior to the agreement start date.

We proposed to specify these requirements in a new provision at § 425.600(d). This provision would be used to evaluate eligibility for specific participation options for any ACO that is applying to enter the Shared Savings Program for the first time or to re-enter after termination or expiration of its previous participation agreement, or any ACO that is renewing its participation. As specified in the proposed definition of re-entering ACO, we also proposed to apply the provisions at § 425.600(d) to new ACOs identified as re-entering ACOs because greater than 50 percent of their ACO participants have recent prior participation in the same ACO. Thus, the proposed provision at § 425.600(d) would also apply in determining eligibility for these ACOs to enter the BASIC track's glide path for agreement periods beginning on July 1, 2019, and in subsequent years. Because the 40 percent threshold that we proposed to use to identify ACOs as experienced or inexperienced with performance-based risk on the basis of their ACO participants' prior participation in certain Medicare ACO initiatives is lower than the 50 percent threshold that would be used to identify new legal entities as re-entering ACOs based on the prior participation of their ACO participants in the same ACO, this proposed policy would automatically capture new legal entities identified as re-entering ACOs that have experience with performance-based risk based on the experience of their ACO participants.

We also proposed to add new definitions at § 425.20 for ''Experienced with performance-based risk Medicare ACO initiatives'', ''Inexperienced with performance-based risk Medicare ACO initiatives'' and ''Performance-based risk Medicare ACO initiative''.

We proposed to define ''performance-based risk Medicare ACO initiative'' to mean an initiative implemented by CMS that requires an ACO to participate under a two-sided model during its agreement period. We proposed this would include Track 2, Track 3 or the ENHANCED track, and the proposed BASIC track (including Level A through Level E) of the Shared Savings Program. We also proposed this would include the following Innovation Center ACO Models involving two-sided risk: The Pioneer ACO Model, Next Generation ACO Model, the performance-based risk tracks of the CEC Model (including the two-sided risk tracks for LDO ESCOs and non-LDO ESCOs), and the Track 1+ Model. The proposed definition also included such other Medicare ACO initiatives involving two-sided risk as may be specified by CMS.

We proposed to define ''experienced with performance-based risk Medicare ACO initiatives'' to mean an ACO that CMS determines meets either of the following criteria:

- The ACO is the same legal entity as a current or previous ACO that is participating in, or has participated in, a performance-based risk Medicare ACO initiative as defined under § 425.20, or that deferred its entry into a second Shared Savings Program agreement period under Track 2 or Track 3 in accordance with § 425.200(e).
- 40 percent or more of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative as defined under § 425.20, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under Track 2 or Track 3 in accordance with § 425.200(e), in any of the 5 most recent performance years prior to the agreement start date.

As we previously discussed, we proposed to discontinue use of the ''sit-out'' period under § 425.222(a) as well as the related ''sit-out'' period for ACOs that deferred renewal under § 425.200(e). Thus, we proposed to identify all Track 1 ACOs that deferred renewal as being experienced with performance-based risk Medicare ACO initiatives. This would include ACOs that are within a fourth and final year of their first agreement period under Track 1 because they were approved to defer entry into a second agreement period under Track 2 or Track 3, and ACOs that have already entered their second agreement period under a two-sided model after a one year deferral. Under § 425.200(e)(2), in the event that a Track 1 ACO that has deferred its renewal terminates its participation agreement before the start of the first performance year of its second agreement period under a two-sided model, the ACO is considered to have terminated its participation agreement for its second agreement period under § 425.220. In this case, when the ACO seeks to re-enter the program after termination, it would need to apply for a two-sided model. Our proposal to consider ACOs that deferred renewal to be experienced with performance-based risk Medicare ACO initiatives and therefore eligible for either the BASIC track's Level E (if a low revenue ACO and certain other requirements are met) or the ENHANCED track, would ensure that ACOs that deferred renewal continue to be required to participate under a two-sided model in all future agreement periods under the program consistent with our current policy under § 425.200(e)(2).

We proposed to define ''inexperienced with performance-based risk Medicare ACO initiatives'' to mean an ACO that CMS determines meets all of the following requirements:

- The ACO is a legal entity that has not participated in any performance-based risk Medicare ACO initiative as defined under § 425.20, and has not deferred its entry into a second Shared Savings Program agreement period under Track 2 or Track 3 in accordance with § 425.200(e); and
- Less than 40 percent of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative as defined under § 425.20, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under Track 2 or Track 3 in accordance with § 425.200(e), in each of the 5 most recent performance years prior to the agreement start date.

Under our proposed approach, for an ACO to be eligible to enter an agreement period under the BASIC track's glide path, less than 40 percent of its ACO participants can have participated in a performance-based risk Medicare ACO initiative in each of the five prior performance years. This proposed requirement was modeled after the threshold currently used in the Track 1+ Model (see Track 1+ Model Fact Sheet), although with a longer look back period. Based on experience with the Track 1+ Model during the 2018 application cycle, we did not believe that the proposed parameters would be excessively restrictive. We considered the following issues in developing our proposed approach: (1) Whether to consider participation of ACO participants in a particular ACO, or cumulatively across multiple ACOs, during the 5-year look back period; (2) whether to use a shorter or longer look back period; and (3) whether to use a threshold amount lower than 40 percent.

We proposed that in applying this threshold, we would not limit our consideration to ACO participants that participated in the same ACO or the same performance-based risk Medicare ACO initiative during the look back period. Rather, we would determine, cumulatively, what percentage of ACO participants were in any performance-based risk Medicare ACO initiative in each of the 5 most recent performance years prior to the agreement start date.

We provided the following illustrations help to clarify the use of the proposed threshold for determining ACO participants' experience with performance-based risk Medicare ACO initiatives.

For applicants applying to enter the BASIC track for an agreement period beginning on July 1, 2019, for example, we proposed that we 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 of the Shared Savings Program, the Track 1+ Model, the Pioneer ACO Model, the Next Generation ACO Model, or the performance-based risk tracks of the CEC Model. In future years (in determining eligibility for participation options for agreement periods starting in 2020 and subsequent years), we would also consider prior participation in the BASIC track and ENHANCED track (which we proposed would become available for agreement periods beginning on July 1, 2019 and in subsequent years).

An ACO would be ineligible for the BASIC track's glide path if, for example, in the performance year prior to the start of the agreement period, 20 percent of its ACO participants participated in a Track 3 ACO and 20 percent of its ACO participants participated in a Next Generation ACO, even if the ACO did not meet or exceed the 40 percent threshold in any of the remaining 4 performance years of the 5-year look back period.

We considered a number of alternatives for the length of the look back period for determining an ACO's experience or inexperience with performance-based risk Medicare ACO initiatives. For example, we considered using a single performance year look back period, as used under the Track 1+ Model. We also considered using a longer look back period, for example of greater than 5 performance years, or a shorter look back period that would be greater than 1 performance year, but less than 5 performance years, such as a 3 performance year look back period.

A number of considerations informed our proposal to use a 5 performance year look back period. For one, a longer look back period would help to guard against a circumstance where an ACO enters the BASIC track's glide path, terminates its agreement after one or 2 performance years under a one-sided model and seeks to enter the program under the one-sided model of the glide path. Whether or not the ACO applies to enter the program as the same legal entity or a new legal entity, the proposed eligibility criteria would identify this ACO as experienced with performance-based risk Medicare ACO initiatives if its ACO participant list remains relatively unchanged. Second, a longer look back period may reduce the incentive for organizations to wait out the period in an effort to re-form as a new legal entity with the same or very similar composition of ACO participants for purposes of gaming program policies. Third, a longer look back period also recognizes that new ACOs composed of ACO participants that were in performance-based risk Medicare ACO initiatives many years ago (for instance more than 5 performance years prior to the ACO's agreement start date) may benefit from gaining experience with the program's current requirements under the glide path, prior to transitioning to higher levels of risk and reward. Fourth, and lastly, in using the 5 most recent performance years prior to the start date of an ACO's agreement period, for ACOs applying to enter an agreement period beginning on July 1, 2019, we proposed to consider the participation of ACO participants during the first 6 months of 2019. This would allow us to capture the ACO participants' most recent prior participation in considering an ACO's eligibility for participation options for an agreement period beginning July 1, 2019. An alternative approach that bases the look back period on prior calendar years would overlook this partial year of participation in 2019.

We also considered using a threshold amount lower than 40 percent. Based on checks performed during the 2018 application cycle, for the average Track 1+ Model applicant, less than 2 percent of ACO participants had participated under performance-based risk in the prior year. The maximum percentage observed was 30 percent. In light of these findings, we considered whether to propose a lower threshold for eligibility to participate in the BASIC track's glide path. However, our goal was not to be overly restrictive, but rather to ensure that ACOs with significant experience with performance-based risk are appropriately placed. While we indicated our preference for 40 percent for its consistency with the Track 1+ Model requirement, we also sought comment on other numeric thresholds.

As previously discussed in this section, some restriction would be needed to prevent all current and 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, from taking advantage of additional time under a one-sided model in the BASIC track's glide path. We explained that an approach that restricts the amount of time a former Track 1 ACO or a new ACO, identified as a re-entering ACO because of its ACO participants' prior participation in a Track 1 ACO, may participate in the one-sided models of the BASIC track's glide path (Level A and Level B) would balance several concerns. Allowing Track 1 ACOs and eligible re-entering ACOs some opportunity to continue participation in a one-sided model within the BASIC track's glide path could smooth their transition to performance-based risk. For example, it would provide these ACOs a limited time under a one-sided model in a new agreement period under the BASIC track, during which they could gain experience with their rebased historical benchmark, and prepare for the requirements of participation in a two-sided model (such as establishing a repayment mechanism arrangement). Limiting time in the one-sided models of the BASIC track's glide path for former Track 1 ACOs and new ACOs that are identified as re-entering ACOs because of their ACO participants' recent prior participation in the same Track 1 ACO would also allow these ACOs to progress more rapidly to performance-based risk, and therefore further encourage accomplishment of the program's goals.

After weighing these considerations, we proposed 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. Former Track 1 ACOs and new ACOs identified as re-entering ACOs because of their ACO participants' prior participation in a Track 1 ACO would not be eligible to participate under Level A of the glide path. Therefore, if an ACO enters the glide path at Level B and is automatically transitioned through the levels of the glide path, the ACO would participate in Level E for the final 2 performance years of its agreement period. For a former Track 1 ACO or a new ACO identified as a re-entering ACO because of its ACO participants' prior participation in a Track 1 ACO that enters an agreement period in the BASIC track's glide path beginning on July 1, 2019, the ACO could participate under Level B for a 6-month performance year from July 1, 2019 through December 31, 2019 and the 12 month performance year 2020 (as

discussed in section II.A.7.c. of this final rule). A former Track 1 ACO or a new ACO identified as a re-entering ACO because of its ACO participants' prior participation in a Track 1 ACO that begins an agreement period in the BASIC track's glide path in any subsequent year (2020 and onward) could participate in Level B for 1 performance year before advancing to a two-sided model within the glide path.

We also considered a more aggressive approach to transitioning ACOs with experience in Track 1 to performance-based risk. Specifically, we considered whether the one-sided models of the BASIC track's glide path should 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. Under this alternative, ACOs that are experienced with Track 1, would be required to enter the BASIC track's glide path under performance-based risk at Level C, D or E. This alternative would more aggressively transition ACOs along the glide path. This approach would recognize that some of these ACOs may have already had the opportunity to participate under a one-sided model for 6 performance years (or 7 performance years for ACOs that elect to extend their agreement period for the 6-month performance year from January 1, 2019 through June 30, 2019), and should already have been taking steps to prepare to enter performance-based risk to continue their participation in the program under the current requirements, and therefore should not be allowed to take advantage of additional time under a one-sided model. For ACOs that have participated in a single agreement period in Track 1, an approach that requires transition to performance-based risk at the start of their next agreement period would be more consistent with the proposed redesign of participation options, under which ACOs would be allowed only 2 years, or 2 years and 6 months in the case of July 1, 2019 starters, under the one-sided models of the BASIC track's glide path. We sought comment on this alternative approach.

We proposed to specify these requirements in revisions to the regulations under § 425.600, which would be applicable for determining participation options for agreement periods beginning on July 1, 2019, and in subsequent years. We sought comment on these proposals for determining an ACO's participation options by evaluating the ACO legal entity's and ACO participants' experience or inexperience with performance-based risk Medicare ACO initiatives. In particular, we welcomed commenters' input on our proposal to assess ACO participants' experience with performance-based risk Medicare ACO initiatives using a 40 percent threshold, and the alternative of employing a threshold other than 40 percent, for example, 30 percent. We welcomed comments on the proposed 5 performance year look back period for determining whether an ACO is experienced or inexperienced with performance-based risk Medicare ACO initiatives, and our consideration of a shorter look back period, such as 3 performance years. We also welcomed comments on our proposal to limit former Track 1 ACOs and 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 to a single performance year under the one-sided models of the BASIC track's glide path (two performance years, in the case of an ACO starting its agreement period under the BASIC track on July 1, 2019), and the alternative approach that would preclude such ACOs from participating in one-sided models of the BASIC track's glide path.

Comment: Some commenters supported the proposed approach to differentiating participation options based on the experience or inexperience of the ACO legal entity or its ACO participants.

Some commenters expressed concern that the proposed approach to identifying ACOs experienced with performance-based risk Medicare ACO initiatives was too broad. One commenter explained that the approach assumes transferability of experience across population and geography. Another commenter asserts that the determination of experience based on ACO participants rather than the ACO legal entity puts new ACOs at a substantial disadvantage, particularly in markets where most providers have been in an ACO. This commenter believes that experience of the ACO participants does not necessarily equate to the ACO being experienced. Several commenters expressed concern that a 40 percent threshold leaves a majority of participants who would have no prior experience with the accountable care model, and which need more time to familiarize themselves with program requirements and the type of system reforms inherent to participating in a population-based APM.

Some commenters expressed concern that the distinctions for determining participation options, including between ACOs experienced with performance-based risk Medicare ACO initiatives or inexperienced with performance-based risk Medicare ACO initiatives add complexity to the program. Several commenters expressed concern that ACOs would have difficulty anticipating these determinations. One commenter explained that the proposed complexities for determining ACO participation options could make it hard for some groups to understand which track/level to participate in and how long to remain in such track/level. Furthermore, these complexities could disincentivize healthcare providers from participating in the Shared Savings Program. Several commenters recommended that CMS provide additional guidance on the different participation parameters and options so that healthcare providers have more information for their planning process. For example this commenter suggested that CMS provide ACOs with detailed descriptions of each definition used in determining participation options (low revenue ACO/high revenue ACO, and experienced with performance-based risk Medicare ACO initiatives/inexperienced with performance-based risk Medicare ACO initiatives) well in advance of any decision deadline. One commenter recommended using a policy that allows ACOs to easily understand their options for participation ahead of time. One commenter recommended CMS clarify the timelines and detailed processes for how it will monitor, review and communicate to ACOs each ACO's status with respect to their categorization.

One commenter suggested that the distinction between experienced versus inexperienced with performance-based risk Medicare ACO initiatives should only be applied to determining whether and for how long an ACO entity may participate in a one-sided model. This commenter did not support ACO entities being required to participate in the ENHANCED track due to experience with performance-based risk Medicare ACO initiatives, preferring instead that all ACO entities be allowed to participate in Level E of the BASIC track.

Commenters suggested a variety of alternative approaches including the following:

- One commenter suggested that CMS consider the experience of both the ACO participant TINs and NPIs in making the determination whether the ACO is experienced with performance-based risk Medicare ACO initiatives. This commenter explained that a straight percentage of TINs is more straightforward, however, the

commenter expressed that it could be unnecessarily limiting to ACOs comprised of large, single TIN entities. This commenter suggested that CMS should consider allowing ACOs to use a calculation based on TINs or NPIs as appropriate for their composition.

- One commenter suggested that CMS consider whether the ACO previously managed a majority of the same beneficiary population.
- One commenter suggested that we allow greater flexibility in choice of participation options to ''high performing'' ACOs, and requiring ''low performers'' to either quickly demonstrate success or be terminated.
- A few commenters suggested CMS consider an ACO to be experienced with performance-based risk Medicare ACO initiatives if the ACO completes an entire agreement period under a performance-based risk Medicare ACO initiative, explaining their concern about cases where an ACO could be considered experienced with performance-based risk models after only one year of participation in a performance-based risk initiative.
- One commenter suggested that CMS restrict the definition of an experienced ACO to those with prior experience in the Shared Savings Program. The commenter explained that the rules of every individual APM are complex and can vary significantly from model to model, so the definition of an ''experienced'' ACO in this model should be limited to experience in the Shared Savings Program.

Response: We appreciate commenters' support for the proposal to determine participation options for ACOs, including consideration of whether an ACO is experienced or inexperienced with performance-based risk Medicare ACO initiatives in combination with determining whether the ACO is a low revenue ACO or high revenue ACO (as discussed in section II.A.5.b. of this final rule).

We acknowledge that the approach to identifying participation options for ACOs based on a combination of factors, including whether an ACO is experienced or inexperienced with performance-based risk Medicare ACO initiatives, and whether an ACO is low revenue ACO versus high revenue ACO, will add some complexity to program policies and certain operational processes. However, we believe these policies provide necessary safeguards to ensure that the amount of time an ACO is allowed under one-sided models and lower levels of risk in the BASIC track's glide path are not susceptible to gaming and to ensure ACOs participate in financial models that are commensurate with their level of experience in the Shared Savings Program and other Medicare ACO initiatives. We believe it is important to hold ACOs and ACO participants accountable for their prior experience in which they become familiar with the accountable care models generally, as well as with the Shared Savings Program requirements.

On the point raised by the commenter that the proposed approach assumes transferability of experience across populations and geography, we note there are commonalities and synergies between the Shared Savings Program and other Medicare ACO initiatives, which include their overall aims to improve quality of care and lower growth in expenditures for a population of assigned Medicare FFS beneficiaries. Given the similarity in the fundamental goals of Medicare ACO initiatives, and including the Shared Savings Program and other value-based initiatives, we believe there is a degree of transferability of experience by ACO participants across these initiatives and to ACOs from providers and suppliers experienced with other value-based payment arrangements.

We disagree with the commenter's suggestion that new legal entities are disadvantaged by the experience of their ACO participants, which under the proposed approach is used to determine ACO participation options. We believe ACOs make strategic decisions about which ACO participants to recruit to maximize their potential gain from program participation. We also note that under the program's shared governance requirements at § 425.106(c)(3), at least 75 percent control of the ACO's governing body must be held by ACO participants. We believe that new legal entities that meet the 40 percent threshold for experienced with performance-based risk Medicare ACO initiatives (based on the recent prior experience of their ACO participants) will be significantly informed by their ACO participants' experience. Considering these factors, we continue to believe that ACOs that include a significant number of ACO participants with recent prior experience with Shared Savings Program requirements, or similar requirements of other performance-based risk Medicare ACO initiatives, should be placed in participation options that are reflective of the sophistication of their organization.

The approach to distinguishing ACOs based on their experience or inexperience with performance-based risk Medicare ACO initiatives is intended to achieve the commenter's suggestion to differentiate which ACOs may be able to participate under a one-sided model or lower levels of performance-based risk within the BASIC track's glide path. However, as we explained in response to comments in section II.A.5.b of this final rule, we decline to allow ACOs to remain in Level E of the BASIC track indefinitely, and we are finalizing an approach (more generally) that would limit the amount of time ACOs may remain in the BASIC track prior to participating in the ENHANCED track.

We decline to adopt the commenters' suggestions for alternative approaches to distinguishing participation options based on the ACO's and ACO participants' level of experience with performance-based risk Medicare ACO initiatives. We believe that considering the prior participation of ACO providers/suppliers would add a level of complexity to the determination, and would also be inconsistent with our use of ACO participant TINs in program operations. Also, as we previously explained, ACOs' assigned populations vary year to year. We therefore decline the commenter's suggestion to determine an ACO's experience with the program based on whether the ACO managed the same beneficiary population in the past. We decline to determine an ACO's track of participation based on their prior financial or quality performance in the program, as we believe that ACOs that project performing well in the program are more likely to self-select to more aggressively pursue participation under higher levels of risk and potential reward. We also decline to exclude ACOs that did not complete an entire agreement period during which the ACO was under a performance-based risk Medicare ACO initiative, including certain terminated ACOs and ACO participants with a single year of participation, from the definition of experienced with performance-based risk Medicare ACO initiatives. We believe this approach would leave the program vulnerable to gaming through short-term participation, termination and re-entry, which we believe could be potentially destabilizing and disruptive to ACOs and healthcare markets and the care delivered to Medicare FFS beneficiaries. In particular, this would create a circumstance we are trying to protect against where ACOs could participate under the BASIC track's glide path, terminate prior to the conclusion of their 5-year agreement period and enter a new agreement period under the glide path. We also decline to narrow the proposed definitions for inexperienced and experienced with performance-based risk Medicare ACO initiatives to focus only on participation in the Shared Savings Program, as we believe ACOs' and ACO participants' experience in other Medicare ACO initiatives (including models with similar

requirements for accountability for the quality and cost of care for Medicare FFS beneficiaries, and in some cases higher levels of risk and potential reward) should be considered.

Further, we believe we have set forth clear rules on the approach we will use to determine participation options under the redesign of the Shared Savings Program based on a combination of factors. We proposed and are finalizing (in this final rule) definitions of the term ''low revenue ACO'' and ''high revenue ACO,'' ''inexperienced with performance-based risk Medicare ACO initiatives'' and ''experienced with performance-based risk Medicare ACO initiatives,'' and ''performance-based risk Medicare ACO initiative''. We will consider the commenters' suggestion to include detailed descriptions of these terms, and how these concepts will be used in determining participation options, in material we provide to ACOs informing them of our determination of the ACO's status with respect to each of these criteria.

As we indicated in our response to comments requesting timely feedback on CMS' determination of low revenue ACO versus high revenue ACO status, in section II.A.5.b of this final rule, we note that we anticipate providing timely feedback to ACOs throughout program application cycles on whether the ACO is likely to be determined to be inexperienced with performance-based risk Medicare ACO initiatives or experienced with performance-based risk Medicare ACO initiatives, and a low revenue ACO or high revenue ACO (among other factors), in order to ensure ACOs have the information they need to make decisions about program participation and to take action to align with program requirements.

Comment: One commenter suggested that CMS should consider some flexibility for ACOs identified as experienced with performance-based risk Medicare ACO initiatives with small assigned populations (less than 5,000) to permit their initial participation to include Levels C or D of the BASIC track at the option of the ACO, rather than limiting their participation options to either Level E of the BASIC track or the ENHANCED track.

Response: Section 1899(b)(2)(D) of the Act requires ACOs to have a minimum of 5,000 assigned beneficiaries in order to be eligible to participate in Shared Savings Program. Consistent with this requirement, the program's regulations provide that ACOs with fewer than 5,000 assigned beneficiaries are ineligible for program participation (§ 425.110(a)). As we discuss in section II.A.6.b.(3). of this final rule, we are modifying our policies on determining the MSR/MLR for ACOs participating in two-sided models that have elected a fixed MSR/MLR whose populations fall below 5,000 assigned beneficiaries for performance years beginning on July 1, 2019 and in subsequent years. Under these final policies, we will apply a variable MSR/MLR based on the size of the ACO's assigned population, instead of the fixed MSR/MLR elected by the ACO prior to entering performance-based risk. This will result in a relatively higher MSR/MLR (greater than 3.9 percent), and therefore a higher threshold for the ACO to exceed to be eligible for shared savings, and relatively higher threshold to protect the ACO from liability for shared losses, which could result from random variation.

We also decline to create a lower risk participation option for ACOs with small populations, as suggested by the commenter. As discussed in section II.A.5.b of this final rule, we are finalizing an approach to distinguish participation options for ACOs (in part) using a claims-based approach to identifying low revenue ACOs versus high revenue ACOs as opposed to the alternatives we considered including distinguishing ACOs based on the size of their assigned populations.

Comment: A few commenters suggested using a higher threshold for determining whether an ACO is experienced with performance-based risk Medicare ACO initiatives based on the experience of its ACO participants, so that more ACOs would meet the definition of inexperienced with performance-based risk Medicare ACO initiatives; such as a threshold of 50 percent or 60 percent instead of 40 percent as proposed.

Some commenters suggested increasing the threshold from 40 percent to 50 percent to align with the threshold proposed in the definition of re-entering ACO, for identifying new ACOs composed of ACO participants with previous experience in the same Shared Savings Program ACO in recent years. One commenter explained that it is confusing to use different percentages for determining ACO participants' experience with performance-based risk Medicare ACO initiatives (40 percent) and ACO participants with prior experience in the same Shared Savings Program ACO under the proposed definition of re-entering ACO (50 percent).

One commenter recommended CMS define an ''experienced'' ACO as one in which at least the majority of ACO participants participated in a the same performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model, in any of the five most recent performance years prior to the agreement start date. The commenter stated that experience and performance of an ACO in one location has little bearing on how the ACO might perform in another location, explaining that market factors contribute significantly to ACO performance. ACOs performing identically could achieve savings in one market but not another.

As previously described in section II.A.5.c.4.(a) of this final rule, some commenters suggested that CMS should monitor the impact of the policies for identifying re-entering ACOs and ACOs that are experienced with performance-based risk Medicare ACO initiatives, as well as to create an appeals process for these determinations. They recommended using a threshold of 50 percent for both of these determinations (rather than using the proposed 40 percent threshold for determining ACOs experienced with performance-based risk Medicare ACO initiatives) and also setting an additional criterion that would allow an ACO determined to be a re-entering ACO or experienced performance-based risk Medicare ACO initiatives to appeal the determination if less than 30 percent of its ACO participants were previously part of the same legal entity.

Response: We continue to believe a threshold of 40 percent, for assessing ACO participants' experience with performance-based risk Medicare ACO initiatives is the appropriate percentage. For one, it is consistent with the percentage threshold used in determining whether an ACO was sufficiently inexperienced with performance-based risk to participate under the Track 1+ Model. Further, we believe that a threshold of 40 percent will capture ACOs significantly composed of ACO participants experienced with performance-based risk Medicare ACO initiatives. We believe increasing the threshold would allow experienced ACOs to participate under relatively lower-risk options when in fact their composition suggests their readiness for higher levels for risk and potential reward. Further, we believe it is necessary to apply a higher percentage in the definition of re-entering ACOs, since we are identifying the majority (greater than 50 percent) of ACO participants that participated in the same Shared Savings Program ACO within the look back period (see section II.A.5.c.(4).(a). of this final rule). The

purpose of the higher percentage threshold in the definition of re-entering ACO is to identify a single ACO in which the majority of a new legal entity's ACO participants previously participated in the Shared Savings Program, for the purposes of identifying the agreement period the re-entering ACO should be considered participating under for program policies that phase-in over time. In contrast, the definition of experienced with performance-based risk Medicare ACO initiatives identifies ACOs that include a significant proportion of ACO participants that have recent prior experience in two-sided risk accountable care models, as part of an approach for identifying whether the ACO is prepared to participate under relatively higher levels of performance-based risk. Therefore we decline the commenters' suggestions to use a higher threshold in the definitions of inexperienced with performance-based risk Medicare ACO initiatives and experienced with performance-based risk Medicare ACO initiatives.

We continue to prefer our proposed approach to consider participation of ACO participants cumulatively across multiple ACOs, rather than in a particular ACO, during the 5-year lookback period, because it would allow us to potentially identify more ACOs that may be experienced with risk compared to the narrower options suggested by the commenters. We therefore decline the commenters' suggestion that we identify experienced ACOs as those in which at least the majority of ACO participants participated in the same Medicare ACO (which would include Innovation Center models). We also decline the commenters' suggestion that we limit the determination of experienced ACOs based on participation of ACO participants in the same Shared Savings Program ACO (such as for consistency with the definition of re-entering ACO). We believe these approaches would allow some ACOs with a significant proportion of ACO participants experienced with performance-based risk in different Medicare ACO initiatives to participate under options that are designed for ACOs inexperienced with Medicare's accountable care models.

We decline to adopt the commenters' recommendations to modify the process for initially determining ACOs that are experienced with performance-based risk Medicare ACO initiatives (as well as the determination of re-entering ACOs as previously responded to in section II.A.5.c.4.(a) of this final rule), to include an initial determination for whether an ACO is experienced with performance-based risk Medicare ACO initiatives, a secondary test to identify whether the ACO is eligible to request an appeal, and finally an appeal process for the final determination. We previously explained that we believe such an approach would add complexity as well as uncertainty as ACOs would need to request an appeal and await a final determination. Additionally, we currently have an established process for ACOs to request reconsiderations, as specified in subpart I of the program's regulations.

More generally, we agree with commenters suggesting that we evaluate and monitor the policy once implemented. Although we did not specifically address this issue in the discussion in the August 2018 proposed rule regarding monitoring for changes during the agreement period, we are concerned about the possibility that ACOs will enter the BASIC track's glide path because they are determined to be inexperienced with performance-based risk Medicare ACO initiatives, and over the course of their agreement period, dramatically change their composition to take advantage of this lower-risk option when their new composition suggests that they are prepared to take on more significant performance-based risk. We intend to closely monitor ACO participant list change requests for this issue.

Comment: One commenter suggested that the look back period for determining threshold should be shortened from 5 years, but did not indicate an alternative for how long of a look back period should be used by CMS.

Response: We continue to believe a look back period of 5 performance years is an appropriate length to ensure we identify ACOs with recent prior experience with performance-based risk Medicare ACO initiatives. We described a number of considerations that led to our proposal of a 5 performance year look back period in the definitions of inexperienced with performance-based risk Medicare ACO initiatives and experienced with performance-based risk Medicare ACO initiatives in the August 2018 proposed rule (83 FR 41828), as restated in this section of this final rule, including that a 5 performance year look back period could reduce the incentive for organizations to wait out the period in an effort to re-form as a new legal entity with the same or very similar composition of ACO participants for purposes of gaming program policies.

Comment: Some commenters expressed concerns about requiring ACOs experienced with performance-based risk to take on higher levels of two-sided risk under the proposed redesigned participation options. As summarized in section II.A.5.b of this final rule, many commenters suggested additional flexibility to allow high revenue ACOs experienced with performance-based risk Medicare ACO initiatives to continue participation under lower levels of risk rather than be limited to participation under the ENHANCED track. For example, commenters suggested that ACOs should be permitted to remain in the BASIC track's Level E (or an equivalent level of risk as the Track 1+ Model) indefinitely without being forced to progress to the ENHANCED track.

One commenter suggested that former Track 3 ACOs should be given the option to participate in the BASIC track as all other ACOs, among other flexibilities in their participation options, since these ACOs voluntarily entered the highest level of risk and reward in the Shared Savings Program.

As an alternative, one commenter suggested that ACOs experienced with performance-based risk Medicare ACO initiatives should be allowed the option of entering an agreement period under either Level D or Level E of the BASIC track. This is contrary to the proposed approach that would limit ACOs experienced with performance-based risk Medicare ACO initiatives to either an agreement period under Level E of the BASIC track (if a low revenue ACO), or the ENHANCED track.

Response: We continue to believe in the importance of progressing ACOs to the highest level of risk and potential reward in the program to drive the most meaningful change in providers' and suppliers' behavior toward achieving the program's goals. Further, we continue to believe that it is necessary to establish policies to safeguard against experienced ACOs taking advantage of participation options under the BASIC track's glide path intended for ACOs inexperienced with the accountable care model in Medicare. Therefore we continue to believe in the necessity of the proposed approach to require ACOs identified as experienced with performance-based risk Medicare ACO initiatives to participate under the higher levels of risk and potential reward that we are finalizing with this final rule, specifically Level E of the BASIC track (if eligible) or the ENHANCED track.

Further we note that under the policies we are finalizing with this final rule, an ACO that is identified as a low revenue ACO and experienced with performance-based risk Medicare ACO

initiatives will be eligible to participate for up to two agreement periods in Level E of the BASIC track. In response to the commenter's concerns, we note that this policy applies to low revenue ACOs identified as experienced with performance-based because of their prior participation in Track 3 of the Shared Savings Program, as it would also similarly apply to ACOs identified as experienced with performance-based risk Medicare ACO initiatives because of their participation in the other two-sided models specified in the definition of performance-based risk Medicare ACO initiatives.

Comment: Some commenters point to concerns related to the inclusion of the Track 1+ Model in the definition of performance-based risk Medicare ACO initiative. Some commenters expressed concern that under the proposed approach, high revenue ACOs that transitioned to the Track 1+ Model within their current agreement period would be required to renew under the ENHANCED track, whereas their counterparts that remained under Track 1 would be eligible to enter a one-sided model of the BASIC track's glide path. Some commenters view this approach as disadvantageous or unreasonable to ACOs that voluntarily elected to accelerate their transition to risk and switched to the Track 1+ Model. Commenters explained that these Track 1+ Model ACOs would be required to make a significant jump from the Track 1+ Model level of risk and reward to the ENHANCED track level of risk and reward with only minimal experience with in performance-based risk.

Some commenters pointed out that ACOs entering the Track 1+ Model for their third performance year, performance year 2018, will not know the final results of this year until after their new agreement period begins under the proposed approach for a July 1, 2019 start date. This is a significant concern since performance year 2018 is the first year of two-sided risk for these ACOs, which are required to continue participation in two-sided risk for their next agreement period.

Commenters addressing this issue typically recommended that all current Track 1+ Model ACOs, independent of whether they are identified by CMS as high revenue ACOs or low revenue ACOs, should be permitted to continue their participation in the Shared Savings Program under Level E of the BASIC track for an agreement period of at least 5 years, to gain experience with performance-based risk.

One commenter, indicating confusion over the applicability of the proposed policies in determining participation options, asked if ACOs currently in the Track 1+ Model would be eligible to participate in the BASIC track's glide path including being allowed one year of participation under a one-sided model.

Response: We are persuaded by commenters' concerns that the proposed policies could disrupt the progressive transition to risk by Track 1 ACOs that took an initial and important step by entering the Track 1+ Model within their current agreement period, with an expectation that they might be able to continue in a similar level of risk and reward for a second 3-year agreement period. Therefore, we are finalizing a limited exception to allow ACOs that transitioned to the Track 1+ Model within their current agreement period (therefore ACOs with a first or second agreement period start date in 2016 or 2017 that entered the Track 1+ Model in 2018), which are considered high revenue ACOs, a one-time option to renew for a consecutive agreement period of at least 5 years under Level E of the BASIC track. We are specifying this participation option in a provision of the regulations text at § 425.600(d)(1)(ii)(B). We note that low revenue ACOs identified as experienced with performance-based risk Medicare ACO initiatives would have an opportunity to participate for up to two agreement periods under Level E of the BASIC track. To clarify in response to the commenter's confusion, we note that former Track 1+ Model ACOs are ineligible for the BASIC track's glide path because they would be identified as experienced with performance-based risk Medicare ACO initiatives.

We do not believe it is necessary to extend this same exception to ACOs that entered or renewed for a 3-year agreement period under the Track 1+ Model with an agreement start date of January 1, 2018. Under the original design of the Track 1+ Model, we would have allowed entry into the model for an agreement period start date of 2018, 2019 and 2020 (as discussed in section II.F of this final rule). ACOs would not have been able to renew their participation under the Model for a second 3-year agreement period beginning January 1, 2021. Instead, under the terms of the Track 1+ Model Participation Agreement and the current Shared Savings Program regulations, these ACOs would have had the option to continue their participation in the Shared Savings Program in an agreement period under either Track 2 or Track 3. With the changes to the program's participation options we are finalizing with this final rule, ACOs that entered the Track 1+ Model for first or second agreement period beginning on January 1, 2018 will have the following options: Low revenue ACOs would be eligible to participate in Level E of the BASIC track for up to two agreement periods; high revenue ACO would be limited to participating in the ENHANCED track.

Comment: We received a few comments specifically addressing the proposal to limit an ACO eligible for the BASIC track's glide path to enter under Level B if the ACO has previous participation in Track 1. Several commenters supported CMS' proposal to allow 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, to enter a new agreement period under either Level B, C, D or E. Several commenters indicated the importance of allowing these ACOs an opportunity to participate for at least one performance year under a one-sided model before transitioning to performance-based risk. One commenter explained that this approach would give ACOs with experience in the program but without experience in performance-based risk a reasonable amount of time in the redesigned program structure before being required to move to performance-based risk. The commenter preferred the proposed approach to the potentially more aggressive approach CMS considered in which ACOs with experience in Track 1 would be required to start at Level C of the BASIC track or higher.

Several commenters suggested that all ACOs should be allowed to start at Level A of the BASIC track. One commenter stated that early adopters should not be penalized by forcing them into performance-based risk while other new ACO entrants are allowed to remain in one-sided models for several more years. One commenter seemed to suggest that the proposed approach may differentiate whether ACOs may enter Level A or Level B of the BASIC track's glide path depending on the length of time they previously participated in Track 1.

Response: We are finalizing as proposed the approach for glide path entry for former Track 1 ACOs and new ACOs that are identified as re-entering ACOs because of their ACO participants' recent prior participation in the same Track 1 ACO. These ACOs, if eligible to enter the BASIC track's glide path, will be restricted to a single year of participation under a one-sided model (Level B) before being

automatically transitioned to risk and reward under the glide path (except for ACOs with an agreement period starting July 1, 2019, which would be permitted to continue in Level B for a second performance year starting January 1, 2020). We appreciate commenters' support for this proposed approach which recognizes that ACOs with prior experience in Track 1 may need additional time under a one-sided model to prepare for performance-based risk, but are likely better prepared to more rapidly progress to performance-based risk because of their experience in the Shared Savings Program. Therefore, we decline the commenter's suggestion that these ACOs be allowed to enter the BASIC track's glide path at Level A.

Further, we believe the comments reflect the need to clarify that this policy restricting entry into the BASIC track's glide path to Level B applies consistently to any former Track 1 ACO and new ACO that is identified as a re-entering ACO because of its ACO participants' recent prior participation in the same Track 1 ACO, regardless of how many performance years or agreement periods the ACO participated under Track 1.

Comment: As described and addressed elsewhere in our summary of comments in section II.A. of this final rule, many commenters expressed concerns about the pace of transitioning ACOs to performance-based risk under the proposed designed participation options. Some commenters specifically expressed concern about the design of the BASIC track that allows new, inexperienced ACOs only two performance years under a one-sided model before requiring ACOs to enter performance-based risk. One commenter explained that new ACOs need time to adjust to the program requirements. One commenter encouraged CMS to prioritize the entrance of new participants, and especially low revenue ACOs and ACOs inexperienced with performance-based risk Medicare ACO initiatives, into the Shared Savings Program as it implements the redesign of the participation options.

Some commenters expressed concern that the proposed approach may require too quick of a progression to higher levels of performance-based risk by small, rural and physician-only ACOs. One commenter expressed concern that ACOs that have actually achieved savings but do not have the financial resources to go to risk would be forced out of the program.

More generally, some commenters stated a critical component of performance improvement lies in the ACO's ability to analyze the performance data being provided to the ACO and make targeted improvements based on this information. Under CMS' current proposal, ACOs would have only one year of performance data before being required to move to a performance-based risk model. One commenter explained that the timing of benchmark notification, data receipt and shared savings determinations under the program render such a short period of time effectively useless to determine if the ACO's care coordination and other redesigns are having the intended effect. The commenter explained further that ACOs do not receive a preliminary benchmark or historical data until after the performance year has begun. They also do not receive a final shared savings determination until seven or eight months after the conclusion of the performance year. As a result, the commenter stated, ACOs are functionally blind to their financial performance for the entire length of a performance year and into the following year, which makes it difficult for ACOs to determine how to invest any returns or how to alter their care delivery to achieve savings and improve quality. The commenter believes the proposed progression to performance-based risk within the BASIC track's glide path forces ACOs to take on performance-based risk without much-needed information, setting many ACOs up for failure.

To address these concerns, several commenters recommended that CMS allow new, inexperienced ACOs three performance years in a one-sided model, rather than two performance years, before requiring them to take on performance-based risk.

Several commenters recommended that CMS allow new ACOs at least four performance years in a one-sided model to provide the ACOs with two to three years of performance data, to identify trends and opportunities for transformation and improvement before they are moved to a two-sided model. This commenter suggested, for example, CMS could implement a policy allowing all new ACOs to remain in Level A of the BASIC track for two performance years and Level B of the BASIC track for an additional two performance years before requiring the ACO to move to Level C in the fifth and final performance year of their 5-year agreement. Alternatively, commenters suggest that CMS could allow new ACOs to remain in a one-sided model for the duration of their first 5-year agreement period, and then permit the ACO to begin their second 5-year agreement period at Level C or Level D of the BASIC track where they would participate for three performance years and progress to Level E for the remaining two performance years.

Several commenters suggesting these alternative approaches to allowing inexperienced ACOs additional time under a one-sided model of the BASIC track's glide path recommended that CMS maintain the opportunity for ACOs to elect to more rapidly enter higher levels of risk and reward, as proposed (see section II.A.4.b. of this final rule).

Response: We are persuaded by commenters that ACOs new to the Shared Savings Program that are inexperienced with performance-based risk Medicare ACO initiatives may need additional time under a one-sided model to gain experience with program participation and to prepare for the transition to performance-based risk. We believe the need for this additional time in a one-sided model is particularly acute among low revenue ACOs. As described in comments summarized elsewhere in this final rule, for example, small, rural and physician-only ACOs, which are more likely to be low revenue ACOs, may lack the financial reserves needed to support establishment of a repayment mechanism arrangement. These ACOs may be able to better accrue the needed financial resources through earned shared savings in their initial years of program participation (if they are eligible to share in these savings).

Therefore we are finalizing a modification to our proposals to allow an additional participation option in the BASIC track's glide path for ACO legal entities without prior experience in the Shared Savings Program (that is, new legal entities that are not identified as a re-entering ACOs) that are identified as low revenue ACOs. To be eligible for the BASIC track's glide path, these ACOs would have been determined to be inexperienced with performance-based risk Medicare ACO initiatives based on an evaluation of their ACO legal entity and also ACO participants (according to the 40 percent threshold). We will allow these ACOs to participate under a one-sided model for up to three performance years (or four performance years for ACOs entering an agreement period beginning July 1, 2019). However, in exchange for this additional year under a one-sided model, these ACOs would forfeit their progression along the glide path to Level C and Level D and therefore automatically advance to Level E for the remaining performance years of their agreement period.

We note that this alternative participation option will not be available to new ACOs that are identified as re-entering ACOs because

of their ACO participants' recent prior participation in the same Track 1 ACO.

With this alternative, we are allowing for an additional participation option that more closely resembles the current opportunity for ACOs to participate for a 3-year agreement period in a one-sided model, and then transition to Level E of the BASIC track, with the level of risk and potential reward currently available under the popular Track 1+ Model. Therefore, we believe this policy (under which ACOs forgo participation in Level C and Level D of the BASIC track's glide path) is responsive to some commenters' suggestions for such alternatives, and also supported by our early experience with the Track 1+ Model. Among ACOs renewing for a second agreement period beginning January 1, 2018, we observed that 5 Track 1 ACOs renewed under the Track 1+ Model. However, as discussed elsewhere in this section of this final rule, we strongly believe that ACOs need to make the transition to two-sided risk within their 5-year agreement period of the BASIC track's glide path, an approach which some commenters also supported. Nevertheless, we are sensitive to commenters' concern about the need for ACOs to have more performance information before transitioning to higher levels of performance-based risk. Considering these factors, in combination, we believe it would be an attractive alternative that meets the objectives of our program's redesign to offer the option for certain ACOs to elect to remain under a one-sided model of the BASIC track's glide path for an additional performance year prior to transitioning to Level E of the BASIC track for the remaining years of their agreement period. As discussed in the Regulatory Impact Analysis (section V of this final rule), we believe this alternative would be protective of the Trust Funds because it could encourage program entry by the types of organizations that have tended to be higher-performing (small, physician-only and rural ACOs), and also encourage these ACOs to more aggressively pursue the program's goals by moving to higher risk (under Level E) faster. We note also that we are finalizing the option for eligible ACOs without previous experience in the Shared Savings Program to participate under the BASIC track's glide path, where they enter at Level A and are automatically advanced through the remaining four levels of the glide path, concluding at Level E. Therefore, this will remain a participation option for organizations that prefer a more incremental progression to increasing levels of two-sided risk.

In the new provision of the regulations at § 425.600(a)(4) we are specifying an exception to the policy that ACOs participating in the BASIC track's glide path are automatically advanced to the next level of the glide path at the start of each subsequent performance year of the agreement period. This exception, applicable to an ACO legal entity without prior experience in the Shared Savings Program (that is, a new legal entity that is not identified as a re-entering ACO) that is identified as a low revenue ACO (participating in the BASIC track's glide path and therefore inexperienced with performance-based risk Medicare ACO initiatives), allows for the following: (1) The ACO elects to enter the BASIC track's glide path at Level A, and is automatically advanced to Level B for performance year 2 (or performance year 3 in the case of ACOs entering an agreement period beginning on July 1, 2019); (2) prior to the automatic advancement of the ACO to Level C, the ACO may elect to remain in Level B for performance year 3 (performance year 4 in the case of ACOs entering an agreement period beginning on July 1, 2019); (3) in the case of an ACO that elects to remain in Level B for an additional performance year, the ACO forgoes participation in Level C and Level D of the glide path and is automatically advanced to Level E at the start of performance year 4 (or performance year 5 in the case of ACOs entering an agreement period beginning on July 1, 2019). We are making certain modifications to § 425.600 (such as to incorporate section headers) for clarity. We are also specifying a provision related to this participation option in the regulations text at § 425.605(b)(2)(ii), on the timing of the ACO's selection of its MSR/MLR before entering a two-sided model of the BASIC track's glide path.

To determine if an ACO is eligible to make this election to remain in Level B for another performance year, we would re-evaluate the ACO to determine if it continues to meet the definition of a low revenue ACO and the definition of an ACO that is inexperienced with performance-based risk Medicare ACO initiatives.

Further, we believe this policy, to allow additional flexibility for new legal entities, that are low revenue ACOs, and inexperienced with performance-based risk Medicare ACO initiatives, to participate for up to 3 performance years under a one-sided model of the BASIC track's glide path before transitioning to Level E of the BASIC track, in combination with other final policies within this final rule address commenters' concerns and suggestions for a relatively gentler glide path to two-sided risk for small, rural and physician-only ACOs (or generally low revenue ACOs), and support continued participation of these ACOs in the Shared Savings Program. We summarized these other factors in section II.A.5.b.(2) of this final rule, and in brief these include the following: (1) Increasing the threshold of ACO participant revenue as a percentage of benchmark used in identifying low revenue ACOs; (2) allowing for higher sharing rates in the BASIC track's glide path; and (3) modifications to the approach for determining repayment mechanism arrangement amounts to potentially reduce the burden of these arrangements on lower-revenue ACOs participating in the ENHANCED track.

Under our final policies we will determine low revenue ACOs based on a higher threshold percentage, 35 percent instead of 25 percent as proposed (see section II.A.5.b of this final rule). Therefore, a potentially greater number of ACOs may be eligible for this alternative participation option.

We decline commenters' suggestions that certain ACOs be exempt from transitioning to performance-based risk or higher levels of risk and potential reward. As we explain elsewhere in this section of this final rule, we believe the progression to performance-based risk is critical to driving the most meaningful change in providers' and suppliers' behavior toward achieving the program's goals, and that participation in two-sided models, and ultimately the ENHANCED track, should be the goal for all Shared Savings Program ACOs. More generally we believe the previously described policy modifications will help ensure program entry and continued participation by relatively risk-averse ACOs.

Comment: One commenter stated that the definition of deferred renewal as described in the August 2018 proposed rule is not sufficiently clear. The commenter suggested that CMS clarify the definition of a ''deferred ACO'' so that it could be easily determined by an ACO to avoid confusion.

Response: As described in section II.A.2 of this final rule we are discontinuing the deferred renewal participation option, which was made available to ACOs that participated under Track 1 for a first agreement period beginning on either January 1, 2014 or January 1, 2015. Under this policy, specified in § 425.200(e), at the time of renewal for a second agreement period, the ACO elected to extended its

initial agreement period under Track 1 for an additional year for a total of 4 performance years, and thereby deferred entering in a second agreement period under either Track 2 or Track 3. As we previously described in section II.A.2 of this final rule, few ACO selected the deferred renewal option.

Comment: Some commenters addressed generally the concern about gaming participation options. One commenter stated support for CMS to closely monitor ''gaming'' behavior and to take action when specific gaming behavior is identified.

One commenter explained that shortening the time an ACO may remain in a one-sided model and extending the agreement period to five years (which affects how often benchmarks are rebased), increases the incentives to participate in ''gaming''. The commenter suggested that certain, well-defined precautionary measures may be warranted.

One commenter in general encouraged CMS to explore the ways bad actors may use current or new structures to take advantage of programmatic rules or beneficiaries.

Response: We appreciate commenters' concerns about the possibility that ACOs may attempt to game program requirements to yield more favorable participation options for their organization. We continue to believe that the combination of policies we are establishing with this final rule to ensure program integrity are protective of the Trust Funds, as well as protective of beneficiaries by ensuring ACOs are held accountable for their financial and quality performance. This includes: Limiting more experienced ACOs to higher-risk participation options; more rigorously screening for good standing among ACOs seeking to renew their participation in the program or re-enter the program after termination or expiration of their previous agreement; identifying ACOs re-forming under new legal entities as re-entering ACOs if greater than 50 percent of their ACO participants have recent prior participation in the same ACO in order to hold these ACO accountable for their ACO participants' experience with the program; and holding ACOs in two-sided models accountable for partial-year losses if either the ACO or CMS terminates the agreement before the end of the performance year (discussed in section II.A.6.d.(3) of this final rule).

Final Action: After consideration of public comments, we are finalizing our proposal to specify requirements for evaluating an ACO's eligibility for specific participation options for agreement periods beginning on July 1, 2019, and in subsequent years, in a new provision at § 425.600(d), with the following modifications as discussed in this section of this final rule: (1) Allow the option for an ACO legal entity without prior experience in the Shared Savings Program (a new legal entity that is not identified as a re-entering ACO) that is identified as a low revenue ACO participating in the BASIC track's glide path to elect an additional year of participation under a one-sided model in exchange for transitioning more rapidly to Level E for the remaining years of their agreement period; and (2) ensuring ACOs that entered the Track 1+ Model within their current agreement period have the opportunity to renew for a subsequent agreement period under Level E of the BASIC track.

We are finalizing our proposal to add new definitions at § 425.20 for ''Experienced with performance-based risk Medicare ACO initiatives'', ''Inexperienced with performance-based risk Medicare ACO initiatives'' and ''Performance-based risk Medicare ACO initiative'' without modification.

We define ''performance-based risk Medicare ACO initiative'' to mean an initiative implemented by CMS that requires an ACO to participate under a two-sided model during its agreement period. This includes Track 2, Track 3 or the ENHANCED track, and the proposed BASIC track (including Level A through Level E) of the Shared Savings Program. This also included the following Innovation Center ACO Models involving two-sided risk: The Pioneer ACO Model, Next Generation ACO Model, the performance-based risk tracks of the CEC Model (including the two-sided risk tracks for LDO ESCOs and non-LDO ESCOs), and the Track 1+ Model. This definition also includes such other Medicare ACO initiatives involving two-sided risk as may be specified by CMS.

We define ''experienced with performance-based risk Medicare ACO initiatives'' to mean an ACO that CMS determines meets either of the following criteria:

(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 as defined under 425.20, or that deferred its entry into a second Shared Savings Program agreement period under Track 2 or Track 3 in accordance with § 425.200(e).

(2) 40 percent or more of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative as defined under § 425.20, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under Track 2 or Track 3 in accordance with § 425.200(e), in any of the 5 most recent performance years prior to the agreement start date.

We define ''inexperienced with performance-based risk Medicare ACO initiatives'' to mean an ACO that CMS determines meets all of the following requirements:

(1) The ACO is a legal entity that has not participated in any performance-based risk Medicare ACO initiative as defined under § 425.20, and has not deferred its entry into a second Shared Savings Program agreement period under Track 2 or Track 3 in accordance with § 425.200(e); and

(2) Less than 40 percent of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative as defined under § 425.20, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under Track 2 or Track 3 in accordance with § 425.200(e), in each of the 5 most recent performance years prior to the agreement start date.

In summary, in combination with determining an whether ACOs are low revenue ACOs versus high revenue ACOs as described in section II.A.5.b of this final rule, we are finalizing the addition of a new paragraph (d) under § 425.600, to provide that CMS will identify ACOs as inexperienced or experienced with performance-based risk Medicare ACO initiatives for purposes of determining an ACO's eligibility for certain participation options, as follows (with certain exceptions, as noted):

• If an ACO is identified as a high revenue ACO, the following options would apply:

++ If we determine the ACO is inexperienced with performance-based risk Medicare ACO initiatives, the ACO may enter the BASIC track's glide path, or the ENHANCED track. With the exception of ACOs that previously participated in Track 1 and new ACOs identified as re-entering ACOs because of their ACO participants' prior participation in a Track 1 ACO, an ACO may enter the BASIC track's glide path at any level (Level A through Level E). Therefore, eligible ACOs that are new to the program, identified as initial applicants and not as re-entering ACOs, would have the flexibility to enter the glide path at any one of the five levels. An ACO that previously participated in Track 1 or a new ACO identified as a re-entering ACO because more than 50 percent of its ACO participants have recent prior experience in the same Track 1 ACO may enter the glide path under either Level B, C, D or E.

++ If we determine the ACO is experienced with performance-based risk Medicare ACO initiatives, the ACO may only enter the ENHANCED track. However, an

ACO in a first or second agreement period beginning in 2016 or 2017 identified as experienced with performance-based risk Medicare ACO initiatives based on participation in the Track 1+ Model may renew for a consecutive agreement period beginning on July 1, 2019, or January 1, 2020 (respectively), either under Level E of the BASIC track, or the ENHANCED track.

• If an ACO is identified as a low revenue ACO, the following options would apply:

++ If we determine the ACO is inexperienced with performance-based risk Medicare ACO initiatives, the ACO may enter the BASIC track's glide path, or the ENHANCED track. An ACO may enter the BASIC track's glide path at any level (Level A through Level E). The following exceptions apply:

—An ACO that previously participated in Track 1 or a new ACO identified as a re-entering ACO because more than 50 percent of its ACO participants have recent prior experience in the same Track 1 ACO may enter the glide path under either Level B, C, D or E.

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

++ If we determine the ACO is experienced with performance-based risk Medicare ACO initiatives, the ACO may enter Level E of the BASIC track (highest level of risk and potential reward) or the ENHANCED track. As discussed in section II.A.5.b. of this final rule, low revenue ACOs are limited to two agreement periods of participation under the BASIC track.

(c) Applicability of Policies That Phase-In

In the August 2018 proposed rule (83 FR 41829 through 41832), we explained that we would consider an ACO's experience with the program or other performance-based risk Medicare ACO initiatives in determining which agreement period an ACO should be considered to be entering for purposes of applying policies that phase-in over the course of the ACO's first agreement period and subsequent agreement periods: (1) The weights applied to benchmark year expenditures (equal weighting in second or subsequent agreement periods instead of weighting the 3 benchmark years (BYs) at 10 percent (BY1), 30 percent (BY2), and 60 percent (BY3)); (2) the weights used in calculating the regional adjustment to an ACO's historical benchmark, which phase in over multiple agreement periods; and (3) the quality performance standard, which phases in from complete and accurate reporting of all quality measures in the first performance year of an ACO's first agreement period to pay-for-performance over the remaining years of the ACO's first agreement period, and ACOs continue to be assessed on performance in all subsequent performance years under the program (including subsequent agreement periods). We noted that for purposes of this discussion, we considered agreement periods to be sequential and consecutive. For instance, after an ACO participates in its first agreement period, the ACO would enter a second agreement period, followed by a third agreement period, and so on.

We proposed to specify under § 425.600(f)(1) that an ACO entering the program for the first time (an initial entrant) would be considered to be entering a first agreement period in the Shared Savings Program for purposes of applying program requirements that phase-in over time, regardless of its experience with performance-based risk Medicare ACO initiatives. Under this approach, in determining the ACO's historical benchmark, we would weight the benchmark year expenditures as follows: 10 Percent (BY1), 30 percent (BY2), and 60 percent (BY3). We explained that under the proposed approach to applying factors based on regional FFS expenditures beginning with an ACO's first agreement period, we would apply a weight of either 25 percent or 35 percent in determining the regional adjustment amount depending on whether the ACO is higher or lower spending compared to its regional service area. (As described in section II.D. of this final rule, we are modifying our proposed phase-in of the weights used in calculating the regional adjustment. Under the policies we are adopting in this final rule, we would apply a weight of either 15 percent or 35 percent in determining the regional adjustment amount for an ACO in its first agreement period.) Further, under § 425.502, an initial entrant would be required to completely and accurately report all quality measures to meet the quality performance standard (referred to as pay-for-reporting) in the first performance year of its first agreement period, and for subsequent years of the ACO's first agreement period the pay-for-performance quality performance standard would phase-in.

We proposed to divide re-entering ACOs into three categories in order to determine which agreement period an ACO will be considered to be entering for purposes of applying program requirements that phase-in over time, and to specify this policy at § 425.600(f)(2). For an ACO whose participation agreement expired without having been renewed, we proposed the ACO would re-enter the program under the next consecutive agreement period. For example, if an ACO completed its first agreement period and did not renew, upon re-entering the program, the ACO would participate in its second agreement period.

For an ACO whose participation agreement was terminated under § 425.218 or § 425.220, we proposed the ACO re-entering the program would be treated as if it is starting over in the same agreement period in which it was participating at the time of termination, beginning with the first performance year of the new agreement period. For instance, if an ACO terminated at any time during its second agreement period, the ACO would be considered participating in a second agreement period upon re-entering the program, beginning with the first performance year of their new agreement period. Alternatively, we considered determining which performance year a terminated ACO should re-enter within the new agreement period, in relation to the amount of time the ACO participated during its most recent prior agreement period. For example, under this approach, an ACO that terminated its participation in the program in the third performance year of an agreement period would be treated as re-entering the program in performance year three of the new agreement period. However, we noted that this alternative approach could be complicated given the proposed transition from 3-year agreements to agreement periods of at least 5 years.

For a new ACO identified as a re-entering ACO because greater than 50 percent of its ACO participants have recent prior participation in the same ACO, we would consider the prior participation of the ACO in which the majority of the ACO participants in the new ACO were participating in order to determine the agreement period in which the new ACO would be considered to be entering the program. That is, we would determine the applicability of program policies to the new ACO based on the number of agreement periods the other entity participated in the program. If the

participation agreement of the other ACO was terminated or expired, the previously described rules for re-entering ACOs would also apply. For example, if ACO A is identified as a re-entering ACO because more than 50 percent of its ACO participants previously participated in ACO B during the relevant look back period, we would consider ACO B's prior participation in the program. For instance, if ACO B terminated during its second agreement period in the program, we would consider ACO A to be entering a second agreement period in the program, beginning with the first performance year of that agreement period. However, if the other ACO is currently participating in the program, the new ACO would be considered to be entering into the same agreement period in which this other ACO is currently participating, beginning with the first performance year of that agreement period. For example, if ACO A is identified as a re-entering ACO because more than 50 percent of its ACO participants previously participated in ACO C during the relevant look back period, and ACO C is actively participating in its third agreement period in the program, ACO A would be considered to be participating in a third agreement period, beginning with the first performance year of that agreement period.

We proposed to specify at § 425.600(f)(3) that renewing ACOs would be considered to be entering the next consecutive agreement period for purposes of applying program requirements that phase-in over time. This proposed approach would be consistent with current program policies for ACOs whose participation agreements expire and that immediately enter a new agreement period to continue their participation in the program. For example, an ACO that entered its first participation agreement on January 1, 2017, and concludes this participation agreement on December 31, 2019, would renew to enter its second agreement period beginning on January 1, 2020. Further, under the proposed definition of ''Renewing ACO'', an ACO that terminates its current participation agreement under § 425.220 and immediately enters a new agreement period to continue its participation in the program would also be considered to be entering the next consecutive agreement period. For example, an ACO that entered its first participation agreement on January 1, 2018, and terminates its agreement effective June 30, 2019, to enter a new participation agreement beginning on July 1, 2019, would be considered to be a renewing ACO that is renewing early to enter its second agreement period beginning on July 1, 2019. This approach would ensure that an ACO that terminates from a first agreement period and immediately enters a new agreement period in the program could not take advantage of program flexibilities aimed at ACOs that are completely new to the Shared Savings Program, such as the pay-for-reporting quality performance standard available to ACOs in their first performance year of their first agreement period under the program. We would therefore apply a consistent approach among renewing ACOs by placing these ACOs in the next agreement period in sequential order.

This proposed approach would replace the current approach to determining which agreement period an ACO would be considered to be entering into, for a subset of ACOs, as specified in the provision at § 425.222(c), which we proposed to discontinue using. This proposed approach would ensure that ACOs that are experienced with the program or with performance-based risk Medicare ACO initiatives are not participating under policies designed for ACOs inexperienced with the program's requirements or similar requirements under other Medicare ACO initiatives, and also would help to preserve the intended phase-in of requirements over time by taking into account ACOs' prior participation in the program.

The proposed approach would help to ensure that ACOs that are new to the program are distinguished from renewing ACOs and ACOs that are re-entering the program, and would also ensure that program requirements are applied in a manner that reflects ACOs' prior participation in the program, which would limit the opportunity for more experienced ACOs to seek to take advantage of program policies. These policies protect against ACOs terminating or discontinuing their participation, and potentially re-forming as a new legal entity, simply to be able to apply to re-enter the program in a way that could allow for the applicability of lower weights used in calculating the regional adjustment to the benchmark or to avoid moving to performance-based risk more quickly on the BASIC track's glide path or under the ENHANCED track.

The proposed approach to determining ACO participation options and the proposal to limit access the BASIC track's glide path to ACOs that are inexperienced with performance-based risk, in combination with the rebasing of ACO benchmarks at the start of each new agreement period, mitigated our concerns regarding ACO gaming. We explained our belief that the requirement that ACOs' benchmarks are rebased at the start of each new agreement period, in combination with the proposed new requirements governing ACO participation options, would be sufficiently protective of the Trust Funds to guard against undesirable ACO gaming behavior. Under our proposed policies for identifying ACOs that are experienced with performance-based risk Medicare ACO initiatives, ACOs that terminate from the BASIC track's glide path (for example) and seek to re-enter the program, and renewing ACOs (including ACOs renewing early for a new agreement period beginning July 1, 2019) that are identified as experienced with performance-based risk Medicare ACO initiatives could only renew under Level E of the BASIC track (if an otherwise eligible low revenue ACO) or the ENHANCED track. This mitigated our concerns about ACOs re-forming and re-entering the program, or serially terminating and immediately participating again as a renewing ACO, since there would be consequences for the ACO's ability to continue participation under lower-risk options that may help to deter these practices.

We acknowledge that under our proposals regarding early renewals (that is, our proposal that ACOs that terminate their current agreement period and immediately enter a new agreement period without interruption qualify as renewing ACOs), it would be possible for ACOs to serially enter a participation agreement, terminate from it and enter a new agreement period, to be considered entering the next consecutive agreement period in order to more quickly take advantage of the higher weights used in calculating the regional adjustment to the benchmark. However, we noted that these ACOs' benchmarks would be rebased, which would help to mitigate this concern. We sought comment on possible approaches that would prevent ACOs from taking advantage of participation options to delay or hasten the phase-in of higher weights used in calculating the regional adjustment to the historical benchmark, while still maintaining the flexibility for existing ACOs to quickly move from a current 3-year agreement period to a new agreement period under either the BASIC track or ENHANCED track.

Final Action: We received no comments on this proposal and therefore are finalizing as proposed to specify the following policies in § 425.600(f). For agreement periods beginning on July 1, 2019, and in

subsequent years, CMS determines the agreement period an ACO is entering for purposes of applying the following program requirements that phase-in over multiple agreement periods: (i) The quality performance standard as described in § 425.502(a); (ii) the weight used in calculating the regional adjustment to the ACO's historical benchmark as described in § 425.601(f); and (iii) the use of equal weights to weight each benchmark year as specified in § 425.601(e).

An ACO entering an initial agreement period is considered to be entering a first agreement period in the Shared Savings Program. A renewing ACO is considered to be entering the next consecutive agreement period in the Shared Savings Program.

A re-entering ACO is considered to be entering a new agreement period in the Shared Savings Program as follows: (i) An ACO whose participation agreement expired without having been renewed re-enters the program under the next consecutive agreement period in the Shared Savings Program; (ii) an ACO whose participation agreement was terminated under § 425.218 or § 425.220 re-enters the program at the start of the same agreement period in which it was participating at the time of termination from the Shared Savings Program, beginning with the first performance year of that agreement period; or (iii) a new ACO identified as a re-entering ACO enters the program in an agreement period that is determined based on the prior participation of the ACO in which the majority of the new ACO's participants were participating. Regarding this third category of ACOs, if the participation agreement of the other ACO was terminated or expired, the previously described rules for re-entering ACOs would also apply. However, if the other ACO is currently participating in the program, the new ACO would be considered to be entering into the same agreement period in which this other ACO is currently participating, beginning with the first performance year of that agreement period.

As discussed in section II.D. of this final rule, we are maintaining a phase-in for the regional adjustment weights for ACOs with start dates in the program before July 1, 2019, according to the structure similar to that established in the June 2016 final rule (for example, we will continue to use regional factors for the first time in resetting benchmarks for the third agreement period for 2012 and 2013 starters); however, we are making modifications to the weights used in these calculations and the length of time over which the maximum weight is phased in. Table 6 includes examples of the phase-in of the modified regional adjustment weights based on agreement start date and applicant type (initial entrant, renewing ACO, or re-entering ACO). This table illustrates the weights that would be used in determining the regional adjustment to the ACO's historical benchmark under this final rule to differentiate initial entrants, renewing ACOs (including ACOs that renew early), and re-entering ACOs for purposes of policies that phase-in over time.

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TABLE 6—EXAMPLES OF PHASE-IN OF MODIFIED REGIONAL ADJUSTMENT WEIGHTS BASED ON AGREEMENT START DATE AND APPLICANT TYPE

Applicant Type	First time regional adjustment used: 35 percent or 15 percent (if spending above region)	Second time regional adjustment used: 50 percent or 25 percent (if spending above region)	Third time regional adjustment used: 50 percent or 35 percent (if spending above region)	Fourth and subsequent time regional adjustment used: 50 percent weight
New entrant with start date on July 1, 2019	Applicable to first agreement period starting on July 1, 2019	Applicable to second agreement period starting in 2025	Applicable to third agreement period starting in 2030	Applicable to fourth agreement period starting in 2035 and all subsequent agreement periods
Renewing ACO for agreement period starting on July 1, 2019, with initial start date in 2012, 2013, or 2016	Applicable to third (2012/2013) or second (2016) agreement period starting on July 1, 2019	Applicable to fourth (2012/2013) or third (2016) agreement period starting in 2025	Applicable to fifth (2012/2013) or fourth (2016) agreement period starting in 2030	Applicable to sixth (2012/2013) or fifth (2016) agreement period starting in 2035 and all subsequent agreement periods
Early renewal for agreement period starting on July 1, 2019, ACO with initial start date in 2014 that terminates effective June 30, 2019	Currently applies to second agreement period starting in 2017 as follows: 35 percent or 25 percent (if spending above region)	Applicable to third agreement period starting on July 1, 2019	Applicable to fourth agreement period starting in 2025	Applicable to fifth agreement period starting in 2030 and all subsequent agreement periods

Applicant Type	First time regional adjustment used: 35 percent or 15 percent (if spending above region)	Second time regional adjustment used: 50 percent or 25 percent (if spending above region)	Third time regional adjustment used: 50 percent or 35 percent (if spending above region)	Fourth and subsequent time regional adjustment used: 50 percent weight
Re-entering ACO with initial start date in 2014 whose agreement expired December 31, 2016 (did not renew) and re-enters second agreement period starting on July 1, 2019	Applicable to second agreement period starting on July 1, 2019 (ACO considered to be re-entering a second agreement period)	Applicable to third agreement period starting in 2025	Applicable to fourth agreement period starting in 2030	Applicable to fifth agreement period starting in 2035 and all subsequent agreement periods
Re-entering ACO with second agreement period start date in 2017 terminated during performance year 2 (2018) and re-enters second agreement period starting on July 1, 2019	Applicable to second agreement period starting on July 1, 2019 (ACO considered to be re-entering a second agreement period)	Applicable to third agreement period starting in 2025	Applicable to fourth agreement period starting in 2030	Applicable to fifth agreement period starting in 2035 and all subsequent agreement periods

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(d) Condensed Shared Savings Program Application

In developing the proposals to redesign the Shared Savings Program's participation options, we also revisited our current policy that allows certain organizations with experience in Medicare ACO initiatives to use a condensed application form to apply to the Shared Savings Program (83 FR 41832 through 41833). Under § 425.202(b), we allow for use of a condensed Shared Savings Program application form by organizations that participated in the PGP demonstration. Former Pioneer Model ACOs may also use a condensed application form if specified criteria are met (including that the applicant is the same legal entity as the Pioneer ACO and the ACO is not applying to participate in the one-sided model). For the background on this policy, we refer readers to discussions in earlier rulemaking. (See 76 FR 67833 through 67834, and 80 FR 32725 through 32728.)

The PGP demonstration ran for 5 years from April 2005 through March 2010, and the PGP transition demonstration began in January 2011 and concluded in December 2012.[15] The Pioneer ACO Model began in 2012 and concluded in December 2016.[16] Many former PGP demonstration sites and Pioneer ACOs have already transitioned to other Medicare ACO initiatives including the Shared Savings Program and the Next Generation ACO Model. Accordingly, we believed would no longer be necessary to maintain the provision permitting these entities to use condensed application forms. First, since establishing this policy, we have modified the program's application to reduce burden on all applicants. See 82 FR 53217 through 53222. Second, our proposed approach for identifying ACOs experienced with performance-based risk Medicare ACO initiatives for purposes of determining an ACO's participation options would require former Pioneer Model ACOs to participate under the higher levels of risk: Either the highest level of risk and potential reward in the BASIC track (Level E), or the ENHANCED track. This includes, for example, a former Pioneer ACO that applies to the Shared Savings Program using the same legal entity, or if 40 percent or more of the ACO participants in the ACO are determined to be experienced with the Pioneer ACO Model or other two-sided model Medicare ACO initiatives within the 5 performance year look back period prior to the start date of the ACO's agreement period in the Shared Savings Program.

Under the proposed approach to determining participation options, we

[15] See Fact Sheet on Physician Group Practice Transition Demonstration (August 2012), available at *https://innovation.cms.gov/Files/Migrated-Medicare-Demonstration-x/PGP_TD_Fact_Sheet.pdf.*

[16] See Pioneer ACO Model web page, available at *https://innovation.cms.gov/initiatives/Pioneer-aco-model/.*

would identify these experienced, former Pioneer Model ACOs entering the program for the first time as participating in a first agreement period for purposes of the applicability of the program policies that phase-in over time. On the other hand, if an ACO terminated its participation in the Shared Savings Program, entered the Next Generation ACO Model, and then re-enters the Shared Savings Program, under the proposed approach we would consider the ACO to be entering either: (1) Its next consecutive agreement period in the Shared Savings Program, if the ACO had completed an agreement period in the program before terminating its prior participation; or (2) the same agreement period in which it was participating at the time of program termination. We noted that commenters in earlier rulemaking suggested we apply the benchmark rebasing methodology that incorporates factors based on regional FFS expenditures to former Pioneer ACOs and Next Generation ACOs entering their first agreement period under the Shared Savings Program (see 81 FR 37990). We believed that our proposal to apply factors based on regional FFS expenditures to ACOs' benchmarks in their first agreement periods (see discussion in section II.D. of this final rule) would address these stakeholder concerns.

However, we also considered an alternative approach that would allow ACOs formerly participating in these Medicare ACO models to be considered to be entering a second agreement period for the purpose of applying policies that phase-in over time. We declined to propose this approach at this time, because ACOs entering the Shared Savings Program after participation in another Medicare ACO initiative may need time to gain experience with program's policies. Therefore, we preferred the proposed approach that would allow ACOs new to the Shared Savings Program to gain experience with the program's requirements, by entering the program in a first agreement period.

Therefore, we proposed to amend § 425.202(b) to discontinue the option for certain applicants to use a condensed application when applying to participate in the Shared Savings Program for agreement periods beginning on July 1, 2019 and in subsequent years.

We sought comment on the proposals described in this section and the alternatives considered.

Final Action: We received no comments on this proposal and therefore are finalizing as proposed to amend § 425.202(b) to discontinue the option for certain applicants to use a condensed application when applying to participate in the Shared Savings Program for agreement periods beginning on July 1, 2019 and in subsequent years.

More generally, the participation options available to ACOs based on the policies finalized in this section are summarized in Table 7 (low revenue ACOs) and Table 8 (high revenue ACOs).

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TABLE 7—PARTICIPATION OPTIONS FOR LOW REVENUE ACOs BASED ON APPLICANT TYPE AND EXPERIENCE WITH RISK

Applicant type	**ACO experienced or inexperienced with performance-based risk Medicare ACO initiatives**	**Participation Options** [1]			**Agreement period for policies that phase-in over time** (benchmarking methodology and quality performance)
		BASIC track's glide path (option for incremental transition from one-sided to two-sided models during agreement period)	**BASIC track's Level E** (track's highest level of risk / reward applies to all performance years during agreement period)	**ENHANCED track** (program's highest level of risk / reward applies to all performance years during agreement period)	
New legal entity	Inexperienced	Yes - glide path Levels A through E; new legal entities (not re-entering ACOs) that are low revenue ACOs may elect to enter in Level A, transition to Level B, and remain in Level B for an additional performance year prior to being automatically advanced to Level E for the remaining performance years of their agreement period.	Yes	Yes	First agreement period
New legal entity	Experienced	No	Yes	Yes	First agreement period
Re-entering ACO	Inexperienced - former Track 1 ACOs or new ACOs identified as re-entering ACOs because more than 50 percent of their ACO participants have recent prior experience in a Track 1 ACO	Yes - glide path Levels B through E	Yes	Yes	Either: (1) the next consecutive agreement period if the ACO's prior agreement expired; (2) the same agreement period in which the ACO was participating at the time of termination; or (3) applicable agreement period[2] for new ACO identified as re-entering because of ACO participants' experience in the same ACO

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

Notes: [1] Low revenue ACOs may operate under the BASIC track for a maximum of two agreement periods.
[2] We consider the participation of the ACO in which a majority of the new ACO's participants were participating: (1) If the participation agreement of the other ACO was terminated, then the new ACO re-enters the program at the start of the same agreement period in which the other ACO was participating at the time of termination from the Shared Savings Program, beginning with the first performance year of that agreement period. (2) If the participation agreement of the other ACO expired without having been renewed, then the new ACO re-enters the program under the other ACO's next consecutive agreement period in the Shared Savings Program. (3) If the other ACO is currently participating in the program, the new ACO would be considered to be entering into the same agreement period in which this other ACO is currently participating, beginning with the first performance year of that agreement period.

TABLE 8—PARTICIPATION OPTIONS FOR HIGH REVENUE ACOs BASED ON APPLICANT TYPE AND EXPERIENCE WITH RISK

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

Applicant type	ACO experienced or inexperienced with performance-based risk Medicare ACO initiatives	Participation Options [1]			Agreement period for policies that phase-in over time (benchmarking methodology and quality performance)
		BASIC track's glide path (option for incremental transition from one-sided to two-sided models during agreement period)	**BASIC track's Level E** (track's highest level of risk / reward applies to all performance years during agreement period)	**ENHANCED track** (program's highest level of risk / reward applies to all performance years during agreement period)	
Renewing ACO	Experienced - including former Track 1 ACOs that deferred renewal under a two-sided model	No	No (Except for a one-time renewal option for ACOs with a first or second agreement period beginning in 2016 or 2017 that participated in Track 1+ Model)	Yes	Subsequent consecutive agreement period

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

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

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d. Monitoring for Financial Performance

(1) Background

We provided background on our proposals for monitoring financial performance in section II.A.5.d.(1) of the August 2018 proposed rule (83 FR 41834 through 41835). We explained that the program regulations at § 425.316 enable us to monitor the performance of ACOs. In particular, § 425.316 authorizes monitoring for performance related to two statutory provisions regarding ACO performance: Avoidance of at-risk beneficiaries (section 1899(d)(3) of the Act) and failure to meet the quality performance standard (section 1899(d)(4) of the Act). If we discover that an ACO has engaged in the avoidance of at-risk beneficiaries or has failed to meet the quality performance standard, we can impose remedial action or terminate the ACO (see § 425.316(b) and (c)).

In monitoring the performance of ACOs, we can analyze certain financial data (see § 425.316(a)(2)(i)), but the regulations do not specifically authorize termination or remedial action for poor financial performance. Similarly, there are no provisions that specifically authorize non-renewal of a participation agreement for poor financial performance, although we had proposed issuing such provisions in prior rules.

In the December 2014 proposed rule (79 FR 72802 through 72806), we proposed to allow Track 1 ACOs to renew their participation in the program for a second agreement period in Track 1 if in at least one of the first 2 performance years of the previous agreement period they did not generate losses in excess of their negative MSR, among other criteria. We refer readers to the June 2015 final rule for a detailed discussion of the proposal and related comments (80 FR 32764 through 32767). Ultimately, we did not adopt a financial performance criterion to determine the eligibility of ACOs to continue in Track 1 in the June 2015 final rule. Although some commenters supported an approach for evaluating an ACO's financial performance for determining its eligibility to remain in a one-sided model, many commenters expressed opposition, citing concerns that this approach could be premature and could disadvantage ACOs that need more time to implement their care management strategies, and could discourage participation. At the time of the June 2015 final rule, we were persuaded by commenters' concerns that application of the additional proposed financial performance criterion for continued participation in Track 1 was premature for ACOs that initially struggled to demonstrate cost savings in their first years in the program. Instead, we explained our belief that our authority to monitor ACOs (§ 425.316) allows us to take action to address ACOs that are outliers on financial performance by placing poorly performing ACOs on a special monitoring plan. Furthermore, if our monitoring reveals that an ACO is out of compliance with any of the requirements of the Shared Savings Program, we may request a corrective action plan and, if the required corrective action plan is not submitted or is not satisfactorily implemented, we may terminate the ACO's participation in the program (80 FR 32765).

In the August 2018 proposed rule, we explained that based on our additional experience with monitoring ACO financial performance, the current regulations are insufficient to address recurrent poor financial performance, particularly for ACOs that may be otherwise in compliance with program requirements. Consequently, some ACOs may not have sufficient incentive to remain accountable for the expenditures of their assigned beneficiaries. This may leave the program, the Trust Funds, and Medicare FFS beneficiaries vulnerable to organizations that may be participating in the program for reasons other than meeting the program's goals.

As we stated in the August 2018 proposed rule, we believe that a financial performance requirement is necessary to ensure that the program promotes accountability for the cost of the care furnished to an ACO's assigned patient population, as contemplated by section 1899(b)(2)(A) of the Act. We explained that there is an inherent financial performance requirement that is embedded within the third component of the program's three-part aim: (1) Better care for individuals; (2) better health for populations; and (3) lower growth in Medicare Parts A and B expenditures. Therefore, 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.

(2) Proposed Revisions

We proposed to modify § 425.316 to add a provision for monitoring ACO financial performance. Specifically, we proposed 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.[17] If the ACO is negative outside corridor for a performance year, we proposed that we 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, we proposed that we may immediately or with advance notice terminate the ACO's participation agreement under § 425.218.

We proposed that financial performance monitoring would be applicable for performance years beginning in 2019 and subsequent years. Specifically, we 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. We explained that financial and quality performance results are typically made available to ACOs in the summer following the conclusion of the calendar year performance year. For example, we stated that the financial performance results for performance years beginning on January 1, 2019 and July 1, 2019, would likely be available for CMS review in the summer of 2020 and would be made available to ACOs when that review is complete. The one-sided model monitoring (relative to the ACO's negative MSR) would apply to ACOs in Track 1 or the first 2 years of the BASIC track's glide path, and the two-sided model monitoring (relative to the ACO's MLR) would apply to ACOs under performance-based risk in the BASIC track (including the glide path) and the ENHANCED track, as well as Track 2.

Generally, based on our experience, ACOs in two-sided models tend to terminate their participation after sharing in losses for a single year in Track 2 or Track 3. We have observed that a small, but not insignificant, number of Track 1 ACOs are negative outside corridor in their first 2 performance years in the program. Among 194 Track 1 ACOs that renewed for a second agreement period under Track 1, 19 were negative outside corridor in their first 2 performance years in their first agreement period. This includes 14 of 127 Track 1 ACOs that started their first agreement period in either 2012 or 2013 and renewed for a second agreement period in Track 1 beginning January 1, 2016, as well as 5 of 67 Track 1 ACOs that started their first agreement period in 2014 and renewed for a second agreement period in Track 1 beginning January 1, 2017. Moreover, the majority of these organizations have thus far failed to achieve shared savings in subsequent performance years. For example, of the 14 2012/2013 starters in Track 1 that were negative outside corridor for the first 2 consecutive performance years in their first agreement period, only 2 ACOs achieved shared savings in their third performance year, while 10 were still negative outside corridor and 2 were negative within corridor. All 14 ACOs entered a second agreement period in Track 1 starting on January 1, 2016: In performance year 2016, 5 generated shared savings, 4 were positive within corridor, 4 were negative within corridor, and 1 was negative outside corridor. While some of these ACOs appeared to show improvement, this could be due to the rebasing of the ACOs' historical benchmarks that occurred in 2016. Because the benchmark years for the second agreement period correspond to the performance years of the first agreement period, ACOs that had losses in their initial years are likely to receive a higher rebased benchmark than those that shared savings. We observed similar trends following the first 2 performance years for ACOs that started their first agreement period in 2014 and 2015. Therefore, we explained that our experience does not suggest that a large share of ACOs would be affected.

Alternatively, we considered an approach under which we would monitor ACOs for generating any losses, beginning with first dollar losses, including monitoring for ACOs that are negative inside corridor and negative outside corridor. However, we preferred the proposed approach because the corridor (MLR threshold above the benchmark) protects ACOs against sharing losses that result from random variation.

In the August 2018 proposed rule, and as reiterated in this final rule, we explained that ACOs that continue in the program despite poor financial performance may provide little benefit to the Medicare program while taking advantage of the potential benefits of program participation, such as receipt of program data and the opportunity to enter into certain contracting arrangements with ACO participants and ACO providers/suppliers. The redesign of the program includes a number of features that may encourage continued participation by poor performing ACOs under performance-based risk: The relatively lower levels of risk under the BASIC track, the additional features available to eligible ACOs under performance-based risk

[17] For purposes of the August 2018 proposed rule and this final rule, an ACO is considered to have generated 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.

(the opportunity for physicians and other practitioners participating in eligible two-sided model ACOs to furnish telehealth services under section 1899(l) of the Act, availability of a SNF 3-day rule waiver, and the ability to offer incentive payments to beneficiaries under a CMS-approved beneficiary incentive program), and the opportunity to participate in an Advanced APM for purposes of the Quality Payment Program. Further we explained our concern that ACOs may seek to obtain reinsurance to help offset their liability for shared losses as a way of enabling their continued program participation while undermining the program's goals. Although we considered prohibiting ACOs from obtaining reinsurance to mitigate their performance-based risk, we believed that such a requirement could be overly restrictive and that the proposed financial monitoring approach would be effective in removing from the program ACOs with a history of poor financial performance. We sought comment on this issue, and on ACOs' use of reinsurance, including their ability to obtain viable reinsurance products covering a Medicare FFS population.

We sought comment on these proposals and related considerations.

Comment: Generally, a few commenters supported the concept of removing from the program ACOs with poor performance results. Many commenters expressed concerns about and opposed the proposal to monitor ACOs for poor financial performance and potentially terminate ACOs with 2 performance years of significant losses (negative outside corridor).

Response: We appreciate commenters' support for the need to monitor ACOs for patterns of poor financial performance and to permit CMS to impose remedial action and possibly terminate an ACO for poor financial performance. We summarize and address below the specific concerns of commenters who opposed our proposal.

Comment: Some commenters explained that these provisions, if implemented, would provide CMS with too much discretion to terminate ACO participation in the program, and could further discourage ACOs participating in the Shared Savings Program as this would create additional uncertainty for participants and would also make it difficult to establish agreements with other organizations. Several commenters stated that the resulting loss of participation by ACOs could be disruptive to beneficiaries and providers. One commenter suggested that these disruptions would be harmful because termination of ACOs from the Shared Savings Program would limit the reach of ACO improvements in savings and quality and potentially slow progress in transitioning to value-based care.

Response: In response to commenters' concerns about our potential use of this new policy in an overly broad way, we note that we would carefully consider the need to terminate an ACO for poor financial performance given the potential consequences of this action for the Shared Savings Program, the ACO, its ACO participants, ACO providers/suppliers and beneficiaries, among others. Elsewhere in this section we describe additional factors we may take into consideration in making this determination, which we believe is responsive to the specific concerns that commenters raised, which we describe elsewhere in this section. Nonetheless, we believe the approach we proposed, and are finalizing, offers CMS a means to address ACOs that may continue in the program despite poor financial performance and as a result may provide little or no benefit to the Medicare program while taking advantage of the potential benefits of program participation, such as the ability to benefit from waivers of certain federal rules and requirements, receipt of program data and the opportunity to enter into certain contracting arrangements with ACO participants and ACO providers/suppliers, as well as the opportunity for eligible clinicians in the ACO to qualify for incentive payments under the Quality Payment Program as QPs. This behavior is not protective of the Trust Funds and also suggests that an ACO's approach may be ineffective at meeting the program's goals.

We agree that termination of an ACO's participation from the Shared Savings Program can be potentially disruptive to ACO participants and ACO providers/suppliers, and Medicare FFS beneficiaries. Under the program's regulations, we require terminated ACOs to complete certain close-out procedures, as specified in § 425.221(a), which include requirements that may mitigate the effects of termination on ACO participants, ACO providers/suppliers, and Medicare beneficiaries. Under the program's regulations, we require terminating ACOs to implement close-out procedures in the form and manner and by a deadline specified by CMS related to the following: (i) Notifying ACO participants of termination; (ii) complying with the program's record retention requirements; (iii) retention or destruction of CMS data according to federal requirements; (iv) meeting Shared Savings Program quality reporting requirements for a completed performance year which has implications for ensuring that eligible clinicians meet the MIPS requirements under the Quality Payment Program; and (v) directing beneficiaries to contact their primary care providers if, for example, termination of the ACO will result in discontinuation of certain care processes.

We also note that Medicare FFS beneficiaries always retain their freedom to choose the providers and suppliers from which they seek care. The termination of an ACO would not prevent a beneficiary from choosing to continue receiving care from a provider or supplier that had been an ACO provider/supplier before the ACO's termination.

Comment: Some commenters believe CMS does not need to terminate ACOs if all are forced to move to two-sided risk, viewing the proposed approach as unnecessary. One commenter explained that CMS' proposal to automatically advance ACOs to performance-based risk in the BASIC track's glide path would protect against ACOs that generate losses remaining in the Shared Savings Program just to take advantage of waivers and other provisions. As those ACOs are required to take on increasingly more risk, they would incur too many losses to remain in the program indefinitely. Some commenters suggested that the requirement for ACOs to participate under two-sided models will provide ACOs with incentives to leave the program if they were not able to generate savings. More generally, one commenter indicated that ACOs performing poorly drop out of the program voluntarily so poor financial performance is self-correcting.

Response: We agree that the requirement for ACOs to participate under two-sided models within the redesign of the program established in this final rule should drive ACOs to improved program performance. We also agree that ACOs with poor financial performance, including ACOs that owe shared losses, will tend to voluntarily terminate from the program based on our experience to date with risk tracks. However, as we described in the August 2018 proposed rule (83 FR 41835 through 41836), we remain concerned that some ACOs with poor financial performance will choose to remain in the program even after they have incurred shared losses. ACOs under two-sided models may find the advantages of continued participation outweigh the amount of shared losses owed. ACOs share in a portion of the losses, and lower levels of two-sided

risk may potentially be available to ACOs under the BASIC track. Poor performing ACOs may be encouraged to continue their participation because of the additional features available to eligible ACOs under performance-based risk, such as the opportunity for physicians and other practitioners participating in eligible two-sided model ACOs to furnish telehealth services under section 1899(l) of the Act, the availability of a SNF 3-day rule waiver, and the ability to offer incentive payments to beneficiaries under a CMS-approved beneficiary incentive program. ACOs with shared losses may also seek to continue their participation in Level E of the BASIC track or in the ENHANCED track to participate in an Advanced APM for purposes of the Quality Payment Program.

Comment: As an alternative, some commenters suggested focusing the policy on ACOs with both poor financial performance and other program integrity concerns, but did not specifically identify the types of program integrity concerns that CMS should take into consideration.

Response: We appreciate commenters' suggestion that we consider poor financial performance in combination with other program integrity concerns regarding the ACO. We do not believe we should limit our policy only to ACOs that have both financial performance and program integrity issues. We believe that poor performance is directly reflective of the ACO's ability to achieve the program's goals and that an ACO with no program integrity issues should be removed from the program if it is unable or unlikely to achieve the cost and quality goals of the program. We note that the existence of program integrity issues may already constitute separate grounds for termination.

Comment: As another alternative approach, one commenter suggested that CMS should consider using a blended evaluation process, based on both spend outside the corridor and high cost utilization. The commenter explained that low revenue ACOs can demonstrate consistent reductions in utilization of high spend services, such as in inpatient, emergency room and SNF utilization, yet see the costs associated with that utilization increase.

Response: We note that ACOs that are negative outside corridor tend to have corresponding high utilization. ACOs provide a holistic approach to lowering growth in Medicare FFS expenditures, and we have observed that successful ACOs address spending and utilization across the care continuum or in a majority of claim types. We therefore decline to adjust our approach to monitor and terminate for poor financial performance in certain utilization categories.

The commenter noted that its concern was specific to low revenue ACOs' inability to control costs for inpatient, emergency room and SNF services. Elsewhere in this final rule we have explained our observation that low revenue ACOs tend to be more successful than high revenue ACOs in achieving savings, which suggests that the circumstances the commenter describes may not be a barrier to low revenue ACOs' success in the program. We also note that during the performance year we provide ACOs with program reports with expenditure and utilization data which support ACOs' monitoring of their financial performance trends, including by claims types, and may help ACOs respond to developing trends.

Comment: One commenter suggested that CMS implement the financial monitoring proposal for performance years beginning before January 1, 2019. Specifically, the commenter noted that CMS could use existing performance data for ACOs that are currently participating in the program.

Response: We decline to further modify our approach to adopt the commenter's suggestion that we consider the performance of ACOs in current agreement periods during performance years prior to the applicability date of the policy we are finalizing.

Comment: Some commenters suggested that CMS modify the proposed approach to allow ACOs additional years of poor performance before termination. The commenters suggested that CMS revise the policy to impose action after 3 or more performance years of poor financial performance. Commenters offered a variety of explanations for why the proposal does not give ACOs sufficient time to correct poor financial performance and show positive financial results, including the following.

- Several commenters explained that ACOs will not have sufficient time to make and implement adjustments over 2 performance years due to the timing of financial reconciliation. Performance data for the prior year is not available until the summer of the current performance year. One commenter explained that this timing poses challenges for ACOs to affect performance for the year underway. One commenter suggested that CMS could assist ACOs in achieving shared savings or in lowering costs by making program data and results more transparent and timely so that ACOs can actively monitor their performance in real time.
- Several commenters suggested that new ACOs, and ACOs that modify their ACO participant lists during the agreement period, face challenges as a result of learning curves and a lack of experience. According to these commenters, ACOs should be allowed sufficient time to implement necessary population health, care management, provider engagement, and data strategies to enhance beneficiary care and contain costs. One commenter suggested that ACOs need at least three years to develop the competencies for success. One commenter explained its belief that no ACOs would want to invest the millions of dollars required to set up and operate an ACO if they could be terminated from the program just 24 months later. This commenter suggested there would be sufficient risk to participants under the proposed redesigned program, and that the risk of being terminated this quickly could be too much for many ACOs to bear.
- Other commenters more generally indicated that ACOs need additional time to show positive performance results, explaining that the program's results show ACOs perform better over time. One commenter, MedPAC, explained that if an ACO is improving the efficiency of care delivery, eventually its shared savings will outweigh its shared losses. Accordingly, one or two years of shared losses cannot be seen as a definitive indicator of performance given the small number of beneficiaries in most ACOs. Several commenters expressed concern that the proposed approach to potentially terminate ACOs after two years of poor financial performance, could result in termination of ACOs that may otherwise go on to achieve savings and make quality improvements for their patients if they are allowed to remain in the program.

Response: We disagree with commenters' suggestions that we modify our approach to consider three or more years of poor financial performance prior to potential termination of an ACO from the program. We believe that such an approach would effectively constrain the policy to addressing ACOs with 3 consecutive years of poor financial performance, since results for performance year 3 would not be available until mid-way through performance year 4. If the 3 years of poor financial performance were not consecutive, the policy would only allow for limited scenarios in which we could remove poor performing ACOs. For example, under a policy that provides that ACOs would be terminated after 3 performance years of poor performance, if an ACO was negative outside corridor for performance year 1 and performance year 2 and performance year 4, we would not pursue termination until mid-way through performance year 5 (when the results for the performance year 4 become available). We believe such an approach could allow ACOs

with a pattern of poor performance to remain in the program similar to how poorer performing ACOs persist in the program currently.

We disagree with the commenters' assertions that our proposal does not give ACOs sufficient time to identify and correct poor financial performance. ACOs have access to a variety of resources to assess their expenditure and utilization trends on an ongoing basis and to make adjustments over the course of the performance year. We provide ACOs with quarterly and annual expenditure and utilization reports, among other program reports (including historical benchmark reports, and aggregate reports with demographic data on the ACO's assigned beneficiary population) as well as tools that ACOs can use to track and estimate their performance. We believe ACOs receive data in a timely manner from CMS, including monthly beneficiary-identifiable claim and claim line feed files with Parts A, B, and D data, and have the ability to detect and respond to trends in a more timely fashion than commenters suggested, including before CMS has made a determination of poor financial performance.

We disagree with the commenter that suggested that two performance years of shared losses is not a definitive indicator of poor performance. We have observed that ACOs with shared losses have greater difficulty in achieving shared savings within the same agreement period. As we described in the proposed rule and have restated in this final rule, our previous experience over a 5 performance year span suggests that the majority of ACOs whose first 2 performance years are negative outside corridor fail to achieve savings in subsequent years. Therefore, we believe 2 consecutive years of poor financial performance is a definitive indicator of the ACO's performance trends and sufficient to warrant compliance actions that could include termination. We acknowledge that our experience is based on 3-year agreements (or in the case of the program's initial entrants, agreement periods of 3 years and 9 months, or 3 years and 6 months, and four year agreements in the case of the few ACOs approved to use the deferred renewal option which we are discontinuing with this final rule) and that we are finalizing an approach that implements 5-year agreements. Therefore, we anticipate examining the effects of our financial performance monitoring policy in the context of performance trends over longer agreement periods. Further, as we state elsewhere in this section of this final rule, we will also consider improvement in performance in deciding whether to terminate an ACO for 2 years of poor financial performance. This is especially relevant to ACOs that are negative outside corridor in non-sequential performance years. If an ACO shows a pattern of improving financial performance, or fluctuating financial performance, it may be indicative of the ACO's ability to demonstrate consistent positive performance results in future performance years.

Based on our experience with implementing the program, we disagree with the commenter's assertion that the proposed policy if finalized will discourage ACOs from investing in program participation, out of concern that the potential for return on investment to cover start-up and operating costs is outweighed by the risk of being terminated for non-compliance with program requirements. We acknowledge there is risk to establishing and operating an ACO and believe that this financial performance monitoring policy can provide an additional incentive for ACOs to quickly improve their performance. Since the start of the Shared Savings Program hundreds of ACOs have agreed to participate in the program under the program's current policies under which CMS monitors and takes compliance action, including termination, prior to the conclusion of 3-year agreement periods for ACOs that fail to meet program requirements. We note that we have terminated only a small number of ACOs for failure to meet program requirements. Notably, as we previously described in the background for this section, we terminate ACOs for failure to meet the quality performance standard over 2 consecutive performance years according to § 425.316(c). Therefore we do not believe that ACOs will be discouraged from forming or entering the program because of a financial performance monitoring policy that also requires accountability for meeting the program's goal of lowering growth in expenditures, and under which ACOs may be terminated for poor performance after 2 performance years.

Comment: A few commenters suggested that the proposed policy should be implemented only as a criterion for determining an ACO's eligibility to renew its participation in or to re-enter the program. Several commenters suggested that ACOs should be protected from possible termination for poor financial performance for one full agreement period. These commenters suggested that ACOs that generate losses beyond their MLR by the end of their third performance year could be required to submit and implement a corrective action plan for their fourth performance year (of a 5-year agreement period). Then, as a condition of being approved for a second or subsequent agreement period, ACOs could be expected to meet quality standards and operate within the risk corridor (not generate savings below the MLR).

Response: We decline to adopt the commenter's suggestions because, given 5-year agreement periods, we believe it would be more protective of the Trust Funds and Medicare FFS beneficiaries to allow CMS the flexibility to more quickly remove from the Shared Savings Program ACOs showing losses outside their corridor for two performance years. We note that we are finalizing in section II.A.5.c.(5) of this final rule, our proposal to consider an ACO's past financial performance in determining whether to approve a renewing ACO's or re-entering ACO's Shared Savings Program application.

Comment: Several commenters suggest that if an ACO performs poorly in performance year 1, but performs well in performance year 2 (results for which would be available in performance year 3), then the ACO should be allowed to participate in performance year 4.

Response: The commenters may have misunderstood the proposal. Under the proposed approach, we would not terminate such an ACO for a single year of poor performance. We note that performance results are typically made available to ACOs in the summer following the conclusion of the calendar year performance year. In the commenters' example, the soonest we could terminate the ACO would be after PY 3 results are available, which would occur more than halfway through PY 4. Under our proposal and this final rule, CMS retains discretion not to terminate an ACO after the second year of poor financial performance. In the commenters' example, depending on the circumstances, CMS could either impose additional remedial action in PY 4 or terminate the ACO in PY 4 if the ACO was again negative outside corridor in PY 3. Under this approach, the ACO may be allowed to complete PY 4, and if further corrective action is taken the ACO may be allowed to continue its participation in PY 5.

Comment: A few commenters suggested that CMS should not terminate an ACO for poor financial performance without considering factors that might affect an ACO's performance over its agreement period. One commenter suggested that for ACOs that have achieved significant success in the

past yet are struggling in the current performance year, CMS should not impose termination without considering whether the ACO's poor performance is due to factors such as changes in the assignment methodology and risk adjustment of the patient population. Other commenters suggested we consider the impact of changes to the ACO's participant list and changes in program policies during the agreement period.

Several commenters suggested that CMS consider evidence of performance improvement over time before making a determination to terminate an ACO, but did not provide specific suggestions on how CMS should measure improvement.

Response: We note that according to § 425.212 an ACO is subject to all regulatory changes that become effective during the agreement period, with the exception of the following program areas, unless otherwise required by statute: (1) Eligibility requirements concerning the structure and governance of ACOs; and (2) calculation of sharing rate. We decline to create additional exceptions by not terminating ACOs for poor financial performance based on policy changes that become applicable within the ACO's agreement period. During an ACO's agreement period, we adjust the ACO's historical benchmark to address changes in assignment, such as a result of regulatory changes to the program's assignment methodology, and changes to the ACO's ACO participant list. These adjustments ensure that the ACO's historical benchmark expenditures remain comparable to performance year expenditures. Further, we note that our use of blended regional and national expenditure growth rates in updating the ACO's historical benchmark, as we are finalizing in section II.D. of this final rule, will help to ensure that the ACO's updated benchmark reflects the broader effect of changes to Medicare FFS payment policies that may be reflected in performance year expenditures. Additionally, we believe the applicability of the CMS–HCC risk adjustment methodology is not a factor that needs to be considered because our risk adjustment methodology annually renormalizes risk scores which helps to account for year to year changes in the risk adjustment model.

Commenters did not provide specific suggestions on how we should measure performance improvement, but we agree that performance improvement could justify allowing an ACO to remain in the program after two years of poor financial performance. If the performance years in which the ACO is negative outside corridor are non-sequential, we anticipate considering whether the ACO generated savings or losses in the other performance years. For instance, we would be especially concerned by a pattern where an ACO generated losses outside corridor for non-sequential performance years and generated losses within corridor during the alternate year(s) especially if they missed the MLR by a small margin. This suggests a pattern of poor financial performance and the absence of corrective action to significantly improve performance to meet the program's goals. If the years in which the ACO is negative outside corridor are non-sequential, and the ACO showed a pattern of performance improvement, such as losses or savings within their MSR/MLR corridor, or sharing savings (positive outside corridor), during the alternate year(s), then we would consider this impact and the ACO's ability to continue a pattern of improved financial performance over time.

Comment: Some commenters expressed concerns about the lack of predictability of the ACO's historical benchmark, noting that the values can increase or decrease each performance year. One commenter stated concern about the proposed approach to terminate ACOs if they exceed their benchmarks because the commenter believes that the program's benchmark methodology has been significantly flawed to date. This commenter explained that the construct of the benchmark is complex and many ACOs do not have the skill set or actuarial support to analyze, review and assess the complexities of benchmarking. One commenter stated that it cannot be determined that ACOs that fall outside of their negative corridor, are, in fact, losing the Medicare program money as benchmarks are not valid counterfactuals. One commenter suggested that CMS consider a standard that looks at the ACO's cost growth relative to national expenditure growth trends to demonstrate that the ACO is an outlier requiring corrective action. For example, the commenter suggested that CMS could monitor ACOs based on whether the ACO's expenditure trend is substantially higher than the national expenditure growth trend, such as 5 percentage points higher, and take pre-termination action in those cases.

Response: ACO's historical benchmarks can fluctuate in value during an agreement period because of adjustments for ACO participant list changes, and because of annual risk adjustment and the benchmark update. These policies ensure the continued comparability of the historical benchmark to the ACO's performance year expenditures, for accuracy in determining shared savings and shared losses. We provide program reports, including preliminary and final historical benchmark reports, as well as annual and quarterly aggregate program reports on expenditure and utilization trends and demographic data on the ACO's assigned population, to support ACOs' participation in the program. We also educate ACOs on the use of quarterly program data to predict their financial performance.

We disagree with the commenters who suggested that the program's historical benchmark methodology has significant flaws. We continue to believe that the ACO's historical benchmark is the most accurate measure for determining ACO financial performance. We also believe that the annual adjustment and update to the ACO's historical benchmark improves the accuracy of the benchmark calculations. The annual risk adjustment methodology adjusts the benchmark so that it is reflective of the health status of the ACO's assigned population. The annual update, as modified based on this final rule ensures that the benchmark reflects trends in both regional and national Medicare FFS expenditure growth with more weight on national trends for ACOs serving a larger percentage of beneficiaries in their region. Therefore, we decline the commenter's suggestion that we use an alternative approach to determining financial performance (and identifying poor performers) such as comparing the ACO's cost growth relative to national expenditure growth trends.

Comment: Several commenters explained that an ACO with spending that is slightly higher than its benchmark should not be subject to remedial action or termination. The commenters described a number of reasons why spending for a performance year could be a few percentage points higher than a benchmark. For example, the beneficiary population could experience a worse than usual flu season, the hospital wage index in an ACO's area could increase relative to their benchmark years, the ACO's participant TINs could have joined an Innovation Center initiative that increases spending, or the ACO's eligible clinicians could have earned a MIPS bonus, which CMS includes as ACO expenditures.

Response: We decline the commenters' suggestions to make exceptions to our approach for monitoring and terminating ACOs for poor financial performance by taking

into account various differences in expenditures and payment rates among providers and suppliers. Along similar lines, in earlier rulemaking, we have discussed our consideration of technical adjustments to benchmark and performance year expenditures (see, for example 80 FR 32796 through 32799). As explained in earlier rulemaking, we continue to believe that making extensive adjustments to remove the effect of all policy adjustments from benchmark and performance year expenditures, or allowing for expenditure adjustments on a case-by-case basis, would create an inaccurate and inconsistent picture of ACO patient population spending and may limit innovations in ACOs' redesign of care processes or cost reduction strategies.

Further, we believe that the modifications we are finalizing in section II.D of this final rule, to apply factors based on regional FFS expenditures in establishing, adjusting and updating the ACO's historical benchmark beginning with an ACO's first agreement period (for agreement periods beginning on July 1, 2019, and in subsequent years) mitigate some of the commenters' concerns. In earlier rulemaking, we explained that by replacing the national average FFS expenditure trend and flat dollar update with trends observed for county level FFS assignable beneficiaries in each ACO's unique assignment-weighted regional service area, benchmark calculations will be better structured to account for exogenous trend factors particular to each ACO's region and the pool of potentially assignable beneficiaries therein (for example, higher trend due to a particularly acute flu season or an unusually large area wage index adjustment or change) (81 FR 38004). We believe that the revised approach to updating the benchmark, by blending regional and national expenditure growth rates, which we are finalizing in section II.D. of this final rule, will continue to protect against these concerns. The weight on the national component of the blended update factor is based on an ACO's penetration in its regional service area and the weight on the regional component is equal to one minus the national weight. Because most ACOs are not highly penetrated in their regional service areas, we believe that the blended update factor will still strongly reflect regional trends for the majority of ACOs.

Comment: A few commenters suggested that CMS should take into consideration the impact of extreme and uncontrollable circumstances when monitoring ACOs for losses negative outside corridor and in taking related pre-termination actions. For example, one commenter suggested that ACOs that experienced an extreme and uncontrollable event during their agreement period should be allowed a waiver and/or extension of program requirements and/or deadlines when applicable. This commenter explained that by not providing such an option, some ACOs may be unfairly and prematurely terminated.

Response: We appreciate the commenter's suggestion that we take into account the impact of extreme and uncontrollable circumstances when monitoring and terminating ACOs for poor financial performance. We decline at this time to adopt the commenter's suggestion to provide ACOs affected by extreme and uncontrollable circumstances with a waiver of or exceptions to program requirements we are finalizing to establish policies to monitor and terminate ACOs for poor financial performance.

In the November 2018 final rule (83 FR 59968 through 59979), we finalized the extension of policies that we previously adopted 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. Specifically, these policies address quality performance scoring for ACOs affected by extreme and uncontrollable circumstances and also provide for a reduction in the amount of shared losses owed by ACOs participating under a two-sided model for performance years affected by extreme and uncontrollable circumstances. We also explained our belief that under the approach of using regional factors in establishing and updating the benchmark, as described in section II.D of this final rule, it would not be necessary to make an additional adjustment to ACOs' historical benchmarks to account for expenditure variations related to extreme and uncontrollable circumstances (83 FR 59979).

If we take pre-termination action against an ACO for poor financial performance, the ACO would have the opportunity to explain whether and how its financial performance was affected by extreme and uncontrollable circumstances and how those circumstances may also have affected its ability to take corrective action to improve its performance. We note that the pre-termination actions we could take in the case of poor financial performance are set forth in § 425.216, which include issuance of a warning letter or a request for a corrective action plan. As described in § 425.216(b), a corrective action plan must address what actions the ACO will take to ensure that the ACO, ACO participants, ACO providers/suppliers or other individuals or entities performing functions or services related to the ACO's activities or both correct any deficiencies and comply with all applicable Shared Savings Program requirements. ACOs that are required to submit a corrective action plan would have the opportunity to explain to CMS the particular circumstances that impacted their prior performance, and how they will improve their financial performance. For instance, an ACO that was affected by extreme and uncontrollable circumstances would have the opportunity to explain how these circumstances may have impacted the ACO's assigned beneficiary expenditures. This additional information may assist CMS in better understanding the circumstances that led to the ACO's poor financial performance and allow CMS to better determine appropriate pre-termination options and evaluate the ACO's corrective actions. Nothing in our regulations would prohibit an ACO from offering the same information in response to a warning letter.

We will continue to monitor the impact of extreme and uncontrollable circumstances on ACOs, particularly as we gain experience with the disaster-relief policies we have finalized for performance year 2017 and subsequent performance years. We will consider whether any changes to our policy for monitoring and terminating ACOs for poor financial performance may be necessary to account for the effects of extreme and uncontrollable circumstances. Any such changes would be made through notice and comment rulemaking.

Comment: Some commenters point out there are interactions between the proposed approach for monitoring and terminating ACOs for poor financial performance, and the policy for allowing ACOs in a two-sided model to select their MSR/MLR threshold prior to entering performance-based risk for the agreement period. These commenters expressed concern that the proposed approach to monitoring and terminating ACOs for poor financial performance could disproportionately affect ACOs that take on greater risk by electing a lower MSR/MLR. According to some commenters, CMS' proposed definition of negative outside corridor sets a very low bar, especially for ACOs in downside financial risk models where the ACO can select a MLR as low as 0 percent. Some commenters explained

that many ACOs view selection of the MSR/MLR in a two-sided model as a significant incentive to move into a performance-based risk track, but this proposal would create a double-edged sword whereby an ACO that wants to take on greater accountability through a lower MLR would be faced with the potential of being terminated from the program as a result of spending that exceeds its MLR. One commenter suggested that for ACOs in a two-sided model, CMS should use a variable MLR based on the number of the ACO's assigned beneficiaries (as used to determine the MSR under a one-sided model) for purposes of determining poor financial performance.

Response: We acknowledge the commenters' concerns about the interactions between the existing policy of permitting ACOs under two-sided models to elect a symmetrical MSR/MLR and our proposals with respect to monitoring and termination for poor financial performance. As discussed in section II.A.6.b. of this final rule, ACOs under a one-sided model are subject to a variable MSR based on their number of assigned beneficiaries. ACOs in two-sided models may select a symmetrical MSR/MLR 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 ACO's number of assigned beneficiaries (the same as the MSR that would apply in a one-sided model, and the MLR is equal to the negative MSR). We established the variable MSRs to provide a greater degree of protection from normal variation in expenditures for smaller ACOs. For ACOs that enter an agreement period under a two-sided model, this MSR/MLR selection is made at the time of application. For ACOs participating in the BASIC track's glide path, this election will be made during the application cycle preceding their first performance year in a two-sided model, generally during the calendar year before entry into risk. We believe that ACOs electing their MSR/MLR recognize the implications of their selection, including the potential that a low MSR/MLR will increase the risk of owing shared losses, as they are agreeing to be held accountable for the financial consequences of participation under this level of risk and reward. As a result, we believe they would also consider the potential impact that their selection may have upon their eligibility to continue in the program in the future. Accordingly, we decline the commenter's suggestion to apply a variable MSR/MLR based on the size of the ACO's assigned population instead of the fixed MSR/MLR selected by ACOs, in our approach to identifying ACOs with poor financial performance.

We believe it is appropriate to use ACOs' actual financial performance results in determining whether ACOs are negative outside corridor and in monitoring and terminating ACOs for poor financial performance. In calculating an ACO's financial performance results, we use the MSR/MLR that is applicable to the ACO. For ACOs under a one-sided model we apply a variable MSR based on the number of beneficiaries assigned to the ACO. For ACOs under a two-sided model we apply the ACO's selected MSR/MLR, which is either a symmetrical fixed MSR/MLR between zero percent and 2 percent (in increments of 0.5 percent) or a symmetrical MSR/MLR that varies based on the number of beneficiaries assigned to the ACO. In section II.A.6.b.(3) of this final rule, we are finalizing an approach to modifying the MSR/MLR to address small population sizes for ACOs participating in two-sided models. Under this final policy, we 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 will provide further protection from shared losses for ACOs with small populations. However, we note that the ACOs to which we would apply this policy would be considered out of compliance with the program requirement to maintain a minimum of 5,000 assigned beneficiaries.

Comment: Several commenters suggested that expanding CMS' authority to terminate ACOs from the program based on financial performance undermines the collaborative nature of this program and the positive results that ACOs generate.

Response: We do not believe that establishing this regulatory flexibility to help ensure the integrity of the program undermines our commitment to maintaining a program that encourages and fosters the success of ACOs that are committed to achieving the program's goals.

Comment: One commenter expressed concern that the proposed approach to monitoring and termination for poor financial performance could disadvantage rural providers.

Response: We decline to make an exception for rural ACOs to the policy we are finalizing to monitor and terminate ACOs for poor financial performance. As we described in section II.A.5.b of this final rule, we believe that rural ACOs would tend to be among low revenue ACOs, which have demonstrated better financial performance in the Shared Savings Program compared to ACOs that includes hospitals (for example). Based on our experience with program performance results we do not believe that rural ACOs, such as those whose beneficiaries predominantly reside in non-metropolitan areas, would be disproportionately affected by a policy that monitors and terminates ACOs for poor financial performance, compared to ACOs whose beneficiaries predominantly reside in metropolitan areas.

Comment: Several commenters suggested that CMS should create a direct channel for ACOs to report suspected fraud and abuse. These commenters stated that ACOs continuously monitor their expenditures. The commenters explained that ACOs are also monitoring services rendered by clinicians outside the ACO and keep an eye on reimbursements completely removed from their own financial interests other than to achieve shared savings. ACOs have a frontline ability and financial incentive to identify and report suspicious activity, yet ACOs have no direct access to CMS program integrity functions.

Response: The program has several program and regulatory safeguards in place to encourage ACOs, ACO participants, and providers and suppliers to monitor and report allegations relating to fraud, waste, abuse, and overall program integrity. The Shared Savings Program makes referrals to CMS' Center for Program integrity (CPI) and/or the Office of the Inspector General (OIG) whenever an ACO, ACO participant, or provider/supplier raises an allegation of fraud, waste, or abuse.

Anyone suspecting healthcare fraud, waste or abuse is encouraged to report it to CMS or the OIG. The OIG Hotline accepts tips and complaints from all sources about potential fraud, waste, abuse, and mismanagement in Department of Health and Human Services' programs (see *https://oig.hhs.gov/FRAUD/REPORT-FRAUD/INDEX.ASP* for instructions). Reporting methods are also specified by *CMS' Center for Program Integrity* (see *https://www.cms.gov/About-CMS/Components/CPI/CPIReportingFraud.html* for instructions). Additionally, concerns may be sent to the Shared Savings Program mailboxes, *ACO@cms.hhs.gov* for inquiries from external parties

including non-ACO entities, and *SharedSavingsProgram@cms.hhs.gov* for inquiries from current Shared Savings Program ACOs, and we will refer them to CPI and the OIG.

Comment: Several commenters suggested that CMS develop a process that would allow an ACO to contest its termination for poor financial performance on the grounds that it was due to extenuating circumstances, or based on an error in CMS' calculations.

Response: The reconsideration review process is specified in subpart I of the program regulations. We do not believe it is necessary to establish a separate appeals process (as suggested by commenters) for ACOs to contest termination based on poor financial performance. We note that the imposition of pre-termination actions is not appealable.

Comment: One commenter suggested that CMS revisit the policy for monitoring and evaluation related to financial performance in future rulemaking as it becomes implemented and applicable to ACOs over time.

Response: We appreciate the commenter's suggestion. As with other program policies, we may revisit this approach in future rulemaking based on lessons learned.

Comment: Some commenters responded to CMS' concern that ACOs may seek to obtain reinsurance to help offset their liability for shared losses as a way of enabling their continued program participation while potentially undermining the program's goals.

Several commenters urged that CMS should allow ACOs taking on performance-based risk to obtain and maintain reinsurance. They explained that ACOs need additional methods to repay losses. According to these commenters, reinsurance is an acceptable option for paying back losses associated with taking on risk, and is not an issue of ''gaming'' the system. They explained that it is a prudent practice to have stop loss coverage or reinsurance to address unexpected risk, and this would support ACO participation in the ENHANCED track given the higher level of potential downward risk in this track.

One commenter explained the importance of tools like reinsurance for helping ACOs manage financial risk. The commenter explained that shared losses is only one form of risk associated with beginning an ACO, another being the business risk associated with the financial investments in starting an ACO (including those that begin under a one-sided model). Further, the commenter explained that providers must consider their full book of business, not just Medicare FFS, when determining the best way to protect against losses. The commenter suggested that CMS not limit providers' ability to insure against the closure of their practices.

Several commenters agreed with the discussion in the preamble where we explained our belief that prohibiting ACOs from obtaining reinsurance would be overly restrictive. One commenter found it difficult to believe that prohibiting ACOs under two-sided models from purchasing reinsurance would ultimately benefit participating ACOs and the Medicare program. A few commenters believe that as more ACOs participate under two-sided risk, more ACOs will seek reinsurance or partnerships with health management firms to mitigate risk. Several commenters indicated that the involvement of reinsurance and management firms will also add to the administrative costs of the program, eroding a key cost advantage of the ACO model over Medicare Advantage, and also weakening upside incentives for ACOs because such firms take a cut of savings.

Response: We appreciate commenters' consideration of our concerns about ACOs' use of reinsurance to offset their liability for shared losses as a way of enabling their continued program participation while undermining the program's goals. At this time we are not establishing new requirements to prohibit ACOs from obtaining reinsurance. As we note in section II.A.6.c. of this final rule we have also declined commenters' suggestions to reinstate reinsurance as a permissible form of repayment mechanism arrangement. We may revisit these issues in future rulemaking as we gain additional experience with program policies, and particularly as more ACOs participate under two-sided models, which we anticipate will be the result of this final rule.

Final Action: Based on our consideration of the comments we received, we are finalizing our proposal with a modification to its applicability date. We proposed to apply this approach to monitor financial performance for performance years beginning in 2019, and in subsequent years. We did not receive comments addressing the timing of applicability of the proposed policy. Due to the timing of this final rule, we believe it is appropriate to modify our proposal to finalize the applicability of this approach to performance years beginning on July 1, 2019, and in subsequent performance years.

We are modifying § 425.316 to add paragraph (d) for monitoring ACO financial performance as follows: For performance years beginning on July 1, 2019 and subsequent performance years, CMS determines whether the Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries for the performance year 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. If the Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries for the performance year exceed the ACO's updated benchmark by an amount equal to or exceeding its negative MSR or MLR, CMS may take any of the pre-termination actions set forth in § 425.216. If the Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries for the performance year exceed the ACO's updated benchmark by an amount equal to or exceeding its negative MSR or MLR for another performance year of the agreement period, CMS may immediately or with advance notice terminate the ACO's participation agreement under § 425.218. As we described in our responses to comments in this section of this final rule, we anticipate taking into account certain relevant factors, such as an ACO's improvement over time, before imposing remedial action or termination for poor financial performance.

6. Requirements for ACO Participation in Two-Sided Models

a. Overview

In this section, we address requirements related to an ACO's participation in performance-based risk. In the August 2018 proposed rule, we proposed technical changes to the program's policies on election of the MSR/MLR for ACOs in the BASIC track's glide path, and to address the circumstance of ACOs in two-sided models that elected a fixed MSR/MLR that have fewer than 5,000 assigned beneficiaries for a performance year. We proposed changes to the repayment mechanism requirements to update these policies to address the new participation options included in this final rule, including the BASIC track's glide path under which participating ACOs must transition from a one-sided model to performance-based risk within a single agreement period. We proposed to add a provision that could lower the required repayment mechanism amount for BASIC track ACOs in Levels C, D, or E. In addition, we proposed to add

provisions to permit recalculation of the estimated amount of the repayment mechanism each performance year to account for changes in ACO participant composition, to specify requirements on the duration of repayment mechanism arrangements, to grant a renewing ACO (as defined in proposed § 425.20) the flexibility to maintain a single, existing repayment mechanism arrangement to support its ability to repay shared losses in the new agreement period so long as it is sufficient to cover an increased repayment mechanism amount during the new agreement period (if applicable), and to establish requirements regarding the issuing institutions for a repayment mechanism arrangement. We also proposed new policies to hold ACOs participating in two-sided models accountable for sharing in losses when they terminate, or CMS terminates, their agreement before the end of a performance year, while also reducing the amount of advance notice required for early termination.

b. Election of MSR/MLR by ACOs

(1) Background

As discussed in earlier rulemaking, the MSR and MLR protect against an ACO earning shared savings or being liable for shared losses when the change in expenditures represents normal, or random, variation rather than an actual change in performance (see 76 FR 67927 through 67929; and 76 FR 67936 through 67937). The MSR and MLR are calculated as a percentage of the ACO's updated historical benchmark (see §§ 425.604(b) and (c), 425.606(b), 425.610(b)).

In the June 2015 final rule, we finalized an approach to offer Track 2 and Track 3 ACOs the opportunity to select the MSR/MLR that will apply for the duration of the ACO's 3-year agreement period from several symmetrical MSR/MLR options (see 80 FR 32769 through 32771, and 80 FR 32779 through 32780; §§ 425.606(b)(1)(ii) and 425.610(b)(1)). We explained our belief that offering ACOs a choice of MSR/MLR will encourage ACOs to move to two-sided risk, and that ACOs are best positioned to determine the level of risk they are prepared to accept. For instance, ACOs that are more hesitant to enter a performance-based risk arrangement may choose a higher MSR/MLR, to have the protection of a higher threshold before the ACO would become liable to repay shared losses, thus mitigating downside risk, although the ACO would in turn have a higher threshold to meet before being eligible to receive shared savings. ACOs that are comfortable with a lower threshold of protection from risk of shared losses may select a lower MSR/MLR to benefit from a corresponding lower threshold for eligibility for shared savings. We also explained our belief that applying the same MSR/MLR methodology in both of the risk-based tracks reduces complexity for CMS' operations and establishes more equal footing between the risk models. ACOs applying to the Track 1+ Model were also allowed the same choice of MSR/MLR to be applied for the duration of the ACO's agreement period under the Model.

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 ACO's number of assigned beneficiaries according to the methodology established under the one-sided model under § 425.604(b). The MSR is the same as the MSR that would apply in the one-sided model, and the MLR is equal to the negative MSR.

(2) Timing and Selection of MSR/MLR

In developing the policies for the August 2018 proposed rule, we considered what MSR/MLR options should be available for the BASIC track's glide path, as well as the timing of selection of the MSR/MLR for ACOs entering the glide path under a one-sided model and transitioning to a two-sided model during their agreement period under the BASIC track.

We proposed 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 Shared Savings Program, as applicable to the model under which the ACO is participating along the BASIC track's glide path. We explained that we believe these thresholds remain important to protect against savings and losses resulting from random variation, although we described in section II.A.5.b.(3) of the proposed rule our consideration of an alternate approach that would lower the MSR for low revenue ACOs (83 FR 41819 through 41820). Further, we noted that providing the same MSR/MLR options for BASIC track ACOs under two-sided risk as ENHANCED track ACOs would be consistent with our current policy for Track 2 and Track 3 that allows ACOs to determine the level of risk they will accept while reducing complexity for CMS' operations and establishing more equal footing between the risk models.

Specifically, we proposed that ACOs in a one-sided model of the BASIC track's glide path would have a variable MSR based on the ACO's number of assigned beneficiaries. We proposed to apply the same variable MSR methodology as is used under § 425.604(b) for Track 1. We proposed to specify this variable MSR methodology in a proposed new section of the regulations at § 425.605(b). We also proposed to specify in § 425.605(b) the MSR/MLR options for ACOs under two-sided models of the BASIC track, consistent with the previously described symmetrical MSR/MLR options currently available to ACOs in two-sided models of the Shared Savings Program and the Track 1+ Model (for example, as specified in § 425.610(b)).

Because we proposed to discontinue Track 1, we believed it would be necessary to update the provision governing the symmetrical MSR/MLR options for the ENHANCED track at § 425.610(b), which currently references the variable MSR methodology under Track 1. We proposed to revise § 425.610(b)(1)(iii) to reference the requirements at § 425.605(b)(1) for a variable MSR under the BASIC track's glide path rather than the variable MSR under Track 1. Because we also proposed to discontinue Track 2, concurrently with our proposal to discontinue Track 1, we did not believe it would be necessary to change the existing cross-reference in § 425.606(b)(1)(ii)(C) to the variable MSR methodology under Track 1.

As we explained in the August 2018 proposed rule (83 FR 41837), we continue to believe that an ACO should select its MSR/MLR before assuming performance-based risk, and this selection should apply for the duration of its agreement period under risk. We believe that a policy that allows more frequent selection of the MSR/MLR within an agreement period under two-sided risk (such as prior to the start of each performance year) could leave the program vulnerable to gaming. For example, ACOs could revise their MSR/MLR selections once they have experience under performance-based risk in their current agreement period to maximize shared savings or to avoid shared losses.

However, in light of our proposal to require ACOs to move between a one-sided model (Level A or Level B) and a two-sided model (Level C, D, or E) during an agreement period in the BASIC track's glide path, we stated our belief that it would be appropriate to allow ACOs to make their MSR/MLR selection during the application cycle preceding their first performance year in

a two-sided model, generally during the calendar year before entry into risk. ACOs that enter the BASIC track's glide path under a one-sided model would still be inexperienced with performance-based risk, but they will have the opportunity to gain experience with the program, prior to making this selection. We noted that this approach would be another means for BASIC ACOs in the glide path to control their level of risk exposure.

Therefore, we proposed 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).

In section II.A.5.b.(3) of the proposed rule we also described and sought comment on several approaches to allowing for potentially greater access to shared savings for low revenue ACOs compared to high revenue ACOs. We noted that such approaches would recognize the performance trends of low revenue ACOs based on performance results and the potential that low revenue ACOs would need additional capital, as a means of encouraging their continued participation in the program. One approach we considered would be to allow for a lower MSR during the one-sided model years (Level A and B) for low revenue ACOs in the BASIC track with at least 5,000 assigned beneficiaries for the performance year. For example, we considered a policy under which we would apply a MSR that is a fixed 1 percent. We also considered setting the MSR at a fixed 2 percent, or effectively removing the threshold by setting the MSR at zero percent. However, we 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 our proposal in section II.A.6.b of the proposed rule and as described below in section II.A.6.b.(3) of this final rule.

We noted that a lower MSR (such as a fixed 1 percent) would reduce the threshold level of savings the ACO must generate to be eligible to share in savings. This would give low revenue ACOs greater confidence that they would be eligible to share in savings, once generated. We noted that this may be especially important for small ACOs which otherwise would have MSRs towards the higher end of the range (closer to 3.9 percent, for an ACO with at least 5,000 beneficiaries) for years in which the ACO participates under a one-sided model. However, we did not believe that a lower MSR would be needed to encourage participation by high revenue ACOs. For one, high revenue ACOs are likely to have larger numbers of assigned beneficiaries and therefore more likely to have lower MSRs (ranging from 3 percent to 2 percent, for ACOs with 10,000 or more assigned beneficiaries). Further, we believed that their control over a significant percentage of total Medicare Parts A and B FFS expenditures for their assigned beneficiaries may provide a sufficient incentive for participation as they would have an opportunity to generate significant savings.

In addition to allowing for a lower MSR for ACOs participating in a one-sided model under the BASIC track, we also considered another approach under which we would allow for a relatively higher final sharing rate under the first four levels of the BASIC track's glide path for low revenue ACOs. This approach is described further in section II.A.3.b of this final rule.

Comment: Most commenters discussing the proposals related to timing and selection of the MSR/MLR agreed with allowing ACOs in a two-sided model to select their MLR/MSR, with close to half also explicitly expressing support for the proposed timing of the selection. Commenters frequently noted that they appreciated the flexibility these policies would provide. A few commenters stated this flexibility was important to ACOs that may want to set the MSR/MLR higher or lower depending on how conservative or aggressive their goals are with respect to avoiding shared losses or earning shared savings, respectively. One commenter supported allowing ACOs to choose from a range of MSR values, noting the importance of allowing organizations to assume levels of risk based on their own business decisions. Another commenter noted that continuing to allow ACOs in risk-bearing tracks to select their MSR/MLR provides ACOs with flexibility and autonomy that is critical to building confidence in accepting higher levels of risk. This commenter noted that the symmetrical nature of these rates will also help to protect the Medicare Trust Funds.

One commenter commended CMS for what they described as providing the same options to ACOs in both one- and two-sided models. Another commenter noted that as the program develops it may become more apparent whether a fixed or variable MSR makes the most sense for CMS, ACOs, and beneficiaries, but recommended that CMS extend the choice of fixed and variable MSR/MLR options to all levels of the BASIC track, stating their belief that offering ACOs choices from the start of their participation in the program provides the best pathway for success. Several commenters advocated for using a fixed MSR of 2 or 2.5 percent for ACOs in one-sided models with at least 5,000 assigned beneficiaries, with some noting that this approach could provide a greater incentive for participation among low revenue ACOs and rural ACOs. A few of these commenters also supported using a variable MSR for ACOs in one-sided models that are below the 5,000 beneficiary threshold.

One commenter asked that CMS reconsider its proposals related to the MSR and MLR in order to ''lessen restrictions and remove barriers to participation in risk sharing arrangements,'' but did not specify which aspects of the MSR/MLR proposals they believed to be restrictive or to create barriers.

Several commenters noted that they disagree with CMS' current policy of requiring that an ACO's MSR/MLR selection apply for the duration of its agreement period under risk, which would also apply to ACOs in two-sided levels of the BASIC track under our proposal. Most of these commenters recommended allowing ACOs to change their selection at the start of each performance year. One commenter requested that ACOs be permitted to re-select their MSR/MLR level in the event that CMS modifies the financial conditions of a track during the agreement period.

A few commenters noted that they disagreed with CMS' stated belief that allowing for annual selections could leave the program vulnerable to gaming. They believe instead that modifying this policy to permit annual selections would allow ACOs to continue to advance in operating under performance-based risk, grow competencies, and build understanding of the benchmarking methodology, which they view as essential to informing an ACO's MSR/MLR selection. They also noted that the assigned beneficiary populations of ACOs, and their associated risk profiles, can change significantly over time, affecting an ACO's previous MSR/MLR selection. These commenters also mentioned that other alternative payment models such as the Bundled

Payments for Care Improvement (BPCI) initiative allow their participants to change their risk thresholds more frequently.

Response: We appreciate commenters' feedback on our proposals around the timing for selection of the MSR/MLR for ACOs participating in the proposed BASIC track. We agree with the commenters who noted that our proposal to allow ACOs to select their MSR/MLR prior to moving to a two-sided model within the glide path will provide flexibility for ACOs that will be moving into two-sided risk arrangements in the BASIC track, and we are finalizing this policy as proposed. We continue to believe that offering a choice of MSR/MLR for ACOs participating in two-sided models will encourage ACO participation in these models, and that ACOs are best positioned to determine the level of risk they are prepared to accept. We would like to clarify that our proposal did not extend the choice of an MSR/MLR to ACOs that are participating in the one-sided levels of the BASIC track; however, as we discuss elsewhere in this section, we did consider certain other options for allowing for a lower MSR for low revenue ACOs under a one-sided model. With regard to ACOs participating under a one-sided model within the BASIC track, we believe that the advantages afforded by a variable MSR that protects the Medicare Trust Funds from shared savings payments that are due to normal variation in expenditures, outweigh any suggested advantages of providing the option for these ACOs to select a fixed rate MSR. Under the policy that we are finalizing, ACOs participating in Levels A or B of the BASIC track will have an MSR based on their number of assigned beneficiaries and will have the opportunity to select their MSR/MLR during the application cycle preceding their first performance year in a two-sided model.

We did not propose to change the requirement that the MSR/MLR selection apply for the duration of the agreement period under performance-based risk for ACOs participating in Track 2 or the ENHANCED track. For consistency, and because we still have concerns that allowing for an annual selection could lead to gaming, we believe that it is appropriate that this requirement extend to ACOs entering a two-sided level in the BASIC track. We would also like to clarify that, absent unusual circumstances, we would not seek to modify the financial terms of an ACO's track during an agreement period. Any such change could only be adopted through rulemaking and, per § 425.212, any regulatory changes to the sharing rate, unless required by statute, do not apply to ACOs during an agreement period. We note, for example, that ACOs currently participating in Tracks 1 and 2 will be allowed to complete their existing agreement period under the financial conditions of their current track, even though these tracks will no longer be available as participation options for ACOs entering a new agreement period on or after July 1, 2019, pursuant to this final rule.

Comment: A number of commenters supported a combination of a lower MSR and higher sharing rates for low revenue ACOs participating in the BASIC track and offered several different alternatives. Commenters explained that combining a lower MSR and higher final sharing rate was necessary to ensure there are sufficient and attainable incentives to support ACOs' efforts to improve quality and lower cost, to provide early returns on investments as well as predictability of savings and the financial support ACOs need to ensure successful participation, and to incentivize low revenue and physician-led ACOs to participate in the redesigned participation options.

Response: We appreciate the feedback provided by commenters on the approaches we considered to increase incentives for low revenue ACOs participating in the BASIC track. As discussed in section II.A.3.b. of this final rule, we are finalizing a 40 percent sharing rate for all one-sided model levels of the BASIC track's glide path and a 50 percent sharing rate for two-sided model levels in the BASIC track's glide path. Additionally, in section II.A.5.c of this final rule, we are finalizing an exception that will permit new legal entities determined to be low revenue ACOs that are inexperienced with performance-based risk Medicare ACO initiatives to participate for 3 performance years under a one-sided model within the BASIC track's glide path (or 4 performance years in the case of ACOs entering an agreement period beginning on July 1, 2019) prior to being automatically advanced to Level E of the BASIC track for the remaining years of their agreement period. As we believe these policies, which represent modifications of our original proposals, will improve the incentives for participation by low revenue ACOs, we decline to adopt a lower MSR for low revenue ACOs participating in the one-sided model levels of the BASIC track at this time. Furthermore, as we noted earlier in this section and have discussed in prior rulemaking (see for example, 80 FR 32761), we continue to believe that the use of a variable MSR for ACOs in one-sided models is appropriate in order to protect the Trust Funds from paying shared savings for savings that may result from random variation rather than from care coordination and quality improvement by the ACO.

Final Action: After considering the comments received, we are finalizing the policies governing the MSR/MLR for ACOs in the BASIC track at § 425.605(b), with a modification to include a new paragraph at § 425.605(b)(2)(ii)(D) to provide that ACOs that elect the option to participate in a third year under a one-sided model based on the policy we are finalizing in section II.A.5.c of this final rule will select their MSR/MLR prior to transitioning to Level E. Under the final policies, ACOs in a one-sided model of the BASIC track's glide path will have a variable MSR based on the number of beneficiaries assigned to the ACO. The variable MSR will be determined using the same methodology that is currently used for Track 1. ACOs in a two-sided model of the BASIC track will be able to choose among the MSR/MLR options that are available to ACOs participating in Track 2 or the ENHANCED track. ACOs participating under Level A or B of the BASIC track's glide path will choose the MSR/MLR to be applied before the start of their first performance year in a two-sided model. This selection will occur before the ACO enters Level C, D or E of the BASIC track's glide path, depending on whether the ACO is automatically transitioned to a two-sided model (Level C or E) or elects to more quickly transition to a two-sided model within the glide path (Level C, D, or E), and will be in effect for the duration of the agreement period that the ACO is under two-sided risk. We are also finalizing as proposed the changes to § 425.610(b)(1)(iii) to add a cross reference the new provision at § 425.605(b)(2).

(3) Modifying the MSR/MLR To Address Small Population Sizes

As discussed in the introduction to this section, the MSR and MLR protect against an ACO earning shared savings or being liable for shared losses when the change in expenditures represents normal, or random, variation rather than an actual change in performance. ACOs in two-sided risk models that have opted for a fixed MSR/MLR can choose a MSR/MLR of zero percent or a symmetrical MSR/MLR equal to 0.5 percent, 1.0 percent, 1.5 percent, or 2.0 percent. As discussed elsewhere in this final rule, we proposed that ACOs in a two-sided model of the new BASIC

track would have the same options in selecting their MSR/MLR, including the option of a variable MSR/MLR based on the number of beneficiaries assigned to the ACO.

Under the current regulations, for all ACOs in Track 1 and any ACO in a two-sided risk model that has elected a variable MSR/MLR, we determine the MSR and MLR (if applicable) for the performance year based on the number of beneficiaries assigned to the ACO for the performance year. For ACOs with at least 5,000 assigned beneficiaries in the performance year, the variable MSR can range from a high of 3.9 percent (for ACOs with at least 5,000 assigned beneficiaries) to a low of 2.0 percent (for ACOs with approximately 60,000 or more assigned beneficiaries). See § 425.604(b). For two-sided model ACOs under a variable MSR/MLR, the MLR is equal to the negative of the MSR.

Under section 1899(b)(2)(D) of the Act, in order to be eligible to participate in the Shared Savings Program an ACO must have at least 5,000 assigned beneficiaries. In earlier rulemaking, we established the requirements under § 425.110 to address situations in which an ACO met the 5,000 assigned beneficiary requirement at the start of its agreement period, but later falls below 5,000 assigned beneficiaries during a performance year. We refer readers to the November 2011 and June 2015 final rules and the CY 2017 PFS final rule for a discussion of the relevant background and related considerations (see 76 FR 67807 and 67808, 67959; 80 FR 32705 through 32707; 81 FR 80515 and 80516). CMS deems an ACO to have initially satisfied the requirement to have at least 5,000 assigned beneficiaries if 5,000 or more beneficiaries are historically assigned to the ACO participants in each of the 3 benchmark years, as calculated using the program's assignment methodology (§ 425.110(a)). CMS initially makes this assessment at the time of an ACO's application to the program. As specified in § 425.110(b), if at any time during the performance year, an ACO's assigned population falls below 5,000, the ACO may be subject to the pre-termination actions described in § 425.216 and termination of the participation agreement by CMS under § 425.218. As a pre-termination action, CMS may require the ACO to submit a corrective action plan (CAP) to CMS for approval (§ 425.216). While under a CAP for having an assigned population below 5,000 assigned beneficiaries, an ACO remains eligible for shared savings and liable for shared losses (§ 425.110(b)(1)). If the ACO's assigned population is not at least 5,000 by the end of the performance year specified by CMS in its request for a CAP, CMS terminates the ACO's participation agreement and the ACO is not eligible to share in savings for that performance year (§ 425.110(b)(2)).

As specified in § 425.1110(b)(1), 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 with respect to the ACO's MSR/MLR: (1) For ACOs subject to a variable MSR and MLR (if applicable), the MSR and MLR (if applicable) will be set at a level consistent with the number of assigned beneficiaries; (2) For ACOs with a fixed MSR/MLR, the MSR/MLR will remain fixed at the level consistent with the choice of MSR and MLR that the ACO made at the start of the agreement period.

To implement the requirement for the variable MSR and MLR (if applicable) to be set at a level consistent with the number of assigned beneficiaries, the CMS Office of the Actuary (OACT) calculates the MSR ranges for populations smaller than 5,000 assigned beneficiaries. The following examples are based on our operational experience: If an ACO's assigned beneficiary population drops to 3,000, the MSR would be set at 5 percent; if the population falls to 1,000 or 500, the MSR would correspondingly rise to 8.7 percent or 12.2 percent, respectively. These sharp increases in the MSR reflect the greater random variation that can occur when expenditures are calculated across a small number of assigned beneficiaries.

In the August 2018 proposed rule (83 FR 41838), we noted that to date, the number of ACOs that have fallen below the 5,000-beneficiary threshold for a performance year has been relatively small. Among 432 ACOs that were reconciled in PY 2016, there were 12 ACOs with fewer than 5,000 assigned beneficiaries. In PY 2015 there were 15 (out of 392 ACOs) below the threshold and in PY 2014 there were 14 (out of 333 ACOs). While the majority of these ACOs had between 4,000 and 5,000 beneficiaries, we observed the performance year population fall as low as 513 for one ACO. Among the 472 ACOs that were subject to financial reconciliation for performance year 2017, over 20 ACOs (4.2 percent) fell below 5,000 assigned beneficiaries for the performance year, with three ACOs with under 1,000 assigned beneficiaries.

Consistent with overall program participation trends, most ACOs that fell below the 5,000-beneficiary threshold in performance year 2017 and in prior performance years were participating in Track 1. These ACOs have thus automatically been subject to a variable MSR. With increased participation in performance-based risk models, however, we anticipate an increased likelihood of observing ACOs that have a fixed MSR/MLR of plus or minus 2 percent or less falling below the 5,000-beneficiary threshold.

Indeed, program data have demonstrated the popularity of the fixed MSR/MLR among ACOs in two-sided models. In PY 2016, the first year that ACOs in two-sided models were allowed to choose their MSR/MLR, 21 of 22 eligible ACOs selected one of the fixed options. Among the 42 Track 2 and Track 3 ACOs participating in PY 2017, 38 selected a MSR/MLR that does not vary with the ACO's number of assigned beneficiaries, including 11 that are subject to a MSR or MLR of zero percent. Among 101 ACOs participating in two-sided models in PY 2018, 80 are subject to one of the fixed options, including 18 with a MSR and MLR of zero percent.

In the August 2018 proposed rule, we indicated that while we continue to believe that ACOs operating under performance-based risk models should have flexibility in determining their exposure to risk through the MSR/MLR selection, we are concerned about the potential for rewarding ACOs with a fixed MSR/MLR that are unable to maintain a minimum population of 5,000 beneficiaries through the payment of shared savings for expenditure variation that is likely the result of normal expenditure fluctuations, rather than the performance of the ACO. If the ACO's minimum population falls below 5,000, the ACO is no longer in compliance with program requirements. The reduction in the size of the ACO's assigned beneficiary population would also raise concerns that any shared savings payments made to the ACO would not reward true cost savings, but instead would pay for normal expenditure fluctuations. We noted, however, that an ACO under performance-based risk potentially would be at greater risk of being liable for shared losses, also stemming from such normal expenditure variation. If an ACO's assigned population falls below the minimum requirement of 5,000 beneficiaries, a solution to improve the confidence that shared savings and shared losses do not represent normal variation, but meaningful changes in expenditures, would be to apply a symmetrical MSR/MLR that varies based on the number of beneficiaries assigned to the ACO.

The values for the variable MSR are shown in Table 9. As previously

described, the MLR is equal to the negative MSR. In this table, the MSR ranges for population sizes varying between from 5,000 to over 60,000 assigned beneficiaries are consistent with the current approach to determining a variable MSR based on the size of the ACO's population (see § 425.604(b)), and the corresponding variable MLR. We have also added new values, calculated by the CMS OACT, for population sizes varying from one to 4,999, as shown in Table 9. For ACOs with populations between 500–4,999 beneficiaries, the MSR would range between 12.2 percent (for ACOs with 500 assigned beneficiaries) and 3.9 percent (for ACOs with 4,999 assigned beneficiaries). For ACOs with populations of 499 assigned beneficiaries or fewer, we would calculate the MSR to be equal to or greater than 12.2 percent, with the MSR value increasing as the ACO's assigned population decreases.

TABLE 9—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

Therefore, we proposed to modify § 425.110(b) to provide that we 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. We proposed to use this approach beginning with performance years starting in 2019. The variable MSR/MLR would be determined using the same approach based on number of assigned beneficiaries that is currently used for two-sided model ACOs that have selected the variable option. 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. While we believed this proposal would have a fairly limited reach in terms of number of ACOs impacted, we stated our belief that it is nonetheless important for protecting the integrity of the Trust Funds and better ensuring that the program is rewarding or penalizing ACOs for actual performance. We also noted that the policy, if finalized, would make it more difficult for an ACO under performance-based risk that falls below the 5,000-beneficiary threshold to earn shared savings, but would also provide greater protection against owing shared losses.

We also proposed to revise the regulations at § 425.110 to reorganize the provisions in paragraph (b), so that all current and proposed policies for determining the MSR and MLR would apply to all ACOs whose population falls below the 5,000-beneficiary threshold and that are reconciled for shared savings or shared losses, as opposed to being limited to ACOs under a CAP, as provided in the existing provision at § 425.110(b)(1). Specifically, we proposed to move the current provisions on the determination of the MSR/MLR at paragraphs (b)(1)(i) and (ii) to a new provision at paragraph (b)(3) where we would also distinguish between the policies applicable to determining the MSR/MLR for performance years starting before January 1, 2019, and those that we proposed to apply for performance years starting in 2019 and subsequent years.

We proposed 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. We noted that the proposed ranges are consistent with the program's

current policy for setting the MSR and MLR (in the event a two-sided model ACO elected the variable MSR/MLR) when the population falls below 5,000 assigned beneficiaries, and therefore similar ranges would be applied in determining the variable MSR/MLR for performance year 2017 and 2018. These ranges in § 425.604(b) are cross-referenced in the regulations for Track 2 at § 425.606(b)(1)(ii)(C) and therefore would also apply to Track 2 ACOs if their population falls below 5,000 assigned beneficiaries. Further, as discussed in section II.A.6.b.(2). of this final rule, we proposed to specify under a new section of the regulations at § 425.605(b)(1) the range of MSR values that would apply under a one-sided model of the BASIC track's glide path, which would also be used in determining the variable MSR/MLR for ACOs participating in two-sided models under the BASIC track and ENHANCED track. We sought 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. In particular, we sought commenters' feedback on whether the proposed approach described in this section could improve accountability of ACOs.

We also noted that the requirement of section 1899(b)(2)(D) of the Act, for an ACO to have at least 5,000 assigned beneficiaries, would continue to apply. The additional consequences for ACOs with fewer than 5,000 assigned beneficiaries, as specified in § 425.110(b)(1) and (2) would also continue to apply. Under § 425.110(b)(2), ACOs are not eligible to share savings for a performance year in which they are terminated for noncompliance with the requirement to maintain a population of at least 5,000 assigned beneficiaries. As discussed in section II.A.6.d. of this final rule, in the August 2018 proposed rule, we also proposed to revise our regulations governing the payment consequences of early termination to include policies applicable to involuntarily terminated ACOs. Under this proposed approach, two-sided model ACOs would be liable for a pro-rated share of any shared losses determined for the performance year during which a termination under § 425.110(b)(2) becomes effective.

Comment: One commenter noted that CMS established the original MSR/MLR rates at a desired confidence level of 90 percent but, based on their own analysis, they believe that CMS miscalculated and created thresholds that were closer to 75 percent, meaning many ACOs receive shared savings payments or repay losses based on random chance. The commenter recommended that CMS consider widening the MSR and MLR thresholds, such as by using a confidence level of 99 percent, to protect ACOs from paying random losses and CMS from sharing random savings.

In contrast, a few other commenters suggested that the current range for variable MSRs is too high. One commenter suggested that with a floor of 2 percent for ACOs with 60,000 or more assigned beneficiaries and higher values for smaller ACOs, the current range of MSR values disincentivizes small ACOs from participating in the program. Another commenter asked CMS to consider reducing the variable MSR to a range of 1 percent to 2.9 percent. They noted that when the MSR is too high it is challenging for ACOs to be eligible for shared savings and there is a strong disincentive for ACOs to continue in the program. They believed that the proposed changes to the benchmarking methodology would reduce volatility and improve accuracy of benchmarks and that the range of the MSR should be reduced to reflect this.

Response: We appreciate commenters' feedback on the range of values used to determine the variable MSR. We believe that there are tradeoffs in setting the MSR range. We are concerned that widening the range based on a 99 percent confidence level, while protecting the Trust Funds from paying for savings and protecting risk-bearing ACOs from repaying losses due to normal variation, would prevent the payment of savings (or collection of losses) in too many cases where savings or losses were not a result of normal variation. We also believe that imposing more stringent thresholds before ACOs are eligible to earn shared savings would be a deterrent to participation. At the same time, we are also unwilling to lower the range of values used to determine the variable MSR for ACOs in a one-sided risk model. While this would, as commenters suggest, likely incentivize participation, we are concerned that lowering the range would not provide adequate protection to the Medicare Trust Funds.

Final Action: We did not receive any comments on our proposal to use a variable MSR/MLR when performing shared savings and shared losses calculations if the assigned beneficiary population for an ACO participating under a two-sided model falls below 5,000 for the performance year regardless of whether the ACO selected a fixed or variable MSR/MLR. We are finalizing this policy as proposed through revisions to § 425.110(b), but are revising the applicability date, such that the new policy will apply to performance years beginning on or after July 1, 2019, rather than January 1, 2019, in order to ensure that this change applies only prospectively. We are also making minor revisions to paragraph (b)(1) for improved clarity and consistency.

We are also finalizing our proposals 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) and the addition of a new section of the regulations at § 425.605(b)(1) that includes the range of MSR values that will apply under the one-sided model of the BASIC track's glide path and will also be used in determining the variable MSR/MLR for ACOs participating in two-sided models under the BASIC track and ENHANCED track.

c. ACO Repayment Mechanisms

(1) Background

We discussed in earlier rulemaking the requirement for ACOs applying to enter a two-sided model to demonstrate they have established an adequate repayment mechanism to provide CMS assurance of their ability to repay shared losses for which they may be liable upon reconciliation for each performance year.[18] The requirements for an ACO to establish and maintain an adequate repayment mechanism are described in § 425.204(f), and we have provided additional program guidance on repayment mechanism arrangements.[19] Section 425.204(f) addresses various requirements for repayment mechanism arrangements: The nature of the repayment mechanism; when documentation of the repayment mechanism must be submitted to CMS; the amount of the repayment mechanism; replenishment of the repayment mechanism funds after

[18] See 76 FR 67937 through 67940 (establishing the requirement for Track 2 ACOs). See also 80 FR 32781 through 32785 (adopting the same general requirements for Track 3 ACOs with respect to the repayment mechanism and discussing modifications to reduce burden of the repayment requirements on ACOs).

[19] Medicare Shared Savings Program & Medicare ACO Track 1+ Model, Repayment Mechanism Arrangements, Guidance Document (July 2017, version #6), available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Repayment-Mechanism-Guidance.pdf* (herein Repayment Mechanism Arrangements Guidance).

their use; and the duration of the repayment mechanism arrangement.

Consistent with the requirements set forth in § 425.204(f)(2), in establishing a repayment mechanism for participation in a two-sided model of the Shared Savings Program, ACOs must select from one or more of the following three types of repayment arrangements: Funds placed in escrow; a line of credit as evidenced by a letter of credit that the Medicare program could draw upon; or a surety bond. Currently, our regulations do not specify any requirements regarding the institutions that may administer an escrow account or issue a line of credit or surety bond. Our regulations require an ACO to submit documentation of its repayment mechanism arrangement during the application or participation agreement renewal process and upon request thereafter.

Under our existing regulations, a repayment mechanism arrangement must be adequate to repay at least the minimum dollar amount specified by CMS, which is determined based on an estimation methodology that uses historical Medicare Parts A and B FFS expenditures for the ACO's assigned population. For Track 2 and Track 3 ACOs, 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 ACO's assigned beneficiaries, as determined based on expenditures used to establish the ACO's benchmark for the applicable agreement period, as estimated by CMS at the time of application or participation agreement renewal (see § 425.204(f)(1)(ii), see also Repayment Mechanism Arrangements Guidance). In the Repayment Mechanism Arrangements Guidance, we describe in detail our approach to estimating the repayment mechanism amount for Track 2 and Track 3 ACOs and our experience with the magnitude of the dollar amounts.

Program stakeholders have continued to identify the repayment mechanism requirement as a potential barrier for some ACOs to enter into performance-based risk tracks, particularly small, physician-only and rural ACOs that may lack access to the capital that is needed to establish a repayment mechanism with a large dollar amount. We revised the Track 1+ Model design in July 2017 (See Track 1+ Model Fact Sheet (Updated July 2017)), to allow for potentially lower repayment mechanism amounts for participating ACOs under a revenue-based loss sharing limit (that is, ACOs that do not include an ACO participant that is either (i) an IPPS hospital, cancer center, or rural hospital with more than 100 beds; or (ii) an ACO participant that is owned or operated by such a hospital or by an organization that owns or operates such a hospital). This policy provides greater consistency between the repayment mechanism amount and the level of risk assumed by revenue-based or benchmark-based ACOs and helps alleviate the burden of securing a higher repayment mechanism amount based on the ACO's benchmark expenditures, as required for Track 2 and Track 3 ACOs. We believed this approach would be appropriate for this subset of Track 1+ Model ACOs because they are generally at risk for repaying a lower amount of shared losses than other ACOs that are subject to a benchmark-based loss sharing limit (that is, ACOs that include the types of ACO participants previously identified in this final rule). Therefore, under the Track 1+ Model, a bifurcated approach is used to determine the estimated amount of an ACO's repayment mechanism for consistency with the bifurcated approach to determining the loss sharing limit under the Track 1+ Model. For Track 1+ Model ACOs, CMS estimates the amount of the ACO's repayment mechanism as follows:

- ACOs subject to the benchmark-based loss sharing limit: The repayment mechanism amount is 1 percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, as determined based on expenditures used to establish the ACO's benchmark for the applicable agreement period.
- ACOs subject to the revenue-based loss sharing limit: The repayment mechanism amount is the lesser of (1) 2 percent of the ACO participants' total Medicare Parts A and B FFS revenue, or (2) 1 percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, as determined based on expenditures used to establish the ACO's benchmark.

Under § 425.204(f)(3), an ACO must replenish the amount of funds available through the repayment mechanism within 90 days after the repayment mechanism has been used to repay any portion of shared losses owed to CMS. In addition, our regulations require a repayment mechanism arrangement to remain in effect for a sufficient period of time after the conclusion of the agreement period to permit CMS to calculate and to collect the amount of shared losses owed by the ACO. Under our current Repayment Mechanism Arrangements Guidance, this standard would be satisfied by an arrangement that terminates 24 months following the end of the agreement period.

(2) Repayment Mechanism Amounts

As previously noted, an ACO that is seeking to participate in a two-sided model must submit for CMS approval documentation supporting the adequacy of a mechanism for repaying shared losses, including demonstrating that the value of the arrangement is at least the minimum amount specified by CMS. In the August 2018 proposed rule, we proposed to modify § 425.204(f) to address concerns regarding the amount of the repayment mechanism, to specify the data used by CMS to determine the repayment mechanism amount, and to permit CMS to specify a new repayment mechanism amount annually based on changes in ACO participants.

In general, we believe that, like other ACOs participating in two-sided risk tracks, ACOs applying to participate in the BASIC track under performance-based risk should be required to provide CMS assurance of their ability to repay shared losses by establishing an adequate repayment mechanism. Consistent with the approach used under the Track 1+ Model, we believed 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. We proposed to calculate a revenue-based repayment mechanism amount and a benchmark-based repayment mechanism amount for each BASIC track ACO and require the ACO to obtain a repayment mechanism for the lesser of the two amounts described previously. We believed this aligned with our proposed approach for determining the loss sharing limit for ACOs participating in the BASIC track, described in section II.A.3.b. of this final rule. In addition, we believed this approach would balance concerns about the ability of ACOs to take on performance-based risk and repay any shared losses for which they may be liable with concerns about the burden imposed on ACOs seeking to enter and continue their participation in the BASIC track.

Previously, we have used historical data to calculate repayment mechanism amounts, typically using the same reference year to calculate the estimates consistently for all applicants to a two-sided model. As a basis for the estimate, we have typically used assignment and expenditure data from the most recent prior year for which 12 months of data are available, which tends to be benchmark year 2 for ACOs applying to enter the program or renew their participation agreement (for example, calendar year 2016 data for ACOs

applying to enter participation agreements beginning January 1, 2018). The Repayment Mechanism Arrangements Guidance includes a detailed description of how we have previously estimated 1 percent of the total per capita Medicare Parts A and B FFS expenditures for an ACO's assigned beneficiaries based on the expenditures used to establish the ACO's benchmark. To continue calculating the estimates with expenditures used to calculate the benchmark, we would need to use different sets of historical data for ACOs applying to enter or renew an agreement and those transitioning to a performance-based risk track. That is because ACOs applying to start a new agreement period under the program and ACOs transitioning to risk within different years of their current agreement period will have different benchmark years. To avoid undue operational burden, we proposed in the August 2018 proposed rule to use the most recent calendar year, for which 12 months of data is available to calculate repayment mechanism estimates for all ACOs applying to enter, or transitioning to, performance-based risk for a particular performance year. We believe this approach to using more recent historical data to estimate the repayment mechanism amount would more accurately approximate the level of losses for which the ACO could be liable regardless of whether the ACO is subject to a benchmark-based or revenue-based loss sharing limit.

Therefore, we proposed 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. For an ACO in Track 2 or the ENHANCED track, we proposed that the 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. For a BASIC track ACO, we proposed that the 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. For ACOs with a participant agreement start date of July 1, 2019, we also proposed to calculate the repayment mechanism amount using expenditure data from the most recent calendar year for which 12 months of data are available.

Currently, we generally do not revise the estimated repayment mechanism amount for an ACO during its agreement period. For example, we typically do not revise the repayment mechanism amount during an ACO's agreement period to reflect annual changes in the ACO's certified ACO participant list. However, in the Track 1+ Model, CMS may require the ACO to adjust the repayment mechanism amount if changes in an ACO's participant composition occur within the ACO's agreement period that result in the application of relatively higher or lower loss sharing limits. As explained in the Track 1+ Model Fact Sheet, if the estimated repayment mechanism amount increases as a result of the ACO's change in composition, CMS would require the Track 1+ ACO to demonstrate its repayment mechanism is equal to this higher amount. If the estimated amount decreases as a result of its change in composition, CMS may permit the ACO to decrease the amount of its repayment mechanism (for example, if CMS also determines the ACO does not owe shared losses from the prior performance year under the Track 1+ Model).

As we indicated in the August 2018 proposed rule, we believe a similar approach may be appropriate to address changes in the ACO's composition over the course of an agreement period and to ensure the adequacy of an ACO's repayment mechanism as it enters higher levels of risk within the ENHANCED track or the BASIC track's glide path. During an agreement period, an ACO's composition of ACO participant TINs and the individuals who bill through the participant TINs may change. The repayment mechanism estimation methodology we previously described in this section uses data based on the ACO participant list, including estimated expenditures for the ACO's assigned population, and in the case of the proposed BASIC track, estimated revenue for ACO participant TINs. See for example, Repayment Mechanism Arrangements Guidance (describing the calculation of the repayment mechanism amount estimate). As a result, over time the initial repayment mechanism amount calculated by CMS may no longer represent the expenditure trends for the ACO's assigned population or ACO participant revenue and therefore may not be sufficient to ensure the ACO's ability to repay losses. For this reason and we explained in the August 2018 proposed rule, we believe it would be appropriate to periodically recalculate the amount of the repayment mechanism arrangement.

For agreement periods beginning on or after July 1, 2019, we proposed 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 we determine the estimated amount of the ACO's repayment mechanism has increased, we may require the ACO to demonstrate the repayment mechanism arrangement covers at least an amount equal to this higher amount.

We proposed to make this determination as part of the ACO's annual certification process, in which it finalizes changes to its ACO participant list prior to the start of each performance year. We would recalculate the estimate for the ACO's repayment mechanism based on the certified ACO participant list each year after the ACO begins participation in a two-sided model in the BASIC track or ENHANCED track. If the amount has increased substantially (for example, by at least 10 percent or $100,000, whichever is the lesser value), we would notify the ACO in writing and require the ACO to submit documentation for CMS approval to demonstrate that the funding for its repayment mechanism has been increased to reflect the recalculated repayment mechanism amount. We would require the ACO to make this demonstration within 90 days of being notified by CMS of the required increase.

We recognize that in some cases, the estimated amount may change insignificantly. Requiring an amendment to the ACO's arrangement (such as the case would be with a letter of credit or surety bond) would be overly burdensome and not necessary for reassuring CMS of the adequacy of the arrangement. Therefore, we proposed to evaluate the amount of change in the ACO's repayment mechanism, comparing the newly estimated amount and the amount estimated for the most recent prior performance year. We proposed that, if this amount increases by equal to or greater than either 10 percent or $100,000, whichever is the lesser value, we would require the ACO to demonstrate that it has increased the dollar amount of its arrangement to the recalculated amount. We solicited comments on whether a higher or lower change in the repayment mechanism estimate should trigger the ACO's

obligation to increase its repayment mechanism amount.

However, unlike the Track 1+ Model, we proposed that if the estimated amount decreases as a result of the ACO's change in composition, we would not permit the ACO to decrease the amount of its repayment mechanism. The ACO repayment mechanism estimate does not account for an ACO's maximum liability amount and it is possible for an ACO to owe more in shared losses than is supported by the repayment mechanism arrangement. Because of this, we believe it is more protective of the Trust Funds to not permit decreases in the repayment mechanism amount, during an ACO's agreement period under a two-sided model, based on composition changes.

We believe the requirements for repayment mechanism amounts should account for the special circumstances of renewing ACOs, which would otherwise have to maintain two separate repayment mechanisms for overlapping periods of time. As discussed in section II.A.5.c.(4). of this final rule, we proposed to define ''renewing ACO'' to mean 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. We proposed 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. However, depending on the circumstances, a renewing ACO may have greater potential liability for shared losses under its existing agreement period compared to its potential liability for shared losses under a new agreement period. Therefore, we proposed 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 (see proposed § 425.204(f)(4)(iv)); or (2) the repayment mechanism amount that the ACO was required to maintain during the last performance year of its current agreement. We believed that this proposal would protect the financial integrity of the program by ensuring that a renewing ACO will remain capable of repaying losses incurred under its old agreement period.

Finally, we proposed to consolidate at § 425.204(f)(4) all of our 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. We also proposed to revise the regulations at § 425.204 to streamline and reorganize the provisions in paragraph (f), which we believe is necessary to incorporate these and other proposed requirements discussed in this final rule.

Comment: One commenter supported the flexibility that would be afforded to BASIC track ACOs to establish a repayment mechanism amount based on the lesser of 1 percent of the total per capita Medicare Parts A and B FFS expenditures for its assigned beneficiaries or 2 percent of the total Medicare Parts A and B FFS revenue of its ACO participants. The commenter noted that this proposal would encourage participation in two sided-models by ACOs that would otherwise have been unable to secure funds necessary to participate in a two-sided model.

Response: We appreciate this feedback supporting our repayment mechanism proposal for BASIC track ACOs. We agree with the commenter that this policy should encourage participation by ACOs in two-sided models by reducing the burden associated with establishing a repayment mechanism.

In addition, to address concerns raised by commenters elsewhere in this final rule regarding the burden on ACOs transitioning from the BASIC track to the ENHANCED track (see section II.A.2), we are extending this policy to ACOs participating in the ENHANCED track. We believe that this will reduce the burden associated with establishing a repayment mechanism on lower-revenue ACOs that would qualify for the new revenue-based repayment mechanism. Accordingly, for an ACO participating in a two-sided model under either the BASIC or ENHANCED track, the repayment mechanism amount must be equal to the lesser of (1) 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 the revenue for the most recent calendar year for which 12 months of data are available.

Comment: A few commenters supported our proposal to establish the repayment mechanism amount based on expenditures for the most recent calendar year for which 12 months of data are available, noting this will likely allow for more accurate estimates of the level of losses for which an ACO could be liable.

Response: We appreciate this feedback supporting our proposal to use expenditure data from the most recent calendar year for which 12 months of data are available in determining an ACO's repayment mechanism amount. We agree that this approach should lead to more accurate estimates of the approximate level of losses for which an ACO could be liable. We are finalizing this policy with respect to ACOs participating in the BASIC and ENHANCED tracks. While we originally proposed changes to the regulations to also apply this policy to Track 2 ACOs, we now believe that this policy would be irrelevant to Track 2 ACOs because we are retiring Track 2 as a participation option (see section A.2 of this final rule) and no new Track 2 ACOs will be entering the program on or after July 1, 2019. Furthermore, because we proposed to apply our new policy of recalculating the repayment mechanism amount on an annual basis only for agreement periods beginning on or after July 1, 2019, we will not be required to recalculate repayment mechanism amounts for existing Track 2 ACOs. For these reasons, we are finalizing revisions to § 425.204(f) so that the repayment mechanism amount for Track 2 ACOs will be based on expenditures used to calculate the benchmark, as is our current policy.

Comment: Several commenters disagreed with our proposal to require an ACO to increase the dollar amount of its repayment mechanism arrangement in instances where the estimated repayment mechanism amount has increased by equal to or greater than either 10 percent or $100,000, whichever is the lesser value. These commenters stated that a threshold of the lesser of a 10 percent or $100,000 increase in the estimated repayment mechanism value is too low. The commenters noted that nearly all ACOs with a total cost of care of $200 million

or more would be required to increase their repayment mechanism amount each year under a threshold of $100,000, which would increase the burden on both CMS and ACOs. One commenter recommended that CMS use only a threshold of 10 percent, rather than employing a ''lesser of'' approach.

Another commenter believed that our proposed threshold seemed reasonable but requested that CMS provide information about the number of ACOs that such threshold would potentially impact before finalizing this policy. This commenter also advocated that ACOs required to increase their repayment mechanism amount under such a policy should be provided with adequate time to do so.

Response: We are persuaded by commenters' suggestions to increase the thresholds that would trigger the requirement for an ACO to increase the dollar amount of its repayment mechanism arrangement. We are therefore finalizing a provision that will require an ACO to increase its repayment mechanism amount if the estimated value of the repayment mechanism amount increases by equal to or greater than 50 percent or $1,000,000, whichever is the lesser value. This would replace our originally proposed threshold of 10 percent or $100,000. These revised amounts are based on an analysis we conducted of the most recently available ACO repayment mechanism data. The analysis showed that a higher threshold of 50 percent or $1,000,000 would likely require only ACOs that had the largest changes in their estimated repayment mechanism value (the top 5 to 10 percent of ACOs) to increase their repayment mechanism amounts. We believe that this less restrictive requirement will minimize an ACO's administrative burden and financial institution fees while adjusting for meaningful changes in repayment mechanism amounts that will help protect the Medicare Trust Funds.

Comment: A few commenters expressed the belief that it would be unfair to require repayment mechanism amounts to increase from year to year without also allowing them to decrease. These commenters requested that CMS amend its proposal to allow for decreases in a repayment mechanism amount. The commenters also requested that CMS provide flexibility to release funds available through the repayment mechanism for a limited period of time (for example, for a 60 day period) for ACOs that need to change their repayment mechanism during an agreement period. We presume that the commenter suggested this to allow an ACO to switch to a new repayment mechanism without having to put up new monies, but the commenter does not directly state or suggest this.

Response: We decline at this time to allow ACOs to reduce their repayment mechanism amount if their estimated repayment mechanism value decreases. As we noted in the background to this section, the repayment mechanism estimate does not account for an ACO's maximum liability amount, and it is possible for an ACO to owe more in shared losses than is supported by a repayment mechanism arrangement. For this reason, we believe it would be more protective of the Trust Funds to not permit decreases in the repayment mechanism amount during an ACO's agreement period under a two-sided model. Similarly, the suggestion to allow release of funds for a limited period of time is outside the scope of our proposal and we therefore decline to adopt such suggestion at this time. We will monitor the number of ACOs that are affected by our finalized policy and the extent of the administrative burden on ACOs and on CMS and will use this information to refine our policies through future notice and comment rulemaking, if warranted.

Comment: Several commenters suggested the proposed repayment mechanism amounts were too high. A few commenters recommended that the repayment mechanism amount for BASIC track ACOs be lowered to 0.5 percent of the ACO's total per capita Medicare Parts A and B FFS expenditures or 1 percent of the total Medicare Parts A and B FFS revenue of its ACO participants. The commenters believed these lower amounts would be sufficient to prompt third-party due diligence and establish credit worthiness within the probable range of shared losses.

Several other commenters expressed concern that rural ACOs would not be able to fund the required repayment mechanism amounts. Some noted that small rural hospitals, rural health clinics, and FQHCs lack the necessary resources to bear the additional expense. Another noted that small ACOs in rural areas may not have the cash flow to support ACO activities that produce savings and establish a repayment mechanism arrangement at the same time. Another commenter requested that when calculating a repayment mechanism amount CMS take into consideration whether the ACO has experienced an extreme and uncontrollable event. The commenter requested that CMS address the issue when developing its policy for extreme and uncontrollable circumstances.

Several other commenters generally warned about the cost burden associated with the repayment mechanism requirement. One commenter noted that as non-profit, low revenue organization, it would potentially be forced out of the program because of its inability to fund a repayment mechanism due to lack of capital. Another commenter described the cost of having a repayment mechanism as contributing to the ''high hurdle'' of transitioning to accountable care.

Response: We appreciate the feedback on the proposed repayment mechanism amounts and the perspectives offered on rural ACOs, ACOs affected by extreme and uncontrollable circumstances, and other ACOs with limited access to capital. While we recognize that repayment mechanisms impose costs on ACOs, we believe they are necessary to protect the financial integrity of the program and of the Medicare Trust Funds. We believe that providing a ''lesser of'' approach to the repayment mechanism amount for all ACOs in two-sided models will help to mitigate this issue for rural ACOs or ACOs that otherwise face funding constraints. We therefore decline to make changes to the proposed repayment mechanism amounts at this time.

Final Action: After considering the comments received, we are finalizing with modification our proposed provisions at § 425.204(f)(4) regarding the repayment mechanism amount as follows.

We are finalizing § 425.204(f)(4)(i) to state that, for a Track 2 ACO, the repayment mechanism amount must be equal to at least 1 percent of the total per capita Medicare Parts A and B fee-for-service expenditures used to calculate the benchmark for the applicable agreement period, as estimated by CMS at the time of application.

We are finalizing § 425.204(f)(4)(ii) to state that, for a BASIC track or ENHANCED track ACO, the repayment mechanism amount must be equal to the lesser of the following: (A) One percent of the total per capita Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available; or (B) two percent of the total Medicare Parts A and B fee-for-service revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available.

We are finalizing § 425.204(f)(4)(iii) to state that, for agreement periods beginning on or after July 1, 2019, CMS recalculates the ACO's repayment

mechanism amount before the second and each subsequent performance year in the agreement period based on the certified ACO participant list for the relevant performance year. If the recalculated repayment mechanism amount exceeds the existing repayment mechanism amount by at least 50 percent or $1,000,000, whichever is the lesser value, CMS notifies the ACO in writing that the amount of its repayment mechanism must be increased to the recalculated repayment mechanism amount. Within 90 days after receipt of such written notice from CMS, the ACO must submit for CMS approval documentation that the amount of its repayment mechanism has been increased to the amount specified by CMS.

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

(3) Submission of Repayment Mechanism Documentation

Currently, ACOs applying to enter a performance-based risk track under the Shared Savings Program must meet the eligibility requirements, including demonstrating they have established an adequate repayment mechanism under § 425.204(f). We noted in the August 2018 proposed rule that we believed that modifications to the existing repayment mechanism requirements would be necessary to address circumstances that could arise if our proposed approach to allowing ACOs to enter or change risk tracks during the current agreement period is finalized. Specifically, we believed modifications would be necessary to reflect the possibility that an ACO that initially entered into an agreement period under the one-sided model years of the BASIC track's glide path will transition to performance-based risk within their agreement period, and thereby would become subject to the requirement to establish a repayment mechanism.

The current regulations specify that an ACO participating under a two-sided model must demonstrate the adequacy of its repayment mechanism prior to the start of each agreement period in which it takes risk and upon request thereafter (§ 425.204(f)(3)). We are revisiting this policy in light of our proposal to automatically transition ACOs in the BASIC track's glide path from a one-sided model to a two-sided model beginning in their third performance year, and also under our proposal that would allow BASIC ACOs to elect to transition to performance-based risk beginning in their second performance year of the glide path.

We believe ACOs participating in the BASIC track's glide path should be required to demonstrate they have established an adequate repayment mechanism consistent with the requirement for ACOs applying to enter an agreement period under performance-based risk. Therefore, we proposed 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, we proposed 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. We sought comment on these proposals.

Final Action: We received no comments on these proposals. We are therefore finalizing our proposed revisions to § 425.204(f)(3) without modification.

(4) Repayment Mechanism Duration

We acknowledged in the August 2018 proposed rule that the proposed change to an agreement period of at least 5 years would affect the term for the repayment mechanism. Under the program's current requirements, the repayment mechanism must be in effect for a sufficient period of time after the conclusion of the agreement period to permit CMS to calculate the amount of shared losses owed and to collect this amount from the ACO (§ 425.204(f)(4)).

We pointed readers to the June 2015 final rule for a discussion of the requirement for ACOs to demonstrate that they would be able to repay shared losses incurred at any time within the agreement period, and for a reasonable period of time after the end of each agreement period (the ''tail period''). We explained that this tail period must be sufficient to permit CMS to calculate the amount of any shared losses that may be owed by the ACO and to collect this amount from the ACO (see 80 FR 32783). This is necessary, in part, because financial reconciliation results are not available until the summer following the conclusion of the performance year. We have interpreted this requirement to be satisfied if the repayment mechanism arrangement remains in effect for 24 months after the end of the agreement period (see Repayment Mechanism Arrangements Guidance). Once ACOs are notified of shared losses, based on financial reconciliation, they have 90 days to make payment in full (see §§ 425.606(h) and 425.610(h)).

We proposed to specify at § 425.204(f)(6) the general rule 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. Based on our experience with repayment mechanisms, we believed ACOs would be able to work with financial institutions to establish repayment mechanism arrangements that would cover a 5-year agreement period plus a 24-month tail period. This proposed approach would have been consistent with the program's current guidance.

We proposed some exceptions to this general rule. First, we proposed that CMS 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 any shared losses for each of the performance years of the agreement period. We indicated that this may be necessary in rare circumstances to protect the financial integrity of the program.

Second, we proposed that the duration requirement account for the special circumstances of renewing ACOs, which would otherwise have to maintain two separate repayment mechanisms for overlapping periods of time. As previously noted, we proposed at § 425.204(f)(3)(iv) that a renewing ACO can choose to 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 increased, if necessary. We proposed at § 425.204(f)(6) 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.

We considered the amount of time by which we would require the existing repayment mechanism to be extended. As discussed in section II.A.5. of this final rule, renewing ACOs (as we proposed to define that term at § 425.20) may have differing numbers of years remaining under their current repayment mechanism arrangements depending on whether the ACO is renewing at the conclusion of its existing agreement period or if the ACO is an early renewal (terminating its current agreement to enter a new agreement period without interruption in participation). We recognized that it may be difficult for ACOs that are completing the term of their current agreement period to extend an existing repayment mechanism by 7 years (that is, for the full 5-year agreement term plus 24 months). Therefore, we considered whether the program would be adequately protected if we permitted the existing repayment mechanism to be extended long enough to cover the first 2 or 3 performance years of the new agreement period (that is, an extension of 4 or 5 years, respectively, including the 24-month tail period). We solicited comment on whether we should require a longer or shorter extension.

We explained that, if we permit an ACO to extend its existing repayment mechanism for less than 7 years, we would require the ACO to extend the arrangement periodically upon notice from CMS. Under this approach, the ACO would eventually have a repayment mechanism arrangement that would not expire until at least 24 months after the end of the new agreement period. We sought comment on whether this approach should also apply to an ACO entering two-sided risk for the first time (that is, an ACO that is not renewing its participation agreement). We would continue to permit a renewing ACO to maintain two separate repayment mechanisms (one for the current agreement period and one for the new agreement period).

Under our proposal, if CMS notifies a renewing ACO that its repayment mechanism amount will be higher for the new agreement period, the ACO may either (i) establish a second repayment mechanism arrangement in the higher amount for 7 years (or for a lesser duration that we have specified in this final rule), or (ii) increase the amount of its existing repayment mechanism to the amount specified by CMS and extend the term of the repayment mechanism arrangement for an amount of time specified by CMS (7 years or for a lesser duration that we have specified in this final rule). We proposed that, on the other hand, if CMS notifies a renewing ACO that the repayment mechanism amount for its new agreement period is equal to or lower than its existing repayment mechanism amount, then the ACO could similarly choose to extend the duration of its existing repayment mechanism instead of obtaining a second repayment mechanism for the new agreement period. However, in that case, the ACO would be required to maintain the repayment mechanism at the existing higher amount.

Third, we believed that the term of a repayment mechanism may terminate earlier than 24 months after the agreement period if it is no longer needed. Under certain conditions, we permit early termination of a repayment mechanism and release of the arrangement's remaining funds to the ACO. These conditions are specified in the Repayment Mechanism Arrangements Guidance, and we proposed to include similar requirements at § 425.204(f)(6). Specifically, we proposed 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. For example, if a renewing ACO opts to establish a second repayment mechanism for its new agreement period, it may request to cancel the first repayment mechanism after reconciliation for the final performance year of its previous agreement period if it owes no shared losses for the final performance year and it has repaid all shared losses, if any, incurred during the previous agreement period.

We solicited 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.

Comment: We did not receive any comments in support of our proposal to require, as a general rule, that an ACO's repayment mechanism 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, or up to a seven-year period for ACOs entering a five-year agreement period under two-sided risk. A few commenters requested that CMS remove the 24-month tail period, expressing concerns that a 24-month tail period would increase financial requirements for ACOs. These commenters believe that if CMS decides to finalize the 24-month tail period policy, then the agency should be liable to pay for additional shared savings discovered during the 24-months following the end of an agreement period.

Several other commenters recommended that we shorten the repayment mechanism tail period to 12 months, noting that this would meet the run-out time for financial reconciliation and allow sufficient time for an ACO to repay any associated shared losses. Another commenter stated that a 24-month tail period would place undue burden on small and low-revenue ACOs and recommended that CMS use a 12- to 18-month tail period instead, which the commenter believes is a sufficient period for CMS to determine if an ACO has incurred shared losses and for an ACO to repay those losses.

Response: We are persuaded by commenters' concerns regarding the potential burden associated with our proposed requirement that ACOs have in effect a repayment mechanism for the duration of the ACO's participation in a two-sided model plus 24 months after the conclusion of the agreement period (which, as proposed, would require such ACOs to procure a repayment mechanism for a five-year agreement period plus an additional 24-month tail period). We agree that financial reconciliation and the repayment of any losses will normally occur within 12 months following the conclusion of a performance year except in very limited circumstances. Because we believe that such exceptions would be rare based on or our experience in collecting shared losses from ACOs, we believe the added risk to the Trust Funds of reducing the tail period to 12 months would be limited and is outweighed by the desire to reduce burden on ACOs. We are therefore finalizing a policy to reduce the length of the required tail period to 12 months following the end of the agreement period.

Comment: Several commenters raised concerns about the ability of an ACO to obtain a repayment mechanism that would cover a 5-year agreement period plus our proposed 24-month tail period. One commenter specifically raised concerns about the ability of rural ACOs to obtain a repayment mechanism that would satisfy our proposed duration requirement due to the insufficient

collateral available to independent, rural physicians and a likely unwillingness of lenders to extend credit when there may be changes to regulations under the Shared Savings Program after the repayment mechanism is issued. The commenter noted that if an ACO does not have funding to pay for a repayment mechanism and is therefore forced to terminate its participation in the program, then the ACO will lose its investment and anticipated shared savings.

Other commenters expressed concern that the lengthened duration would adversely affect ACOs that use surety bonds as a repayment mechanism, noting that that surety bonds are rarely issued beyond five years. One commenter noted that a seven-year surety bond would likely require an ACO to bear significant carrying costs. Another commenter stated that the requirement to maintain a seven-year term would severely limit the availability of surety bonds available to ACOs and would most likely require 100 percent collateral, thereby imposing a significant liquidity and capital burden on ACOs. The commenter indicated that this would be especially problematic for physician-led and small, rural ACOs that lack access to low-cost capital. Another commenter advised that extending repayment mechanisms to five-year agreement period with a 24-month tail might limit the availability of surety bonds to ACOs because the higher risk associated with the longer duration of the bonded obligation could cause issuers to tighten their underwriting standards.

Some commenters recommended a repayment mechanism duration of no more than 3 years, with annual renewal of the repayment mechanism through the end of the tail period. One commenter suggested that this alternative, coupled with a reduction of the threshold for requiring an ACO to update its repayment mechanism amount, would protect the financial integrity of the program, streamline to one consistent repayment mechanism, and preserve the viability of surety bonds and letters of credit for physician-led and small, rural ACOs.

Response: We appreciate the concerns raised by stakeholders regarding the potential impact of our proposed repayment mechanism duration requirements on the availability of repayment mechanism arrangements, including the availability of surety bonds. We first reiterate that we are reducing the total required duration of a repayment mechanism arrangement by reducing the length of the required tail period from 24 months to 12 months following the end of an agreement period. Based on this modification to our proposed repayment mechanism duration policy and our experience with repayment mechanisms, we continue to believe that ACOs, including ACOs that obtain surety bonds, will be able to work with financial institutions to establish repayment mechanism arrangements that will cover a 5-year agreement period plus the 12-month tail period. For example, we note that five of eight ACOs that exercised the deferred renewal option finalized in the June 2016 final rule, secured an approved surety bond for a 6-year term.

In addition, we are modifying our policy to permit ACOs to satisfy the duration requirement by establishing a repayment mechanism that covers a term of at least the first two performance years in which the ACO is participating under a two-sided model and that provides for automatic, annual 12-month extensions of the repayment mechanism such that the repayment mechanism will eventually remain in effect for the duration of the agreement period plus 12 months following the conclusion of the agreement period. For example, an ACO seeking to enter into a participation agreement with CMS under the ENHANCED track on January 1, 2020 could choose to establish a repayment mechanism with a term of six years to cover the five-year agreement period plus a 12-month tail period. Alternatively, the ACO could establish a repayment mechanism covering the first two performance years (ending December 31, 2021) and providing for automatic annual 12 month extensions starting at the end of the first performance year. After the repayment mechanism has been in effect for one performance year (that is, at the end of 2020, the first performance year of the agreement period), the term would automatically be extended by an additional 12 months (through December 31, 2022). Additional automatic 12-month extensions would occur on a rolling basis at the end of the second, third, and fourth performance years of the agreement period, with the last of these extending the arrangement until 12 months after the end of the agreement period (through December 31, 2025).

For an ACO entering into a participation agreement with CMS under two-sided risk on July 1, 2019 that chooses this option (that is, a repayment mechanism that has a term of at least two performance years and that provides for automatic, annual 12-month extensions), the initial term of the repayment mechanism arrangement would be 18 months because the repayment mechanism would cover the 6-month performance beginning July 1, 2019 and the 12-month performance year beginning January 1, 2020. At the end of 2019 (after the repayment mechanism has been in effect for one performance year), the term of the repayment mechanism would automatically be extended by 12 months through the end of the third performance year of the agreement period (through December 31, 2021). Because the agreement period would include six performance years in total, additional automatic 12-month extensions would occur on a rolling basis at the end of the second, third, fourth, and fifth performance years, ultimately extending the arrangement until 12 months after the end of the agreement period (through December 31, 2025).

The initial term of the repayment mechanism cannot expire before the end of the second performance year because the amount of any shared losses incurred for the first performance year will not be known until the second half of the second performance year. We note that the annual 12-month extensions would be occurring one year before the repayment mechanism would otherwise expire. However, the rolling 12-month extensions ensure that a new performance year will not start without ensuring that the repayment mechanism will remain in effect when the ACO is obligated to repay shared losses, if any, for that new performance year. As discussed below, we are finalizing a similar policy for any renewing ACO that wishes to use its existing repayment mechanism to guarantee its ability to repay shared losses.

We believe that allowing ACOs to obtain a repayment mechanism with a shorter initial term will provide additional flexibility to and lessen the potential burden on ACOs, including physician-led, small and rural ACOs. Furthermore, we believe that requiring automatic, annual 12-month extensions of the repayment mechanism will also reduce the burden on an ACO to take action to extend or renew the term of its repayment mechanism, while sufficiently protecting the Medicare Trust Funds. We also believe that this policy, along with the ''lesser of'' repayment mechanism amounts policy that we are finalizing (as described in section II.A.6.c.(2) of this final rule), addresses concerns that certain ACOs have limited access to funds to obtain a repayment mechanism.

While we believe that the modifications to the repayment mechanism policies that we are finalizing in this rule will, in total,

reduce burden on ACOs relative to the proposed policies, we recognize that some ACOs may still be unable to meet the repayment mechanism requirements and would need to terminate their participation in the program. We note that in these cases, the policies for payment consequences of early termination that we are finalizing in section II.A.6.d.(3) of this final rule would apply.

Comment: One commenter affiliated with surety bond issuers recommended that the regulation should clearly state that extending the duration or increasing the amount of a surety bond requires the surety's consent, and that refusal by the surety to extend or increase the bond should not trigger a default under the existing bond.

Response: We realize that the surety would need to consent to extending the duration or increasing the amount of a surety bond, but we do not believe that our regulations need to be revised to state this. If the surety refuses to extend the term of the bond or to increase the amount of the bond, the ACO would be required to enter into a different or additional repayment mechanism arrangement that satisfies the terms of our regulations. We therefore decline to adopt the commenter's recommendation.

Comment: One commenter supported a policy we considered in the proposed rule that would allow a renewing ACO to extend its existing repayment mechanism long enough to cover the first 2 or 3 performance years of its new agreement period, provided that the ACO periodically extends its repayment mechanism until the end of the tail period. The commenter believes that this option would balance the need to protect the integrity of the program while not necessarily creating a burden that would inhibit continued ACO participation, which could occur if ACOs are required to obtain a seven-year extension on top of an existing repayment term. The commenter noted that a seven-year extension could be prohibitively difficult for an ACO to secure.

Response: We appreciate this commenter's feedback on the alternative approach for extension of a renewing ACO's existing repayment mechanism, which we considered in the proposed rule. We agree with the commenter's concerns and are therefore finalizing a policy that would allow a renewing ACO two options for extending its existing repayment mechanism to meet the duration requirement.

Under the first option, a renewing ACO's existing repayment mechanism would be extended to cover the new agreement period plus 12 months following the end of the new agreement period. For example, an ACO that started participating under Track 2 of the Shared Savings Program in 2017 would have established a five year repayment mechanism expiring on December 31, 2021 (covering its current three-year agreement period plus a 24-month tail period). If the ACO renews its participation in the program under the ENHANCED Track on January 1, 2020, then the ACO would have two years of its existing repayment mechanism remaining at time of renewal and could therefore satisfy the duration requirement by extending its existing repayment mechanism arrangement by four years (until December 31, 2025) when entering its new five-year agreement period. The remaining term of the existing repayment mechanism (two years) plus the extension (four years) would together cover the full duration of the new five-year agreement period plus the 12-month tail period.

Under the second option, a renewing ACO's existing repayment mechanism would be extended, if necessary, to cover a term of at least the first two performance years of the new agreement period and would provide for automatic, annual 12-month extensions of the repayment mechanism such that the repayment mechanism will eventually remain in effect until 12 months following the completion of the new agreement period. For example, consider an ACO that has one year remaining on its existing repayment mechanism at the time it renews its participation on January 1, 2020. In this case, the existing arrangement would need to be extended by one year (until December 31, 2021) such that the new term of the existing repayment arrangement does not expire before the end of the second performance year of the new agreement period. The arrangement would also need to be amended to include a clause that provides for automatic, annual 12-month extensions of the arrangement starting at the end of the first performance year of the new agreement period. Thus, at the end of the first performance year in December 2020, the repayment mechanism (which would otherwise expire on December 31, 2021) would be extended an additional 12 months and thereby expire on December 31, 2022. At the end of the second performance year in December 2021, the repayment mechanism would again be extended another 12 months and thereby expire on December 31, 2023. Eventually, the rolling annual 12-month extensions would cause the repayment mechanism to expire 12 months after the end of the agreement period (on December 31, 2025), and no further extensions would be required.

We believe that these options for the extension of an existing repayment mechanism arrangement will help ensure payment of shared losses and alleviate the concerns raised by the commenter about lengthy extensions potentially inhibiting continued ACO participation in the program. We also wish to note that these options would also be available to an ACO that voluntarily terminates its existing agreement period and then immediately enters a new agreement period without a break in participation (described as an early renewal in section II.A.5.c.(4) of this final rule) and would be applied in the same manner. Finally we wish to clarify that renewing ACOs (including early renewals) can also choose to establish a new repayment mechanism arrangement that either covers the full duration of the new agreement period plus the 12-month tail period or covers a term of at least two years and provides for automatic annual 12-month extensions as described above.

Comment: One commenter supported our proposal to permit early termination of a repayment mechanism under certain conditions, such as when we determine that the ACO does not owe shared losses under the Shared Savings Program for any of the performance years of the ACO's agreement period.

Response: We thank the commenter for their support of this proposal. We are finalizing our policy regarding early termination of a repayment mechanism as proposed.

Final Action: After considering the comments received, we are finalizing with modification our proposed provisions regarding the duration of the repayment mechanism at § 425.204(f)(6) as follows.

We are finalizing § 425.204(f)(6) to state that with limited exceptions, a repayment mechanism must be in effect for the duration of an ACO's participation under a two-sided model plus 12 months after the conclusion of the agreement period.

We are finalizing § 425.204(f)(6)(i) to state that for an ACO that is establishing a new repayment mechanism to meet this requirement, the repayment mechanism must satisfy one of the following criteria: (A) The repayment mechanism covers the entire duration of the ACO's participation under a two-sided model plus 12 months following the conclusion of the agreement period; or (B) the repayment mechanism covers an term of at least the first two

performance years in which the ACO is participating under a two sided model and provides for automatic, annual 12-month extensions of the repayment mechanism such that the repayment mechanism will eventually remain in effect through the duration of the agreement period plus 12 months following the conclusion of the agreement period.

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

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

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

We note that, as modified, paragraphs § 425.204(f)(6)(i) and (ii), set forth the ways in which an ACO may meet the general requirement for the repayment mechanism described in § 425.204(f)(6).

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

(5) Institutions Issuing Repayment Mechanism Arrangements

We also proposed 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. With the proposed changes to offer only the BASIC track and ENHANCED track for agreement periods beginning on July 1, 2019 and in subsequent years, we anticipate an increase in the number of repayment mechanism arrangements CMS will review with each annual application cycle. We believe the proposed new requirements regarding the financial institutions with which ACOs establish their repayment mechanisms would provide CMS greater certainty about the adequacy of repayment mechanism arrangements and ultimately ease the process for reviewing and approving the ACO's repayment mechanism arrangement documentation.

Currently, as described in the program's Repayment Mechanism Arrangements Guidance, CMS will accept an escrow account arrangement established with a bank that is insured by the Federal Deposit Insurance Corporation (FDIC), a letter of credit established at a FDIC-insured institution, and a surety bond issued by a company included on the U.S. Department of Treasury's list of certified (surety bond) companies (available at *https://www.fiscal.treasury.gov/fsreports/ref/suretyBnd/c570_a-z.htm*). We have found that arrangements issued by these institutions tend to be more conventional arrangements that conform to the program's requirements. However, we recognize that some ACOs may work with other types of financial institutions that may offer similarly acceptable products, but which may not conform to the standards described in our existing Repayment Mechanism Arrangements Guidance. For example, some ACOs may prefer to use a credit union to establish an escrow account or a letter of credit for purposes of meeting the repayment mechanism arrangements requirement, but credit unions are insured under the National Credit Union Share Insurance Fund program, rather than by the FDIC. Although the insuring entity is different, credit unions typically are insured up to the same insurance limit as FDIC-insured banks and are otherwise capable of offering escrow accounts and letters of credit that meet program requirements. We also believe that incorporating more complete standards for repayment mechanisms into the regulations would provide additional clarity for ACOs regarding acceptable repayment mechanisms and will help to avoid situations where an ACO may obtain a repayment mechanism arrangement from an entity that ultimately is unable to pay CMS the value of the repayment mechanism in the event CMS seeks to use the arrangement to recoup shared losses for which the ACO is liable.

Since the June 2015 final rule, several ACO applicants have requested use of arrangements from entities other than those described in our Repayment Mechanism Arrangements Guidance, such as a letter of credit issued by the parent corporation of an ACO, and funds held in escrow by an attorney's office. In reviewing these requests, we found a similar level of complexity resulting from the suggested arrangements as we did with our earlier experiences reviewing alternative repayment arrangements, which were permitted during the initial years of the Shared Savings Program until the regulations were revised in the June 2015 final rule to remove the option to establish an appropriate alternative repayment mechanism. In proposing to eliminate this option, we explained that a request to use an alternative repayment mechanism increases administrative complexity for both ACOs and CMS during the application process and is more likely to be declined by CMS (see 79 FR 72832). Although our program guidance (as specified in Repayment Mechanism

Arrangements Guidance, version 6, July 2017) encourages ACOs to obtain a repayment mechanism from a financial institution, these recent requests for approval of more novel repayment arrangements have alerted CMS to the potential risk that ACOs may seek approval of repayment mechanism arrangements from organizations other than those that CMS has determined are likely to be most financially sound and able to offer products that CMS can readily verify as appropriate repayment mechanisms that ensure the ACO's ability to repay any shared losses.

Therefore, we proposed 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. We anticipated 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. The proposed revisions would bring clarity to the program's requirements, which will assist ACOs in selecting, and reduce burden on CMS in reviewing and approving, repayment mechanism arrangements. We welcomed commenters' suggestions on these proposed requirements for ACOs regarding the issuing institution for repayment mechanism arrangements.

Comment: Several commenters expressed support for our proposal to expand the list of institutions with which an ACO may establish a repayment mechanism to include any insured institution. Some commenters noted that credit unions may provide ACOs with more economical repayment mechanism arrangements and could increase market competition, which could potentially lower the overall cost of accessing repayment mechanisms. Another commenter expressed appreciation for our proposed policies on the basis that they would alleviate burden and reduce barriers to participation for small and rural ACOs.

Several other commenters expressed the belief that ACOs need repayment mechanism alternatives other than the arrangements that we addressed in our Repayment Mechanism Arrangements Guidance or proposed in the August 2018 proposed rule. Some commenters specifically requested that CMS allow insurance or reinsurance coverage as a repayment mechanism. A few commenters noted that reinsurance is an established health care industry standard, and that accepting reinsurance as a repayment mechanism would encourage more ACOs to participate in the ENHANCED track. Other commenters noted that some ACOs already obtain reinsurance in addition to meeting their repayment mechanism obligations and that CMS should therefore consider reinsurance to be an acceptable repayment mechanism, as we did in our November 2011 final rule (76 FR 67979).

Other commenters requested that we to permit ACOs to establish alternative repayment mechanisms as we did in our November 2011 final rule (76 FR 67979). These commenters expressed the belief that having alternative options would facilitate ACO participation in the program. While the commenters recognized the additional administrative complexity of permitting ACO to establish alternative arrangements, they believe that the number of ACOs seeking these such arrangements would be small, thus limiting the burden on ACOs and CMS during the repayment mechanism application process.

A few commenters recommended that CMS consider allowing ACOs to repay losses through reduced payment rates for ACO eligible clinicians, similar to the MACRA financial risk standards. The commenters believe that some ACOs would prefer such a method over repaying losses in a lump sum. These commenters also recommended that CMS remove the repayment mechanism requirement when an ACO can prove that it has an investor or financial backer with a demonstrated high credit rating. Such financial backers could include outside investors, insurers, or hospitals or health systems that are involved with the ACO and providing financial support. The commenters believe that the current repayment mechanism process is time consuming and costly and that this suggested alternative could reduce those burdens while still protecting the Medicare Trust Funds.

Response: We appreciate the support offered for our proposal to expand the list of institutions with which an ACO may establish a repayment mechanism, as well as the feedback from other stakeholders recommending that CMS offer ACOs additional options for establishing a repayment mechanism arrangement. As indicated by some of the commenters, we originally allowed ACOs to obtain reinsurance coverage or to establish another appropriate repayment mechanism in the early years of the program. However, we elected to eliminate those alternatives in the June 2015 final rule (see 80 FR 32783–32784). We noted in that rule that no ACO had ultimately established reinsurance as its repayment mechanism. ACOs that explored that option told us that it was difficult to obtain reinsurance in part because of insurers' lack of experience with the Shared Savings Program and the ACO model, and because Shared Savings Program ACOs take on performance-based risk rather than insurance risk. Additionally, we indicated that the terms of reinsurance policies could vary greatly and prove difficult for CMS to effectively evaluate. We also noted that, based on our experience, alternative repayment mechanisms increased administrative complexity for ACOs and CMS during the application process, and were more likely to be rejected by CMS than one of the specified repayment mechanisms.

While we indicated in the June 2015 rule that we would potentially consider reinstating reinsurance as a repayment mechanism option at some point in the future, we did not propose to reinstate either reinsurance or alternative repayment mechanisms in the August 2018 rule, and we therefore consider these comments to fall outside the scope of this final rule. We similarly believe that suggestions to allow ACOs to repay loses through reductions to payment rates or to waive the repayment mechanism in the presence of a creditworthy financial backer fall outside the scope of this final rule. We would need to further evaluate these suggestions before considering whether to propose them in future rulemaking.

Final Action: After considering comments received, we are finalizing § 425.204(f)(2) as proposed to specify that an ACO that will participate in a two-sided model must establish one or more of the following repayment mechanisms in an amount and by a deadline specified by CMS in accordance with § 425.204: An escrow account with an insured institution; a surety bond from a company included on the U.S. Department of Treasury's List of Certified Companies; or a line of credit at an insured institution (as evidenced by a letter of credit that the Medicare program can draw upon).

d. Advance Notice for and Payment Consequences of Termination

(1) Background

Sections 425.218 and 425.220 of the regulations describe the Shared Savings Program's termination policies. Section 425.221, added by the June 2015 final rule, specifies the close-out procedures and payment consequences of early termination. Under § 425.218, CMS can terminate the participation agreement with an ACO when the ACO fails to comply with any of the requirements of the Shared Savings Program. As described in § 425.220, 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 its termination.

The November 2011 final rule establishing the Shared Savings Program indicated at § 425.220(b) (although this provision was subsequently revised) that ACOs that voluntarily terminated during a performance year would not be eligible to share in savings for that year (76 FR 67980). The June 2015 final rule revised this policy to specify in § 425.221(b)(1) that if an ACO voluntarily terminates with an effective termination date of December 31st of the performance year, the ACO may share in savings only if it has completed all required close-out procedures by the deadline specified by CMS and has satisfied the criteria for sharing savings for the performance year. ACOs that voluntarily terminate with an effective date of termination prior to December 31st of a performance year and ACOs that are involuntarily terminated under § 425.218 are not eligible to share in savings for the performance year. In the November 2018 final rule (83 FR 59958 and 59959) we finalized revisions to § 425.221(b) to allow our policies on the payment consequences of early termination to apply to ACOs participating in a 6-month performance year from January 1, 2019, through June 30, 2019.

The current regulations also do not impose any liability for shared losses on two-sided model ACOs that terminate from the program prior to the last calendar day of a given performance year. As explained in the June 2015 final rule, the program currently has no methodology for partial year reconciliation (80 FR 32817). As a result, ACOs that voluntarily terminate before the end of the performance year are neither eligible to share in savings nor accountable for any shared losses.

In the August 2018 proposed rule (83 FR 41843 and 41844), we indicated that the existing policies on termination and the payment consequences of early termination raise concerns for both stakeholders and CMS. First, stakeholders have raised concerns that the current requirement for 60 days advance notice of a voluntary termination is too long because it does not allow ACOs to make timely, informed decisions about their continued participation in the program. Further, we noted that we were concerned that under the current policy, ACOs in two-sided models that are projecting losses have an incentive to leave the program prior to the end of a performance year, whereas ACOs that are projecting savings are likely to stay. Absent a change in our current policies on early termination, we believed these incentives could have a detrimental effect on the Medicare Trust Funds.

(2) Advance Notice of Voluntary Termination

In the August 2018 proposed rule, we stated that we were sympathetic to stakeholder concerns that the existing requirement for a 60-day notification period may hamper ACOs' ability to make timely and informed decisions about their continued participation in the program. A key factor in the timing of ACOs' participation decisions is the availability of program reports. Financial reconciliation reports (showing CMS' determination of the ACO's eligibility for shared savings or losses) are typically made available in the summer following the conclusion of the calendar year performance year (late July–August of the subsequent calendar year). Due to the timing of the production of quarterly reports (with information on the ACO's assigned beneficiary population, and expenditure and utilization trends), an ACO contemplating a year-end termination typically only has two quarters of feedback for the current performance year to consider in its decision-making process. This is because quarterly reports are typically made available approximately 6 weeks after the end of the applicable calendar year quarter. For example, quarter 3 reports would be made available to ACOs in approximately mid-November of each performance year. These dates for delivery of program reports also interact with the application cycle timeline (with ACOs typically required to notify CMS of their intent to apply in May, typically before quarter 1 reports are available, and submit applications during the month of July, prior to receiving quarter 2 reports), as applicants seek to use financial reconciliation data for the prior performance year and quarterly report data for the current performance year to make participation decisions about their continued participation, particularly ACOs applying to renew their participation for a subsequent agreement period.

In the proposed rule, we stated that our belief that adopting a shorter notice requirement would provide ACOs with more flexibility to consider their options with respect to their continued participation in the program. We therefore proposed 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.

Comment: We received several comments supporting our proposal to reduce the notice requirement for voluntary termination to 30 days, with some commenters noting that this change would allow an ACO to have more data on which to base its participation decision for the upcoming performance year. A few other commenters noted that they would support reducing the minimum notification period if an ACO that complied with the notice requirement could voluntarily terminate from the program without financial reconciliation for that year.

Response: We appreciate the commenters' support for this policy and agree that reducing the length of the notice requirement would allow an ACO to consider additional information, such as the information provided in their third quarter feedback reports, when making its participation decisions for the upcoming performance year and are finalizing this policy as proposed. As described in the next section of this final rule, we are also finalizing our proposal, with modification, to conduct financial reconciliation for voluntarily terminating ACOs with an effective date of termination after June 30 and, if applicable, to pro-rate any shared losses. This policy for voluntarily terminating ACOs will be applicable for 12-month performance years beginning on or after January 1, 2020, delayed from the original proposed date of January 1, 2019. Under this policy, ACOs giving at least 30 days advance notice for an effective termination date on or before June 30 of the performance year will not be subject to financial reconciliation and will not be accountable for shared

losses for the performance year in which their termination becomes effective.

Final Action: After considering the comments received on this issue, we are finalizing the proposed revisions to § 425.220 to reduce the minimum notification period for voluntary termination from 60 to 30 days without modification.

(3) Payment Consequences of Termination

In section II.6.d.3 of the August 2018 proposed rule, we discussed the payment consequences of early termination of an ACO's participation agreement. We reconsidered the program's current policies on payment consequences of termination under § 425.221 in light of our proposal to reduce the amount of advance notice from ACOs of their voluntarily termination of participation under § 425.220. While we believed that the proposal to shorten the notice period for voluntary termination under § 425.220 from 60 to 30 days would be beneficial to ACOs, we recognized that it might increase gaming among risk-bearing ACOs facing losses, as ACOs would have more time and information to predict their financial performance with greater accuracy.

To deter gaming while still providing flexibility for ACOs in two-sided models to make decisions about their continued participation in the program, we considered several policy alternatives to hold these ACOs accountable for some portion of the shared losses generated during the performance year in which they terminate their participation in the program.

We first considered a policy similar to that used in the Next Generation ACO (NGACO) Model whereby ACOs may terminate without penalty if they provide notice of termination to CMS on or before February 28, with an effective date 30 days after the date of the notice (March 30). ACOs that terminate after that date are subject to financial reconciliation. These ACOs are liable for any shared losses determined.[20] The NGACO Model adopted March 30 as the deadline for the effective termination date in order to align with timelines for the Quality Payment Program. Specifically, this date ensures that clinicians affiliated with a terminating NGACO will not be included in the March 31 snapshot date for QP determinations. However, while we acknowledged the merit of reducing provider uncertainty around Quality Payment Program eligibility, we also recognized that in the early part of the performance year ACOs have a limited amount of information on which to base termination decisions. We noted that we are especially concerned that holding ACOs accountable for full shared losses may lead many organizations to leave the program early in the performance year, including those that would have ultimately been eligible for shared savings had they continued their participation. Post-termination, Shared Savings Program ACOs no longer have access to the same program resources that can help facilitate care management, such as beneficiary-identifiable claims data or payment rule waivers, including the SNF 3-day rule waiver. This could make it more challenging for these entities to reduce costs, possibly offsetting any benefits to the Medicare Trust Funds from reduced gaming.

Given the drawbacks of setting an early deadline for ACOs to withdraw without financial risk, we also considered a policy under which risk-bearing ACOs that voluntarily terminate with an effective date after June 30 of a performance year would be liable for a portion of any shared losses determined for the performance year. We explained that we believe June 30 is a reasonable deadline for the effective date of termination as it allows ACOs time to accumulate more information and make decisions regarding their continued participation in the program. As is the case under current policy, for eligible clinicians in an ACO that terminates its participation in a Shared Savings Program track that is an Advanced APM effective between March 31 and June 30, we would make QP determinations as specified in our regulation at § 414.1425(b) based on one or more QP determination snapshot periods (January 1–March 31, and possibly also January 1–June 30). But, in accordance with our regulations at § 414.1425(c)(5) and (d)(3), an eligible clinician who would otherwise have received QP status based on one of those QP determinations would not be a QP or Partial QP for the year. Instead, those eligible clinicians would be subject to MIPS and scored using the APM scoring standard (unless they are excluded from MIPS on some other ground).

We proposed to conduct financial reconciliation for all ACOs in two-sided models that voluntarily terminate after June 30. We proposed to use the full 12 months of performance year expenditure data in performing reconciliation for terminated ACOs with partial year participation. For those ACOs that generate shared losses, we would pro-rate the shared loss amount by the number of months during the year in which the ACO was in the program. To calculate the pro-rated share of losses, CMS would multiply the amount of shared losses calculated for the performance year by the quotient equal to the number of months of participation in the program during the performance year, including the month in which the termination was effective, divided by 12. We would count any month in which the ACO had at least 1 day of participation. Therefore, an ACO with an effective date of termination any time in July would be liable for 7/12 of any shared losses determined, while an ACO with an effective date of termination any time in August would be liable for 8/12, and so forth. An ACO with an effective date of termination in December would be liable for the entirety of shared losses. Terminated ACOs would continue to receive aggregate data reports following termination, but, as under current policy, would lose access to beneficiary-level claims data and any payment rule waivers.

In the August 2018 proposed rule (83 FR 41846), we explained that we believe this approach provides an incentive for ACOs to continue to control growth in expenditures and report quality for the relevant performance year even after they leave the program, as both can reduce the amount of shared losses owed. Increasing the proportion of shared losses owed with the number of months in the year that the ACO remains in the program also helps to counteract the potential for gaming, as ACOs that wait to base their termination decision on additional information would be liable for a higher portion of any shared losses that are incurred. This approach also reflects the fact that ACOs that terminate later in the performance year would have had access to program flexibilities (for example, the SNF 3-day rule waiver) for a longer period of time.

We also considered the payment consequences of early termination for ACOs that are involuntarily terminated by CMS under § 425.218. Although these ACOs are not choosing to leave the program of their own accord and thus are not using termination as a means of avoiding their responsibility for shared losses, we believe they should not be excused from responsibility for some portion of shared losses simply because they failed to comply with program requirements.

[20] In the August 2018 proposed rule (83 FR 41845), we inadvertently stated that the ACOs that terminate from the NGACO Model with an effective date of termination after March 30 are also eligible to share in savings. We wish to clarify that ACOs that terminate from the NGACO Model at any point after the start of the performance year are not eligible to earn shared savings for that performance year.

Further, as we explained in the August 2018 proposed rule, we believe it is more appropriate to hold involuntarily terminated ACOs accountable for a portion of shared losses during any portion of the performance year. Since involuntary terminations can occur throughout the performance year, establishing a cut-off date for determining the payment consequences for these ACOs could allow some ACOs to avoid accountability for their losses. Therefore, we proposed to pro-rate shared losses for ACOs in two-sided models that are involuntarily terminated by CMS under § 425.218 for any portion of the performance year during which the termination becomes effective. We proposed that the same methodology as previously described for pro-rating shared losses for voluntarily terminated ACOs would also apply to determine shared losses for involuntarily terminated ACOs.

We considered whether to allow ACOs voluntarily terminating after June 30 but before December 31 an opportunity to share in a portion of any shared saving earned. However, we decided to limit the proposed changes to shared losses. While we recognized that this approach might appear to favor CMS, we noted our belief that ACOs expecting to generate savings are less likely to terminate early in the first place. We explained that under the program's current regulations at § 425.221(b)(1), ACOs that voluntarily terminate effective December 31 and that meet the current criteria in § 425.221 may still share in savings. We note that this provision was subsequently revised in November 2018 final rule (83 FR 59958 and 59959) to refer to an effective date of termination of the last calendar day of the performance year, in order to allow the policies governing the payment consequences of early termination to apply to ACOs participating in a 6-month performance year from January 1, 2019, through June 30, 2019.

In the August 2018 proposed rule, we proposed to amend § 425.221 to provide that ACOs in two-sided models that are terminated by CMS under § 425.218 or certain ACOs that voluntarily terminate under § 425.220 will be liable for a pro-rated amount of any shared losses determined for the performance year in which the termination becomes effective, with the pro-rated amount reflecting the number of months during the performance year that the ACO was in the program. We proposed to apply this policy to ACOs in two-sided models for performance years beginning in 2019 and subsequent performance years.

We also proposed to specify in the regulations at § 425.221 the payment consequences of termination during CY 2019 for ACOs preparing to enter or participating under agreements beginning July 1, 2019. First, as discussed in detail in section II.A.7. of the proposed rule, we would reconcile ACOs based on the respective 6-month performance year methodology for their participation during a 6-month period in 2019 in which they are either in a current agreement period beginning on or before January 1, 2019, or under a new agreement period beginning on July 1, 2019. We proposed that an ACO would be eligible to receive shared savings for a 6-month performance year during 2019, if they complete the term of this performance year, regardless of whether they choose to continue their participation in the program after the end of the performance year. That is, we would reconcile: ACOs that started a first or second agreement period on January 1, 2016, that extend their agreement period for a fourth performance year, and complete this performance year (concluding June 30, 2019); and ACOs that enter an agreement period on July 1, 2019, and terminate December 31, 2019, the final calendar day of their first performance year (defined as a 6-month period).

For an ACO that participates for a portion of a 6-month performance year during 2019 (January 1, 2019, through June 30, 2019, or July 1, 2019, through December 31, 2019) we proposed the following: (1) If the ACO terminates its participation agreement effective before the end of the performance year, we would not reconcile the ACO for shared savings or shared losses (if a two-sided model ACO); (2) if CMS terminates a two-sided model ACO's participation agreement effective before the end of the performance year, the ACO would not be eligible for shared savings and we would reconcile the ACO for shared losses and pro-rate the amount reflecting the number of months during the performance year that the ACO was in the program.

To determine pro-rated shared losses for a portion of the 6-month performance year, we would determine shared losses incurred during CY 2019 and multiply this amount by the quotient equal to the number of months of participation in the program during the performance year, including the month in which the termination was effective, divided by 12. We would count any month in which the ACO had at least one day of participation. Therefore, if an ACO that started a first or second agreement period on January 1, 2016, extended its agreement period for a 6-month performance year from January 1, 2019, through June 30, 2019, and was terminated by CMS with an effective date of termination of May 1, 2019, the ACO would be liable for 5/12 of any shared losses determined. If a July 1, 2019 starter was terminated by CMS with an effective date of termination of November 1, 2019, the ACO would also be liable for 5/12 of any shared losses determined. An ACO with an effective date of termination in December would be liable for the entirety of shared losses for the 6-month performance year.

Second, ACOs that are starting a 12-month performance year in 2019 would have the option to participate for the first 6 months of the year prior to terminating their current agreement and entering a new agreement period beginning on July 1, 2019. This includes ACOs that would be starting their 2nd or 3rd performance year of an agreement period in 2019, as well as ACOs that deferred renewal under § 425.200(e) and are starting a new agreement period in Track 2 or Track 3 on January 1, 2019. We proposed that ACOs with an effective date of termination of June 30, 2019, that enter a new agreement period beginning on July 1, 2019, would be eligible for pro-rated shared savings or shared losses for the 6-month period from January 1, 2019, through June 30, 2019, determined according to § 425.609.

In the August 2018 proposed rule (83 FR 41846), we noted that we believe some ACOs may act quickly to enter one of the new participation options made available under the proposed redesign of the program. We explained our view that ACOs that complete the 6-month period of participation in 2019 should have the opportunity to share in the savings or be accountable for the losses for this period. However, we acknowledged that certain ACOs may ultimately realize they are not yet prepared to participate under a new agreement beginning on July 1, 2019 and seek to terminate quickly. We stated that although we would encourage ACOs to consider making the transition to one of the newly available participation options in 2019 in order to more quickly enter a participation agreement based on the proposed polices, we also did not want to unduly bind ACOs that aggressively pursue these new options. We believed the proposed approach would provide a means for ACOs to terminate their current participation agreement effective on June 30, 2019, prior to renewing their participation for an agreement period beginning July 1, 2019, or to quickly terminate from a

new agreement period beginning on July 1, 2019, without the concern of liability for shared losses for a portion of the year.

In addition to the proposed changes to § 425.221(b) to accommodate the proposed new requirements governing the payment consequences of early termination, we also proposed further revisions to streamline and reorganize the provisions in § 425.221(b), which we believed were necessary to incorporate the proposed requirements. We sought comment on these proposals and the alternative policies discussed in section II.6.d.3 of the proposed rule.

In section II.E.4 of the August 2018 proposed rule (83 FR 41899), we proposed policies to mitigate the impacts of extreme and uncontrollable circumstances on ACO quality and financial performance. As part of these proposals, we discussed an approach for mitigating shared losses for ACOs participating in a performance-based risk track (83 FR 41903 and 41904). In this discussion, we acknowledged that it is possible that ACOs that either voluntarily terminate after June 30th of a 12-month performance year or are involuntarily terminated and will be reconciled to determine a pro-rated share of any shared losses could also be affected by extreme and uncontrollable circumstances. In this case, we proposed that the amount of shared losses calculated for the calendar year would be adjusted to reflect the number of months and the percentage of the assigned beneficiary population affected by extreme and uncontrollable circumstances, before we calculate the pro-rated amount of shared losses for the portion of the year the ACO participated in the Shared Savings Program. For example, assume that: A disaster was declared for October 2019 through December 2019; an affected ACO had been involuntarily terminated on March 31, 2019 and will be reconciled for its participation during the portion of the performance year from January 1, 2019 through March 31, 2019. The ACO is determined to have shared losses of $100,000 for calendar year 2019; and 25 percent of the ACO's assigned beneficiaries reside in the disaster area. In this scenario, we would adjust the ACO's losses in the following manner: $\$100,000 - (\$100,000 \times 0.25 \times 0.25) = \$100,000 - \$6,250 = \$93,750$, then we would multiply these losses by the portion of the year the ACO participated $= \$93,750 \times 0.25 = \$23,437.50$.

We proposed to specify in revisions to §§ 425.606(i) and 425.610(i), and in the proposed new provision for the BASIC track at § 425.605(f), that the policies regarding extreme and uncontrollable circumstances proposed in section II.E.4 of the August 2018 proposed rule would also apply to ACOs that are reconciled for a partial year of performance under § 425.221(b)(2) as a result of voluntary or involuntary early termination. The proposed revisions to §§ 425.606(i) and 425.610(i) also addressed the applicability of these policies to a Track 2 or Track 3 ACO that starts a 12-month performance year on January 1, 2019, and then elects to voluntarily terminate its participation agreement with an effective termination date of June 30, 2019, and enters a new agreement period starting on July 1, 2019; these ACOs would be reconciled for the performance period from January 1, 2019, through June 30, 2019, consistent with the proposed new provision at § 425.221(b).

Comment: One commenter expressed support for our proposal to pro-rate shared losses for any ACO in a two-sided model that voluntarily terminates after June 30 or that is involuntarily terminated by CMS under § 425.218. The commenter also supported our proposed methodology for calculating pro-rated shared losses.

Several commenters agreed that an ACO that voluntarily terminates from the program should be held responsible for repayment of pro-rated shared losses based on the date of termination; however, they expressed their belief that an ACO that is involuntarily terminated by CMS should not be held responsible for any shared losses. They believe that an ACO that is involuntarily terminated by CMS is willing to continue to participate in the program and comply with program requirements, and, therefore, if CMS chooses to terminate any such ACO's participation agreement, CMS should be the one to absorb any losses.

Response: We appreciate the support for our proposals to pro-rate shared losses and for our proposed methodology for calculating pro-rated shared losses. We are finalizing these policies as proposed with the exception of the date of applicability which, as described below, is being delayed to performance years starting on or after July 1, 2019.

We disagree with the commenters who believe that an ACO that is subject to involuntary termination by CMS under § 425.218 should be unaccountable for any shared losses. Under § 425.218, CMS may terminate an ACO's participation agreement when the ACO, or its ACO participants, ACO provider/suppliers or other individuals or entities performing functions or services related to ACO activities, failed to comply with one or more program requirements. Accordingly, we believe that it would be unfair to treat any such ACO more favorably with respect to the payment consequences of early termination than an ACO that voluntarily decided to terminate its participation agreement.

Comment: Several commenters requested that we reconsider allowing ACOs that voluntarily terminate after June 30 (but before December 31) an opportunity to share in a portion of any savings earned. A few of these commenters noted that there may be scenarios in which an ACO is forced to terminate early, and the ACO should not be penalized when such scenarios occur. Another commenter suggested that we allow an ACO that terminates early to continue to be eligible to share in savings so long as the ACO meets the criteria set forth in § 425.221. It was unclear whether this commenter was expressing support for our existing policy set forth in § 425.221, regarding an ACO's eligibility to receive shared savings when the ACO terminates its participation prior to the end of its agreement period with an effective date of December 31 of a performance year, or whether the commenter believes that an ACO should be eligible to receive shared savings when it terminates its participation agreement before December 31 of a performance year so long as the ACO completes the requisite close-out procedures described in the current provision at § 425.221(a).

Response: We continue to believe that it is important to maintain incentives for continued program participation and therefore, we decline to make any changes to our existing policies regarding the eligibility of an ACO to share in savings when the ACO voluntarily terminates its participation agreement. Under the program's current regulations at § 425.221(b)(1), an ACO that voluntarily terminates its participation agreement effective on the last calendar day of the performance year and that meets the criteria in § 425.221 may still share in savings.

Comment: One commenter opposed our proposal to conduct financial reconciliation for ACOs in two-sided models that voluntarily terminate after June 30, stating that it would compel an ACO to assume greater risk for losses during the year in which it voluntarily terminates. The commenter also noted that there are significant adjustments to benchmarks that occur as part of the annual financial reconciliation that are unknowable to ACOs early in the year, providing limited time for planning and decision-making regarding program participation. The commenter further

stated that most ACOs have invested significant resources to participate in the program and usually terminate only as a last resort.

Response: We recognize that, in contrast to our current regulations, our proposed policies regarding the payment consequences of early termination would place ACOs at risk for shared losses in a year in which they voluntarily terminate prior to the end of the performance year. We also recognize that ACOs deciding whether to terminate early will be required to do so with incomplete information. While we do not intend to harm ACOs that decide to terminate as a last resort, we believe that our proposed policies are necessary to safeguard the Medicare Trust Funds against ACOs potentially gaming their participation decisions.

Comment: Several commenters, while not expressing general opposition to requiring a voluntarily terminating ACO to repay a pro-rated share of shared losses, did disagree with our proposal to use June 30 as the cut-off date for determining whether an ACO would be liable, noting that ACOs would not have sufficient information on which to base a termination decision that early in the year. One commenter expressed the belief that the proposed date was problematic given 60- to 90-day lags associated with being able to perform claims-based analytics and therefore recommended that CMS simply continue the current practice of not pro-rating shared losses for early termination. Another commenter noted that an ACO would only have one quarter of performance year data by that point and would not have yet received its financial reconciliation report for the prior performance year. This commenter noted that a June 30 deadline would also conflict with the performance period for QPs under the Quality Payment Program, which ends on August 31, thus potentially affecting their ability to qualify as participating in an Advanced APM. The commenter recommended that CMS should therefore hold an ACO accountable for shared losses only if the ACO voluntarily terminates with an effective termination date on or after August 31.

Commenters also suggested several other different alternatives to the proposed June 30 cut-off date. Several commenters expressed the belief that ACOs should have three quarters of data available to them to make an informed decision about continued participation. A few other commenters suggested using an effective date of termination for this policy that is 30 days after the receipt of second quarter data. Another commenter requested using September 30 as the cut-off date, noting this deadline would allow ACOs time to fully analyze two quarters of financial data before making the decision to voluntarily terminate. Another commenter supported using a September 30 date for ACOs in their first year under any risk track model and, in particular, for ACOs in Level C of the BASIC track.

Response: We believe there are trade-offs between allowing ACOs more time and information to make participation decisions without penalty and requiring an earlier cut-off date to reduce the risk of gaming. We continue to believe that the proposed cut-off date of June 30 strikes a balance between these trade-offs. We also acknowledge one commenter's point that under this policy there may be cases in which an ACO voluntarily terminates with an effective date after June 30 but before August 31 would mean that QPs participating in the ACO would no longer qualify as participating in an Advanced APM even though the ACO would still be accountable for a portion of any shared losses. However, we believe that the potential benefits to the Trust Funds outweighs this concern. For these reasons, we decline to adopt the commenters' suggested alternatives and are finalizing our proposal to hold ACOs in two-sided models that voluntarily terminate with an effective date after June 30 liable for a pro-rated share of shared losses.

Comment: One commenter recommended that CMS take into consideration whether an ACO had experienced an extreme and uncontrollable circumstance when applying the proposed policies around payment consequences of early termination. The commenter requested that the proposed methodology exclude losses that occur as a direct result of an extreme and uncontrollable event.

Response: In the November 2018 final rule we finalized our proposals to extend the extreme and uncontrollable circumstances policies used for performance year 2017 to performance year 2018 and subsequent years (see 83 FR 59968 through 59979). In this final rule we are finalizing additional changes to address how these policies will be implemented for ACOs that are responsible for pro-rated shared losses under our new policies governing the payment consequences of early termination and that experience an extreme and uncontrollable event during the calendar year in which their termination becomes effective. Specifically, we will calculate the ACO's shared loss amount based on the 12 month calendar year, adjusting the shared losses amount to reflect the number of months and the percentage of the assigned beneficiary population affected by extreme and uncontrollable circumstances, before we calculate the pro-rated amount of shared losses for the portion of the year the ACO participated in the Shared Savings Program before termination. Accordingly, the policies we are finalizing regarding the payment consequences of early termination do in fact consider whether an ACO experienced an extreme and uncontrollable circumstance during the performance year and the losses that may have occurred as a result of any such circumstance.

Final Action: After considering the comments received, we are finalizing the proposals described in this section with modifications to reflect a new date of applicability. We are amending § 425.221(b) of the regulations to provide that for performance years beginning on or after July 1, 2019, ACOs in two-sided models with an effective termination date before the last calendar day of the performance year that voluntarily terminate under § 425.220 with an effective date of termination after June 30 or that are terminated by CMS at any time during the performance year will be liable for a pro-rated amount of any shared losses determined, with the pro-rated amount reflecting the number of months during the performance year that the ACO was in the program.

We originally proposed that the modifications to our policies on the payment consequences of early termination would be effective for performance years beginning in 2019. As a result of the delayed date of applicability, we are not finalizing our proposal to require ACOs under a two-sided risk model that begin a 6-month performance year on January 1, 2019, and that are involuntarily terminated by CMS to repay a pro-rated amount of any shared losses determined. However, we are finalizing our proposal that ACOs under a two-sided model that begin a 6-month performance year on July 1, 2019, and that are involuntarily terminated by CMS would be required to repay a pro-rated amount of any shared losses determined. We are finalizing this provision at § 425.221(b)(2)(ii). As reflected in § 425.221(b)(3)(i), we are also finalizing our proposal that ACOs that start a 12-month performance year on January 1, 2019, that subsequently terminate their participation agreement with an effective date of termination of June 30, 2019, and enter a new agreement period beginning on July 1, 2019, would be

eligible for pro-rated shared savings or accountable for pro-rated shared losses for the 6-month period from January 1, 2019, through June 30, 2019, as determined in accordance with § 425.609.

We are also finalizing our proposal that the amount of shared losses determined for ACOs that are liable for pro-rated shared losses due to early termination will be adjusted to account for extreme and uncontrollable circumstances through revisions to §§ 425.606(i) and 425.610(i) and in the new provision for the BASIC track at § 425.605(f).

7. Participation Options for Agreement Periods Beginning in 2019

a. July 1, 2019 Agreement Start Date and Early Renewal Option

(1) Background From the August 2018 Proposed Rule on Proposals for 6-Month Performance Years During CY 2019

In the August 2018 proposed rule (83 FR 41847 through 41849), we proposed a July 1, 2019 start date for ACOs to enter agreement periods under the proposed new participation options within the BASIC track and the ENHANCED track, and a voluntary 6-month extension for ACOs whose first or second agreement periods expire December 31, 2018 to ensure these ACOs could continue their participation in the program without interruption. In conjunction with these proposals, we would also need a methodology to determine performance for ACOs under two, 6-month performance years during CY 2019, from January 1, 2019, through June 30, 2019, and from July 1, 2019, through December 31, 2019.

We explained that in the November 2011 final rule establishing the Shared Savings Program, we implemented an approach for accepting and reviewing applications from ACOs for participation in the program on an annual basis, with agreement periods beginning January 1 of each calendar year. We also finalized an approach to offer two application periods for the first year of the program, allowing for an April 1, 2012 start date and a July 1, 2012 start date. In establishing these alternative start dates for the program's first year, we explained that the statute does not prescribe a particular application period or specify a start date for ACO agreement periods (see 76 FR 67835 through 67837). We considered concerns raised by commenters about a January 1, 2012 start date, which would have closely followed the November 2011 publication of the final rule. Specifically, commenters were concerned about the ability of potential ACOs to organize, complete, and submit an application in time to be accepted into the first cohort as well as our ability to effectively review applications by January 1, 2012. Comments also suggested that larger integrated health care systems would be able to meet the application requirements on short notice while small and rural entities might find this timeline more difficult and could be unable to meet the newly-established application requirements for a January 1 start date (76 FR 67836).

In the August 2018 proposed rule, we explained that the considerations that informed our decision to establish alternative start dates at the inception of the Shared Savings Program were also relevant in determining the timing for making the proposed new participation options available. We explained that postponing the start date for agreement periods under these new participation options until later in 2019 would allow ACOs time to consider the new participation options and prepare for program changes; make investments and other business decisions about participation; obtain buy-in from their governing bodies and executives; complete and submit an application that conforms to the new participation options, if finalized; and resolve any deficiencies and provider network issues that may be identified, including as a result of program integrity and law enforcement screening. Postponing the start date for new agreement periods would also allow both new applicants and ACOs currently participating in the program an opportunity to make any changes to the structure and composition of their ACO as may be necessary to comply with the new program requirements for the ACO's preferred participation option, if changes to the participation options are finalized as proposed.

Therefore, we proposed 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. As described in the August 2018 proposed rule, we anticipated the application cycle for the July 1, 2019 start date would begin in early 2019. We also elected to forgo the application cycle that otherwise would take place during CY 2018 for a January 1, 2019 start date for new Shared Savings Program participation agreements, initial use of the SNF 3-day rule waiver (as further discussed in section II.A.7.c.(1). of this final rule), and entry into the Track 1+ Model (as further discussed in section II.F. of this final rule). We explained that although several ACOs that entered initial agreements beginning in 2015 had deferred renewal into a second agreement period by 1 year in accordance with § 425.200(e) and will begin participating in a new 3-year agreement period beginning on January 1, 2019 under a performance-based risk track, applications would not be accepted from other ACOs for a new agreement period beginning on January 1, 2019. We proposed that the July 1, 2019 start date would be a one-time opportunity, and thereafter we would resume our 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. Therefore, we anticipated also offering an application cycle in 2019 for a January 1, 2020 start date for new, 5-year participation agreements, and continuing to offer an annual start date of January 1 thereafter. We acknowledged that a delayed application due date for an agreement period beginning in 2019 could affect parties planning to participate in the Shared Savings Program for performance year 2019 and that are relying on the pre-participation waiver. Guidance for affected parties was posted on the CMS website. See Medicare Shared Savings Program Waivers: Special ACO Pre-Participation Waiver Guidance for the 2019 Application Cycle (Issued: August 9, 2018), available at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/2019-Pre-Participation-Waiver-Guidance.pdf.*

We also explained that under the current Shared Savings Program regulations, the policies for determining financial and quality performance are based on an expectation that a performance year will have 12 months that correspond to the calendar year. Beneficiary assignment also depends on use of a 12-month assignment window, with retrospective assignment based on the 12-month calendar year performance year, and prospective assignment based on an offset assignment window before the start of the performance year. Given the calendar year basis for performance years under the current regulations, we considered 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.

To address the implications of a midyear start date on program participation and applicable program requirements, we considered our previous experience with the program's

initial entrants, April 1, 2012 starters and July 1, 2012 starters. In particular, we considered our approach for determining these ACOs' first performance year results (see § 425.608). The first performance year for April 1 and July 1 starters was defined as 21 and 18 months respectively (see § 425.200(c)(2)). The methodology we used to determine shared savings and losses for these ACOs' first performance year consisted of an optional interim payment calculation based on the ACO's first 12 months of participation and a final reconciliation occurring at the end of the ACO's first performance year. This final reconciliation took into account the 12 months covered by the interim payment period as well as the remaining 6 or 9 months of the performance year, thereby allowing us to determine the overall savings or losses for the ACO's first performance year. All ACOs opting for an interim payment reconciliation, including ACOs participating under Track 1, were required to assure CMS of their ability to repay monies determined to be owed upon final first year reconciliation. For Track 2 ACOs, the adequate repayment mechanism required for entry into a performance-based risk arrangement was considered to be sufficient to also assure return of any overpayment of shared savings under the interim payment calculation. Track 1 ACOs electing interim payment were similarly required to demonstrate an adequate repayment mechanism for this purpose. (See 76 FR 67942 through 67944).

This interim payment calculation approach used in the program's first year resulted in relatively few ACOs being eligible for payment based on their first 12 months of program participation. Few Track 1 ACOs established the required repayment mechanism in order to be able to receive an interim payment of shared savings, if earned. Not all Track 2 ACOs, which were required to establish repayment mechanisms as part of their participation in a two-sided model, elected to receive payment for shared savings or to be held accountable for shared losses based on an interim payment calculation. Of the 114 ACOs reconciled for a performance year beginning on April 1 or July 1, 2012, only 16 requested an interim payment calculation in combination with having established the required repayment mechanism. Of these 16 ACOs, 9 were eligible for an interim payment of shared savings, of which one Track 1 ACO was required to return the payment based on final results for the performance year. One Track 2 ACO repaid interim shared losses, which were ultimately returned to the ACO based on its final results for the performance year.

This approach to interim and final reconciliation was developed for the first two cohorts of ACOs, beginning in the same year and to which the same program requirements applied. The program has since evolved to include different benchmarking methodologies (depending on whether an ACO is in its first agreement period, or second agreement period beginning in 2016 or in 2017 and subsequent years) and different assignment methodologies (prospective assignment and preliminary prospective assignment with retrospective reconciliation), among other changes. In the August 2018 proposed rule, we expressed concern about introducing further complexity into program calculations by proposing to follow a similar approach of offering an extended performance year with the option for an interim payment calculation with final reconciliation for ACOs affected by the delayed application cycle for agreement periods starting in 2019.

To address the implications of a midyear start date on program participation and applicable program requirements, we proposed to use an approach that would maintain financial reconciliation and quality performance determinations based on a 12-month calendar-year period, but would pro-rate shared savings/shared losses for each potential 6-month period of participation during 2019. Accordingly, we proposed an approach for implementing the proposed July 1, 2019 start date that included 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, would have the opportunity to 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 would be voluntary and an ACO could choose not to make this election and therefore conclude its participation in the program with the expiration of its current agreement period on December 31, 2018. As discussed in section II.A.7.a.(2) of this final rule, we finalized the 6-month extension and the related policies for the 6-month performance year from January 1, 2019, through June 30, 2019, in the November 2018 final rule.

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. If the ACO's application is approved by CMS, the ACO could enter a new agreement period beginning on July 1, 2019. (We would consider these ACOs to be early renewals.) ACOs currently in an agreement period that includes a 12-month performance year 2019 that choose to terminate their current participation agreement effective June 30, 2019, and enter a new agreement period beginning on July 1, 2019, would be reconciled for their performance during the first 6 months of 2019. As described in section II.A.5.c.(5).(b). of this final rule, an ACO's participation options for the July 1, 2019 start date would depend on whether the ACO is a low revenue ACO or a high revenue ACO and the ACO's experience with performance-based risk Medicare ACO initiatives. As described in the August 2018 proposed rule, and section II.A.5.c.(5).(c) of this final rule, an early renewal ACO would be considered to be entering its next consecutive agreement period for purposes of the applicability of policies that phase-in over time (the weight used in the regional benchmark adjustment, equal weighting of the benchmark years, and the quality performance standard).

In the August 2018 proposed rule, we considered several alternatives to the proposal to offer an agreement period of 5 years and 6 months beginning on July 1, 2019 (made up of 6 performance years, the first of which is 6 months in duration). We considered whether to offer instead an agreement period of five performance years (including a first performance year of 6 months). Under this alternative the agreement period would be 4 years and 6 months in duration. As previously described, in section II.A.2. of this final rule in connection with the discussion of our

proposal to extend the agreement period from 3 years to 5 years, program results have shown that ACOs tend to perform better the longer they are in the program and longer agreement periods provide additional time for ACOs to perform against a benchmark based on historical data from the 3 years prior to their start date. Further, the proposed changes to the benchmarking methodology (see section II.D. of this final rule) would result in more accurate benchmarks and mitigate the effects of reliance on increasingly older historical data as the agreement period progresses. We believed these considerations were also relevant to the proposed one-time exception to allow for a longer agreement period of 5 years and 6 months for ACOs that enter a new agreement period on July 1, 2019.

We also considered forgoing 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. We noted that this approach would allow ACOs additional time to consider the redesign of the program, make organizational and operational plans, and implement business and investment decisions, and would avoid the complexity of needing to determine performance based on 6-month performance years during CY 2019. However, our proposed approach of offering an application cycle during 2019 for an agreement period start date of July 1, 2019, would allow for a more rapid progression of ACOs to the redesigned participation options, starting in mid-2019. Further, we noted that under this alternative, we would also want to offer ACOs that started a first or second agreement period on January 1, 2016, a means to continue their participation between the conclusion of their current 3-year agreement (December 31, 2018) and the start of their next agreement period (January 1, 2020), should the ACO wish to continue in the program. Under an alternative that would postpone the start date for the new participation options to January 1, 2020, we would need to allow ACOs that started a first or second agreement period on January 1, 2016, to elect a 12-month extension of their current agreement period to cover the duration of CY 2019.

We also proposed a number of modifications to the regulations text in order to effectuate the decision to delay the start date to July 1, 2019, and to allow for agreement periods of at least five years as opposed to 3-year agreement periods. We proposed modifications to the definitions of ''agreement period'' and ''performance year'' in § 425.20. We proposed modifications to the provision at § 425.200(b)(2) to reflect that the term of the participation agreement is 3 years and 6 months for an ACO that entered an agreement period starting on January 1, 2016, that elects to extend its agreement period until June 30, 2019. We proposed to add a heading to § 425.200(b)(3) to specify that the provision applies to agreement periods beginning in 2017 and 2018. In addition, we proposed to add a new provision at § 425.200(b)(4) to specify that, for agreement periods beginning in 2019 the start date is—(1) January 1, 2019, and the term of the participation agreement is 3 years for ACOs whose first agreement period began in 2015 and who deferred renewal of their participation agreement under § 425.200(e); or (2) July 1, 2019, and the term of the participation agreement is 5 years and 6 months. We also proposed to add a new provision at § 425.200(b)(5) to specify that, for agreement periods beginning in 2020 and subsequent years, the start date is January 1 of that year and the term of the participation agreement is 5 years.

In light of the proposed modifications to § 425.200(c) to establish two 6-month performance years during CY 2019, we also proposed to revise the regulation at § 425.200(d), which reiterates an ACO's obligation to submit quality measures in the form and manner required by CMS for each performance year of the agreement period, to address the quality reporting requirements for ACOs participating in a 6-month performance year during CY 2019.

We sought comment on these proposals and the related considerations, as well as the alternatives considered.

(2) Background on the November 2018 Final Rule Establishing a Voluntary 6-Month Performance Year From January 1, 2019, Through June 30, 2019 for Eligible ACOs

In the November 2018 final rule (83 FR 59941 through 59959), we finalized a voluntary 6-month extension for ACOs that entered a first or second agreement period beginning on January 1, 2016, whose agreement periods would otherwise expire December 31, 2018. We also adopted a methodology for determining financial and quality performance for the 6-month performance year from January 1, 2019, through June 30, 2019, in a new section of the regulations at § 425.609. Under this methodology, we will perform reconciliation for ACOs that extend their agreement period for the 6-month performance year from January 1, 2019, through June 30, 2019, based on the ACO's performance during the entire 12-month calendar year, and then pro-rate the calendar year shared savings or shared losses to reflect the ACO's participation in that 6-month period.

We also finalized certain changes to the program's regulations to establish the 6-month extension and to make certain technical and conforming changes. We finalized as proposed the modifications to the definition of ''agreement period'' in § 425.20 to broaden the definition to generally refer to the term of the participation agreement and the revisions to § 425.200(a) to allow for agreement periods greater than 3 years. We also finalized our proposal to add a provision at § 425.200(b)(2) specifying that the term of the participation agreement is 3 years and 6 months for an ACO that entered an agreement period starting on January 1, 2016, that elects to extend its agreement period until June 30, 2019.

We also finalized as proposed the revision to the definition of ''performance year'' in § 425.20 to mean the 12-month period beginning on January 1 of each year during the agreement period, unless otherwise specified in § 425.200(c) or noted in the participation agreement. Therefore, we also finalized the proposed revisions to § 425.200(c) to make necessary formatting changes and specify an additional exception to the definition of performance year as a 12-month period. Specifically, we finalized our proposal to add a provision specifying that for an ACO that entered a first or second agreement period with a start date of January 1, 2016, and that elects to extend its agreement period by a 6-month period, the ACO's fourth performance year is the 6-month period between January 1, 2019, and June 30, 2019.

In light of the modifications we finalized to § 425.200(c) to establish a 6-month performance year during CY 2019, we also finalized the proposed revisions to the regulation at § 425.200(d), which reiterates an ACO's obligation to submit quality measures in the form and manner required by CMS for each performance year of the agreement period, to address the quality reporting requirements for ACOs participating in the 6-month performance year from January 1, 2019, through June 30, 2019. We noted that ACOs electing the voluntary 6-month extension will be required to report quality measures for the 2019 reporting period, based on CY 2019, consistent with the existing quality reporting process and methodology.

(3) Establishing a July 1, 2019 Start Date and Early Renewal Option

In the following discussion, we address the comments we received on our proposal to allow for a July 1, 2019 agreement start date, as well as the alternatives we considered to this proposed approach. We also address comments we received on the proposed early renewal option that would allow ACOs currently in an agreement period that includes a 12-month performance year 2019 that choose to terminate their current participation agreement effective June 30, 2019, and enter a new agreement period beginning on July 1, 2019, to be reconciled for their performance during the first 6 months of 2019. We described these proposals in section II.A.7.a.(1) of this final rule.

Comment: Some commenters supported the proposed approach of offering a July 1, 2019 agreement start date, indicating the importance of providing ACOs the opportunity to begin or continue their participation in the program. Some commenters expressed their disappointment that the delay in rulemaking prevented a new cohort of ACOs from starting on January 1, 2019, and indicated that many ACOs have been eagerly awaiting application details and are prepared to participate in 2019. These commenters explained that while the timing will present challenges, such as a compressed timeline to analyze program changes, review application materials, make decisions regarding participation and gather all of the required information to submit applications, it is critical that CMS continue to offer a participation option for 2019. One commenter explained that given the interconnected relationship between the Shared Savings Program and the Quality Payment Program, it is crucial that CMS policy development not inadvertently deter ACOs from transitioning to risk in 2019.

Of the commenters addressing the timing for implementation of the redesigned participation options, many commenters urged CMS to implement the redesigned participation options under the BASIC track and the ENHANCED track for agreement periods beginning on January 1, 2020 and in subsequent years. Many of these commenters suggested allowing ACOs whose agreement periods expire on December 31, 2018, a 12-month extension instead of a 6-month extension.

Commenters expressed the following concerns with the proposed July 1, 2019 start date:

- Commenters raised concerns regarding the approach for determining performance for the two, 6-month performance years, as summarized elsewhere in section II.A.7 of this final rule. Some commenters expressed concerns about the complexity caused by ACOs being reconciled under two different methodologies for each 6-month performance year during CY 2019, with some ACOs operating under current program rules and others operating under new program rules. One commenter stated that the proposed July 1, 2019 start date, if implemented, would add confusion and make the program less predictable for participating providers whose prior experience with the program has been based on full calendar year performance periods.
- Some commenters expressed concerns about rapid implementation of the proposed redesigned participation options. One commenter explained that in past experience when CMS has rushed the application period and start date it has resulted in implementation issues. One commenter pointed to the significant changes proposed to the program, and the lateness of the proposed rule as reasons to move the start date from July 1, 2019, to January 1, 2020. Several commenters suggested that CMS should ensure there is enough time for CMS and participants to consider the participation options, and prepare for an application cycle after the final rule is finalized. A few commenters requested that CMS delay the implementation of the redesigned participation options under the BASIC track and the ENHANCED track until January 1, 2020, if CMS is not ready to implement the new participation options for a July 1, 2019 start date.

Another commenter suggested allowing at least a 6-month preparation period for the application cycle after publication of the final rule so that ACOs and ACO participants can adequately prepare and successfully implement any changes adopted in the final rule.

- Several commenters expressed concerns about the timing of a mid-year start date, because ACOs would have limited data about their performance during performance year 2018, and the first 6-months of 2019 (if applicable).
- One commenter stated that a July 1, 2019 start date would result in only six months to improve performance.

Commenters explained that the advantages of a January 1, 2020 start date included the following:

- Allowing additional time for ACOs and program stakeholders to assess the policy changes and for ACOs, ACO participants and ACO providers/suppliers to make participation decisions to maximize their financial and quality outcomes. One commenter explained that CMS and program stakeholders will need time to disseminate information to physicians.
- Giving new ACOs adequate time to form and to review participation criteria.
- Allowing CMS additional time to ensure smooth and effective implementation of the significant changes that were proposed in the August 2018 proposed rule.
- Avoiding the complexity of the July 1, 2019 start date and the methodology for determining performance for the two, 6-month performance years during CY 2019. One commenter explained a January 2020 start date was preferable because it would give ACOs the opportunity to succeed under the new participation options for a full 12-month performance year, as opposed to requiring these ACOs to participate in two partial years under 2 different methodologies.
- Allowing ACOs entering performance-based risk models additional time to prepare their repayment mechanism arrangements, including to raise capital for their repayment mechanism.

Other commenters more generally urged CMS to slow the pace of regulatory change for the Shared Savings Program. One commenter explained that early adopters of the Shared Savings Program have expressed dissatisfaction with CMS' repeated changes to the program requirements and structure, which the commenter describes as burdensome particularly for rural and small health systems. One commenter expressed their appreciation for the changes to date implemented by CMS throughout the Medicare program to meaningfully reduce provider burden and allow providers to spend more time with patients. However, the commenter expressed their belief that implementing new Shared Savings Program participation agreements under such an accelerated timeframe does not align with these other welcomed reductions in provider burden or with CMS' goals of strengthening and stabilizing the Shared Savings Program.

Response: We appreciate commenters' support for the proposed one-time, July 1, 2019 agreement period start date. This mid-year start date would allow for continuity in participation by ACOs whose agreement periods expire December 31, 2018, that elect to voluntarily extend their current agreement period for the 6-month performance year from January 1, 2019, through June 30, 2019, under the policies adopted in the November 2018 final rule (83 FR 59942 through 59946), without requiring additional rulemaking to establish an option for a longer extension. Recently, 90 percent of eligible ACOs with a first or second agreement period start date of January 1, 2016, whose agreements would otherwise expire on December 31, 2018, elected to voluntarily extend their agreements for the 6-month performance year from January 1, 2019, through June 30, 2019. We believe this demonstrates a high level of interest by ACOs in continuing their participation in the program by preserving their option to renew their participation uninterrupted for a new agreement period starting on July 1, 2019.

Further, as discussed in the August 2018 proposed rule, we continue to believe it is important to create a pathway for ACOs to more rapidly transition to performance-based risk. Allowing for a July 1, 2019 agreement start date would allow for a more rapid progression to the redesigned participation options under the BASIC track and the ENHANCED track, compared to alternatives that would postpone implementation of the redesigned participation options until 2020 or later. We also recognize the possibility that there are prospective ACOs that may have been unable to apply to enter the program given our decision to forgo an application cycle in CY 2018 for a January 1, 2019 agreement start date, and a July 1, 2019 start date will allow them to enter the program sooner.

We refer readers to the November 2018 final rule (83 FR 59942 through 59946) for our responses to comments on the length of the extension available to ACOs whose agreement periods expire December 31, 2018. We believe many of the same considerations discussed in those responses are relevant in responding to the comments suggesting that we forgo an application cycle in CY 2019 and offer an initial agreement start date under the redesigned participation options of January 1, 2020 (necessitating a 12 month extension for ACOs whose agreement periods expire December 31, 2018). For instance, we believe ACOs whose agreement periods expire on December 31, 2018, have been weighing their participation options in advance of applying to renew for a subsequent agreement period, and will have additional time to make these determinations during the 6-month extension (if elected). In particular, ACOs reaching the end of their second agreement period under Track 1, would already have been weighing their participation options under two-sided models, given the current requirement that ACOs transition to a two-sided model by the start of their third agreement period in the program. In fact, our decision to finalize the 6-month extension allows ACOs completing their second agreement period in Track 1 to continue participation under their current agreement period and thereby have additional time under a one-sided model that otherwise would not have been available to them.

In response to commenters' concerns about the timing of a mid-year agreement period start date in relation to the availability of performance results for prior performance years, including performance year 2018 and the 6-month performance year from January 1, 2019, through June 30, 2019, we note that we provide ACOs with quarterly and annual aggregate program reports as well as other tools that they can use to track and estimate their performance. We educate ACOs on the use of quarterly program data to predict their financial performance. Therefore, we believe that ACOs have access to a variety of resources to assess their performance trends in order to help inform their participation decisions.

With respect to the commenter's concern that ACOs entering the program with an agreement period start date of July 1, 2019 would have only six months to improve performance, we note that such ACOs may take steps to ensure their readiness to meet the program's objectives in advance of program entry. Specifically, we believe that ACOs preparing to enter an initial agreement period starting on July 1, 2019, may wish to take steps to ensure their operational readiness by implementing redesigned care processes in preparation to meet the program's goals beginning July 1, 2019. These steps will assist these ACOs in succeeding under the approach for determining performance for the 6-month performance year from July 1, 2019, through December 31, 2019, which we are finalizing in this final rule, under which they will be accountable for pro-rated performance during the entire CY 2019. Further we believe ACOs new to the Shared Savings Program that are considering participation under the BASIC track's glide path may find the longer agreement period available with the July 1, 2019 start date advantageous. With an agreement period spanning 5 years and 6 months, ACOs that start in the program on July 1, 2019, would gain additional time in the program under the same historical benchmark prior to benchmark rebasing. As we previously described in section II.A.2. of this final rule, ACOs may find the greater predictability of benchmarks under longer agreement periods to be an advantage. Under our policies described in section II.A.7.c.(7). of this final rule, ACOs entering the BASIC track's glide path under a one-sided model, for an agreement period beginning on July 1, 2019, gain an additional 6-months of participation under a one-sided model, prior to being automatically advanced through the glide path. Therefore, eligible ACOs entering an agreement period beginning on July 1, 2019, may participate for a total of 2.5 years (3 performance years) under a one-sided model if they begin in Level A and transition through each level of the glide path, or 3.5 years (4 performance years) if the ACO is a new legal entity, low revenue ACO that enters in Level A, transitions to Level B, and opts to remain in Level B for an extra performance year before transitioning to Level E for the remaining years of its agreement period.

We appreciate commenters' concerns about the possible need for additional time for CMS to prepare to implement the redesigned participation options. However, the timeframe for implementing the initial offering of the redesigned participation options for a July 1, 2019 start date is operationally feasible. We have recently redesigned our ACO management system, which supports application management functions among other functions. This management system facilitates our implementation of the redesigned participation options finalized in this final rule. The system changes include providing new user friendly interfaces for ACOs to manage their ACO participant list and list of ACO providers/suppliers. We have received positive feedback from ACOs on the functionality of this new system, which includes opportunities for real-time feedback on the Medicare enrollment status of ACO participants and streamlined processes. We also note that compared to the first year of the program where we had 3 application cycles, in advance of the April 1, 2012, July 1, 2012, and January 1, 2013 start dates, we will have only two application cycles in CY 2019, in advance of the July 1, 2019 start date and January 1, 2020 start date. Furthermore, unlike the first year of the program, we now have experience with 8 application cycles, and have applied lessons learned to streamline the process to make it more user friendly and efficient after each cycle. As a result, we will be able to provide an efficient and transparent process for ACOs to apply for a new agreement period beginning on July 1, 2019, so that they may begin participation under the redesigned program options as soon as possible.

On balance, we believe it is important not to delay the implementation of the redesigned participation options under the Shared Savings Program, and to offer an opportunity for ACOs to enter the program or renew their participation for an agreement period under the new BASIC track or the ENHANCED track beginning on July 1, 2019. While we recognize that ACOs, ACO participants, and ACO providers/suppliers will need to adapt to the redesigned program requirements, we decline commenters'

suggestions that we delay the implementation of these changes, and thereby maintain the status quo, in an effort to avoid the burden associated with what we believe are necessary program changes to drive ACOs to more aggressively pursue the program's goals of lowering growth in Medicare FFS expenditures and improving quality of care for Medicare beneficiaries.

We appreciate commenters' concerns about the potential complexity of the approach for determining performance for 6-month performance years during CY 2019, as opposed to an alternative approach that would allow for implementation of the redesigned participation options for agreement periods beginning on January 1, 2020, and subsequent years, which would maintain 12-month performance years. To assist ACOs in understanding the operational details of participation in a 6-month performance year from July 1, 2019, through December 31, 2019, we anticipate providing education and offering outreach to ACOs through the various methods available, including guidance documents, webinars, FAQs and a weekly newsletter.

In sections II.A.7.b. and II.A.7.c. of this final rule we respond to comments on the specific aspects of the methodology for determining financial and quality performance for the 6-month performance year from July 1, 2019, through December 31, 2019, and other aspects of program participation affected by a 6-month performance year, including concerns about ACOs participating in two 6-month performance years during CY 2019.

Comment: One commenter urged CMS to stagger the implementation of the proposed program redesign, so that it would apply on July 1, 2019, as proposed only to those ACOs that have been in the Shared Savings Program the longest, and would go into effect on January 1, 2020, for organizations that joined the program more recently, and January 1, 2021 for organizations that began in the program in 2018.

Response: We decline the commenter's suggested approach for staggering the program redesign policies based upon an ACO's experience within the Shared Savings Program. As discussed previously, we continue to believe it is important to create a pathway for ACOs to more rapidly transition to performance-based risk. We note, as explained in section II.A.2 of this final rule, ACOs within a current agreement period may complete their current agreement under their existing track (Track 1, Track 2, Track 3, or the Track 1+ Model). Under the policies we proposed and are finalizing, these ACOs would be required to renew in either the BASIC track or the ENHANCED track to continue their participation in the Shared Savings Program for a subsequent agreement period. For example, ACOs that entered a first or second agreement period beginning on January 1, 2016, and that elect the voluntary 6-month extension for the performance year from January 1, 2019, through June 30, 2019, would need to renew under the redesigned program participation options for a new agreement period beginning on July 1, 2019. ACOs with a first or second agreement period start date of January 1, 2017, or January 1, 2018, would be required to renew in either the BASIC track or the ENHANCED track to continue their participation in the Shared Savings Program for a subsequent agreement period beginning on January 1, 2020, or January 1, 2021 (respectively).

Comment: Several commenters expressed confusion over whether ACOs may complete their current 3-year agreement period, or if early renewal for an agreement beginning on July 1, 2019, is mandatory. One commenter questioned whether the early renewal option includes the 6-month extension from January 1, 2019, through June 30, 2019.

Response: We wish to clarify that early renewal is voluntary. Early renewal does not include a 6-month extension from January 1, 2019, through June 30, 2019, which was finalized in the November 2018 final rule and is limited to ACOs that entered a first or second agreement period beginning on January 1, 2016, whose agreement periods would otherwise expire on December 31, 2018. However, we note that early renewal will be available for ACOs that begin a 12-month performance year on January 1, 2019, and voluntarily elect to terminate their participation agreement with an effective date of termination of June 30, 2019, in order to enter a new agreement period starting on July 1, 2019. As discussed in section II.A.7.b. of this final rule, these early renewal ACOs would be reconciled for the 6-month performance period from January 1, 2019, through June 30, 2019, and for the 6-month performance year from July 1, 2019, through December 31, 2019.

Comment: A few commenters expressed their support for the availability of the ACO Pre-Participation Waiver to protect ACO-related start-up arrangements in anticipation of new participants in the Shared Savings Program and the proposed redesigned program tracks.

Response: We thank the commenters for their feedback. Comments on the waivers of fraud and abuse laws are beyond the scope of this rulemaking. However, we note that on August 9, 2018, OIG and CMS jointly issued special guidance on the start date and end dates of the ACO Pre-Participation Waiver for the 2019 application cycle. See Medicare Shared Savings Program Waivers: Special ACO Pre-Participation Waiver Guidance for the 2019 Application Cycle (Issued: August 9, 2018), available at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/2019-Pre-Participation-Waiver-Guidance.pdf.* Complete information on fraud and abuse waivers issued in connection with the Shared Savings Program is available at: *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html.* No waivers of any fraud and abuse authorities are being issued in this final rule.

Final Action: After consideration of the public comments received, we are finalizing our proposal for a one-time July 1, 2019 agreement period start date as the initial opportunity for ACOs to enter an agreement period under the redesigned participation options of the BASIC track or the ENHANCED track as described in sections II.A.2. and II.A.3. of this final rule. Further, as described in section II.A.5.c. of this final rule, we are finalizing our proposals with respect to the removal of the ''sit-out'' period after termination, and the definition of ''renewing ACO'' and are revising our regulations to allow an ACO to terminate its current participation agreement and renew early by entering a new agreement period without a break in participation. Under these final policies, ACOs that begin a 12-month performance year on January 1, 2019, may voluntarily elect to terminate their participation agreement with an effective date of termination of June 30, 2019, in order to enter a new agreement period under the new participation options starting on July 1, 2019.

We are finalizing the proposed modifications to § 425.200(b)(3) to add a heading to specify that the provision applies to agreement periods beginning in 2017 and 2018. We are also finalizing the addition of a new provision at § 425.200(b)(4) to specify that, for agreement periods beginning in 2019 the start date is—(1) January 1, 2019, and the term of the participation agreement is 3 years for ACOs whose first agreement period began in 2015 and who deferred renewal of their participation agreement under § 425.200(e); or (2) July 1, 2019, and the

term of the participation agreement is 5 years and 6 months. We are also finalizing the addition of a new provision at § 425.200(b)(5) specifying that, for agreement periods beginning in 2020 and subsequent years, the start date is January 1 of the applicable year, and the term of the participation agreement is 5 years.

We are also finalizing the proposed revisions to § 425.200(c) to incorporate an additional exception to the definition of performance year as a 12-month period. We are adding paragraph (c)(3) specifying that for an ACO that entered an agreement period with a start date of July 1, 2019, the ACO's first performance year of the agreement period is defined as the 6-month period between July 1, 2019, and December 31, 2019.

The provision at § 425.200(d), as revised in the November 2018 final rule, reiterates an ACO's obligation to submit quality measures in the form and manner required by CMS for each performance year of the agreement period, including as applicable according to § 425.609. Because the existing language of § 425.200(d), as revised by the November 2018 final rule, is broad enough to cover the quality reporting requirements for both 6-month performance years as specified under § 425.609, no further revision to this provision is required at this time to reflect our decision to finalize the July 1, 2019 agreement start and the provisions in § 425.609(c) governing the 6-month performance year from July 1, 2019, through December 31, 2019 (see section II.A.7.c.(4) of this final rule for a discussion of the related quality reporting requirements).

b. Methodology for Determining Financial and Quality Performance for the 6-Month Performance Year During 2019

(1) Overview

In this section we discuss our final policies for determining financial and quality performance for the 6-month performance year from July 1, 2019, through December 31, 2019. We also finalize an approach for determining performance during the period from January 1, 2019, through June 30, 2019, for ACOs that begin a 12-month performance year on January 1, 2019, and terminate their participation agreement with an effective date of termination of June 30, 2019, in order to enter a new agreement period starting on July 1, 2019. Consistent with our proposal in the August 2018 proposed rule (83 FR 41851 through 41853), the methodology that we are adopting for making this determination aligns with the methodology for determining financial and quality performance for ACOs whose agreement periods would otherwise expire on December 31, 2018, that voluntarily elect to extend their agreement for the 6-month performance year from January 1, 2019, through June 30, 2019, as finalized in the November 2018 final rule (83 FR 59946 through 59951) and as specified at § 425.609(b). As we noted in the August 2018 proposed rule, this approach to reconciling ACO performance for a 6-month performance year (or performance period) during 2019 will not alter the methodology that will be applied to determine financial performance for ACOs that complete a 12 month performance year corresponding to CY 2019 (83 FR 41850). In this section of this final rule, we also explain that the policies we are adopting require use of our authority under section 1899(i)(3) of the Act.

Consistent with the approach taken in the August 2018 proposed rule, we use two terms, ''6-month performance year'' and ''performance period'' in discussing the 6-month periods during 2019. We use the term ''6-month performance year'' to refer to the following: (1) The fourth performance year from January 1, 2019, through June 30, 2019, for ACOs that started a first or second agreement period on January 1, 2016, and extend their current agreement period for this 6-month period; and (2) the first performance year from July 1, 2019, through December 31, 2019, for ACOs that enter an agreement period beginning on July 1, 2019. For an ACO starting a 12-month performance year on January 1, 2019, that terminates its participation agreement with an effective date of termination of June 30, 2019, and enters a new agreement period beginning on July 1, 2019, we refer to the 6-month period from January 1, 2019, through June 30, 2019, as a ''performance period''.

In section II.A.7.b. of the August 2018 proposed rule, we proposed to use the same overall approach to determining ACO financial and quality performance for the two 6-month performance years during CY 2019 (the 6-month performance year from January 1, 2019, through June 30, 2019, and the 6-month performance year from July 1, 2019, through December 31, 2019). We noted that the specific policies used to calculate factors used in making these determinations would differ based on the ACO's track, its agreement period start date, and the agreement period in which the ACO participates (for factors that phase-in over multiple agreement periods). In the August 2018 proposed rule, we proposed to specify the methodologies for reconciling these 6-month performance years during 2019 in a new section of the regulations at § 425.609.

Under our proposed approach to determining performance for ACOs participating in the 6-month performance years (or the 6-month performance period) during 2019, CMS would reconcile the financial and quality performance of these ACOs after the conclusion of CY 2019. For ACOs that extended their agreement period for the 6-month performance year from January 1, 2019, through June 30, 2019, or ACOs that terminated their agreement period early on June 30, 2019, and entered a new agreement period beginning on July 1, 2019, CMS would first reconcile the ACO based on its performance during the entire 12-month calendar year, and then pro-rate the calendar year shared savings or shared losses to reflect the ACO's participation in that 6-month period. In a separate calculation, CMS would reconcile an ACO that participated for a 6-month performance year from July 1, 2019, through December 31, 2019, for the 12-month calendar year in a similar manner, and pro-rate the shared savings or shared losses to reflect the ACO's participation during that 6-month performance year.

In the August 2018 proposed rule (83 FR 41850 and 41851), we explained this approach would avoid a more burdensome interim payment process that could accompany an alternative approach of implementing, for example, an 18-month performance year from July 1, 2019 to December 31, 2020. Consistent with the policies that applied to the 18- and 21-month performance years offered for the first cohorts of Shared Savings Program ACOs, such a policy could require ACOs to establish a repayment mechanism that otherwise might not be needed, create uncertainty over whether the ACO may ultimately need to repay CMS based on final results for the extended performance year, and delay ACOs seeing a return on their investment in program participation, if eligible for shared savings.

We explained our belief that the proposed approach of determining performance during a 6-month performance year (or performance period) based on data for the full 12-month calendar year would allow continuity in program operations (including operations that occur on a calendar year basis) for ACOs that have either one or two 6-month performance years (or performance period) within CY 2019. Specifically, the proposed

approach would allow for payment reconciliation to remain on a calendar year basis, which would be most consistent with the calendar year-based methodology for calculating benchmark expenditures, trend and update factors, risk adjustment, county expenditures and regional adjustments. We also explained that deviating from a 12-month reconciliation calculation by using fewer than 12 months of expenditures could interject actuarial biases relative to the benchmark expenditures, which are based on 12-month benchmark years. As a result, we believed this approach to reconciling ACOs based on a 12-month period would protect the actuarial soundness of the financial reconciliation methodology. We also explained our belief that the alignment of the proposed approach with the standard methodology used to perform the same calculations for 12-month performance years that correspond to a calendar year would make it easier for ACOs and other program stakeholders to understand the proposed methodology.

As is the case with typical calendar year reconciliations in the Shared Savings Program, we anticipated results with respect to participation during CY 2019 would be made available to ACOs in summer 2020. We explained that this would allow those ACOs that are eligible to share in savings as a result of their participation in the program during CY 2019 to receive payment of shared savings following the conclusion of the calendar year consistent with the standard process and timing for annual payment reconciliation under the program. We proposed to provide separate reconciliation reports for each 6-month performance year (or performance period) and to pay shared savings or recoup shared losses separately for each 6-month performance year (or performance period) during 2019 based on these results.

In section II.A.7.b.(2). of the August 2018 proposed rule (83 FR 41851 through 41853), we described in detail our proposed approach to determining an ACO's performance for the 6-month performance year from January 1, 2019, through June 30, 2019. These policies were adopted in the November 2018 final rule (83 FR 59946 through 59951) and are specified in paragraph (b) of a new section of the regulations at § 425.609.

(2) Determining Performance for the 6-Month Performance Year From July 1, 2019, Through December 31, 2019

In section II.A.7.b.(3). of the August 2018 proposed rule (83 FR 41853 through 41854), we described in detail our proposed approach to determining an ACO's performance for the 6-month performance year from July 1, 2019, through December 31, 2019. Our proposed policies addressed the following: (1) The ACO participant list that will be used to determine beneficiary assignment; (2) the approach to assigning beneficiaries for the 6-month performance year; (3) the quality reporting period for the 6-month performance year; (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 for the ACO for the performance year. We proposed to specify the methodology for reconciling the 6-month performance year from July 1, 2019, through December 31, 2019, in paragraph (c) of a new section of the regulations at § 425.609.

We noted that in determining performance for the 6-month performance year from July 1, 2019, through December 31, 2019, we would follow the same general methodological steps for calculating pro-rated shared savings and shared losses as would apply for the 6-month performance year from January 1, 2019 through June 30, 2019. However, we noted that, for example, the applicable benchmarking methodology, which is based on the ACO's agreement period in the program, and financial model, which is based on the track in which the ACO is participating, would be different.

We proposed to use the ACO participant list for the performance year beginning July 1, 2019, to determine beneficiary assignment, consistent with the assignment methodology the ACO selected at the start of its agreement period under proposed § 425.400(a)(4)(ii). As discussed in section II.A.7.c. of the August 2018 proposed rule (83 FR 41855 through 41856), this would be the ACO participant list that was certified as part of the ACO's application to enter an agreement period beginning on July 1, 2019.

To determine beneficiary assignment, we proposed to consider the allowed charges for primary care services furnished to the beneficiary during a 12 month assignment window, allowing for a 3 month claims run out. For the 6-month performance year from July 1, 2019, through December 31, 2019, we proposed to determine the assigned beneficiary population using the following assignment windows:

- For ACOs under preliminary prospective assignment with retrospective reconciliation, the assignment window would be CY 2019.
- For ACOs under prospective assignment, Medicare FFS beneficiaries would be prospectively assigned to the ACO based on the beneficiary's use of primary care services in the most recent 12 months for which data are available. We would use an assignment window before the start of the agreement period on July 1, 2019. As an example, we noted that we could use an assignment window from April 30, 2018, through March 31, 2019 (note that the example in the proposed rule inadvertently included only 11 months and should have been April 1, 2018, through March 31, 2019). Under this approach, the 3-month gap between the end of the assignment window and the start of the performance year would be consistent with the typical gap for calendar year performance years that begin on January 1. Beneficiaries would remain prospectively assigned to the ACO at the end of CY 2019 unless they meet any of the exclusion criteria under § 425.401(b) during the calendar year.

As discussed in section II.A.7.c.(4). of the August 2018 proposed rule (83 FR 41856), to determine ACO performance during either 6-month performance year in 2019, we proposed to use the ACO's quality performance for the 2019 reporting period, and to calculate the ACO's quality performance score as provided in § 425.502.

Consistent with current program policy, we would determine assignment for the benchmark years based on the ACO's certified ACO participant list for the agreement period beginning on July 1, 2019.

For the 6-month performance year from July 1, 2019, through December 31, 2019, we would calculate the benchmark and assigned beneficiary expenditures as though the performance year were the entire calendar year. The ACO's historical benchmark would be determined according to the methodology applicable to the ACO based on its agreement period in the program. We proposed to apply the methodology for establishing, updating and adjusting the ACO's historical benchmark as specified in proposed § 425.601, except that data from CY 2019 would be used in place of data for the 6-month performance year in certain calculations, as follows:

- The benchmark would be adjusted for changes in severity and case mix between benchmark year 3 and CY 2019 based on growth in prospective HCC risk scores, subject to a symmetrical cap of positive or negative 3 percent that would apply for the agreement period such that the adjustment between BY3 and any performance year in the agreement period would never be more than 3 percent in either direction. (See the discussion in section II.D.2. of the August 2018 proposed rule.)

• The benchmark would be updated to CY 2019 according to the methodology described under proposed § 425.601(b) using a blend of national and regional growth rates. (See the discussion in section II.D.3.(d). of the August 2018 proposed rule.)

For determining performance during the 6-month performance year from July 1, 2019, through December 31, 2019, we would apply the methodology for determining shared savings and shared losses according to the approach specified for the ACO's track under its agreement period beginning on July 1, 2019: The proposed BASIC track (§ 425.605) or ENHANCED track (§ 425.610). However, we acknowledged that some exceptions to the otherwise applicable methodology would be needed because we were proposing to calculate the expenditures for assigned beneficiaries over the full CY 2019 for purposes of determining shared savings and shared losses for the 6-month performance year from July 1, 2019 through December 31, 2019. We proposed to use the following steps to calculate shared savings and shared losses:

• Average per capita Medicare expenditures for Parts A and B services for CY 2019 would be calculated for the ACO's performance year assigned beneficiary population. Additionally, when calculating CY 2019 expenditures to be used in determining performance for the July 1, 2019 through December 31, 2019 performance year, we would include expenditures for all assigned beneficiaries that are alive as of January 1, 2019, including those with a date of death prior to July 1, 2019, except prospectively assigned beneficiaries that are excluded under § 425.401(b). We explained that the inclusion of beneficiaries with a date of death before July 1, 2019, is necessary to maintain consistency with benchmark year and regional expenditure adjustments and associated trend and update factor calculations.

• We would compare these expenditures to the ACO's updated benchmark determined for the calendar year as previously described.

• We would apply the MSR and MLR (if applicable).

++ The ACO's assigned beneficiary population for the performance year starting on July 1, 2019, would be used to determine the MSR for one-sided model ACOs (under Level A or Level B of the BASIC track) and the variable MSR/MLR for ACOs in a two-sided model that selected this option at the start of their agreement period. In the event a two-sided model ACO selected a fixed MSR/MLR at the start of its agreement period, and the ACO's performance year assigned population falls below 5,000 beneficiaries, the MSR/MLR would be determined based on the number of assigned beneficiaries as proposed in section II.A.6.b. of the August 2018 proposed rule (83 FR 41837 through 41839).

++ To qualify for shared savings, the ACO's average per capita Medicare expenditures for its performance year assigned beneficiaries during CY 2019 must be below its updated benchmark for the year by at least the MSR established for the ACO.

++ To be responsible for sharing losses with the Medicare program, the ACO's average per capita Medicare expenditures for its performance year assigned beneficiaries during CY 2019 must be above its updated benchmark for the year by at least the MLR established for the ACO.

• We would determine the shared savings amount if we determine the ACO met or exceeded the MSR, and if the ACO met the minimum quality performance standards established under § 425.502, and as described in section II.A.7.c.(4) of the August 2018 proposed rule (83 FR 41856 through 41858), and otherwise maintained its eligibility to participate in the Shared Savings Program. We would determine the shared losses amount if we determine the ACO met or exceeded the MLR. To determine these amounts, we would do the following:

++ We would apply the final sharing rate or loss sharing rate to first dollar savings or losses.

++ For ACOs that generated savings that met or exceeded the MSR, we would multiply the difference between the updated benchmark expenditures and performance year assigned beneficiary expenditures by the applicable final sharing rate based on the ACO's track and its quality performance under § 425.502.

++ For ACOs that generated losses that met or exceeded the MLR, we would multiply the difference between the updated benchmark expenditures and performance year assigned beneficiary expenditures by the applicable shared loss rate based on the ACO's track and its quality performance under § 425.502 (for ACOs in the ENHANCED track where the loss sharing rate is determined based on the ACO's quality performance).

• We would adjust the shared savings amount for sequestration by reducing by 2 percent and compare the sequestration-adjusted shared savings amount to the applicable performance payment limit based on the ACO's track.

• We would compare the shared losses amount to the applicable loss sharing limit based on the ACO's track.

• We would pro-rate any shared savings amount, as adjusted for sequestration and the performance payment limit, or any shared losses amount, as adjusted for the loss sharing limit, by multiplying by one half, which represents the fraction of the calendar year covered by the 6-month performance year. This pro-rated amount would be the final amount of shared savings that would be paid to the ACO for the 6-month performance year or the final amount of shared losses that would be owed by the ACO for the 6-month performance year.

We sought comment on these proposals.

Comment: Several commenters expressed concerns that under the proposed approach, ACOs participating in the performance year from July 1, 2019, through December 31, 2019, would also be accountable for their financial performance during the first six months of CY 2019. Several commenters indicated that ACOs would not have program reports or sufficient patient data to affect care for their assigned population during the first six months of CY 2019, during the period prior to the start of their agreement period. These commenters noted this concern with respect to ACOs that are entering an initial agreement period beginning on July 1, 2019, as well as ACOs that are currently participating in the program that make ACO participant list changes effective for a new agreement period beginning on July 1, 2019. To address this issue, one commenter suggested that one approach could be to create a 6-month benchmark comparison that adjusts for the ACO's participation in a portion of the year, taking into account differences in expenditures based on seasonality.

Response: We appreciate the commenters' concern that ACOs entering agreement periods beginning on July 1, 2019, may have relatively little data in order to be able to understand and affect change for their assigned Medicare FFS population for the 6-month performance year, but would be accountable for the cost and quality of care for this beneficiary population for the entire 12 month CY 2019. We note, beneficiaries who are prospectively assigned or preliminary prospectively assigned to the ACO would have received the plurality of their primary care services from physicians and other practitioners in the ACO during the 12 month assignment window. As a result, ACO participants will have data based on the services they furnished to these Medicare FFS beneficiaries. Additionally, to assist in addressing this concern, we will provide aggregate and beneficiary-level data, consistent with §§ 425.702 and 425.704 (respectively), shortly after ACOs begin the agreement period. We will provide each ACO with an Assignment List Report identifying the ACO participant and ACO provider/supplier who provided the most primary care services to an assigned beneficiary during the assignment window. Further, we will provide monthly beneficiary-identifiable claim and claim line feed data files. The first time a beneficiary is included in an eligible ACO's claim and claim line feed data files we provide 36 months of historical Part A, B and D data to the ACO.

Additionally, quarterly and annual aggregate reports include expenditure and utilization trends, and demographic data on the ACO's assigned population

will be provided during the performance year. This information should help ACOs identify the practitioners with data necessary to coordinate care for their beneficiaries, observe trends in the care for the ACO's assigned population, and support the ACO's care coordination activities for its assigned population during the 6-month performance year from July 1, 2019, through December 31, 2019.

We continue to believe the proposed approach is the most appropriate methodology for determining an ACO's financial and quality performance for the 6-month performance year from July 1, 2019, through December 31, 2019, based on its performance during the entire 12-month calendar year. This approach maintains alignment with the program's existing methodology for using 12 months of expenditure data in determining the ACO's financial performance, and also allows for the use of a 12-month period for quality measure assessment. Further, this approach maintains alignment with the methodology we finalized for the 6-month performance year from January 1, 2019, through June 30, 2019, in the November 2018 final rule. We therefore decline to adopt the commenter's suggestion to use an alternative approach of calculating the benchmark based on a period of other than 12 months, such as 6 months.

Comment: A few commenters suggested that ACOs beginning an agreement period on July 1, 2019, should participate in an 18-month first performance year under the new agreement. Another commenter suggested that CMS allow for 18-month performance years in subsequent years, as well as for agreement periods beginning on July 1, 2019.

Response: We decline to adopt the commenters' suggestions that we allow for an 18-month performance year for ACOs entering agreement periods beginning on July 1, 2019, and in subsequent years. In the August 2018 proposed rule (83 FR 41850 through 41851), we explained our concerns about using a performance year that is determined based on a period other than 12 months, and described the challenges with our experience with the program's initial 21-month and 18-month performance years for ACOs entering the Shared Savings Program with start dates in 2012. We expressed our concerns that using such an approach might introduce further complexity into program calculations, and could require ACOs to establish a repayment mechanism that otherwise might not be required, adding additional burden and expense. In addition, we noted that this approach would create uncertainty over whether the ACO may ultimately need to repay CMS based on final results for the extended performance year and delay ACOs seeing a return on their investment in program participation if eligible for shared savings.

Comment: Many commenters expressed concerns about the potential burden on ACOs of managing and implementing the necessary modifications to operational processes to account for two separate beneficiary populations (derived from two separate ACO participant lists, and potentially two different assignment windows and assignment methodologies) in one calendar year, while also meeting program expectations. Several commenters indicated that the burdens associated with this approach could result in shared losses and/or possible exit from the program by ACOs under a two-sided model.

A few commenters expressed this concern, in particular, for ACOs under the prospective assignment methodology. They explained that while some beneficiaries will be attributed to the ACO for both performance periods, there will be a portion of an ACO's beneficiary population that is assigned for only one performance period. For beneficiaries assigned for only the first performance period, the ACO would have to continue to deploy resources to manage this population even after they are no longer assigned to the ACO. For beneficiaries assigned only in the second performance period, the ACO would be responsible for costs incurred in the first half of the year when the ACO had no ability to manage these beneficiaries' care. As a result, ACOs will have to scale up resources and infrastructure in order to mitigate the impact on quality and cost. Moreover, with little influence over beneficiaries' expenditures outside of the performance period, ACOs could potentially be at risk for exceeding their benchmark.

To address these concerns, some commenters suggested that CMS use a single assignment window and beneficiary assignment methodology to determine an ACO's assigned beneficiary population for the entire CY 2019, including for ACOs that participate in multiple performance years during 2019, regardless of whether the ACO is in the fourth performance year of an extended agreement period, the first half of a 12-month performance year starting on January 1, 2019, or an initial performance year under the proposed BASIC track or ENHANCED track starting on July 1, 2019. Specifically, some commenters suggested that we use the assignment window from October 1, 2017, through September 30, 2018, for determining prospective assignment for both 6-month performance years. These commenters believe this approach to determining prospective assignment would remove the challenges associated with population churn and the mismatch between at-risk expenditures and potential savings. Several commenters made this suggestion as part of describing an alternative approach under which we would use the ACO participant list certified by the ACO for the performance year beginning on January 1, 2019, in determining a prospectively assigned population for both 6-month performance years. However, other commenters urged CMS to allow ACOs participating in a performance year beginning on January 1, 2019, to make changes to their ACO participant lists before entering a new agreement period beginning on July 1, 2019. See discussion in section II.A.7.c.(2). of this final rule.

Response: We agree with commenters' suggestions that for purposes of determining prospective assignment for the 6-month performance year from July 1, 2019, through December 31, 2019, it is preferable to use an offset assignment window from October 1, 2017, through September 30, 2018, rather than a later assignment window, as we originally proposed. We believe that maintaining the same prospective assignment window for both 6-month performance years during CY 2019 has a number of advantages, including avoiding inconsistencies between the performance year and benchmark year assignment windows, and reducing the potential differences in the populations assigned to the ACO for each performance year during CY 2019. We note, however, that ACO participant list differences between each 6-month performance year could still result in significantly different assigned beneficiary populations, even when the assignment window remains the same. Given our desire to offer currently participating ACOs entering a new agreement period starting on July 1, 2019, an opportunity to make changes to their ACO participant lists applicable for the 6-month performance year starting on July 1, 2019, we decline the commenters' suggestion that we use the same ACO participant list finalized for the performance year starting on January 1, 2019, in determining beneficiary assignment for the performance year from July 1, 2019, through December 31, 2019.

Accordingly, for the performance year from July 1, 2019, through December 31, 2019, for ACOs under the preliminary

prospective assignment methodology, the assigned beneficiary population would be determined after the end of the performance year, consistent with how it is currently determined for ACOs under the preliminary prospective assignment methodology, based on the 12-month calendar year that corresponds to the performance year. For ACOs under the prospective assignment methodology the assignment window for the 6-month performance year from July 1, 2019, through December 31, 2019, would be the same as the assignment window for the 6-month performance year from January 1, 2019, through June 30, 2019. Therefore, for ACOs that participate in both 6-month performance years during CY 2019, if the ACO maintains the same ACO participant list for all of CY 2019 and the same beneficiary assignment methodology, then the assigned beneficiary population for the July 1, 2019, through December 31, 2019 performance year would be expected to closely resemble the assigned beneficiary population for the performance year or performance period from January 1, 2019, through June 30, 2019.

However, we also recognize that under the redesign of program participation options, ACOs entering an agreement period beginning on July 1, 2019, would have the opportunity to select the beneficiary assignment methodology that would apply for the 6-month performance year from July 1, 2019, through December 31, 2019, and this could result in the ACO being under a different assignment methodology than it was under for the first 6 months of CY 2019. In this case, there may be greater differences in the assigned beneficiary populations for each 6-month performance year for ACOs that participate in both 6-month performance years, even if their ACO participant list remains similar or unchanged.

Final Action: After consideration of the public comments received, we are finalizing, with modifications, the proposed approach for determining financial and quality performance for ACOs participating in a 6-month performance year from July 1, 2019, through December 31, 2019. Our final policies are specified in paragraph (c) of § 425.609.

For ACOs that select a prospective beneficiary assignment methodology for the 6-month performance year from July 1, 2019, through December 31, 2019, we plan to use an assignment window from October 1, 2017, through September 30, 2018, to align with the assignment window used to determine prospective assignment for performance years beginning on January 1, 2019. This is a modification to our proposal to use an assignment window reflecting the most recent 12 months of data available as described in the August 2018 proposed rule. Accordingly, we are revising the provision at § 425.609(c)(1)(ii)(A) to state that for ACOs under prospective assignment, the assignment window is the same as the assignment window that applies under § 425.609(b)(1)(ii)(A) for ACOs under prospective assignment for the 6-month performance year from January 1, 2019, through June 30, 2019.

As explained in section II.D of this final rule, we are finalizing our proposed changes to the risk adjustment methodology with modification. Consistent with our original proposal, growth in prospective HCC risk scores will be subject to a cap of positive 3 percent, but we are not finalizing our proposal to cap downward adjustments in these risk scores. Therefore we are making necessary conforming changes to the provision at § 425.609(c)(3)(i)(A) to reflect this change.

In addition, in the November 2018 final rule we made certain clarifying revisions to the introductory text in § 425.609(b). Accordingly, we are also modifying the introductory text at § 425.609(c) to incorporate similar clarifying revisions.

In summary, we will do the following to determine the ACO's financial and quality performance during the 6-month performance year from July 1, 2019, through December 31, 2019. (Where applicable, we have identified references to policies we are finalizing elsewhere in this final rule.)

We will use the ACO participant list for the performance year beginning July 1, 2019, to determine beneficiary assignment, consistent with the assignment methodology the ACO selected at the start of its agreement period according to the provision we are finalizing at § 425.400(a)(4)(ii) (as discussed in section II.A.4.c of this final rule).

We will use the ACO's quality performance for the 2019 reporting period to determine the ACO's quality performance score as specified in § 425.502, and as described in section II.A.7.c.(4) of this final rule.

We will establish, adjust and update the ACO's historical benchmark according to the benchmarking policies we are finalizing for agreement periods beginning on July 1, 2019, and in subsequent years, except that the benchmark will be adjusted for changes in severity and case mix based on growth in prospective HCC risk scores between BY3 and CY 2019, subject to a cap of positive 3 percent, and the benchmark will be updated to CY 2019. (See section II.D. of this final rule and the new section of the regulations at § 425.601.) We will compare the ACO's updated historical benchmark to the expenditures during CY 2019 for the ACO's performance year assigned beneficiaries.

We will apply the MSR and MLR (if applicable). The ACO's assigned beneficiary population for the performance year starting on July 1, 2019, will be used to determine the MSR for one-sided model ACOs (under Level A or Level B of the BASIC track) and the variable MSR/MLR for ACOs in a two-sided model that selected this option at the start of their agreement period. The provisions on the MSR/MLR are specified in a new section of the regulations at § 425.605(b) for the BASIC track, and § 425.610(b) for the ENHANCED track. In the event a two-sided model ACO selected a fixed MSR/MLR at the start of its agreement period, and the ACO's performance year assigned population falls below 5,000 beneficiaries, the MSR/MLR will be determined based on the number of assigned beneficiaries, according to the approach we are finalizing at § 425.110(b)(3), as discussed in section II.A.6.b.(3). of this final rule.

If the difference between the ACO's updated benchmark and assigned beneficiary expenditures is positive and is greater than or equal to the MSR and the ACO has met the quality performance standard, the ACO will be eligible for shared savings. If the ACO is in a two-sided model and the difference between the ACO's updated benchmark and assigned beneficiary expenditures is negative and is greater than or equal to the MLR (in absolute value terms), the ACO will be liable for shared losses. ACOs will share in first dollar savings and losses. The amount of any shared savings will be determined using the applicable final sharing rate, which is determined based on the ACO's track for the agreement period (and the payment model within that track, if applicable) and taking into account the ACO's quality performance for 2019. We will adjust the amount of shared savings for sequestration, and then cap the amount of shared savings at the applicable performance payment limit for the ACO's track. Similarly, the amount of any shared losses will be determined using the loss sharing rate for the ACO's track and, as applicable, for ACOs in tracks with a loss sharing rate that depends upon quality performance, the ACO's quality performance for 2019. We will then cap the amount of shared losses at the

applicable loss sharing limit for the ACO's track (and the payment model within that track, if applicable). We will then pro-rate the amount of shared savings or shared losses by multiplying by one-half, which represents the fraction of the calendar year covered by the 6-month performance year. This pro-rated amount is the final amount of shared savings earned or shared losses owed by the ACO for the 6-month performance year from July 1, 2019, through December 31, 2019.

(3) Determining Performance for the 6-Month Performance Period From January 1, 2019, Through June 30, 2019, for Early Renewals

Under the policies we are finalizing in this final rule to remove the ''sit-out'' period after termination (see section II.A.5.c. of this final rule) and to allow for a July 1, 2019 agreement start date (see section II.A.7.a. of this final rule), ACOs that begin a 12-month performance year on January 1, 2019, may voluntarily elect to terminate their participation agreement with an effective date of termination of June 30, 2019, in order to enter a new agreement period starting on July 1, 2019 (referred to as early renewal). Under the changes that we are finalizing to our policies governing the payment consequences of early termination at § 425.221, ACOs with an effective date of termination of June 30, 2019, that enter a new agreement period beginning on July 1, 2019, will be eligible for pro-rated shared savings or liable for pro-rated shared losses for the 6-month period from January 1, 2019, through June 30, 2019, determined according to § 425.609.

In the August 2018 proposed rule (83 FR 41849 and 41850), we proposed to determine performance for the 6-month performance period from January 1, 2019, through June 30, 2019, for ACOs renewing early for a July 1, 2019 agreement start date, using the same methodology as would be used to determine an ACO's performance for the 6-month performance year from January 1, 2019, through June 30, 2019. In the November 2018 final rule (83 FR 59946 through 59951), we finalized the methodology for determining an ACO's performance for this 6-month performance year in a new provision of the regulations at § 425.609(b). In the August 2018 proposed rule, we described the applicability of certain aspects of this methodology to early renewal ACOs for the 6-month performance period from January 1, 2019, through June 30, 2019. We noted that the approach for determining beneficiary assignment, and for adjusting and updating the historical benchmark for the 6-month performance year from January 1, 2019, through June 30, 2019, would be consistent with the assignment and benchmarking methodologies in the program's regulations applicable for performance years beginning on January 1, 2019. Therefore, these policies would similarly apply to determining performance for the period from January 1, 2019, through June 30, 2019, for early renewals. Accordingly, in the August 2018 proposed rule, we proposed to include a cross reference to the provision under § 425.221 in the introductory text to § 425.609(b) in order to allow reconciliation of early renewals for the performance period from January 1, 2019, through June 30, 2019, to be based on their financial performance during the entire 12-month calendar year 2019 according to the methodology in the provision at § 425.609.

In section II.A.7.c. of this final rule we discuss other modifications that we are making to § 425.609 to address the applicability of certain policies to ACOs participating in a 6-month performance year or performance period in 2019. The affected policies include the following: the quality measure sampling methodology (section II.A.7.c.(4)); the extreme and uncontrollable circumstances policies (section II.A.7.c.(5)); payment and recoupment (section II.A.7.c.(6)); and sharing of CY 2019 aggregate data (section II.A.7.c.(9)).

Final Action: We did not receive any comments specifically addressing the methodology for determining financial and quality performance for the 6-month performance period from January 1, 2019, through June 30, 2019, for ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019. Therefore, we are finalizing without modification our proposal to determine performance for the 6-month performance period from January 1, 2019, through June 30, 2019, for ACOs renewing early for the July 1, 2019 agreement start date, by applying the same methodology as is used to determine an ACO's performance for the 6-month performance year from January 1, 2019, through June 30, 2019 (finalized at § 425.609(b) in the November 2018 final rule). We are also finalizing revisions to the introductory text at § 425.609(b) to incorporate a reference to the provision at § 425.221(b)(3)(i), which specifies that an ACO starting a 12-month performance year on January 1, 2019, that terminates its participation agreement with an effective date of termination of June 30, 2019, and that enters a new agreement period beginning on July 1, 2019, is eligible for pro-rated shared savings or liable for pro-rated shared losses for the 6-month period from January 1, 2019, through June 30, 2019, as determined in accordance with § 425.609.

(4) Use of Authority Under Section 1899(i)(3) of the Act

In the August 2018 proposed rule (83 FR 41851), we explained our belief that the proposals to determine shared savings and shared losses for the 6-month performance years starting on January 1, 2019, and July 1, 2019 (or the 6-month performance period from January 1, 2019, through June 30, 2019, for ACOs that elect to voluntarily terminate their existing participation agreement, effective June 30, 2019, and enter a new agreement period starting on July 1, 2019), using expenditures for the entire CY 2019 and then pro-rating these amounts to reflect the shorter performance year, require the use of our authority under section 1899(i)(3) of the Act to use other payment models. Section 1899(d)(1)(B)(i) of the Act specifies that, in each year of the agreement period, an ACO is eligible to receive payment for shared savings only if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark under section 1899(d)(1)(B)(ii) of the Act. We explained our belief that the proposed approach to calculating the expenditures for assigned beneficiaries over the full calendar year, comparing this amount to the updated benchmark for 2019, and then pro-rating any shared savings (or shared losses, which already are implemented using our authority under section 1899(i)(3) of the Act) for the 6-month performance year (or performance period) involves an adjustment to the estimated average per capita Medicare Part A and Part B FFS expenditures determined under section 1899(d)(1)(B)(i) of the Act that is not based on beneficiary characteristics. Such an adjustment is not contemplated under the plain language of section 1899(d)(1)(B)(i) of the Act. As a result, we stated it would be necessary to use our authority under section 1899(i)(3) of the Act to calculate performance year expenditures and determine the final amount of any shared savings (or shared losses) for a 6-month performance year (or performance period) during 2019, in the proposed manner.

In order to use our authority under section 1899(i)(3) of the Act to adopt an

alternative payment methodology to calculate shared savings and shared losses for a 6-month performance year (or performance period) during 2019, we must determine that the alternative payment methodology will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without additional program expenditures. In the August 2018 proposed rule, we explained our belief that the proposed approach of allowing ACOs that started a first or second agreement period on January 1, 2016, to extend their agreement period for a 6-month performance year from January 1, 2019, through June 30, 2019, and of allowing entry into the program's redesigned participation options beginning on July 1, 2019, if finalized, would support continued participation by current ACOs that must renew their agreements to continue participating in the program, while also resulting in more rapid progression to two-sided risk by ACOs within current agreement periods and ACOs entering the program for an initial agreement period. As discussed in the Regulatory Impact Analysis of the August 2018 proposed rule (83 FR 41915 through 41928), it was our belief that this approach would continue to allow for lower growth in Medicare FFS expenditures based on projected participation trends. Therefore, we did not believe that the proposed methodology for determining shared savings or shared losses for ACOs in a 6-month performance year (or performance period) during 2019 would result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology in section 1899(d) of the Act. Further, we noted that the proposed approach to measuring ACO quality performance for a 6-month performance year (or performance period) based on quality data reported for CY 2019 would maintain accountability for the quality of care ACOs provide to their assigned beneficiaries. Participating ACOs would also have an incentive to perform well on the quality measures in order to maximize the shared savings they may receive and minimize any shared losses they must pay in tracks where the loss sharing rate is determined based on the ACO's quality performance. Therefore, we noted our expectation that the proposed approach to reconciling ACOs for a 6-month performance year (or performance period) during 2019 would continue to lead to improvement in the quality of care furnished to Medicare FFS beneficiaries.

In the November 2018 final rule, we finalized the proposed approach to determining financial and quality performance for the 6-month performance year from January 1, 2019, through June 30, 2019. In that final rule (83 FR 59949 through 59950), we explained our belief that the approach to determining shared savings and shared losses for this 6-month performance year meets the requirements for use of our authority under section 1899(i)(3) of the Act because it will not result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology in section 1899(d) of the Act and will lead to continued improvement in the quality of care furnished to Medicare FFS beneficiaries.

Similarly, as discussed in the Regulatory Impact Analysis section of this final rule (see section V), we believe the approach to determining shared savings and shared losses for the 6-month performance year from July 1, 2019, through December 31, 2019, for ACOs that enter an agreement period beginning on July 1, 2019, and for the 6-month performance period from January 1, 2019, through June 30, 2019, for ACOs that elect to voluntarily terminate their existing participation agreement, effective June 30, 2019, and enter a new agreement period starting on July 1, 2019, meets the requirements for use of our authority under section 1899(i)(3) of the Act. The considerations we described in the August 2018 proposed rule in relation to the proposed methodology and in the November 2018 final rule in conjunction with finalizing the methodology for determining shared savings and shared losses for the 6-month performance year from January 1, 2019, through June 30, 2019, were relevant in making this determination.

Specifically, we do not believe that the methodology for determining shared savings or shared losses for ACOs in a 6-month performance year (or performance period), as finalized in this section of this final rule, will result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology in section 1899(d) of the Act. We believe the following factors would allow for lower growth in Medicare FFS expenditures based on projected participation trends: (1) In combination with the voluntary 6-month extension we finalized in the November 2018 final rule for ACOs whose agreement periods expire on December 31, 2018, the July 1, 2019 agreement start date will support continued participation by these ACOs; (2) the early renewal option for the July 1, 2019 agreement start date could also result in more rapid progression to two-sided risk by ACOs within current agreement periods; and (3) the July 1, 2019 start date encourages participation by new ACOs in initial agreement periods under redesigned participation options in which ACOs will more rapidly progress to performance-based risk.

Further, we believe the approach we are finalizing for reconciling early renewal ACOs for the 6-month performance period from January 1, 2019 through June 30, 2019, and for reconciling the 6-month performance year from July 1, 2019, through December 31, 2019, for ACOs that begin a new agreement period on July 1, 2019, will continue to lead to improvement in the quality of care furnished to Medicare FFS beneficiaries. As described elsewhere in this section of this final rule, the approach to measuring ACO quality performance for the 6-month performance year from July 1, 2019, through December 31, 2019, or for the 6-month performance period from January 1, 2019, through June 30, 2019, based on quality data reported for CY 2019, will maintain accountability for the quality of care ACOs provide to their assigned beneficiaries. Participating ACOs will have an incentive to perform well on the quality measures in order to maximize the shared savings they may receive and minimize any shared losses they must pay in tracks where the loss sharing rate is determined based on the ACO's quality performance.

c. Applicability of Program Policies to ACOs Participating in a 6-Month Performance Year or Performance Period in 2019

In the August 2018 proposed rule (83 FR 41854), we proposed that program requirements under 42 CFR part 425 that are applicable to the 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 year, unless otherwise stated. We finalized this approach with respect to ACOs participating in the 6-month performance year from January 1, 2019, through June 30, 2019, in the November 2018 final rule (83 FR 59951). In that final rule, we explained that we received no comments on this general proposal, which would allow routine program operations to continue to apply for ACOs participating under a shorter performance year, and ensure consistency in the applicability and

implementation of our requirements across all program participants, including ACOs participating in a 6-month performance year. For these same reasons, we are also finalizing this approach with respect to ACOs participating in the 6-month performance year from July 1, 2019, through December 31, 2019, and the 6-month performance period from January 1, 2019, through June 30, 2019. This approach will ensure program policies are applied consistently for all ACOs participating in a 6-month performance year from January 1, 2019, through June 30, 2019 and/or from July 1, 2019, through December 31, 2019, and to ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019.

In this section, we describe the program participation options that are affected by our decision to forgo an application cycle in CY 2018 for a January 1, 2019 start date, and offer instead an application cycle in CY 2019 for a July 1, 2019 start date. We also discuss modifications to program policies to allow for the 6-month performance period from January 1, 2019, through June 30, 2019 for early renewal ACOs, and the 6-month performance year from July 1, 2019, through December 30, 2019. These modifications include updates to the existing provisions in § 425.609, which were initially established for the 6-month performance year from January 1, 2019, through June 30, 2019, to extend them to the 6-month performance period from January 1, 2019, through June 30, 2019, and the 6-month performance year from July 1, 2019, through December 30, 2019.

(1) Application Cycle for Use of a SNF 3-Day Rule Waiver Beginning July 1, 2019

Eligible ACOs may apply for use of a SNF 3-day rule waiver at the time of application for an initial agreement or to renew their participation. Further, as described in sections II.B.2.a. and II.F. of this final rule, ACOs within a current agreement period under Track 3, or the Track 1+ Model may apply for a SNF 3-day rule waiver, which if approved would begin at the start of the next performance year. As discussed in section II.B.2.a. of this final rule, we are finalizing our proposal to make the SNF 3-day rule waiver under the Shared Savings Program more broadly available to BASIC track ACOs (under a two-sided model) and ENHANCED track ACOs, regardless of their choice of beneficiary assignment methodology.

As described in the November 2018 final rule (83 FR 59951), in light of our decision to forgo an application cycle in CY 2018 for a January 1, 2019 agreement start date, we are not offering an opportunity for ACOs to apply for a start date of January 1, 2019, for initial use of a SNF 3-day rule waiver. The application cycle for the July 1, 2019 start date will be the next opportunity for eligible ACOs to begin use of a SNF 3-day rule waiver, if they apply for and are approved to use the waiver as part of the application cycle for the July 1, 2019 start date. This includes ACOs within an existing agreement period in Track 3 that would not otherwise have the opportunity to apply to begin use of the waiver until January 1, 2020. We note that the existing regulation at § 425.612(b), which requires applications for waivers to be submitted to CMS in the form and manner and by a deadline specified by CMS, provides the flexibility to accommodate a July 1, 2019 SNF 3-day rule waiver start date for eligible ACOs in a performance year beginning on January 1, 2019. As a result, we do not need to make any corresponding revisions to this provision to accommodate the July 1, 2019 start date.

Final Action: We received generally supportive comments for our SNF 3-day rule waiver proposals, and we point readers to the related discussion in section II.B.2.a. of this final rule. We are finalizing without modification our proposal to offer ACOs within existing agreement periods in Track 3 and the Track 1+ Model the opportunity to apply to begin use of a SNF 3-day rule waiver as part of the application cycle for the July 1, 2019 start date.

(2) Annual Certifications and ACO Participant List Modifications

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

As we explained in the August 2018 proposed rule (83 FR 41855), in the case of ACOs that participate for a portion of CY 2019 under one agreement and enter a new agreement period starting on July 1, 2019, the certifications made in advance of the performance year starting on January 1, 2019, would have relevance only for the 6-month period from January 1, 2019, through June 30, 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, from July 1, 2019, through December 31, 2019.

Each ACO is required to certify its list of ACO participant TINs before the start of its agreement period, before every performance year thereafter, and at such other times as specified by CMS in accordance with § 425.118(a). A request to add ACO participants must be submitted prior to the start of the performance year in which these additions would become effective. In order to remove an ACO participant, an ACO must notify CMS no later than 30 days after termination of an ACO participant agreement, and the entity is deleted from the ACO participant list effective as of the termination date of the ACO participant agreement. However, absent unusual circumstances, the ACO participant list that was certified prior to the start of the performance year is used for the duration of the performance year. An ACO's certified ACO participant list for a performance year is used to determine beneficiary assignment for the performance year and therefore also the ACO's quality reporting samples and financial performance. See § 425.118(b)(3) and see also Medicare Shared Savings Program ACO Participant List and Participant Agreement Guidance (July 2018, version 5), available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO-Participant-List-Agreement.pdf.* As we explained in the August 2018 proposed rule, these policies would apply for ACOs participating in a 6-month performance year consistent with the terms of the existing regulations.

As we explained in the August 2018 proposed rule (83 FR 41855) and reiterated in the November 2018 final rule (83 FR 59952), ACOs that started a first or second agreement period on January 1, 2016, that extend their agreement period for a 6-month performance year beginning on January 1, 2019, will have the opportunity during 2018 to make changes to their ACO participant list to be effective for the 6-month performance year from

January 1, 2019, through June 30, 2019. If these ACOs elect to continue their participation in the program for a new agreement period starting on July 1, 2019, they would have an opportunity to submit a new ACO participant list as part of their renewal application for the July 1, 2019 start date.

An ACO that enters a new agreement period beginning on July 1, 2019, will 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 will remain in effect for the full performance year from July 1, 2019, through December 31, 2019. These ACOs will have the opportunity to add or delete ACO participants prior to the start of the next performance year, following the established schedule. Any additions to the ACO participant list that are approved by CMS will become effective at the start of performance year 2020.

The program's current regulations prevent duplication of shared savings payments; thus, under § 425.114, ACOs may not participate in the Shared Savings Program if they include an ACO participant that participates in another Medicare initiative that involves shared savings. In addition, under § 425.306(b)(2), each ACO participant that submits claims for services used to determine the ACO's assigned beneficiary population must be exclusive to one Shared Savings Program ACO. If, during a benchmark or performance year (including the 3-month claims run out for such benchmark or performance year), an ACO participant that participates in more than one ACO submits claims for services used in assignment, CMS will not consider any services billed through the TIN of the ACO participant when performing assignment for the benchmark or performance year, and the ACO may be subject to the pre-termination actions set forth in § 425.216, termination under § 425.218, or both.

In the August 2018 proposed rule (83 FR 41855 and 41856), we noted the following examples regarding ACO participants that submit claims for services that are used in 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, only 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 on July 1, 2019.

Comment: Some commenters urged CMS to provide ACOs with opportunities to add and delete ACO participants throughout the performance years (or performance period) during 2019 and to clarify when such opportunities would be available. One commenter encouraged CMS to allow ACO participants to switch ACOs effective for the July 1, 2019 agreement start date, even if the ACO participant is in an ACO with an existing participation agreement that expires after July 1, 2019.

Response: As we described in the August 2018 proposed rule, an ACO that enters a new agreement period beginning on July 1, 2019, would submit and certify its ACO participant list before July 1, 2019, according to the existing requirements in § 425.118(a). We do not believe it is operationally feasible to allow, as the commenters suggest, ACOs within a 12-month performance year beginning on January 1, 2019, to make ACO participant list changes effective for the second half of the year, unless the ACO is an early renewal ACO that elects to voluntarily terminate its existing participation agreement, effective June 30, 2019, and enter a new agreement period starting on July 1, 2019. For ACOs participating in a 12-month performance year during 2019, such mid-year changes to their ACO participant lists would alter the 2019 prospective assignment lists (if applicable), and may have other significant operational impacts (such as on benchmark calculations). Therefore, we will allow ACOs to submit ACO participant change requests in accordance with usual program procedures in order to indicate additions, updates, and deletions to their existing ACO participant lists and, if applicable, SNF affiliate lists at the following times: During 2018, in advance of a 12-month or 6-month performance year beginning on January 1, 2019; and as part of the application cycle for a July 1, 2019 agreement start date for ACOs applying to enter, renew or re-enter an agreement period in the Shared Savings Program.

Comment: More generally, a few commenters suggest that there is a lost opportunity for ACO participants to collaborate if some join an ACO for the 6-month performance year beginning on July 1, 2019, and other ACO participants are added to the same ACO for the performance year beginning on January 1, 2020.

Response: Although it is possible that ACOs with a July 1, 2019 agreement start date may be precluded from adding certain providers and suppliers to their ACO participant list for the 6-month performance year from July 1, 2019, through December 31, 2019, because they are already participating in another ACO, there will be only a short amount of time before the ACO may modify its ACO participant list for the performance year beginning January 1, 2020, to include these entities. In addition, this initial 6-month performance year will give the original ACO participants time to gain experience with the ACO and its selected payment track before additional ACO participants are added at the start of performance year 2020. We also note that ACO participant list additions are optional. We encourage ACOs to carefully consider the impact of modifying their ACO participant lists, given the potential impact of these changes on a variety of program operations, including assignment, the ACO's historical benchmark, performance-year financial calculations, and the quality reporting sample.

(3) Repayment Mechanism Requirements

ACOs must demonstrate that they have in place an adequate repayment mechanism prior to entering a two-sided model. Consistent with the final policy described in section II.A.6.c of this final rule, and the new provision at § 425.204(f)(6), the repayment mechanism must be in effect for the duration of an ACO's participation in a two-sided model plus 12 months following the conclusion of the agreement period. An ACO may fulfill this requirement by establishing a repayment mechanism that covers the

entire agreement period plus an additional 12 months or by obtaining a repayment mechanism with a term of at least the first two performance years in which the ACO is participating under a two-sided model and that provides for automatic, annual 12-month extensions of the repayment mechanism through the remaining duration of the agreement period such that the repayment mechanism will eventually remain in effect until 12 months following the conclusion of the agreement period.

Consistent with the final policy described in section II.A.6.c. of this final rule and in § 425.204(f)(4)(iv), a renewing ACO that is currently participating under a two-sided model and enters a new agreement period beginning on July 1, 2019, will also be permitted to use its existing repayment mechanism to establish its ability to repay shared losses incurred for performance years in its new agreement period. An ACO choosing this option would be required to either extend the term of the existing repayment mechanism such that it is in effect until 12 months following the end of the new agreement period or extend the term of the existing repayment mechanism, if necessary, such that it covers the first two performance years of the new agreement period and provides for automatic, annual 12-month extensions of the repayment mechanism, which will result in the repayment mechanism eventually remaining in effect for 12 months after the end of the new agreement period. The ACO would also be required to increase the amount of its repayment mechanism to reflect the new repayment mechanism amount determined for its new agreement period, unless CMS notifies the renewing ACO that the repayment mechanism amount for its new agreement period is equal to or lower than its existing repayment mechanism amount. If the repayment mechanism amount calculated for the new agreement period is lower than the existing repayment mechanism amount, the ACO would be required to maintain the repayment mechanism at the existing higher amount.

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

We refer readers to section II.A.6.c. of this final rule for a discussion of comments received on the proposed changes to the repayment mechanism requirements.

(4) Quality Reporting and Quality Measure Sampling

As described in the August 2018 proposed rule (83 FR 41856 through 41858), to determine an ACO's quality performance during either 6-month performance year during 2019, we proposed to use the ACO's quality performance for the 2019 reporting period as determined under § 425.502. For ACOs that participate in only one of the 6-month performance years (such as ACOs that started a first or second agreement period on January 1, 2016, that extend their agreement period by 6 months and do not continue in the program past June 30, 2019, or ACOs that enter an initial agreement period beginning on July 1, 2019), we would also account for the ACO's quality performance using quality measure data reported for the 12-month CY 2019. ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019, would also be required to complete quality reporting for the 2019 reporting period, and we would determine quality performance for the performance period from January 1, 2019, through June 30, 2019, in the same manner as for ACOs with a 6-month performance year from January 1, 2019, through June 30, 2019, that enter a new agreement period beginning on July 1, 2019.

As we explained in the August 2018 proposed rule, the following considerations support this proposed approach. For one, use of a 12-month period for quality measure assessment maintains alignment with the program's existing quality measurement approach, and aligns with the proposed use of 12 months of expenditure data (for CY 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. ACO professionals that are MIPS eligible clinicians (not QPs based on their participation in an Advanced APM or otherwise excluded from MIPS) would continue to be scored under MIPS using the APM scoring standard that covers all of 2019. (For further discussion of the interactions with the Quality Payment Program see section II.A.7.c.(8). of this final rule.) Second, the measure specifications for the quality measures used under the program require 12 months of data. See for example, the Shared Savings Program ACO 2018 Quality Measures Narrative Specification Document (January 20, 2018), available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/2018-reporting-year-narrative-specifications.pdf*. Third, in light of our proposal to use 12 months of expenditures (based on CY 2019) in determining shared savings and shared losses for a 6-month performance year, it would also be appropriate to hold ACOs accountable for the quality of the care furnished to their assigned beneficiaries during this same timeframe. Fourth, and lastly, using an annual quality reporting cycle for the 6-month performance year would avoid the need to introduce new reporting requirements, and therefore potential additional burden on ACOs, that would arise from a requirement that ACOs report quality separately for each 6-month performance year during CY 2019.

The ACO participant list is used to determine beneficiary assignment for purposes of generating the quality reporting samples. Beneficiary assignment is performed using the applicable assignment methodology under § 425.400, either preliminary prospective assignment or prospective assignment, with excluded beneficiaries removed under § 425.401(b), as applicable. 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.

As discussed in section II.A.7.c.(2). of this final rule, ACOs that participate in both 6-month performance years during 2019 may use a different ACO participant list for each performance year (for example, in the case of an ACO that started a first or second agreement period on January 1, 2016, that extends its current agreement period by 6 months, and then makes changes to its

ACO participant list as part of its renewal application for a July 1, 2019 start date). Further, as explained in section II.A.7.c.(4). of the August 2018 proposed rule, under our proposed approach, it was possible that different assignment methodologies and assignment windows would be used to assign beneficiaries to ACOs for the two 6-month performance years during 2019. Therefore, we considered which certified ACO participant list and assignment methodology to use to identify the samples of beneficiaries for quality reporting for the entire 2019 reporting period for ACOs participating in one or both of the 6-month performance years during 2019 (or the 6-month performance period for ACOs that elect to voluntarily terminate their existing participation agreement, effective June 30, 2019, and enter a new agreement period starting on July 1, 2019).

For purposes of determining the quality reporting samples for the 2019 reporting period, we proposed 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. We explained our belief that this approach would result in the most relevant beneficiary samples for 2019 quality reporting. For instance, for purposes of measures reported by ACOs through the CMS Web Interface, ACOs must work together with their ACO participants and ACO providers/suppliers to abstract data from medical records for reporting. In the case of an ACO that started a new agreement period on July 1, 2019, basing assignment for the CMS Web Interface quality reporting sample on the most recent ACO participant list would allow this coordination to occur between the ACO and its current ACO participant TINs, rather than requiring the ACO to coordinate with ACO participants from a prior performance year that may no longer be included on the ACO participant list for the agreement period beginning on July 1, 2019. Further, basing the sample for the CAHPS for ACOs survey on the most recent ACO participant list could ensure the ACO receives feedback from the ACO's assigned beneficiaries on their experience of care with ACO participants and ACO providers/suppliers based on the ACO's current ACO participant list, rather than based on its prior ACO participant list. This could allow for more meaningful care coordination improvements by the ACO in response to the feedback from the survey. Additionally, we believed this proposed approach to determining the ACO's quality reporting samples was also appropriate for an ACO that participates in only one 6-month performance year during 2019 because the most recent certified ACO participant list applicable for the performance year would also be the certified ACO participant list that is used to determine financial performance.

For ACOs that enter an agreement period beginning on July 1, 2019, including new ACOs, ACOs that extended their prior participation agreement for the 6-month performance year from January 1, 2019, through June 30, 2019, and ACOs that start a 12-month performance year on January 1, 2019, and terminate their participation agreement with an effective date of termination of June 30, 2019, and enter a new agreement period beginning on July 1, 2019, we proposed to use the certified ACO participant list for the performance year starting on July 1, 2019, to determine the quality reporting samples for the 2019 reporting period. This most recent certified ACO participant list would therefore be used to determine the quality reporting samples for the 2019 reporting year, which would be used to determine performance for the 6-month performance year from January 1, 2019, through June 30, 2019 (or performance period for ACOs that elect to voluntarily terminate their existing participation agreement, effective June 30, 2019, and enter a new agreement period starting on July 1, 2019) and the 6-month performance year from July 1, 2019, through December 31, 2019.

Beneficiary assignment for purposes of generating the quality reporting samples would be based on the assignment methodology applicable to the ACO during its 6-month performance year from July 1, 2019, through December 31, 2019, under § 425.400, either preliminary prospective assignment or prospective assignment, with excluded beneficiaries removed under § 425.401(b), as applicable. We anticipated the assignment windows for the quality reporting samples would be as follows based on our operational experience: (1) Samples for claims-based measures would be determined based on the assignment list for calendar year quarter 4; (2) the sample for CMS Web Interface measures would be determined based on the assignment list for calendar year quarter 3, which equates to the ACO's first quarter of its 6-month performance year beginning on July 1, 2019; and (3) the sample for the CAHPS for ACOs survey would be determined based on the initial prospective or preliminary prospective assignment list for the 6-month performance year beginning on July 1, 2019.

We believed it would be necessary to use the initial assignment list for the CAHPS for ACOs survey sample, to make use of the most recent available prospective assignment list data and quarterly preliminary prospective assignment data for ACOs for the 6-month performance year beginning on July 1, 2019. Further, for CMS Web Interface measures and claims-based measures, the proposed approach would be consistent with the current methodology for determining the samples.

We proposed to specify the ACO participant list 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(b) and (c).

In the November 2018 final rule (83 FR 59953 through 59955), we finalized an approach under which we will use the ACO's latest certified ACO participant list (the ACO participant list effective on January 1, 2019) to determine the quality reporting samples for the 2019 reporting period for ACOs that extend their participation agreement for the 6-month performance year from January 1, 2019, through June 30, 2019. This policy is specified at § 425.609(b).

Comment: One commenter supported CMS' proposal to require ACOs that participate in both the 6-month performance year (or performance period) from January 1, 2019, through June 30, 2019, and the 6-month performance year from July 1, 2019, through December 31, 2019, to report the CMS Web Interface measures only once for the 2019 reporting period, and to use the most recent ACO participant list as of July 1, 2019, to determine the quality reporting samples. The commenter noted that this proposed approach would reduce administrative burden for participating providers.

However, several comments indicated commenters mistakenly believed that ACOs participating in both the 6-month performance year (or performance period) from January 1, 2019, through June 30, 2019, and the 6-month performance year from July 1, 2019, through December 31, 2019, would be required to report quality data twice for CY 2019. One commenter stated that reporting twice would be expensive and time consuming.

Response: As we explained in the November 2018 final rule (83 FR 59954),

because we proposed to use quality performance during all of CY 2019 to assess quality performance in both of the 6-month performance years (or performance period) in CY 2019, we proposed that ACOs would only be required to report quality once for CY 2019, regardless of whether they complete their participation in the program following the conclusion of the 6-month performance year from January 1, 2019, through June 30, 2019, or if they renew for a new agreement period beginning on July 1, 2019. Therefore, ACOs participating in the 6-month performance year from January 1, 2019, through June 30, 2019, and the 6-month performance year from July 1, 2019, through December 31, 2019, will only report quality once for CY 2019. We will apply the program's sampling methodology, as we have described in this section of this final rule, to determine the beneficiaries eligible for the samples for claims-based measures (as calculated by CMS), CMS Web Interface reporting, and the CAHPS for ACOs survey. We will follow the same approach to determine quality performance for the 6-month performance period from January 1, 2019, through June 30, 2019, and the 6-month performance year from July 1, 2019, through December 31, 2019, for ACOs that elect to voluntarily terminate their existing participation agreement, effective June 30, 2019, and enter a new agreement period starting on July 1, 2019.

We also note that for the 2019 reporting period, ACOs would be required to report quality data through the CMS Web Interface, according to the method and timing of submission established by CMS. The period for reporting quality data through the CMS Web Interface typically occurs for a 12-week period between January and March, following the conclusion of the calendar year. Thus, ACOs that participate in a 6-month performance year from July 1, 2019, through December 31, 2019, along with all other Shared Savings Program ACOs that participate in the program in 2019 would be required to report for the 2019 reporting period, and would report quality data through the CMS Web Interface during the designated reporting period in early 2020. Similarly, ACOs participating in the 6-month performance year from July 1, 2019, through December 31, 2019, would be required to contract with a CMS-approved vendor to administer the CAHPS for ACOs survey for the 2019 reporting period, consistent with program-wide policies applicable to all other ACOs.

Final Action: After considering the comments received, we are finalizing our proposal to determine an ACO's quality performance during the 6-month performance year from July 1, 2019, through December 31, 2019, using the ACO's quality performance for the 12-month CY 2019 (2019 reporting period) as determined under § 425.502. The approach we finalized in the November 2018 final rule, for determining an ACO's quality performance for the 6-month performance year from January 1, 2019, through June 30, 2019, using the ACO's quality performance for the 12-month CY 2019 (2019 reporting period) as determined under § 425.502, will apply to determine quality performance for the performance period from January 1, 2019, through June 30, 2019, for ACOs that elect to voluntarily terminate their existing participation agreement, effective June 30, 2019, and enter a new agreement period starting on July 1, 2019.

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

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

(5) Applicability of Extreme and Uncontrollable Circumstances Policies

In section II.E.4. of the August 2018 proposed rule (83 FR 41899 through 41906), we proposed that the policies for addressing extreme and uncontrollable circumstances would apply to ACOs participating in each of the 6-month performance years during 2019 (or the 6-month performance period for ACOs that elect to voluntarily terminate their existing participation agreement, effective June 30, 2019, and enter a new agreement period starting on July 1, 2019). Because we had proposed to use 12 months of data, based on the calendar year, to determine quality and financial performance for the two 6-month performance years (or performance period) during 2019, we explained our belief that it would be necessary to account for disasters occurring in any month(s) of CY 2019 for ACOs participating in a 6-month performance year (or performance period) during 2019 regardless of whether the ACO is actively participating in the Shared Savings Program at the time of the disaster. Therefore, for ACOs affected by a disaster in any month of 2019, we would use the alternative scoring methodology specified in § 425.502(f) to determine the quality performance score for the 2019 quality reporting period, if the reporting period is not extended. In order to determine financial performance for ACOs with a 6-month performance year (or performance period) in CY 2019 that are affected by an extreme or uncontrollable circumstance during CY 2019, we proposed to first determine shared losses for the ACO over the full calendar year, adjust the ACO's losses for extreme and uncontrollable circumstances, and then determine the portion of shared losses for the 6-month performance year (or performance period) according to the methodology proposed under § 425.609. We proposed to specify the applicability of these disaster relief policies to determining an ACO's financial and quality performance for a 6-month performance year (or performance period) in a new section of the regulations at § 425.609(d).

We also proposed to apply our policies regarding extreme and uncontrollable circumstances to ACOs that are liable for a pro-rated share of losses, determined based on their financial performance during the entire performance year, as a consequence of voluntary termination of a 12-month performance year after June 30, or involuntary termination by CMS. We proposed that the amount of shared losses calculated for the calendar year would be adjusted to reflect the number of months and the percentage of the assigned beneficiary population affected by extreme and uncontrollable

circumstances, before we calculate the pro-rated amount of shared losses for the portion of the year the ACO participated in the Shared Savings Program. For ACOs that are involuntarily terminated during the 6-month performance year from July 1, 2019, through December 31, 2019, pro-rated shared losses for the 6-month performance year would be determined based on assigned beneficiary expenditures for the full calendar year 2019 and then would be pro-rated to account for the partial year of participation prior to the involuntary termination and the impact of extreme and uncontrollable circumstances on the ACO. We proposed to specify these policies in modifications to § 425.221(b), and through new provisions at § 425.605(f)(2)(i) (a new section of the regulations establishing the BASIC track), § 425.606(i)(2)(i) (Track 2), and § 425.610(i)(2)(i) (ENHANCED track).

In the November 2018 final rule (83 FR 59968 through 59979), we extended the policies for addressing the impact of extreme and unusual circumstances on financial and quality performance that we had previously adopted for performance year 2017 to performance year 2018 and subsequent years. The policies governing the calculation of shared losses in the event of extreme and unusual circumstances are at § 425.606(i) for Track 2. For Track 3, as renamed in this final rule the ENHANCED track, the policies are at § 425.610(i). The policies for determining the ACO's quality performance score are at § 425.502(f). In a new section of the regulations at § 425.609(d), we specified that these policies would also apply to the determination of an ACO's financial and quality performance for the 6-month performance year from January 1, 2019, through June 30, 2019.

Final Action: There were no comments directed specifically at our proposals with respect to the application of our policies for addressing the impact of extreme and uncontrollable circumstances to ACOs participating in a 6-month performance year from July 1, 2019, through December 31, 2019. We are finalizing as proposed the policies for determining the financial and quality performance for the 6-month performance year from July 1, 2019, through December 31, 2019, for ACOs affected by extreme and uncontrollable circumstances during CY 2019. We are finalizing revisions to § 425.609(d)(1) to add to a reference to the provision at § 425.609(c), which governs the determination of shared losses for ACOs participating in a 6-month performance year from July 1, 2019, through December 31, 2019. Therefore, for ACOs with a 6-month performance year from July 1, 2019, through December 31, 2019, that are affected by an extreme or uncontrollable circumstance during CY 2019, we will first determine shared losses for the ACO over the full calendar year, adjust the ACO's losses for extreme and uncontrollable circumstances, and then determine the portion of shared losses for the 6-month performance year (or performance period) according to the methodology under § 425.609(c). As discussed in section II.A.7.c.(4) of this final rule and as specified in the regulations at § 425.609(c)(2), for ACOs participating in the 6-month performance year from July 1, 2019, through December 31, 2019 we will use the ACO's quality performance for the 2019 reporting period to determine the ACO's quality performance score as specified in § 425.502. As finalized in the November 2018 final rule, the provision at § 425.502(f) specifies the policies for determining an ACO's quality performance score when the ACO is affected by extreme and uncontrollable circumstances. Therefore, these policies will also apply to the determination of an ACO's quality performance during the 6-month performance year from July 1, 2019, through December 31, 2019, in the event the ACO is affected by an extreme and uncontrollable circumstance during CY 2019.

There were no comments directed specifically at our proposals with respect to the application of our policies for addressing the impact of extreme and uncontrollable circumstances to ACOs participating in a performance period from January 1, 2019, through June 30, 2019, because they elect to voluntarily terminate their existing participation agreement, effective June 30, 2019, and enter a new agreement period starting on July 1, 2019. We are finalizing our proposal to adjust shared losses for the 6-month performance period from January 1, 2019, through June 30, 2019, to address the impact of extreme and uncontrollable circumstances on ACOs that elect to voluntarily terminate their existing participation agreement, effective June 30, 2019, and enter a new agreement period starting on July 1, 2019. As we previously described in section II.A.7.b.(3). of this final rule, early renewal ACOs will be reconciled for the 6-month performance period from January 1, 2019, through June 30, 2019, according to § 425.609(b). Further, we are finalizing as proposed the revisions to § 425.606(i)(2)(i) (Track 2) and § 425.610(i)(2)(i) (ENHANCED track) in order to apply the disaster relief policies in determining shared losses for the 6-month performance period from January 1, 2019, through June 30, 2019, for early renewing ACOs.

More generally, there were no comments directed at our proposals to revise § 425.606(i)(2)(i) (Track 2) and § 425.610(i)(2)(i) (ENHANCED track), and to add a new provision at § 425.605(f) (BASIC track), to apply the disaster relief policies to ACOs accountable for pro-rated shared losses as a payment consequence of early termination under the revisions to § 425.221(b) that we are making in this final rule. We are finalizing these policies as proposed. These policies will also apply to determining pro-rated shared losses for ACOs that are involuntarily terminated from a 6-month performance year from July 1, 2019, through December 31, 2019.

Lastly, as discussed in II.A.2. of this final rule, we are finalizing our proposed addition of the new BASIC track. Therefore, we are also revising § 425.609(d)(1) to add a cross reference to § 425.605(f) so that the policies for adjusting shared losses for extreme and uncontrollable circumstances will apply to ACOs participating in two-sided models of the BASIC track during the 6-month performance year from July 1, 2019, through December 31, 2019.

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

In the August 2018 proposed rule (83 FR 41858), we proposed policies regarding CMS' notification to ACOs of shared savings and shared losses, and the timing for an ACO's repayment of shared losses, for both the 6-month performance year (or performance period) from January 1, 2019, through June 30, 2019, and the 6-month performance year from July 1, 2019, through December 31, 2019. We proposed to provide separate reconciliation reports for each 6-month performance year, and to pay shared savings or recoup shared losses separately for each 6-month performance year. Since we proposed to perform financial reconciliation for both 6-month performance years during 2019 after the end of CY 2019, we anticipated 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).

We proposed to apply the same policies regarding notification of shared savings and shared losses, and the timing of repayment of shared losses, to ACOs in 6-month performance years that apply under our current regulations to ACOs in 12-month performance years. We proposed 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, we proposed that: (1) CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due; (2) CMS provides written notification to an ACO of the amount of shared losses, if any, that it must repay to the program; and (3) if an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

Because we anticipated results for both 6-month performance years would be available at approximately the same time, we acknowledged 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.

In earlier rulemaking, we considered the circumstance where, over the course of its participation in the Shared Savings Program, an ACO may earn shared savings in some years and incur losses in other years. We considered whether the full amount of shared savings payments should be paid in the year in which they accrue, or whether some portion should be withheld to offset potential future losses. However, we did not finalize a withholding from shared savings. See 76 FR 67941 and 67942. Instead, an ACO's repayment mechanism provides a possible source of recoupment for CMS should the ACO fail to timely pay shared losses within the 90-day repayment window.

We revisited these considerations about withholding shared savings payments in light of our proposed approach to determining ACO performance for the two 6-month performance years at approximately the same time following the conclusion of CY 2019. We proposed to conduct reconciliation for each 6-month performance year at the same time. After reconciliation for both 6-month performance years is complete, we 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, we proposed 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. This approach would guard against CMS making a payment to an organization that has an unpaid debt to the Medicare program, and therefore would be protective of the Trust Funds. We believed this approach would also be less burdensome for ACOs, for example, in the event that the ACO's shared losses are completely offset by the ACO's shared savings. We noted that this approach to offsetting shared losses against any shared savings could result in a balance of either unpaid shared losses that must be repaid, or a remainder of shared savings that the ACO would be eligible to receive.

We proposed to specify these policies on payment and recoupment for ACOs in 6-month performance years within CY 2019 in a new section of the regulations at § 425.609(e). In the November 2018 final rule (83 FR 59955 and 59956), we finalized at § 425.609(e) requirements for CMS to notify ACOs of shared savings and shared losses, and the timing for an ACO's repayment of shared losses, for the 6-month performance year from January 1, 2019, through June 30, 2019.

Comment: Some commenters explained that receiving separate reconciliation reports for the two performance periods only adds to the complexity of the program, including deciphering appropriate financial distributions, if applicable.

Response: Given that we are determining financial performance for two separate 6-month performance years, based on separate historical benchmark calculations, financial models, and assigned beneficiary populations, we believe it necessary to provide separate reconciliation report packages to ACOs for each 6-month performance year. We believe ACOs are interested in the specific details of the performance calculations, and would also to seek to understand how their performance compares between the two 6-month performance years (if applicable).

Final Action: Although we received comments on our proposed approach to notifying ACOs of their results for each 6-month performance year separately, we did not receive comments addressing our proposal regarding the timing for ACOs' repayment of shared losses for 6-month performance year from July 1, 2019, through December 31, 2019, or on our proposal 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 for ACOs that have mixed results for the two 6-month performance years of 2019.

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

We note that we are finalizing our proposed policies with a change in the enumeration scheme. Specifically, we are placing the general provisions regarding notification to ACOs of shared savings and losses at § 425.609(e)(1), and we are placing the policies addressing ACOs with mixed results for the two 6-month performance periods at § 425.609(e)(2). In the introductory text of § 425.609(e)(1), we are including references to the performance period from January 1, 2019, through June 30, 2019, and the 6-month performance year from July 1, 2019, through December 31, 2019. We are also adding a cross-reference to § 425.605(e) regarding the notification requirements for the new BASIC track, and we are maintaining the existing cross-reference to the notification requirements under

§ 425.610(h), which now applies to ACOs participating in the ENHANCED track.

Under the revised § 425.609(e)(1), CMS notifies the ACO of shared savings or shared losses separately for the January 1, 2019, through June 30, 2019 performance year (or performance period) and the July 1, 2019, through December 31, 2019 performance year, consistent with the notification requirements specified in §§ 425.604(f), 425.605(e), 425.606(h), and 425.610(h), as applicable. Specifically, CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due. CMS provides written notification to an ACO of the amount of shared losses, if any, that it must repay to the program. If an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

We are finalizing as proposed the policies for addressing ACOs that have mixed results for the two 6-month performance years (or performance period) of 2019, earning shared savings for one performance year (or performance period) and owing shared losses for the other performance year (or performance period). We are revising the regulations to add a new provision at § 425.609(e)(2) to specify that if an ACO is reconciled for both the January 1, 2019, through June 30, 2019 performance year (or performance period) and the July 1, 2019, through December 31, 2019 performance year, CMS issues a separate notice of shared savings or shared losses for each performance year (or performance period), and if the ACO has shared savings for one performance year (or performance period) and shared losses for the other performance year (or performance period), CMS reduces the amount of shared savings by the amount of shared losses. If any amount of shared savings remains after completely repaying the amount of shared losses owed, the ACO is eligible to receive payment for the remainder of the shared savings. If the amount of shared losses owed exceeds the amount of shared savings earned, the ACO is accountable for payment of the remaining balance of shared losses in full.

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

Under our proposed design of the BASIC track's glide path, ACOs that enter the glide path at Levels A through D would be automatically advanced to the next level of the glide path at the start of each subsequent performance year of the agreement period. The five levels of the glide path would phase-in over the duration of an ACO's agreement period. The design of the BASIC track's glide path is therefore tied to the duration of the agreement period.

With our proposal to offer agreement periods of 5 years and 6 months to ACOs with July 2019 start dates, we believed it was necessary to address how we would apply the policy for moving ACOs along the glide path in an agreement period with a duration of more than 5 years. As discussed in section II.A.7.c.(7) of the August 2018 proposed rule (83 FR 41858 through 41859), we proposed a one-time exception to be specified in § 425.600, whereby the automatic advancement policy would not apply to the second performance year for an ACO entering the BASIC track's glide path for an agreement period beginning on July 1, 2019. For performance year 2020, the ACO would remain in the same level of the BASIC track's glide path that it entered for the 6-month performance year beginning on July 1, 2019, unless the ACO uses the proposed flexibility to advance to a higher level of risk and potential reward more quickly. The ACO would automatically advance to the next level of the BASIC track's glide path at the start of performance year 2021 and all subsequent performance years of the agreement period, unless the ACO chooses to advance more quickly. This proposed approach would allow a modest increase in the amount of time initial entrants in the BASIC track's glide path could remain under a particular level, including a one-sided model.

Generally, commenters favored an approach that would allow ACOs to remain under a one-sided model of the BASIC track's glide path for additional time. See section II.A.3.b. of this final rule for comment summaries concerning the automatic progression along the BASIC track's glide path. We did not receive any comments specifically addressing the proposed one-time exception to the automatic advancement policy, applicable to the second performance year of the BASIC track's glide path for an ACO entering an agreement period beginning July 1, 2019.

Final Action: We are finalizing as proposed a one-time exception to be specified at § 425.600(a)(4)(i)(B)(*2)(i*), whereby the automatic advancement policy will not apply to the second performance year for an ACO entering the BASIC track's glide path for an agreement period beginning on July 1, 2019. For performance year 2020, the ACO will remain in the same level of the BASIC track's glide path it entered for the 6-month performance year beginning on July 1, 2019, unless the ACO chooses to advance to a higher level of risk and potential reward more quickly. The ACO will automatically advance to the next level of the BASIC track's glide path at the start of performance year 2021 and all subsequent performance years of the agreement period, unless the ACO chooses to advance more quickly.

(8) Interactions With the Quality Payment Program

As described in section II.A.7.c.(8). of the August 2018 proposed rule (83 FR 41859), we 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. In the CY 2018 Quality Payment Program final rule with comment period, we finalized a policy for APMs that start or end during the QP Performance Period. Specifically, under § 414.1425(c)(7)(i), for Advanced APMs that start during the QP Performance Period and are actively tested for at least 60 continuous days during a QP Performance Period, CMS will make QP determinations and Partial QP determinations for eligible clinicians in the Advanced APM. CMS makes QP determinations for eligible clinicians in an Advanced APM three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination dates: March 31, June 30, and August 31 (§ 414.1425(b)(1)) (sometimes referred to as snapshot dates). We explained that an Advanced APM (such as a two-sided model of the Shared Savings Program) would need to begin operations by July 1 of a given performance year in order to be actively tested for at least 60 continuous days before August 31—the last date on which QP determinations are made during a QP Performance Period (as specified in § 414.1425(b)(1)). Therefore, we believed that our 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.

Further, as described in section II.A.7.c.(4) of the August 2018 proposed rule (see 83 FR 41856), our proposal to use a 12-month period for quality measure assessment for either 6-month performance year (or the 6-month performance period) during 2019 would maintain alignment with the program's existing quality measurement approach.

This approach would also continue to align the program's quality reporting period with policies under the Quality Payment Program. We explained that ACO professionals that are MIPS eligible clinicians (not QPs based on their participation in an Advanced APM or otherwise excluded from MIPS) would continue to be scored under MIPS using the APM scoring standard that covers all of 2019.

In the November 2018 final rule (83 FR 59956 and 59957), we responded to comments on QP determinations for eligible clinicians participating in an ACO whose agreement period expires on December 31, 2018, that elects a voluntary extension for the 6-month performance year from January 1, 2019, through June 30, 2019, and does not continue in the program past June 30, 2019. We also clarified what happens to an eligible clinician's QP status if they are participating in an ACO that is in a track that meets the Advanced APM criteria and elects to extend for the 6-month performance year from January 1, 2019, through June 30, 2019, and either voluntarily terminates or is involuntarily terminated prior to June 30, 2019. Further, we responded to comments on the proposal to require ACOs in a 6-month performance year from January 1, 2019, through June 30, 2019, to report on quality based on 12-months of data for 2019, and the MIPS quality reporting requirements for MIPS eligible clinicians in ACOs that elect to extend their participation agreement for the 6-month performance year from January 1, 2019, through June 30, 2019.

Comment: One commenter raised the possibility for confusion around the applicability of the APM scoring standard under the MIPS or the availability of APM incentive payments for eligible clinicians in ACOs that move from lower risk in the 6-month performance year (or performance period) from January 1, 2019, through June 30, 2019, to an Advanced APM for the 6-month performance year from July 1, 2019, through December 31, 2019. One commenter requested that CMS consider ACOs that enter two-sided risk models that meet the Advanced APM criteria for agreement periods beginning on July 1, 2019, to be participating in the Advanced APM for the entire calendar year for purposes of computing the QP thresholds for participating eligible clinicians. One commenter expressed concern that the July 1, 2019 start date will create confusion among some providers, due to the likely interaction with the snapshots that are used to determine QP status under the Quality Payment Program. For example, the commenter stated that for eligible clinicians in an ACO that transitions from Track 1 to the ENHANCED track for an agreement period beginning on July 1, 2019, there would only be a single snapshot period upon which to base the QP determination. One commenter recommended that CMS make it clear that ''renewing'' Track 2 and Track 3 ACOs may move into the new ENHANCED track without jeopardizing their participation in an Advanced APM and potential QP status for their eligible clinicians for that year of the transition.

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

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

Comment: Some commenters requested clarification on how quality reporting for a 6-month performance year based on 12-months of data for 2019 will satisfy the MIPS quality reporting requirements for MIPS eligible clinicians in ACOs that participate in a 6-month performance year from July 1, 2019, through December 31, 2019.

Response: We believe the comments reflect the need for clarification about whether 2019 quality performance for a 6-month performance year from July 1, 2019, through December 31, 2019, under the Shared Savings Program will count the same as a full year of performance for purposes of the APM scoring standard. That is, would the 2019 quality reporting for the 6-month performance year count toward the final MIPS score in the same way that it would for an ACO that is participating in a full 12-month performance year in the program.

As discussed in section II.A.7.c.(4). of this final rule, we are finalizing a policy of using a 12-month period for quality performance assessment for the 6-month performance year from July 1, 2019, through December 31, 2019, in order to maintain alignment with the program's existing quality measurement approach, and with policies under the Quality Payment Program. ACO professionals that are MIPS eligible clinicians (not QPs based on their participation in an Advanced APM or otherwise excluded from MIPS) participating in an ACO that completes a 6-month performance year from July 1, 2019, through December 31, 2019, would be scored under MIPS using the APM Scoring Standard for 2019, based on quality data submitted for all of 2019 during the regular submission period in early 2020.

(9) Sharing CY 2019 Aggregate Data With ACOs in 6-Month Performance Period From January 2019 Through June 2019

As established in the November 2018 final rule (83 FR 59957), we will

continue to provide ACOs participating in a 6-month performance year from January 1, 2019, through June 30, 2019, with aggregate reports for all four quarters of CY 2019 based on the ACO participant list in effect for that 6-month performance year. This policy is specified in revisions to § 425.702. In the August 2018 proposed rule (83 FR 41859), we proposed to apply this same policy for ACOs that participate in the first 6 months of a 12-month performance year in 2019 but then terminate their participation agreement with an effective date of termination of June 30, 2019, and enter a new agreement period beginning July 1, 2019. We explained that this would give ACOs a more complete understanding of the Medicare FFS beneficiary population that is the basis for reconciliation for the 6 month period from January 1, 2019, through June 30, 2019, by allowing them to continue to receive data, including demographic characteristics and expenditure/utilization trends for this assigned beneficiary population for the entire calendar year. We believed this proposed approach would allow us to maintain transparency by providing ACOs with data that relates to the entire period for which the expenditures for the beneficiaries assigned to the ACO for this 6-performance period would be compared to the ACO's benchmark (before pro-rating any shared savings or shared losses to reflect the length of the performance year), and maintain consistency with the reports delivered to ACOs that participate in a 12-month performance year in 2019. Otherwise, we could be limited to providing ACOs with aggregate reports only for the first and second quarters of 2019, even though under our proposed methodology for assessing the financial performance of ACOs in a 6-month performance period would involve consideration of expenditures from outside this period during 2019.

Comment: One commenter believed ACOs participating in both 6-month performance years (or the 6-month performance period) will be burdened by having two sets of aggregate program reports from CMS (such as assignment summary reports, and expenditure/utilization trend reports), and incorrectly asserted that ACOs will receive two sets of monthly beneficiary-identifiable claim and claim line feed data files.

Response: We believe many ACOs participating in the 6-month performance years (or the 6-month performance period) during 2019 will seek an in-depth understanding of their performance trends during each of the 6-month performance years (or the 6-month performance period) and will also want to assess how their financial performance compares between the two 6-month periods (if applicable). We believe these ACOs would be supported by the availability of quarterly and annual program reports on their assigned beneficiary population for each performance year (or performance period), including demographic information and expenditure/utilization trends for the applicable assigned beneficiary population. We also recognize, however, that how an ACO uses these data is often specific to the individual circumstances of the organization and its data analysis capacity, among other factors.

Further, we provide monthly beneficiary-identifiable data, in claim and claim line feed files, to eligible ACOs based on the requirements specified in § 425.704. We provide ACOs with beneficiary identifiable claims data for prospectively assigned beneficiaries, and for assignable beneficiaries who receive primary care services from an ACO participant that submits claims for primary care services used to determine the ACO's assigned population during the performance year. We note that these files include Parts A, B, and D data, and support the ACO's quality assessment and improvement activities, and population-based activities relating to improved health. Under the program's current policies, we would deliver the monthly claim and claim line feed files to the ACO for the relevant population within each performance year, determined based on the certified ACO participant list in effect for that performance year. Operationally, this means eligible ACOs participating in the 6-month performance year (or performance period) from January 1, 2019, through June 30, 2019 will receive claim and claim line feed files each month based on the ACO participant list certified prior to the start of their performance year beginning on January 1, 2019. These ACOs will receive data files containing claims with dates of service through June 2019. Eligible ACOs participating in the 6-month performance year from July 1, 2019, through December 31, 2019 will receive claim and claim line feed files each month based on the ACO participant list certified prior to the start of July 1, 2019. These ACOs will receive data files containing claims with dates of service through December 2019.

In the November 2018 final rule (83 FR 59957), we also summarized and addressed comments requesting additional guidance and education on whether there will be disruptions in sharing claims files with ACOs participating in a 6-month performance year in CY 2019. We refer readers to that discussion for additional information on this issue.

Final Action: After considering the comments we received on our data sharing proposal, we are finalizing our proposal to provide ACOs participating in a 6-month performance period from January 1, 2019, through June 30, 2019, with aggregate reports for all four quarters of CY 2019 based on the ACO participant list in effect for the first 6 months of the year. In section II.A.7.b.(3) of this final rule we describe modifications that we are making to § 425.609(b) in order to extend this provision to the determination of pro-rated shared savings and shared losses for the performance period from January 1, 2019, through June 30, 2019, for ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019. The policy for sharing aggregate data with ACOs in a 6-month performance year from January 1, 2019, through June 30, 2019, is specified in the existing provision at § 425.702, as revised by the November 2018 final rule, which applies to ''an ACO eligible to be reconciled under § 425.609(b).'' Therefore, with the policies established in this final rule, this existing provision on sharing CY 2019 aggregate data will apply not only to ACOs in a 6-month performance year from January 1, 2019, through June 30, 2019, but also to ACOs that terminate their current agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019.

(10) Technical or Conforming Changes To Allow for 6-Month Performance Years

In the August 2018 proposed rule (83 FR 41859 and 41860), we proposed to make certain technical, conforming changes to provisions of the Shared Savings Program regulations to reflect our proposal to add a new provision at § 425.609 to govern the calculation of the financial results for the 6-month performance years within CY 2019. In the November 2018 final rule, we finalized a subset of the proposed technical, conforming changes as necessary to reflect the addition of the new provision at § 425.609 to govern the calculation of the financial results for the 6-month performance year from January 1, 2019, through June 30, 2019 (83 FR 59957 through 59958).

There were no comments directed specifically at our proposed technical and conforming changes to allow for a

6-month performance year from July 1, 2019, through December 31, 2019.

The following changes finalized in the November 2018 final rule for purposes of the 6-month performance year from January 1, 2019, through June 30, 2019, will also apply to the 6-month performance year from July 1, 2019, through December 31, 2019.

Our revisions to § 425.315 (the policies on reopening determinations of shared savings and shared losses to correct financial reconciliation calculations) to incorporate a reference to notification of shared savings and shared losses for ACOs in a 6-month performance year within CY 2019, as specified in § 425.609(e).

Our revisions to § 425.100 to add a reference to § 425.609 in order to include ACOs that participate in a 6-month performance year during 2019 in the general description of ACOs that are eligible to receive payments for shared savings under the program.

Our revisions to § 425.400(a)(1)(ii), describing the step-wise process for determining beneficiary assignment for each performance year, to specify that this process applies to ACOs participating in a 6-month performance year within CY 2019, and that assignment is determined based on the beneficiary's utilization of primary care services during the entirety of CY 2019, as specified in § 425.609.

In this final rule, we are finalizing the remaining proposed modifications to the Shared Savings Program regulations to incorporate additional technical and conforming changes that are necessary to ensure that the policies previously finalized for ACOs in a 6-month performance year from January 1, 2019, through June 30, 2019, will also apply to ACOs in a 6-month performance year from July 1, 2019, through December 31, 2019.

In § 425.401(b), describing the exclusion of beneficiaries from an ACO's prospective assignment list at the end of a performance year or benchmark year and quarterly each performance year, we proposed to specify that these exclusions would occur at the end of CY 2019 for purposes of determining assignment to an ACO in a 6-month performance year in accordance with §§ 425.400(a)(3)(ii) and 425.609. In the November 2018 final rule, we finalized the applicability of this policy to determining prospective assignment for ACOs participating in a 6-month performance year from January 1, 2019, through June 30, 2019. With this final rule, we are further modifying § 425.401(b) to add a cross-reference to § 425.609(c)(1)(ii), which governs the determination of prospective assignment for ACOs participating in a 6-month performance year from July 1, 2019, through December 31, 2019.

We proposed to incorporate references to § 425.609 in the regulations that govern establishing, adjusting, and updating the benchmark, including proposed § 425.601, and the existing provisions at § 425.602, and § 425.603, to specify that the annual risk adjustment and update to the ACO's historical benchmark for the 6-month performance years during 2019 would use factors based on the entirety of CY 2019. For clarity and simplicity, we proposed to add a paragraph to each of these sections to explain the following: (1) Regarding the annual risk adjustment applied to the historical benchmark, when CMS adjusts the benchmark for the 6-month performance years described in § 425.609, the adjustment will reflect the change in severity and case mix between benchmark year 3 and CY 2019; (2) Regarding the annual update to the historical benchmark, when CMS updates the benchmark for the 6-month performance years described in § 425.609, the update to the benchmark will be based on growth between benchmark year 3 and CY 2019. In the November 2018 final rule, we finalized these amendments, as applicable to the January 1, 2019, through June 30, 2019 performance year with the addition of provisions § 425.602(c) and § 425.603(g).

In a new section of the regulations at § 425.601(g), on establishing, adjusting, and updating the benchmark for agreement periods beginning on July 1, 2019, and in subsequent years (as discussed in section II.D. of this final rule), we are specifying that the annual risk adjustment and update to the ACO's historical benchmark for the 6-month performance year from July 1, 2019, through December 31, 2019, will use factors based on the entirety of CY 2019. The provision explains the following: (1) Regarding the annual risk adjustment applied to the historical benchmark, when CMS adjusts the benchmark for the 6-month performance year described in § 425.609(c), the adjustment will reflect the change in severity and case mix between benchmark year 3 and CY 2019; (2) Regarding the annual update to the historical benchmark, when CMS updates the benchmark for the 6-month performance year described in § 425.609(c), the update to the benchmark will be based on growth between benchmark year 3 and CY 2019.

We also proposed to incorporate references to § 425.609 in the following provisions regarding the calculation of shared savings and shared losses, § 425.604, proposed § 425.605, § 425.606, and § 425.610. For clarity and simplicity, we proposed to add a paragraph to each of these sections explaining that shared savings or shared losses for the 6-month performance years are calculated as described in § 425.609. That is, all calculations will be performed using CY 2019 data in place of performance year data. In the November 2018 final rule, we finalized these amendments, as applicable to the January 1, 2019, through June 30, 2019 performance year with the addition of provisions at § 425.604(g), § 425.606(j), and § 425.610(j).

We are now finalizing the proposal to apply the same approach to determining shared savings and shared losses for the 6-month performance year from July 1, 2019, through December 31, 2019. Therefore, in a new section of the regulations at § 425.605(g), we are specifying that shared savings or shared losses for the 6-month performance year from July 1, 2019, through December 31, 2019, are calculated as described in § 425.609 for ACOs participating under the BASIC track (as discussed in sections II.A.2. and II.A.3. of this final rule). In addition, we are also finalizing our proposal to add a new section of the regulations at § 425.610(k), on the calculation of shared savings and losses for the 6-month performance year from July 1, 2019, through December 31, 2019, for ACOs participating under the ENHANCED track (as discussed in section II.A.2 of this final rule).

In the August 2018 proposed rule, we proposed to add a reference to § 425.609 in § 425.204(g) to allow for consideration of claims billed under merged and acquired entities' TINs for purposes of establishing an ACO's benchmark for an agreement period that includes a 6-month performance year. Upon further consideration, we do not believe it is necessary at this time to revise § 425.204(g) to incorporate a reference to § 425.609. The provision at § 425.204(g) describes the use of certain claims in establishing an ACO's benchmark. However, § 425.609 only makes changes to the way in which the benchmark is adjusted and updated to allow for a 6-month performance year. For ACOs participating in a 6-month performance year (or performance period) in 2019, the ACO's benchmark would already be established under §§ 425.601 (as finalized in this final rule), 425.602 or 425.603 (as applicable).

B. Fee-for-Service Benefit Enhancements

1. Background

As discussed in earlier rulemaking (for example, 80 FR 32759), we believe

that models where ACOs bear a degree of financial risk have the potential to induce more meaningful systematic change than one-sided models. We explained that two-sided performance-based risk provides stronger incentives for ACOs to achieve savings and, as discussed in detail in the Regulatory Impact Analysis (see section V. of this final rule), our experience with the program indicates that ACOs in two-sided models generally perform better than ACOs that participate under a one-sided model. ACOs that bear financial risk have a heightened incentive to restrain wasteful spending by their ACO participants and ACO providers/suppliers. This, in turn, may reduce the likelihood of over-utilization of services. Relieving these ACOs of the burden of certain statutory and regulatory requirements may provide ACOs with additional flexibility to innovate further, which could in turn lead to even greater cost savings, without inappropriate risk to program integrity.

In the December 2014 proposed rule (79 FR 72816 through 72826), we discussed in detail a number of specific payment rules and other program requirements for which we believed waivers could be necessary under section 1899(f) of the Act to permit effective implementation of two-sided performance-based risk models in the Shared Savings Program. We invited comments on how these waivers could support ACOs' efforts to increase quality and decrease costs under two-sided risk arrangements. Based on review of these comments, in the June 2015 final rule (80 FR 32800 through 32808), we finalized a waiver of the requirement in section 1861(i) of the Act for a 3-day inpatient hospital stay prior to the provision of Medicare-covered post-hospital extended care services for beneficiaries who are prospectively assigned to ACOs that participate in Track 3 (§ 425.612). We refer to this waiver as the SNF 3-day rule waiver. We established the SNF 3-day rule waiver to provide an additional incentive for ACOs to take on risk by offering greater flexibility for ACOs that have accepted the higher level of performance-based risk under Track 3 to provide necessary care for beneficiaries in the most appropriate care setting.

Section 50324 of the Bipartisan Budget Act added section 1899(l) of the Act (42 U.S.C. 1395jjj(l)) to provide certain Shared Savings Program ACOs the ability to provide telehealth services. Specifically, beginning January 1, 2020, for telehealth services furnished by a physician or practitioner participating in an applicable ACO, the home of a beneficiary is treated as an originating site described in section 1834(m)(4)(C)(ii) and the geographic limitation under section 1834(m)(4)(C)(i) of the Act does not apply with respect to an originating site described in section 1834(m)(4)(C)(ii), including the home of the beneficiary.

In the August 2018 proposed rule (83 FR 41861–41867), we proposed modifications to the existing SNF 3-day rule waiver and proposed to establish regulations to govern telehealth services furnished in accordance with section 1899(l) of the Act to prospectively assigned beneficiaries by physicians and practitioners participating in certain applicable ACOs. We also proposed to use our authority under section 1899(f) of the Act to waive the requirements of section 1834(m)(4)(C)(i) and (ii) of the Act as necessary to provide for a 90-day grace period to allow for payment for telehealth services furnished to a beneficiary who was prospectively assigned to an applicable ACO, but was subsequently excluded from assignment to the ACO. We also proposed to require that ACO participants hold beneficiaries financially harmless for telehealth services that are not provided in compliance with section 1899(l) of the Act or during the 90-day grace period, as previously discussed.

2. Proposed Revisions

a. Shared Savings Program SNF 3-Day Rule Waiver

(1) Background

The SNF 3-day rule waiver under § 425.612 allows for Medicare payment for otherwise covered SNF services when ACO providers/suppliers participating in eligible Track 3 ACOs admit eligible prospectively assigned beneficiaries, or certain excluded beneficiaries during a grace period, to an eligible SNF affiliate without a 3-day prior inpatient hospitalization. All other provisions of the statute and regulations regarding Medicare Part A post-hospital extended care services continue to apply. This waiver became available starting January 1, 2017, and all ACOs participating under Track 3 or applying to participate under Track 3 are eligible to apply for the waiver.

We limited the waiver to ACOs that elect to participate under Track 3 because these ACOs are participating under two-sided risk and, under the prospective assignment methodology used in Track 3, beneficiaries are assigned to the ACO at the start of the performance year and remain assigned for the entire year, unless they are excluded. Thus it is clearer to the ACO which beneficiaries are eligible to receive services under the waiver than it would be to an ACO under Track 1 or Track 2, which use a preliminary prospective assignment methodology with retrospective reconciliation (80 FR 32804). As we explained in the August 2018 proposed rule (83 FR 41861), we continue to believe that it is appropriate to limit the waiver to ACOs participating under a two-sided risk model because, as discussed in the background to this section, models under which ACOs bear a degree of financial risk hold greater potential than one-sided models to induce more meaningful systematic change, promote accountability for a patient population and coordination of patient medical care, and encourage investment in redesigned care processes. As a result, models under which ACOs bear a degree of financial risk provide a stronger incentive for ACOs not to over utilize services than do one-sided models. It is important to establish clear policies as to the availability of the SNF 3-day rule waiver for coverage of SNF services furnished to a particular beneficiary without a prior 3 day inpatient stay to permit the ACOs and their SNF affiliates to comply with the conditions of the waiver and to facilitate our ability to monitor for misuse. It would also be feasible to establish such clarity for ACOs electing to participate in a two-sided risk model under a preliminary prospective assignment methodology with retrospective reconciliation.

Under preliminary prospective assignment with retrospective reconciliation, ACOs are given up-front information about their preliminarily assigned FFS beneficiary population. This information is updated quarterly to help ACOs refine their care coordination activities. Under the revised criteria for sharing data with ACOs finalized in the June 2015 final rule, beginning with performance year 2016, we have provided ACOs under preliminary prospective assignment with quarterly and annual assignment lists that identify the beneficiaries who are preliminarily prospectively assigned, as well as beneficiaries who have received at least one primary care service in the most recent 12-month period from an ACO participant that submits claims for services used in the assignment methodology (see § 425.702(c)(1)(ii)(A), and related discussion in 80 FR 32734 through 32737). The specific beneficiaries preliminarily assigned to an ACO during each quarter can vary.

(2) Proposals

As described in section II.A.4.c. of the August 2018 proposed rule (83 FR

41811) and again in this final rule, we proposed to allow ACOs to select the beneficiary assignment methodology to be applied at the start of their agreement period (prospective assignment or preliminary prospective assignment with retrospective reconciliation) and the opportunity to elect to change this selection prior to the start of each performance year. Further, as described in sections II.A.3. and II.A.4.b. of the August 2018 proposed rule (83 FR 41801 & 41810) and again in this final rule, we proposed that BASIC track ACOs entering the track's glide path under a one-sided model would be automatically transitioned to a two-sided model during their agreement period and could elect to enter two-sided risk more quickly (prior to the start of their agreement period or as part of an annual election to move to a higher level of risk within the BASIC track).

As described in the August 2018 proposed rule (83 FR 41861), in light of these proposed flexibilities for program participation, as well as our experience in providing ACOs under preliminary prospective assignment with data on populations of beneficiaries, we stated that it would be appropriate to expand eligibility for the SNF 3-day rule waiver to include ACOs participating in a two-sided model under preliminary prospective assignment. As explained in the August 2018 proposed rule and again in this section, we originally excluded Track 2 ACOs, which participate under two-sided risk, from eligibility for the SNF 3-day rule waiver because beneficiaries are assigned to Track 2 ACOs using a preliminary prospective assignment methodology with retrospective reconciliation and thus it could be unclear to ACOs which beneficiaries would be eligible to receive services under the waiver. We proposed that risk-bearing ACOs selecting preliminary prospective assignment with retrospective reconciliation should be offered the same tools and flexibility to increase quality and decrease costs that are available to ACOs electing prospective assignment, to the maximum extent possible. We stated that it would be possible to provide ACOs that select preliminary prospective assignment with retrospective reconciliation with more clarity regarding which beneficiaries may be eligible to receive services under the waiver if we were to establish a cumulative list of beneficiaries preliminarily assigned to the ACO during the performance year. It would be appropriate to establish such a cumulative list because the beneficiaries preliminarily assigned to an ACO may vary during each quarter of a performance year.

Under preliminary prospective assignment with retrospective reconciliation, once a beneficiary receives at least one primary care service furnished by an ACO participant, the ACO has an incentive to coordinate care of the Medicare beneficiary, including SNF services, for the remainder of the performance year because of the potential for the beneficiary to be assigned to the ACO for the performance year. Under our proposed approach, we would not remove preliminarily prospectively assigned beneficiaries from the list of beneficiaries eligible to receive SNF services under the waiver on a quarterly basis. Instead, once a beneficiary is listed as preliminarily prospectively assigned to an eligible ACO for the performance year, according to the assignment lists provided by CMS to an ACO at the beginning of each performance year and for quarters 1, 2, and 3 of each performance year, then the SNF 3-day rule waiver would remain available with respect to otherwise covered SNF services furnished to that beneficiary by a SNF affiliate of the ACO, consistent with the requirements of § 425.612(a), for the remainder of the performance year.

We proposed that the waiver would be limited to SNF services provided after the beneficiary first appeared on the preliminary prospective assignment list for the performance year, and that a beneficiary would no longer be eligible to receive covered services under the waiver if he or she subsequently enrolls in a Medicare group (private) health plan or is otherwise no longer enrolled in Part A and Part B. In other words, ACOs participating in a performance-based risk track and under preliminary prospective assignment with retrospective reconciliation would receive an initial performance year assignment list followed by assignment lists for quarters 1, 2, and 3 of each performance year, and the SNF 3-day rule waiver would be available with respect to all beneficiaries who have been identified as preliminarily prospectively assigned to the ACO on one or more of these four assignment lists, unless they enroll in a Medicare group health plan or are no longer enrolled in both Part A and Part B. Providers and suppliers are expected to confirm a beneficiary's health insurance coverage to determine if they are eligible for FFS benefits. In addition, we noted that under existing Medicare payment policies, services furnished to Medicare beneficiaries outside the U.S. are not payable except under very limited circumstances. Therefore, in general, 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 payable.

We note that our proposal to allow preliminarily prospectively assigned beneficiaries to remain eligible for the SNF 3-day rule waiver until the end of the performance year may include beneficiaries who ultimately are excluded from assignment to the ACO based upon their assignment to another Shared Savings Program ACO or their alignment with an entity participating in another shared savings initiative. Thus, a beneficiary may be eligible for admission under a SNF 3-day rule waiver based on being preliminarily prospectively assigned to more than one ACO during a performance year. As previously discussed, we believe ACOs that bear a degree of financial risk have a strong incentive to manage the care for all beneficiaries who appear on any preliminary prospective assignment list during the year and to continue to focus on furnishing appropriate levels of care because they do not know which beneficiaries ultimately will be assigned to the ACO for the performance year. Further, because there remains the possibility that a beneficiary could be preliminarily prospectively assigned to an ACO at the beginning of the year, not preliminarily assigned in a subsequent quarter, but then retrospectively assigned to the ACO at the end of the performance year, we believe it is appropriate that preliminarily prospectively assigned beneficiaries remain eligible to receive services under the SNF 3-day rule waiver for the remainder of the performance year to aid ACOs in coordinating the care of their entire beneficiary population. Because the ACO will ultimately be held responsible for the quality and costs of the care furnished to all beneficiaries who are assigned at the end of the performance year, we believe the ACO should have the flexibility to use the SNF 3-day rule waiver to permit any beneficiary who has been identified as preliminarily prospectively assigned to the ACO during the performance year to receive covered SNF services without a prior 3 day hospital stay when clinically appropriate. For this reason, we do not believe it is necessary to extend the 90-day grace period that applies to beneficiaries assigned to waiver-approved ACOs participating under the prospective assignment

methodology to include beneficiaries who are preliminarily prospectively assigned to a waiver-approved ACO. Rather, beneficiaries who are preliminarily prospectively assigned to a waiver-approved ACO will remain eligible to receive services furnished in accordance with the SNF 3-day rule waiver for the remainder of that performance year unless they enroll in a Medicare group health plan or are otherwise no longer enrolled in Part A and Part B. In addition, in order to help protect beneficiaries from incurring significant financial liability for SNF services received without a prior 3-day inpatient stay after an ACO's termination date, we would also like to clarify that an ACO must include, as a part of the notice of termination to ACO participants under § 425.221(a)(1)(i), a statement that its ACO participants, ACO providers/suppliers, and SNF affiliates may no longer use the SNF 3-day rule waiver after the ACO's date of termination. We would also like to clarify 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.

In summary, we proposed to revise the regulations at § 425.612(a)(1) to expand eligibility for the SNF 3-day rule waiver to include ACOs participating in a two-sided model under preliminary prospective assignment with retrospective reconciliation. The SNF 3-day rule waiver would be available for such ACOs with respect to all beneficiaries who have been identified as preliminarily prospectively assigned to the ACO on the initial performance year assignment list or on one or more assignment lists for quarters 1, 2, and 3 of the performance year, for SNF services provided after the beneficiary first appeared on one of the assignment lists for the applicable performance year. The beneficiary would remain eligible to receive SNF services furnished in accordance with the waiver unless he or she is no longer eligible for assignment to the ACO because he or she is no longer enrolled in both Part A and Part B or has enrolled in a Medicare group health plan.

Finally, as described in the August 2018 proposed rule (83 FR 41862), stakeholders representing rural health providers have pointed out that the SNF 3-day rule waiver is not currently available for SNF services furnished by critical access hospitals and other small, rural hospitals operating under a swing bed agreement. Section 1883 of the Act permits certain small, rural hospitals to enter into a swing bed agreement, under which the hospital can use its beds, as needed, to provide either acute or SNF care. As defined in the regulations at 42 CFR 413.114, a swing bed hospital is a hospital or CAH participating in Medicare that has CMS approval to provide post-hospital SNF care and meets certain requirements. These stakeholders indicate that because there are fewer SNFs in rural areas, there are fewer opportunities for rural ACOs to enter into agreements with SNF affiliates. These stakeholders also believe that the current policy may disadvantage beneficiaries living in rural areas who may not be in close proximity to a SNF and would need to travel longer distances to benefit from the SNF 3-day rule waiver. The stakeholders requested that we revise the regulations to permit providers that furnish SNF services under a swing bed agreement to be eligible to partner with ACOs for purposes of the SNF 3-day rule waiver.

In order to furnish SNF services under a swing bed agreement, hospitals must be substantially in compliance with the SNF participation requirements specified at 42 CFR 482.58(b), whereas CAHs must be substantially in compliance with the SNF participation requirements specified at 42 CFR 485.645(d). However, currently, providers furnishing SNF services under a swing bed agreement are not eligible to partner and enter into written agreements with ACOs for purposes of the SNF 3-day rule waiver because: (1) The SNF 3-day rule waiver under the Shared Savings Program regulations at § 425.612(a)(1) waives the requirement for a 3-day prior inpatient hospitalization only with respect to otherwise covered SNF services furnished by an eligible SNF and does not extend to otherwise covered post-hospital extended care services furnished by a provider under a swing bed agreement; and (2) CAHs and other rural hospitals furnishing SNF services under swing bed agreements are not included in the CMS 5-star Quality Rating System and, therefore, cannot meet the requirement at § 425.612(a)(1)(iii)(A) that, to be eligible to partner with an ACO for purposes of the SNF 3-day rule waiver, the SNF must have and maintain an overall rating of 3 or higher under the CMS 5-star Quality Rating System.

For the reasons described in the June 2015 final rule (80 FR 32804), we believe it is necessary to offer ACOs participating under two-sided risk models additional tools and flexibility to manage and coordinate care for their assigned beneficiaries, including the flexibility to admit a beneficiary for SNF-level care without a prior 3-day inpatient hospital stay. We agree with stakeholders that there are fewer SNFs in rural areas. Therefore, we agree with rural stakeholders that risk-bearing ACOs in rural areas would be better able to coordinate and manage care, and thus to control unnecessary costs, if the SNF 3-day rule waiver extended to otherwise covered SNF services provided by a hospital or CAH under a swing bed agreement. We believe this proposal would primarily benefit ACOs located in rural areas because most CAHs and hospitals that are approved to furnish post-acute SNF-level care via a swing bed agreement are located in rural areas. Consistent with this proposal, we also proposed to revise the regulations governing the SNF 3-day rule waiver at § 425.612(a)(1) to indicate that, for purposes of determining eligibility to partner with an ACO for the SNF 3-day rule waiver, SNFs include providers furnishing SNF services under swing bed arrangements. In addition, we proposed to revise § 425.612(a)(1)(iii)(A) to specify that the minimum 3-star rating requirement applies only if the provider furnishing SNF services is eligible to be included in the CMS 5-star Quality Rating System. We do not have a comparable data element to the CMS 5-star Quality Rating System for hospitals and CAHs under swing bed agreements; however, under § 425.612(d)(2), we monitor and audit the use of payment waivers in accordance with § 425.316. We will continue to monitor the use of the SNF 3-Day Rule Waiver and reserve the right to terminate an ACO's SNF 3-day rule waiver if the waiver is used inappropriately or beneficiaries are not receiving appropriate care.

Additionally, we note the possibility that a beneficiary could be admitted to a hospital or CAH, have an inpatient stay of less than 3 days, and then be admitted to the same hospital or CAH under its swing bed agreement. As previously discussed, we believe ACOs that bear a degree of financial risk have a stronger incentive not to over utilize services and have an incentive to recommend a beneficiary for admission to a SNF only when it is medically appropriate. We also note this scenario could occur when a beneficiary meets the generally applicable 3-day stay requirement. Thus, we do not believe extending the SNF 3-day rule waiver to include services furnished by a hospital or CAH under a swing bed agreement would create a new gaming opportunity.

To reduce burden and confusion for eligible ACOs not currently approved for a SNF 3-day rule waiver, we

proposed that these revisions would be applicable for SNF 3-day rule waivers approved for performance years beginning on July 1, 2019, and in subsequent years. This would allow for one, as opposed to multiple, application deadlines thus reducing the overall burden for ACOs applying for the waiver and prevent confusion over ACO outreach and communication materials related to application deadlines. Because we are forgoing the application cycle for a January 1, 2019 start date, we proposed to apply the revisions to ACOs approved to use the SNF 3-day rule waiver for performance years beginning on July 1, 2019, and in subsequent years. This includes both ACOs that start a new agreement period under the proposed new participation options on July 1, 2019, and those ACOs that are applying for a waiver during the term of an existing participation agreement. For ACOs currently participating in the Shared Savings Program with an agreement period beginning in 2017 or 2018, that have previously been approved for a SNF 3-day rule waiver, the proposed revisions to the SNF 3-day rule waiver would be applicable starting on July 1, 2019, and for all subsequent performance years. ACOs with an approved SNF 3-day rule waiver would be able to modify their 2019 SNF affiliate list for the performance year beginning on January 1, 2019; however, they would not be able to add a hospital or CAH operating under a swing bed agreement to their SNF affiliate list until the July 1, 2019 change request review cycle. CMS would notify all ACOs, including ACOs with a 12 month performance year 2019, of the schedule for this change request review cycle.

Consistent with these proposed revisions to the SNF 3-day rule waiver, we proposed to add a new provision at § 425.612(a)(1)(vi) to allow ACOs participating in performance-based risk within the BASIC track or ACOs participating in Track 3 or the ENHANCED track to request to use the SNF 3-day rule waiver. We did not propose to make the revisions to the SNF 3-day rule waiver applicable for Track 2 ACOs because we proposed to phase out Track 2, as discussed at section II.A.2. of this final rule. ACOs currently participating under Track 2 that choose to terminate their existing participation agreement and reapply to the Shared Savings Program under the ENHANCED track or BASIC track, at the highest level of risk and potential reward, as described under section II.A.2. of this final rule, would be eligible to apply for the SNF 3-day rule waiver.

For the reasons discussed in this section, we believe that the proposed modifications of the SNF 3-day rule waiver would provide additional incentives for ACOs to participate in the Shared Savings Program under performance-based risk and are necessary to support ACO efforts to increase quality and decrease costs under performance-based risk arrangements. We invited comments on these proposals and related issues.

Comment: Many commenters supported our proposed changes to the SNF 3-day rule waiver. In particular, some reasons commenters stated that they were supportive of the proposed changes to the SNF 3-day rule waiver were that it supports patient engagement, care coordination, and aids ACOs in increasing quality and reducing unnecessary costs. Many commenters were particularly supportive of our proposal to allow two-sided ACOs that selected the preliminary prospective with retrospective reconciliation assignment methodology to apply for the SNF 3-day rule waiver as well as our proposal to allow facilities under a swing bed agreement to partner with ACOs as SNF affiliates.

Response: We appreciate commenters' support for the proposed policies regarding the SNF 3-day rule waiver.

Comment: One commenter opposed allowing ACOs under the preliminary prospective with retrospective reconciliation assignment methodology the opportunity to apply for a SNF 3-day rule waiver. The commenter stated there is potential for mishaps related to cost sharing and benefit availability for beneficiaries who ultimately are not assigned to an ACO.

Response: We proposed that beneficiaries who appear on the initial, Q1, Q2, and Q3 preliminary prospective assignment list reports will remain eligible for the SNF–3 day rule waiver for the performance year, unless they are no longer eligible for both Part A and Part B or enroll in a Medicare group health plan, in order to minimize confusion concerning beneficiary eligibility. We also note that FFS eligibility status for all beneficiaries, regardless of assignment methodology, may change; therefore, beneficiary insurance coverage and cost sharing responsibilities should be verified at the time they receive services. Therefore, we disagree with the commenter that there are special concerns related to whether a beneficiary is ultimately assigned to an ACO under preliminary prospective assignment with retrospective reconciliation with respect to the SNF 3-day rule waiver, and we decline to modify the proposal based on this comment.

Comment: A few commenters opposed the proposal to allow facilities under a swing bed agreements to partner with ACOs as SNF affiliates. Specifically, some commenters stated it would represent an unfair trade practice and would be inconsistent with restrictions applied to traditional SNFs. One commenter suggested continuously monitoring SNF affiliates under swing bed agreements to ensure they maintain a high-level of care. Other commenters suggested requiring facilities under swing bed agreements to provide a sufficient demonstration of hardship in placement of discharging patients with adequate post-acute care in order to be eligible to partner with an ACO as a SNF affiliate.

Response: As we noted previously, in order to furnish SNF services under a swing bed agreement, hospitals must be substantially in compliance with the SNF participation requirements specified at 42 CFR 482.58(b), and CAHs must be substantially in compliance with the SNF participation requirements specified at 42 CFR 485.645(d). While we believe the CMS 5-Star Quality Rating System is a good measure to help assure beneficiaries that the SNF affiliate provides quality care, there are instances when the Star Quality Rating System does not apply, and we believe it is important to provide beneficiaries with the opportunity to be admitted to a SNF if their health care providers believe they do not require a 3-day inpatient stay. In order to provide beneficiaries in rural areas the opportunity to use the SNF 3-day rule waiver, we believe it is necessary to provide an exception to the CMS 5-Star Quality Rating System requirement for SNF providers furnishing SNF services under a swing bed arrangement. We will monitor the use of the SNF 3-Day Rule Waiver and reserve the right to terminate an ACO's SNF 3-day rule waiver if the waiver is used inappropriately or beneficiaries are not receiving appropriate care. We do not believe it is necessary to require hospitals or CAHs under a swing bed agreements to demonstrate hardship in placement of discharging patients with adequate post-acute care as they have already sufficiently demonstrated to CMS they meet the requirements to operate under a swing bed agreement. Beneficiaries in rural areas have fewer post-acute care facility options, therefore we do not believe it is necessary to require facilities in rural areas to provide further documentation demonstrating the number of facilities

located near their rural beneficiary populations.

Comment: Some commenters disagreed with limiting the SNF 3-day rule waiver to ACOs participating under performance-based risk tracks. These commenters suggested allowing all Shared Savings Program ACOs to apply for the SNF–3-day rule waiver. One commenter provided the following reasons in support of this suggestion: (1) ACOs should have the ability to reform their practice patterns before they are required to take on financial risk, (2) beneficiaries may experience ''iatrogenic harm'' from a hospital stay longer than they need, and (3) the Shared Savings Program has experienced reductions in SNF utilizations demonstrating that ACOs are not interested in over utilizing SNF care.

Response: We agree with commenters that ACOs participating in the Shared Savings Program have incentives to not over utilize care and reform their practice patterns; however, based on our experience with Track 1 we have learned that a SNF 3-day rule waiver is not a necessary incentive to encourage ACOs to participate under a one-sided model. We continue to believe that using the authority under section 1899(f) of the Act to waive certain payment or other program requirements may be necessary to permit effective implementation of two-sided performance-based risk tracks under the Shared Savings Program (80 FR 32799).

Comment: One commenter opposed further modifications to the SNF 3-day rule waiver until CMS evaluates the impact the waiver has had on patient outcomes in the program.

Response: We continue to monitor the use of the SNF 3-day rule waiver and reserve the right to terminate an ACO's SNF 3-day rule waiver if the waiver is used inappropriately or beneficiaries are not receiving appropriate care. To date, we have not observed misuse of the SNF 3-day rule waiver, nor have we received complaints from (or about) beneficiaries negatively impacted by the SNF 3-day rule waiver. We will continue to monitor the implementation of this waiver.

Comment: Several commenters submitted suggestions concerning our requirement that SNF affiliates have and maintain an overall rating of 3 or higher under the CMS 5-star Quality Rating System (§ 425.612(a)(1)(iii)(A)). Commenters report that the measure is difficult to attain, which limits the SNFs eligible to partner with ACOs, reduces the effectiveness of the waiver, and limits beneficiary choice. Some commenters suggested modifying this requirement to use only one star rating data element instead of the overall score. One commenter suggested that as APMs, ACOs are self-regulated to provide low-cost, high-quality care; therefore; the star rating requirement is not necessary. Some commenters suggested we provide a list of SNFs that are eligible SNF affiliates for ACOs to partner with.

Response: We did not propose to change the requirement for SNF affiliates that are not operating under a swing bed arrangement to have and maintain an overall rating of 3 or higher under the CMS 5-star Quality Rating System in the proposed rule. We decline at this time to remove the star rating requirement for facilities eligible for a rating under the CMS 5-star Quality Rating System because, as stated in earlier rulemaking, we believe this requirement provides beneficiaries with evidence that the SNF provides quality care (80 FR 32805). We will continue to evaluate the requirements of the SNF 3-day rule waiver and will propose any modifications we believe may be necessary to aid ACOs in successfully coordinating and delivering high quality beneficiary care in future rulemaking. We do not believe it is necessary to produce a list of SNF affiliates for ACOs to partner with since the CMS 5-star Quality Rating System is publicly available for both ACOs and beneficiaries to view the overall quality score for Medicare enrolled SNFs.

Comment: A few commenters suggested we modify the beneficiary eligibility requirement which limits the SNF 3-day rule waiver to beneficiaries that do not currently reside in a SNF or other long-term care facility (§ 425.602(a)(1)(ii)(B)). Commenters stated these beneficiaries also provide the opportunity to lower costs if they become eligible for the SNF 3-day rule waiver. One commenter suggested all beneficiaries seen at a hospital on an ACO participant list should be eligible for the SNF 3-day rule waiver. Another commenter suggested all assignable beneficiaries for ACOs under the prospective assignment methodology should become eligible for the SNF 3-day rule waiver as this would be equitable to the proposal to include quarterly beneficiaries assigned under the preliminary prospective with retrospective reconciliation assignment methodology.

Response: We did not propose any modifications to § 425.602(a)(1)(ii)(B) at this time. However, we have concerns that long-term care facilities might have an incentive to inappropriately apply the SNF 3-day rule waiver to beneficiaries residing in their facility as the payment rate is different between the two types of facility stays. Consistent with the approach taken under the Pioneer ACO Model and Next Generation ACO Model, we do not consider independent or assisted living facilities to be long-term care settings for purposes of determining a beneficiary's eligibility to receive SNF services pursuant to the SNF 3-day rule waiver. We do not believe it is appropriate to extend the SNF 3-day rule waiver to all beneficiaries who are seen at a hospital on an ACO's participant list or beneficiaries assignable to an ACO under the prospective assignment methodology. Under § 425.702(c)(1)(ii)(C), we provide ACOs that have selected the prospective assignment methodology with a list of their prospectively assigned beneficiaries so that the ACO knows the universe of beneficiaries who could be assigned to the ACO for the performance year, and we believe it is appropriate for the waiver to be used with respect to those beneficiaries. Additionally, ACOs under the prospective assignment methodology have their assignment list set at the start of each performance year and no beneficiaries are added to the list. Assignable beneficiaries will not be added during the performance year to the assigned beneficiary population for an ACO under the prospective assignment methodology for purposes of either the quality reporting sample or financial reconciliation. Therefore, we do not believe it is appropriate to extend the SNF–3-day rule waiver to beneficiaries who cannot be included on the final list of assigned beneficiaries for an ACO. We do not believe these suggested modifications to the SNF 3-day rule waiver would be necessary to permit effective implementation of two-sided performance-based risk tracks under the Shared Savings Program (80 FR 32799).

Comment: Some commenters suggested we revise § 425.612(a)(1)(ii)(G) which requires a beneficiary to ''have been evaluated and approved for admission to the SNF within 3 days prior to the SNF admission by an ACO provider/supplier who is a physician'' to be eligible for the SNF 3-day rule waiver. Commenters suggested we allow other qualified clinicians to evaluate the beneficiary. A few commenters stated that this requirement creates additional burden and sometimes additional billable services when a physician must evaluate a beneficiary who has already been evaluated by an ACO provider/supplier who is a NP, PA, or CNS.

Response: In order to be eligible to receive covered SNF services under the

SNF 3-day rule waiver, a beneficiary must have been evaluated and approved for admission to the SNF within 3 days prior to the admission by an ACO provider/supplier who is a physician, consistent with the beneficiary evaluation and admission plan. We do not believe that this criterion precludes review and approval by an ACO provider/supplier who is a physician of an evaluation conducted by another provider/supplier, for example, approval by the ACO medical director or other ACO provider/supplier who is a physician involved in the beneficiary's care of a recommendation for SNF admission by an NP, PA, of CNS who has directly evaluated the beneficiary. Additionally, under § 425.613, ACO providers/suppliers in risk-bearing ACOs under the prospective assignment methodology may be able to conduct the evaluation via a telehealth service, if all applicable requirements are met.

Comment: One commenter recommended we require ACOs to enhance communication and interoperability of EHRs with SNFs. The commenter suggested that improving the dissemination of electronic health records among providers will result in improved coordination of services and reduced inefficiencies as patients' transition from one care setting to another. The commenter further supported this suggestion stating it aligns with CMS' goal of improved interoperability and would result in improved services.

Response: While we believe EHRs are mutually beneficial for ACOs and SNFs, and we encourage their use among health care providers, we decline to require SNF affiliates to implement EHRs to align with the ACOs they partner with. We are concerned such a requirement could create inefficiencies or have other unintended consequences, as SNF affiliates are not required to remain exclusive to a single ACO. SNF affiliates can partner with more than one Shared Savings Program ACO as well as with ACOs participating in other Medicare shared savings initiatives. In addition, such a requirement would be beyond the scope of the policies proposed in the August 2018 proposed rule.

Final Action: After considering the comments received in response to the proposals to revise the SNF 3-day rule waiver, we are finalizing the policies as proposed. Specifically, we are finalizing the revisions to § 425.612(a)(1) to expand eligibility for the SNF 3-day rule waiver to include ACOs participating in a two-sided model under preliminary prospective assignment with retrospective reconciliation. We are finalizing revisions to § 425.612(a)(1) to indicate that, for purposes of determining eligibility to partner with an ACO for the SNF 3-day rule waiver, SNFs include providers furnishing SNF services under swing bed arrangements. Additionally, we are finalizing revisions to § 425.612(a)(1)(iii)(A) to specify that the minimum 3-star rating requirement applies only if the provider furnishing SNF services is eligible to be included in the CMS 5-star Quality Rating System. Lastly, we are finalizing a new provision at § 425.612(a)(1)(vi) to allow ACOs participating in performance-based risk within the BASIC track or ACOs participating in Track 3 or the ENHANCED track to request to use the SNF 3-day rule waiver.

b. Billing and Payment for Telehealth Services

(1) Background

Under section 1834(m) of the Act, Medicare pays for certain Part B telehealth services furnished by a physician or practitioner under certain conditions, even though the physician or practitioner is not in the same location as the beneficiary. As of 2018, the telehealth services must be furnished to a beneficiary located in one of the types of originating sites specified in section 1834(m)(4)(C)(ii) of the Act and the originating site must satisfy at least one of the requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act. An originating site is the location at which a beneficiary who is eligible to receive a telehealth service is located at the time the service is furnished via a telecommunications system.

Generally, for Medicare payment to be made for telehealth services under the PFS, several conditions must be met (§ 410.78(b)). Specifically, the service must be on the Medicare list of telehealth services and must meet all of the following requirements for payment:

- The telehealth service must be furnished via an interactive telecommunications system, as defined at § 410.78(a)(3). CMS pays for telehealth services provided through asynchronous (that is, store and forward) technologies, defined at § 410.78(a)(1), only for Federal telemedicine demonstration programs conducted in Alaska or Hawaii.
- The service must be furnished to an eligible beneficiary by a physician or other practitioner specified at § 410.78(b)(2) who is licensed to furnish the service under State law as specified at § 410.78(b)(1).
- The eligible beneficiary must be located at an originating site at the time the service being furnished via a telecommunications system occurs. The eligible originating sites are specified in section 1834(m)(4)(C)(ii) of the Act and § 410.78(b)(3) and, for telehealth services furnished during 2018, include the following: The office of a physician or practitioner, a CAH, RHC, FQHC, hospital, hospital-based or CAH-based renal dialysis center (including satellites), SNF, and community mental health center.
- As of 2018, the originating site must be in a location specified in section 1834(m)(4)(C)(i) of the Act and § 410.78(b)(4). The site must be located in a health professional shortage area that is either outside of a Metropolitan Statistical Area (MSA) or within a rural census tract of an MSA, located in a county that is not included in an MSA, or be participating in a Federal telemedicine demonstration project that has been approved by, or receives funding from, the Secretary of Health and Human Services as of December 31, 2000.

When these conditions are met, Medicare pays a facility fee to the originating site and provides separate payment to the distant site practitioner for the service.

Section 1834(m)(4)(F)(i) of the Act defines Medicare telehealth services to include professional consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when furnished via a telecommunications system. A list of Medicare telehealth services is available through the CMS website (at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.html*). Under section 1834(m)(4)(F)(ii) of the Act, CMS has an annual process to consider additions to and deletions from the list of telehealth services. CMS does not include any services as telehealth services when Medicare does not otherwise make a separate payment for them.

Under the Next Generation ACO Model, the Innovation Center has been testing a Telehealth Expansion Benefit Enhancement under which CMS has waived the geographic and originating site requirements for services that are on the list of telehealth services when furnished to aligned beneficiaries by eligible telehealth practitioners (see the CMS website at *https://innovation.cms.gov/Files/x/nextgenaco-telehealthwaiver.pdf*). The purpose of this waiver is to test whether giving participating ACOs the flexibility to furnish telehealth services in more geographic areas and from the beneficiary's home will lower costs, improve quality, and better engage beneficiaries in their care.

(2) Provisions of the Bipartisan Budget Act for Telehealth in the Shared Savings Program

Section 50324 of the Bipartisan Budget Act amends section 1899 of the Act to add a new subsection (l) to provide certain ACOs the ability to expand the use of telehealth. The Bipartisan Budget Act provides that,

with respect to telehealth services for which payment would otherwise be made that are furnished on or after January 1, 2020 by a physician or practitioner participating in an applicable ACO to a Medicare FFS beneficiary prospectively assigned to the applicable ACO, the following shall apply: (1) The home of a beneficiary shall be treated as an originating site described in section 1834(m)(4)(C)(ii) of the Act, and (2) the geographic limitation under section 1834(m)(4)(C)(i) of the Act shall not apply with respect to an originating site, including the home of a beneficiary, subject to State licensing requirements. The Bipartisan Budget Act defines the home of a beneficiary as the place of residence used as the home of a Medicare FFS beneficiary.

The Bipartisan Budget Act defines an ''applicable ACO'' as an ACO participating in a two-sided model of the Shared Savings Program (as described in § 425.600(a)) or a two-sided model tested or expanded under section 1115A of the Act, for which FFS beneficiaries are assigned to the ACO using a prospective assignment method.

The Bipartisan Budget Act also provides that, in the case where the home of the beneficiary is the originating site, there shall be no facility fee paid to the originating site. It further provides that no payment may be made for telehealth services furnished in the home of the beneficiary when such services are inappropriate to furnish in the home setting, such as services that are typically furnished in inpatient settings such as a hospital.

Lastly, the Bipartisan Budget Act requires the Secretary to conduct a study on the implementation of section 1899(l) of the Act that includes an analysis of the utilization of, and expenditures for, telehealth services under section 1899(l). No later than January 1, 2026, the Secretary must submit a report to Congress containing the results of the study, together with recommendations for legislation and administrative action as the Secretary determines appropriate.

(3) Proposals

We proposed to add a new section of the Shared Savings Program regulations at § 425.613 to govern the payment for certain telehealth services furnished, in accordance with section 1899(l) of the Act, as added by the Bipartisan Budget Act. As required by section 1899(l) of the Act, we proposed to treat the beneficiary's home as an originating site and not to apply the originating site geographic restrictions under section 1834(m)(4)(C)(i) of the Act for telehealth services furnished by a physician or practitioner participating in an applicable ACO. Thus, we proposed to make payment to a physician or practitioner billing though the TIN of an ACO participant in an applicable ACO for furnishing otherwise covered telehealth services to beneficiaries prospectively assigned to the applicable ACO, including when the originating site is the beneficiary's home and without regard to the geographic limitations under section 1834(m)(4)(C)(i) of the Act. As we note in section II.A.4.c. of the August 2018 proposed rule (83 FR 41811) and again in this final rule, the Shared Savings Program offers two similar, but distinct, assignment methodologies, prospective assignment and preliminary prospective assignment with retrospective reconciliation. We proposed to apply these policies regarding payment for telehealth services to ACOs under a two-sided model that participate under the prospective assignment method. We believed that these ACOs meet the definition of applicable ACO under section 1899(l)(2)(A) of the Act. Because final assignment is not performed under the preliminary prospective assignment methodology until after the end of the performance year, we do not believe it is ''a prospective assignment method'' as required under section 1899(l)(2)(A)(ii). Although we do not believe that ACOs that participate under the preliminary prospective assignment with retrospective reconciliation method meet the definition of an applicable ACO, we welcomed comments on our interpretation of this provision.

We proposed that the policies governing telehealth services furnished in accordance with section 1899(l) of the Act would be effective for telehealth services furnished in performance years beginning in 2020 and subsequent years by physicians or practitioners participating in ACOs that are operating under a two-sided model with a prospective assignment methodology for the applicable performance year. This would include physicians and practitioners participating in ACOs with a prospective assignment method for a performance year in the ENHANCED track (including Track 3 ACOs with an agreement period starting in 2018 or on January 1, 2019), or in levels C, D, or E of the BASIC track. Because ACOs participating in the Track 1+ Model are participating in a two-sided model tested under section 1115A and use prospective assignment, we note that physicians and practitioners participating in Track 1+ ACOs would also be able to furnish and be paid for telehealth services in accordance with section 1899(l) of the Act. Physicians and practitioners participating in Track 2 ACOs would not be able to furnish and be paid for telehealth services in accordance with section 1899(l) of the Act because Track 2 ACOs do not participate under a prospective assignment methodology. Additionally, the ability to furnish and be paid for telehealth services in accordance with section 1899(l) of the Act would not extend beyond the term of the ACO's participation agreement. If CMS terminates an ACO's participation agreement under § 425.218, then the ability of physicians and other practitioners billing through the TIN of an ACO participant to furnish and be paid for telehealth services in accordance with section 1899(l) of the Act will end on the date specified in the notice of termination. Further, to help protect beneficiaries from potential exposure to significant financial responsibility. we would also like to clarify that an ACO must include, as a part of its notice of termination to ACO participants under § 425.221(a)(1)(i), a statement that physicians and other practitioners who bill through the TIN of an ACO participant can no longer furnish and be paid for telehealth services in accordance with section 1899(l) of the Act after the ACO's date of termination.

As discussed in section II.A.4. of the August 2018 proposed rule (83 FR 41810) and again in this final rule, we proposed to allow ACOs in the BASIC and ENHANCED tracks the opportunity to change their beneficiary assignment methodology on an annual basis. As a result, the ability of physicians and other practitioners billing through the TIN of an ACO participant in these ACOs to furnish and be paid for telehealth services in accordance with section 1899(l) of the Act could change from year to year depending on the ACO's choice of assignment methodology. Should an ACO in the BASIC track or ENHANCED track change from the prospective assignment methodology to preliminary prospective assignment methodology with retrospective reconciliation for a performance year, the ACO would no longer satisfy the requirements to be an applicable ACO for that year and physicians and other practitioners billing through the TIN of an ACO participant in that ACO could only furnish and be paid for telehealth services if the services meet all applicable requirements, including the

originating site requirements, under section 1834(m)(4)(C) of the Act.

We proposed that the beneficiary's home would be a permissible originating site type for telehealth services furnished by a physician or practitioner participating in an applicable ACO. Under this proposal, in addition to being eligible for payment for telehealth services when the originating site is one of the types of originating sites specified in section 1834(m)(4)(C)(ii) of the Act, a physician or other practitioner billing through the TIN of an ACO participant in an applicable ACO could also furnish and be paid for such services when the originating site is the beneficiary's home (assuming all other requirements are met). As discussed earlier, section 1899(l)(1)(A) of the Act, as added by section 50324 of the Bipartisan Budget Act, defines a beneficiary's home to be the place of residence used as the home of the beneficiary. In addition, we proposed that Medicare would not pay a facility fee when the originating site for a telehealth service is the beneficiary's home.

Further, we proposed that the geographic limitations under section 1834(m)(4)(C)(i) of the Act would not apply to any originating site, including a beneficiary's home, for telehealth services furnished by a physician or practitioner billing through the TIN of an ACO participant in an applicable ACO. This would mean that a physician or practitioner billing through the TIN of an ACO participant in an applicable ACO could furnish and be paid for telehealth services when the beneficiary receives those services while located at an originating site in an urban area that is within an MSA, assuming all other requirements are met. We also proposed to require that, consistent with section 1899(l)(1)(B) of the Act, the originating site must comply with State licensing requirements.

We proposed that the treatment of the beneficiary's home as an originating site and the non-application of the originating site geographic restrictions would be applicable only to payments for services on the list of Medicare telehealth services. The approved list of telehealth services is maintained on our website and is subject to annual updates (*https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.html*). However, as provided in section 1899(l)(3)(B) of the Act, in the case where the beneficiary's home is the originating site, Medicare will not pay for telehealth services that are inappropriate to be furnished in the home even if the services are on the approved list of telehealth services. Therefore, we proposed that ACO participants must not submit claims for services specified as inpatient only when the service is furnished as a telehealth service and the beneficiary's home is the originating site. For example, CPT codes G0406, G0407, G0408, G0425, G0426, and G0427 are used for reporting inpatient hospital visits and are included on the 2018 approved telehealth list. As described in Chapter 12, section 190.3.1, of the Medicare Claims Processing Manual,[21] Medicare pays for inpatient or emergency department telehealth services furnished to beneficiaries located in a hospital or SNF; therefore, consistent with the current FFS telehealth requirements, we believe it would be inappropriate for an ACO participant to submit a claim for an inpatient telehealth visit when the originating site is the beneficiary's home.

As described in the August 2018 proposed rule (83 FR 41865), we are concerned about potential beneficiary financial liability for telehealth services provided to beneficiaries excluded from assignment under the Shared Savings Program. A beneficiary prospectively assigned to an applicable ACO at the beginning of a performance year can subsequently be excluded from assignment if he or she meets the exclusion criteria specified under § 425.401(b). To address delays in communicating beneficiary exclusions from the assignment list, the Telehealth Expansion Benefit Enhancement under the Next Generation ACO Model provides for a 90-day grace period that functionally acts as an extension of beneficiary eligibility to receive services under the Benefit Enhancement and permits some additional time for the ACO to receive quarterly exclusion lists from CMS and communicate beneficiary exclusions to its participants. We also provide for a 90-day grace period with respect to the Shared Savings Program SNF 3-day rule waiver under § 425.612(a)(1), which allows for coverage of qualifying SNF services furnished to a beneficiary who was prospectively assigned to an ACO that has been approved for the waiver at the beginning of the performance year, but was excluded in the most recent quarterly update to the ACO's prospective assignment list.

Based upon the experience in the Next Generation ACO Model, we believe it would be inadvisable not to provide some protection for beneficiaries who are prospectively assigned to an applicable ACO at the start of the year, but are subsequently excluded from assignment. It is not operationally feasible for CMS to notify the ACO and for the ACO, in turn, to notify its ACO participants and ACO providers/suppliers immediately of the beneficiary's exclusion. The lag in communication may then cause a physician or practitioner billing under the TIN of an ACO participant to unknowingly furnish a telehealth service to a beneficiary who no longer qualifies to receive telehealth services under section 1899(l) of the Act. Therefore, we proposed to use our waiver authority under section 1899(f) of the Act to waive the originating site requirements in section 1834(m)(4)(C) of the Act as necessary to provide for a 90-day grace period for payment of otherwise covered telehealth services, to allow sufficient time for CMS to notify an applicable ACO of any beneficiary exclusions, and for the ACO then to inform its ACO participants and ACO providers/suppliers of those exclusions. We believe it is necessary, to protect beneficiaries from potential financial liability related to use of telehealth services furnished by physicians and other practitioners billing through the TIN of an ACO participant in an applicable ACO, to establish this 90-day grace period in the case of a prospectively assigned beneficiary who is later excluded from assignment to an applicable ACO.

More specifically, we proposed to waive the originating site requirements in section 1834(m)(4)(C) of the Act to allow for coverage of telehealth services furnished by a physician or practitioner billing through the TIN of an ACO participant in an applicable ACO to an excluded beneficiary within 90 days following the date that CMS delivers the relevant quarterly exclusion list under § 425.401(b). We proposed to amend § 425.612 to add a new paragraph (f) establishing the terms and conditions of this waiver. This waiver would permit us to make payment for otherwise covered telehealth services furnished during a 90 day grace period to beneficiaries who were initially on an applicable ACO's list of prospectively assigned beneficiaries for the performance year, but were subsequently excluded during the performance year. Under the terms of this waiver, CMS would make payments for telehealth services furnished to such a beneficiary as if they were telehealth services authorized under section

[21] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf.*

1899(l) of the Act if the following conditions are met:

- The beneficiary was prospectively assigned to an applicable ACO at the beginning of the relevant performance year, but was excluded in the most recent quarterly update to the assignment list under § 425.401(b);
- The telehealth services are furnished to the beneficiary by a physician or practitioner billing through the TIN of an ACO participant in an applicable ACO within 90 days following the date that CMS delivers the quarterly exclusion list to the applicable ACO.
- But for the beneficiary's exclusion from the applicable ACO's assignment list, CMS would have made payment to the ACO participant for such services under section 1899(l) of the Act.

In addition, as described in the August 2018 proposed rule (83 FR 41865) we are concerned that there could be scenarios where a beneficiary could be charged for non-covered telehealth services that were a result of an inappropriate attempt to furnish and be paid for telehealth services under section 1899(l) of the Act by a physician or practitioner billing through the TIN of an ACO participant in an applicable ACO. Specifically, we are concerned that a beneficiary could be charged for non-covered telehealth services if a physician or practitioner billing through the TIN of an ACO participant in an applicable ACO were to attempt to furnish a telehealth service that would be otherwise covered under section 1899(l) of the Act to a FFS beneficiary who is not prospectively assigned to the applicable ACO, and payment for the telehealth service is denied because the beneficiary is not eligible to receive telehealth services furnished under section 1899(l) of the Act. We believe this situation could occur as a result of a breakdown in one or more processes of the applicable ACO and its ACO participants. For example, the ACO participant may not verify that the beneficiary appears on the ACO's prospective assignment list, as required under section 1899(l) of the Act, prior to furnishing a telehealth service. In this scenario, Medicare would deny payment of the telehealth service claim because the beneficiary did not meet the requirement of being prospectively assigned to an applicable ACO. We are concerned that, once the claim is rejected, the beneficiary may not be protected from financial liability, and thus could be charged by the ACO participant for non-covered telehealth services that were a result of an inappropriate attempt to furnish telehealth services under section 1899(l), potentially subjecting the beneficiary to significant financial liability. In this circumstance, we proposed to assume that the physician or other practitioner's intent was to rely upon section 1899(l) of the Act. We believe this is a reasonable assumption because, as a physician or practitioner billing under the TIN of an ACO participant in an applicable ACO, the healthcare provider should be well aware of the rules regarding furnishing telehealth services and, by submitting the claim, demonstrated an expectation that CMS would pay for telehealth services that would otherwise have been rejected for lack of meeting the originating site requirements in section 1834(m)(4)(C) of the Act. We believe that in this scenario, the rejection of the claim could easily have been avoided if the ACO and the ACO participant had procedures in place to confirm that the requirements for furnishing such telehealth services were satisfied. Because each of these entities is in a better position than the beneficiary to know the requirements of the Shared Savings Program and to ensure that they are met, we believe that the applicable ACO and/or its ACO participants should be accountable for such denials and the ACO participant should be prevented from charging the beneficiary for the non-covered telehealth service. Therefore, we proposed that in the event that CMS makes no payment for telehealth services furnished to a FFS beneficiary and billed through the TIN of an ACO participant in an applicable ACO and the only reason the claim was non-covered is because the beneficiary was not prospectively assigned to the ACO or was not in the 90 day grace period, all of the following beneficiary protections would apply:

- 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, including being required to submit a corrective action plan (CAP) under § 425.216(b) for CMS approval. If the ACO is required to submit a CAP and, after being given an opportunity to act upon the CAP, the ACO fails to implement the CAP or demonstrate improved performance upon completion of the CAP, we may terminate the participation agreement as specified under § 425.216(b)(2). These proposed beneficiary protections are reflected in the proposed new regulation at § 425.613, which implements the requirements of section 1899(l) of the Act and establishes the policies governing the use of telehealth services by applicable ACOs and their ACO participants and ACO providers/suppliers.

Lastly, in the August 2018 proposed rule, we included a proposed change to the public reporting requirements under § 425.308 to include an ACO's use of payment rule waivers under § 425.612, if applicable, or telehealth services under § 425.613, if applicable, or both.

We welcomed comments on these proposals for implementing the requirements of section 1899(l) of the Act, as added by the Bipartisan Budget Act, and related issues. Our proposed policies concerning the applicability of the SNF 3-day rule waiver and expanded coverage for telehealth services in accordance with section 1899(l) of the Act by track are summarized in Table 10.

TABLE 10—AVAILABILITY OF PAYMENT AND PROGRAM POLICIES TO ACOs BY TRACK

Policy	Policy Description	Track 1 (One-sided Model; Discontinued for Future Agreement Periods)	Track 2 (Two-sided Model; discontinued for Future Agreement Periods)	Track 1+ Model (Two-sided Model)	BASIC Track (New Track)	ENHANCED Track (Current Track 3 Financial Model)
Telehealth Services furnished in accordance with section 1899(l) 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)	N/A (because this Track uses preliminary prospective assignment)	For performance year 2020 and onward (prospective assignment) [1]	For performance year 2020 and onward, applicable for performance years under a two-sided model (prospective assignment)	For performance year 2020 and onward (prospective assignment)
SNF 3-Day Rule Waiver [2]	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)	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)	For performance years beginning on July 1, 2019 and subsequent years (prospective or preliminary prospective assignment)

Notes: [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(l) to Track 1+ Model ACOs as described in section II.F. of this final rule.
[2] As discussed in section II.A.7.c. and II.F. of this final 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.

Comment: A number of commenters expressed their support for the proposals to make payments to physicians or practitioners for furnishing otherwise covered telehealth services, including when the originating site is the beneficiary's home. Several commenters wrote that the telehealth proposals would specifically help those who are home bound, or lack transportation, to have access to primary care services that would otherwise be unavailable. A few commenters supported the proposal to allow the beneficiary's home to be the originating site, and encouraged CMS to remove all originating site requirements.

Response: We appreciate commenters' support for the proposed policies for implementing the telehealth requirements of section 1899(l) of the Act, as added by the Bipartisan Budget Act.

Comment: A few commenters generally supported our telehealth proposals, but expressed uncertainty about how this new provision would impact FQHCs and encouraged CMS to clarify the language in the proposed rule to clearly allow FQHCs to provide telehealth services through their participation in an ACO.

Response: Although RHCs and FQHCs are authorized to serve as an originating site for telehealth services, RHCs and FQHCs are not authorized to serve as a distant site for telehealth consultations. We also wish to clarify that RHCs and FQHCs may not share space, staff, supplies, equipment, and/or other resources with an onsite Medicare Part B FFS practice operated by the same RHC or FQHC physician(s) and/or non-physician(s) practitioners. Additionally, RHC and FQHC practitioners may not furnish or separately bill for RHC or FQHC-covered professional services as a Part B provider in the RHC or FQHC. Additional details about these prohibitions are available in Chapter 13 of the Medicare Benefit Policy Manual (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c13.pdf*). Therefore, practitioners furnishing services in a RHC or FQHC facility cannot furnish telehealth services, though a beneficiary may use an RHC/FQHC facility as an originating site.

Comment: One commenter requested a real time benefit eligibility system for physician offices.

Response: The Shared Savings Program regulations do not prohibit ACOs from creating a beneficiary eligibility system to aid their ACO providers and suppliers in identifying prospectively assigned beneficiaries. Beneficiary FFS coverage should be verified at the time they receive services to determine eligibility.

Comment: One ACO commenter stated rural populations do not have access to the proper technology to effectively implement telehealth services, which would limit the practical usage of the proposal for this ACO.

Response: The Bipartisan Budget Act and this final rule do not impose any new limitations on delivery of telehealth services, instead the new provisions allow for a greater number of beneficiaries to be eligible to receive covered telehealth services. Eligible beneficiaries without the proper technology to receive telehealth services from their home remain eligible to receive such services from other originating sites such as a practitioner's office or an RHC or FQHC.

Comment: Commenters generally supported the proposal to apply the proposed telehealth policies to ACOs under a two-sided model. However, they encouraged CMS to expand the coverage to include ACOs under the preliminary prospective with retrospective reconciliation assignment methodology in order to create consistency with the SNF waiver, and make the proposals more streamlined for CMS to manage. A few commenters suggested that CMS allow ACOs to apply the telehealth proposals to voluntary aligned beneficiaries who are assigned to an ACO under the preliminary prospective with retrospective reconciliation assignment methodology. One commenter suggested that telehealth coverage be extended to ACOs under one-sided tracks, stating that ACOs in shared savings only

models have generated more savings than ACOs in two-sided models.

Response: We appreciate the commenters' support; however, CMS does not believe it is necessary to implement the Shared Savings Program to use its waiver authority to broaden the expansion of coverage for telehealth services beyond what Congress has specified for the Shared Savings Program. Section 1899(l)(2)(A) of the Act specifies in the definition of applicable ACO the requirements that an ACO must operate under a two-sided model under which beneficiaries are assigned using a prospective assignment methodology. Therefore, in view of Congress' decision to limit the expansion of coverage of telehealth services under section 1899(l) of the Act to physicians and practitioners in applicable ACOs, we do not believe it would be necessary for purposes of carrying out the Shared Savings Program to use our authority under section 1899(f) of the Act to issue a waiver allowing ACO providers/suppliers participating in ACOs operating under a one-sided model or to which beneficiaries are preliminary prospectively assigned to receive payment for expanded telehealth services in the same manner as for telehealth services furnished under 1899(l).

Comment: Several commenters suggested the implementation of a waiver under section 1899(f) to allow the proposed telehealth policies to begin on July 1, 2019.

Response: We proposed that the policies governing telehealth services furnished in accordance with section 1899(l) of the Act would be effective for telehealth services furnished in performance years beginning in 2020 and subsequent years in accordance with the Bipartisan Budget Act. Therefore, consistent with the effective date specified by Congress, we decline to use our authority under section 1899(f) of the Act to issue a waiver to allow physicians and practitioners participating in applicable ACOs to furnish telehealth services pursuant to section 1899(l) of the Act in the 6 months between July 1, 2019, and December 31, 2019.

Comment: One commenter requested that CMS clarify how we would determine a ''telehealth service must not be inappropriate to furnish in the home setting'' (§ 425.613(a)(1)(iv)) and define the ''inappropriate use of telehealth services'' (§ 425.613(d)(2)). Additionally, the commenter asked whether there would be different coding requirements for telehealth services delivered where the beneficiary's home is the originating site.

Response: As we previously detailed, we have determined CPT codes G0406, G0407, G0408, G0425, G0426, and G0427 are inappropriate to furnish in the home setting. We identified these codes because they are specific to an inpatient setting and we believe it is inappropriate to deliver any service identified as an inpatient service in the home of a beneficiary. ACO providers/suppliers furnishing telehealth services must comply with all applicable Shared Savings Program and FFS regulations concerning furnishing telehealth services. Telehealth originating site claims are submitted independently from the physician services claims; beneficiaries and practitioners must refrain from submitting claims for an originating site facility fee when the services is furnished in the beneficiary's home.

Comment: One commenter agreed with the 90-day grace period for beneficiaries, and that ACO TINs should not charge beneficiaries if they inappropriately furnish a telehealth service to a beneficiary. Another commenter suggested waiving cost-sharing obligations for beneficiaries receiving telehealth services wherever possible.

Response: We thank commenters for their support. We proposed telehealth services furnished in accordance with section 1899(l) of the Act in accordance with the Bipartisan Budget Act. The Bipartisan Budget Act does not include provisions allowing providers and suppliers to waive cost-sharing obligations; therefore, we decline to create additional provisions addressing telehealth service cost-sharing requirements.

Comment: One commenter suggested that telepsychiatry plays an important role in the health care system through improving patient outcomes and reducing costs for patients with undiagnosed mental illness and substance use disorders. Another commenter suggested CMS allow beneficiaries to receive telehealth services from their home or residence from an emergency physician. The commenter cited the shortage of hospitals and emergency departments in rural communities as the reason they believed this would be an appropriate service.

Response: The list of telehealth services is updated through the annual physician fee schedule. The public has the opportunity to submit requests to add or delete services on an ongoing basis. We invite the commenter to make suggestions for additions to the Medicare list of telehealth services through this process.

Comment: One commenter expressed concern that requiring ACO providers/suppliers to preview quarterly beneficiary assignment lists prior to delivering telehealth services, and not receiving payment if the beneficiary was not eligible to receive telehealth services, would be an administrative burden for ACOs.

Response: Section 1899(l) of the Act requires that physicians and practitioners must be participating in an ACO to which beneficiaries are assigned using a prospective assignment method to be eligible to furnish covered telehealth services under that subsection, which services must be furnished to an assigned beneficiary. Shared Savings Program ACOs and their ACO providers/suppliers are not required to provide telehealth services, but if they chose to, the beneficiaries to whom they furnish such services must appear on the ACO's prospective assignment list.

Comment: One commenter suggested that ACOs should publicly report their delivery of telehealth services via their participation in the Shared Savings Program; the commenter suggested that this would prevent ACO participants from misusing benefit enhancements provided by CMS.

Response: We agree that transparency is important for reducing misuse of telehealth service delivery. In the August 2018 proposed rule, we proposed modifications to § 425.308 to include public reporting of an ACO's use of payment rule waivers under § 425.612, if applicable, or telehealth services under § 425.613, if applicable, or both.

Comment: One commenter suggested that any application to bill for telehealth services furnished pursuant to § 1899(l) needs to be concise for risk-bearing ACOs.

Response: Our proposed policies under § 425.613 did not include any application process.

Final Action: After considering the comments received in response to the proposed policies for implementing the telehealth requirements of section 1899(l) of the Act, as added by the Bipartisan Budget Act, we are finalizing the proposed policies for ACOs participating under performance-based risk that has elected the prospective assignment methodology under § 425.400(a)(3). Accordingly, we are also finalizing the addition of § 425.613. Lastly, we are finalizing the proposed modifications to § 425.308(b)(6) to include a requirement for public reporting of an ACO's use of payment

rule waivers under § 425.612, if applicable, or telehealth services under § 425.613, if applicable, or both.

C. Providing Tools To Strengthen Beneficiary Engagement

1. Background on Beneficiary Engagement

Section 1899(b)(2)(G) of the Act requires an ACO to ''define processes to promote . . . patient engagement.'' Strengthening beneficiary engagement is one of CMS' goals to help transform our health care system into one that delivers better care, smarter spending and healthier people, and that puts the beneficiary at the center of care. We stated in the November 2011 final rule that the term ''patient engagement'' means the active participation of patients and their families in the process of making medical decisions (76 FR 67828). The regulation at § 425.112 details the patient-centeredness criteria for the Shared Savings Program, and requires that ACOs implement processes to promote patient engagement (§ 425.112(b)(2)).

In addition, section 50341 of the Bipartisan Budget Act, which amends section 1899 of the Act, allows certain ACOs to each establish a beneficiary incentive program for assigned beneficiaries who receive qualifying primary-care services in order to encourage Medicare FFS beneficiaries to obtain medically necessary primary care services. In order to implement the amendments to section 1899 of the Act, and consistent with our goal to strengthen beneficiary engagement, we proposed policies in the August 2018 proposed rule to allow any ACO in Track 2, levels C, D, or E of the BASIC track, or the ENHANCED track to establish a CMS-approved beneficiary incentive program to provide incentive payments to eligible beneficiaries who receive qualifying services.

Furthermore, we proposed to revise our policies related to beneficiary notifications. Specifically, we proposed to require additional content for beneficiary notifications and that beneficiaries receive such notices at the first primary care visit of each performance year. Finally, we sought comment on whether we should create an alternative beneficiary assignment methodology, in order to promote beneficiary free choice, under which a beneficiary would be assigned to an ACO if the beneficiary has ''opted-in'' to assignment to the ACO.

2. Beneficiary Incentives

a. Overview

As we indicated in the August 2018 proposed rule, we believe that patient engagement is an important part of motivating and encouraging more active participation by beneficiaries in their health care. We continue to believe that ACOs that engage beneficiaries in the management of their health care may experience greater success in the Shared Savings Program. In the November 2011 final rule (see 76 FR 67958), we noted that some commenters had suggested that beneficiary engagement and coordination of care could be enhanced by providing additional incentives to beneficiaries that would potentially motivate and encourage beneficiaries to become actively involved in their care. One commenter gave the example of supplying scales to beneficiaries with congestive heart failure to help them better manage this chronic disease. Other commenters were concerned that certain beneficiary incentives such as gifts, cash, or other remuneration could be inappropriate incentives for receiving services or remaining assigned to an ACO or with a particular ACO participant or ACO provider/supplier.

In the November 2011 final rule, we finalized a provision at § 425.304(a)(1) that prohibits ACOs, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities from providing gifts or other remuneration to beneficiaries as incentives for (i) receiving items and services from or remaining in an ACO or with ACO providers/suppliers in a particular ACO, or (ii) receiving items or services from ACO participants or ACO providers/suppliers. However, in response to comments, we finalized a provision at § 425.304(a)(2) to provide that, subject to compliance with all other applicable laws and regulations, an ACO, ACO participants, and ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities may provide in-kind items or services to beneficiaries if there is a reasonable connection between the items or services and the medical care of the beneficiary, and the items or services are preventive care items or services, or advance a clinical goal of the beneficiary, including adherence to a treatment regime; adherence to a drug regime; adherence to a follow-up care plan; or management of a chronic disease or condition. For example, an ACO provider may give a blood pressure monitor to a beneficiary with hypertension in order to encourage regular blood pressure monitoring and thus educate and engage the beneficiary to be more proactive in his or her disease management. In this instance, such a gift would not be considered an improper incentive to encourage the beneficiary to remain with an ACO, ACO participant, or ACO provider/supplier.

We noted in the August 2018 proposed rule that nothing precludes ACOs, ACO participants, or ACO providers/suppliers from offering a beneficiary an incentive to promote his or her clinical care if the incentive does not violate the Federal anti-kickback statute (section 1128B(b) of the Act), the civil monetary penalties law provision relating to beneficiary inducements (section 1128A(a)(5) of the Act, known as the Beneficiary Inducements CMP), or other applicable law. For additional information on beneficiary incentives that may be permissible under the Federal anti-kickback statute and the Beneficiary Inducements CMP, see the final rule published by the Office of Inspector General (OIG) on December 7, 2016 titled ''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'' (81 FR 88368), as well as other resources that can be found on the OIG website at *oig.hhs.gov.*

In addition, as we explained in the August 2018 proposed rule, we believe that the existing regulation at § 425.304(a)(2) already provides ACOs with a considerable amount of flexibility to offer beneficiary incentives to encourage patient engagement, promote care coordination, and achieve the objectives of the Shared Savings Program. Further, ACOs, ACO participants, and ACO providers/suppliers need not furnish beneficiary incentives under the existing regulation at § 425.304(a)(2) to every beneficiary; they have the flexibility to offer incentives on a targeted basis to beneficiaries who, for example, are most likely to achieve the clinical goal that the incentive is intended to advance. Although the appropriateness of any in-kind beneficiary incentives must be determined on a case-by-case basis, we believe a wide variety of incentives could be acceptable under the existing regulation under § 425.304(a)(2), including, for example, the following:

- Vouchers for over-the-counter medications recommended by a health care provider.
- Prepaid, non-transferable vouchers that are redeemable for transportation services

solely to and from an appointment with a health care provider.

- Items and services to support management of a chronic disease or condition, such as home air-filtering systems or bedroom air-conditioning for asthmatic patients, and home improvements such as railing installation or other home modifications to prevent re-injury.
- Wellness program memberships, seminars, and classes.
- Electronic systems that alert family caregivers when a family member with dementia wanders away from home.
- Vouchers for those with chronic diseases to access chronic disease self-management, pain management and falls prevention programs.
- Vouchers for those with malnutrition to access meals programs.
- Phone applications, calendars or other methods for reminding patients to take their medications and promote patient adherence to treatment regimes.

As the previously stated examples indicate, we consider vouchers, that is, certificates that can be exchanged for particular goods or services (for example, a certificate for one free gym class at a local gym), to be ''in-kind items or services'' under existing § 425.304(a)(2) (redesignated as § 425.304(b) in this final rule). Accordingly, an ACO may offer vouchers as beneficiary incentives under § 425.304(a)(2) so long as the vouchers meet all the other requirements of § 425.304(a)(2).

In addition, we explained in the August 2018 proposed rule that, for purposes of the Shared Savings Program, we consider gift cards that are in the nature of a voucher, that is, gift cards that can be used only for particular goods or services, to be ''in-kind items or services'' that can be offered under existing § 425.304(a)(2), provided that the requirements are satisfied. A gift card that is not in the nature of a voucher, however, such as a gift card to a general store, would not meet the requirements for ''in-kind item or service'' under existing § 425.304(a)(2). Furthermore, we consider a gift card that can be used like cash, for example, a VISA or Amazon ''gift card,'' to be a ''cash equivalent'' that can be offered only as an incentive payment under an approved beneficiary incentive program, provided that all of the criteria set forth in § 425.304(c), as finalized, are satisfied. We emphasized that, as previously stated, the determination and appropriateness of any in-kind beneficiary incentive must be determined on a case-by-case basis.

Although we believe that ACOs, ACO participants, ACO providers/suppliers and other individuals or entities performing functions or services related to ACO activities are already permitted to furnish a broad range of beneficiary incentives under existing § 425.304(a)(2) (including the previously stated examples), we noted that stakeholders have advocated that ACOs be permitted to offer a more flexible, and extensive range of beneficiary incentives that are not currently allowable under § 425.304. In particular, stakeholders have sought to offer monetary incentives that beneficiaries could use to purchase retail items, which would not qualify as in-kind items or services under § 425.304.

b. Provisions of the Bipartisan Budget Act for ACO Beneficiary Incentive Programs

As previously noted, and as explained in the August 2018 proposed rule, in order to encourage Medicare FFS beneficiaries to obtain medically necessary primary care services, the recent amendments to section 1899 of the Act permit certain ACOs to establish beneficiary incentive programs to provide incentive payments to assigned beneficiaries who receive qualifying primary care services. We believe that such amendments will empower individuals and caregivers in care delivery. Specifically, the Bipartisan Budget Act added section 1899(m)(1)(A) of the Act, which allows ACOs to apply to operate an ACO beneficiary incentive program. The Bipartisan Budget Act also added a new subsection (m)(2) to section 1899 of the Act, which provides clarification regarding the general features, implementation, duration, and scope of approved ACO beneficiary incentive programs. In addition, the Bipartisan Budget Act added section 1899(b)(2)(I) of the Act, which requires ACOs that seek to operate a beneficiary incentive program to apply to operate the program at such time, in such manner, and with such information as the Secretary may require.

Section 1899(m)(1)(A) of the Act, as added by the Bipartisan Budget Act, allows ACOs participating in certain payment models described in section 1899(m)(2)(B) of the Act to apply to establish an ACO beneficiary incentive program to provide incentive payments to Medicare FFS beneficiaries who are furnished qualifying services. Section 1899(m)(1)(A) of the Act also specifies that the Secretary shall permit an ACO to establish such a program at the Secretary's discretion and subject to such requirements, including program integrity requirements, as the Secretary determines necessary.

Section 1899(m)(1)(B) of the Act requires the Secretary to implement the ACO beneficiary incentive program provisions under section 1899(m) of the Act on a date determined appropriate by the Secretary, but no earlier than January 1, 2019 and no later than January 1, 2020. In addition, section 1899(m)(2)(A) of the Act, as added by the Bipartisan Budget Act, specifies that an ACO beneficiary incentive program shall be conducted for a period of time (of not less than 1 year) as the Secretary may approve, subject to the termination of the ACO beneficiary incentive program by the Secretary.

Section 1899(m)(2)(H) of the Act provides that the Secretary may terminate an ACO beneficiary incentive program at any time for reasons determined appropriate by the Secretary. In addition, the Bipartisan Budget Act amended section 1899(g)(6) of the Act to provide that there shall be no administrative or judicial review under section 1869 or 1878 of the Act, or otherwise, of the termination of an ACO beneficiary incentive program.

Section 1899(m)(2)(B) of the Act requires that an ACO beneficiary incentive program provide incentive payments to all of the following Medicare FFS beneficiaries who are furnished qualifying services by the ACO: (1) Medicare FFS beneficiaries who are preliminarily prospectively or prospectively assigned (or otherwise assigned, as determined by the Secretary) to an ACO in a Track 2 or Track 3 payment model described in § 425.600(a) (or in any successor regulation) and (2) Medicare FFS beneficiaries who are assigned to an ACO, as determined by the Secretary, in any future payment models involving two-sided risk.

Section 1899(m)(2)(C) of the Act, as added by the Bipartisan Budget Act, defines a qualifying service, for which incentive payments may be made to beneficiaries, as a primary care service, as defined in § 425.20 (or in any successor regulation), with respect to which coinsurance applies under Medicare part B. Section 1899(m)(2)(C) of the Act also provides that a qualifying service is a service furnished through an ACO by: (1) An ACO professional described in section 1899(h)(1)(A) of the Act who has a primary care specialty designation included in the definition of primary care physician under § 425.20 (or any successor regulation) (2) an ACO professional described in section 1899(h)(1)(B) of the Act; or (3) a FQHC or RHC (as such terms are defined in section 1861(aa) of the Act).

As added by the Bipartisan Budget Act, section 1899(m)(2)(D) of the Act provides that an incentive payment made by an ACO under an ACO beneficiary incentive program shall be in an amount up to $20, with the

maximum amount updated annually by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year. Section 1899(m)(2)(D) of the Act also requires that an incentive payment be in the same amount for each Medicare FFS beneficiary regardless of the enrollment of the beneficiary in a Medicare supplemental policy (described in section 1882(g)(1) of the Act), in a State Medicaid plan under Title XIX or a waiver of such a plan, or in any other health insurance policy or health benefit plan. Finally, section 1899(m)(2)(D) of the Act requires that an incentive payment be made for each qualifying service furnished to a beneficiary during a period specified by the Secretary and that an incentive payment be made no later than 30 days after a qualifying service is furnished to the beneficiary.

Section 1899(m)(2)(E) of the Act, as added by the Bipartisan Budget Act, provides that no separate payment shall be made to an ACO for the costs, including the costs of incentive payments, of carrying out an ACO beneficiary incentive program. The section further provides that this requirement shall not be construed as prohibiting an ACO from using shared savings received under the Shared Savings Program to carry out an ACO beneficiary incentive program. In addition, section 1899(m)(2)(F) of the Act provides that incentive payments made by an ACO under an ACO beneficiary incentive program shall be disregarded for purposes of calculating benchmarks, estimated average per capita Medicare expenditures, and shared savings for purposes of the Shared Savings Program.

As added by the Bipartisan Budget Act, section 1899(m)(2)(G) of the Act provides that an ACO conducting an ACO beneficiary incentive program shall, at such times and in such format as the Secretary may require, report to the Secretary such information and retain such documentation as the Secretary may require, including the amount and frequency of incentive payments made and the number of Medicare FFS beneficiaries receiving such payments. Finally, section 1899(m)(3) of the Act excludes payments under an ACO beneficiary incentive program from being considered income or resources or otherwise taken into account for purposes of: (1) Determining eligibility for benefits or assistance under any Federal program or State or local program financed with Federal funds; or (2) any Federal or State laws relating to taxation.

c. Beneficiary Incentive Programs

In order to implement the changes set forth in section 1899(b)(2) and (m) of the Act, we proposed to add regulation text at § 425.304(c) that would allow ACOs participating under certain two-sided models to establish beneficiary incentive programs to provide incentive payments to assigned beneficiaries who receive qualifying services. In developing such proposed policy, we considered the statutory provisions set forth in section 1899(b)(2) and (m) of the Act, as amended, as well as the following: The application process for establishing a beneficiary incentive program; who can furnish an incentive payment; the amount, timing, and frequency of an incentive payment; how an incentive payment may be financed, and necessary program integrity requirements. We addressed each of these considerations in the August 2018 proposed rule.

As previously explained, section 1899(m)(1)(A) of the Act authorizes ''an ACO participating under this section under a payment model described in clause (i) or (ii) of paragraph (2)(B)'' to establish an ACO beneficiary incentive program. In turn, section 1899(m)(2)(B)(i) of the Act describes ACOs participating in ''Track 2 and Track 3 payment models as described in section 425.600(a) . . . (or in any successor regulation).'' Section 1899(m)(2)(B)(ii) of the Act describes ACOs participating in ''any future payment models involving two-sided risk.'' As discussed in section II.A.2. of the August 2018 proposed rule, we proposed to (1) discontinue Track 2 as a participation option and limit its availability to agreement periods beginning before July 1, 2019; (2) rename Track 3 the ''ENHANCED track''; and (3) require ACOs with agreement periods beginning July 1, 2019 and in subsequent years to enter either the ENHANCED track (which entails two-sided risk) or the new BASIC track (in which Levels A and B have one-sided models and Levels C, D, and E have two-sided risk). As noted in proposed § 425.600(a)(3), for purposes of the Shared Savings Program, all references to the ENHANCED track would be deemed to include Track 3; the terms are synonymous. As discussed in section II.A.2. and II.A.3. of this final rule, we are finalizing these policies as proposed. Accordingly, Track 2 and ENHANCED track ACOs are described under section 1899(m)(2)(B)(i) of the Act, and ACOs in Levels C, D, or E of the BASIC track are described under section 1899(m)(2)(B)(ii) of the Act. As a result, Track 2 ACOs, ENHANCED track ACOs, and ACOs in Levels, C, D, or E of the BASIC track are authorized to establish beneficiary incentive programs under section 1899(m)(1)(A) of the Act.

Section 1899(m)(1)(B) of the Act states that the ''Secretary shall implement this subsection on a date determined appropriate by the Secretary. Such date shall be no earlier than January 1, 2019, and no later than January 1, 2020.'' We proposed to allow ACOs to establish a beneficiary incentive program beginning no earlier than July 1, 2019. As discussed later in this section, ACOs that are approved to operate a beneficiary incentive program shall conduct the program for at least 1 year, as required by section 1899(m)(2)(A) of the Act, unless CMS terminates the ACO's beneficiary incentive program. As we explained in the August 2018 proposed rule (83 FR 41870), this means, for example, that an ACO currently participating in the Shared Savings Program under Track 2 or Track 3 whose agreement period expires on December 31, 2019 would be ineligible to operate a beneficiary incentive program starting on July 1, 2019 because the ACO would have only 6 months of its agreement remaining as of July 1, 2019. Under our proposed policy, the ACO would, however, be permitted to start a beneficiary incentive program on January 1, 2020 (assuming it renews its agreement to participate in the Shared Savings Program).

We considered the operational impact of having both a midyear beneficiary incentive program cycle (for ACOs that seek to establish a beneficiary incentive program beginning on July 1, 2019) and a calendar year beneficiary incentive program cycle (for ACOs that seek to establish a beneficiary incentive program beginning on January 1, 2020, or a later January 1 start date). We stated our belief that it could be confusing for ACOs, and difficult for CMS to monitor approved beneficiary incentive programs, if some ACOs begin their beneficiary incentive programs in July 2019 and other ACOs begin their beneficiary incentive programs in January 2020. We explained in the August 2018 proposed rule that, under this approach, annual certifications regarding intent to continue a beneficiary incentive program (as further discussed herein) would be provided by ACOs at different times of the year, depending on when each ACO established its beneficiary incentive program. To address this, we believe it is necessary to require ACOs that establish a beneficiary incentive

program on July 1, 2019 to commit to an initial beneficiary incentive program term of 18 months (with certifications required near the conclusion of the 18-month period and for each consecutive 12-month period thereafter). However, we proposed that any ACO that establishes a beneficiary incentive program beginning on January 1 of a performance year would be required to commit to an initial beneficiary incentive program term of 12 months. This would allow the term cycles of all ACO beneficiary incentive programs to later ''sync'' so that they all operate on a calendar year beginning on January 1, 2021. As an alternative, we considered permitting all ACOs to establish a beneficiary incentive program beginning January 1, 2020. However, we expressed our belief that some ACOs may prefer to establish a beneficiary incentive program on July 1, 2019, rather than delay until January 1, 2020.

The statute does not prescribe procedures that ACOs must adhere to in applying to establish a beneficiary incentive program. In addition, beyond the requirement that ACOs participate in Track 2, Track 3 (which, as we previously discussed, will be renamed the ''ENHANCED track'') or a ''future payment model involving two-sided risk'' (sections 1899(m)(2)(B)(i) and (ii) of the Act), the new provisions do not describe what factors we should consider in evaluating whether an ACO should be permitted to establish a beneficiary incentive program. Instead, section 1899(m)(1)(A) of the Act states that the ''Secretary shall permit such an ACO to establish such a program at the Secretary's discretion and subject to such requirements . . . as the Secretary determines necessary.'' We proposed that the application for the beneficiary incentive program be in a form and manner specified by CMS, which may be separate from the application to participate in the Shared Savings Program. We explained that in our proposal that we would provide additional information regarding the application on our website.

We proposed to permit eligible ACOs to apply to establish a beneficiary incentive program during the July 1, 2019 application cycle or during a future annual application cycle for the Shared Savings Program. In addition, we proposed to permit an eligible ACO that is mid-agreement to apply to establish a beneficiary incentive program during the application cycle prior to the performance year in which the ACO chooses to begin implementing its beneficiary incentive program. We explained that this proposed policy would apply to ACOs that enter a two-sided model at the start of an agreement period but that do not apply to establish a beneficiary incentive program at the time of their initial or renewal application to the Shared Savings Program. This means, for example, that an ACO that enters the Shared Savings Program under a two-sided model but that does not seek to offer a beneficiary incentive program until its second performance year could apply to offer a beneficiary incentive program during the application cycle in advance of its second performance year. This would also apply to ACOs that enter the BASIC track's glide path under a one-sided model and that apply to establish a beneficiary incentive program beginning with a performance year under a two-sided model (see discussion in sections II.A.3.b. and II.A.4.b. of this final rule).

We proposed that an ACO be required to operate its beneficiary incentive program effective at the beginning of the performance year following CMS' approval of the ACO's application to establish the beneficiary incentive program. The ACO would then be required to operate the approved beneficiary incentive program for the entirety of such 12-month performance year (for ACOs that establish a beneficiary incentive program on January 1, 2020, or a later January 1 start date) or for an initial 18-month period (for ACOs that establish a beneficiary incentive program on July 1, 2019).

We proposed that an ACO with an approved beneficiary incentive program application be permitted to operate its beneficiary incentive program for any consecutive performance year if it complies with certain certification requirements. Specifically, we proposed that an ACO that seeks to continue to offer its beneficiary incentive program beyond the initial 12-month or 18-month term (as previously discussed) be required to certify, in the form and manner and by a deadline specified by CMS, its intent to continue to operate its beneficiary incentive program for the entirety of the next performance year, and that its beneficiary incentive program continues to meet all applicable requirements. We explained in the August 2018 proposed rule that CMS may terminate a beneficiary incentive program, in accordance with § 425.304(c)(7), as proposed, if an ACO fails to provide such certification. We believe this certification requirement is necessary for CMS to monitor beneficiary incentive programs. We explained that we would provide further information regarding the annual certification process through subregulatory guidance.

In addition to the application and certification requirements previously described, we considered whether an ACO that offers a beneficiary incentive program should be required to notify CMS of any modification to its beneficiary incentive program prior to implementing such modification. We solicited comments on this issue.

With respect to who may receive an incentive payment, we stated in the August 2018 proposed rule that a FFS beneficiary would be eligible to receive an incentive payment if the beneficiary is assigned to an ACO through either preliminary prospective assignment with retrospective reconciliation, as described in § 425.400(a)(2), or prospective assignment, as described in § 425.400(a)(3). We noted that Track 2 is under preliminary prospective assignment with retrospective reconciliation under § 425.400(a)(2). In addition, as discussed in section II.A.4. of the proposed rule, we proposed to permit BASIC track and ENHANCED track ACOs to enter an agreement period under preliminary prospective assignment, as described in § 425.400(a)(2), or under prospective assignment, as described in § 425.400(a)(3). Further, we explained that a beneficiary may choose to voluntarily align with an ACO, and, if eligible for assignment, the beneficiary would be prospectively assigned to the ACO (regardless of track) for the performance year under § 425.402(e)(1). Therefore, consistent with our proposed policy regarding which ACOs may establish a beneficiary incentive program, we explained that any beneficiary assigned to an ACO that is participating under Track 2; Levels C, D, or E of the BASIC track; or the ENHANCED track would be eligible to receive an incentive payment under that ACO's CMS-approved beneficiary incentive program.

Section 1899(m)(2)(C) of the Act sets forth the definition of a qualifying service for purposes of the beneficiary incentive program. We mirrored the language in the proposed regulation text noting that ''a qualifying service is a primary care service,'' as defined in § 425.20, ''with respect to which coinsurance applies under part B,'' furnished through an ACO by ''an ACO professional who has a primary care specialty designation included in the definition of primary care physician'' under § 425.20; an ACO professional who is a physician assistant, nurse practitioner, or clinical nurse specialist; or a FQHC or RHC. Accordingly, we explained that, under our proposal, any service furnished by an ACO professional who is a physician but does

not have a specialty designation included in the definition of primary care physician would not be considered a qualifying service for which an incentive payment may be furnished.

With respect to the amount of any incentive payment, we stated that section 1899(m)(2)(D)(i) of the Act provides that an incentive payment made by an ACO in accordance with a beneficiary incentive program shall be ''in an amount up to $20.'' Accordingly, we proposed to incorporate a $20 incentive payment limit into the regulation. We also proposed to adopt the provision at section 1899(m)(2)(D)(i) of the Act, which provides that the $20 maximum amount must be ''updated annually by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year.'' To avoid minor changes in the updated maximum amount, however, we expressed our belief that it would be necessary to round the updated maximum incentive payment amount to the nearest whole dollar. We explained that we would post the updated maximum payment amount on the Shared Savings Program website and/or in a guidance document regarding beneficiary incentive programs.

We also proposed to adopt the requirement that the incentive payment be ''in the same amount for each Medicare fee-for-service beneficiary'' without regard to enrollment of such a beneficiary in a Medicare supplemental policy, in a State Medicaid plan, or a waiver of such a plan, or in any other health insurance policy or health plan. (Section 1899(m)(2)(D)(ii) of the Act.) Accordingly, under our proposal, all incentive payments distributed by an ACO under its beneficiary incentive program must be of equal monetary value. In other words, an ACO would not be permitted to offer higher-valued incentive payments for particular qualifying services or to particular beneficiaries. However, we explained that an ACO would be able to provide different types of incentive payments (for example, a gift card to some beneficiaries and a check to others) depending on a beneficiary's preference, so long as all incentive payments offered by the ACO under its beneficiary incentive program were of equal monetary value.

Furthermore, as required by section 1899(m)(2)(D)(iii) of the Act, we proposed that an ACO furnish an incentive payment to an eligible beneficiary each time the beneficiary receives a qualifying service. In addition, in accordance with section 1899(m)(2)(D)(iv) of the Act, we proposed to require that each incentive payment be ''made no later than 30 days after a qualifying service is furnished to such a beneficiary.''

We considered the individuals and entities that should be permitted to offer incentive payments to beneficiaries under a beneficiary incentive program. We noted in the August 2018 proposed rule that section 1899(m)(2)(D) of the Act, which addresses incentive payments, contemplates that incentive payments be furnished directly by an ACO to a beneficiary. In addition, we expressed our belief that this requirement would be necessary because the ACO is in the best position to ensure that any incentive payments offered are distributed only to eligible beneficiaries and that other program requirements are met. We therefore proposed to require that the ACO legal entity, and not ACO participants or ACO providers/suppliers, furnish the incentive payments directly to beneficiaries. We sought comment, however, on other potential methods for distributing an incentive payment to a beneficiary.

As previously explained, section 1899(m)(1)(A) of the Act allows the Secretary to establish ''program integrity requirements, as the Secretary deems necessary.'' Given the significant fraud and abuse concerns associated with offering cash incentives, we expressed our belief that it would be necessary to prohibit ACOs from distributing incentive payments to beneficiaries in the form of cash. Cash incentive payments would be inherently difficult to track for reporting and auditing purposes since they would not necessarily be tied to documents providing written evidence that a cash incentive payment was furnished to an eligible beneficiary for a qualifying service. The inability to trace a cash incentive would make it difficult for CMS to ensure that an ACO has uniformly furnished incentive payments to all eligible beneficiaries and has not made excessive payments or otherwise used incentive payments to improperly attract ''healthier'' beneficiaries while disadvantaging beneficiaries who are less healthy or have a disability. Therefore, we proposed to require that incentive payments be in the form of a cash equivalent, which includes instruments convertible to cash or widely accepted on the same basis as cash, such as checks and debit cards.

In addition, we considered record retention requirements related to beneficiary incentive programs. Section 1899(m)(2)(G) of the Act provides that an ACO ''conducting an ACO Beneficiary Incentive Program . . . shall, at such times and in such format as the Secretary may require . . . retain such documentation as the Secretary may require, including the amount and frequency of incentive payments made and the number of Medicare fee-for-service beneficiaries receiving such payments.'' We explained our belief that it is important for an ACO to be accountable for its beneficiary incentive program and to mitigate any gaming, fraud, or waste that may occur as a result of its beneficiary incentive program. Accordingly, we proposed that any ACO that implements a beneficiary incentive program maintain records that include the following information: Identification of each beneficiary that received an incentive payment, including name and HICN or Medicare beneficiary identifier; the type (such as check or debit card) and amount (that is, the value) of each incentive payment made to each beneficiary; the date each beneficiary received a qualifying service and the HCPCS code for the corresponding service; the identification of the ACO provider/supplier that furnished the qualifying service; and the date the ACO provided each incentive payment to each beneficiary. We proposed that an ACO that establishes a beneficiary incentive program be required to maintain and make available such records in accordance with § 425.314(b). In addition to these record retention proposals, we explained that any ACO that establishes a beneficiary incentive program would be expected to update its compliance plan (as required under § 425.300(b)(2)), to address any finalized regulations that address beneficiary incentive programs.

Furthermore, we proposed that an ACO be required to fully fund the costs associated with operating a beneficiary incentive program, including the cost of any incentive payments. We further proposed to prohibit ACOs from accepting or using funds furnished by an outside entity, including, but not limited to, an insurance company, pharmaceutical company, or any other entity outside of the ACO, to finance its beneficiary incentive program. We explained our belief that these requirements are necessary to reduce the likelihood of undue influence resulting in inappropriate steering of beneficiaries to specific products or providers/suppliers. We sought comments on this issue.

We also proposed to incorporate language in section 1899(m)(2)(E) of the Act, which provides that ''[t]he Secretary shall not make any separate payment to an ACO for the costs, including incentive payments, of

carrying out an ACO Beneficiary Incentive Program . . . Nothing in this subparagraph shall be construed as prohibiting an ACO from using shared savings received under this section to carry out an ACO Beneficiary Incentive Program.'' Specifically, we proposed under § 425.304(a)(2) that the policy regarding use of shared savings apply with regard to both in-kind items and services furnished under § 425.304(b) and incentive payments furnished under § 425.304(c).

Further, we proposed to prohibit ACOs from shifting the cost of establishing or operating a beneficiary incentive program to a Federal health care program, as defined at section 1128B(f) of the Act. Essentially, ACOs would not be permitted to bill the cost of an incentive payment to any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government. We expressed our belief this requirement is necessary because billing another Federal health care program for the cost of a beneficiary incentive program would potentially violate section 1899(m)(2)(E) of the Act which prohibits the Secretary from making any separate payment to an ACO for the costs of carrying out a beneficiary incentive program, including the costs of incentive payments. We sought comments on all of our proposed program integrity requirements.

In addition, we proposed to implement the language in section 1899(m)(2)(F) of the Act that ''incentive payments made by an ACO . . . shall be disregarded for purposes of calculating benchmarks, estimated average per capita Medicare expenditures, and shared savings under this section.'' We also proposed to disregard incentive payments made by an ACO for purposes of calculating shared losses under this section given that that shared savings would be disregarded.

Furthermore, we proposed to implement the language set forth in section 1899(m)(3) of the Act, which provides that ''any payment made under an ACO Beneficiary Incentive Program . . . shall not be considered income or resources or otherwise taken into account for the purposes of determining eligibility for benefits or assistance (or the amount or extent of benefits or assistance) under any Federal program or any State or local program financed in whole or in part with Federal funds; or any Federal or state laws relating to taxation.'' We included this in our proposal at § 425.304(c)(6).

With regard to termination of a beneficiary incentive program, section 1899(m)(2)(H) of the Act provides that the ''Secretary may terminate an ACO Beneficiary Incentive Program . . . at any time for reasons determined appropriate by the Secretary.'' We explained our belief that it would be appropriate for CMS to terminate an ACO's use of the beneficiary incentive program for failure to comply with the requirements of our finalized proposals at § 425.304, in whole or in part, and for the reasons set forth in § 425.218(b), and we proposed this policy at § 425.304(c)(7). We solicited comment on whether it would be appropriate for the Secretary to terminate a beneficiary incentive program in other circumstances as well, or whether an ACO should have the ability to terminate its beneficiary incentive program early. In addition, we proposed to require any ACO that wishes to reestablish a beneficiary incentive program after termination to reapply in accordance with the procedures established by CMS. We also proposed to modify our regulations at § 425.800 to implement the language set forth in section 1899(g)(6) of the Act, which provides that there shall be no administrative or judicial review under section 1869 or 1878 of the Act or otherwise of the termination of an ACO beneficiary incentive program.

With regard to evaluation of beneficiary incentive programs, we noted that section 50341(c) of the Bipartisan Budget Act requires that, no later than October 1, 2023, the Secretary evaluate and report to Congress an analysis of the impact of implementing beneficiary incentive programs on health expenditures and outcomes. We welcomed comments on whether there might be information that we should require ACOs to maintain (in addition to the information that would be maintained as part of record retention requirements set forth at proposed § 425.304(c)(4)(i)) to support such an evaluation of beneficiary incentive programs. We noted, however, that we do not want to discourage participation by imposing overly burdensome data management requirements on ACOs. We therefore sought comment on reporting requirements for ACOs that are approved to establish a beneficiary incentive program.

In addition, we noted that under the existing regulations for monitoring ACO compliance with program requirements, CMS may employ a range of methods to monitor and assess ACOs, ACO participants and ACO providers/suppliers to ensure that ACOs continue to satisfy Shared Savings Program eligibility and program requirements (§ 425.316). We explained that the scope of this provision would include monitoring ACO, ACO participant, and ACO provider/supplier compliance with the requirements for establishing and operating a beneficiary incentive program.

We considered whether beneficiaries should be notified of the availability of a beneficiary incentive program. Because beneficiary incentives may be subject to abuse, we expressed our belief that it is necessary, and we proposed, to prohibit the advertisement of a beneficiary incentive program. We explained that we were considering, however, whether ACOs should be required to make beneficiaries aware of the incentive via approved outreach material from CMS. For example, under the program's existing regulations (§ 425.312(a)), including as revised in section II.C.3.a. of this final rule, all ACO participants are required to notify beneficiaries that their ACO providers/suppliers are participating in the Shared Savings Program. We solicited comment on whether the notifications required under § 425.312(a) should include information regarding the availability of an ACO's beneficiary incentive program, and, if so, whether CMS should supply template language on the topic. We also sought comment on how and when an ACO might otherwise notify its beneficiaries that its beneficiary incentive program is available, without inappropriately steering beneficiaries to voluntarily align with the ACO or to seek care from specific ACO participants, and, whether it would be appropriate to impose restrictions regarding advertising a beneficiary incentive program. We noted that we would expect any beneficiary notifications regarding incentive payments to be maintained and made available for inspection in accordance with § 425.314.

To ensure transparency and to meet the requirements of section 1899(m)(2)(G) of the Act requiring that an ACO ''conducting an ACO Beneficiary Incentive Program. . . shall, at such times and in such format as the Secretary may require, report to the Secretary such information. . .as the Secretary may require, including the amount and frequency of incentive payments made and the number of Medicare fee-for-service beneficiaries receiving such payments,'' we further proposed to revise the program's public reporting requirements in § 425.308 to require any ACO that has been approved to implement a beneficiary incentive program to publicly report certain information about incentive payments

on its public reporting web page. Specifically, we proposed to require ACOs to publicly report, for each performance year, the total number of beneficiaries who receive an incentive payment, the total number of incentive payments furnished, 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 type of each incentive payment (for example, check or debit card) furnished. We noted that this proposed policy would require reporting for the 6-month performance year that begins on July 1, 2019. We sought comment on whether information about a beneficiary incentive program should be publicly reported by the ACO or simply reported to CMS annually or upon request.

In summary, we proposed to revise the regulation at § 425.304 to enable an ACO participating in Track 2, levels C, D, or E of the BASIC track, or the ENHANCED track, to establish a beneficiary incentive program to provide incentive payments to beneficiaries for qualifying primary care services in compliance with the requirements outlined in the revised regulations.

Our proposed policies concerning an ACO's ability to establish a beneficiary incentive program are summarized in Table 11.

TABLE 11—ABILITY OF ACOs TO ESTABLISH A PROPOSED BENEFICIARY INCENTIVE PROGRAM BY TRACK

Policy	Policy Description	Track 1 (One-sided Model; Proposed to Discontinue)	Track 2 (Two-sided Model; Proposed 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 (preliminary 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)

Note: An ACO must operate a beneficiary incentive program for an initial period of 18 months (for ACOs approved to operate a beneficiary incentive program beginning on July 1, 2019), or 12 months (for ACOs approved to operate a beneficiary incentive program beginning on January 1 of a performance year). Therefore, an ACO completing an agreement period on December 31, 2019 is not eligible to establish a beneficiary incentive program on July 1, 2019 but may establish a program beginning when entering a renewed agreement period.

Comment: Commenters generally supported our proposed policies regarding beneficiary incentive programs. Commenters stated that the provision of beneficiary incentive payments may lead to more patient engagement opportunities. Some commenters specifically expressed that our proposed policy is not overly restrictive and is instead attentive to minimizing provider and beneficiary burden.

A few commenters who generally supported the proposal expressed that CMS should ensure that each ACO that implements a beneficiary incentive program has maximum flexibility to tailor the program so that it fits the needs of the ACO's beneficiaries. One commenter expressed support for our proposal because it would give ACOs the flexibility to determine what types of incentives to use (that is, in-kind incentives or incentive payments under a CMS-approved beneficiary incentive program).

However, several commenters expressed concern about the potential administrative burden and operational costs associated with implementing a beneficiary incentive program and expressed that such programs should remain optional. One commenter expressed that, because an ACO must bear the costs of any incentive payment and furnish an incentive payment to each assigned beneficiary for each qualifying service, the costs to an ACO that serves high-risk patients may be greater than the costs to an ACO that serves low-risk patients (because high-risk patients may need receive more qualifying services). The commenter indicated that our proposed policy would therefore likely discourage ACOs from transitioning to performance-based risk. Other commenters stated generally that a beneficiary incentive program would create additional frustration for staff and add expense to office operations.

Response: While we appreciate the concerns raised by commenters regarding the administrative and operational costs associated with operating a beneficiary incentive program, we emphasize that ACOs are not required to establish a beneficiary incentive program. Instead, each eligible ACO has the discretion to decide

whether to apply to offer such a program. We believe it is important to provide certain ACOs under two-sided risk with the option to establish a CMS-approved beneficiary incentive program as an additional tool for managing the care of assigned beneficiaries. Thus, pursuant to and consistent with the requirements in section 1899(m) of the Act, we will permit certain ACOs to apply to establish a beneficiary incentive program. Any ACO that wishes to establish a beneficiary incentive program should evaluate the costs and potential administrative burden and whether it has the resources to successfully implement a beneficiary incentive program prior to submitting an application because an ACO that submits an application to establish a beneficiary incentive program would be required to implement the program if its application is approved.

In terms of flexibility for ACOs to design their beneficiary incentive program to fit the needs of its beneficiaries, we are providing ACOs with some flexibility to determine the value of the incentive payments that they will furnish under a beneficiary incentive program (that is, a value of up to $20 per incentive payment to each assigned beneficiary for each qualifying service received) and the form of incentive payments (that is, whether an incentive payments will be made as a check, debit card, or a traceable cash equivalent). However, due to various restrictions in section 50341 of the Bipartisan Budget Act and the potential for fraud and abuse, we are otherwise limiting an ACO's flexibility with regard to how it may implement a beneficiary incentive program. We intend to monitor beneficiary incentive programs to determine whether it may be appropriate to afford ACOs additional flexibility in implementing a beneficiary incentive program in future rulemaking.

Comment: One commenter recommended that CMS extend the window in which an ACO must provide an incentive payment to beneficiary from 30 to 45 days from the date the qualifying service is furnished. Another commenter suggested that CMS allow ACOs to provide beneficiaries with a $40 incentive payment once annually, similar to the Next Generation ACO Model.

Response: As we previously explained, section 1899(m)(2)(D) of the Act requires that an incentive payment be made for each qualifying service furnished to a beneficiary be made no later than 30 days after a qualifying service is furnished to the beneficiary. Therefore, in order to comply with section 1899(m)(2)(D) of the Act, we decline to extend the payment window for a qualifying service beyond 30 days or to allow ACOs to provide beneficiaries with a $40 incentive payment once annually.

Comment: One commenter requested that CMS clarify whether incentive payments furnished under an approved beneficiary incentive program could implicate the federal fraud and abuse laws, such as the civil monetary penalties law provision relating to beneficiary inducements.

Response: Section 1128B(b)(3)(K) of the Act states that ''illegal remuneration'' under the anti-kickback statute does not include ''an incentive payment made to a Medicare fee-for-service beneficiary by an ACO under an ACO Beneficiary Incentive Program established under subsection (m) of section 1899, if the payment is made in accordance with the requirements of such subsection and meets such other conditions as the Secretary may establish.'' Further, pursuant to section 1128(A)(i)(6)(B) of the Act, a practice permissible under the anti-kickback statute, whether through statutory exception or regulations issued by the Secretary, is also excepted from the beneficiary inducements CMP. Parties are encouraged to consult legal counsel as needed.

Comment: Several commenters raised program integrity concerns regarding beneficiary incentive programs and suggested that CMS closely monitor any approved beneficiary incentive program. A few commenters stated that CMS should be mindful of inadvertently allowing ACOs to use beneficiary incentive programs to cherry-pick patients. For example, one ACO suggested that CMS implement safeguards to ensure that high-revenue ACOs do not inadvertently attract healthier patients, which could potentially skew quality metrics. Another commenter expressed similar concerns regarding the lack of safeguards applicable to beneficiary incentive programs, which could present opportunities for gaming. The commenter suggested that CMS implement an audit process, issue guidance, and impose additional requirements designed to minimize beneficiary cherry-picking and to mitigate MA parity concerns to ensure that ACOs would be unable to specifically target and engage certain individuals to selectively control their risk profile. Another commenter recommended that CMS evaluate beneficiary incentive programs prior to the date required by section 50341 of the Bipartisan Budget Act, on the basis that such programs are subject to abuse and may have unintended consequences.

Response: We appreciate the commenters' concerns that some ACOs may attempt to target a beneficiary incentive program toward beneficiaries with certain health profiles and we agree that program safeguards should prohibit an ACO from cherry-picking beneficiaries. We note that we have proposed, and we are finalizing, several safeguards at § 425.304(c) to help mitigate the program integrity risks associated with beneficiary incentive programs. For example, under § 425.304(c)(4)(iv) ACOs will be prohibited from offering an incentive payment as part of an advertisement or solicitation to beneficiaries. In addition, under § 425.304(c)(3)(iv)(C) an ACO will be required to furnish incentive payments in the same amount to each eligible beneficiary. We believe these safeguards will prevent larger, high revenue ACOs with a beneficiary incentive program from steering beneficiaries from smaller, low revenue ACOs that do not have a beneficiary incentive program and will also limit the ability of ACOs to cherry-pick certain beneficiaries.

In addition, we are also finalizing proposed revisions to the audit and record retention requirements set forth at § 425.314(a)(4) and (b)(1) to ensure that we will have the ability to effectively audit an ACO's operation of its beneficiary incentive program. Furthermore, we note that, under the existing regulations for monitoring ACO compliance with program requirements, we may employ a range of methods to monitor and assess ACOs, ACO participants and ACO providers/suppliers to ensure that ACOs continue to satisfy Shared Savings Program eligibility and program requirements (§ 425.316). The scope of this provision would allow us to monitor ACO, ACO participant, and ACO provider/supplier compliance with the requirements for establishing and operating a beneficiary incentive program. We believe that the finalized program integrity requirements at § 425.304(c)(4) and our existing regulatory safeguards will mitigate the commenters' concerns.

Comment: We received several comments related to our proposed bases for termination of an ACO's beneficiary incentive program. One commenter expressed that CMS should have the option to terminate an ACO's beneficiary incentive program when the ACO uses its program to improperly steer or influence beneficiaries, fails to maintain records regarding its program or make such records available to CMS, or otherwise fails to meet the

requirements of the program. The commenter recommended that CMS establish clear standards with which an ACO must comply in order to operate a beneficiary incentive program. The commenter also indicated that termination should be a last resort and suggested that, when a beneficiary incentive program is terminated for noncompliance with program requirements, beneficiaries, the public, and other ACOs, should receive advanced notice of the termination and the opportunity to submit to CMS comments regarding the termination, including CMS's basis for termination.

Response: We plan to issue guidance regarding the bases for which we may require an ACO to terminate its beneficiary incentive program under § 425.304(c)(7). We agree with the commenter that an ACO should notify its assigned beneficiaries that its beneficiary incentive program is terminated in cases where CMS requires such termination due to the ACO's noncompliance with program requirements. However, we disagree with the commenter's suggestion that the public should have advanced notice of the termination and the opportunity to submit comments to CMS. Our bases for termination relate to noncompliance with CMS regulations, accordingly, we believe that providing the public with an opportunity to comment on a proposed termination would be inappropriate. We will monitor ACO implementation of beneficiary incentive programs and we will determine whether termination is appropriate, without public comment, in cases where an ACO is noncompliant with program requirements.

Comment: Some commenters do not believe that the $20 maximum amount for an incentive payment is sufficient to encourage beneficiaries to receive qualifying services. Commenters cited various reasons such as the cost associated with long distance travel. Some of these commenters suggested that CMS permit ACOs to reimburse beneficiaries for transportation costs in addition to furnishing a $20 monetary incentive payment for each qualifying service. One commenter suggested that CMS allow ACOs to share a percentage of savings with its beneficiaries and provide a higher percentage of savings to high-risk patients, so that ACOs can better engage riskier populations. Another commenter expressed that a one-size-fits-all approach to incentive payment amounts might not serve all ACO participants well because ACO participants may operate in different environments and may want to offer incentive payments in different amounts, as appropriate for their region.

Response: We recognize the commenters' concerns regarding setting the maximum value of the incentive payment amount to $20 (as adjusted annually) for each qualifying service. However, this $20 maximum value for any monetary incentive payment is consistent with the requirements in section 1899(m)(2)(D) of the Act. Earlier in the preamble, we explained that, under existing § 425.304(a), an ACO may furnish to beneficiaries prepaid, non-transferable vouchers that are redeemable for transportation services solely to and from an appointment with a health care provider. We believe this addresses the concerns of commenters who believe that CMS should allow ACOs to reimburse beneficiaries for transportation costs in addition to furnishing a $20 monetary incentive payment for each qualifying service. In addition, we explained that Section 1899(m)(2)(D) of the Act requires that an incentive payment offered under a beneficiary incentive program be in the same amount for each Medicare FFS beneficiary. Accordingly, we decline to adopt the suggestion that we allow ACOs to share a percentage of savings with its beneficiaries and provide a higher percentage of savings to high-risk patients. Furthermore, while we understand the commenter's concern about a one-size-fits-all approach to incentive payment amounts, we believe that requiring ACOs to provide a uniform incentive amount for each qualifying service mitigates the potential for abuse, including the potential that ACOs will provide higher incentives in some areas to attract healthier beneficiaries and/or excluding some beneficiaries from receiving an incentive due to their location and/or health status.

Comment: One commenter sought clarification as to whether a beneficiary can receive more than one incentive payment per year, whether a beneficiary can deny receipt of an incentive payment, and what an ACO would need to do if a beneficiary denied an incentive payment.

Response: We reiterate that an ACO approved to operate a beneficiary incentive program is required to furnish an incentive payment to each beneficiary each time a beneficiary receives a qualifying service. Thus, if a beneficiary is prospectively assigned to an ACO participating in the ENHANCED track and receives two primary care services that are considered qualifying services, the ACO operating a beneficiary incentive program would be required to furnish two incentive payments to the beneficiary. Although we do not believe that it will be likely, a beneficiary may deny receipt of an incentive payment, we will provide additional clarification on how ACOs should handle such situations in sub-regulatory guidance.

Comment: Some commenters expressed that an ACO should not be required to finance a beneficiary incentive program and that they should be allowed to finance a program using funds from organizations outside of the ACO. One commenter stated that CMS's concerns regarding undue influence could be mitigated by establishing appropriate safeguards, including accounting mechanisms for outside funds and public disclosure of funding sources.

A few commenters believe that CMS should fund beneficiary incentive programs, including incentive payments. Other commenters proposed that CMS should pay in full for any qualifying service included as part of the Shared Savings Program attribution methodology. These same commenters expressed that CMS should also be responsible for any beneficiary copayment for a qualifying service, rather than requiring an ACO to fund an incentive payment, which a beneficiary may then use to pay for a part of the beneficiary's copayment.

Response: We decline to reconsider our proposed ban on allowing ACOs to use funds from an outside entity to establish or operate a beneficiary incentive program. We are concerned that non-ACO entities would offer remuneration to ACOs in order to influence them to order items or services from the outside entity, which may ultimately affect a beneficiary's care coordination through the ACO. Although this concern may be mitigated by program requirements that further promote transparency, we would still be concerned that ACOs would not accurately disclose outside funding sources and that it would be difficult to track such funding sources. Thus, we decline to reconsider our prohibition on ACOs using funding from entities outside of the ACO to finance a beneficiary incentive programs.

In addition, we disagree with the recommendation that CMS fund beneficiary incentive programs. Section 1899(m)(2)(E) of the Act specifically prohibits the Secretary from making any separate payment to an ACO for the costs of carrying out a beneficiary incentive program, including the costs of incentive payments. In addition, we note that beneficiary incentive programs are voluntary and that any ACO that is concerned about the potential costs

associated with implementing a beneficiary incentive program can choose to refrain from offering such a program. We emphasize that ACOs that choose to refrain from offering a beneficiary incentive program may still choose to offer certain in-kind items and services to beneficiaries in accordance with § 425.304(b).

Comment: A few commenters recommended that CMS consider the significant financial investment required by ACOs that establish a beneficiary incentive program when rebasing benchmarks. One commenter recommended that CMS consider positively adjusting an ACO's performance year financial results based on the ACO's beneficiary incentive program expenses, which will add to the ACO's operational costs and limit the ACO's resources.

Response: Section 1899(m)(2)(F) of the Act provides that ''incentive payments made by an ACO . . . shall be disregarded for purposes of calculating benchmarks, estimated average per capita Medicare expenditures, and shared savings.'' Thus, we decline to adopt suggestions that we consider an ACO's costs associated with establishing or implementing a beneficiary incentive program in rebasing benchmarks or in adjusting an ACO's financial results.

Comment: Some commenters recommended that CMS explore additional tools similar to beneficiary incentive programs to encourage beneficiaries to seek and receive preventative and care management services that ultimately lower costs and reduce unnecessary utilization. One commenter requested that CMS provide descriptive examples of permissible beneficiary incentive programs and implement a system to respond to ACOs' questions regarding such programs. A few commenters suggested that we allow ACOs to furnish beneficiary incentives similar to those provided under Medicare Advantage (MA). One of the commenters specifically expressed that CMS should incorporate aspects of the MA Value-Based Insurance Design Model into the Shared Savings Program, by allowing ACOs to offer supplemental benefits such as food vouchers or reduced cost sharing to align beneficiaries with specified chronic conditions. Another commenter urged CMS to consider allowing ACOs to use patient engagement tools (including those provided by MA), such as allowing NPI-level participation, providing ACOs with upfront funding for transportation services, and waiving certain post-discharge home supervision requirements.

A few commenters proposed that CMS allow ACOs to waive copayments. One of these commenters recommended that CMS, OIG, and the Innovation Center allow ACOs to waive co-payments and deductibles in the ACO's first performance year and then conditionally based on an ACO's achievement of minimum quality scores in subsequent years. Another commenter encouraged CMS to waive patient cost sharing for certain health services that have been shown to successfully provide beneficiaries with preventative care services such as care management (including annual wellness visits and chronic care management services), stating that the administrative burden associated with collecting cost sharing leads many health care providers to simply not offer certain services.

Response: We will take the commenters' suggestions under consideration for future rulemaking, however, at this time, we are implementing beneficiary incentive programs in accordance with the provisions as set forth in section 1899(m) of the Act. We direct commenters to our discussion in the preamble to the August 2018 proposed rule (see 83 FR 41868 through 41874), where we explained the wide variety of incentives that could be acceptable under our existing regulation at § 425.304(a).

Comment: Some commenters suggested that entities other than an ACO should be permitted to distribute incentive payments to beneficiaries. One commenter recommended that we modify our proposed policy to allow ACO participants to furnish incentive payments on the basis that ACO participants will likely share in an ACO's savings and losses. Another commenter stated that it would be more effective if ACO provider/suppliers, and not the ACO legal entity, furnish inventive payments at the point of care. These commenters noted that this would help prevent incentives from being used as a recruitment tool. Another commenter recommended that we permit each individual ACO to determine the best method for distributing incentive payments under its beneficiary incentive program. Other commenters suggested that we allow an ACO to implement its beneficiary incentive program through select ACO participants instead of on an ACO-wide basis.

Response: Section 1899(m)(1)(A) of the Act provides that ''an ACO . . . may apply to establish an ACO Beneficiary Incentive Program to provide incentive payments to such beneficiaries who are furnished qualifying services.'' Additionally, 1899(m)(2)(D) of the Act refers to ''an incentive payment made by an ACO pursuant to an ACO Beneficiary Incentive Program.'' We interpreted these two statements to mean that only an ACO, not an ACO participant or ACO provider/supplier, may furnish incentive payments to beneficiaries. We also believe that ACOs are better equipped to deal with tracking incentives because they receive claims data that they can use to identify beneficiaries who received a qualifying service and must be offered an incentive payment. In addition, we believe that ACOs are better equipped to handle reporting, record retention, and audit requirements associated with beneficiary incentive programs. For example, in most instances, ACOs are better equipped to implement and standardize the necessary reporting structure and record keeping requirements set forth in § 425.304(c). ACO participants are less likely to have the technology necessary to appropriately track and report on the distribution of incentive payments. Allowing ACO participants to furnish incentive payments may result in ACO participants incurring additional cost to update their reporting systems. For these reasons, we decline to permit entities other than an ACO to distribute incentive payments to beneficiaries.

Comment: A few commenters suggested that CMS permit ACOs other than those participating under Track 2, Levels C, D, or E of the BASIC track, or the ENHANCED track to establish beneficiary incentive programs. One of these commenters asserted that allowing additional types of ACOs the opportunity to provide beneficiary incentive programs could provide CMS with better information about the types of incentive payments that work best for different kinds of beneficiaries (such as beneficiaries from different backgrounds or with different conditions). The commenter believes that this type of information could provide CMS with valuable lessons learned and model practices that could later be used to expand and strengthen beneficiary incentive programs across other healthcare settings. Another commenter strongly believed that high-value patient care is dependent upon clinicians having the tools to effectively manage beneficiary care and therefore recommended that we allow ACOs in one-sided model arrangements to provide incentives.

Response: While we appreciate the commenters' concerns, we decline to permit ACOs other than those participating under Track 2, Levels C, D,

or E of the BASIC track, or the ENHANCED track to establish beneficiary incentive programs. Section 1899(m)(2)(B) of the Act authorizes only ''an ACO participating . . . under a payment model described in clause (i) or (ii) of paragraph (2)(B)'' to establish an ACO beneficiary incentive program. As we previously discussed, Track 2 and ENHANCED track ACOs are described under section 1899(m)(2)(B)(i) of the Act, and ACOs in Levels C, D, or E of the BASIC track are described under section 1899(m)(2)(B)(ii) of the Act. As a result, Track 2 ACOs, ENHANCED track ACOs, and ACOs in Levels, C, D, or E of the BASIC track are the only types of ACOs that are authorized to establish beneficiary incentive programs. For these reasons, we decline to permit ACOs participating in one-sided models to establish beneficiary incentive programs.

Comment: In the August 2018 proposed rule, we sought comment on whether beneficiary notifications required under § 425.312(a) should include information regarding the availability of an ACO's beneficiary incentive program, and, if so, whether CMS should supply template language on the topic. We received a variety of comments on this issue. A few commenters supported CMS supplying template language on the basis that it would limit the potential for fraud and abuse. These commenters recommended that CMS test its template language to ensure it is accurate, neutral, and not misleading. One ACO commenter expressed that ACOs should be allowed to develop marketing and outreach materials to explain the program and the terms under which a beneficiary could receive an incentive payment. Another commenter opposed a beneficiary notification requirement for beneficiary incentive programs because not all ACOs have sufficient funding to implement a beneficiary incentive program. The same commenter recommended that CMS provide standardized language only to ACOs that implement a beneficiary incentive program. A few other commenters opposed beneficiary notification requirements and supported a prohibition on advertisements on the basis that notifications and advertisement may be used to inappropriately steer beneficiaries toward an ACO. One commenter believed that advertising of beneficiary incentive programs would be too fraught with program integrity risks but stated that CMS should supply ACOs with template language for beneficiary notifications on the topic.

Response: We have modified our policy to require that an ACO or its ACO participants notify beneficiaries of the availability of the beneficiary incentive program in accordance with § 425.312(b). We continue to believe that patient engagement is an important part of motivating and encouraging more active participation by beneficiaries in their health care and that notifying beneficiaries of their ability to receive an incentive payment may encourage beneficiaries to obtain medically necessary primary care services. We also agree with commenters who believe that ACOs that operate a beneficiary incentive program should use a standardized template, developed by CMS, to inform beneficiaries of the availability of a beneficiary incentive program.

Thus, as detailed in II.C.3.a, under § 425.304(c)(4)(iii) and as set forth in § 425.312, we will require that an ACO or its ACO participants notify assigned beneficiaries of the availability of a beneficiary incentive program using the standardized beneficiary notice template provided by CMS. In § 425.312 we provide the requirements regarding how an ACO must furnish such notifications, specifically, that the notification must be carried out by an ACO or its ACO participants during each relevant performance year by providing each assigned beneficiary with a standardized written notice prior to or at the first primary care visit of the performance year in the form and manner specified by CMS.

We believe it is important that ACOs and/or their ACO participants provide beneficiaries with a standardized, CMS-developed beneficiary notice in order to limit the potential for fraud and abuse. In addition, in an effort to prevent ''cherry-picking'' and ''lemon-dropping'' of beneficiaries, or other types of beneficiary steering, we are finalizing our proposal to prohibit ACOs from offering an incentive payment as part of marketing materials and activities, including but not limited to, an advertisement or solicitation, to a beneficiary. We believe this prohibition is necessary to prevent large, high revenue ACOs that have the necessary capital to establish and operate a beneficiary incentive program from steering beneficiaries away from smaller, low revenue ACOs. We note that the beneficiary incentive program notification required under § 425.304(c)(4)(iii) will be exempt from the prohibition on marketing a beneficiary incentive program.

Upon publication of the rule, CMS will publish guidance regarding beneficiary notifications that include education and outreach materials that an ACO must use to notify beneficiaries' about its beneficiary incentive program. Finally, we agree with commenters' suggestions that we test the template language to ensure it is accurate, neutral, and not misleading. We plan to work with our internal partners to conduct beneficiary focus groups to test the template language.

Comment: We received conflicting commenter feedback regarding our proposed record retention and reporting requirements related to beneficiary incentive programs. A few commenters supported our proposal to require ACOs to maintain and make available to CMS records that identify each beneficiary that received an incentive payment, the ACO provider/supplier that furnished the qualifying service, the amount of each incentive payment made to each beneficiary, the date of service each beneficiary received a qualifying service, and date the ACO provided each incentive payment. These commenters suggested that ACOs should be permitted to publically report this information to enable interested beneficiaries to find more information on beneficiary incentive programs. One of the commenters encouraged CMS to reduce administrative burden by adopting a policy that requires ACOs to maintain records related to their beneficiary incentive programs but does not require ACOs to publicly report information under § 425.308.

Other commenters were opposed to our proposed record retention requirements for approved beneficiary incentive programs, arguing that they impose overly burdensome data managing requirements that will result in additional uncompensated operating expenses that CMS would not reimburse. One commenter stated that our proposal would discourage ACOs from implementing a beneficiary incentive program because it would require them to develop a database to track and annually report on the results of a beneficiary incentive program. Another commenter recommended that CMS reduce burden on ACOs by instead relying on existing claims or other available data for such information.

Response: We appreciate the commenters' concerns regarding the potential burden of our proposed reporting requirements, however, we believe it is important for an ACO to be accountable for its beneficiary incentive program and that such requirements are necessary to help mitigate any fraud, waste, or abuse that may occur under a beneficiary incentive program. In addition, we note that section 1899(m)(2)(G) of the Act provides that

an ACO conducting a beneficiary incentive program ''shall, at such times and in such format as the Secretary may require . . . retain such documentation as the Secretary may require, including the amount and frequency of incentive payments made and the number of Medicare fee-for-service beneficiaries receiving such payments.'' Accordingly, we are finalizing without modification our proposal to require that an ACO that implements a beneficiary incentive program must, in accordance with § 425.314(b), maintain and make available the records described in our proposal at § 425.304(c)(4). We believe that the transparency associated with our proposed reporting requirements is necessary to help mitigate the potential for fraud and program integrity concerns. In addition, we disagree with the suggestion that CMS use its claims data to determine whether a beneficiary received a qualifying service. We cannot safely assume that an ACO distributed an incentive payment for a qualifying service to a beneficiary solely based on claims data.

Comment: A few commenters opposed a policy that we considered in our proposed rule that would require an ACO that offers a beneficiary incentive program to notify CMS of any modification to its beneficiary incentive program prior to implementing such modification. The commenters expressed their belief that this requirement would be too broad and would unnecessarily delay an ACO's ability to implement changes to its operational processes because the ACO would need to await CMS' decision on the ACO's proposed modification to its beneficiary incentive program. One commenter expressed concern that this sort of notification could prevent ACOs from making changes to the program that would ultimately help beneficiaries.

Response: We have revisited whether to require an ACO to notify CMS of any modification to its beneficiary incentive program prior to implementing such modification. After additional consideration, we believe such a policy would support program integrity because it would allow us to ensure that the requested modification meets program requirements. In addition, this policy would allow us to evaluate beneficiary incentive programs as required under § 50341(c) of the BBA. Therefore, we are finalizing at § 425.304(c)(2)(iii) a provision that requires an ACO to submit to CMS a description of any proposed material change to its CMS-approved beneficiary incentive program. Such notice must be submitted in the form and manner and by the deadline specified by CMS. The new provision further states that CMS will promptly evaluate the proposed material change and approve or reject it. We anticipate requiring 30 days advance notice of the proposed changes, which should allow us sufficient time to review the changes and thereby allow ACOs to make the approved changes on a timely basis.

We anticipate providing additional guidance on what constitutes a ''material change'' to a beneficiary incentive program. As an example, because we anticipate that the beneficiary incentive program application will require ACOs to specify the value of the incentive payment that the ACO is planning to issue for each qualifying service, we would consider a material change to include any change in the dollar amount of the incentive.

Comment: Some commenters recommended that CMS expand the definition of qualifying service to include additional services. One commenter suggested that we include annual wellness visits in the definition of qualifying service to promote annual wellness visits as a best practice for beneficiary engagement. One commenter suggested that CMS allow each ACO to select which qualifying services it would incentivize under its beneficiary incentive program. Another commenter suggested that transportation services should be included in the definition of a qualifying service.

Response: CMS appreciates the commenters' feedback. Section 1899(m)(2)(C) of the Act defines ''qualifying service,'' for which incentive payments may be made to beneficiaries, as a primary care service, as defined in § 425.20 (or in any successor regulation), with respect to which coinsurance applies under part B. Section 1899(m)(2)(C) of the Act also provides that a qualifying service is a service furnished through an ACO by: (1) An ACO professional described in section 1899(h)(1)(A) of the Act who has a primary care specialty designation included in the definition of primary care physician under § 425.20 (or any successor regulation); (2) an ACO professional described in section 1899(h)(1)(B) of the Act; or (3) a FQHC or RHC (as such terms are defined in section 1861(aa) of the Act). For this reason, we decline to allow ACOs to select the qualifying services that they would incentivize under a beneficiary incentive program or to include transportation services in the definition of a qualifying service. However, we will consider expanding the definition of primary care service (as defined in § 425.20) in future rulemaking so that additional services, such as wellness visits, may be considered ''qualifying services.''

Comment: One commenter recommended that CMS make available summary information about the use of beneficiary incentive programs by beneficiaries when ACO program results are released to help ACOs determine whether to implement a beneficiary incentive program.

Response: We will consider the commenter's suggestion to provide ACOs with analyses of the use of the beneficiary incentive programs in future years, after we have gathered sufficient program data.

Comment: A few commenters recommended that CMS permit ACOs to use targeted beneficiary incentive payments as tool in population health management. One commenter suggested that enabling ACOs to leverage beneficiary incentives to target certain high-risk populations while excluding lower-risk populations, may maximize an ACO's ability to make the most of limited resources and address the needs of high-risk beneficiaries.

Response: Section 1899(m) of the Act does not differentiate between high- and low-risk beneficiaries and does not authorize CMS to do so. Rather, section 1899(m)(2)(B) requires that an ACO that establishes a beneficiary incentive program provide incentive payments to each assigned Medicare fee-for-service beneficiary who is furnished a qualifying service. Furthermore, we believe it would be unfair to prohibit certain beneficiaries from receiving an incentive payment under an approved beneficiary incentive program and we would not want to dissuade low-risk beneficiaries from receiving preventative care in the form of a primary care service. Accordingly, we decline to adopt the commenters' suggestions.

Final Action: We are finalizing our proposals regarding beneficiary incentive program as follows:

- We are finalizing § 425.304(c)(1) to state that for performance years beginning on July 1, 2019 and for subsequent performance years, an ACO that is participating under Track 2, Levels C, D, or E of the BASIC track, or the ENHANCED track may establish a beneficiary incentive program to provide monetary incentive payments to Medicare fee-for-service beneficiaries who receive a qualifying service.
- We are finalizing our application procedures policy at § 425.304(c)(2) to state that to establish or reestablish a beneficiary incentive program, an ACO must submit a complete application in the form and manner and by a deadline specified by CMS. CMS will evaluate an ACO's application to

determine whether the ACO satisfies the requirements of this section, and approve or deny the application. If an ACO wishes to make a material change to its CMS approved beneficiary incentive program, the ACO must submit a description of the material change to CMS in a form and manner and by a deadline specified by CMS. CMS will promptly evaluate the proposed material change and approve or reject it.

• We are finalizing beneficiary incentive program requirements at § 425.304(c)(3). Under section § 425.304(c)(3) an ACO must begin to operate its approved beneficiary incentive program beginning on July 1, 2019 or January 1 of the relevant performance year. In addition, we are finalizing § 425.304(c)(3)(i) to state that, subject to the termination provisions we are finalizing at § 425.304(c)(7), an ACO must operate its approved beneficiary incentive program for an initial period of 18 months in the case of an ACO approved to operate a beneficiary incentive program beginning on July 1, 2019, or 12 months in the case of an ACO approved to operate a beneficiary incentive program beginning on January 1 of a performance year. For each consecutive year that an ACO wishes to operate its beneficiary incentive program after the CMS-approved initial period, it must certify its intent to continue to operate the beneficiary incentive program for the entirety of the relevant performance year and that the beneficiary incentive program meets all applicable requirements. Furthermore, we are finalizing provisions at § 425.304(c)(3)(ii) to state that a fee-for-service beneficiary is eligible to receive an incentive payment under a beneficiary incentive program if the beneficiary is assigned to the ACO through either preliminary prospective assignment, as described in § 425.400(a)(2), or prospective assignment, as described in § 425.400(a)(3). We are finalizing § 425.304(c)(3)(iii) to state that a qualifying service for the program is a primary care service (as defined in § 425.20) with respect to which coinsurance applies under Part B, if the service is furnished through an ACO by either an ACO professional who has a primary care specialty designation included in the definition of primary care physician under § 425.20, an ACO professional who is a physician assistant, nurse practitioner, or certified nurse specialist, or a FQHC or RHC. In addition, we are finalizing § 425.304(c)(3)(iv) to state that an ACO that establishes a beneficiary incentive program must furnish an incentive payment for each qualifying service furnished to an eligible beneficiary. Each such incentive payment must: (1) Be in the form of a check, debit card, or a traceable cash equivalent; (2) not exceed $20, as adjusted annually by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year, rounded to the nearest whole dollar amount; and (3) be provided by the ACO to the beneficiary no later than 30 days after a qualifying service is furnished. An ACO must furnish incentive payments in the same amount to each eligible Medicare fee-for-service beneficiary without regard to enrollment of such beneficiary in a Medicare supplemental policy (described in section 1882(g)(1) of the Act), in a State Medicaid plan under title XIX or a waiver of such a plan, or in any other health insurance policy or health benefit plan.

• We are finalizing program integrity requirements at § 425.304(c)(4). Specifically, we are finalizing § 425.304(c)(4)(i) to state that an ACO that establishes a beneficiary incentive program must maintain records related to the beneficiary incentive program that include: The identification of each beneficiary that received an incentive payment, including beneficiary name and HICN or Medicare beneficiary identifier; the type and amount of each incentive payment made to each beneficiary; the date each beneficiary received a qualifying service, the corresponding HCPCS code for the qualifying service, and identification of the ACO provider/supplier that furnished the qualifying service; and the date the ACO provided each incentive payment to each beneficiary. In addition, we are finalizing § 425.304(c)(4)(ii) to state that An ACO must not use funds from any entity or organization outside of the ACO to establish or operate a beneficiary incentive program and must not directly, through insurance, or otherwise, bill or otherwise shift the cost of establishing or operating a beneficiary incentive program to a Federal health care program. Furthermore, under § 425.304(c)(4)(iii) we are requiring that an ACO or its ACO participants notify assigned beneficiaries of the availability of the beneficiary incentive program in accordance with § 425.312(b). We are finalizing § 425.304(c)(4)(iv) to state that, except for the beneficiary notifications required under § 425.304(c) section, the beneficiary incentive program must not be the subject of marketing materials and activities, including but not limited to, an advertisement or solicitation to a beneficiary or any potential patient whose care is paid for in whole or in part by a Federal health care program (as defined at 42 U.S.C. 1320a–7b(f)).

• We are finalizing § 425.304(c)(5) to state that CMS disregards incentive payments made by an ACO under § 425.304(c)(1) in calculating an ACO's benchmarks, estimated average per capita Medicare expenditures, and shared savings and losses.

• We are finalizing § 425.304(c)(6) to state that incentive payments made under a beneficiary incentive program are not considered income or resources or otherwise taken into account for purposes of determining eligibility for benefits or assistance (or the amount or extent of benefits or assistance) under any Federal program or under any State or local program financed in whole or in part with Federal funds, or for purposes of any Federal or State laws relating to taxation.

• We are finalizing § 425.304(c)(7) to state that CMS may require an ACO to terminate its beneficiary incentive program at any time for either failure to comply with the requirements set forth in § 425.304 or any of the grounds for ACO termination set forth in § 425.218(b).

d. Clarification of Existing Rules

As explained in the preamble to the August 2018 proposed rule, we are also taking this opportunity to add regulation text at renumbered § 425.304(b)(3) to clarify that the in-kind items or services provided to a Medicare FFS beneficiary under § 425.304 must not include Medicare-covered items or services, meaning those items or services that would be covered under Title XVIII of the Act on the date the in-kind item or service is furnished to the beneficiary. It was always our intention that the in-kind items or services furnished under existing § 425.304(a) be non-Medicare-covered items and services so that CMS can accurately monitor the cost of medically necessary care in the Shared Savings Program and to minimize the potential for fraud and abuse. We also clarify that the 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. Finally, we proposed a technical change to the title and structure of § 425.304. Specifically, we proposed to replace the title of § 425.304 with ''Beneficiary incentives'' and to add a new section § 425.305, with a title ''Other program safeguards'', by redesignating paragraphs § 425.304(b) and (c) as § 425.305(a) and (b), and to make conforming changes to regulations that refer to section § 425.304. Specifically, we proposed to make the following conforming changes: amending § 425.118 in paragraph (b)(1)(iii) by removing ''§ 425.304(b)'' and adding in its place ''§ 425.305(a)''; amending § 425.224 in newly redesignated paragraph (b)(1)(v) by removing ''§ 425.304(b)'' and adding in its place ''§ 425.305(a)''; amending § 425.310 in paragraph (c)(3) by removing ''§ 425.304(a)'' and adding in its place ''§ 425.304''; and amending § 425.402 in paragraph (e)(3)(i) by removing ''§ 425.304(a)(2)'' and adding in its place ''§ 425.304(b)(1).''

Final Action: We did not receive any comments specifically addressing our proposed technical changes to the title and structure of § 425.304. Therefore, we are finalizing our proposed technical changes without modification.

3. Empowering Beneficiary Choice

a. Beneficiary Notifications

(1) Background on Beneficiary Notifications

To ensure full transparency between providers participating in Shared Savings Program ACOs and the beneficiaries they serve, the November 2011 final rule established requirements for how a Shared Savings Program ACO must notify Medicare FFS beneficiaries receiving primary care services at the

point of care that the physician, hospital, or other provider is participating in a Shared Savings Program ACO (76 FR 67945 through 67946). Specifically, the November 2011 final rule established a requirement that ACO participants provide standardized written notices to beneficiaries of both their ACO provider's/supplier's participation in the Shared Savings Program and the potential for CMS to share beneficiary identifiable data with the ACO.

We initially established the beneficiary notification requirements for ACOs to protect beneficiaries by ensuring patient engagement and transparency, including requirements related to beneficiary notification, since the statute does not mandate that ACOs provide information to beneficiaries about the Shared Savings Program (76 FR 67945 through 67946). The beneficiary information notices included information on whether a beneficiary was receiving services from an ACO participant or ACO provider/supplier, and whether the beneficiary's expenditure and quality data would be used to determine the ACO's eligibility to receive a shared savings payment.

In the June 2015 final rule, we amended the beneficiary notification requirement and sought comment on simplifying the process of disseminating the beneficiary information notice. We received numerous comments from ACOs that the beneficiary notification requirement was too burdensome and created some confusion amongst beneficiaries about the Shared Savings Program (80 FR 32739). As a result, we revised the rule so that ACO providers/suppliers would be required to provide the notification by simply posting signs in their facilities and by making the notice available to beneficiaries upon request.

We also amended our rule to streamline the beneficiary notification process by which beneficiaries may decline claims data sharing and finalized the requirement that ACO participants use CMS-approved template language to notify beneficiaries regarding participation in an ACO and the opportunity to decline data sharing. In order to streamline operations, reduce burden and cost on ACOs and their providers, and avoid creating beneficiary confusion, we also streamlined the process for beneficiaries to decline data sharing by consolidating the data opt out process through 1–800–MEDICARE in the June 2015 final rule (80 FR 32737 through 32743). Beneficiaries must contact 1–800–MEDICARE to decline sharing their Medicare claims data or to reverse that decision.

As we explained in the August 2018 proposed rule, under the program's current requirements, an ACO participant (for example physician practices and hospitals) must notify beneficiaries in writing of its participation in an ACO by posting signs in its facilities and, in settings in which beneficiaries receive primary care services, by making a standardized written notice (the ''Beneficiary Information Notice'') available to beneficiaries upon request (§ 425.312). We provide ACOs with templates, in English and Spanish, to share with their ACO participants for display or distribution. To summarize:

- The poster language template indicates the providers' participation in the Shared Savings Program; describes ACOs and what they mean for beneficiary care; highlights that a beneficiary's freedom to choose his or her doctors and hospitals is maintained; and indicates that beneficiaries have the option to decline to have their Medicare Part A, B, and D claims data shared with their ACO or other ACOs. The poster must be in a legible format for display and in a place where beneficiaries can view it.
- The Beneficiary Information Notice template covers the same topics and includes details on how beneficiaries can select their primary clinician via *MyMedicare.gov* and voluntarily align to the ACO.

In addition to these two templates, there are currently two other ways that beneficiaries can learn about ACOs and of their option to decline Medicare claims data sharing with ACOs:

- Medicare & You handbook. The language in the ACO section of the handbook (available at *https://www.medicare.gov/pubs/pdf/10050-Medicare-and-You.pdf*) describes ACOs and tells beneficiaries they will be notified at the point of care if their doctor participates in the Shared Savings Program. It explains what doctor participation in an ACO means for a beneficiary's care and that beneficiaries have the right to receive care from any doctor that accepts Medicare. The ACO section of the handbook also explains that beneficiaries must call 1–800–MEDICARE (1–800–633–4227) to decline sharing their health care information with ACOs or to reverse that decision.
- 1–800–MEDICARE. Customer service representatives are equipped with scripted language about the Shared Savings Program, including background about ACOs. The customer service representatives also can collect information from beneficiaries about declining or reinstating Medicare claims data sharing.

Further, beginning in July 2017, Medicare FFS beneficiaries have been able to login to *MyMedicare.gov* to select the primary clinician whom they believe is most responsible for their overall care coordination (a process we refer to as voluntary alignment). The instructions for selecting a primary clinician are also included in the Medicare & You handbook, issued by CMS annually to Medicare beneficiaries. The Shared Savings Program uses a beneficiary's selection of a primary clinician for assignment purposes, when applicable, for ACOs in all tracks beginning in performance year 2018 (§ 425.402(e)).

We have made information about the Shared Savings Program publicly available to educate ACOs, providers/suppliers, beneficiaries and the general public, and to further program transparency. This includes fact sheets, program guidance and specifications, program announcements and data available through the Shared Savings Program website (see *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html*). This material includes resources designed to educate beneficiaries about the Shared Savings Program and ACOs,[22] and specifically on the voluntary alignment process.[23]

(2) Proposed Revisions

In the August 2018 proposed rule, we proposed to revisit the program's existing requirements at § 425.312 to ensure beneficiaries have a sufficient opportunity to be informed about the program and how it may affect their care and their data (83 FR 41875). We also proposed changes in response to section 50331 of the Bipartisan Budget Act, which amends section 1899(c) of the Act to require that the Secretary establish a process by which Medicare FFS beneficiaries are (1) ''notified of their ability'' to identify an ACO professional as their primary care provider (for purposes of assigning the beneficiary to an ACO, as described in § 425.402(e)) and (2) ''informed of the process by which they may make and change such identification.''

In proposing revisions to § 425.312 we considered how to make the notification a comprehensive resource that compiles certain information about the program and what participation in the program means for beneficiary care. We were concerned that, while there are many sources of information on the program that are available to beneficiaries, the existing information exists in separate resources, which may be time

[22] Accountable Care Organizations & You, available at *https://www.medicare.gov/Pubs/pdf/11588-Accountable-Care-Organizations-FAQs.pdf.*

[23] Empowering Patients to Make Decisions About Their Healthcare: Register for *MyMedicare.gov* and Select Your Primary Clinician, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/vol-alignment-bene-fact-sheet.pdf.*

consuming for beneficiaries to compile, and, as a result, may be underutilized.

In the August 2018 proposed rule, we also considered methods of notification that would better ensure that beneficiaries receive the comprehensive notification at the point of care. Our existing regulations emphasize use of posted signs in facilities and, in settings where beneficiaries receive primary care services, standardized written notices as a means to notify beneficiaries at the point of care that ACO providers/suppliers are participating in the program and of the beneficiary's opportunity to decline data sharing. We expressed our concern that, although standardized written notices must be made available upon request, few beneficiaries, or others who accompany beneficiaries to their medical appointments, may initiate requests for this information and, in turn, beneficiaries may not have the information they need to make informed decisions about their health care and their data.

Finally, in the August 2018 proposed rule, we considered how to minimize burden on the ACO providers/suppliers that would provide the notification. We sought to balance the requirements of the notification to beneficiaries with the increased burden on health care providers that could draw their attention away from patient care.

With these considerations in mind, and to further facilitate beneficiary access to information on the Shared Savings Program, we proposed to modify § 425.312(a) to require additional content for beneficiary notices. We proposed that, beginning July 1, 2019, the ACO participant must notify beneficiaries at the point of care about voluntary alignment in addition to notifying beneficiaries that its ACO providers/suppliers are participating in the Shared Savings Program and that the beneficiary has the opportunity to decline claims data sharing. Specifically, the ACO participant must notify the beneficiary of his or her ability to, and the process by which, he or she may identify or change identification of a primary care provider for purposes of voluntary alignment.

We proposed to modify § 425.312(b) to require that, beginning July 1, 2019, ACO participants must provide the information specified in § 425.312(a) to each Medicare FFS beneficiary at the first primary care visit of each performance year. Under our proposal, an ACO participant would be required to provide this notice during a beneficiary's first primary care visit in the 6-month performance year from July 1, 2019 through December 31, 2019, as well as the first primary care visit in the 12-month performance year that begins on January 1, 2020 (and in all subsequent performance years). We proposed that this notice would be in addition to the existing requirement that an ACO participant must post signs in its facilities and make standardized written notices available upon request.

To mitigate the burden of this additional notification, we proposed to require ACO participants to use a template notice that we would prepare and make available to ACOs. We explained that the template notice would contain all of the information required to be disclosed under § 425.312(a), including information on voluntary alignment. With respect to voluntary alignment, we explained that the template notice would provide details regarding how a beneficiary may select his or her primary care provider on *MyMedicare.gov*, and the step-by-step process by which a beneficiary could designate an ACO professional as his or her primary care provider, and how the beneficiary could change such designation. We also explained that the CMS-developed template notice would encourage beneficiaries to check their ACO professional designation regularly and to update such designation when they change care providers or move to a new area. We stated that the template notice could be provided to beneficiaries at their first primary care visit during a performance year, and the same template notice could be furnished upon request in accordance with our existing regulation at § 425.312(b)(2).

We expressed our belief that this proposed approach would appropriately balance the factors we described and achieve our desired outcome of more consistently educating beneficiaries about the program while mitigating burden of additional notification on ACO participants. In addition, we believed this approach would provide detailed information on the program to beneficiaries more consistently at a point in time when they may be inclined to review the notice and have an opportunity to ask questions and address their concerns. Furthermore, we believed this approach would pose relatively little additional burden on ACO participants, since they are already required to provide written notices to beneficiaries upon request.

We sought comment as to alternative means of dissemination of the beneficiary notice, including the frequency with which and by whom the notice should be furnished. For example, we sought comment on 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. We also sought comment on whether there are alternative media for disseminating the beneficiary notice that might be less burdensome on ACOs, such as dissemination via email.

In addition, we solicited comment on whether the template notice should include other information outlining ACO activities that may be related to or affect a Medicare FFS beneficiary. We explained that such activities could include: ACO quality reporting and improvement activities, ACO financial incentives to lower growth in expenditures, ACO care redesign processes (such as use of care coordinators), the ACO's use of payment rule waivers (such as the SNF 3-day rule waiver), and the availability of an ACO's beneficiary incentive program.

We also welcomed feedback on the format, content, and frequency of our proposed additional notice to beneficiaries about the Shared Savings Program, the benefits and drawbacks to requiring additional notification about the program at the point of care, and the degree of additional burden this notification activity could place on ACO participants. More specifically, we welcomed feedback on 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.

We also took the opportunity to propose regulation text at renumbered § 425.312(a) to clarify our longstanding requirement that beneficiary notification obligations apply with regard to all Medicare FFS beneficiaries, not only to beneficiaries who have been assigned to an ACO (76 FR 67945 through 67946). We sought comment on 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.

Finally, we proposed technical changes to the title and structure of § 425.312. For example, we proposed to replace the title of § 425.312 with ''Beneficiary notifications.''

Comment: Although a few commenters supported our proposed changes to the beneficiary notice requirements, most commenters did not support them. One commenter, a national, nonprofit consumer service organization that works to ensure access to affordable health care for older adults and people with disabilities, supported

the revised beneficiary notice requirements. This commenter stated that CMS templates—especially those that have been consumer-tested for clarity and effectiveness—are appropriate when there is a risk of beneficiary steering, such as with voluntary alignment. A few commenters, including two national non-profit legal senior citizen advocacy organizations and a provider advocacy group, generally supported our proposal but urged us to do consumer testing on the standardized notice that we would develop to ensure relevant information is conveyed accurately and objectively, in a manner that beneficiaries can use and understand.

Some commenters supported our proposal to require that the notice address a beneficiary's ability to, and the process by which a beneficiary may, identify a primary care provider for purposes of voluntary alignment. One commenter expressed the belief that the proposed notice requirements would encourage ACO participants to engage patients in conversations describing patient rights; give beneficiaries critical information about possible consequences of receiving care in an ACO, including whether ACO participants are incentivized in ways that could affect service delivery; and better enable beneficiaries to select the best ACO for their needs. One commenter stated its support for the proposal and believed that beneficiaries are more likely to review the information and ask questions if the notice is provided at the point of care. This commenter suggested that the beneficiary notice should not simply be included with other routine forms.

However, in contrast, a majority of commenters stated that the new notification requirements would be burdensome on practices from a workflow, efficiency, and supply cost perspective. Some commenters opined that it would be challenging to add another notice to the important documents that patients are already asked to review with each visit. Several commenters specifically stated that this proposal was in direct contrast to our Patients over Paperwork initiative. Some commenters stated that the administrative burden imposed by our proposed notification requirements would especially burden ACOs comprised of independent physician practices, which would have difficulty ensuring that beneficiaries do not receive duplicative notices if the beneficiaries see clinicians at different practices during the year.

Some commenters stated that clinical workflows and electronic record systems would require reconfiguration for scheduling additional visit time, incorporating reminder prompts, and documentation of required notice delivery. Some of these commenters also indicated that our proposed policy would require a large investment by ACOs in building out electronic health records (EHR) system workflows, educating providers and staff, and tracking compliance with requirements, taking away from the beneficiaries' care and taking away from limited IT resources.

Many commenters requested that we refrain from implementing mandatory written annual notifications. Several commenters suggested that, if CMS believes that beneficiaries receive the notification, then CMS should instead disseminate the notice to beneficiaries.

Many commenters expressed their belief that our proposed changes would fail to improve the beneficiary notification process and suggested that we continue with our existing beneficiary notification requirements. Some commenters stated that CMS has not provided any evidence that beneficiaries are inadequately notified. Other commenters suggested that, rather than creating a new notice requirement, we should strengthen the existing notifications that ACO participants deliver to beneficiaries. In addition, many commenters noted that we previously tried a similar notification policy that was later removed in the 2015 Shared Savings Program final rule (80 FR 32740) after stakeholders explained that the beneficiary notification template was confusing to beneficiaries.

One commenter disagreed with the proposal while also describing our existing notification requirements as too burdensome for ACO participants. This commenter expressed its belief that it is costly for an ACO to keep up with new templates and replace signs in its facilities every year.

Response: We appreciate the support that we have received for our proposed beneficiary notification requirements. In addition, while we understand the apprehension that many commenters have regarding our proposed beneficiary notification requirements, we believe that it is important to revise our existing notification requirements to ensure that beneficiaries receive information that puts them in the driver's seat and provides them with the information they need to make decisions about their care. The notifications will allow beneficiaries to more fully engage in their health care by helping them better understand their care options and make informed decisions regarding their health care. We believe that this is especially important as the program has made changes to the ways in which beneficiaries may be assigned to an ACO (such as through voluntary alignment) and extended the beneficiary enhancements that are available to ACOs and their assigned beneficiaries.

For these reasons, we believe that it is important that beneficiaries are informed that they are part of an ACO. Again, this information will help beneficiaries better understand their care options and make better-informed decisions regarding their health care. For example, we believe that notifying beneficiaries about an ACO's goals and objectives (for example, improving the health of populations), and each ACO's strategy for achieving such goals and objectives, can serve as a catalyst for educating beneficiaries about the importance of preventive services such as annual wellness visits.

Furthermore, we note that we are required under section 1899(c) of the Act to establish a process by which Medicare fee-for-service beneficiaries are (1) ''notified of their ability'' to identify an ACO professional as their primary care provider (for purposes of assigning the beneficiary to an ACO), and (2) ''informed of the process by which they may make and change such identification.'' We proposed changes to our beneficiary notification requirements in part to address this requirement.

We seek to balance the need to better engage beneficiaries in their health care with the potential for increased burden on ACO participants. Although many sources of information on the program are already available to beneficiaries, as noted in the preamble to the August 2018 proposed rule (80 FR 41875) we are concerned that the existing information exists in separate resources, which may be time consuming for beneficiaries to compile, and as a result, may be underutilized. Moreover, although we appreciate commenters' concerns that our proposed beneficiary notification requirements may require ACOs or ACO participants to bare additional costs, implement system and EHR changes, or allocate additional time for patient visits (so that participants can explain the content of the notice to beneficiaries), we believe that it is necessary to ensure that beneficiaries are aware of the existence of the ACO to which they are assigned, the choice of the ACO participant and its ACO providers/suppliers to participate in the ACO, the beneficiary's alignment options, and, if applicable, information on a beneficiary incentive program.

We believe that the use of CMS-developed templates, which would be developed and tested with stakeholder feedback, will reduce the overall burden on providers. In addition, after evaluating commenters' concerns, we have decided to modify some of our proposed requirements regarding the beneficiary notice to help further reduce the potential for burden on ACOs and ACO participants.

First, we are modifying our proposed policy to allow an ACO or its ACO participants to disseminate the beneficiary notifications. We believe this change may help mitigate the potential for administrative and operational burden on providers. We note that, in accordance with § 425.314(c), it is the ACO that will ultimately be accountable for compliance with the beneficiary notification requirements.

Second, we will not require that the notification be provided to beneficiaries at the point of care during a beneficiary's first primary care visit of each performance year. Instead, we will require that an ACO or its ACO participants disseminate the beneficiary notification at a beneficiary's first primary care service visit of the performance year or at some point earlier in the performance year. We believe that this change will alleviate some of the operational burdens that may be associated with tracking whether a beneficiary received a notice at its first primary care service visit of a performance year.

Third, although we still encourage ACO participants to distribute the notice to beneficiaries at the point of care to address any beneficiary questions or concerns, we would permit an ACO or its ACO participants to distribute beneficiary notifications through electronic transmission (such as email) or mail. We note that regardless of the method of notification used, under § 425.314, the ACO must maintain and make available evidence that a notification was distributed to each beneficiary.

Finally, we note that we have also restructured the beneficiary notification provision at § 425.312 for clarity. Paragraph (a) of that section now relates to the general notification requirement, which applies with regard to all FFS beneficiaries. In addition, paragraph (b) of that section relates to notifications regarding the availability of a beneficiary incentive program, which applies only with regard to assigned beneficiaries in an ACO that operates a beneficiary incentive program. (As explained in section II.C.2.c. of this final rule, such notifications will be required under § 425.304(c)(4)(iii).) We believe that beneficiary incentive program notification should apply only with regard to assigned beneficiaries (the only types of beneficiaries who can receive an incentive payment under a beneficiary incentive program) because requiring an ACO to provide notice of the availability of a beneficiary incentive program to all FFS beneficiaries would essentially amount to marketing of a beneficiary incentive program. We intend to issue subregulatory guidance regarding the two notifications (the general notification and the beneficiary incentive program notification) and anticipate providing two notification templates: One that addresses the general notification requirements at § 425.312(a) and another that addresses only the beneficiary incentive program requirements at § 425.312(b).

Comment: We received many comments and feedback on the means of dissemination of this additional notice to beneficiaries about the Shared Savings Program, including the drawbacks to requiring additional notification about the program at the point of care and the degree of additional burden this notification activity may place on ACO participants. A few commenters stated that ACO participants should be allowed to decide the means of dissemination. Some commenters suggested that CMS allow for the use of recorded telephone messages to disseminate the beneficiary notifications. Many other commenters suggested that CMS allow ACOs and/or ACO participants to distribute beneficiary notices through electronic mediums. Some commenters believed that ACOs should have the option to provide the beneficiary notice in an electronic or paper format. Several commenters suggested that ACOs be given the option to distribute beneficiary notices to Medicare beneficiaries through means such as patient portal messages or letters instead of being required to physically hand out the notices during a face-to-face visit. These commenters believe that ACOs should be permitted to take advantage of EHR capabilities that allow ACOs to identify and send communications to beneficiaries. One commenter stated that ACOs should provide the notice to beneficiaries via email. Another commenter recommended that CMS consider providing ACOs with talking points they can share with their ACO participants and ACO providers/suppliers to guide verbal notifications to beneficiaries, rather than requiring a written beneficiary notice requirement. Finally, one commenter requested that CMS provide ACOs with beneficiary addresses and phone numbers so that ACOs can contact beneficiaries with the standardized notices on the primary care providers' behalf to streamline the process and reduce the administrative burden.

Response: We understand the commenters concerns and, although we still encourage ACO participants to distribute the notice to patients at the point of care to address any questions or concerns that a beneficiary may have, we plan to require an ACO (directly or through its ACO participants) to distribute beneficiary notifications in writing through electronic transmission (such as email) or mail. We decline to allow for the use of non-written notifications (such as recorded telephone messages) because we believe that such notifications would be difficult for us to monitor and for beneficiaries to retrieve for future reference. We will provide additional information regarding permissible methods of notification in guidance, which we will issue prior to the July 1, 2019 effective date.

Comment: Many commenters did not support CMS' proposal to require ACO participants to disseminate the beneficiary notice at the point of care during a beneficiary's first primary care visit of the performance year and provided alternatives to reduce potential administrative and operational burdens. A few commenters suggested that any ACO provider/supplier should be able to disseminate the notice on the beneficiary's first service visit of the year. Some commenters believed that CMS should instead allow ACOs to provide the notice to beneficiaries at any point during a performance year, and not specifically at a beneficiary's first primary care service visit of the performance year. A few commenters stated that there should not be any restrictions on when the notification must be provided to beneficiaries. Some commenters provided suggestions related to the timing of the notice and coordination across CMS programs. For example, one commenter recommended that beneficiary notifications be aligned between the Shared Savings Program and the Next Generation ACO Model.

Response: Based on the feedback we received from commenters and as previously discussed, we will require an ACO or its ACO participants to disseminate the beneficiary notification at a beneficiary's first primary care service visit of the performance year or at some point earlier in the performance year. In this way, we hope to balance the requested flexibility from ACOs and

ACO participants with the need to provide useful and important information to beneficiaries.

In addition, we note that there are substantial differences between the beneficiary notification requirements for the Shared Savings Program, which is a permanent program established under section 1899 of the Act, and the Next Generation ACO Model, which is being tested by the Innovation Center under section 1115A of the Act. We plan, however, to leverage lessons learned and, where possible, align the notifications as we develop the Shared Savings Program beneficiary notification templates.

Comment: Some commenters expressed concern about the content of the beneficiary notice and whether the information contained in the notice would be accessible to beneficiaries. Many commenters suggested that CMS consider beneficiaries' perspective of the notification and simplify the language in the template notice. Several commenters suggested that we work with stakeholders and beneficiary focus groups on developing the notice and determining the best method for dissemination. Some of these commenters suggested that no new or revised notifications should be implemented without input from these groups.

Several commenters stated that ACOs should be allowed to develop the notification language on their own based on guidance from CMS. These commenters believe that allowing ACOs to develop the notification language would help ensure that the notifications account for the culture of the ACO's region and allow ACOs and ACO participants to engage beneficiaries in a more meaningful way.

Several commenters believe that our proposed changes to the content of the beneficiary notice would cause tremendous beneficiary confusion. A number of commenters opined that ACOs would need to dedicate staff to address beneficiary questions regarding the notifications. One commenter stated that, based on its experience, our previous beneficiary notification requirements (which required that an ACO provide such notification at the point of care) added ten minutes per visit so that providers or staff could explain the template notice to beneficiaries. The commenter also criticized the content of our existing template notice, stating that it is not beneficiary friendly nor written at an appropriate literacy level. The commenter stated its belief that the template notice content causes beneficiaries to become concerned that the government has their data and, as a result, opt-out of data sharing, which limits ACOs from receiving data that would help them coordinate beneficiary care. In addition, a few commenters stated that when we previously instituted beneficiary notice requirements that required notice at the point of care, many beneficiaries were confused and expressed fear that their benefits and/or network would be changed, believed the beneficiary notice was a ''Medicare, Social Security and Internal Revenue scam.'' A few commenters stated that some beneficiaries believed that the data-sharing notification was an attempt by the ACO to steal their identities. These commenters also stated that many ACOs had to reassign staff members from clinical duties to answering beneficiary questions about the notifications.

Several commenters expressed their belief that a comprehensive written notice furnished at the time of a planned primary care visit is likely to overwhelm beneficiaries with information about topics that are only tangentially related to that visit, which would impair clinical efficiency and experience of care for that visit. These commenters also expressed that it is unlikely that the information would be retained or retrieved by beneficiaries for later review. One commenter asserted that the notification should provide clear information about ACO activities that have a tangible impact on care experience including care coordination, beneficiary incentive programs, and the SNF 3-day rule waiver. Finally, a few commenters suggested keeping the notice regarding voluntary alignment separate from all other beneficiary notifications.

Response: We appreciates commenters' concerns that the beneficiary notification may cause confusion among beneficiaries. We plan to work with our internal partners to conduct beneficiary focus groups to ensure that the content of the template notice is written in plain language and is easy for beneficiaries to understand. We will also consider working with focus groups in the future to include information regarding an ACO's use of a SNF 3-day rule waiver and other benefit enhancements. We believe that soliciting beneficiary input during development of the template and testing the template will mitigate concerns over the content of the notice.

In addition, we believe that consolidating the general Shared Savings Program notices to Medicare fee-for-service beneficiaries, including the notification regarding voluntary alignment, into a single template will assist ACO participants in informing beneficiaries about their coordination of care. We invite ACO input through established modes of communication with CMS on any templates that we develop and intend to take such comments into consideration during any future revisions of the templates.

We appreciate that some commenters would like to develop the notification language on their own based on guidance from CMS, however, as stated above, we believe that using template language is important to reduce operational burden and to ensure that beneficiaries receive consistent information regarding the program.

Further, we note that the policy we are finalizing will allow ACOs to choose whether to furnish the notifications (directly or through their ACO participants) prior to or at a beneficiary's first primary care visit of the performance year. This additional flexibility addresses commenter concerns that beneficiaries could be overwhelmed by receiving the notifications during the first primary care visit and that furnishing the notice during such visit would impair clinical efficiency and experience of care.

Finally, we will ensure that the notices comply with any applicable Sections 504 and 508 of the Rehabilitation Act of 1973. Section 508 requires Federal agencies to ensure that people with disabilities have comparable access to and use of electronic information technology. Section 504 requires, among other things, that Federal agencies and recipients of Federal financial assistance provide individuals with disabilities with appropriate auxiliary aids where necessary to ensure effective communication.

Final Action: After considering the comments received, we are finalizing with modification our revisions at § 425.312 regarding beneficiary notifications as follows:

- We are finalizing § 425.312(a)(1) to state that an ACO shall ensure that Medicare fee-for-service beneficiaries are notified about all of the following: (1) That each ACO participant and its ACO providers/suppliers are participating in the Shared Savings Program; (2) the beneficiary's opportunity to decline claims data sharing under § 425.708; and (3) beginning July 1, 2019, the beneficiary's ability to, and the process by which, he or she may identify or change identification of the individual he or she designated for purposes of voluntary alignment (as described in § 425.402(e)). Such notification must be carried out through all of the following methods: (1) By an ACO participant posting signs in its facilities and, in settings in which beneficiaries receive primary care services, making standardized

written notices available upon request; and (2) during the performance year beginning on July 1, 2019 and each subsequent performance year, by an ACO or ACO participant providing each beneficiary with a standardized written notice prior to or at the first primary care visit of the performance year in the form and manner specified by CMS.

- We are finalizing § 425.312(b)(1) to state that, beginning July 1, 2019, an ACO that operates a beneficiary incentive program under § 425.304(c) shall ensure that the ACO or its ACO participants notify assigned beneficiaries of the availability of the beneficiary incentive program, including a description of the qualifying services for which an assigned beneficiary is eligible to receive an incentive payment (as described in § 425.304(c)). We are finalizing § 425.312(b)(2) to state that notification of such information must be carried out by an ACO or ACO participant during each relevant performance year by providing each assigned beneficiary with a standardized written notice prior to or at the first primary care visit of the performance year in the form and manner specified by CMS.

b. Beneficiary Opt-In Based Assignment Methodology

In the November 2011 final rule establishing the Shared Savings Program (76 FR 67865), we discussed comments that we had received in response to our proposed assignment methodology suggesting alternative beneficiary assignment methodologies in order to promote beneficiary free choice. For example, some commenters suggested that a beneficiary should be assigned to an ACO only if the beneficiary ''opted-in'' or enrolled in the ACO. We did not adopt an opt-in or enrollment requirement for several reasons, including our belief that such a prospective opt-in approach that allows beneficiaries to voluntarily elect to be assigned to an ACO would completely sever the connection between assignment and actual utilization of primary care services. A patient could choose to be assigned to an ACO from which he or she had received very few or no primary care services at all. However, more recently, some stakeholders have suggested that we reconsider whether it might be feasible to incorporate a beneficiary ''opt-in'' methodology under the Shared Savings Program. These stakeholders believe that under the current beneficiary assignment methodology, it can be difficult for an ACO to effectively manage a beneficiary's care when there is little or no incentive or requirement for the beneficiary to cooperate with the patient management practices of the ACO, such as making recommended lifestyle changes or taking medications as prescribed. The stakeholders noted that in some cases, an assigned beneficiary may receive relatively few primary care services from ACO professionals in the ACO and the beneficiary may be unaware that he or she has been assigned to the ACO. These stakeholders suggested we consider an alternative assignment methodology under which a beneficiary would be assigned to an ACO if the beneficiary ''opted-in'' to the ACO in order to reduce the reliance on the existing assignment methodology under subpart E and as a way to make the assignment methodology more patient-centered, and strengthen the engagement of beneficiaries in their health care. These stakeholders believe that using such an approach to assignment could empower beneficiaries to become better engaged and empowered in their health care decisions.

Although arguably beneficiaries ''opt-in'' to assignment to an ACO under the existing claims-based assignment methodology in the sense that claims-based assignment is based on each beneficiary's exercise of free choice in seeking primary care services from ACO providers/suppliers, in the August 2018 proposed rule (83 FR 41876) we explained our belief that incorporating an opt-in based assignment methodology, and de-emphasizing the claims-based assignment methodology, could have merit as a way to assign beneficiaries to ACOs. Therefore, we noted that we are exploring options for developing an opt-in based assignment methodology to further encourage and empower beneficiaries to become better engaged and empowered in their health care decisions. This approach to beneficiary assignment might also allow ACOs to better target their efforts to manage and coordinate care for those beneficiaries for whose care they will ultimately be held accountable. As discussed in section II.V.2.b. of the November 2018 final rule (83 FR 59959 through 59964), we have recently implemented a voluntary alignment process, which is an electronic process that allows beneficiaries to designate a primary clinician as responsible for coordinating their overall care. If a beneficiary designates an ACO professional as responsible for their overall care and the requirements for assignment under § 425.402(e) are met, the beneficiary will be prospectively assigned to that ACO. For 2018, the first year in which beneficiaries could be assigned to an ACO based on their designation of a primary clinician in the ACO as responsible for coordinating their care, 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.

Voluntary alignment is based upon the relationship between the beneficiary and a single practitioner in the ACO. In contrast, as we described in the August 2018 proposed rule, an opt-in based assignment methodology would be based on an affirmative recognition of the relationship between the beneficiary and the ACO, itself. Under an opt-in based assignment methodology, a beneficiary would be assigned to an ACO if the beneficiary opted into assignment to the ACO. Therefore, under an opt-in approach, ACOs might have a stronger economic incentive to compete against other ACOs and healthcare providers not participating in an ACO because to the extent the ACO is able to increase quality and reduce expenditures for duplicative and other unnecessary care, it could attract a greater number of beneficiaries to opt-in to assignment the ACO. There are a number of policy and operational issues, including the issues previously identified in the November 2011 final rule that would need to be addressed in order to implement an opt-in based methodology to assign beneficiaries to ACOs. These issues include the process under which beneficiaries could opt-in to assignment to an ACO, ACO marketing guidelines, beneficiary communications, system infrastructure to communicate beneficiary opt-ins, and how to implement an opt-in based assignment methodology that responds to stakeholder requests while conforming with existing statutory and program requirements under the Shared Savings Program. We discussed these issues in Section II.C.3.b of the August 2018 proposed rule.

As we explained in the August 2018 proposed rule, we believe under an opt-in based assignment methodology, it would be important for ACOs to manage notifying beneficiaries, collecting beneficiary opt-in data, and reporting the opt-in data to CMS. On an annual basis, ACOs would notify their beneficiary population about their participation in the Shared Savings Program and provide the beneficiaries a window during which time they could notify the ACO of their decision to opt-in and be assigned to the ACO, or to withdraw their opt-in to the ACO. Opting-in to a Shared Savings Program ACO could be similar to enrolling in a MA plan. MA election periods define when an individual may enroll or

disenroll from a MA plan. An individual (or his/her legal representative) must complete an enrollment request (using an enrollment form approved by CMS, an online application mechanism, or through a telephone enrollment) to enroll in a MA plan and submit the request to the MA plan during a valid enrollment period. MA plans are required by 42 CFR 422.60 to submit a beneficiary's enrollment information to CMS within the timeframes specified by CMS, using a standard IT transaction system. Subsequently, CMS validates the beneficiary's eligibility, at which point the MA plan must meet the remainder of its enrollment-related processing requirements (for example, sending a notice to the beneficiary of the acceptance or rejection of the enrollment within the timeframes specified by CMS). Procedures have been established for disenrolling from a MA plan during MA election periods. (For additional details about the enrollment process under MA, see the CMS website at *https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/index.html,* and the Medicare Managed Care Manual, chapter 2, section 40 at *https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/Downloads/CY_2018_MA_Enrollment_and_Disenrollment_Guidance_6-15-17.pdf*).

Because opting-in or withdrawing an opt-in to assignment to a Shared Savings Program ACO could be similar to enrolling or disenrolling in a MA plan, we would need to establish the ACO opt-in process and timing in a way to avoid beneficiary confusion as to the differences between the Shared Savings Program and MA, and whether the beneficiary is opting-in to assignment to an ACO or enrolling in a MA plan. We would also need to determine how frequently beneficiaries would be able to opt-in or withdraw an opt-in to an ACO, and whether there should be limits on the ability to change an opt-in after the end of the opt-in window, in order to reduce possible beneficiary assignment ''churn''. We noted that beneficiaries opting-in to assignment to an ACO would still retain the freedom to choose to receive care from any Medicare-enrolled provider or supplier, including providers and suppliers outside the ACO. The ACO would be responsible for providing the list of beneficiaries who have opted-in to assignment to the ACO, along with each beneficiary's Medicare number, address, and certain other demographic information, to CMS in a form and manner specified by CMS. After we receive this information from the ACO, we would verify that each of the listed beneficiaries meets the beneficiary eligibility criteria set forth in § 425.401(a) before finalizing the ACO's assigned beneficiary population for the applicable performance year. To perform these important opt-in related functions, ACOs might need to acquire new information technology systems, along with additional support staff, to track, monitor and transmit opt-in data to CMS, including effective dates for beneficiaries who opt-in or withdraw an opt-in to the ACO. Furthermore, changes in an ACO's composition of ACO participants and ACO providers/suppliers could affect a beneficiary's interest in maintaining his or her alignment with the ACO through an opt-in approach. As a result, we explained that we believe it would also be critical for an ACO participating under opt-in based assignment to inform beneficiaries of their option to withdraw their opt-in to the ACO, generally, and specifically, in the event that an ACO participant or ACO provider/supplier, from which the beneficiary has received primary care services is no longer participating in the ACO.

MA has marketing guidelines and requirements that apply to enrollment activities to prevent selective marketing or discrimination based on health status. (See 42 CFR 422.2260 through 422.2276 and section 30.4 of the Medicare Marketing Guidelines located at *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.html*.) We explained that if we were to adopt an opt-in process for the Shared Savings Program, we would impose similar requirements to ensure ACOs are providing complete and accurate information to beneficiaries to inform their decision-making regarding opting-in to assignment to an ACO, and not selectively marketing or discriminating based on health status or otherwise improperly influencing beneficiary choice. Additionally, ACOs would be required to establish a method for tracking the beneficiaries they have notified regarding the opportunity to opt-in to assignment to the ACO, and the responses received. Under § 425.314, ACOs agree and must require their ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to agree that CMS has the right to audit, inspect, investigate, and evaluate records and other evidence that pertain to the ACO's compliance with the requirements of the Shared Savings Program. We noted that we believe this provision would authorize CMS to conduct oversight regarding ACOs' records documenting the beneficiaries who received such a notification and the beneficiary responses.

As we stated in the August 2018 proposed rule (83 FR 41877 and 41878), we are also considering how we would implement an opt-in based assignment methodology that addresses stakeholder requests, while conforming to existing program requirements. First, the requirement at section 1899(b)(2)(D) of the Act, that an ACO have at least 5,000 assigned beneficiaries, would continue to apply. Thus, under an opt-in based assignment methodology, an ACO still would be required to have at least 5,000 FFS beneficiaries, who meet our beneficiary eligibility criteria, assigned to the ACO at the time of application and for the entirety of the ACO's agreement period. We indicated that we are concerned that using an opt-in based assignment methodology as the sole basis for assigning beneficiaries to an ACO could make it difficult for many ACOs to meet the 5,000 assigned beneficiary requirement under section 1899(b)(2)(D) of the Act. In particular, we noted that we were considering how an opt-in based assignment methodology would be implemented for new ACOs that have applied to the Shared Savings Program, but have not yet been approved by CMS to participate in the program. It could be difficult for a new ACO to achieve 5,000 beneficiary opt-ins prior to the start of its first performance year under the program, as required by the statute in order to be eligible for the program. It could also be difficult for certain established ACOs, such as ACOs located in rural areas, to achieve and maintain 5,000 beneficiary opt-ins. Smaller assigned beneficiary populations would also significantly increase the minimum savings rate and minimum loss rate (MSR and MLR) thresholds used to determine eligibility for shared savings and accountability for shared losses when these rates are based on the size of the ACO's assigned population as described in section II.A.6.b. of this final rule. Smaller assigned beneficiary populations would also be a potential concern if ACOs and their ACO participants were to target care management to a small subset of patients at the expense of a more comprehensive transformation of care delivery with benefits that would have otherwise extended to a wider mix of

patients regardless of whether they are assigned to the ACO.

Second, under an opt-in assignment approach, we could allow beneficiaries to opt-in before they have received a primary care service from a physician in the ACO, or any service from an ACO provider/supplier. This would be similar to the situation that can sometimes occur under MA, where a beneficiary enrolls in a MA plan without having received services from any of the plan's providers. That means a beneficiary could be assigned to an ACO based solely on his or her opting-in to the ACO, and the ACO would be accountable for the total cost and quality of care provided to the opted-in beneficiary, including care from providers/suppliers that are not participating in the ACO. Section 1899(c) of the Act requires that beneficiaries be assigned to an ACO based on their use of primary care services furnished by physicians in the ACO, or beginning January 1, 2019, services provided in FQHCs/RHCs. In the August 2018 proposed rule, we noted that in order to meet this requirement under an opt-in based assignment methodology, we were considering whether we would need to continue to require that a beneficiary receive at least one primary care service from an ACO professional in the ACO who is a primary care physician or a physician with a specialty used in assignment (similar to our current requirement under § 425.402(b)(1)), in order for the beneficiary to be eligible to opt-in to assignment to the ACO.

Third, we explained that we were considering whether any changes would need to be made to our methodology for establishing an ACO's historical benchmark if we were to implement an opt-in based assignment methodology. Under the current assignment methodology used in the Shared Savings Program, we assign beneficiaries to ACOs for a performance year based upon either voluntary alignment or the claims-based assignment methodology. Because the vast majority of beneficiaries are assigned using the claims-based assignment methodology, we are able to use the same claims-based assignment methodology to assign beneficiaries for purposes of either a performance year or a benchmark year. The expenditures of the beneficiaries assigned to the ACO for a benchmark year are then used in the determination of the benchmark. However, the same approach would not be possible under an assignment methodology based solely on a beneficiary opt-in approach. If we were to adopt an entirely opt-in based assignment methodology, we would need to consider if any changes would need to be made to our methodology for establishing an ACO's historical benchmark to address selection bias and/or variation in expenditures because beneficiaries would not have opted-in to assignment to the ACO during the 3 prior years included in the historical benchmark under § 425.602, § 425.603, or proposed new § 425.601. Thus, under an entirely opt-in based assignment methodology there could be a large disconnect between the beneficiaries who have opted-in to assignment to the ACO for a performance year and the beneficiaries who are assigned to the ACO on the basis of claims for the historical benchmark years. An adjustment to the benchmark would be necessary to address these discrepancies. Alternatively, if we were to adopt a methodology under which we use expenditures from the 3 historical benchmark years only for beneficiaries who have opted-in to assignment to the ACO in the applicable performance year, it could create an imbalance because the expenditures for the years that comprise the historical benchmark would not include expenditures for decedents because beneficiaries necessarily would have survived through the baseline period in order to opt-in for the given performance year. A similar approach was initially applied in the Pioneer ACO Model, but it required complex adjustments to ACOs' benchmarks to account for significantly lower spending in historical base years for assigned beneficiaries, who necessarily survived for the one or more years between the given base year and the applicable performance year in which they were assigned to the ACO. It would likely be even more difficult and complex to consistently and accurately adjust the benchmark in the context of our proposal to change to 5 year agreement periods (or a 6 year agreement period for agreement periods starting on July 1, 2019) because the historical benchmarks would eventually rely on an even smaller subset of base year claims available for beneficiaries who were enrolled in both Medicare Parts A and B during the base year and have survived long enough to cover the up to 7-year gap between the historical base year and the performance year for which they have opted-in to assignment to the ACO.

In light of these issues, we stated that we were considering implementing an opt-in based assignment methodology that would address stakeholder requests that we incorporate such an approach to make the assignment methodology more patient-centered, while also addressing statutory requirements and other Shared Savings Program requirements. Specifically, we explained our belief that it may be feasible to incorporate an opt-in based assignment methodology into the Shared Savings Program in the following manner. We would allow, but not require, ACOs to elect an opt-in based assignment methodology. Under this approach, at the time of application to enter or renew participation in the Shared Savings Program, an ACO could elect an opt-in based assignment methodology that would apply for the length of the agreement period. Under this approach, we would use the assignment methodology under subpart E of the regulations, including the provisions at §§ 425.400, 425.401, 425.402 and 425.404 (herein referred to as the ''existing assignment methodology'' which would be comprised of a claims-based assignment methodology and voluntary alignment), to determine whether an ACO applicant meets the initial requirement under section 1899(b)(2)(D) of the Act to be eligible to participate in the program. We would use this approach because the ACO applicant would not be able to actively seek Medicare beneficiary opt-ins until the next opt-in window. That is, we would continue to determine an ACO's eligibility to participate in the program under the requirement that an ACO have at least 5,000 assigned beneficiaries using the program's existing assignment methodology. Therefore, an ACO that elects to participate under opt-in based assignment could be eligible to enter an agreement period under the program if we determine that it has at least 5,000 assigned beneficiaries in each of the 3 years prior to the start of the ACO's agreement period, based on the claims-based assignment methodology and voluntarily aligned beneficiaries.

If an ACO chooses not to elect the opt-in based assignment methodology during the application or renewal process, then beneficiaries would continue to be assigned to the ACO based on the existing assignment methodology (claims-based assignment with voluntary alignment). As an alternative to allowing ACOs to voluntarily elect participation in an opt-in based assignment methodology we noted that we were also considering discontinuing the existing assignment methodology and applying an opt-in based assignment methodology program-wide (described herein as a hybrid assignment approach which includes beneficiary opt-in, modified

claims-based assignment, and voluntary alignment). As described in the August 2018 proposed rule, ACOs could face operational challenges in implementing opt-in based assignment, and this approach to assignment could affect the size and composition of the ACO's assigned population, specifically to narrow the populations served by ACO. In light of these factors, we stated that we believe it would be important to gain experience with opt-in based assignment as a voluntary participation option before modifying the program to allow only this participation option.

In the August 2018 proposed rule (83 FR 41879 through 41881), we described a hybrid approach under which, for ACOs electing to participate under an opt-in based assignment methodology, we would assign beneficiaries to the ACO based on beneficiary opt-ins, supplemented by voluntary alignment and a modified claims-based methodology. Notwithstanding the assignment methodology under § 425.402(b), under this hybrid approach, a beneficiary would be prospectively assigned to an ACO that has elected the opt-in based assignment methodology if the beneficiary opted in to assignment to the ACO or voluntarily aligned with the ACO by designating an ACO professional as responsible for their overall care. If a beneficiary was not prospectively assigned to such an ACO based on either beneficiary opt-in or voluntary alignment, then the beneficiary would be assigned to such ACO 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. If a beneficiary did not receive at least seven primary care services from one or more ACO professionals in the ACO during the applicable assignment window, then the beneficiary would not be assigned to the ACO on the basis of claims even if the beneficiary received the plurality of their primary care services from the ACO. We noted that this threshold of seven primary care services would be consistent with the threshold established by an integrated healthcare system in a prior demonstration that targeted intervention on chronic care, high risk patients in need of better coordinated care due to their frequent utilization of health care services. A threshold for assignment of seven primary care services would mean that up to 25 percent of an ACO's beneficiaries who would have been assigned to the ACO under the existing assignment methodology under § 425.402(b) could continue to be assigned to the ACO based on claims. We explained that we believed it could be appropriate to establish a minimum threshold of seven primary care services for assigning beneficiaries to ACOs electing an opt-in based assignment methodology because it would enable such ACOs to focus their care coordination activities on beneficiaries who have either opted-in to assignment to the ACO or voluntarily aligned with the ACO, or who are receiving a high number of primary care services from ACO professionals and may have complex conditions requiring care coordination. We sought comment on whether to use a higher or lower minimum threshold for determining beneficiaries assigned to the ACO under a modified claims-based assignment approach.

Under this hybrid approach to assignment, we would allow the ACO a choice of claims-based beneficiary assignment methodology as discussed in section II.A.4.c. of this final rule. Therefore, ACOs that elect to participate under opt-in based assignment for their agreement period would also have the opportunity to elect either prospective or preliminary prospective claims-based assignment prior to the start of their agreement period, and to elect to change this choice of assignment methodology annually.

More generally, we stated that we believe this hybrid assignment methodology, which would incorporate claims-based and opt-in based assignment methods, as well as voluntary alignment, could be preferable to an opt-in only approach. A hybrid assignment methodology would increase the number of beneficiaries for whom the ACO would be accountable for quality and cost of care delivery and thereby provide stronger statistical confidence for shared savings or shared losses calculations and provide a stronger incentive for ACOs and their ACO participants and ACO providers/suppliers to improve care delivery for every FFS beneficiary rather than focusing only on beneficiaries who happen to have opted-in to assignment to the ACO.

For ACOs that enter an agreement period in the Shared Savings Program under an opt-in based assignment methodology, we would allow for a special election period during the first calendar year quarter of the ACO's first performance year for beneficiaries to opt-in to assignment to the ACO. For each subsequent performance year of an ACO's agreement period, the opt-in period would span the first three calendar year quarters (January through September) of the prior performance year. Beneficiaries that opt-in, and are determined eligible for assignment to the ACO, would be prospectively assigned to the ACO for the following performance year. Under this approach, there would be no floor or minimum number of opt-in beneficiaries required. Rather, we would consider whether, in total, the ACO's assigned beneficiary population (comprised of beneficiaries who opt-in, beneficiaries assigned under the modified claims-based assignment approach, and beneficiaries who have voluntarily aligned) meets the minimum population size of 5,000 assigned beneficiaries each performance year to comply with the requirements for continued participation in the program. To illustrate this hybrid assignment approach in determining performance year assignment: If an ACO has 2,500 beneficiaries assigned under the modified claims-based assignment approach who have not otherwise opted-in to assignment to the ACO, and 50 voluntarily aligned beneficiaries who have not otherwise opted-in to assignment to the ACO, then the ACO would be required to have at least 2,450 beneficiaries who have opted-in to assignment to remain in compliance with the program eligibility requirement to have at least 5,000 assigned beneficiaries.

Consistent with current program policy, ACOs electing the opt-in based assignment methodology with a performance year assigned population below the 5,000-minimum may be subject to the pre-termination actions in § 425.216 and termination of their participation agreement under § 425.218. Under the proposals for modifying the MSR/MLR to address small population sizes described in section II.A.6.b.(3). of this final rule, if an ACO that elects an opt-in based assignment methodology has an assigned population below 5,000 beneficiaries, the ACO's MSR/MLR would be set at a level consistent with the number of assigned beneficiaries to provide assurance that shared savings and shared losses represent meaningful changes in expenditures rather than normal variation.

As an alternative approach, we also considered requiring ACOs that have elected an opt-in based assignment methodology to maintain at least a minimum number of opt-in beneficiaries assigned in each performance year of its agreement period. We explained our belief that any minimum population requirement should be proportional to the size of ACO's population, to recognize differences in the population sizes of

ACOs across the program. We also considered whether we should require incremental increases in the size of the ACO's opt-in assigned population over the course of the ACO's agreement period, recognizing that it may take time for ACOs to implement the opt-in approach and for beneficiaries to opt-in. Another factor we considered is the possibility that the size of an ACO's population, and therefore the proportion of opt-in beneficiaries, could be affected by ACO participant list changes, and changes in the ACO providers/suppliers billing through ACO participant TINs, which could affect claims-based assignment, and the size of the ACO's voluntarily aligned population. Changes in the size of the ACO's claims-based assigned and voluntarily aligned populations could cause the ACO to fall out of compliance with a required proportion of opt-in assigned beneficiaries, even if there has been no reduction in the number of opt-in assigned beneficiaries.

We anticipated that under opt-in based assignment, we would not establish restrictions on the geographic locations of the ACOs from which a beneficiary could select. This would be consistent with the program's voluntary alignment process, under which a beneficiary could choose to designate a primary clinician as being responsible for his or her care even if this clinician is geographically distant from the beneficiary's place of residence. Also, currently under the program's existing claims-based assignment methodology, beneficiaries who receive care in different parts of the country during the assignment window can be assigned to an ACO that is geographically distant from the beneficiary's place of residence. This approach also recognizes that a beneficiary could be assigned to a geographically distant ACO as a result of his or her individual circumstances, such as a beneficiary's change in place of residence, the beneficiary spending time in and receiving care in different parts of the country during the year (sometimes referred to as being a ''snowbird''), or the beneficiary receiving care from a tertiary care facility that is geographically distant from his or her home. Further, we noted that this approach is in line with the expanded telehealth policies discussed in section II.B.2.b. of this final rule under which certain geographic and other restrictions would be removed. We welcomed comment on whether to establish geographic limitations on opt-in based assignment such that a beneficiary's choice of ACOs for opt-in would be limited to ACOs located near the beneficiary's place of residence, or where the beneficiary receives his or her care, or a combination of both.

When considering the options for incorporating an opt-in based assignment methodology, we considered if such a change in assignment methodology would also require changes to the proposed benchmarking methodology under § 425.601. A hybrid assignment approach could potentially require modifications to the benchmarking methodology to account for factors such as: Differences in beneficiary characteristics, including health status, between beneficiaries who may be amenable to opting-in to assignment to an ACO, beneficiaries who voluntarily align, and beneficiaries assigned under a modified claims-based assignment methodology who must have received at least seven primary care services from the ACO; differences between the existing claims-based assignment methodology and the alternative claims-based approach under which a minimum of seven primary care services would be required for assignment; and discrepancies caused by the use of the existing claims-based assignment methodology to perform assignment for historical benchmark years and the use of a hybrid assignment methodology for performance years. We explained that, for simplicity, we prefer an approach that would use, to the greatest extent possible, the program's benchmarking methodology, as proposed to be modified as discussed in section II.D. of this final rule. This would allow us to more rapidly implement an opt-in based assignment approach, and may be easier to understand for ACOs and other program stakeholders experienced with the program's benchmarking methodology. We considered the following approach to establishing and adjusting the historical benchmark for ACOs that elect an opt-in based assignment methodology.

As explained in the August 2018 proposed rule (83 FR 41880 through 41882), in establishing the historical benchmark for ACOs electing an opt-in based beneficiary assignment methodology, we would follow the benchmarking approach described in the provisions of the proposed new regulation at § 425.601. In particular, we would continue to determine benchmark year assignment based on the population of beneficiaries that would have been assigned to the ACO under the program's existing assignment methodology in each of the 3 most recent years prior to the start of the ACO's agreement period. However, we would take a different approach to annually risk adjusting the historical benchmark expenditures than the one we had proposed in Section II.D of the proposed rule and in the proposed provisions at §§ 425.605(a)(1) and 425.610(a)(2).

In risk adjusting the historical benchmark for each performance year, we would maintain the current approach of categorizing beneficiaries by Medicare enrollment type; however, we would further stratify the benchmark year 3 and performance year assigned populations into groups that we anticipate would have comparable expenditures and risk score trends. That is, we would further stratify the performance year population into two categories: (1) Beneficiaries who are assigned using the modified claims-based assignment methodology and must have 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. A beneficiary who has opted-in to assignment to the ACO would continue to be stratified in the opted in population throughout the agreement period regardless of whether the beneficiary would have been assigned using the modified claims-based assignment methodology because the beneficiary received seven or more primary care services from the ACO.

We would also further stratify the BY3 population, determined using the existing assignment methodology, into two categories: (1) Beneficiaries who received seven or more primary care services from the ACO; and (2) beneficiaries who received six or fewer primary care services from the ACO.

We explained that we anticipate that beneficiaries who opt-in would likely be a subset of beneficiaries who would have been assigned under the existing claims-based assignment methodology. As previously described, 92 percent of voluntarily aligned beneficiaries were already assigned to the same ACO using the existing claims-based assignment methodology. Further, based on our experience with the program, about 75 percent of ACOs' assigned beneficiaries receive six or fewer primary care service visits annually. Similar to the trend we have observed with voluntarily aligned beneficiaries, we believe the opt-in beneficiaries would tend to resemble in health status and acuity a subset of the ACO's typical claims-based assigned population; that is, we anticipate opt-in beneficiaries, as with voluntarily aligned beneficiaries, would resemble the population of beneficiaries assigned

in the benchmark year that received six or fewer primary care services.

We would determine ratios of risk scores for the comparable populations of performance year and BY3 assigned beneficiaries. We would calculate these risk ratios by comparing the risk scores for the BY3 population with seven or more primary care services with the risk scores for the performance year population with seven or more primary care services who have not otherwise opted-in or voluntarily aligned. We would also calculate risk ratios for the remaining beneficiary population by comparing risk scores for the BY3 population with six or fewer primary care services with the risk scores for the performance year population of opt-in and voluntarily aligned beneficiaries. We would use these ratios to risk adjust the historical benchmark expenditures not only by Medicare enrollment type, but also by these stratifications. That is, for each Medicare enrollment type, we would apply risk ratios comparing the risk scores of the BY3 population with seven or more primary care services and the risk scores of the performance year population with seven or more primary care services to adjust the historical benchmark expenditures for the population with seven or more primary care services in the benchmark period. Similarly, we 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. We presumed this would be a reasonable approach based on our expectation that opt-in beneficiaries will resemble the population of beneficiaries, assigned under the existing claims-based assignment methodology, who have 6 or fewer primary care services with the ACO annually. This presumption was supported by the assumptions that ACOs may selectively market opt-in to lower cost beneficiaries, and beneficiaries that require less intensive and frequent care may be more inclined to opt-in. However, since we lack experience with an opt-in based assignment approach, we indicated that we would monitor the effects of this policy to determine if it is effective in addressing the differences in characteristics between the population assigned for purposes of establishing the ACO's benchmark under the existing assignment methodology and the population assigned for the performance year under the hybrid assignment approach, and if further adjustments may be warranted such as additional adjustments to the historical benchmark to account for such differences.

In rebasing the ACO's benchmark, which occurs at the start of each new agreement period, we would include in the benchmark year assigned population beneficiaries who had opted in to the ACO in a prior performance year that equates to a benchmark year for the ACO's new agreement period. For example, if an ACO elected opt-in for a 5-year agreement period beginning on January 1, 2020, and concluding on December 31, 2024, and a beneficiary opted in and was assigned for performance year 2023 and remained opted in and assigned for performance year 2024, we would include this beneficiary in the benchmark year assigned population for BY2 (2023) and BY3 (2024) when we rebase the ACO for its next agreement period beginning January 1, 2025. We considered that the health status of an opt-in beneficiary may continue to change over time as the beneficiary ages, which would be accounted for in our use of full CMS–HCC risk scores in risk adjusting the rebased historical benchmark. We considered approaches to further adapt the rebasing methodology to account for the characteristics of the ACO's opt-in beneficiaries, and the ACO's experience with participating in an opt-in based assignment methodology.

We considered an approach under which we could determine the assigned population for the ACO's rebased benchmark using the program's existing assignment methodology and incorporate opt-in assigned beneficiaries in the benchmark population. In risk adjusting the ACO's rebased benchmark each performance year, we could use a stratification approach similar to the approach previously described in this discussion. That is we would stratify the BY3 population into two categories: (1) Beneficiaries who received seven or more primary care services from the ACO; and (2) beneficiaries who received six or fewer primary care services from the ACO. We would categorize opt-in beneficiaries, assigned in BY3, into either one of these categories based on the number of primary care services they received from ACO during BY3. We could continue to stratify the performance year population assigned under the hybrid assignment methodology into two categories: (1) Beneficiaries who are assigned using the modified claims-based assignment methodology and must have 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. We would apply risk ratios comparing the risk scores of the BY3 population with seven or more primary care services and the risk scores of the performance year population with seven or more primary care services to adjust the historical benchmark expenditures for the population with seven or more primary care services in the benchmark period. Similarly, we 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.

An alternative approach to rebasing the benchmark for an ACO that elected opt-in assignment in their most recent prior agreement period and continues their participation in an opt-in based assignment methodology in their new agreement period, would be to use the hybrid assignment approach to determine benchmark year assignment. To risk adjust the benchmark for each performance year we could then stratify the BY3 and the performance year assigned populations into two categories: (1) Beneficiaries assigned through the modified claims-based assignment methodology who received seven or more primary care services from the ACO; or (2) beneficiaries who opt-in and beneficiaries who voluntarily align. This approach would move ACOs to participation under a purely hybrid assignment approach since we would no longer use the existing assignment methodology in establishing the benchmark. However, this approach could result in smaller benchmark year assigned populations compared to populations determined based on the more inclusive, existing assignment methodology. In turn, this approach could result in ACOs that were successful at opting-in beneficiaries being ineligible to continue their participation in the program under an opt-in assignment methodology because they do not meet the program's eligibility requirement to have at least 5,000 beneficiaries assigned in each benchmark year.

As described in section II.D. of this final rule, as part of the proposed changes to our benchmarking methodology, we proposed that annual adjustments in prospective CMS–HCC risk scores would be subject to a symmetrical cap of positive or negative 3 percent that would apply for the

agreement period, such that the adjustment between BY3 and any performance year in the agreement period would never be more than 3 percent in either direction. We explained that we were considering whether a modified approach to applying these caps would be necessary for ACOs that elect opt-in based assignment methodology. For example, for the first performance year an opted-in beneficiary is assigned to an ACO, we could allow for full upward or downward CMS–HCC risk adjustment, thereby excluding these beneficiaries from the symmetrical risk score caps. This would allow us to account for newly opted-in beneficiaries' full CMS–HCC scores in risk adjusting the benchmark. In each subsequent performance year, the opted-in beneficiaries remain aligned to the ACO, we could use an asymmetrical approach to capping increases and decreases in risk scores. We would cap increases in the opt-in beneficiaries' CMS–HCC risk scores to guard against changes in coding intensity, but we would apply no cap to decreases in their CMS–HCC risk scores. That is, the risk scores for these opt-in beneficiaries would be subject to the positive 3 percent cap, but not the negative 3 percent cap. We believed this approach would safeguard against ACOs trying to enroll healthy beneficiaries, who would likely be less expensive than their benchmark population, in order to benefit from having a limit on downward risk adjustment. Beneficiaries who have not otherwise opted-in who are assigned to the ACO based on the modified claims-based assignment methodology and those that voluntarily align would be subject to the proposed symmetrical 3 percent cap. We also noted that we do not apply caps to risk scores when we rebase an ACO's historical benchmark, which allows the historical benchmark to reflect the current health status of the beneficiary populations assigned for the benchmark years.

As indicated in the alternatives considered section of the Regulatory Impact Analysis at Section V.D. of the proposed rule, there is limited information presently available to model the behavioral response to an opt-in based assignment methodology, for example in terms of ACOs' willingness to elect such an approach and beneficiaries' willingness to opt-in. However, we noted that for some policies we can draw upon our initial experience with implementing voluntary alignment. As we stated in the August 2018 proposed rule (83 FR 41882), we believe the approach to adjusting benchmarks to address an opt-in based assignment methodology that we described in the proposed rule, could address our concerns about the comparability of benchmark and performance year populations. We noted that if such a policy were to be finalized we would monitor the impact of these adjustments on ACOs' benchmarks, and we would also monitor to determine ACOs' and beneficiaries' response to the opt-in based assignment participation option, characteristics of opt-in beneficiaries and the ACOs they are assigned to, and the cost and quality trends of opt-in beneficiaries to determine if further development to the program's financial methodology would be necessary to account for this approach.

We also anticipated that if we were to establish an opt-in based assignment methodology, we would need to establish program integrity requirements similar to the program integrity requirements with respect to voluntary alignment at § 425.402(e)(3). The ACO, ACO participants, ACO providers/suppliers, ACO professionals, and other individuals or entities performing functions and services related to ACO activities would be prohibited from providing or offering gifts or other remuneration to Medicare beneficiaries as inducements to influence their decision to opt-in to assignment to the ACO. The ACO, ACO participants, ACO providers/suppliers, ACO professionals, and other individuals or entities performing functions and services related to ACO activities would also be prohibited from directly or indirectly, committing any act or omission, or adopting any policy that coerces or otherwise influences a Medicare beneficiary's decision to opt-in to assignment to an ACO. Offering anything of value to a Medicare beneficiary as an inducement to influence the Medicare beneficiary's decision to opt-in (or not opt-in) to assignment to the ACO would not be considered to have a reasonable connection to the medical care of the beneficiary, as required under the proposed provision at § 425.304(b)(1).

Finally, we emphasized that, as is the case for all FFS beneficiaries currently assigned to an ACO on the basis of claims or voluntary alignment, under an opt-in based assignment methodology, beneficiaries who opt-in to assignment to an ACO would retain their right to seek care from any Medicare-enrolled provider or supplier of their choosing, including providers and suppliers outside the ACO.

We solicited comment on whether we 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. We welcomed comments as to 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 to enable 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 ACO professionals, and may have complex conditions requiring a significant amount of care coordination. We sought comment on whether this minimum threshold for use in determining modified claims-based assignment should be set at a higher or lower. We also welcomed comments on an appropriate methodology for establishing and adjusting an ACO's historical benchmark under an opt-in based assignment methodology. Further, we sought comment on how to treat opt-in beneficiaries when rebasing the historical benchmark for renewing ACOs. Additionally, we welcomed comments on any other considerations that 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.

In the August 2018 proposed rule (83 FR 41882 and 41883), we explained that we envisioned that if we were to incorporate such an opt-in based assignment methodology, the election by ACOs would be entirely voluntary. ACOs that did not elect this beneficiary assignment option would continue to have their beneficiaries assigned using the existing claims-based assignment methodology with voluntary alignment under § 425.402. However, we also sought comment on whether we should discontinue the existing assignment methodology under subpart E and instead assign beneficiaries 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. Under such an approach, the use of a modified benchmarking methodology could help

to ensure that an appropriate weight would be placed on the risk-adjusted expenditures of the ACO's opt-in population as this population increases in size.

Comment: A majority of commenters did not support the idea of an opt-in based assignment methodology. Many commenters preferred that CMS maintain the existing claims-based assignment methodology with voluntary alignment and not replace it with an opt-in or a hybrid assignment methodology. One commenter stated that, as described in the proposed rule, the beneficiary opt-in would move the program away from its fundamental purpose and that ACOs should focus on recruiting the right doctors and other health care providers to improve the health of their patients, not recruiting patients to opt-in to the ACO.

Another commenter expressed concerns about the small number of beneficiaries that would opt into an ACO, stating that it is extremely unlikely that many beneficiaries who were not already assigned through claims or by designating a primary care provider would choose to opt into an ACO. One commenter believed that because there is no connection between opt-in enrollment and actual utilization of primary care services, an opt-in based assignment methodology is not the answer to stakeholder concerns about the current beneficiary assignment methodology or changes in the assigned beneficiary population from year to year. A few commenters expressed concerns that establishing an ACO's benchmark under an opt-in methodology would become more complicated (due to opt-in beneficiaries potentially having different expected cost growth than the average beneficiary) and difficult (due to the 5,000 minimum beneficiary threshold requirement). One commenter expressed concerns about the hybrid approach, stating that the seven-claim threshold is high enough to fundamentally change the Shared Savings Program, because the vast majority of potentially attributable ACO beneficiaries are not high-risk and, therefore, may never need seven primary care services in a given period of time. One commenter suggested that beneficiary assignment would fall dramatically under an opt-in assignment methodology and CMS would have to implement a much higher shared savings rate in order to support the large ACO investments that a beneficiary enrollment process would require.

Several commenters were concerned that an opt-in assignment methodology could have significant operational impact on ACOs. One commenter stated that if the opt-in assignment methodology involved active outreach by providers, it would impose additional work streams and resource use on practices. Another commenter stated that although opt-in based enrollment is a valuable idea utilized by health plans, many ACOs do not have the infrastructure, including staff, to operate such a process. Another commenter stated that altering the assignment methodology to require beneficiaries to actively elect an ACO would create insurmountable administrative complexities and would be confusing to beneficiaries. One commenter stated that the process is likely to increase administrative burdens for ACOs, particularly those which are made up of independent physicians. The commenter recommended that, CMS should ensure that ACOs that do not have the resources available to actively pursue beneficiary opt-in are not inadvertently punished through additional changes to the claims-based assignment methodology.

One commenter stated that beneficiary opt-in would effectively end physician participation in the Shared Savings Program and that physician practices, especially those that are unaffiliated with a health system or a health plan, do not have the resources needed to develop and implement the complex, continuous enrollment and reporting processes described in the proposed rule. The commenter believed that a requirement that beneficiaries opt-in to assignment to an ACO would significantly increase the costs of administering and running an ACO, skewing the cost-benefit analysis that many physician practices consider before joining the program.

Response: We appreciate the commenters' feedback regarding our considerations in relation to the possible development of an opt-in based assignment methodology. These comments will help to inform any future consideration of an opt-in based assignment methodology.

Comment: Several commenters supported CMS in exploring options for developing a voluntary opt-in based assignment methodology to complement the existing assignment methodology under subpart E. These commenters suggested that such an approach may make the assignment methodology more patient-centered and further encourage and empower beneficiaries to become better engaged in their healthcare decisions. Some commenters were supportive of an opt-in based assignment methodology to support beneficiary engagement. These commenters provided a variety of reasons for their support:

- To give beneficiaries greater agency in directing their care choices. Beneficiaries should know how to navigate the system in which they receive care, understand the sets of incentives that may drive health care decisions, and appreciate their own role within an ACO to ensure they have the best opportunity to attain their health goals.
- To provide ACOs with the ability to ''market'' their quality statistics for increased awareness of their network, similar to employee annual healthcare enrollment.
- To help drive demand for coordinated, value-based care within Medicare FFS.
- To supplement the current measures of quality and value under the Shared Savings Program.

One commenter supported a hybrid approach with a modified claims-based assignment approach that focuses on the most complex patients, such as high risk patients or those receiving care for chronic conditions. Another commenter supported a hybrid approach that would enable beneficiaries to either voluntarily align with an ACO-participating physician or nurse practitioner of their choice or to opt-in to the ACO directly. The commenter stated that the hybrid approach could be extended universally to all ACOs by default provided claims-based assignment continued to be based on the plurality of primary care services as opposed to a minimum threshold (for example, seven qualified primary care services) for those who do not opt-in. Another commenter suggested that CMS release additional information and data on the possible seven-primary care service threshold, as they are concerned that this threshold is too high and could have the unintended consequence of significantly lowering several ACOs' assigned beneficiary counts. One commenter supported the potential opt-in based assignment methodology, as long as ACOs can voluntarily participate but believed that there should be geographic limits placed in assigning ACO beneficiaries.

Response: We thank commenters for their comments. As we have indicated, we will share these comments with the Innovation Center for consideration as part of the development of any future opt-in based assignment methodology.

Comment: Several commenters recommended that further research and testing is needed on the implications of an opt-in approach before implementing such an alternative assignment methodology in the Shared Savings Program. For example, several commenters suggested that CMS test alternative approaches in smaller models in a variety of markets to determine whether they meet

programmatic goals. One commenter recommended testing appropriate marketing opportunities for ACOs, analogous to those in Medicare Advantage. Another commenter suggested that any changes to the assignment methodology should be incremental and first be pilot-tested. One commenter recommended that, before offering a pure opt-in assignment methodology or a hybrid approach, CMS should continue to explore the potential burdens ACOs could encounter if beneficiaries are permitted to opt-in to assignment to an ACO and how the option would be explained to beneficiaries.

Many commenters were concerned with the level of beneficiary outreach and education that would be necessary to implement an opt-in approach. One commenter stated that through yearly focus groups, they found that most beneficiaries are not familiar with ACOs and any policy that would allow beneficiaries to opt-in would require a great deal of beneficiary education and generate a large amount of beneficiary unease. One commenter suggested that if CMS were to move forward with an opt-in assignment approach, ACOs would need to provide beneficiaries with timely, easily accessible, and clear information about which providers are a part of the ACO, the ACO's quality rating, the number and types of complaints filed against the ACO (if any), and any other information that will help beneficiaries make the best decision given their healthcare needs. The commenter also recommended that the information should be presented in a standardized format that is easy to understand as well as culturally and linguistically appropriate. One commenter suggested that CMS develop informational materials in a variety of modalities, formats, and languages to ensure Medicare beneficiaries have a clear understanding of the benefits and potential risks/compromises associated with ACOs. The commenter also recommended that CMS develop beneficiary informational materials and instructions that contain enough information for beneficiaries to provide informed consent and understand what their election means. Finally, one commenter suggested allowing beneficiaries to opt-in by telephone, mailing, and at the point of care in the physician's office in addition to the current electronic method.

Several commenters expressed concern that the opt-in for beneficiaries is redundant with voluntary alignment as beneficiaries already have the option to choose a primary clinician and thus opt-in to an ACO in which the clinician participates. One commenter expressed concern that the similarity between the opt-in option and the voluntary alignment option may cause confusion among beneficiaries. One commenter suggested CMS should continue to monitor the effectiveness of voluntary alignment before implementing an opt-in policy and that the benefits of beneficiary opt-in versus beneficiary voluntary alignment are not clear. Some commenters recommended that before moving towards the development of an opt-in methodology, CMS focus on making improvements to increase the use of the voluntary alignment option, which would serve as an incremental improvement in response to the broader challenge of educating Medicare beneficiaries about ACOs. One commenter suggested aligning an opt-in based assignment methodology with the voluntary alignment option so that the beneficiary can essentially ''opt-in'' to the ACO by selecting their primary clinician.

Response: We appreciate the commenters' feedback regarding our considerations in relation to the possible development of an opt-in based assignment methodology. We will consider the feedback provided by the commenters as part of any future consideration of an opt-in based assignment methodology.

Comment: Some commenters compared an opt-in based assignment methodology to Medicare Advantage. One commenter stated that the opt-in based assignment methodology discussed in the proposed rule seems contrary to the goals of beneficiary engagement and the beneficiary freedom of choice offered under FFS Medicare and would be significantly similar to managed care plans, which could create confusion between the Shared Savings Program and Medicare Advantage. Another commenter raised concerns based on its current Medicare Advantage experience, which strongly suggests that beneficiaries do not actively make plan choices for themselves. This commenter stated that adding a requirement that beneficiaries choose to be part of an ACO does not seem like an assignment method that will result in the long-term stabilization and success of the program, while creating administrative burden and confusion for beneficiaries. One commenter stated that the shared savings economic model simply does not support the type of investments that Medicare Advantage plans make in enrolling beneficiaries.

A commenter stated that one primary advantage of ACOs over Medicare Advantage plans is their lower administrative costs. The commenter contends that once an opt-in based assignment methodology is implemented, ACO administrative costs would increase. Another commenter stated that beneficiaries and providers already require constant reminders of the differences between a Shared Savings Program ACO and a Medicare Advantage Plan and an opt-in based assignment methodology into the Shared Savings Program would provide further confusion. One commenter believed that, unlike in Medicare Advantage, beneficiaries would not have a clear financial incentive to enroll in an ACO because doing so would have no effect on their premium or cost-sharing arrangements. The commenter further contends that Medicare FFS beneficiaries often place a high value on their freedom of choice and may be concerned that enrollment in an ACO would restrict them to a particular network. Another commenter expressed concerns that an opt-in methodology for ACOs could overlap and interfere with Medicare Advantage enrollment and expressed concern that there would not be appropriate regulations in place, such as those that apply in Medicare Advantage, and as a result providers could ''cherry-pick'' patients who are more likely to help performance or ''lemon-drop'' patients who may be more costly.

Response: We thank the commenters for their feedback and will share these comments with the Innovation Center to further inform the development of a model testing an opt-in based assignment methodology.

Final Action: We are not finalizing an opt-in assignment methodology for the Shared Savings Program at this time; however, we will work with the Innovation Center to develop a model to determine the viability of an opt-in assignment methodology and may consider adopting such an approach in the Shared Savings Program through future rulemaking.

D. Benchmarking Methodology Refinements

1. Background

An ACO's historical benchmark is calculated 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 (§§ 425.602(a), 425.603(b) and (c)). For ACOs that have continued their participation for a second or subsequent agreement period, the benchmark years for their current agreement period are the 3 calendar

years of their previous agreement period.

There are currently differences between the methodology used to establish the ACO's first agreement period historical benchmark (§ 425.602) and the methodology for establishing the ACO's rebased historical benchmark in its second or subsequent agreement period (§ 425.603). We refer readers to discussions of the benchmark calculations in earlier rulemaking for details on the development of the current policies (see November 2011 final rule, 76 FR 67909 through 67927; June 2015 final rule, 80 FR 32785 through 32796; June 2016 final rule, 81 FR 37953 through 37991). For example, in resetting (or rebasing) an ACO's historical benchmark, we replace the national trend factor (used in in the first agreement period methodology) with regional trend factors, and we use a phased approach to adjust the rebased benchmark to reflect a percentage of the difference between the ACO's historical expenditures and FFS expenditures in the ACO's regional service area. This rebasing methodology incorporating factors based on regional FFS expenditures was finalized in the June 2016 final rule and is used to establish the benchmark for ACOs beginning a second or subsequent agreement period in 2017 and later years. An interim approach was established in the June 2015 final rule under which we adjusted the rebased benchmarks for ACOs that entered a second agreement period beginning in 2016 to account for savings generated in their first agreement period (§ 425.603(b)(2)).

In developing the June 2016 final rule, we considered the weight that should be applied in calculating the regional adjustment to an ACO's historical expenditures. We finalized a phased approach to transition to a higher weight in calculating the regional adjustment, where we determine the weight used in the calculation depending on whether the ACO is found to have lower or higher spending compared to its regional service area (§ 425.603(c)(9)). For ACOs that have higher spending compared to their regional service area, the weight placed on the regional adjustment is reduced to 25 percent (compared to 35 percent) in the first agreement period in which the regional adjustment is applied, and 50 percent (compared to 70 percent) in the second agreement period in which the adjustment is applied. Ultimately a weight of 70 percent will be applied in calculating the regional adjustment for all ACOs beginning no later than the third agreement period in which the ACO's benchmark is rebased using this methodology, unless the Secretary determines that a lower weight should be applied.

The annual update to the ACO's historical benchmark also differs for ACOs in their first versus second or subsequent agreement periods. In an ACO's first agreement period, the benchmark is updated each performance year based solely on the absolute amount of projected growth in national FFS spending for assignable beneficiaries (§ 425.602(b)). Although section 1899(d)(1)(B)(ii) of the Act requires us to update the benchmark using the projected absolute amount of growth in national per capita expenditures for Medicare Parts A and B services, we used our authority under section 1899(i)(3) of the Act to adopt an alternate policy under which we calculate the national update based on assignable beneficiaries, a subset of the Medicare FFS population as defined under § 425.20. For ACOs in a second or subsequent agreement period (beginning in 2017 and later years), we update the rebased benchmark annually to account for changes in FFS spending for assignable beneficiaries in the ACO's regional service area (§ 425.603(d)). We also used our authority under section 1899(i)(3) of the Act to adopt this alternate update factor based on regional FFS expenditures.

For all ACOs, at the time of reconciliation for each performance year, we further adjust the benchmark to account for changes in the health status and demographic factors of the ACO's performance year assigned beneficiary population (§§ 425.602(a)(9), 425.603(c)(10)). We use separate methodologies to risk-adjust the benchmark for populations of newly assigned and continuously assigned beneficiaries. For newly assigned beneficiaries, we use CMS–HCC prospective risk scores to adjust for changes in severity and case mix. We use demographic factors to adjust for changes in the health status of beneficiaries continuously assigned to the ACO. However, if the CMS–HCC prospective risk scores for the ACO's continuously assigned population decline, CMS will adjust the benchmark to reflect changes in severity and case mix for this population using the lower CMS–HCC prospective risk score. CMS–HCC prospective risk scores are based on diagnoses from the prior calendar year, as well as demographic factors.

In section II.D. of the August 2018 proposed rule (83 FR 41883) we proposed several changes to the program's benchmarking methodology. We proposed to replace the current risk adjustment methodology that separately considers newly and continuously assigned beneficiaries with an approach that uses changes in CMS–HCC prospective risk scores for all beneficiaries, subject to a symmetrical cap. We also proposed to incorporate regional expenditures into benchmarks starting in an ACO's first agreement period, to modify the regional adjustment to the historical benchmark by revising the schedule of weights that are applied to the adjustment and imposing a cap on the dollar amount of the adjustment, and to use a blend of regional and national trend factors to trend and update the benchmark. These proposals are described in more detail in sections II.D.2 and II.D.3 of this final rule.

Comment: A few commenters provided general support for the proposed changes to the program's benchmarking methodologies, with one commenter noting they could lead to more accurate determinations of savings and losses. This commenter also believed that the benchmarking proposals would help to encourage high performing ACOs to remain in the program and not be forced out due to inaccurate and unfair benchmarks. However, the commenter did not specify which elements of the current approach they believe to be inaccurate or unfair.

Response: We appreciate the general support offered for the proposed modifications to the benchmarking methodologies. We believe our proposals to allow for more complete upward risk adjustment and to incorporate regional factors into benchmarks during an ACO's first agreement period, which we are finalizing in this final rule, will help to improve benchmark accuracy by making an ACO's historical benchmark more reflective of the health status of its assigned beneficiary population and the local circumstances the ACO faces.

Comment: A few commenters called for improving the transparency and predictability and reducing the complexity of the program's benchmarking methodology. One commenter stated that greater transparency would allow ACOs to perform enhanced analytics and to better forecast their future performance. Several other commenters urged CMS to provide ACOs with additional data, including the data used by the agency to develop benchmarks. One commenter explained that this would allow ACOs to replicate CMS' methodology and improve their understanding of their own benchmarks. This commenter noted further that the current lack of clarity regarding the determination of

the benchmark is a serious financial risk that may deter continued participation. Other commenters generally called for greater alignment between the Shared Savings Program and Medicare Advantage in terms of spending targets or rates of growth in benchmarks, noting this would add predictability, reduce complexity, and create a more level playing field with respect to spending targets for the health care providers in a region. Another commenter suggested that staff in CMS regional offices representing the Shared Savings Program develop more expertise in the benchmarking methodology so that they could provide ACO leaders with one-on-one technical assistance in the place of more generalized webinars.

Response: We believe that the policies we are finalizing in this rule, including simplifying the risk adjustment methodology and adopting a more consistent benchmarking methodology across agreement periods, will promote both transparency and predictability. We appreciate commenters' input on how to further improve transparency and will consider these suggestions as we develop future education and outreach plans. We also note that we will continue to make data available, such as the county expenditure and county assigned beneficiary public use files and ACO public use files containing ACO-level financial and quality results for each performance year, which will allow stakeholders to perform their own analyses. We also appreciate commenters' interest in fostering greater alignment between the Shared Savings Program and Medicare Advantage. We will continue to explore opportunities to align the requirements of the two programs.

Comment: One commenter requested that CMS refrain from making any changes to the benchmarking or financial performance methodology during an existing agreement period. Further, they requested that CMS provide ACOs with sufficient data to assess the impact of such changes on their performance and allow them to elect whether to adopt the change immediately or defer to the next agreement period.

Response: We would like to note that the changes to the program's benchmarking methodology and to the financial risk models being finalized in this rule will be effective for new agreement periods beginning on July 1, 2019, and in subsequent years. ACOs that start a 12-month performance year on January 1, 2019, will have the option to complete the remaining years of their agreement period under their current track and subject to their existing benchmarking methodology. However, with the elimination of the required ''sit-out period'' being finalized in this rule (see section II.A.5.c.(4).(b) of this final rule), ACOs that wish to transition to the new policies sooner may do so by terminating their current participation agreement and immediately beginning a new agreement period. We believe that this approach will provide ACOs that are partway through an agreement period with more flexibility around the speed at which they transition to the new policies. As noted in the response to the previous comment, we will continue to make public use data available that can be used by ACOs to inform their decision-making.

2. Risk Adjustment Methodology for Adjusting Historical Benchmark Each Performance Year

a. Background

When establishing the historical benchmark, we use 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. The effect of this policy is to apply full CMS–HCC risk adjustment to account for changes in case mix in the assigned beneficiary population between the first and third benchmark years and between the second and third benchmark years. For consistency, this approach is also used in adjusting the historical benchmark to account for changes to the ACO's certified ACO participant list for performance years within an agreement period and when resetting the ACO's historical benchmark for its second or subsequent agreement period. See §§ 425.602(a)(3) and (8), 425.603(c)(3) and (8); see also Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (May 2018, version 6) available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/program-guidance-and-specifications.html.* Further, we use full CMS–HCC risk adjustment when risk adjusting county level FFS expenditures and to account for differences between the health status of the ACO's assigned population and the assignable beneficiary population in the ACO's regional service area as part of the methodology for adjusting the ACO's rebased historical benchmark to reflect regional FFS expenditures in the ACO's regional service area (see § 425.603(c)(9)(i)(C), (e)).

To account for changes in beneficiary health status between the historical benchmark period and the performance year, we perform risk adjustment using a methodology that differentiates between newly assigned and continuously assigned beneficiaries, as defined in § 425.20. As specified under §§ 425.604(a), 425.606(a), and 425.610(a), we use CMS–HCC prospective risk scores to account for changes in severity and case mix for newly assigned beneficiaries between the third benchmark year (BY3) and the performance year. We use demographic factors to adjust for these changes in continuously assigned beneficiaries. However, if the CMS–HCC prospective risk scores for the continuously assigned population are lower in the performance year, we use the lower CMS–HCC prospective risk scores to adjust for changes in severity and case mix in this population. As we described in earlier rulemaking, this approach provides a balance between accounting for actual changes in the health status of an ACO's population while limiting the risk due to coding intensity shifts—that is, efforts by ACOs, ACO participants, and/or ACO providers/suppliers to find and report additional beneficiary diagnoses so as to increase risk scores—that would artificially inflate ACO benchmarks (see for example, 81 FR 38008).

As described in the Shared Savings and Losses and Assignment Methodology specifications referenced previously in this section, all CMS–HCC and demographic beneficiary risk scores used in financial calculations for the Shared Savings Program are renormalized to ensure that the mean risk score among assignable beneficiaries in the national FFS population is equal to one. Renormalization helps to ensure consistency in risk scores from year to year, given changes made to the underlying risk score models. All risk adjustment calculations for the Shared Savings Program, including risk score renormalization, are performed separately for each Medicare enrollment type (ESRD, disabled, aged/dual eligible for Medicare and Medicaid, and aged/non-dual eligible for Medicare and Medicaid).

In practice, to risk adjust expenditures from one year to another, we multiply the expenditures that are to be adjusted by the quotient of two renormalized risk scores, known as the risk ratio. For example, to risk adjust the expenditures for an ACO's assigned beneficiary population from the first benchmark year to the third, we multiply benchmark year 1 (BY1) expenditures, by a risk ratio equal to the mean renormalized risk score among the ACO's assigned beneficiaries in benchmark year 3 (BY3) divided by the

mean renormalized risk score among the ACO's assigned beneficiaries in BY1. One percent growth in renormalized risk scores between 2 years would be expressed by a risk ratio of 1.010. This ratio reflects growth in risk for the ACO's assigned beneficiary population relative to that of the national assignable population.

ACOs and other program stakeholders have expressed various concerns about the methodology for risk adjusting an ACO's benchmark each performance year, as described in comments on previous rulemaking (see 76 FR 67916 through 67919, 80 FR 32777 through 32778, 81 FR 37962 through 37968). We refer readers to these earlier rules for more detailed discussions of the issues raised by stakeholders. A common concern raised is that the current risk adjustment methodology does not adequately adjust for changes in health status among continuously assigned beneficiaries between the benchmark and performance years. Commenters have argued that the lack of upward CMS–HCC risk adjustment in response to increased patient acuity makes it harder for ACOs to realize savings and serves as a barrier to more ACOs taking on performance-based risk.

Stakeholders have also raised concerns that the current methodology, under which risk adjustment is performed separately for newly and continuously assigned beneficiaries, creates uncertainty around benchmarks. One commenter in prior rulemaking described the policy as rendering the role of risk scores ''opaque'', making it difficult for ACOs to anticipate how risk scores may affect their financial performance (81 FR 37968). We have attempted to increase transparency around the program's risk adjustment process by providing beneficiary-level risk score information in quarterly and annual reports, as well as by providing detailed explanations of the risk adjustment calculations to ACOs through webinars. However, despite these efforts, concerns about transparency remain, as evidenced by the many requests for technical assistance from ACOs related to risk adjustment.

b. Proposed Revisions

We appreciate the concerns regarding our current risk adjustment methodology raised by stakeholders, who have indicated that the current approach may not adequately recognize negative changes in health status that occur at the individual beneficiary level, particularly among continuously assigned beneficiaries who have experienced an acute event, such as a heart attack, stroke, or hip fracture, between the third benchmark year and the applicable performance year. We recognize that such acute events, which almost always require a hospitalization, are likely to have an upward impact on CMS–HCC risk scores that is not attributable to provider coding initiatives.

At the same time, we remain concerned that CMS–HCC risk scores, in general, are susceptible to increased diagnostic coding efforts. As noted previously, we employ full CMS–HCC risk adjustment when establishing an ACO's historical benchmark for its first agreement period, when adjusting the benchmark to account for participant list changes within an agreement period, and when resetting the benchmark for a second or subsequent agreement period, as we believe that doing so improves the accuracy of the benchmark. We have observed evidence of a modest increase in diagnostic coding completeness in the benchmark period for ACOs in their second agreement period (rebased ACOs). Simulation results suggest that rebased ACOs were more likely to benefit from full CMS–HCC risk adjustment in the benchmark period than were ACOs in a first agreement period. For rebased ACOs, the benchmark period coincides with their first agreement period in the Shared Savings Program, a time when these ACOs and their ACO participants and ACO providers/suppliers had an incentive to engage in increased coding so as to maximize their performance year risk scores, as well as their rebased benchmark in the next agreement period. ACOs in a first agreement period would have had less incentive to encourage their ACO participants and ACO providers/suppliers to engage in coding initiatives during the benchmark period as it took place before they entered the program. We recognize, however, that increased coding by ACO participants and ACO providers/suppliers may also reflect efforts to facilitate care coordination, quality improvement, and population management activities which require more complete clinical information at the point of care.

We also acknowledge that our current approach to risk adjustment for the performance year makes it difficult for ACOs to predict how their financial performance may be affected by risk adjustment. The current approach involves multiple steps including identifying newly and continuously assigned beneficiaries for each ACO for both the performance year and BY3, computing mean CMS–HCC risk scores for both populations and mean demographic risk scores for the continuously assigned beneficiary population by Medicare enrollment type, conducting a test to determine whether an ACO will receive CMS–HCC or demographic risk adjustment for its continuously assigned population, and determining and applying the risk ratios used to adjust benchmark expenditures for the performance year. Although we have made efforts to explain these steps in detail through our program specifications, report documentation, and webinars, and have made beneficiary-level risk score data available, we frequently receive requests for technical assistance in this area suggesting that the methodology is still not entirely clear to ACOs.

To balance these competing concerns, during the development of the proposed rule we considered policies that would allow for some upward growth in CMS–HCC risk scores between the benchmark period and the performance year, while still limiting the impact of ACO coding initiatives, and also provide greater clarity for ACOs than the current methodology. In contemplating alternative policies, we also considered lessons learned from other CMS initiatives, including models tested by the Innovation Center. Finally, as we wished to encourage ACOs to take on higher levels of risk, we considered the importance of adopting a balanced risk adjustment methodology that would provide ACOs with some protection against decreases in risk scores.

In the August 2018 proposed rule (83 FR 41885), we explained that our preferred approach would be to eliminate the distinction between newly and continuously assigned beneficiaries. We would use full CMS–HCC risk adjustment for all assigned beneficiaries between the benchmark period and the performance year, subject to a symmetrical cap of positive or negative 3 percent for the agreement period, which would apply such that the adjustment between BY3 and any performance year in the agreement period would never be more than 3 percent in either direction. In other words, the risk ratios applied to historical benchmark expenditures to capture changes in health status between 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. As is the case under the current policy, risk adjustment calculations would still 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 still be renormalized to the national assignable beneficiary population for that enrollment type before the cap is applied. Table 12 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, for any performance year in the agreement period:

TABLE 12—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

In the 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; the ACO would receive full upward and downward adjustment, respectively, for these enrollment types.

As we explained in the August 2018 proposed rule, this approach would provide full CMS–HCC risk adjustment for ACOs with changes in CMS–HCC risk below the cap, and a partial adjustment for ACOs with changes in CMS–HCC risk above the cap. Initial modeling suggested that among the 239 ACOs that received demographic risk adjustment for their continuously assigned population under the current policy in PY 2016 (55 percent of the 432 total ACOs reconciled), around 86 percent would have received a larger positive adjustment to their benchmark had this policy been in place. Therefore, as we stated in the August 2018 proposed rule, we believed this approach would more consistently account for worsening health status of beneficiaries compared to the current policy. This could reduce the incentive for ACOs to avoid complex patients and potentially lead more ACOs to accept higher levels of performance-based risk. However, because of the cap on the increase in CMS–HCC risk, we believed that this policy would continue to provide protection to the Medicare Trust Funds against unwarranted increases in CMS–HCC prospective risk scores that are due to increased coding intensity, by limiting the impact of such increases on ACO benchmarks.

By instituting a symmetrical cap, this approach would also limit large decreases in CMS–HCC prospective risk scores across all assigned beneficiaries. We believed that such an approach would provide ACOs with a greater incentive to assume performance-based risk than the current methodology, which provides ACOs with no protection from risk score decreases. Among the 193 ACOs that received CMS–HCC risk adjustment under the current policy for their continuously assigned population in PY 2016, 69 percent would have received a smaller negative adjustment with the symmetrical 3 percent cap. We also believed that this approach, which mirrors one of the risk adjustment methodologies tested in the Next Generation ACO Model, would have an advantage over the current Shared Savings Program policy in that it would be more straightforward, making it easier for ACOs to understand and determine the impact of risk adjustment on their benchmark. ACOs would be subject to risk adjustment within a clearly defined range, allowing them to more easily predict their performance.

Our proposed choice of 3 percent as the preferred level for the symmetrical cap was influenced by program experience. A review of CMS–HCC risk score trends among Shared Savings Program ACOs found that a 3 percent cap on changes in aged/non-dual CMS–HCC risk scores (the enrollment category that represents the majority of assigned beneficiaries for most ACOs) would limit positive risk adjustment for less than 30 percent of ACOs, even when there is a 5-year lapse between BY3 and the performance year, which would be the case in the final year of a 5 year agreement period under the proposal discussed in section II.A.2. of this final rule (or a 6-year lapse for the final performance year of the agreement period for ACOs that start a new agreement period on July 1, 2019, under the proposal discussed in section II.A.2. of this final rule). A 3-percent symmetrical cap was also advocated by some commenters on the 2016 proposed rule, who encouraged the Shared Savings Program to adopt a risk adjustment model similar to the one being used by the Next Generation ACO Model (see 81 FR 37968). Although we stated that we believed that a 3 percent cap on changes in CMS–HCC risk scores would be reasonable and appropriate, we also considered alternate levels for a cap or allowing full CMS–HCC risk adjustment with no cap at all. However, we were concerned that a lower cap would not offer enough ACOs meaningfully greater protection against health status changes relative to the current approach. At the same time, we were concerned that adopting a higher cap, or allowing for full, uncapped risk adjustment would not provide sufficient protection against potential coding initiatives.

After consideration of these alternatives, we proposed to change the program's risk adjustment methodology to use CMS–HCC prospective risk scores 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. The cap would reflect the maximum change in risk scores allowed in an agreement period between BY3 and any

performance year in the agreement period. For ACOs participating in a 5 year and 6-month agreement period beginning on July 1, 2019, as discussed in section II.A.7. of this final rule, the cap would represent the maximum change in risk scores for the agreement period between BY3 and CY 2019 in the context of determining financial performance for the 6-month performance year from July 1, 2019, through December 31, 2019, as well as the maximum change in risk scores between BY3 and any of the subsequent five performance years of the agreement period. We would apply this approach to ACOs participating under the proposed BASIC track, as reflected in the proposed new section of the regulations at § 425.605, and to ACOs participating under the proposed ENHANCED track, as reflected in the proposed modifications to § 425.610. We sought comment on this proposal, including the level of the cap.

Comment: Many of the stakeholders that commented on the proposed changes to the risk adjustment methodology applauded the proposed discontinuation of the current methodology, which distinguishes between newly and continuously assigned beneficiaries, and generally supported CMS' efforts to better recognize changes in beneficiary risk scores during an agreement period. A few commenters noted that the current policy creates unnecessary confusion and complexity, while another commenter believed that not allowing for upward CMS–HCC adjustment for all beneficiaries was unreasonable. Another commenter described the proposed approach as being simpler than the current methodology while being more protective of changes in patient mix.

Unlike other commenters, MedPAC encouraged CMS to continue to distinguish between newly and continuously assigned beneficiaries, but to modify the current methodology to adjust benchmarks based on only demographic factors for continuously assigned beneficiaries and based on CMS–HCC scores for newly assigned beneficiaries. Under this approach we would no longer use CMS–HCC risk scores to perform downward adjustments for continuously assigned beneficiaries, which would remove the asymmetry of the current methodology. MedPAC expressed concern that the proposed methodology would allow ACO benchmarks to increase due to either more aggressive coding efforts or the worsening health status of assigned beneficiaries and that an ACO would potentially be penalized when patients' health is maintained or better managed, which they noted is a key objective of the program. They believe that their recommended alternative would improve the alignment of ACO financial incentives with beneficiary health status, allowing ACOs to benefit financially when they do a good job of maintaining patient's health.

Response: We appreciate commenters' support of our proposal to eliminate the current methodology used to risk adjust historical benchmark expenditures and our desire to better recognize changes in beneficiary health status while still protecting the Medicare Trust Funds from increases in coding intensity. We agree with commenters that the elimination of the current methodology, which distinguishes between newly and continuously assigned beneficiaries, should provide a less complex and more transparent risk adjustment approach.

We believe that MedPAC's suggested approach would not accomplish one of the goals of our proposed modification to the risk adjustment methodology, which was to provide better recognition for changes in beneficiary health status between the benchmark period and the performance year. We are also concerned that by limiting downward adjustments in risk scores for continuously assigned beneficiaries to the changes in demographic risk scores for this population, MedPAC's recommended methodology could create windfall gains for an ACO if average CMS–HCC risk scores for the ACO's continuously assigned beneficiaries decrease more (or increase less) between the benchmark period and the performance year than the national average.

Comment: Several commenters appeared to support the proposed symmetrical 3 percent cap on changes in risk scores, with one requesting that it be allowed to go into effect for performance years beginning on January 1, 2019. They suggested that the proposed change would reduce the uncertainty regarding the impact of risk adjustment on ACO financial results due to the 6-month agreement period extension for some ACOs. Other commenters who supported this proposal requested that CMS provide greater transparency regarding the expected impacts of the proposed cap and encouraged CMS to monitor the cap to ensure that it is providing proper balance between CMS's concerns about increases in coding intensity and the desire for health care providers to accurately capture beneficiary health status. However, most of the commenters who offered general support for the proposed changes to the risk adjustment methodology, as well as other commenters, opposed the proposed symmetrical 3 percent cap.

Several commenters, including commenters representing academic and research institutions, physician associations, health care alliances and task forces, and individual ACOs, expressed concern that that the proposed symmetrical cap on risk score changes may have unintended consequences by introducing incentives for ACO to engage in favorable risk selection; that is, to avoid sicker beneficiaries or to seek out healthier beneficiaries. A few commenters recommended that, at a minimum, CMS eliminate the proposed downside cap.

Many commenters expressed concerns that the proposed cap would not be sufficient to adequately capture health status changes over a 5-year agreement period. A number of commenters representing the same organization stated that the proposed cap would not protect health care providers who serve the most medically complicated patients and would make shared savings unattainable by continuing to incorrectly capture the health status of beneficiaries. Several other commenters described the 3 percent cap as arbitrary and insufficient when applied across a five-year agreement period. Others called for increasing the cap on upward adjustments over the length of the agreement period in order to account for the aging of the population and natural progression of disease over the agreement period and to best capture acuity increases in years farthest from the benchmark. Another commenter noted that an upward cap on risk adjustment would limit the ability to capture random changes in patient mix which, in turn, would reduce the predictability of an ACO's financial performance and make the program less attractive. Another commenter suggested that artificially capping risk scores denies ACOs access to information that provides an accurate picture of patient health status. One commenter pointed out that a symmetrical 3 percent cap would leave both ACOs and CMS vulnerable to significant changes in population demographics. Another commenter liked that the proposed cap was more consistent with policies used in the Next Generation ACO Model but was concerned that, when applied over a 5-year agreement period, the 3 percent cap would penalize ACOs that treat high risk patients or patients whose burden of illness increases over time.

While the perceived inability of the proposed cap to capture health status changes over a five year agreement

period was the most commonly cited concern among commenters, many commenters also had concerns about the potential impact of the proposed cap on upward benchmark adjustments for ACOs whose providers are new to the concept of risk adjustment, ACOs that are engaged in efforts to improve their diagnostic coding to better reflect the acuity of their patients, or ACOs that are working to manage care for complex patients who were previously receiving only episodic services. One commenter expressed the belief that limiting increases in CMS–HCC risk scores punishes ACOs that are attempting to accurately capture the conditions of their patients and suggested that the proposed cap would lead to greater restrictions on changes in risk scores than the current policy. Other commenters had similar concerns, indicating that the proposed upward limit on risk score growth would discourage efforts by ACOs to improve diagnostic coding. One commenter stated that accurate risk adjustment based on patients' complete CMS–HCC) classification was one of the key components to organizational success in a Shared Savings Program ACO and expressed the belief that the proposed cap would not provide sufficient incentives for health care providers to make investments in improving their documentation and coding practices. Another commenter noted that as patients receive better, more coordinated care, their risk profile will also increase and that health care providers should be encouraged to continue to care for complex patients who could benefit from comprehensive care management.

One commenter did not offer a suggestion for a specific alternative to the proposed symmetrical 3 percent cap but requested that CMS provide the modeling upon which it based its proposal so that ACOs can analyze the same data that CMS used and provide recommendations for a higher cap that would meet the needs of both CMS and ACOs. However, many other commenters offered a variety of alternatives to the proposed cap. The most common recommendation was for a symmetrical 5 percent cap over the agreement period. One commenter stated that this cap would be more accurate over a 5-year term. Another commenter justified this higher cap for the agreement period by noting that ACOs may experience changes in the population that affect the risk score by more than 1 percent per year. Another suggestion offered by several commenters was to allow risk scores to change by 3 percent annually over the course of the agreement period, such that an ACO's risk score would be allowed to change by 3 percent in the first year of the agreement period, by an additional 3 percent in the second year, and so on. One commenter suggested that a 3 percent annual cap would preserve stability and better reflect the clinical complexity and patient characteristics of an ACO's population. Commenters also suggested other alternatives including fixed caps for the agreement period above 5 percent, caps that increase for each subsequent year of the agreement period, or caps that vary based on ACO size or ACO track.

Alternatively, several commenters called for full, uncapped CMS–HCC risk adjustment. A few commenters suggested that using risk scores that are renormalized to the national population would protect the Medicare Trust Funds from increased coding without the need for caps. Another commenter noted that uncapped risk adjustment would be consistent with risk adjustment in Medicare Advantage. Others suggested that full risk adjustment would help organizations that serve higher acuity patient populations and would protect small and medium size ACOs from changes in risk profiles that can result from patient churn. One commenter expressed the belief that capping risk adjustment would harm ACOs that have been affected by an extreme and uncontrollable circumstance, as such events can have negative impacts on beneficiary mental and physical health that would not be present in the benchmark years.

Response: We appreciate all of the comments we received on these proposals. After considering the comments received in response to our proposed changes to the risk adjustment methodology, we are finalizing our proposal to use CMS–HCC risk scores to adjust the historical benchmark for all beneficiaries. While we are finalizing our proposal to cap positive risk score changes at 3 percent, we are not finalizing our proposal to limit negative risk score changes. Although we originally believed that a symmetrical cap would offer a balanced approach and provide an incentive for ACOs to accept performance-based risk by protecting them from large negative adjustments to their benchmark expenditures, we ultimately share the concern raised by some commenters that this approach would encourage favorable risk selection. If ACOs seek to attract low-cost beneficiaries or avoid high-cost beneficiaries, they could lower their performance year expenditures without any corresponding adjustment to their benchmark due to the cap on negative risk adjustments. We believe that this effect would be detrimental to medically complex patients, who may miss the opportunity to receive better coordinated care through an ACO, as well as to the Medicare Trust Funds.

However, after additional consideration, we are finalizing our proposal to apply a 3 percent cap on upward risk adjustment. We remain concerned that adopting a higher cap on risk score increases, or adopting no cap, would provide insufficient protection against efforts to increase coding intensity.

We disagree with the premise implied by some commenters that the overall disease burden of an ACO's assigned beneficiary population will necessarily increase over a longer agreement period. The cap on risk score increases will be applied to changes in an ACO's mean renormalized CMS–HCC risk score between benchmark year 3 and the performance year. The changes in the mean risk scores will reflect both changes in health status among beneficiaries that are assigned to the ACO in both periods and the impact of beneficiaries exiting and entering the ACO's assigned beneficiary population between the two periods. We might expect disease burden to increase among the stable component of the ACO's assigned beneficiary population because, by default, this population will be older during the performance year than during the third benchmark year. However, the impact of the churn in the ACO's beneficiary population is indeterminate, meaning that it could increase or decrease the ACO's average risk score. For example, an ACO's overall mean risk score could decrease if a disproportionately large number of new Medicare enrollees are assigned to the ACO in the performance year, even if the mean risk score for the stable component of the population has increased. We continue to believe that a positive 3 percent cap represents a reasonable balance between recognizing potential differences in health status between an ACO's benchmark year 3 and performance year populations and protecting the Trust Funds against excessive coding.

We recognize that changes in risk scores can occur when providers and suppliers increase the completeness and accuracy of their diagnostic coding, even if these efforts are not made with an intention of gaming. We do not believe that the proposed 3 percent cap in upward risk adjustment that we are finalizing would necessarily harm or reduce incentives for ACOs that are attempting to more accurately capture

the conditions of their patients. As we described in the August 2018 proposed rule, our analysis based on performance year 2016 found that the proposed 3 percent cap on risk score increases would have been less restrictive than the current approach for ACOs that received demographic risk adjustment for their continuously assigned population and would have the added benefit of being simpler and more transparent.

We also noted in the proposed rule that in a review of risk score trends among Shared Savings Program ACOs, a 3 percent cap on changes in aged/non-dual risk scores would limit positive risk adjustment for less than 30 percent of ACOs over a 5- or 6-year period. This analysis, which was based on CMS–HCC risk score trends between 2009 and 2015 and between 2010 and 2015 (using benchmark and performance year risk score data from performance year 2015 results) and trends between 2011 and 2016 (using benchmark and performance year risk score data from performance year 2016 results), found generally comparable results for the other three Medicare enrollment types. The aged/dual category showed the highest percentage of ACOs that would be bound by a positive 3 percent cap over a 5- or 6-year period at 30 to 33 percent. We have since performed additional analysis that looked at 5-year trends in ACO CMS–HCC risk scores using benchmark and performance year data from results for performance years 2014 through 2017. This expanded analysis found similar results, with the share of ACOs with 5-year risk score increases exceeding 3 percent ranging from 20 percent for ESRD to 32 percent for aged/dual. We would like to note, however, that even for ACOs affected by the cap, there will most often be a varying mix of risk ratios across the four enrollment types. Furthermore, capping will not limit a potential benchmark increase related to shifts in beneficiaries from lower to higher-cost enrollment types (for example, growth in the proportion of aged/dual beneficiaries between benchmark year 3 and the performance year). We would like to note that for stakeholders interested in conducting their own analyses of risk score trends, the Shared Savings Program ACO public use files, available on the CMS website for performance years 2013 through 2017, include ACO-level CMS–HCC risk scores for each benchmark year and performance year.

We appreciate the concern raised by one commenter about the implications of the risk adjustment cap on ACOs whose assigned beneficiaries reside in areas impacted by an extreme and uncontrollable circumstance. We believe that the 3 percent cap that we are finalizing will allow for greater growth in risk scores for continuously assigned beneficiaries relative to the current policy. Thus, we believe the policy will better recognize any negative health status changes experienced by ACO assigned beneficiaries residing in disaster-affected areas than our current approach, while still guarding against increases in coding intensity.

Although we believe that the 3 percent cap on positive risk adjustment that we are finalizing in this rule is reasonable, we will monitor the impacts of the cap as we gain experience with the new policy and, if appropriate, will propose modifications through future notice and comment rulemaking.

Comment: Several commenters recommended that any cap be applied at the aggregate level rather than the enrollment type level. One commenter suggested that capping the risk ratios in the aggregate across the four beneficiary enrollment types to account for smaller sample sizes and resulting higher volatility for certain enrollment types. Another commenter noted that applying the cap at the aggregate level would be more appropriate to accurately reflect the changing risk and mix of an ACO's population. An additional commenter expressed the belief that ACOs should not be penalized if they have low risk score growth overall but high growth in any one given eligibility category.

Response: We appreciate the perspectives offered by commenters on whether the risk score cap should be applied at the enrollment type level or the aggregate level. Although an aggregate approach could potentially address concerns about greater volatility among enrollment types with fewer beneficiaries, we believe that the proposed approach of applying the cap separately for each enrollment type would be more consistent with other benchmarking calculations, which are also performed for each enrollment type, and would also be more transparent. We therefore are finalizing our proposal to apply the cap on risk adjustment increases at the enrollment type level.

Comment: Several commenters acknowledged that excessive coding was a potential concern but encouraged CMS to consider an approach other than capping CMS–HCC risk score growth to address this issue. One commenter suggested implementing a coding intensity adjustment like the one used in Medicare Advantage, creating audit mechanisms to detect inappropriate coding, and introducing harsh penalties for ACOs found to engage in these practices. Some of these ideas were echoed by other commenters who suggested that CMS consider approaches used by Medicare Advantage or make greater use of auditing. Another commenter suggested using ACO Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey data to determine the extent to which increases in CMS–HCC scores reflect changes in coding versus changes in health status and to use that information to limit benchmark increases in a more refined, ACO-specific manner after an initial grace period.

One commenter recommended using a prospectively-determined annual coding factor adjustment that CMS could, with advance regulatory notice to ACOs, retroactively modify if the final observed risk trend for the applicable performance years deviates significantly from what was projected. The commenter noted that this approach is currently used in the Next Generation ACO Model and that it would be preferable to the renormalization approach currently employed in the Shared Savings Program because it would allow ACOs more predictability in their financial forecasting.

Response: We did not propose or seek comment on alternative mechanisms for addressing coding concerns in the proposed rule and are therefore not adopting any of these suggestions at this time. We believe the cap we are finalizing on positive growth in renormalized risk scores provides a transparent approach to limiting the potential adverse effects of ACO-level coding initiatives. However, we will continue to monitor this issue and, if necessary, we will make appropriate refinements to the risk adjustment methodology to address coding concerns through future rulemaking.

Comment: Some commenters offered other criticisms of the program's current risk adjustment methodology or the CMS–HCC model, with a number suggesting refinements. For example, several commenters recommended that risk adjustment should account for social and economic factors, with one commenter suggesting that CMS use clinical and social characteristics included in the CAHPS survey to further adjust ACO benchmarks. One commenter recommended including a frailty adjustment such as is used in the Programs for All-Inclusive Care for the Elderly (PACE) program to better reflect the true cost of caring for patients near the end of life. Another commenter suggested that CMS explore changes to the risk adjustment model to lower the influence of provider-reported risk

factors and rely more on demographic factors and beneficiary-reported diagnoses, functional status, and other factors that can provide equal or greater explanatory statistical power than the current model. A different commenter also noted that the program's risk adjustment methodology still does not account for important factors such as functional status and severity or stage of illness. Another commenter requested that CMS refine the CMS–HCC risk adjustment methodology to better account for the unique characteristics and needs of the SNF population.

One commenter noted that the CMS–HCC risk adjustment model does not recognize all chronic conditions using chronic ischemic heart disease without angina pectoris as an example. This commenter noted that individuals with heart disease (with or without angina) require on-going care management for this chronic condition and health care providers need the resources to do so. The same commenter also noted that the current annual adjustment to the historical benchmark for changes in beneficiary health status at the time of reconciliation does not take into consideration disease progression and/or unforeseen circumstances or changes in health status and/or acuity. They believed that an increase in adjustment frequency would assist ACOs in being more successful. A separate commenter also suggested that CMS fully recalculate benchmarks more frequently, but did not explain what they perceived as the benefits of this option.

Another commenter recommended that risk scores for ACO beneficiaries should mirror risk scoring for Medicare Advantage patients but did not provide further context for this suggestion. A different commenter suggested that CMS adopt a rolling risk adjustment methodology similar to the one that is used in the Next Generation ACO Model in place of the current approach that compares each performance year to benchmark year 3.

A few other commenters recommended that CMS modify the current methodology to use the same CMS–HCC risk score model to calculate risk scores for both the benchmark years and the performance year. Another commenter requested that CMS make adjustments to ACO baseline scores, not just benchmarks, as many conditions that may be newly documented when patients are assigned to an ACO are not new diagnoses for the patient. A few commenters requested that CMS implement the same risk adjustment policy for the Shared Savings Program and Medicare Advantage or across all Medicare programs to ensure parity, while another recommended that CMS consider policies that equalize current actuarial disparities that result from risk adjustment across Medicare programs.

Response: We appreciate the concerns raised by commenters and the suggestions offered for refining the Shared Savings Program's general risk adjustment methodology, which for each benchmark or performance year, relies on the national CMS–HCC prospective risk adjustment model used in Medicare Advantage for that same calendar year. Using the CMS–HCC prospective risk adjustment model allows the Shared Savings Program to align with Medicare Advantage and allows us to incorporate risk adjustment enhancements and refinements, such as future adjustments for beneficiaries with multiple conditions, as they are incorporated into the CMS–HCC model over time. We will share the feedback received on the CMS–HCC model with our CMS colleagues that administer that model.

We decline at this time to adopt commenters' suggestions for further refinements to the risk adjustment methodology for the Shared Savings Program. We believe that the modifications to the risk adjustment methodology that we are finalizing will better recognize changes in health status in an ACO's assigned beneficiary population than the current methodology, while still providing a degree of protection against intensive coding practices. We also note that our current practice of using risk scores that are renormalized to the national assignable FFS population adjusts for changes in the underlying CMS–HCC models that may occur between benchmark years or between benchmark years and the performance year.

Final Action: After considering the comments received and additional internal analysis, we are finalizing some, but not all, of our proposed changes to the program's risk adjustment methodology. Specifically, we will use CMS–HCC prospective risk scores to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries, subject to a cap of positive 3 percent for the agreement period for agreement periods beginning on July 1, 2019, and in subsequent years. This cap will reflect the maximum increase in risk scores allowed between BY3 and any performance year in the agreement period. For ACOs participating in a 5 year and 6-month agreement period beginning on July 1, 2019, as discussed in section II.A.7. of this final rule, the cap will represent the maximum change in risk scores for the agreement period between BY3 and CY 2019 in the context of determining financial performance for the 6-month performance year from July 1, 2019, through December 31, 2019, as well as the maximum change in risk scores between BY3 and any of the subsequent five performance years of the agreement period. The cap will be applied separately for each of the four enrollment types. We will apply this approach for ACOs participating under the BASIC track through a new provision of the regulations at § 425.605(a), and for ACOs participating under the proposed ENHANCED track through modifications to the existing provision at § 425.610(a). We are not finalizing our proposal to apply a 3 percent cap on negative risk score changes.

3. Use of Regional Factors When Establishing and Resetting ACOs' Benchmarks

a. Background

As described in the background for this section, we apply a regional adjustment to the rebased historical benchmark for ACOs entering a second or subsequent agreement period in 2017 or later years. This adjustment reflects a percentage of the difference between the regional FFS expenditures in the ACO's regional service area and the ACO's historical expenditures. The percentage used in calculating the adjustment is phased in over time, ultimately reaching 70 percent, unless the Secretary determines a lower weight should be applied and such lower weight is specified through additional notice and comment rulemaking.

In the June 2016 final rule, we laid out the steps used to calculate and apply the regional adjustment (see 81 FR 37963). These steps are recapped here:

- First, we calculate the ACO's rebased historical benchmark and regional average expenditures for the most recent benchmark year for each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible), resulting in average per capita expenditure values for each of the Medicare enrollment types. The regional average expenditure amounts are adjusted for differences between the health status of the ACO's assigned beneficiary population and that of the assignable population in the ACO's regional service area.
- For each Medicare enrollment type, we then determine the difference between the average per capita regional amount and the average per capita amount of the ACO's rebased historical benchmark. These values may be positive or negative. For example, the difference between these values for a particular Medicare enrollment type will be

expressed as a negative number if the value of the ACO's rebased historical benchmark expenditure for that Medicare enrollment type is greater than the regional average amount.

- Next, we multiply the resulting difference for each Medicare enrollment type by the applicable percentage weight used to calculate the amount of the regional adjustment for that agreement period. The products (one for each Medicare enrollment type) resulting from this step are the amounts of the regional adjustments that will be applied to the ACO's historical benchmark.
- We then apply the adjustment to the ACO's rebased historical benchmark by adding the adjustment amount for the Medicare enrollment type to the ACO's rebased historical benchmark expenditure for the same Medicare enrollment type.
- We next multiply the regionally-adjusted value of the ACO's rebased historical benchmark for each Medicare enrollment type by the proportion of the ACO's assigned beneficiary population for that Medicare enrollment type, based on the ACO's assigned beneficiary population for benchmark year 3.
- Finally, we sum expenditures across the four Medicare enrollment types to determine the ACO's regionally-adjusted rebased historical benchmark.

In the June 2016 final rule, we also detailed how the percentage weight used to calculate the regional adjustment will be phased in over time (see 81 FR 37971 through 37974). For the first agreement period in which this methodology applies, ACOs for which the weighted average adjustment across the enrollment types is positive (net positive adjustment) will receive a weight of 35 percent for all enrollment types (including individual enrollment types for which the adjustment is negative) and ACOs for which the weighted average adjustment is negative (net negative adjustment) will receive a weight of 25 percent for all enrollment types (including individual enrollment types for which the adjustment is positive). For the second agreement period in which the methodology applies, ACOs with a net positive adjustment will receive a weight of 70 percent for all enrollment types and ACOs with a net negative adjustment will receive a weight of 50 percent for all enrollment types. By the third agreement period in which the methodology applies, ACOs with either a net positive or a net negative adjustment will receive a weight of 70 percent for all enrollment types, unless the Secretary determines that a lower weight should be applied.

This regional adjustment is one of three ways in which regional expenditures are currently incorporated into the program's methodology for resetting the historical benchmark for an ACO's second or subsequent agreement period. We also use regional, instead of national, trend factors for each enrollment type to restate BY1 and BY2 expenditures in BY3 terms when calculating the rebased benchmark, and we use regional update factors to update the regionally-adjusted rebased historical benchmark to the performance year at the time of financial reconciliation. As described in the June 2016 final rule (81 FR 37977 through 37981), we used our statutory authority under section 1899(i)(3) of the Act to adopt a policy under which we update the benchmark using regional factors in lieu of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program as required under section 1899(d)(1)(B)(ii) of the Act.

The regional trend factors used to calculate an ACO's rebased benchmark and the regional update factors used to update the benchmark to the performance year represent growth rates in risk-adjusted FFS expenditures among assignable beneficiaries in the ACO's regional service area, including beneficiaries assigned to the ACO. An ACO's regional service area is defined at § 425.20 as all counties in which at least one of the ACO's assigned beneficiaries resides. To calculate expenditures used in determining the regional adjustment and the trend and update factors, we first calculate risk-adjusted FFS expenditures among assignable beneficiaries for each county in the ACO's regional service area and then weight these amounts by the proportion of the ACO's assigned beneficiaries residing in each county, with all calculations performed separately by Medicare enrollment type (ESRD, disabled, aged/dual, aged/non-dual).

In the June 2016 final rule, we discussed the benefits that we believe to be associated with incorporating regional expenditures into ACO benchmarks. We explained, for example, that the incorporation of regional expenditures provides an ACO with a benchmark that is more reflective of FFS spending in the ACO's region than a benchmark based solely on the ACO's own historical expenditures (see 81 FR 37955). We believe that this approach creates stronger financial incentives for ACOs that have been successful in reducing expenditures to remain in the program, thus improving program sustainability. Many commenters expressed support for the approach, citing it as an improvement over the existing rebasing methodology (see 81 FR 37956). In the June 2016 final rule, we also discussed how using regional trend and update factors would allow us to better capture the cost experience in the ACO's region, the health status and socio-economic dynamics of the regional population, and location-specific Medicare payments when compared to using national FFS expenditures (see 81 FR 37976 through 37977). In that rule, we stated our intention to explore the possibility of incorporating regional expenditures, including the regional adjustment and regional trend and update factors, in the benchmark established for an ACO's first agreement period (see 81 FR 37973). In section II.D.3.b. of this final rule, we discuss our proposals for incorporating regional expenditures into the benchmarks for ACOs in their first agreement period under the program.

We also acknowledged in the June 2016 final rule that the incorporation of regional expenditures into ACO benchmarks can have differential effects depending on an ACO's individual circumstances (see 81 FR 37955). For example, ACOs with low historical expenditures relative to their regional service area will see their rebased historical benchmark increase due to the regional adjustment, whereas the benchmarks for higher spending ACOs will be reduced. One concern is that, as the higher weights for the regional adjustment are phased in over time, the benchmarks for low-spending ACOs may become overly inflated to the point where these organizations need to do little to maintain or change their practices to generate savings. For higher-spending ACOs, there is the concern that a negative regional adjustment will discourage program participation or discourage these ACOs from caring for complex, high-cost patients. There is also concern about the longer-term effects on participation resulting from lower trend and update factors among ACOs that have had past success in reducing expenditures and that serve a high proportion of the beneficiaries within certain counties in their regional service area. In sections II.D.3.c. and II.D.3.d. of this final rule, we discuss our proposals in the August 2018 proposed rule designed to mitigate these concerns.

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

A number of stakeholders offering comments on the February 2016 proposed rule advocated for extending the policies incorporating regional expenditures proposed for determining the rebased benchmarks for ACOs entering a second or subsequent

agreement period under the program to the methodology for establishing the benchmarks for ACOs in their first agreement period under the program (see 81 FR 37971). While we declined to modify the methodology used to establish benchmarks for ACOs in a first agreement period to incorporate regional expenditures as part of the June 2016 final rule, we did signal our intention to explore this matter further after gaining experience with the new rebasing methodology (see 81 FR 37973).

Since the publication of the June 2016 final rule we have employed the new methodology to determine rebased benchmarks for ACOs starting second agreement periods in 2017 and 2018. This experience has reinforced our belief that a benchmarking methodology that incorporates regional expenditures, in addition to an ACO's own historical expenditures, is important for the sustainability of the program. For agreement periods starting in 2017, for example, we found that around 80 percent of ACOs receiving a rebased benchmark benefitted from receiving a regional adjustment. Having observed variation across ACO regional service areas, we also maintain that the incorporation of regional expenditure trends can lead to more accurate benchmarks that better reflect experience in ACOs' individual regions than benchmarks computed solely using national factors. As we explained in the August 2018 proposed rule (83 FR 41887), we believe that introducing regional expenditures into the benchmarking methodology for ACOs in a first agreement period, as has been recommended by stakeholders, would serve to further strengthen the incentives under the program, improve program sustainability, and increase the accuracy of benchmark calculations for new ACOs by making their benchmarks more reflective of the regional environment in which these organizations operate. We also believe that adopting a more consistent benchmarking methodology would provide greater simplicity and more predictability for ACOs. Under this approach, ACOs entering the program would only be required to familiarize themselves with a single benchmarking methodology that would apply for all agreement periods under the program.

For the previously stated reasons, we proposed 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. Under this proposal, we would use almost the same methodology for determining the historical benchmarks for ACOs in their first agreement period as would apply for ACOs in their second or subsequent agreement period, including all policies proposed in the August 2018 proposed rule, should they be finalized, regarding establishing the historical benchmark at the start of the agreement period, adjusting the historical benchmark for each performance year within an agreement period, and updating the benchmark for each performance year (or for CY 2019 in the context of determining the financial performance of ACOs during the 6-month performance year from July 1, 2019, through December 31, 2019, as discussed in section II.A.7. of this final rule). The only distinction between the methodology that would be used to determine the historical benchmark for ACOs in their first agreement period and those in a second or subsequent agreement period would be the weights that are applied to the 3 benchmark years. Under this proposal, we 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. As described in the June 2015 final rule (80 FR 32787 through 32788), the use of equal weights when calculating the rebased benchmark was motivated by the concern that placing higher weights on the later benchmark years would reduce the incentive for ACOs that generate savings or that are trending positive in their first agreement period to participate in the program over the longer run, or reduce incentives for ACOs to achieve savings in the final year of their first agreement period. This concern is not relevant for ACOs in a first agreement period. Therefore, for these ACOs, we favored maintaining the existing weights, which we believe are more accurate because they capture the ACO's most recent experience in the benchmark period.

We proposed to add a new provision to the regulations at § 425.601 that would describe how we would 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. We sought comment on this proposal.

Comment: The majority of comments we received on the proposal to incorporate regional expenditures in an ACO's first agreement period were generally supportive of the idea. One commenter also offered support for the proposed implementation timeline and a few commenters noted that they agreed with using weights of 25 and 35 for the regional adjustment for ACOs in their initial agreement period. Some commenters, while providing general support for the proposal, did not necessarily agree with CMS' proposals to modify the regional adjustment or the trend and update factors used in benchmarking discussed in sections II.D.3.c and II.D.3.d of this final rule, respectively. One commenter supported the proposal to incorporate regional expenditures into an ACO's benchmark starting in its first agreement period and our proposal to continue using weights of 10 percent, 30 percent, and 60 percent for the first, second, and third benchmark years in an ACO's first agreement period, respectively, but requested that CMS provide additional clarification on how these proposals would impact the majority of ACOs participating in the program.

Commenters provided various justifications for their support of incorporating regional expenditures into an ACO's initial benchmark:

- Several commenters noted that incorporating regional trends would allow the benchmark to better reflect an ACO's local environment, with a few stating such benchmarks would be more accurate and fairer.
- A few commenters noted their belief that using a blend of ACO historical expenditures and regional expenditure data is preferable to relying on only one or the other and supported implementing the regional adjustment when an ACO first enters the program rather than waiting until at least the second agreement period. Other commenters remarked that the earlier incorporation of regional factors into benchmarks was particularly important given the proposed longer five-year agreement periods.
- Several commenters suggested that incorporating regional expenditures into the benchmark for an ACO's first agreement period could improve incentives for participation among low-cost ACOs, with some noting it could incentivize participation among low cost providers without necessarily discouraging less efficient providers from entering the program.
- One commenter expressed the belief that incorporating a regional adjustment in an ACO's first agreement period can correct for issues stemming from mean reversion. They noted that a modest positive regional adjustment could provide an incentive for participation for low spending ACOs whose expenditure growth is likely to increase as they regress to the mean and that a modest negative regional adjustment could reduce potential windfall gains that would otherwise go to high spending ACOs that are likely to

see slower expenditure growth without entirely removing their incentive to participate.

- Several commenters supported moving towards regional benchmarks because it accelerated the process of aligning the Shared Savings Program with Medicare Advantage.
- One commenter generally supported inclusion of regional expenditures in Shared Savings Program benchmarks because the Next Generation ACO Model incorporates regional expenditures in its benchmarking methodology.
- One commenter noted that the proposed policy would provide predictability and simplicity for ACOs as they seek to understand the nuances of the regulatory environment.
- One commenter appeared to misunderstand the proposal, noting that it might force an ACO to ''use national trending for the first contract rather than regional.'' They stated that using national growth rates was a disadvantage to most ACOs and has a disparate impact on urban and rural ACOs. The commenter urged CMS to incorporate regional factors in determining the benchmark for an ACO's first agreement period as well as subsequent agreement periods.

Response: We thank commenters for their support of the proposal to apply regional expenditures in determining the benchmark for an ACO's first agreement period, which we are finalizing, along with the proposed policies described in sections II.D.3.c and II.D.3.d of this final rule. We believe that this policy will provide a greater incentive for lower cost ACOs to participate in the program, allow benchmarks to better reflect the local environment in which an ACO operates, and reduce complexity by using a comparable benchmarking methodology across all agreement periods.

Comment: Several commenters opposed incorporating regional expenditures into an ACO's first agreement period benchmark due to concerns about how the policy would impact incentives for higher cost ACOs. One commenter opposed the use of a regional adjustment in an ACO's first agreement period and recommended eliminating such adjustments from the program's benchmarking methodology entirely. This commenter expressed the belief that these adjustments, particularly if implemented in an ACO's first agreement period, would lead to exit by ACOs with spending above their region's average given the program's voluntary nature. In their view, there is a significant risk that the Shared Saving Program ''will degenerate into a program that is viable only for providers that are already more efficient for their region or serve patients who are healthier and lower-risk in ways not captured by the HCC score.'' A few other commenters also expressed concerns that the policy would harm ACOs that serve patients with special needs, threatening the viability of such ACOs or making it unattractive for ACOs to include providers and suppliers that treat such patients, with one providing hypothetical examples to demonstrate how difficult it would be for an ACO with costs notably higher than its region to achieve share savings—or avoid shared losses—even if the ACO was successful in reducing spending. Other commenters offering general support for the proposal still warned that incorporating regionally-adjusted benchmarks too quickly could discourage participation by high spending health care providers, causing CMS to miss the opportunity to realize savings while at the same time subsidizing already low-spending providers. They urged CMS to proceed with this policy in a way that encourages participation by high spending providers and suppliers in this voluntary program. Another commenter encouraged CMS to monitor the impact of the regional benchmarking methodology on participation by provider/supplier type, and to make refinements if necessary to ensure participation.

Response: We appreciate the concerns raised by the commenters that incorporating regional adjustments into ACO historical benchmarks too quickly could reduce the attractiveness of the Shared Savings Program to ACOs that have been historically inefficient compared to their region or that treat high cost, special needs patients. As described in the next section, we are finalizing a modification to the schedule of weights used in calculating the regional adjustment, which will reduce the weight that is applied to the regional adjustment in the first agreement period for ACOs that have higher costs than their region. We believe that using a lower weight to determine the regional adjustment in these circumstances will improve the business case for more higher-cost ACOs to participate in the program.

Comment: One commenter expressed the belief that changing the regional benchmarking methodology may deter new entrants and drive existing ACOs to leave the program. However, it was somewhat unclear as to whether they were opposed to the proposed changes or to the incorporation of regional expenditures into ACOs' benchmarks in general. They noted that ACOs in regions where spending and benchmarks are low have little incentive to participate in the program because they have less opportunity to reduce costs and increase savings for CMS; however, they did not suggest an alternative approach that would ameliorate their concerns.

Response: We believe that the extension of regional adjustments to ACOs in their first agreement period will tend to increase incentives for ACOs that are low cost relative to their region compared to the current benchmarking methodology. For ACOs in a second or subsequent agreement period, the modifications to the regional adjustment described in section II.D.3.c. of this final rule will tend to limit the absolute size of adjustments for ACOs that are efficient relative to their region compared to the current policy. However, we believe that these adjustments will continue to be generous enough to retain participation by many existing ACOs that are efficient relative to their region and should improve the business case for participation among ACOs that have higher costs than their regions, especially considering our decision in this final rule to lower the weight of the regional adjustment for such higher cost ACOs to 15 percent in the first agreement period (compared to 25 percent in the proposed rule). For ACOs operating in low-cost regions whose historical costs are comparable to their region, we believe that the modifications we are finalizing will have a limited impact relative to the current policy.

Comment: A few commenters raised concerns about the implications of incorporating regional factors into the calculation of benchmarks for ACOs in rural areas. One commenter noted that regional benchmarking did not make sense for many rural clinics because they are competing against themselves and they quickly arrive at the limit of expenditures they can control. Another commenter expressed concern that regional adjustments are not accurate for rural-based health care systems. They believe that in rural areas served by one health care system most primary care visits are with a specialist and the assignable beneficiary population tends to be skewed towards more costly and complex patients. They requested that CMS expand the definition of region to include nearby markets where physician access is more evenly distributed and also exclude rural areas from regional adjustment, though it was unclear whether the commenter was requesting that CMS exclude rural counties from regional expenditure calculations or requesting that rural ACOs be exempt from receiving a regional adjustment to their benchmark. A different commenter perceived the program's benchmarking

methodology to be flawed, explaining that it is structured to provide bonuses to high cost providers who reduce spending while not rewarding cost-efficient providers who enter the program and keep costs down. They believe that the current proposals do not go far enough to address these perceived flaws, particularly for beneficiaries in rural areas and environments with cost-based reimbursement, such as Critical Access Hospitals; but they did not explain why they believed the proposed changes to be inadequate. The commenter advocated for broader changes to Medicare payment policy for rural providers and requested that CMS engage with rural stakeholders to further explore a benchmarking methodology that would reflect such changes.

Response: As we have acknowledged, the incorporation of regional factors into ACO benchmarks would have varying effects on ACOs depending on each organization's individual circumstances. We believe that this is also the case for ACOs operating in rural areas. As described in section II.D.3.d of this final rule, we are finalizing our proposed policy of using blended national and regional trend and update factors for all ACOs, which we believe will help to mitigate concerns about ACOs, including rural ACOs, that are dominant in their region driving regional trends. For such ACOs, the national component of the blend would tend to receive a high weight. For a rural ACO whose assigned beneficiaries comprise a large share of assignable beneficiaries in its region, we would expect the impact of the regional adjustment on an historical benchmark to be small because the ACOs' historical expenditures would be similar to regional expenditures. In practice, we have observed that few of the ACOs that have received benchmarks that incorporate regional factors under the methodology at § 425.603(c) for second agreement periods starting in 2017 and 2018 have had penetration rates higher than 50 percent and those ACOs whose beneficiaries reside primarily in non-metropolitan areas (a proxy for rural ACOs) have received a mix of positive and negative regional adjustments.

We decline to modify our policies for defining an ACO's regional service area to encompass nearby markets or to exclude counties in which some of an ACO's assigned beneficiaries reside. We believe that such modifications could lead to a regional expenditure value that is not reflective of the area in which an ACO operates or may simply add complexity to the methodology without materially changing its outcome. We also decline to provide an exemption to the regional adjustment for ACOs operating in rural areas or any other ACOs as we favor a consistent, program-wide policy. We appreciate one commenter's recommendation that we seek to better address issues related to reimbursement of rural providers; however, we believe such issues would require further study and are outside the scope of this final rule.

Comment: One commenter noted that while the proposed policy to incorporate regional expenditures into the calculation of the benchmark starting in an ACO's first agreement period might make sense in some areas of the country, there are many areas in the state of California where they believe that additional efficiencies cannot be realized. They believe that providers in California are at a significant disadvantage under this program due to the state's historically low spending growth compared to other areas of the country. The commenter urged CMS to consider changes for providers in such markets but did not specify which changes they believe would remedy this issue.

Response: We have acknowledged that the program's benchmarking methodology can have different effects on ACOs depending on whether they are located in a high or low growth region and how their own historical spending compares with that of their region. While the introduction of blended national and regional trend and update factors may reduce the first agreement period benchmark of ACOs located in regions with below average growth compared to the current methodology that uses only national trends, all else being equal, the blend should help these ACOs in subsequent agreement periods in which they would have been subject to purely regional trends under current policy.

Final Action: After considering the comments received, we are finalizing our proposal to incorporate regional expenditures into the benchmarking methodology starting in an ACO's first agreement period for all ACOs entering the program for an agreement period beginning on July 1, 2019, and in subsequent years. Under this policy we will use almost the same methodology to determine the historical benchmarks for ACOs in their first agreement period as for ACOs in their second or subsequent agreement period, including the policies described in sections II.D.3.c and II.D.3.d. that we are adopting in this final rule. The only distinction between the methodology that will be used to determine the historical benchmark for ACOs in their first agreement period and those in a second or subsequent agreement period will be the weights that are applied to the three benchmark years. We will continue to use weights of 10 percent, 30 percent, and 60 percent to weight the three 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. These policies are included in the new provision at § 425.601, which will govern the determination of historical benchmarks for all ACOs for agreement periods starting on July 1, 2019, or in subsequent agreement periods. We are also finalizing conforming changes to §§ 425.602 and 425.603 to indicate that these provisions will now apply to the determination of the historical benchmark for ACOs entering a first agreement period on or before January 1, 2018, or ACOs entering a second or subsequent agreement period on or before January 1, 2019, respectively. We note that we originally proposed changes to the regulations to indicate that § 425.602 would apply to ACOs entering a first agreement on or before January 1, 2019. However, given our decision to forgo the application cycle for a January 1, 2019 start date, there will be no ACOs beginning a first agreement period on that date.

c. Modifying the Regional Adjustment

In finalizing the phase-in structure for the original regional adjustment in the June 2016 final rule, we acknowledged that it might be necessary to reevaluate the effects of the regional adjustment on the Shared Savings Program and, if warranted, to modify the adjustment through additional rulemaking. Therefore, we adopted a policy under which the maximum weight to be applied to the adjustment would be 70 percent, unless the Secretary determines that a lower weight should be applied, as specified through future rulemaking (see 81 FR 37969 through 32974). Relevant considerations in determining the appropriate weight to be applied to the adjustment include, but are not limited to, effects on net program costs; the extent of participation in the program; and the efficiency and quality of care received by beneficiaries.

In the August 2018 proposed rule (83 FR 41888), we noted that we had revaluated the effects of the regional adjustment as part of the regulatory impact analysis required for the proposed rule (see section IV. of the proposed rule) and had also taken into consideration our experience in applying the regional adjustment under

the policies established in the June 2016 final rule. We noted that while we continued to believe that it is necessary to employ a benchmarking methodology that incorporates expenditures in an ACO's regional service area in addition to the ACO's own historical expenditures in order to maintain or improve program sustainability, we were concerned that, if unaltered, the regional adjustment will have unintended consequences and adverse effects on ACO incentives as discussed in the Regulatory Impact Analysis for the proposed rule.

By design, the regional adjustment results in more generous benchmarks for ACOs that spend below their regions. We noted in section II.D.3.c. of the proposed rule that our initial experience with the regional adjustment found that 80 percent of ACOs that renewed for a second agreement period starting in 2017 received a positive adjustment. These ACOs saw their benchmarks increase by 1.8 percent, on average, when the adjustment was applied with the 35 percent weight, with several ACOs seeing increases of over 5 percent, and one over 7 percent. We also noted that preliminary results for ACOs that renewed for a second agreement period starting in 2018 showed a similar share of ACOs receiving a positive adjustment and one ACO seeing an adjustment of over 10 percent. We noted our concern that as the weight applied to the regional adjustment increases, benchmarks for the ACOs with the lowest spending relative to their region would become overly inflated to the point where they would need to do little to change their care practices to generate savings, which could reduce incentives for these ACOs to improve the efficiency of care provided to beneficiaries.

We noted that, on the other hand, the regional adjustment reduces benchmarks for ACOs with higher spending compared to their region. Among 14 ACOs that received a net negative regional adjustment to their benchmark in 2017, the average reduction was 1.6 percent, with one ACO seeing a reduction of over 7 percent. These adjustments were calculated using only a 25 percent weight. Although preliminary results for ACOs that started a second agreement period in 2018 showed slightly smaller negative adjustments, on average, we were concerned that the ACOs with the highest relative costs, some of which have targeted specific beneficiary populations that are inherently more complex and costly than the regional average, would find little value in remaining in the Shared Savings Program when faced with a significantly reduced benchmark as the weight applied to the adjustment increases.

To reduce the likelihood that the regional adjustment will have these undesired effects, we proposed policies that would limit the magnitude of the adjustment by reducing the weight that is applied to the adjustment and imposing an absolute dollar limit on the adjustment. We explained that we believe moderating the regional adjustment would lower potential windfall gains to lower-cost ACOs and could help to improve the incentive for higher-cost ACOs to continue to participate in the program.

First, we proposed to amend the schedule of weights used to phase in the regional adjustment. Consistent with our current policy, the first time that an ACO is subject to a regional adjustment, we would apply a weight of 35 percent if the ACO's historical spending was lower than its region and a weight of 25 percent if the ACO's historical spending was higher than its region. The second time that an ACO is subject to a regional adjustment, we would apply a weight of 50 percent if the ACO's historical spending was lower than its region and 35 percent if the ACO's historical spending was higher than its region. The third or subsequent time that an ACO is subject to a regional adjustment we would apply a weight of 50 percent in all cases.

We sought to make two points related to the proposed schedule of weights clear. First, consistent with our current policy under § 425.603(c)(8) for determining the adjusted benchmark for the second or subsequent performance year of an ACO's agreement period, in calculating an adjusted benchmark for an ACO that makes changes to its ACO participant list or assignment methodology, we would use the same set of weights as was used for the first performance year in the agreement period. For example, an ACO that is subject to a weight of 25 percent in its first performance year of an agreement period would continue to be subject to a weight of either 35 or 25 percent, depending on whether the ACO's historical expenditures, as adjusted, are higher or lower than its region, for any subsequent years in the same agreement period.

Second, for renewing or re-entering ACOs (see section II.A.5.c. of this final rule) that previously received a rebased historical benchmark under the current benchmarking methodology adopted in the June 2016 final rule, we would consider the agreement period the ACO is entering upon renewal or re-entry in combination with the weight previously applied to calculate the regional adjustment to the ACO's benchmark in the ACO's most recent prior agreement period to determine the weight that would apply in the new agreement period. We included several examples of the application of these policies (83 FR 41889). In the final action statement for this section of the final rule we provide updated examples based on the policies we are finalizing.

The weights included in the proposed new schedule were chosen in part to maintain consistency with the current schedule, which already includes the 25, 35, and 50 percent values. Furthermore, we stated our belief that using 50 percent as the maximum weight would be appropriate because it strikes an even balance between rewarding an ACO for attainment (efficiencies already demonstrated at the start of the agreement period) versus improvement during the agreement period over its past historical performance.

We also noted that while this proposal would reduce the maximum regional adjustment as compared to current regulations, our proposal to extend the regional adjustment to ACOs in their first agreement period in the program would increase the number of years that an ACO would be subject to the adjustment. Thus, the lower maximum weight in later years would be balanced to some extent by an earlier phase-in.

Based on the magnitude of regional adjustments observed in the first 2 years under the existing rebasing methodology, which were calculated using the lowest weights under the current phase-in schedule, we were concerned that reducing the maximum weight on the adjustment may not be sufficient to guard against the undesired effects of large positive or negative regional adjustments on incentives faced by individual ACOs. Therefore, to complement the proposed changes to the schedule of weights used to phase-in the regional adjustment, we also considered options for imposing a cap on the dollar amount of the regional adjustment. We believed that limiting regional adjustments for ACOs that are particularly low- or high-cost relative to their regions, would better align incentives for these ACOs with program goals, while continuing to reward ACOs that have already attained efficiency relative to their regional service areas.

We thus also proposed to cap the regional adjustment amount using a flat dollar amount equal to 5 percent of 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.

We explained our belief that defining the cap based on national per capita expenditures would offer simplicity and transparency in that, for each enrollment type, a single value would be applicable for all ACOs with the same agreement start date. When selecting the level of the proposed cap, we aimed to choose a level that would only constrain the adjustment for the most extreme ACOs. When looking at the distribution of observed final regional adjustments among the 73 ACOs that received a rebased benchmark in 2017, we found that the amount of the regional adjustment calculated for around 95 percent of these ACOs would fall under a symmetrical cap equal to 5 percent of national FFS expenditures. We also noted our belief that capping the amount of the regional adjustment at this level would continue to provide a meaningful reward for ACOs that are efficient relative to their region, while reducing windfall gains for the ACOs with the lowest relative costs. Similarly, capping the amount of a negative regional adjustment at this level would continue to impose a penalty on ACOs that are less efficient relative to their region, but by guarding against extremely high negative adjustments, should increase the program's ability to retain ACOs that serve complex patients and that may need some additional time to lower costs.

We explained that to implement the cap, we would continue to calculate the difference between the average per capita regional amount and the per capita rebased benchmark amount for each Medicare enrollment type. We would continue to multiply the difference for each enrollment type by the appropriate weight (determined using the schedule described previously) in order to determine the uncapped adjustment for each Medicare enrollment type. For positive adjustments, the final adjustment amount for a particular enrollment type would be set equal to the lesser of the uncapped adjustment or a dollar amount equal to 5 percent of the national per capita FFS expenditures for assignable beneficiaries in that enrollment type for BY3. For negative adjustments, the final adjustment amount for a particular enrollment type would be set equal to the greater (that is, the smaller negative value) of either the uncapped adjustment or the negative of 5 percent of the national per capita FFS expenditures for assignable beneficiaries in that enrollment type for BY3. We would then apply the final adjustment for each enrollment type to the benchmark expenditures for that enrollment type in the same manner that we currently apply the uncapped regional adjustment. Table 13 provides an illustrative example of how the final adjustment would be determined.

TABLE 13—HYPOTHETICAL DATA ON APPLICATION OF CAP TO REGIONAL ADJUSTMENT AMOUNT

Medicare Enrollment Type	Uncapped Adjustment	National Assignable FFS Expenditure	5 percent of National Assignable FFS Expenditure	Final Adjustment
ESRD	$4,214	$81,384	$4,069	$4,069
Disabled	-$600	$11,128	$556	-$556
Aged/dual eligible	$788	$16,571	$829	$788
Aged/non-dual eligible	-$367	$9,942	$497	-$367

In this example, the ACO's positive adjustment for ESRD would be constrained by the cap because the uncapped adjustment amount exceeds 5 percent of the national assignable FFS expenditure for the ESRD population. Likewise, the ACO's negative adjustment for the disabled population would also be reduced by the cap. The adjustments for aged/dual and aged/non-dual eligible populations would not be affected.

We also considered an alternative approach under which the cap would be applied at the aggregate level rather than at the Medicare enrollment type level. Under this approach, we would calculate regional adjustments by Medicare enrollment type as we do currently and then determine the weighted average of these adjustments, using the enrollment distribution in the ACO's BY3 assigned beneficiary population, to arrive at a single aggregate regional adjustment. We would then determine a weighted average of national per capita FFS expenditures for assignable beneficiaries across the four enrollment types, again using the enrollment distribution in the ACO's BY3 assigned beneficiary population, to arrive at a single aggregate national expenditure value. We would calculate a symmetrical aggregate cap equal to positive or negative 5 percent of the aggregate national expenditure value and compare this cap to the uncapped aggregate regional adjustment amount to determine the final aggregate regional adjustment. Specifically, if the uncapped aggregate regional adjustment amount is above the aggregate cap, then the final aggregate regional adjustment would equal the cap. However, if the uncapped aggregate regional adjustment amount is below the aggregate cap, then the final aggregate regional adjustment would equal the uncapped regional adjustment amount. The regional adjustment calculated for each Medicare enrollment type would then be multiplied by the ratio of the final aggregate regional adjustment to the uncapped aggregate regional adjustment. If the uncapped aggregate regional adjustment exceeds the

aggregate cap, this ratio will be less than one and the regional adjustment for each Medicare enrollment type would be reduced by the same percentage. If the uncapped aggregate regional adjustment is less than or equal to the aggregate cap, the ratio will equal one and the regional adjustment would not be reduced for any Medicare enrollment type.

For example, if the uncapped aggregate regional adjustment amount was $550 and the aggregate cap was $500, the final aggregate regional adjustment would be $500. The regional adjustment for each Medicare enrollment type would be multiplied by a ratio of $500 to $550 or 0.909. This is equivalent to reducing the adjustment for each enrollment type by 9.1 percent. As another example, if the uncapped aggregate regional adjustment was $450 and the aggregate cap remained at $500, the final aggregate regional adjustment would be $450 because it is less than the aggregate cap. The regional adjustment for each Medicare enrollment type would be multiplied by a ratio equal to 1, and thus would not be reduced.

Initial modeling found the two methods to be comparable for most ACOs but suggested that our proposed approach (capping the regional adjustment at the Medicare enrollment type level) is somewhat more effective at limiting larger upside or downside adjustments. We explained that this was likely because the aggregate approach smooths out variation in adjustments across individual enrollment types. For example, for some ACOs, large positive adjustments in one enrollment type may be offset by smaller positive adjustments, or negative adjustments in other enrollment types under the aggregate approach. We explained that the proposed approach also aligns with our current benchmark calculations, which are done by Medicare enrollment type, and provides greater accuracy and transparency. Under this approach, the cap would only reduce the magnitude of the adjustment for a particular enrollment type if the original uncapped value of the adjustment is relatively large. This would not necessarily be the case under the aggregate approach, where adjustments for all enrollment types, large or small, would be reduced if the aggregate regional adjustment exceeds the aggregate cap.

In the August 2018 proposed rule (83 FR 41890), we expressed our belief that imposing a cap on the magnitude of the adjustment, coupled with the proposed changes to the schedule of weights used in applying the regional adjustment, would help to reduce windfall gains to low-spending ACOs and would also help to reduce the incentive for higher spending ACOs to leave the program by limiting the negative adjustments these ACOs will experience. We anticipated that the proposed cap on the regional adjustment would provide stronger incentives for higher spending ACOs to remain in the program (by reducing the magnitude of the benchmark decrease associated with negative regional adjustments) than disincentives for lower spending ACOs. We noted that we expected this latter group would still be sufficiently rewarded by the regional adjustment under the proposed approach to encourage their continued participation in the program. However, we also noted our belief that by reducing the windfall gains for these ACOs, the proposed constraints on the regional adjustment would lead to greater incentives for these ACOs to further reduce spending in order to increase their shared savings payments.

In summary, we proposed both to modify the schedule of weights used to phase in the regional adjustment and to impose a cap on the dollar amount of the adjustment. For the first agreement period that an ACO is subject to the regional adjustment, we proposed to apply a weight of 35 percent if the ACO's historical spending was lower than its region and a weight of 25 percent if the ACO's historical spending was higher than its region. For the second agreement period, we proposed to apply weights of 50 percent and 35 percent for lower and higher spending ACOs, respectively. For the third or subsequent agreement period, we proposed to apply a weight of 50 percent for all ACOs. Additionally, we would impose a symmetrical cap on the regional adjustment equal to positive or negative 5 percent of the national per capita FFS expenditures for assignable beneficiaries for each enrollment type. We proposed to apply the modified schedule of weights and the cap on the regional adjustment for agreement periods beginning on July 1, 2019, and in subsequent years. The policies proposed in section II.D.3.c of the proposed rule were included in the proposed new provision at § 425.601, which would govern the determination of historical benchmarks for all ACOs for agreement periods starting on July 1, 2019, and in subsequent years. We sought comment on these proposals, as well as the alternative capping methodology considered. We also sought comment on the proposed timeline for application of these proposals.

Comment: One commenter supported the proposed maximum weight of 50 percent on the regional adjustment, stating that they agreed with CMS' reasoning behind the proposed policy and noted that it would also help to ensure that smaller Medicare markets and larger markets with greater ACO concentration would sustain competitive pressure, both between ACOs within a particular market and between the Shared Savings Program and traditional Medicare FFS payment polices, across multiple agreement periods.

However, nearly all of the other commenters that addressed our proposals to modify the regional adjustment opposed reducing the maximum weight on the regional adjustment from 70 percent to 50 percent. One commenter described the proposal to lower the maximum weight as premature. They noted that the current policy was only finalized two years ago and, given the existing phase-in schedule, no ACO has yet reached a weight of 70 percent. Several commenters expressed the belief that this policy would penalize ACOs that have performed well or put them at a competitive disadvantage, with some commenters disputing CMS' characterization of large positive regional adjustments as potential windfalls. One commenter suggested that lowering the maximum weight could reduce recruitment and retention of high value and experienced ACOs. Another commenter stated that this proposal, combined with the proposal to cap the regional adjustment, would make it more difficult for ACOs to earn shared savings that they could then use to cover the incremental costs of accountable care. One commenter favored retaining the 70 percent maximum adjustment because they believe it would lead to greater alignment between the Shared Savings Program and Medicare Advantage given the regional nature of the benchmarking and bid process in that program. A few commenters suggested that this proposal was an example of CMS ''changing the rules,'' which, one commenter noted, can erode confidence in the program. Another commenter stated they did not support the proposed modifications to the regional adjustment; but, in their justification of this position they appeared to be conflating the proposed modifications the regional adjustment with the proposal to use a blend of national and regional factors to establish and update the benchmark.

Response: We appreciate commenters' feedback related to our proposal to reduce the maximum weight of the regional adjustment from 70 percent to 50 percent. We view the regional

adjustment as providing a more accurate benchmark that recognizes ACOs that have attained efficiency relative to their region as well as a means of incentivizing these ACOs to participate in the program and further reduce spending. We also recognize that greater alignment of the Shared Savings Program with Medicare Advantage is a shared goal among a number of commenters. However, based on our first two years of experience in applying regional adjustments in the calculation of ACO historical benchmarks, we continue to believe that the proposed limit on the regional adjustment for ACOs that are low cost relative to their region will help to ensure that these ACOs are not in a position where they can earn shared savings with little to no additional reductions in cost, a situation that we believe would arise if the weight placed on the adjustment is permitted to rise to 70 percent, as provided under the current schedule.

We also continue to believe that many ACOs would still have an incentive to participate in the program with a maximum weight of 50 percent on the regional adjustment. This belief is influenced by our experience with the Next Generation ACO Model. The model provided for up to a 1 percent increase to benchmarks for ACOs with lower spending compared to their region. ACOs with lower spending than their region elected to participate in the model, and overall, the model showed that beneficiaries aligned to Next Generation ACOs had lower spending than other fee-for-service beneficiaries who were not aligned with an ACO in their region, as noted by the first year evaluation (*https://innovation.cms.gov/Files/reports/nextgenaco-firstannrpt.pdf*). The policies we are finalizing in this rule will provide a significantly larger adjustment than that tested by the Next Generation ACO Model, even when accounting for the maximum 50 percent weight applied to the regional adjustments in future agreement periods and the symmetrical cap equal to 5 percent of national per capita expenditures for Parts A and B services for assignable beneficiaries.

Comment: A number of commenters suggested alternative phase-in schedules or levels for the weights applied to the regional adjustment:

- Several commenters suggested the following schedule of weights for ACOs that have lower or higher expenditures, respectively, relative to their region: 30 or 25 percent in first agreement period in which the ACO is subject to the regional adjustment, 50 or 35 percent in second agreement period receiving adjustment; 70 or 50 percent in third agreement period receiving adjustment; and 70 for all ACOs in the fourth and subsequent agreement periods. Another commenter also recommended using weights of 70 or 50 percent in the third agreement period in which an ACO is subject to the regional adjustment but did not comment on which weights should be applied for other agreement periods;
- One commenter recommended that CMS implement a more gradual phase-in than the proposed approach and provide maximum flexibility and choices for ACOs. They suggested applying a weight that increases over the course of an ACO's first five-year agreement period with a regional adjustment, such as a 10 percent weight in the first two years, 20 percent in the second two years, and 30 percent in the final year;
- A few commenters recommended that CMS adopt the following phase-in schedule: 35 or 25 percent in the first agreement period with a regional adjustment, 60 or 45 percent in the second agreement with a regional adjustment, and 70 percent in the third and all subsequent agreement periods with a regional adjustment. The same commenters also recommended that CMS consider an alternative under which an ACO would have an option to gradually incorporate regional expenditure data into their benchmarks, with an increase of 10 percent annually during an agreement period.
- A few commenters recommended raising the maximum weight on the adjustment to 75 percent.

As described in section II.D.3.b of this final rule, several commenters had concerns that incorporating regional adjustments in an ACO's first agreement period would disincentivize participation among ACOs whose costs have historically been high relative to their region, with some advising CMS not to incorporate such adjustments too quickly. MedPAC noted its belief that blending ACO-specific historical costs with regional FFS costs through the application of the regional adjustment is a reasonable approach, but also suggested that the share of the benchmark attributed to regional costs should start low and be refined as program results are evaluated over time. Another commenter also called for gradually incorporating regional data into benchmarks in order to better account for the specific characteristics of the patient population of each individual ACO.

One commenter recommended eliminating regional adjustments that blend ACO historical spending with regional spending. The commenter presented evidence to suggest that regional adjustments led to the exit from the program of ACOs with a first agreement period ending on December 31, 2016, and spending above their region's average. They expressed concern that the pattern of selective participation would grow only worse if ACOs are required to assume downside risk as negative regional adjustments would cause some higher cost ACOs to face certain shared losses. They believe that the proposals to reduce the maximum weight on the regional adjustment to 50 percent and to cap the amount of the adjustment at 5 percent of national Medicare FFS expenditures would do little to mitigate the risk that the program would become viable only for ACOs serving healthier patients. In lieu of a regional adjustment, the commenter recommended incentivizing efficiency relative to an ACO's region by increasing the sharing rates for lower cost ACOs.

Response: We appreciate commenters' suggestions for alternatives to the proposed phase-in schedule and weight levels for the regional adjustment. We also appreciate the recommendation that we incentivize efficiency among lower cost ACOs through modifications to the sharing rate as opposed to through a regional adjustment, but we believe this suggestion falls outside the scope of policies contemplated in the August 2018 proposed rule.

We continue to believe that reducing the maximum weight of the regional adjustment from 70 percent to 50 percent is appropriate in order to promote continuous improvement and prevent potential windfall gains to lower cost ACOs. Further, and as previously described based on our experience with a more modest positive adjustment tested in the Next Generation ACO Model for ACOs shown to be efficient relative to their region, we are not convinced by the comments that reducing the weight to this level would significantly deter lower cost ACOs from participating in the program.

However, based on comments received on the proposals described in this section and in section II.D.3.b of this final rule, we are concerned that our proposed policies for modifying the regional adjustment may not sufficiently improve incentives for ACOs that are high cost relative to their region to enter or remain in the program. In particular, we are concerned by evidence presented by one commenter regarding the selective exit by certain ACOs with a first agreement period ending on December 31, 2016, and by the possibility raised by a few commenters that a negative regional adjustment could, by itself, cause some ACOs to owe shared losses. We believe that it is important to maintain incentives for participation among higher cost ACOs, as these ACOs can offer high potential for savings for the Trust Funds and, in some cases, may serve complex, high-risk patients who would benefit from improved care management. To that

end, we are therefore finalizing a modified schedule of weights that would slow the phase-in of the regional adjustment for these ACOs relative to our original proposal. Specifically, for the first agreement period that an ACO is subject to a regional adjustment, we will apply a weight of 15 percent if the ACO's historical spending was higher than its region, for the second agreement period that an ACO is subject to a regional adjustment we will apply a weight of 25 percent if the ACO was higher than its region, for the third agreement period that an ACO is subject to a regional adjustment we will apply a weight of 35 percent if the ACO was higher than its region, and for the fourth and all subsequent agreement periods that an ACO is subject to a regional adjustment we will apply a weight of 50 percent. In the final action statement for this section we provide examples of how this policy would be applied for renewing or re-entering ACOs that were previously subject to a regional adjustment under the current methodology.

We selected 15 percent as the initial weight of the regional adjustment for ACOs that are higher spending than their region in order to balance our concerns about maintaining participation incentives with maintaining incentives to reduce spending. In making this selection, we performed an analysis in which we examined, ex post facto, what level of weight applied to regional adjustments for higher cost ACOs entering the program in performance year 2014 would have produced roughly comparable average shared savings payments to those earned on average by lower cost ACOs entering the program in same performance year. A simulated 15 percent weight for higher cost ACOs resulted in the desired balance with shared savings to lower cost ACOs. This analysis supports our belief that reducing the weight that will be applied to a negative regional adjustment in an ACO's first agreement period will preserve a reasonable business case for participation by higher cost ACOs and improve the incentive for higher cost ACOs to enter the program and that slowing the phase-in of the weights will help to retain these ACOs in subsequent agreement periods. We believe increased participation among such ACOs will lead to coordinated care for more Medicare beneficiaries and generate additional savings for the Medicare Trust Funds.

Comment: Commenters had mixed reactions to the proposed symmetrical cap on the regional adjustment, with a majority requesting that CMS impose a higher cap or no cap at all. Among commenters that opposed capping the adjustment, one commenter described the proposed 5 percent level as arbitrary and a few others expressed the belief that CMS should not intervene in the market in this manner and should allow competition among ACOs and other providers to address and eventually mitigate outlier situations. Several commenters suggested that limiting the magnitude of the regional adjustment would undermine policy goals, with one noting that the cap could reduce the incentive for ACOs to drive costs lower. One commenter expressed the belief that the proposed cap on the regional adjustment is based on the false assumption that low Medicare expenditures are due to an inordinately healthy population or extremely efficient healthcare delivery system, when they may in fact be due to a lack of patient access to appropriate services as they explain is the case in the state of Hawaii. This commenter believes that the program's current regional benchmarking methodology would appropriately assist ACOs in Hawaii with achieving savings and reward these ACOs for seeking to improve upon the already low cost of care per beneficiary.

A few commenters that opposed limiting the regional adjustment recommended that if CMS decides to move forward with the proposed cap, the agency should increase the level of the cap. Some suggested using a cap of positive or negative 7 percent. Another commenter recommended an 8 percent cap applied at the aggregate level rather than at the enrollment type level. They noted that this higher cap would allow for an efficiency return similar to what Medicare Advantage plans can receive net of their administrative costs for administering the plan (around 7 percent). This commenter also noted that if CMS were choosing between a policy to cap the regional adjustment at 5 percent and a policy to limit the weights on the adjustment, they would prefer that CMS limit the weight on the adjustment and either eliminate or raise the cap. Several other commenters appeared to support the idea of a cap on the regional adjustment, but also recommended that CMS consider raising the level of the cap with specific suggestions ranging from 7 percent to 10 percent. One commenter noted that they understood CMS' rationale in wanting to mitigate the effects of excessive regional adjustments but believe that such adjustments can benefit a region by leveling costs across health care providers within the region as more organizations transition to value-based care and can provide an incentive for high-cost ACOs to decrease costs and for low-cost organizations to join efforts towards furnishing value-based care. Others believed a higher cap would be sufficient to ''control for outliers.''

By contrast, other commenters supported the proposed 5 percent cap on the regional adjustment or requested that the cap be made even more stringent. One commenter expressed the belief that the proposed cap would reduce the current disincentive for ACOs serving complex, frail, and functionally limited populations to continue in the program and another noted that it would ''control for outliers.'' One commenter recommended that CMS adopt a lower cap than 5 percent, stating that this lower cap would be beneficial for ACOs serving complex and costly populations whose expenditures are not fully predicted by risk scores.

Several commenters agreed with the proposed symmetrical cap of 5 percent of national Medicare FFS expenditures but requested that CMS incentivize ACOs to take on more risk by providing ACOs in two sided models with an option to use national benchmarks instead of benchmarks that incorporate regional factors. They believe this option would be desirable for ACOs in historically low-cost regions that would otherwise not be willing to take on risk. A few other commenters that did not necessarily support the proposed 5 percent cap also suggested that CMS allow use of national rather than regional factors to determine the benchmark for physician-led ACOs or ACOs in small markets dominated by one or two health systems.

Response: We are finalizing our proposal to implement a symmetrical cap equal to 5 percent of national per capita FFS expenditures for assignable beneficiaries for each enrollment type. We recognize that there are tradeoffs in adopting any cap and that limiting the magnitude of positive adjustments could reduce incentives for participation or further cost reduction efforts among ACOs that have low costs, whether due to efficiency, patient mix, or limited patient access to services. However, we continue to believe that a symmetrical 5 percent cap on the regional adjustment will protect the Medicare Trust Funds from excessive positive adjustments and will improve incentives for participation among higher-cost ACOs, particularly when combined with the modified schedule of weights that we are adopting in this rule, which slows the phase-in of the regional adjustment for ACOs with historical costs above their region.

Additionally, we are not contemplating policies that would allow certain ACOs to move to a benchmark that incorporates national rather than regional factors at this time. Given the existing variations in expenditures between regions, we believe that the use of regional factors in determining the benchmarks for all ACOs, will ensure that these benchmarks better reflect the specific circumstances each ACO faces.

Comment: One commenter asserted that CMS did not provide convincing evidence that the proposed modifications to the regional adjustment would strike the appropriate balance between competing objectives, including providing incentives for ACOs to reduce spending (by reducing the impact of current spending on future benchmarks) and for efficient ACOs to extend participation, addressing mean reversion, and reducing disincentives for higher cost ACOs to participate. The commenter noted that the appropriate size of the adjustment may vary over time, just as the primary rationale for an adjustment changes over time. The commenter explained that in an ACO's first agreement period the primary rationale for an adjustment is to address mean reversion and in later agreement periods the primary rationale is to reduce the link between an ACO's current performance and future benchmarks, thus providing an incentive for ACOs to continue to reduce spending. Furthermore, the commenter encouraged CMS to conduct additional analysis and offered suggestions for what that analysis might entail and recommended that the agency refine its proposals for modifying the regional adjustment, if warranted.

Response: We appreciate this commenter's input on the factors that should be considered when determining the appropriate magnitude of the regional adjustment, as well as the suggestions for additional analyses. We agree with the commenter that determining the appropriate magnitude of the regional adjustment involves weighing different considerations such as how to incentivize both high and low cost ACOs to participate in the program and reduce spending and how to avoid making windfall payments to ACOs. We believe that the changes we are adopting in this rule attempt to balance these various concerns. We will monitor and evaluate the impact of the changes that we are making the regional adjustment in this final rule, and as we gain experience may propose additional refinements through future notice and comment rulemaking, if warranted.

Comment: We received few comments on our proposal to apply the proposed cap at the enrollment type level. One commenter expressed support for this proposal, stating that this approach would best serve to limit the most extreme adjustments to ACO benchmarks and also aligns with the current method for calculating ACO benchmarks. Another commenter would prefer CMS to apply the proposed 5 percent cap at the aggregate level. This commenter noted that when applied at the enrollment type level, the proposed approach would effectively apply a cap of less than 5 percent, in aggregate, if any one of the four categories is below the 5 percent cap. The commenter believes this result would reduce incentives for ACOs to perform well.

Response: As we described in the proposed rule, our analysis found that implementing the cap at the aggregate level rather than by enrollment type as proposed would have little impact for most ACOs, but we acknowledge that for some ACOs the proposed approach would be somewhat more stringent. We continue to prefer the enrollment type-level approach for this reason as we believe it will better allow us to meet of our goals of reducing potential windfalls and improving incentives for higher cost ACOs. This approach also aligns more closely with other benchmark calculations, as noted by one commenter. We are finalizing our proposal to apply the cap separately for each enrollment type.

Comment: A few commenters stressed the importance of careful risk adjustment when combining an ACO's historical expenditures with regional average expenditures through a regional adjustment; however, one commenter noted that risk adjustment will always be inadequate to some degree. While this commenter did not agree with using regional adjustments at the current time, they suggested that if regional adjustments are used in the future, CMS should implement additional measures to ensure that ACOs are not penalized for serving higher-risk patients. In particular, the commenter suggested offering ACOs a per-beneficiary care management fee that is higher for higher-risk patients.

Response: We agree with these commenters that it is important to adjust for differences in health status between an ACO's assigned beneficiary population and the assignable beneficiary population in its region when calculating and applying the regional adjustment to the historical benchmark, which is why in the June 2016 final rule (81 FR 37967) we finalized a policy of using full CMS–HCC risk adjustment for this purpose. We appreciate the commenter's suggestion that we adopt further measures to ensure that ACOs are not penalized for serving higher risk patients; however, we believe that their recommendation of offering a per-beneficiary care management fee is outside the scope of the policies addressed in the proposed rule.

Comment: Several commenters recommended modifying the regional adjustment by removing an ACO's own assigned beneficiaries from the regional expenditure amount used to calculate the adjustment. One commenter recommended revising the definition of an ACO's regional service area to include only counties where at least one percent of an ACO's assigned beneficiaries reside to reduce complexity and provide a better reflection of an ACO's regional service area. Another commenter requested that the regional comparison be based on the FFS population because they note that their ACO drives their regional market.

Response: In the June 2016 final rule, CMS made the policy decision to calculate regional expenditures based on all assignable FFS beneficiaries in an ACO's regional service area, including beneficiaries assigned to that ACO or any ACO (see 81 FR 37960). We discussed in the August 2018 proposed rule some of our ongoing concerns about a policy that would exclude ACO-assigned beneficiaries from these calculations (see section II.D.3.d of the proposed rule). These concerns include the potential for bias due to small sample sizes or differences in the spending and utilization patterns between ACO-assigned and non-assigned beneficiaries, the potential incentive for ACOs to avoid high risk beneficiaries, and greater operational complexity. In the June 2016 final rule, we also discussed our rationale for including in the definition an ACO's regional service area all counties in which at least one assigned beneficiary resides (81 FR 37959). We believe this approach is necessary to accurately reflect the diversity of the ACO's assigned beneficiary population and provide a complete picture of the ACO's regional service area. We are unclear if the commenter requesting a comparison based on the FFS population is requesting that the regional adjustment be based on a comparison between the ACO's own historical expenditures and national FFS expenditures or between the ACO's own historical expenditures and regional expenditures based on all FFS beneficiaries rather than assignable beneficiaries. We did not contemplate either approach in the proposed rule, as we did not propose any changes to the population used in the regional

adjustment calculation. Accordingly, we decline to make any changes to our current policy of calculating regional expenditures based on all assignable beneficiaries in an ACO's regional service area, including beneficiaries assigned to that ACO or any other ACO. However, as described in section II.D.3.d. of this final rule, ACOs whose assigned beneficiaries comprise a large share of their regional assignable populations will receive a higher weight on the national component of the blended trend and update factors used in benchmark calculations.

Final Action: After considering the comments received, we are finalizing with modification our proposal to modify the schedule of weights used to phase in the regional adjustment and are finalizing, as proposed, the proposal to impose a cap on the dollar amount of the adjustment. For the first agreement period that an ACO is subject to the regional adjustment, we will apply a weight of 35 percent if the ACO's historical spending was lower than its region and a weight of 15 percent if the ACO's historical spending was higher than its region. For the second agreement period, we will apply weights of 50 percent and 25 percent for lower and higher spending ACOs, respectively. For the third agreement period, we will apply weights of 50 percent and 35 percent, respectively. For the fourth or subsequent agreement period, we will apply a weight of 50 percent for all ACOs. Additionally, we will impose a symmetrical cap on the regional adjustment equal to positive or negative 5 percent of the national per capita FFS expenditures for assignable beneficiaries for each enrollment type.

We proposed to apply the modified schedule of weights and the cap on the regional adjustment for agreement periods beginning on July 1, 2019, and in subsequent years. These policies will be included in a new provision of the regulations at § 425.601, which will govern the determination of historical benchmarks for all ACOs for agreement periods starting on July 1, 2019, and in subsequent years.

We note that for renewing or re-entering ACOs (see section II.A.5.c. of this final rule) that previously received a rebased historical benchmark under the current benchmarking methodology set forth in § 425.603, we will consider the agreement period the ACO is entering upon renewal or re-entry in combination with the weight previously applied to calculate the regional adjustment to the ACO's benchmark in the ACO's most recent prior agreement period to determine the weight that will apply in the new agreement period. For example, an ACO that was subject to a weight of 35 or 25 percent in its second agreement period in the Shared Savings Program (first agreement period subject to a regional adjustment) under the current benchmarking methodology that enters its third agreement period in the program (second agreement period subject to a regional adjustment) would, under the policies we are adopting in this final rule, be subject to a weight of 50 or 25 percent. By contrast, if the same ACO terminated during its second agreement period and subsequently re-enters the program, the ACO would face a weight of 35 or 15 percent until the start of its next agreement period. For a new ACO identified as a re-entering ACO because greater than 50 percent of its ACO participants have recent prior participation in the same ACO, we will consider the weight most recently applied to calculate the regional adjustment to the benchmark for the ACO in which the majority of the new ACO's participants were participating previously.

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

As discussed previously, we believe 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 year has the advantage of producing more accurate benchmarks. Regional trend and update factors allow us to better capture the cost experience in the ACO's region, the health status and socio-economic dynamics of the regional population, and location-specific Medicare payments when compared to using national FFS expenditures. However, in the August 2018 proposed rule (83 FR 41891) we acknowledged the concern raised by stakeholders that the use of regional trend or update factors may affect ACOs' incentives to reduce spending growth or to continue participation in the program, particularly in circumstances where an ACO serves a high proportion of beneficiaries in select counties making up its regional service area. For such an ACO, a purely regional trend will be more influenced by the ACO's own expenditure patterns, making it more difficult for the ACO to outperform its benchmark and conflicting with our goal to move ACOs away from benchmarks based solely on their own historical costs. We therefore considered options that would continue to incorporate regional expenditures into trend and update factors while still protecting incentives for ACOs that serve a high proportion of the Medicare FFS beneficiaries in their regional service area.

One approach, supported by a number of stakeholders commenting on the 2016 proposed rule, would be to exclude an ACO's own assigned beneficiaries from the population used to compute regional expenditures. However, as we explained in the June 2016 final rule (81 FR 37959 through 37960), we believe that such an approach would create 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. The latter could occur, for example, if an ACO tends to focus on a specialized beneficiary population. We are also concerned that excluding an ACO's own assigned beneficiaries from the population could provide ACOs with an incentive to influence the assignment process by seeking to provide more care to healthy beneficiaries and less care to more costly beneficiaries. Given these concerns, in developing the proposals for the August 2018 proposed rule we chose to focus on alternative options that would address stakeholder concerns by using a combination of national and regional factors.

The first approach we considered would use 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 (referred to as the national-regional blend). By incorporating a national trend factor that is more independent of an ACO's own performance, we believe that the national-regional blend would reduce the influence of the ACO's assigned beneficiaries on the ultimate trend factor applied. It would also lead to greater symmetry between the Shared Savings Program and Medicare Advantage which, among other adjustments, applies a national projected trend to update county-level expenditures.

Under this approach, the national-regional blend would be calculated as 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, calculated as described in section II.D.3.d of the proposed rule. 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 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. These trend factors would be calculated in the same manner as the national trend factors used to trend benchmark year expenditures for ACOs in a first agreement period under the current regulations. For example, the national trend factor for the aged/non-dual population for BY1 would be equal to BY3 per capita FFS expenditures among the national aged/non-dual assignable population divided by BY1 per capita FFS expenditures among the national aged/non-dual assignable population. Consistent with our current approach, the per capita FFS expenditures used in these calculations would not be explicitly risk-adjusted. By using risk ratios based on risk scores renormalized to the national assignable population, as described in section II.D.2. of this final rule, we are already controlling for changes in risk in the national assignable population elsewhere in the benchmark calculations, rendering further risk adjustment of the national trend factors unnecessary.

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. The regional trend factors reflect changes in expenditures within given counties over time, as well shifts in the geographic distribution of an ACO's assigned beneficiary population. This is due to the fact that regional expenditures for each year are calculated as the weighted average of county-level expenditures for that year where the weight for a given county is the proportion of the ACO's assigned beneficiaries residing in that county in that year.

The weights used to blend the national and regional components would be calculated separately for each Medicare enrollment type using data for BY3. To calculate the national weights, we would first calculate for each enrollment type the share of assignable beneficiaries that are assigned to the ACO in each county in the ACO's regional service area. We would then weight each county's share by the proportion of the ACO's total assigned beneficiary population in that enrollment type residing in that county to obtain the regional share. This weighting approach mirrors the methodology used to calculate regional expenditures, as it gives higher precedence to counties where more of the ACO's assigned beneficiaries reside when determining the ACO's overall penetration in its region.

As an example, assume an ACO has 11,000 assigned beneficiaries with aged/non-dual eligible enrollment status and the ACO's regional service area consists of two counties, County A and County B. There were 10,000 assignable aged/non-dual beneficiaries residing in County A in BY3, with 9,000 assigned to the ACO in that year. There were 12,000 assignable aged/non-dual beneficiaries residing in County B with 2,000 assigned to the ACO. The weight for the national component of the blended trend factor for the aged/non-dual enrollment type would be:
[(Assigned Beneficiaries in County A/ Assignable Beneficiaries in County A) × (Assigned Beneficiaries in County A/ Total Assigned Beneficiaries)] + [(Assigned Beneficiaries in County B/ Assignable Beneficiaries in County B) × (Assigned Beneficiaries in County B/ Total Assigned Beneficiaries)] or
[(9,000/10,000) × (9,000/11,000)] + [(2,000/12,000) × (2,000/11,000)], or 76.7 percent. The weight given to the regional component of the blended trend factor for aged/non-dual enrollment type in this example would be 23.3 percent. Because this hypothetical ACO has high penetration in its regional service area, the national component of the blended trend factor would receive a much higher weight than the regional component.

Initial modeling among 73 ACOs that renewed for a second agreement period in 2017 found that the weighted average share of assignable beneficiaries in an ACO's regional service area that are assigned to the ACO ranged from under 1 percent to around 60 percent, when looking at all four enrollment types combined, with a median of 12.3 percent and a mean of 15.1 percent. Among the 73 ACOs, 8 (11 percent) had regional shares above 30 percent. We found similar distributions when looking at the four enrollment types individually. Among ACOs with overall regional shares above 30 percent, the simulated use of blended trend factors caused changes in benchmarks (relative to current policy) of −0.8 percent to 0.3 percent, with half seeing a slight negative impact and the other half seeing a slight positive impact. Based on these statistics, it appears that most ACOs currently do not have significant penetration in their regional service areas. As a result, we would expect that for most ACOs the regional component of the blended trend factor would receive a higher weight than the national component and that the overall impact of the national-regional blend on benchmarks relative to current policy would be small. Should penetration patterns change over time, the blended formula would automatically shift more weight to the national component of the trend factor.

We would also use a national-regional blend when updating the historical benchmark for each performance year. That is, we would multiply historical benchmark expenditures for each Medicare enrollment type by an update factor that blends national and regional expenditure growth rates between BY3 and the performance year. The national component for each update factor would equal performance year per capita FFS expenditures for the national assignable beneficiary population for that enrollment type divided by BY3 per capita FFS expenditures for the national assignable beneficiary population for that enrollment type. As described above, the FFS expenditures for the national population would not be risk-adjusted. The regional component for each update factor would equal the weighted average of risk-adjusted county FFS expenditures among assignable beneficiaries, including the ACO's assigned beneficiaries, in the ACO's regional service area in the performance year divided by the weighted average of risk-adjusted county FFS expenditures among assignable beneficiaries, including the ACO's assigned beneficiaries, in the ACO's regional service area in BY3. This regional component would be computed in the same manner as the regional updates used to update the rebased benchmark for ACOs that enter a second or subsequent agreement period in 2017 or later years under the current regulations. The weights used to blend the national and regional components of the update factor would be calculated in the same manner as the weights that we proposed to use in calculating the blended trend factors for the historical benchmark, except they would be based on performance year rather than BY3 data. That is, the weight assigned to the national component would represent the share of assignable beneficiaries in

ACO's regional service area that are assigned to the ACO (based on a weighted average of county-level shares) in the performance year and the weight assigned to the regional component would be equal to 1 minus that share.

In addition to the national-regional blend, we considered an alternate approach that would incorporate national trends at the county level instead of at the regional service area level (national-county blend). Under this alternative, for each county that is in an ACO's regional service area in BY3, we would calculate trend factors to capture growth in county-level risk-adjusted expenditures for assignable beneficiaries from BY1 to BY3 and from BY2 to BY3. Each county-level trend factor would be blended with the national trend factor. The blended trend factor for each county would be a weighted average of the national and county-level trends where the weight applied to the national component would be the share of assignable beneficiaries in the county that are assigned to the ACO in BY3. The weight applied to the county component of the blend would be 1 minus the national weight.

After computing the blended trend factor for each county, we would determine the weighted average across all counties in the ACO's regional service area in BY3, using the proportion of assigned beneficiaries residing in each county in BY3 as weights to obtain an overall blended trend factor. We would then apply this overall blended trend factor to the expenditures for the ACO's assigned beneficiary population for the relevant benchmark year. All calculations would be done separately for each Medicare enrollment type. A similar approach would be used to compute update factors between BY3 and the performance year, but using weights based on share of assignable beneficiaries in each county that are assigned to the ACO in the performance year.

Returning to the hypothetical ACO from above, under the national-county blend we would calculate separate blended trend factors for County A and County B. For County A, the national component would receive a weight of 90.0 percent (9,000/10,000) and the county component would receive a weight of 1 minus 90.0 percent, or 10.0 percent. For County B, the national component would receive a weight of 16.7 percent (2,000/12,000) and the county component would receive a weight of 1 minus 16.7 percent, or 83.3 percent. After computing the blended trend factor for each county, we would take the weighted average across the two counties, with County A's blended trend factor receiving a weight of 81.8 percent (9,000/11,000) and County B's blended trend factor receiving a weight of 18.2 percent (2,000/11,000).

Our modeling suggested that, for most ACOs, applying the blend at the county-level would yield similar results to the national-regional blend. However, for ACOs that have experienced shifts in the geographic distribution of their assigned beneficiaries over time, we found the two methods to diverge. This is because the national-regional blend reflects not only changes in expenditures within specific counties over time, but also changes in the geographic distribution of the ACO's own assigned beneficiaries. The national-county blend, by contrast, holds the geographic distribution of an ACO's assigned beneficiaries fixed at the BY3 distribution (for trend factors) or at the performance year distribution (for update factors), potentially reducing accuracy.

In the August 2018 proposed rule, we also expressed the concern that calculating trends at the county rather than regional level, in addition to being less accurate, would be less transparent to ACOs. While national and regional trends are both used under our current benchmarking policies, and are thus familiar to ACOs, county-level trends would present a new concept. For these reasons, we explained that we favored the approach that incorporates national trends at the regional rather than county level.

Finally, we considered yet another 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. Specifically, if the share of assignable beneficiaries in an ACO's regional service area that are assigned to that ACO (computed as described above as a weighted average of county-level shares) is above the 90th percentile among all currently active ACOs for a given enrollment type in BY3, we would use national trend factors to trend forward BY1 and BY2 expenditures to BY3. For ACOs that are below the 90th percentile for a given enrollment type, we would continue to use regional factors as we do under the current policy. We would use a similar approach for the update factors, except the threshold would be based on the share of assignable beneficiaries that are assigned to the ACO in the performance year rather than BY3. Among the 73 ACOs that entered a second agreement period in 2017, the 90th percentile for the four enrollment types ranged between 25 and 30 percent of assignable beneficiaries in the ACO's regional service area. We noted that one drawback of this approach relative to the blended approaches previously described is that it would treat ACOs that are just below the threshold and just above the threshold very differently, even though they may be similarly influencing expenditure trends in their regional service areas.

We also noted that as we had previously indicated with respect to regional trends (see, for example, 81 FR 37976) and as suggested by our modeling, the national-regional blend, as well as the other options considered, would have mixed effects on ACOs depending on how the expenditure trends in an ACO's regional service area differ from the national trend. ACOs that have high penetration in their regional service area and that have helped to drive lower growth in their region relative to the national trend would benefit from this policy. ACOs that have contributed to higher growth in their regions would likely have lower benchmarks as a result of this policy than under current policy, helping to protect the Medicare Trust Fund and providing increased incentives for these ACOs to lower costs.

Based on the considerations previously discussed, we proposed to use a blend of national and regional trend factors (that is, the national-regional blend) to trend forward BY1 and BY2 to BY3 when determining the historical benchmark. We also proposed to use a blend of national and regional update factors, computed as described in section II.D.3.d of the proposed rule, to update the historical benchmark to the performance year (or to CY 2019 in the context of determining the financial performance of ACOs for the 6-month performance year from July 1, 2019 through December 31, 2019, as proposed in section II.A.7. of the proposed rule). The blended trend and update factors would apply to determine the historical benchmark for 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. We also made clear that in the event an ACO makes changes to its certified ACO participant list for a given performance year or its assignment methodology selection, the weight that would be applied to the national and regional components of the blended trend and update factors would be recomputed to reflect changes in the composition of the ACO's assigned beneficiary population in BY3.

Because the proposed blended update factor would be used in place of an update factor based on the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original FFS program as called for in section 1899(d)(1)(B)(ii) of the Act, we noted that this proposal would require us to use our authority under section 1899(i)(3) of the Act. This provision grants the Secretary the authority to use other payment models, including payment models that use alternative benchmarking methodologies, if the Secretary determines that doing so would improve the quality and efficiency of items and services furnished under Title XVIII and the alternative methodology would result in program expenditures equal to or lower than those that would result under the statutory payment model.

In the August 2018 proposed rule (83 FR 41893), we expressed our belief that by combining a national component that is more independent of an ACO's own experience with a regional component that captures location-specific trends, the proposed blended update factor would mitigate concerns about ACO influence on regional trend factors, improving the accuracy of the benchmark update and potentially protecting incentives for ACOs that may have high penetration in their regional service areas. As such, we believed that this proposed change to the statutory benchmarking methodology would improve the quality and efficiency of the program. As discussed in the Regulatory Impact Analysis for the August 2018 proposed rule (section IV. of the proposed rule), we projected that this proposed approach, in combination with other changes to the statutory payment model proposed elsewhere in the proposed rule, as well as current policies established using the authority of section 1899(i)(3) of the Act, would not increase program expenditures relative to those under the statutory payment model.

In summary, we proposed to use a blend of national and regional trend factors to trend forward BY1 and BY2 to BY3 when determining the historical benchmark and a blend of national and regional update factors to update the historical benchmark to the performance year (or to CY 2019 in the context of determining the financial performance of ACOs for the 6-month performance year from July 1, 2019 through December 31, 2019, as proposed in section II.A.7. of the proposed rule). The national component of the blended trend and update factors would receive a weight equal to the share of assignable beneficiaries in the regional service area that are assigned to the ACO, computed as described in section II.D.3.d of the proposed rule by taking a weighted average of county-level shares. The regional component of the blended trend and update factors would receive a weight equal to 1 minus the national weight. 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. These proposed policies were included in the proposed new provision at § 425.601, which would govern the determination of historical benchmarks for all ACOs for agreement periods starting on July 1, 2019, or in subsequent years. We sought 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.

Comment: One commenter strongly supported the use of blended regional and national trend factors when calculating the historical benchmark. This commenter expressed the belief that this policy would ensure that ACOs whose assigned beneficiaries comprise a large percentage of the region's Medicare FFS beneficiaries are not adversely impacted by their successful efforts to reduce the total cost of care. The commenter believes that this policy will encourage large ACOs to remain in the program and increases the likelihood that they will continue to generate savings over multiple agreement periods. Another commenter supported the use of blended national and regional trend factors as long as the regional trend factor is based on FFS beneficiaries and does not include beneficiaries enrolled in Medicare Advantage.

Several other commenters generally agreed with the concept of blending national and regional growth rates to trend or update benchmarks with greater weight given to national trends for ACOs that serve a large share of the FFS population in their areas but requested that CMS exclude ACO assigned beneficiaries from the regional component of the blend. A few commenters suggested excluding ACO assigned beneficiaries from the national component as well. A larger number of commenters recommended using purely regional trend factors based on a regional population that excludes ACO assigned beneficiaries to trend and update benchmarks instead of a blend. Other commenters were also in favor of excluding ACO assigned beneficiaries in regional trends but did not specify whether they believed this should occur in addition to or in place of a blend. Commenters also appeared to have mixed views on whether the exclusion should be limited to a particular ACO's own assigned beneficiaries, all Shared Savings Program assigned beneficiaries, or beneficiaries assigned to any Medicare shared savings initiative. One commenter did not specifically call for removing ACO assigned beneficiaries from regional calculations but requested that CMS take additional steps to address the problem of regionally significant ACOs driving expenditures in their service areas. As noted in section II.D.3.c. of this final rule, some commenters also called for excluding ACO assigned beneficiaries from the regional expenditures used to calculate an ACO's regional adjustment.

One commenter noted that while the proposed blending of national and regional growth rates would likely be an improvement over the current approach used in the rebasing methodology adopted in the June 2016 final rule, it would only partially improve the incentive for ACOs that are dominant in their region to reduce spending and that by placing a significant weight on the national component in these situations, the blend would do a worse job of capturing the local spending trends facing an ACO. Another commenter expressed similar views, noting that the proposed national-regional blend was ''a step in the right direction'' but could over-emphasize the national trend component, which ignores local market dynamics. The commenter believes that the blend would diminish the incentive that ACOs have to concentrate in high trend areas of the country and to control trend at the local level. In addition, this commenter believes that excluding ACO assigned beneficiaries from the regional reference population is a simpler solution that eliminates the situation where an ACO is being directly evaluated against itself. Several other commenters also raised concerns about ACOs competing against themselves or influencing regional trends when assigned beneficiaries are included in regional expenditure calculations, which could make it more difficult for an ACO to realize savings or to be comfortable taking on increasing amounts of risk. Other commenters suggested that including ACO assigned beneficiaries in regional trends reduced incentives for ACOs to participate or to reduce expenditures, particularly among rural ACOs. Several other commenters

suggested that removing ACO assigned beneficiaries was necessary to obtain a true comparison between an ACO and its region or would produce more accurate benchmarks.

Several commenters also provided suggestions for how to address potential small sample size issues that could result from removing ACO assigned beneficiaries from regional expenditure calculations including expanding the geographic area to include adjacent or otherwise similar counties, using Hospital Referral Regions in place of counties, averaging over multiple years, increasing weights on counties with lower proportions of assigned beneficiaries, or employing other statistical techniques. One commenter noted that if the Shared Savings Program grows to the point where the non-ACO FFS population is very small, CMS should select a desirable rate at which benchmarks should grow and apply it to all ACOs.

Response: We appreciate the comments we received on our proposal to use a blend of national and regional growth rates to trend and update the historical benchmark. We agree with commenters that our proposed approach of using a blend of national and regional growth rates to trend and update the historical benchmark would help to address concerns about ACOs with high penetration driving the trends in their regions and are finalizing this proposal. For the reasons described in the June 2016 final rule (81 FR 37960), we did not propose to remove ACO assigned beneficiaries from the regional or national populations used to compute growth rates or the regional adjustment and are not adopting commenters' recommendations regarding this approach at this time. As we noted in the June 2016 final rule, we believe that removing assigned beneficiaries could lead to biased calculations, particularly in the case of ACOs serving higher cost beneficiaries within their regions and we have significant concerns about the complexity of the customized calculations that would be necessary to remove each ACO's own assigned beneficiaries from the calculation of growth rates, as suggested by some commenters. We believe such calculations would be operationally burdensome and less transparent. As we are not modifying our proposal in order to remove ACO assigned beneficiaries from the determination of either regional or national growth rates, we do not believe it is necessary to adopt commenters' various recommendations for addressing small sample size issues.

National and regional expenditures will continue to be based on assignable beneficiaries in the FFS population during the applicable benchmark or performance year. Beneficiaries with months of Medicare Advantage enrollment during a particular benchmark or performance year may be included in the assignable beneficiary population for that year, but we would only consider the months in which those beneficiaries were enrolled in both Parts A and B and not enrolled in Medicare Advantage in making expenditure calculations.

Comment: One commenter disagreed with the proposed approach of using a blend of national and regional growth rates, stating that this holds organizations in areas with historically low spending growth to a higher standard than those who are in high spending growth areas by assuming that regions with slower growth will be able to maintain these low trends when, in fact, the opposite may be true. The commenter believes that CMS should incentivize organizations in low growth areas to participate by using national trends only and by applying a more dramatic increase in their trend. Specifically, the commenter recommended that organizations that are in regions with growth trends below the national average and that have had historical spending at or below 85 percent of the national average should receive a 3 percent increase to their growth factor based national trends. Organizations with historical spending at or below 90 percent or 95 percent of the national average could receive a 2 percent or 1 percent added to their trend, respectively. Another commenter stated that he supported the move towards a national-regional blend, but also believes that the current proposal penalizes organizations with historically low spending growth. This commenter also supported a 3 percent increase to the trend factor for ACOs in regions with below average cost growth that have historical spending at or below 85 percent of the national average. Both commenters expressed the belief that this approach would encourage organizations in California and other efficient areas to transition to a risk-based APM instead of continuing in MIPS. Another commenter recommended that CMS consider using a prospectively determined trend rate, which would allow for greater predictability of financial results by ACOs, noting that such trend rates are used in the Next Generation ACO Model and Medicare Advantage program. Similarly, one commenter called for using a ''pre-determined inflation adjustment''.

Response: We do not agree with one commenter's assertion that the proposed policy of using a blend of national and regional growth rates to trend or update the benchmark assumes that regions with slow growth will continue to have slow growth, because the proposed policy relies on retrospective growth rates, which reflect actual growth rates. In contrast, we believe that using prospectively determined trend rates or adjustments, as suggested by some commenters, could have this problem, even if this approach may offer other advantages.

We do recognize that, all else being equal, ACOs in regions with slower than average growth would fare worse under the blended approach than they would under a policy that relies on purely national growth rates. However, we believe that it is important to balance the goal of creating incentives for participation with the desire to reflect the local circumstances of an ACO's region, in order to avoid windfall gains to ACOs that are located in low growth areas.

We also believe that providing a growth rate ''add on'' for efficient ACOs in such areas could help to increase participation by ACOs in these areas, but could similarly lead to windfall gains to the detriment of the Trust Funds.

Comment: One commenter suggested that the proposed policies would not adequately solve the disparity in regional trend factors. They noted that ACOs in some areas of the country are faced with trying to beat national trends while regional trends are much higher.

Response: We believe that our proposal to incorporate regional factors into an ACO's benchmark for its first agreement period, which we are finalizing, helps to address the concern raised by this commenter that ACOs in areas with high cost growth are at a disadvantage when national factors are used to trend or update the benchmark. Under the new policy that we are adopting in this final rule, all ACOs, including those in their first agreement period, will receive a blend of national and regional trend and update factors. Furthermore, for most ACOs, the weight applied to the regional growth rate will likely be higher than the weight applied to the national growth rate.

Comment: Several commenters did not agree with our proposal for weighting the regional and national components of growth rates. One commenter expressed the belief that this weighting should be based on multilevel statistical modeling approaches rather than what the commenter described as an arbitrary weighting scheme. Another

commenter expressed concern about weighting the regional benchmark in inverse proportion to an ACO's market share, noting that the better an ACO performs, the more it reduces its regional benchmark, effectively reducing the opportunity for future savings. Another commenter also opposed applying a greater weight to the national trend factor based on market penetration stating that an assessment of an ACO's effectiveness should not be tied to the size of market penetration and that CMS should be able to set a financial target in a market that determines whether or not an ACO was effective in generating savings, rather than creating a moving target based on an ACO's individual circumstances. One additional commenter, while not specifically addressing the proposed weighting methodology, expressed the belief that regional factors should be a bigger percentage of the formulas as healthcare is a local phenomenon.

Response: We are finalizing our proposed methodology for blending regional and national factors, which automatically adjusts the weight of the two components to reflect the percentage of an ACO's assigned beneficiaries relative to its region. We believe this approach will be more transparent and familiar to ACOs than an approach that relies on statistical modeling, while still reducing the extent to which the overall blended trend factor reflects an individual ACO's performance for ACOs that are highly penetrated in their region. As we noted in the proposed rule, we observed a median penetration rate for ACOs of around 12 percent. Therefore, we anticipate that for the majority of ACOs this weighing approach will provide a higher weight for regional factors (for example, 88 percent based on the median) as opposed to national factors.

We disagree with commenters that basing the weights of the national growth factor on an ACO's market penetration constitutes an assessment of an ACO's performance. The rationale behind using an ACO's market penetration to determine the national weight is meant to reduce the impact that an ACO's own expenditure patterns will have on the growth rates used to trend and update its benchmark.

Comment: A few commenters recommended modifying the update that is applied to an ACO's benchmark for a performance year that is affected by an extreme an uncontrollable circumstance. For example, these commenters recommended that CMS apply a growth rate that is the higher of the national growth rate for assignable beneficiaries or the regional growth rate for assignable beneficiaries (excluding an ACO's own assigned beneficiaries). A few other commenters recommended that CMS use the proposed blend of national and regional expenditure growth rates to update the benchmark in ''normal times'' but use a purely regional growth rate in the event of an extreme and uncontrollable circumstance.

Response: In the November 2018 final rule (83 FR 59968 through 59979) we finalized policies to extend, with minor modifications, the performance year 2017 extreme and uncontrollable circumstances policies to performance year 2018 and subsequent years. These policies include an alternate quality scoring methodology for ACOs that are affected by extreme and uncontrollable circumstances and an adjustment to shared losses based on the percentage of the total months in the performance year affected by extreme and uncontrollable circumstances and the percentage of the ACO's assigned beneficiaries residing in an affected area. In that final rule, we explained our belief that the use of regional growth rates in determining benchmark update factors for all ACOs, as we are finalizing in this final rule, would provide an inherent adjustment to the historical benchmark for expenditure changes resulting from extreme and uncontrollable circumstances during the agreement period.

We appreciate commenters' suggestions for additional approaches to providing relief for ACOs impacted by extreme and uncontrollable circumstances. We are concerned that the suggestion offered by some commenters of using the higher of the national or regional rate implicitly assumes that expenditures will always rise in a year affected by an extreme and uncontrollable circumstance, which may not always be the case. We therefore believe this approach would not appropriately address instances where expenditures for an ACO declined between the benchmark period and the performance year due to an extreme and uncontrollable event occurring during the performance year. It also may not appropriately address circumstances where expenditures are higher in the benchmark period than they otherwise would have been due to an extreme and uncontrollable event and then show a decline between the benchmark period and the performance year. We believe that a blended national-regional trend factor will better correct for such variations than a national trend factor alone, because regional expenditures are more likely than national expenditures to share the expenditure impacts of a natural disaster experienced by an individual ACO. We also decline to adopt the suggestion of using a purely regional growth rate in place of a blended growth rate in cases where there is an extreme and uncontrollable event in the benchmark period or the performance year as we believe that even following an extreme and uncontrollable event, it is still important to use a national-regional blend to address concerns about ACOs with high market penetration driving the expenditure growth rate in their own regions.

Final Action: After considering the comments received, we are finalizing our proposal to use a blend of national and regional trend factors to trend forward BY1 and BY2 to BY3 when determining the historical benchmark and a blend of national and regional update factors to update the historical benchmark to the performance year (or to CY 2019 in the context of determining the financial performance of ACOs for the 6-month performance year from July 1, 2019, through December 31, 2019, as finalized in section II.A.7. of this the final rule). The national component of the blended trend and update factors will receive a weight equal to the share of assignable beneficiaries in the regional service area that are assigned to the ACO, computed by taking a weighted average of county-level shares. The regional component of the blended trend and update factors will receive a weight equal to 1 minus the national weight. The proposed blended trend and update factors will apply for 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. These policies are included in the new provision at § 425.601, which will govern the determination of historical benchmarks for all ACOs for agreement periods starting on July 1, 2019, or in subsequent years.

As explained in the August 2018 proposed rule, the use of a blended update factor requires us to use our authority under section 1899(i)(3) of the Act. This provision grants the Secretary the authority to use other payment models, including payment models that use alternative benchmarking methodologies, if the Secretary determines that doing so would improve the quality and efficiency of items and services furnished under Title XVIII and the alternative methodology would result in program expenditures equal to or lower than those that would result under the statutory payment model. As discussed in the Regulatory Impact Analysis (section V. of this final rule),

we continue to believe that using a blend of national and regional growth rates to update the benchmark, in combination with the other changes to the statutory payment model being finalized in this final rule, as well as current policies established using the authority of section 1899(i)(3) of the Act, would not increase program expenditures beyond the expenditures that would otherwise occur under the statutory payment methodology in section 1899(d) of the Act. Specifically, we believe that these policies together will result in more accurate and predictable benchmarks for use over longer agreement periods during which ACOs will be required to participate under performance-based risk. We believe policies that encourage ACOs to take greater accountability for the cost of the care furnished to their assigned beneficiaries offer greater incentives for ACOs to invest in effective care management efforts that lead to improved coordination of beneficiary care and to continue to improve quality of care and out-perform other Medicare fee-for-service providers on related quality of care and outcome measures. As a result, we believe the policies that we are adopting in this final rule using our authority under section 1899(i)(3) of the Act, including the modifications to the methodology for updating the historical benchmark discussed in this section, will lead to continued improvement in the quality of care furnished to Medicare fee-for-service-beneficiaries.

4. Technical Changes To Incorporate References to Benchmark Rebasing Policies

We proposed to make certain technical, conforming changes to the following provisions to reflect our proposal to add a new section of the regulations at § 425.601 to govern the calculation of the historical benchmark for all agreement periods starting on July 1, 2019, and in subsequent years. We also proposed to make conforming changes to these provisions to incorporate the policies on resetting, adjusting, and updating the benchmark that were adopted in the June 2016 final rule, and codified in the regulations at § 425.603.

- Under subpart C, which governs application procedures, add references to §§ 425.601 and 425.603 in § 425.204(g);
- Under subpart D, which governs the calculation of shared savings and losses, add references to § 425.603 in §§ 425.604 (Track 1) and 425.606 (Track 2); and add references to §§ 425.601 and 425.603 in § 425.610 (ENHANCED track);
- As part of the modifications to § 425.610, make a wording change to the paragraph currently numerated as (a)(2)(ii) that could not be completed with the June 2016 final rule due to a typographical error. In this paragraph, we would remove the phase ''adjusts for changes'', and in its place add the phrase ''CMS adjusts the benchmark for changes''; and
- Under subpart I, which governs the reconsideration review process, add references to §§ 425.601 and 425.603 to § 425.800(a)(4). In addition, as previously described, we have used our authority under section 1899(i)(3) of the Act to modify certain aspects of the statutory payment and benchmarking methodology under section 1899(d) of the Act. Accordingly, we also proposed to amend § 425.800(a)(4) to clarify that the preclusion of administrative and judicial review applies only to the extent that a specific calculation is performed in accordance with section 1899(d) of the Act.

Final Action: We did not receive any comments regarding these proposed technical changes to incorporate references to benchmark rebasing policies. We are finalizing the changes described in this section as proposed. We also received no comments specifically addressing our proposal to revise § 425.800 to clarify that the preclusion of administrative and judicial review with respect to certain financial calculations applies only to the extent that a specific calculation is performed in accordance with section 1899(d) of the Act. We are finalizing these modifications as proposed.

E. Updating Program Policies

1. Overview

In section II.E of the proposed rule, we proposed revisions designed to update certain policies under the Shared Savings Program. The policies discussed in sections II.E.2. through II.E.6 of the August 2018 proposed rule were addressed in the November 2018 final rule (83 FR 59959 through 59988). In section II.E.7 of the proposed rule, we solicited comments on how Medicare ACOs and Part D sponsors could be encouraged to collaborate so as to improve the coordination of pharmacy care for Medicare FFS beneficiaries. We discuss the comments received in response to this solicitation in section II.E.2 of this final rule.

2. Coordination of Pharmacy Care for ACO Beneficiaries

Medicare ACOs and other stakeholders have indicated an interest in collaborating to enhance the coordination of pharmacy care for Medicare FFS beneficiaries to reduce the risk of adverse events and improve medication adherence. For example, areas where ACOs and the sponsors of stand-alone Part D PDPs might collaborate to enhance pharmacy care coordination include establishing innovative approaches to increase clinician formulary compliance (when clinically appropriate) and medication compliance; providing pharmacy counseling services from pharmacists; and implementing medication therapy management. Part D sponsors may be able to play a greater role in coordinating the care of their enrolled Medicare FFS beneficiaries and having greater accountability for their overall health outcomes, such as for beneficiaries with chronic diseases where treatment and outcome are highly dependent on appropriate medication use and adherence. Increased collaboration between ACOs and Part D sponsors may facilitate better and more affordable drug treatment options for beneficiaries by encouraging the use of generic prescription medications, where clinically appropriate, or reducing medical errors through better coordination between health care providers and Part D sponsors.

As we explained in the August 2018 proposed rule, we believe that Medicare ACOs and Part D sponsors may be able to enter into appropriate business arrangements to support improved pharmacy care coordination, provided such arrangements comply with all applicable laws and regulations. However, challenges may exist in forming these arrangements. Under the Pioneer ACO Model, an average of 54 percent of the beneficiaries assigned to Pioneer ACOs in 2012 were also enrolled in a PDP in that year, with the median ACO having at most only 13 percent of its assigned beneficiaries enrolled in a plan offered by the same PDP parent organization. For performance year 2016, we found that approximately 70 percent of the beneficiaries assigned to Shared Savings Program ACOs had continuous Part D coverage.

We believe timely access to data could improve pharmacy care coordination. Although CMS already provides Medicare ACOs with certain Part D prescription drug event data, it may be useful for both Medicare ACOs and Part D sponsors to share certain clinical data and pharmacy data with each other to support coordination of pharmacy care. Any data sharing arrangements between ACOs and Part D sponsors should comply with all applicable legal requirements regarding the privacy and confidentiality of such data, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules.

In the August 2018 proposed rule, we solicited comment on how Medicare ACOs, and 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 to achieve better health outcomes, better health care, and lower per-capita expenditures for Medicare beneficiaries. In addition, we sought comment on what kind of support would be useful for Medicare ACOs and Part D sponsors in establishing new, innovative business arrangements to promote pharmacy care coordination to improve overall health outcomes for Medicare beneficiaries. We also sought comment on issues related to how CMS, Medicare ACOs and Part D sponsors might structure the financial terms of these arrangements to reward Part D sponsors' contributions towards achieving program goals, including improving the beneficiary's coordination of care. Lastly, we sought comment on whether ACOs are currently partnering with Part D sponsors, if there are any barriers to developing these relationships (including, but not limited to, data and information sharing), and if there are any recommendations for how CMS can assist, as appropriate, with reducing barriers and enabling more robust data sharing.

Comment: Many commenters were supportive of CMS' request for comments on how Medicare ACOs, and 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. Several commenters stated that improved collaboration between Medicare ACOs and Part D Plans (PDPs) would provide more comprehensive care and improve overall quality, by enhancing care coordination, medication adherence, potentially reducing the risk of adverse drug events, and offering pharmacy counseling services that could ensure that patients receive timely access to the most appropriate form of treatment for their given condition. A commenter suggested that the timing of data sharing between CMS, ACOs, and PDPs would be important for successful collaboration. Another commenter suggested that data sharing between PDPs and ACOs could create pathways for achieving efficiencies in drug expenditures and reduce burden. Another commenter suggested that CMS should provide Part D claims data that would assist ACOs in addressing crucial care management issues and improve outcomes. In addition, the commenter stated that they believed there should be financial incentives for PDPs and ACOs to coordinate and align care.

Many commenters offered suggestions for improving the coordination between PDPs and ACOs. A few commenters suggested CMS should investigate ways to make pharmacy data more readily available to ACOs so they can share this information with their ACO providers/suppliers. The commenters indicated that the use of enabling technology, such as secure data access portals and data sets accessible using Application Programming Interfaces, could provide ACOs timely access to claims data for their aligned beneficiaries. Commenters suggested that timely access to these data could allow ACOs to develop provider alert processes that could improve care. In addition, one commenter suggested that CMS should consider developing a Shared Savings Program voluntary demonstration that incorporates ACO accountability for Part D costs. Another commenter suggested CMS explore opportunities to allow waivers that would allow lower prescription drug copayments for ACO assigned beneficiaries. Another commenter suggested CMS incorporate community pharmacies that provide coordinated patient care into the Shared Savings Program to improve outcomes for patients who are high risk or are in underserved areas. Another commenter encouraged CMS to consider medication management as a critical potential modifier of health status, encourage the use of pharmacists as a primary point of intersection between ACOs and Part D plans, improve access to clinical and pharmacy data, and adopt performance-based payments to reflect pharmacists' contributions to cost reduction and improved coordination. A few commenters expressed concerns about Shared Savings Program ACOs and PDPs working together to improve pharmacy coordination. One commenter expressed concern regarding the differences between Part D Medication Management Therapy (MTM) and medication management services provided through coordinated care models, and specifically noted variation in beneficiary eligibility for MTM services, depending on their Part D plan. The commenter asked that CMS address current barriers to beneficiary eligibility for MTM before making any additional changes to policies under the Shared Savings Program to improve care coordination with pharmacies. One commenter requested more details on CMS' plan to promote information sharing, and along with another commenter, expressed concern regarding the capability of PDPs and ACOs to undertake information sharing and the costs that they believed would be incurred.

Response: We thank the commenters for their input on the coordination of pharmacy care for ACO assigned beneficiaries. As we plan for any future updates and changes to the Shared Savings Program, we will consider this feedback from commenters before making any proposals related to the coordination of pharmacy care.

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

1. Background

In section II.F. of the August 2018 proposed rule (83 FR 41912), we discussed the applicability of our proposed policies to Track 1+ Model ACOs, and in the November 2018 final rule (83 FR 59988 through 59990) we described the applicability of certain policies adopted in that final rule to Track 1+ Model ACOs.

In these earlier rules, we explained that the Track 1+ Model was established under the Innovation Center's authority at section 1115A of the Act, to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care for Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. We noted that 55 Shared Savings Program Track 1 ACOs entered into the Track 1+ Model beginning on January 1, 2018. This includes 35 ACOs that entered the model within their current agreement period (to complete the remainder of their agreement period under the model) and 20 ACOs that entered into a new 3-year agreement under the model.

To enter the Track 1+ Model, ACOs must be approved to participate in the model and are required to agree to the terms and conditions of the model by executing a Track 1+ Model Participation Agreement available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/track-1plus-model-par-agreement.pdf.* Track 1+ Model ACOs are also required to have been approved to participate in the Shared Savings Program (Track 1) and to have executed a Shared Savings Program Participation Agreement. As indicated in the Track 1+ Model Participation Agreement, in accordance with our authority under section 1115A(d)(1) of the Act, CMS has waived certain requirements of the Shared Savings Program that otherwise would

be applicable to ACOs participating in Track 1 of the Shared Savings Program, as necessary for purposes of testing the Track 1+ Model, and established alternative requirements for the ACOs participating in the Track 1+ Model.

We explained that, unless stated otherwise in the Track 1+ Model Participation Agreement, the requirements of the Shared Savings Program under 42 CFR part 425 continue to apply. Consistent with § 425.212, Track 1+ Model ACOs are subject to all applicable regulatory changes, including but not limited to, changes to the regulatory provisions referenced within the Track 1+ Model Participation Agreement, that become effective during the term of the ACO's Shared Savings Program Participation Agreement and Track 1+ Model Participation Agreement, unless otherwise specified through rulemaking or amendment to the Track 1+ Model Participation Agreement. We also noted that the terms of the Track 1+ Model Participation Agreement permit the parties (CMS and the ACO) to amend the agreement at any time by mutual written agreement.

2. Unavailability of Application Cycles for Entry Into the Track 1+ Model in 2019 and 2020

In the August 2018 proposed rule (83 FR 41912 through 41913), we discussed the unavailability of application cycles for entry into the Track 1+ Model in 2019 and 2020. We explained that an ACO's opportunity to join the Track 1+ Model aligns with the Shared Savings Program's application cycle. The original design of the Track 1+ Model included 3 application cycles for ACOs to apply to enter or, if eligible and if applicable, to renew their participation in the Track 1+ Model for an agreement period start date of 2018, 2019, or 2020. We noted that the 2018 application cycle had closed, and that 55 ACOs began participating in the Track 1+ Model on January 1, 2018. As discussed in section II.A.7. of the August 2018 proposed rule (83 FR 41847) and section V.B.1.a of the November 2018 final rule (83 FR 59942 through 59946), we are not offering an application cycle for a January 1, 2019 start date for new agreement periods under the Shared Savings Program. Therefore, we explained that we would similarly not offer a start date of January 1, 2019, for participation in the Track 1+ Model.

In the August 2018 proposed rule (83 FR 41912 through 41913), we explained that we had re-evaluated the need for continuing the Track 1+ Model as a participation option for 2019 and 2020 in light of the proposal to offer the BASIC track (including a glide path for eligible ACOs) as a participation option beginning in 2019. Like the Track 1+ Model, the BASIC track would offer relatively lower levels of risk and potential reward than Track 2 and the ENHANCED track. The BASIC track's glide path would allow the flexibility for eligible ACOs to enter a one-sided model and to automatically progress through levels of risk and reward that end at a comparable level of risk and reward (Level E) to that offered in the Track 1+ Model and also to qualify as participating in an Advanced APM. ACOs in the glide path could also elect to more quickly enter higher levels of risk and reward within the BASIC track. We stated that if the proposed approach to adding the BASIC track were finalized and made available for agreement periods beginning in 2019 and subsequent years, we would discontinue future application cycles for the Track 1+ Model. In that case, the Track 1+ Model would not accept new model participants for start dates of July 1, 2019, or January 1, 2020, or in subsequent years.

As described in section II.A.2. and II.A.3. of this final rule, we are finalizing the BASIC track to include Level E, with a level of risk and reward that is comparable to the Track 1+ Model. Therefore, we will forgo future application cycles for the Track 1+ Model, as we believe offering both the BASIC track and the Track 1+ Model would create unnecessary redundancy in participation options within CMS' Medicare ACO initiatives. As we explained in the August 2018 proposed rule (83 FR 41912 through 41913), the high level of interest in the Track 1+ Model indicates a positive response to its design, and therefore we believe we have met an important goal of testing the Track 1+ Model. We have also incorporated lessons learned from our initial experience with the Track 1+ Model in the design of the BASIC track, including the levels of risk and reward under the BASIC track, and by allowing for potentially lower, and therefore less burdensome, repayment mechanism amounts for ACOs with relatively lower estimated ACO participant Medicare FFS revenue compared to estimated benchmark expenditures for their assigned Medicare FFS beneficiary population. Further, we will evaluate the quality and financial performance of the Track 1+ Model ACOs and consider the results of this evaluation in the development of future policies for the Shared Savings Program.

Existing Track 1+ Model ACOs will be able to complete the remainder of their current agreement period in the model, or terminate their current participation agreements (for the Track 1+ Model and the Shared Savings Program) and apply to enter a new Shared Savings Program agreement period under either the BASIC track (Level E) or the ENHANCED track (as described in section II.A.5. of this final rule).

Additionally, as discussed in section II.A.7.c.(1). of the August 2018 proposed rule (83 FR 41854 through 41855) and section V.B.1.c.(1). of the November 2018 final rule (83 FR 59951), ACOs currently participating in the Track 1+ Model will not have the opportunity to apply to use a SNF 3-day rule waiver starting on January 1, 2019, as a result of our decision to forgo an annual application cycle for a January 1, 2019 start date in the Shared Savings Program. However, as discussed in section II.A.7.c.(1). of this final rule, we are making an exception to the January 1 start date for use of a SNF 3-day rule waiver to allow for a July 1, 2019 start date for eligible Track 1+ Model ACOs that apply for and are approved to use a SNF 3-day rule waiver.

Comment: Some commenters supported the proposed approach to incorporating Level E into the Shared Savings Program under a new BASIC track, to make a participation option with the same level of risk and potential reward as the Track 1+ Model a permanent part of the program.

However, a few commenters expressed concern about our plan to discontinue the Track 1+ Model if we finalize the BASIC track design to include a participation option with an equivalent level of risk and potential reward as the Track 1+ Model. For example, one commenter stated that some ACOs went into the Track 1+ Model in 2018 in the middle of their current agreement period with the expectation that Track 1+ would be available as a renewal option for a full 3-year agreement period. Another commenter suggested, as an alternative approach to redesigning the program's participation options, that CMS eliminate downside risk requirements for low revenue ACOs by retaining Track 1, eliminating the BASIC track, and allowing voluntary participation in the Track 1+ Model (among other suggestions).

Response: We appreciate commenters' support for the BASIC track design, which as discussed in section II.A.3. of this final rule, we are finalizing to include Level E that is comparable to the level of risk and reward as offered in the Track 1+ Model. We are therefore discontinuing future application cycles for the Track 1+ Model, and we will not accept new model participants for start

dates of July 1, 2019, or in subsequent years. Further, under our final policies for determining participation options, discussed in section II.A.5.c. of this final rule, an ACO with a first or second agreement period beginning in 2016 or 2017 identified as a high revenue ACO and experienced with performance-based risk Medicare ACO initiatives based on prior participation in the Track 1+ Model may renew for its next agreement period beginning on July 1, 2019, or January 1, 2020 (respectively) under Level E of the BASIC track. Further, eligible ACOs identified as low revenue ACOs and experienced with performance-based risk Medicare ACO initiatives (including based on the participation of the ACO or its ACO participants in the Track 1+ Model) may also participate for up to two agreement periods under Level E of the BASIC track.

3. Applicability of Final Policies To Track 1+ Model ACOs Through Revised Program Regulations or Revisions to Track 1+ Model Participation Agreements

In section II.F. of the August 2018 proposed rule (83 FR 41913 through 41914), we provided a comprehensive discussion of the applicability of the proposed policies to Track 1+ Model ACOs to allow these ACOs to better prepare for their future years of participation in the program and the Track 1+ Model. We explained that there are two ways in which the proposed policies would become applicable to Track 1+ Model ACOs: (1) Through revisions to existing regulations that currently apply to Track 1+ Model ACOs, and (2) through revisions to the ACO's Track 1+ Model Participation Agreement. In the November 2018 final rule, we described the applicability of certain final policies adopted in that final rule to Track 1+ Model ACOs (83 FR 59988 through 59990).

Generally, comments regarding the application of specific proposals to Track 1+ Model ACOs have been addressed as part of the discussion of comments in the relevant section of this final rule. Accordingly, in this section of this final rule, we are not repeating comments related to the applicability of the proposed policies to ACOs participating in the Track 1+ Model.

Therefore, unless specified otherwise, the changes to the program's regulations finalized in this final rule that are applicable to Shared Savings Program ACOs within a current agreement period will apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 1, so long as the applicable regulation has not been waived under the Track 1+ Model. Similarly, to the extent that certain requirements of the regulations that apply to ACOs under Track 2 or Track 3 have been incorporated for ACOs in the Track 1+ Model under the terms of the Track 1+ Model Participation Agreement, any changes to those regulations as finalized in this final rule will also apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 2 or Track 3. For example, the following final policies will apply to Track 1+ Model ACOs:

- Changes to the repayment mechanism requirements (see section II.A.6.c. of this final rule). We believe these requirements are similar to the requirements under which Track 1+ Model ACOs established their repayment mechanisms, such that no revision to those arrangements will be required. Further, pursuant to the changes to the repayment mechanism requirements that we are adopting in this final rule, we note that any Track 1+ Model ACO that seeks to renew its Shared Savings Program participation agreement will be permitted to use its existing repayment mechanism arrangement to support its continued participation in the Shared Savings Program under a two-sided model in its next agreement period, provided that the amount and duration of the repayment mechanism arrangement are updated as specified by CMS.
- For the performance year beginning on July 1, 2019 and each subsequent performance year, the requirement to notify Medicare FFS beneficiaries regarding voluntary alignment by providing each beneficiary with a standardized written notice prior to or at the first primary care visit of each performance year (section II.C.3.a.(2). of this final rule).

We also intend to apply the following policies finalized in this final rule to Track 1+ Model ACOs through an amendment to the Track 1+ Model Participation Agreement executed by CMS and the ACO:

- Monitoring for and consequences of poor financial performance (section II.A.5.d. of this final rule).
- Revising the MSR/MLR to address small population sizes (section II.A.6.b.(3). of this final rule).
- Payment consequences of early termination for ACOs under performance-based risk (section II.A.6.d. of this final rule).
- Certain requirements related to the furnishing of telehealth services beginning on January 1, 2020, as provided under section 1899(l) of the Act (see section II.B.2.b.(2). of this final rule). As previously described, the Bipartisan Budget Act provides for coverage of certain telehealth services furnished by physicians and practitioners in ACOs participating in a model tested or expanded under section 1115A of the Act that operate under a two-sided model and for which beneficiaries are assigned to the ACO using a prospective assignment method. ACOs participating in the Track 1+ Model meet these criteria. We believe it is appropriate to apply the same requirements under the Track 1+ Model with respect to telehealth services furnished under section 1899(l) of the Act that apply to other Shared Savings Program ACOs that are applicable ACOs for purposes of that subsection. This will ensure consistency across program operations, payments, and beneficiary protection requirements for Track 1+ Model ACOs and other Shared Savings Program ACOs with respect to telehealth services furnished under section 1899(l) of the Act.

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

A. Background

In December 2017, we issued an interim final rule with comment period titled ''Medicare Shared Savings Program: Extreme and Uncontrollable Circumstances Policies for Performance Year 2017'' (hereinafter referred to as the December 2017 interim final rule with comment period''), which appeared in the **Federal Register** on December 26, 2017 (82 FR 60912). In the December 2017 interim final rule with comment period, we established policies for assessing the financial and quality performance of Medicare Shared Savings Program (Shared Savings Program) Accountable Care Organizations (ACOs) affected by extreme and uncontrollable circumstances during performance year 2017, including the applicable quality reporting period for the performance year. Under the Shared Savings Program, providers of services and suppliers that participate in ACOs continue to receive traditional Medicare FFS payments under Parts A and B, but the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements. ACOs in performance-based risk tracks may also share in losses. The December 2017 interim final rule with comment period established extreme and uncontrollable circumstances policies for the Shared Savings Program that applied to ACOs subject to extreme and uncontrollable events, such as Hurricanes Harvey, Irma, and Maria, and the California wildfires, during performance year 2017, including the applicable quality data reporting period for the performance year.

We received 11 timely pieces of correspondence in response to the December 2017 interim final rule with comment period. In the following sections of this final rule, we summarize and respond to these public comments.

B. Shared Savings Program Extreme and Uncontrollable Circumstances Policies for Performance Year 2017

In the December 2017 interim final rule with comment period we expressed our agreement with stakeholders that the financial and quality performance of ACOs located in areas subject to extreme and uncontrollable circumstances could be significantly and adversely affected. We also agreed that due to the widespread disruptions that occurred during 2017 in areas affected by Hurricanes Harvey, Irma, and Maria, and the California wildfires, new policies were warranted for assessing quality and financial performance of Shared Savings Program ACOs in the affected areas. We believed it was appropriate to adopt policies to address stakeholder concerns that displacement of beneficiaries may make it difficult for ACOs to access medical record data required for quality reporting, and might reduce the beneficiary response rate on survey measures. In addition, medical records needed for quality reporting may have been inaccessible. We also believed it was appropriate to adopt policies to address stakeholders' concerns that ACOs might be held responsible for sharing losses with the Medicare program resulting from catastrophic events outside the ACO's control given the increase in utilization, migration of patient populations leaving the impacted areas, and the mandatory use of natural disaster payment modifiers making it difficult to identify whether a claim would otherwise have been denied under normal Medicare fee-for-service (FFS) rules.

Prior to the issuance of the December 2017 interim final rule with comment period, we did not have policies under the Shared Savings Program for addressing ACO quality performance scoring and the determination of the shared losses owed by ACOs participating under performance-based risk tracks in the event of an extreme or uncontrollable circumstance. In the interim final rule with comment period titled Medicare Program; Quality Payment Program: Extreme and Uncontrollable Circumstance Policy for the Transition Year that appeared in the **Federal Register** on November 16, 2017 (hereinafter referred to as the Quality Payment Program IFC) (82 FR 53895), we established an automatic policy to address extreme and uncontrollable circumstances, including Hurricanes Harvey, Irma, and Maria, for the Merit-based Incentive Payment System (MIPS) for the 2017 performance year. (The specific regions identified as being affected by Hurricanes Harvey, Irma, and Maria for the 2017 MIPS performance year are provided in detail in section III.B.1.e. of the Quality Payment Program IFC (82 FR 53898)). In the Quality Payment Program IFC, we stated that should additional extreme and uncontrollable circumstances arise for the 2017 MIPS performance period that trigger the automatic extreme and uncontrollable circumstance policy under the Quality Payment Program, we would communicate that information through routine communication channels, including but not limited to issuing program memoranda, emails to stakeholders, and notices on the Quality Payment Program website, *qpp.cms.gov* (82 FR 53897). For example, in the December 2017 interim final rule with comment period we noted that we had recently issued guidance to stakeholders indicating that the MIPS Extreme and Uncontrollable Circumstance Policy would also apply to MIPS eligible clinicians affected by the California wildfires (see *https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Interim-Final-Rule-with-Comment-fact-sheet.pdf*).

In the December 2017 interim final rule with comment period, we expressed the belief that it was also appropriate to establish automatic extreme and uncontrollable circumstances policies under the Shared Savings Program for performance year 2017 due to the urgency of providing relief to Shared Savings Program ACOs impacted by Hurricanes Harvey, Irma, and Maria, and the California wildfires, because their quality scores could have been adversely affected by these disasters and some ACOs could have been at risk for additional shared losses due to the costs associated with these extreme and uncontrollable events. Therefore, given the broad impact of the three hurricanes and the wildfires, and to address any additional extreme and uncontrollable circumstances that could have arisen during 2017 or the quality data reporting period for the performance year, we explained that we were establishing the policies described in the December 2017 interim final rule with comment period for the Shared Savings Program for performance year 2017.

For program clarity and to reduce unnecessary burdens on affected ACOs, we aligned the automatic extreme and uncontrollable circumstances policies under the Shared Savings Program with the policy established under the Quality Payment Program. Specifically, the Shared Savings Program extreme and uncontrollable circumstances policies would apply when we determine that an event qualifies as an automatic triggering event under the Quality Payment Program. We would use the determination of an extreme and uncontrollable circumstance under the Quality Payment Program, including the identification of affected geographic areas and applicable time periods, for purposes of determining the applicability of the extreme and uncontrollable circumstances policies with respect to both financial performance and quality reporting under the Shared Savings Program. These policies would also apply with respect to the determination of an ACO's quality performance in the event that an extreme and uncontrollable event occurred during the applicable quality data reporting period for performance year 2017 and the reporting period was not extended. We believed it was appropriate to extend these policies to encompass the quality reporting period, unless the reporting period was extended, because we would not have the quality data necessary to measure an ACO's quality performance for 2017 if the ACO was unable to submit its quality data as a result of a disaster occurring during the submission window. We noted, for example, that if an extreme and uncontrollable event were to occur in February 2018, which would be during the quality data reporting period for performance year 2017 that was then scheduled to end on March 16, 2018 at 8 p.m. eastern daylight time, then the extreme and uncontrollable circumstances policies would apply for quality data reporting for performance year 2017, if the reporting period was not extended. We did not believe it was appropriate to extend this policy to encompass the quality data reporting period if the reporting period is extended because affected ACOs would have an additional opportunity to submit their quality data, enabling us to measure their quality performance in 2017. However, we noted that, because a disaster that occurs after the end of the performance year would have no impact on the determination of an ACO's financial performance for performance year 2017, we would make no adjustment to shared losses in the event an extreme or uncontrollable event occurred during the quality data reporting period.

Comment: Almost all stakeholders that submitted a comment in response to the December 2017 interim final rule with comment period expressed general support for addressing extreme and uncontrollable circumstances in the Shared Savings Program, and no

commenters expressed general opposition. Most commenters also addressed one or more of the specific policies described in that rule.

Response: We appreciate the comments that were offered and have since implemented the policies finalized in the December 2017 interim final rule with comment period when determining quality scores used in performance year 2017 financial reconciliation and in determining shared losses owed for performance year 2017 by ACOs in two-sided models.

We considered the comments received in response to the December 2017 interim final rule with comment period in developing our proposals to extend the extreme and uncontrollable circumstances policies that were established for performance year 2017 to performance year 2018 and subsequent performance years. These proposals were included in the August 2018 proposed rule (83 FR 41900–41906). In the November 2018 final rule (83 FR 59968–59979), we adopted final policies for determining the quality performance of and mitigating shared losses owed by Shared Savings Program ACOs affected by extreme and uncontrollable circumstances in performance year 2018 and subsequent performance years.

In the remainder of this section, we will summarize and respond to public comments submitted in response to the December 2017 interim final rule with comment period.

Comment: Several commenters supported aligning Shared Savings Program policies surrounding extreme and uncontrollable circumstances with the policies established under the Quality Payment Program for performance year 2017, including the identification of an automatic triggering event and affected geographic areas, with a commenter expressing the belief that such alignment should also apply for future performance years. A few commenters supporting alignment across these programs urged CMS to be more transparent and to improve communication to ACOs regarding affected areas and applicable time periods, as well as options available to affected ACOs.

A commenter supported the goal of alignment across programs, but urged CMS to monitor, evaluate, and modify, if necessary, the policies included in the December 2017 interim final rule with comment period to ensure that Shared Savings Program participants do not experience unintended consequences from use of Quality Payment Program determinations regarding triggering events and affected counties. This commenter raised the possibility that a triggering event determined under Quality Payment Program could have a different impact in terms of scope and severity on ACOs participating in the Shared Savings program. A commenter did not opine on whether program policies should be aligned with the Quality Payment Program but expressed the belief that any determination of affected counties should include both Federal Emergency Management Agency (FEMA)-designated ''Public Assistance'' and FEMA-designated ''Individual Assistance'' areas. Another commenter recommended that the determination of the time period for an extreme and uncontrollable event be made consistent with the timelines for the emergency declarations by the Federal government.

Response: We appreciate the comments supporting the alignment of the extreme and uncontrollable circumstances policies under the Shared Savings Program with policies under the Quality Payment Program with respect to identifying automatic triggering events and the affected geographic areas. We continue to believe, as we described in the December 2017 interim final rule with comment period, that this approach avoids confusion and reduces unnecessary burdens on affected ACOs. Accordingly, we finalized the extension of this policy for performance year 2018 and future years in the November 2018 final rule (83 FR 59969–59973).

In the Quality Payment Program IFC we explained that we anticipated that the types of events that could trigger the extreme and uncontrollable circumstances policies would be events designated by a FEMA major disaster or a public health emergency declared by the Secretary, although we indicated that we would review each situation on a case-by-case basis (82 FR 53897). While we favor alignment across the two programs for the aforementioned reasons and expect to consider declarations made by other Federal government agencies, we continue to believe that it is important to maintain a degree of flexibility to best respond to the circumstances of an individual emergency and decline to adopt fixed criteria for determining triggering events and affected areas. We note that for performance year 2017 information on triggering events and affected areas was made available through publicly available QPP fact sheets (for example: *https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Interim-Final-Rule-with-Comment-fact-sheet.pdf*). Additionally, we used the time periods associated with public health emergencies declared by the Secretary. Following the declaration of a public health emergency, the Secretary may temporarily modify or waive certain Medicare requirements to support the ability of health care providers to provide timely care to people impacted by an emergency or disaster to the maximum extent feasible. For consistency, we believe that it is appropriate to use the same time periods when implementing the Shared Savings Program extreme and uncontrollable circumstances policies. We also believe that this approach is transparent as the dates of such emergencies are publicly available on the CMS Emergency Response and Recovery website (now renamed the Emergency Preparedness & Response Operations website, *https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/EPRO-Home.html*). Accordingly, we anticipate continuing to follow this approach going forward.

1. Determination of Quality Performance Scores for ACOs in Affected Areas

ACOs and their ACO participants and ACO providers/suppliers are frequently located across several different geographic regions or localities, serving a mix of beneficiaries who may be differentially impacted by hurricanes, wildfires, or other triggering events. Therefore, we needed to establish a policy for determining when an ACO, which may have ACO participants and ACO providers/suppliers located in multiple geographic areas, should qualify for the automatic extreme and uncontrollable circumstance policies for the determination of quality performance. We explained that we would determine whether an ACO had been affected by an extreme and uncontrollable circumstance by determining whether 20 percent or more of the ACO's assigned beneficiaries resided in counties designated as an emergency declared area in performance year 2017, as determined under the Quality Payment Program as discussed in section III.B.1.e. of the Quality Payment Program IFC (82 FR 53898) or the ACO's legal entity was located in such an area. An ACO's legal entity location would be based on the address on file for the ACO in CMS' ACO application and management system. We used 20 percent of the ACO's assigned beneficiary population as the minimum threshold to establish an ACO's eligibility for the policies regarding quality reporting and quality performance scoring included in the December 2017 interim final rule with comment period because we believed the 20 percent threshold provided a reasonable way to identify ACOs whose

quality performance may have been adversely affected by an extreme or uncontrollable circumstance, while excluding ACOs whose performance would not likely be significantly affected. The 20 percent threshold was selected to account for the effect of an extreme or uncontrollable circumstance on an ACO that has the minimum number of assigned beneficiaries to be eligible for the program (5,000 beneficiaries), and in consideration of the average total number of unique beneficiaries for whom quality information is required to be reported in the combined CAHPS survey sample (860 beneficiaries) and the CMS web interface sample (approximately 3,500 beneficiaries). (There may be some overlap between the CAHPS sample and the CMS web interface sample.) Therefore, we estimated that an ACO with an assigned population of 5,000 beneficiaries typically would be required to report quality information on a total of 4,000 beneficiaries. Thus, we believed that the 20-percent threshold would ensure that an ACO with the minimum number of assigned beneficiaries would have an adequate number of beneficiaries across the CAHPS and CMS web interface samples in order to fully report on these measures. However, we also understood that some ACOs that have fewer than 20 percent of their assigned beneficiaries residing in affected areas have a legal entity that is located in an emergency declared area. Consequently, their ability to quality report may have been equally impacted since the ACO legal entity may have been unable to collect the information from the ACO participants or may have experienced infrastructure issues related to capturing, organizing and reporting the data to CMS. If less than 20 percent of the ACO's assigned beneficiaries resided in an affected area and the ACO's legal entity was not located in a county designated as an affected area, then we noted that we believed that there was unlikely to be a significant impact upon the ACO's ability to report or on the representativeness of the quality performance score that would be determined for the ACO.

We noted that we would determine what percentage of the ACO's performance year assigned population was affected by a disaster based on the final list of beneficiaries assigned to the ACO for the performance year. Although beneficiaries are assigned to ACOs under Track 1 and Track 2 based on preliminary prospective assignment with retrospective reconciliation after the end of the performance year, we noted that these ACOs would be able to use their quarterly assignment lists, which include beneficiaries' counties of residence, for early insight into whether they are likely to meet the 20 percent threshold. For purposes of the December 2017 interim final rule with comment period, we used preliminary information on beneficiary assignment for the 2017 performance year to estimate the number of ACOs that were affected by the hurricanes and the California wildfires in 2017. We estimated that 105 of the 480 ACOs (approximately 22 percent) would meet the minimum threshold of having 20 percent or more of their assigned beneficiaries residing in an area designated as impacted by Hurricanes Harvey, Irma, and Maria, and the California wildfires or have their legal entity located in one of these areas. Of the ACOs that we originally estimated would be impacted by the disasters in 2017, 92 percent had more than 20 percent of their assigned beneficiaries residing in emergency declared areas.

For purposes of determining quality performance scoring for performance year 2017, we noted that if 20 percent or more of an ACO's assigned beneficiaries resided in an area impacted by the disaster or the ACO's legal entity was located in such an area, the ACO's minimum quality score would be set to equal the mean Shared Savings Program ACO quality score for all ACOs for performance year 2017. We would set the minimum quality score equal to the mean quality score for all Shared Savings Program ACOs nationwide, because the mean reflects the full range of quality performance across all ACOs in the Shared Savings Program. More specifically, the mean ACO quality score is equal to the combined ACO quality score for all ACOs meeting the quality performance standard for the performance year divided by the total number of ACOs meeting the quality performance standard for the performance year. To illustrate, we noted that the mean Shared Savings Program ACO quality performance score for all participating ACOs for performance year 2016 was approximately 95 percent. We also explained that in the event an affected ACO is able to complete quality reporting for performance year 2017, and the ACO's calculated quality score is higher than the mean Shared Savings Program ACO quality score, we would apply the higher score.

In earlier rulemaking, we finalized a policy under which ACOs that demonstrate quality improvement on established quality measures from year-to-year will be eligible for up to 4 bonus points per domain (79 FR 67927 through 67931, § 425.502(e)(4)). To earn bonus points, an ACO must demonstrate a net improvement in performance on measures within a domain. We noted in the December 2017 interim final rule with comment period that if an ACO was not able to complete quality reporting for performance year 2017, it would not be possible for us to assess the ACO's improvement on established quality measures since performance year 2016. Therefore, if an ACO receives a quality score for performance year 2017 based on the mean quality score, the ACO would not be eligible for bonus points awarded based on quality improvement.

We noted our belief that it was appropriate to adjust the quality performance scores for ACOs in affected areas because we anticipated that these ACOs would likely be unable to collect or report the necessary information to CMS as a result of the extreme and uncontrollable circumstance, and/or the ACO's quality performance score would be significantly and adversely affected. Section 1899(b)(3)(C) of the Act gives us the authority to establish the quality performance standards used to assess the quality of care furnished by ACOs. Accordingly, we modified the quality performance standard specified under § 425.502 by amending paragraph (e)(4) and adding a new paragraph (f) to address potential adjustments to the quality performance score for performance year 2017 of ACOs determined to be affected by extreme and uncontrollable circumstances. We stated that for performance year 2017, including the applicable quality data reporting period for the performance year if the reporting period is not extended, in the event that we determined that 20 percent or more of an ACO's final list of assigned beneficiaries for the performance year, as determined under subpart E of the Shared Savings Program regulations, resided in an area that is affected by an extreme and uncontrollable circumstance as determined under the Quality Payment Program, or that the ACO's legal entity was located in such an area, we would use the following approach to calculate the ACO's quality performance score instead of the methodology specified in § 425.502(a) through (e).

- The ACO's minimum quality score would be set to equal the mean Shared Savings Program ACO quality score for performance year 2017.
- If the ACO is able to completely and accurately report all quality measures, we would use the higher of the ACO's

quality score or the mean Shared Savings Program ACO quality score.

• If the ACO receives a quality score based on the mean, the ACO would not be eligible for bonus points awarded based on quality improvement.

We would apply determinations made under the Quality Payment Program with respect to whether an extreme and uncontrollable circumstance has occurred and the affected areas. We would have sole 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.

We also stated that, for purposes of the MIPS APM scoring standard, MIPS eligible clinicians in Medicare Shared Savings Program ACOs that did not completely report quality for 2017; and therefore, received the mean ACO quality score under the Shared Savings Program would receive a score of zero percent in the MIPS quality performance category. However, these MIPS eligible clinicians would receive a score of 100 percent in the improvement activities (IAs) performance category, which would be sufficient for them to receive a 2017 MIPS final score above the performance threshold. This would result in at least a slight positive MIPS payment adjustment in 2019. Additionally, if the ACO participants were able to report advancing care information (ACI) (now referred to as the promoting interoperability category), the MIPS eligible clinicians in the ACO would receive an ACI performance category score under the APM scoring standard, which would further increase their final score under MIPS.

Comment: Several commenters supported considering ACOs to be impacted by an extreme and uncontrollable circumstance if 20 percent or more of their assigned beneficiaries reside in an affected area or if the ACO's legal entity is located in such an area. However, a commenter requested that CMS continue to monitor the effects of this policy for each new triggering event to determine whether the 20 percent threshold is appropriate. The commenter explained that it could be necessary to lower the threshold if it is observed that ACOs with a smaller percentage of beneficiaries residing in an affected area display significantly reduced performance compared to prior years. Another commenter recommended that CMS analyze test cases to determine if quality performance could be affected at lower thresholds. The same commenter also suggested that CMS apply the extreme and uncontrollable circumstance policy to ACOs for which 50 percent of NPIs billing under the ACO are located in an impacted area. Another commenter noted it was unclear whether 20 percent is the appropriate threshold and believes that CMS should observe the effect of the 2017 events on ACOs and develop more flexible permanent policies to fully capture ACOs for which quality performance might have been affected. Another commenter, while agreeing with the criteria described in the December 2017 interim final rule with comment period, urged CMS to also provide an option for ACOs that do not meet the criteria to submit a hardship request if they believe that they were significantly affected by an extreme and uncontrollable event. They explained that CMS could review and approve such requests on a case-by-case basis.

Response: We continue to believe that the criteria that we adopted for performance year 2017 in the December 2017 interim final rule with comment period, and which we used for determining performance year 2017 quality scores, are reasonable and offer predictability. We believe that using a threshold that may change with each triggering event would provide less certainty, especially if such a threshold could not be determined until after the disaster has occurred. We believe that the 20 percent threshold, which was influenced by population size considerations, remains a reasonable level. At this level, the threshold helps to ensure that an ACO with the minimum number of assigned beneficiaries to be eligible to participate in the program (5,000 beneficiaries) would still have an adequate number of non-affected beneficiaries on which to report on CAHPS and CMS web interface measures. Furthermore, based on our experience from performance year 2017, we do not believe that this threshold is too high as we observed that over 40 percent of ACOs with more than 20 percent of beneficiaries residing in disaster-affected areas received their own quality score because it was higher than the average score. We will continue to monitor this statistic for events occurring in future performance years to gauge whether the threshold remains appropriate.

In the November 2018 final rule, we modified the policy adopted in the December 2017 interim final rule with comment period of using an ACO's final assigned beneficiary list for performance year 2017 to determine the percentage of assigned beneficiaries residing in an affected area, and finalized a policy for performance year 2018 and subsequent performance years of using an ACO's assignment list used for the Web Interface sample (typically the quarter 3 assignment list) to determine the percentage of assigned beneficiaries residing in an affected area. This refinement to our approach, which was based on our experience in applying the extreme and uncontrollable circumstances policies for performance year 2017, will allow ACOs to determine before the end of the quality reporting period whether they meet this criterion based on triggering events that have occurred up until that time. Given the timing of December 2017 interim final rule with comment period, this type of advance notice was not feasible. This modification of the policy for future performance years was also influenced by comments that we received in response to the December 2017 interim final rule with comment period, described earlier in this section, which requested that CMS provide better communication to affected ACOs regarding their options.

While we considered a commenter's suggestion to expand the criteria for determining impacted ACOs to include those ACOs for which 50 percent or more of the NPIs billing under the TINs of the ACO participants are located in an impacted area, we believed that including this additional criterion would create additional operational complexity and less transparency as we do not currently provide information on the location of ACO providers/suppliers in program reports. We therefore elected not to propose this option in the August 2018 proposed rule and, in response to a similar recommendation from a commenter, declined to adopt this approach in the November 2018 final rule (83 FR 59972). In response to the commenters that suggested we create a hardship exceptions process, we note that in the December 2017 interim final rule with comment period and the November 2018 final rule, we have elected to adopt automatic policies to address extreme and uncontrollable circumstances in lieu of hardship requests that must be considered on a case-by-case basis in order to increase certainty and reduce administrative burden for both ACOs and CMS.

Comment: We received several comments that supported using the higher of the ACO's own quality score or the mean quality score. A commenter agreed that an ACO should not be eligible for bonus points based on quality improvement if the ACO receives the mean quality score. A few others that supported using the higher of the ACO's own score or the national mean were concerned that there would

be no way for ACOs receiving the mean score to demonstrate quality improvement or receive bonus points. They recommended that CMS consider alternative mechanisms by which these ACOs could demonstrate quality improvement with a commenter suggesting that CMS recognize and account for quality improvement efforts made by ACOs outside the time period affected by an extreme and uncontrollable event. Another commenter did not opine on the use of the mean quality score but requested clarification on how bonus points would be determined when a state of emergency crossed years.

Response: We implemented the policy of using the higher of the ACO's own quality score or the mean quality score that was finalized in the December 2017 interim final rule with comment period in determining quality performance for affected ACOs for performance year 2017. In the August 2018 proposed rule (83 FR 41900–41903), we proposed to extend this policy for performance year 2018 and subsequent performance years, and in the November 2018 final rule (83 FR 59969–59974), we finalized this proposal. We appreciate the support offered for this policy among stakeholders that submitted comments in response to the December 2017 interim final rule with comment period.

In the November 2018 final rule, we also adopted for performance year 2018 and subsequent performance years the policy under which an ACO that receives the mean Shared Savings Program quality performance score for a given performance year will not be eligible for bonus points awarded based on quality performance during that year. However, it is worth noting that in calculating the mean quality score we include the scores of ACOs that earned bonus points for quality improvement as well as the scores of 100 percent earned by ACOs in their first performance year for which the quality performance standard is based on complete and accurate reporting of all quality measures. ACOs that failed to meet the quality performance standard are excluded from the mean.

In the November 2018 final rule (83 FR 59969–59974) we finalized a policy under which, if an ACO receives the mean score for a performance year, in the next performance year for which the ACO reports quality data and receives a quality performance score based on its own performance, we will measure quality improvement based on a comparison between the ACO's performance in that year and in the most recently available prior performance year in which the ACO reported quality. We explained that under this approach, the comparison will continue to be between consecutive years of quality reporting, but these years may not be consecutive calendar years. If an ACO reports quality data in a year in which it is affected by an extreme and uncontrollable circumstance, but receives the national mean quality score, we will use the ACO's own quality performance to determine quality improvement bonus points in the following year. For example, if an ACO reported quality data in years 1, 2, and 3 of an agreement period, but received the national mean quality score in year 2 as the result of an extreme or uncontrollable circumstance, we would determine quality improvement bonus points for year 3 by comparing the ACO's year 3 quality performance with its year 2 performance. In contrast, if the ACO received the mean score in year 2 because it did not report quality, we would compare year 3 with year 1 to determine the bonus points for year 3.

For events for which the applicable time period for includes multiple calendar years, we intend to treat the portion of the period falling within each year as if it were a separate event for purposes of identifying ACOs eligible for the alternative quality scoring methodology and for computing any adjustment to shared losses. Consider for example a hypothetical event for which the applicable time period spanned from September 2017 to March 2018. An ACO would be deemed to be affected by this event in performance year 2017 for purposes of quality scoring if 20 percent or more of the ACO's final performance year 2017 assigned beneficiaries resided in an affected geographic area or the ACO's legal entity was located in such an area, and we would use the alternative quality performance scoring policy finalized in the December 2017 interim final rule with comment period for performance year 2017 to determine its quality performance score for that performance year. The same ACO would be deemed affected by the disaster in performance year 2018 if 20 percent or more of the ACO's quarter 3 assigned beneficiary population (that is, the population used for Web Interface sampling) resided in an affected area or the ACO's legal entity was located in such an area. We would determine the quality performance score for the ACO for performance year 2018 using the alternative quality performance scoring policy adopted in the November 2018 final rule for performance year 2018. An ACO receiving the mean quality score in either year would not be eligible for bonus points for quality improvement in that year although, as previously noted, the mean score would include the scores of ACOs that earned bonus points for quality improvement as well as scores of 100 percent earned by ACOs in their first performance year. If a disaster-affected ACO receives its own quality score for performance year 2017 it would be eligible for bonus points based on a comparison of its 2017 quality performance and 2016 quality performance. If the ACO receives its own quality score for performance year 2018 it would be eligible for bonus points based on a comparison of its 2018 quality performance and its quality performance in the most recent prior year in which it reported quality.

Comment: A commenter believed that the quality performance scores for disaster-affected ACOs could be set to the mean, but these scores should not be used to calculate future benchmarks or subsequent year thresholds until complete and accurate reporting can be achieved.

Response: We appreciate this commenter's support of the policy to set an ACO's quality score to the higher of its own calculated score or the national mean. We would like to clarify that ACOs' quality performance scores are not used to calculate quality measure benchmarks. Rather, the quality measure benchmarks are calculating using actual ACO performance and all other available and applicable Medicare FFS data.

Comment: A commenter expressed the belief that an ACO that achieved above-average quality performance in the prior performance year but is unable to report quality data due to an extreme and uncontrollable event in 2017, should not be penalized with a much lower quality score for 2017. They recommended that in instances where an ACO is unable to report quality data due to an extreme or uncontrollable event, CMS should use the higher of the ACO's quality score from the prior performance year or the mean quality score for all Shared Savings Program ACOs for the current performance year.

Response: We acknowledge that the mean quality score could be lower, or higher, than the score disaster-affected ACOs would have received in the absence of a disaster. However, we have concerns with the commenter's recommendation that we apply the higher of the ACO's quality score from the prior year or the mean quality score. ACO quality performance can vary from year-to-year and the fact that an ACO had a high quality score in prior years does not necessarily guarantee that the

ACO would have had an above average score in the affected year in the absence of the natural disaster. This is particularly true for ACOs in their early years of participation in the Shared Savings Program for which the prior year's performance score may have included a higher number of pay-for-reporting measures, thus making the quality scores incomparable. Lastly, we would remind stakeholders that the national mean quality score includes the quality scores of 100 percent earned by ACOs in their first performance year, thus increasing the mean. For these reasons, we did not employ this approach for performance year 2017 and neither proposed nor finalized this approach for performance year 2018 and subsequent years.

Comment: A commenter sought clarification on whether an ACO would have the opportunity to either opt-in or opt-out of the finalized quality scoring policy for performance year 2019.

Response: The final policies for determining an ACO's quality performance score in the event of an extreme and uncontrollable circumstance are automatic, meaning that ACOs are not required to opt-in and are not permitted to opt-out. As noted elsewhere in this section, our intention in adopting automatic policies was to increase certainty and reduce burden associated with optional or case-dependent policies. Additionally, the policies are designed such that ACOs can only benefit from the application of them. That is, if the ACO's calculated quality score is higher than the mean quality score, the ACO's higher calculated quality score will be used.

Comment: A commenter noted that impacted ACOs that are unable to collect or report necessary quality information would also be very likely to trigger the audit process. This commenter recommended that any ACO for which quality performance was determined under the interim final rules established in the December 2017 interim final rule with comment period should not be subject to the Quality Measures Validation (QMV) Audit Process if a high number of Medical Record Not Found (MRNF) ''skips'' are present.

Response: For performance year 2017, we considered whether an ACO was affected by an extreme and uncontrollable circumstance when identifying which ACOs would be subject to a Quality Measures Validation Audit of their CMS Web Interface data and we did not include disaster-affected ACO that skipped an anomalously high number of beneficiaries in the audit sample. We anticipate taking a similar approach for performance year 2018 and future years.

Comment: We received several comments related to the interaction of the extreme and uncontrollable circumstances policy for quality performance scoring and MIPS. We explained in the December 2017 interim final rule with comment period that MIPS eligible clinicians in Medicare Shared Savings Program ACOs that do not completely report quality for 2017 and therefore receive the mean ACO quality score would receive a score of zero percent in the MIPS quality performance category. However, these MIPS eligible clinicians would receive a score of 100 percent in the improvement activities (IAs) performance category, which would be enough for them to receive a 2017 MIPS final score above the performance threshold. This would result in at least a slight positive MIPS payment adjustment in 2019. We explained further that if the ACO participants were able to report advancing care information (ACI), the MIPS eligible clinicians in the ACO would receive an ACI performance category score under the APM scoring standard, which would further increase their final score under MIPS.

A commenter strongly opposed this approach and recommended that CMS instead use the higher of the mean quality performance category score or the organization's performance year 2016 quality performance category score to determine the ACO's quality performance category score under the MIPS APM scoring standard. They went on to note that this would be particularly important in future years when the MIPS minimum performance threshold will increase. A few other commenters also expressed the belief that the approach used for performance year 2017 should not be used for future performance years. For example, a commenter supported the approach used for performance year 2017 because it would still allow MIPS eligible clinicians to receive a final score above the performance threshold, but noted that, in future years, receiving 100 percent for the improvement activities performance category would not be sufficient to allow MIPS eligible clinicians in the ACO to avoid a negative payment adjustment. They recommended that, in this case, CMS should set the MIPS score equal to the performance threshold. Another commenter suggested that CMS consider redistributing the weights of the performance categories under the MIPS program as an alternative, nothing that that under the Quality Payment Program, CMS has policies allowing for redistribution of the weights of the performance categories when warranted. A third commenter encouraged CMS to automatically assign a neutral payment adjustment to eligible clinicians in a MIPS APM ACO that is unable to report due to extreme and uncontrollable circumstances. This commenter also recommended that in a case in which the ACO is unable to report but the component eligible clinician or TIN reports separately, CMS apply the higher of the two scores.

Response: As we described in the December 2017 interim final rule with comment period, and as commenters noted, for performance year 2017, for purposes of the APM scoring standard, MIPS eligible clinicians in a disaster-affected ACO that did not report quality for the performance year, and therefore received the mean quality score under the Shared Savings Program, received a score of zero percent in the MIPS quality performance category. In the August 2018 proposed rule (83 FR 41902) and in the November 2018 final rule (83 FR 59974), we clarified that for performance year 2018 and subsequent years, such clinicians, would have the MIPS quality performance category reweighted to zero percent, regardless of whether or not any of the ACO participant TINs reported quality outside the ACO. This reweighting under MIPS results in MIPS performance category weighting of 75 percent for the Promoting Interoperability (PI) performance category and 25 percent for Improvement Activities performance category consistent with our policy at § 414.1370(h)(5)(i)(B). If, for any reason, the PI performance category is also reweighted to zero, which could be more likely when there is a disaster, there would be only one performance category, triggering the policy under which the ACO would receive a neutral (threshold) MIPS score, as provided in § 414.1380(c). However, if any of the ACO participant TINs do report PI, then the ACO participant TIN or TINs' PI performance category scores would be used to score the ACO under the MIPS scoring standard, the PI performance category would not be reweighted, and the policy of assigning a neutral (threshold) MIPS score would not be triggered. We believe that this approach should mitigate the concerns raised by commenters as MIPS eligible clinicians in a disaster-affected ACO receiving the mean quality score under the Shared Savings Program will no longer receive a zero percent score in the MIPS quality performance category as they would have done under the performance year

2017 policy. Instead, this category would be reweighted to zero percent.

2. Mitigating Shared Losses for ACOs Participating in a Performance-Based Risk Track

In the December 2017 interim final rule with comment period, we also modified the payment methodology under Tracks 2 and 3 established under the authority of section 1899(i) of the Act to mitigate shared losses owed by ACOs affected by extreme and uncontrollable circumstances during performance year 2017. We explained that under this policy, we would reduce the ACO's shared losses, if any, determined to be owed under the existing methodology for calculating shared losses in part 425, subpart G of the regulations by an amount determined by multiplying the shared losses by two factors: (1) The percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance; and (2) the percentage of the ACO's assigned beneficiaries who resided in an area affected by an extreme and uncontrollable circumstance. We would determine the percentage of the ACO's performance year assigned beneficiary population that was affected by the disaster based on the final list of beneficiaries assigned to the ACO for the performance year. For example, assume that an ACO is determined to owe shared losses of $100,000 for performance year 2017, a disaster was declared for October through December during the performance year, and 25 percent of the ACO's assigned beneficiaries resided in the disaster area. In this scenario, we would adjust the ACO's losses in the following manner:

$$\$100{,}000 - (\$100{,}000 \times 0.25 \times 0.25) = \$100{,}000 - \$6{,}250 = \$93{,}750.$$

We believed it was appropriate to adopt this policy to address stakeholders' concerns that ACOs could be held responsible for sharing losses with the Medicare program resulting from catastrophic events outside the ACO's control given the increase in utilization, difficulty of coordinating care for patient populations leaving the impacted areas, and the mandatory use of natural disaster payment modifiers making it difficult to identify whether a claim would otherwise have been denied under normal Medicare FFS rules. Absent this relief, we believed ACOs that were then participating in Tracks 2 and 3 might reconsider whether they would be able to continue their participation in the Shared Savings Program under a performance-based risk track. We noted that the approach we were adopting in the December 2017 interim final rule with comment period would balance the need to offer relief to affected ACOs with the need to continue to hold those ACOs accountable for losses incurred during the months in which there was no applicable disaster declaration and for the assigned beneficiary population that was outside the area affected by the disaster. We also noted that these policies would not change the status of Track 2 or Track 3 of the Shared Savings Program as an Advanced Alternative Payment Model (APM) for purposes of the Quality Payment Program or prevent an eligible clinician in a performance-based risk ACO from becoming a Qualifying APM Participant for purposes of the APM incentive under the Quality Payment Program.

We also explored an alternative approach for mitigating the potential losses for ACOs in performance-based risk tracks that were affected by extreme and uncontrollable circumstances. Under this approach, we would remove claims for services furnished to assigned beneficiaries in the impacted areas by an ACO participant that are submitted with a natural disaster modifier before calculating financial performance. However, we believed that this alternative approach could, for some affected ACOs, result in the exclusion of a significant amount of their total claims at financial reconciliation, making it very difficult to measure the ACOs' financial performance.

We also emphasized that all ACOs would continue to be entitled to share in any savings they may achieve for performance year 2017. The calculation of savings and the determination of shared savings payment amounts would not be affected by the policies to address extreme and uncontrollable circumstances. ACOs in all three tracks of the program would receive shared savings payments, if any, as determined under part 425 subpart G.

We also considered the possible impact of extreme and uncontrollable circumstances on an ACO's expenditures for purposes of determining the benchmark (§ 425.602 and § 425.603). The additional costs incurred as a result of an extreme or uncontrollable circumstance would likely impact the benchmark determined for the ACO's subsequent agreement period in the Shared Savings Program, as performance years of the current agreement period become the historical benchmark years for the subsequent agreement period. We noted our belief that the increase in expenditures for a particular calendar year would result in a higher benchmark value when the same calendar year is used to determine the ACO's historical benchmark, and in calculating adjustments to the rebased benchmark based on regional FFS expenditures (§ 425.603). We also noted our belief that any effect of including these additional expenditures in determining the ACO's benchmark for the subsequent agreement period could be mitigated somewhat because the ACO's expenditures during the three base years included in the benchmark are weighted equally, and regional expenditures would also increase as a result of the disaster. Therefore, we anticipated the effect on the regional adjustment under § 425.603(c)(9) would be minimal. Although we did not modify the program's historical benchmark methodology in the December 2017 interim final rule with comment period, we noted that we planned to observe the impact of the 2017 hurricanes and wildfires on ACO expenditures, and that we might revisit the need to make adjustments to the methodology for calculating the benchmark in future rulemaking.

We explained that to exercise our authority under section 1899(i)(3) of the Act to use other payment models, we must demonstrate that the payment model—(1) does not result in program expenditures that are higher than those that would have resulted under the statutory payment model under section 1899(d) of the Act and (2) will improve the quality and efficiency of items and services furnished under Medicare. In assessing the impacts of the policy for mitigating shared losses for Track 2 and Track 3 ACOs affected by extreme and uncontrollable circumstances in 2017, we considered: The impact of the potential loss of participation in the program by ACOs affected by disasters should we not implement the policy described in the December 2017 interim final rule with comment period, and the anticipated minimal impact of adjusting losses for ACOs affected by disasters, as described in the regulatory impact statement for the December 2017 interim final rule with comment period. On the basis of this assessment, we believed that incorporating this extreme and uncontrollable circumstances policy for performance year 2017 into the payment methodologies for Tracks 2 and 3 would meet the requirements of section 1899(i) of the Act by not increasing expenditures above the costs that would be incurred under the statutory payment methodology under section 1899(d) of the Act and by encouraging affected ACOs to remain in the program, which we believed would

increase the quality and efficiency of the items and services furnished to the beneficiaries they serve. We also noted that to the extent the policies in the December 2017 interim final rule with comment period constituted a change to the Shared Savings Program payment methodology for 2017 after the start of the performance year, we believed that, consistent with section 1871(e)(1)(A)(ii) of the Act, and for reasons discussed in section III of the IFC, it would be contrary to the public interest not to adjust the shared losses calculated for ACOs in Tracks 2 and 3 to reflect the impact of the extreme and uncontrollable circumstances during 2017.

We invited comments on the policies being finalized in the December 2017 interim final rule with comment period for performance year 2017, including the applicable quality data reporting period for performance year 2017 under the Shared Savings Program. We noted our belief that these automatic extreme and uncontrollable circumstance policies would reduce burden and financial uncertainty for ACOs, ACO participants, and ACO providers/suppliers affected by catastrophes, including ACOs affected by Hurricanes Harvey, Irma, and Maria, and the California wildfires, and would also align with existing Medicare policies under the Quality Payment Program for 2017.

We also noted that in future rulemaking, we intended to propose permanent policies under the Shared Savings Program to address extreme and uncontrollable circumstances in future performance years. Therefore, we also invited public comment on policies and issues that we should consider when developing proposals for these permanent policies.

We also welcomed comments on how to address the impact of extreme and uncontrollable events on historical benchmark calculations, which we would consider in developing any future proposals. In particular, we sought comments as to whether and how the historical benchmark should be adjusted to reflect extreme and uncontrollable events that occur during a benchmark year, how to establish the threshold for determining whether a significant change in expenditures occurred, whether and how to account for changes in expenditures that have an aggregate positive or negative impact on the historical benchmark, and whether and how to reweight the benchmark years when calculating the historical benchmark if one or more benchmark years is impacted by an extreme and uncontrollable event.

Comment: The majority of stakeholders that submitted comments in response to the December 2017 interim final rule with comment period expressed support for the concept of mitigating shared losses for ACOs in two-sided models that were affected by extreme and uncontrollable circumstances, though several offered suggestions for modifying the approach finalized for performance year 2017 or expanding its scope. For example, a commenter recommended that should extreme and uncontrollable circumstances affect ACOs in future years, CMS should compare the expenditures for Track 2 and Track 3 ACOs in impacted areas to the 2017 benchmarks to determine an approach that is fair and statistically reliable; however, it was unclear whether the commenter was suggesting that CMS compare expenditures to the historical benchmarks computed for purposes of Shared Savings Program financial calculations or to some other measure of expected 2017 spending. A commenter noted that extreme and uncontrollable circumstances can result in long-term disruptions in care beyond the time period during which an area is declared a natural disaster area and recommended that CMS consider a process for establishing a time period beyond the timeframe of the disaster declaration during which CMS will continue to mitigate an ACO's losses. Several commenters expressed the belief that the policy adopted in the December 2017 interim final rule with comment period did not go far enough and suggested that CMS consider waiving shared losses completely or allowing two-sided ACOs to temporarily convert to a one-sided model for affected years. One of these commenters noted that this alternative would likely affect an ACO's status as participating in an advanced APM but could prevent organizations from terminating their participation in the Shared Savings Program altogether and could provide an incentive for more providers to take on downside risk. Another commenter also suggested using a modifier to adjust shared losses but did not provide further details on this approach. Another commenter agreed with CMS' decision not to exclude claims submitted with a natural disaster modifier when mitigating shared losses, noting that it is uncertain whether providers submit claims with a modifier. This same commenter questioned what would happen for shared losses mitigation in the event that a state of emergency spans two calendar years.

Response: We appreciate the support commenters offered for taking steps to mitigate the impacts of extreme and uncontrollable circumstances on ACOs in two-sided models. We implemented the policy finalized in the December 2017 interim final rule with comment period for performance year 2017. There were 11 ACOs with shared losses for the performance year. Because ACOs are not required to meet a minimum threshold number of assigned beneficiaries in an affected area to qualify for this policy, all eleven ACOs received an adjustment to their shared losses ranging from $980 to over $400,000. While we are sympathetic to the challenges faced by ACOs impacted by natural disasters, we decline at this time to consider eliminating shared losses for impacted ACOs or allowing ACOs to temporarily switch to a one-sided model as we still believe that it is important for ACOs that have taken on risk to be held accountable for shared losses incurred during months in which there was no applicable disaster declaration and for the assigned beneficiary population that was outside the area affected by the disaster.

We also decline to adopt the other suggestions made by commenters, such as continuing to mitigate shared losses over a longer time period or to use payment modifier codes to adjust shared losses. For performance year 2017, we used the time periods associated with public health emergencies declared by the Secretary in applying the adjustment to shared losses and we expect to continue this practice moving forward. As described earlier in this section, we believe this approach provides consistency with the time periods during which waivers of other Medicare requirements are in place, as well as transparency. We are concerned that an approach that would mitigate shared losses over an extended period beyond the public health emergency declaration would potentially need to be applied on a case-by-case basis to account for the circumstances surrounding individual disasters. We wish to avoid this type of policy as we are concerned that it would lead to delays in determining whether relief would be available and create uncertainty for ACOs. With respect to the suggestion that we use payment modifier codes to adjust shared losses, as we describe later in this section, we have concerns that, in practice, the payment modifier codes are not used consistently and therefore would not provide an appropriate means for adjusting shared losses.

In the November 2018 final rule, we extended the policy used to mitigate shared losses for performance year 2017

to performance year 2018 and subsequent years. Accordingly, we would like to clarify what would happen if the applicable time period for an extreme and uncontrollable event spans two calendar years. Consider an event with an applicable time period that spans from October in Year 1 through January in Year 2. In determining the adjustment to shared losses in Year 1, we would use the percentage of the final Year 1 assigned beneficiary population residing in the affected area and the percentage of Year 1 that was affected (2 of 12 months). In determining the adjustment to shared losses in Year 2, we would use the percentage of the Year 2 final assigned beneficiary population residing in the affected area and the percentage of Year 2 that was affected (1 out of 12 months).

Comment: Several commenters encouraged CMS to also address the financial impact of extreme and uncontrollable circumstances on the determination of shared savings for ACOs in all tracks. A few noted that all ACOs have invested significant resources to participate in the Shared Savings Program and they are at risk of not being able to recoup their investment if a natural disaster jeopardizes their opportunity to share in savings.

Response: We appreciate the comments regarding the potential impacts of extreme and uncontrollable circumstances on shared savings payments. Some of the policies we have considered, such as using natural disaster payment modifiers to identify and remove claims for beneficiaries in affected areas when computing ACO expenditures, would have the potential to address adverse impacts on both shared savings and shared losses. However, based an analysis we performed of 2017 claims data for ACO assigned beneficiaries (see the November 2018 final rule (83 FR 59976) for more details), we are concerned that natural disaster payment modifier codes would not serve as a useful means for comprehensively identifying relevant claims. We also have concerns that removing claims for affected beneficiaries and time periods would add considerable complexity and could lead to biased expenditure estimates.

Although we did not adopt an explicit adjustment to the shared savings payment for disaster-affected ACOs in either the December 2017 interim final rule with comment period or the November 2018 final rule, we note that our alternative methodology for quality scoring can indirectly increase an ACO's shared savings payment. In performance year 2017, 62 of 117 disaster-affected ACOs received the national mean quality score, as it was higher than the score the ACO would have received in the absence of the policy. A higher quality score increases the final sharing rate that is applied to an ACO's total savings, and thus can increase the ACO's shared savings payment.

Comment: A few stakeholders offered comments on whether or how CMS should account for extreme and uncontrollable circumstances when setting financial benchmarks for ACOs. A commenter supported the policy of not making any changes to the benchmark but requested that CMS continually monitor the impact of triggering events on an ACO's benchmark for subsequent agreement periods, noting that it was possible that some ACOs may have much lower costs in benchmark years as the result of certain types of events and it would be unfair to penalize these ACOs. Another commenter acknowledged the challenges of appropriately adjusting benchmarks to reflect numerous possible situations and the potential for unintended consequences. This commenter requested that CMS provide more data on affected ACOs to allow for the evaluation of potential benchmark adjustments. Another commenter requested an example to demonstrate our view that the anticipated effect of extreme and uncontrollable circumstances on benchmarks that incorporate regional factors would be minimal. The same commenter requested clarification of how benchmark calculations would be affected in cases where an emergency spans two calendar years.

Response: We appreciate the comments and questions raised by stakeholders regarding possible approaches for addressing extreme and uncontrollable circumstances when calculating ACOs' historical benchmarks. In the December 2017 interim final rule with comment period, we declined to modify the program's historical benchmark methodology for extreme and uncontrollable circumstances. In the August 2018 proposed rule (83 FR 41904–41906), we explained that we believed our proposal to incorporate regional trend factors in our calculations to establish and update the historical benchmark for all ACOs would provide an inherent adjustment to the benchmark for expenditure variations related to extreme and uncontrollable circumstances. In section II.D. of this final rule, we are finalizing our proposals to incorporate regional expenditures into the calculation of benchmark trend and update factors for all ACOs, including those in their first agreement period. We continue to believe that this methodology will provide an inherent adjustment to the benchmark to account for the impact of extreme and uncontrollable circumstances on ACO expenditures without suffering from the drawbacks of some of other methods considered, such as removing claims with disaster payment modifiers or claims for beneficiaries in affected areas and time periods. However, we will continue to monitor this approach and would propose adjustments, if needed, through future rulemaking.

Comment: A commenter requested that CMS consider the impact on ACOs when a triggering event reduces the number of assigned beneficiaries below 5,000. The commenter suggested that CMS establish policies ensuring that an ACO whose assigned beneficiary population decreases below the threshold of 5,000 as the result of an extreme and uncontrollable event be given adequate time to rebuild its patient population prior to the next agreement period. Another commenter questioned whether ACOs falling below the threshold as the result of a disaster would be subject to a penalty. The same commenter requested clarification on how the percentage of ACO population affected by a disaster would be determined for a Track 3 ACO when assigned beneficiaries have moved out of the area.

Response: ACOs that are subject to the prospective beneficiary assignment methodology will continue to be held accountable for their prospectively assigned population for the performance year, regardless of whether the beneficiaries remain in the same geographic area, as long as they continue to reside in the United States, do not enroll in Medicare Advantage, and have at least one month of Parts A and B coverage and no months of Part A only or Part B only coverage. Thus, for an ACO that is subject to the prospective assignment methodology, the impact of a disaster on the size of its beneficiary population for the performance year should be small. However, we appreciate the fact that extreme and uncontrollable events could lead to out-migration from the affected area, which could, in turn, have negative effects on an ACO's prospectively assigned beneficiary population for future periods or on the current performance year (or future benchmark year) assignment for an ACO that is subject to preliminary prospective assignment with retrospective reconciliation.

Under section 1899(b)(2)(D) of the Act, in order to be eligible to participate

in the Shared Savings Program an ACO must have at least 5,000 beneficiaries. CMS deems an ACO to have initially satisfied the requirement to have at least 5,000 assigned beneficiaries if 5,000 or more beneficiaries are historically assigned to the ACO participants in each of the 3 benchmark years as calculated using the program's assignment methodology (§ 425.110(a)). We decline to modify our policy for determining whether a renewing ACO has satisfied the statutory requirement to make a special exception for ACOs that have been affected by an extreme and uncontrollable circumstance as we cannot be certain whether a below-threshold population during the benchmark years is due to out-migration resulting from the disaster or to other factors. Furthermore, there would be no assurance that an ACO's assigned beneficiary population would sufficiently increase during the performance period to comply with the statutory requirement. We note that as part of their application to renew their participation in the program for a new agreement period, all ACOs can modify their ACO participant list to try to expand their assigned beneficiary population to meet the threshold. ACOs that are unable to meet the 5,000 assigned beneficiary threshold would have the opportunity to re-enter the program after the size of their patient population has recovered.

Furthermore, we want to note that ACOs that fall below the 5,000 assigned beneficiary threshold during an agreement period are not automatically terminated from the program. As specified in § 425.110(b), if at any time during the performance year an ACO's assigned population falls below 5,000, the ACO may be subject to the predetermination actions described in § 425.216 and termination of the participation agreement by CMS under § 425.218. Because ACOs have the opportunity to modify their ACO participant lists prior to the start of each performance year, such ACOs may have time to sufficiently rebuild their assigned population before they must be terminated from the program, and in time for renewal. We also note that under the policies being finalized in section II.A.5.c. of this final rule, ACOs that are involuntarily terminated from the program under § 425.218 or that voluntarily terminate under § 425.220 may apply to re-enter without the previously required ''sit-out'' period.

Following consideration of the comments received in response to the December 2017 interim final rule with comment period, we are not making any changes to the extreme and uncontrollable circumstances policies that were adopted for performance year 2017. In the November 2018 final rule, we finalized policies for providing relief for ACOs impacted by extreme and uncontrollable circumstances in performance year 2018 and subsequent years. In that final rule, we amended the provisions at §§ 425.502(e)(4) and (f); 425.606(i) and 425.610(i) that were originally adopted in the December 2017 interim final rule with comment period in order to reflect these revised policies.

IV. Collection of Information Requirements

As stated in section 3022 of the Affordable Care Act, Chapter 35 of title 44, United States Code, shall not apply to the Shared Savings Program. Consequently, the information collection requirements contained in this final rule need not be reviewed by the Office of Management and Budget.

V. Regulatory Impact Analysis

A. Statement of Need

This final rule is necessary in order to make certain payment and policy changes to the Medicare Shared Savings Program established under section 1899 of the Social Security Act. The Shared Savings Program promotes accountability for a patient population, fosters the coordination of items and services under Parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery.

The need for the policies is summarized in the statement of the rule's purpose in section I. of this final rule and described in greater detail throughout the discussion of the policies in section II. of this final rule. As we have previously explained in this final rule, ACOs in two-sided models have shown significant savings to the Medicare program and are advancing quality. However, the majority of ACOs remain under a one-sided model. Some of these ACOs are increasing Medicare spending (and therefore generating losses) while benefiting from waivers of certain federal requirements in connection with their participation in the program. These ACOs may also be encouraging consolidation in the market place and reducing competition and choice for Medicare FFS beneficiaries. Under the redesign of the Shared Savings Program we are adopting in this final rule, ACOs of different compositions, and levels of experience with the accountable care model may continue to participate in the program, but the provisions included in this final rule will put the program on a path towards achieving a more measureable move to value and lead to savings for the Medicare program, while promoting a competitive and accountable marketplace.

In summary, this final rule will redesign the participation options, including the payment models, available to Shared Savings Program ACOs to encourage their transition to performance-based risk. As part of this approach, CMS will extend the length of ACOs' agreement periods from 3 to 5 years as well as make changes to the program's benchmarking methodology to allow for benchmarks that better reflect the ACO's regional service area expenditures beginning with its first agreement period, while also mitigating the effects of factors based on regional FFS expenditures on ACO benchmarks more generally. These policies are necessary to improve the value proposition of the program for currently participating ACOs considering continuing their participation, as well as for organizations considering entering the program. Further, these changes are timely as large cohorts of the program's early entrants, the vast majority of which are currently participating in the program's one-sided model (Track 1), face a required transition to performance-based risk at the start of their next agreement period.

Other key changes to the program's regulations are also necessary, including to implement new requirements established by the Bipartisan Budget Act, which generally allow for additional flexibilities in payment and program policies for ACOs and their participating providers and suppliers. Specifically, we are finalizing policies to implement provisions of the Bipartisan Budget Act that allow certain ACOs to establish CMS-approved beneficiary incentive programs to provide incentive payments to assigned beneficiaries who receive qualifying primary care services; permit payment for expanded use of telehealth services furnished by physicians or other practitioners participating in an applicable ACO that is subject to a prospective assignment methodology; and provide greater flexibility in the assignment of Medicare FFS beneficiaries to ACOs by allowing ACOs in tracks under a retrospective beneficiary assignment methodology a choice of prospective assignment for the agreement period. Additionally, this final rule will extend the availability of the program's existing SNF 3-day rule waiver to all ACOs participating under performance-based risk to support these ACOs in coordinating care across

settings to meet the needs of their patient populations.

To provide ACOs time to consider the new participation options and prepare for program changes, make investments and other business decisions about participation, obtain buy-in from their governing bodies and executives, and complete and submit a Shared Savings Program application for a performance year beginning in 2019, we elected to forgo the application cycle in 2018 for an agreement start date of January 1, 2019, and instead in the November 2018 final rule (83 FR 59946) we finalized a voluntary 6-month extension for ACOs with a participation agreement ending on December 31, 2018, to allow these ACOs an opportunity to extend their current agreement period for an additional 6-month performance year. Under the policies we are adopting in this final rule, these ACOs will be able to apply for a new agreement period under the BASIC track or ENHANCED track beginning on July 1, 2019. ACOs entering a new agreement period on July 1, 2019, will have the opportunity to participate in the program under an agreement period spanning 5 years and 6 months, where the first performance year is the 6-month period between July 1, 2019, and December 31, 2019. This final rule includes the methodology for determining ACO financial performance for the 6-month performance year from July 1, 2019, through December 31, 2019.

B. Overall Impact

We examined the impacts of this final rule as 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), Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017), 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)).

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). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. Executive Order 13771 directs agencies to categorize all impacts which generate or alleviate costs associated with regulatory burden and to determine the action's net incremental effect.

1. Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success (CMS–1701–F2)

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate 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, we have prepared a RIA, which to the best of our ability presents the costs and benefits of the rulemaking.

In keeping with our standard practice, the main analysis presented in this RIA compares the expected outcomes under the policies included in this final rule to the expected outcomes under current regulations. We provide our analysis of the expected costs of the final payment model under section 1899(i)(3) of the Act to the costs that would be incurred under the statutory payment model under section 1899(d) of the Act in section V.E. of this final rule.

2. Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Extreme and Uncontrollable Circumstances Policies (CMS–1701–F)

We noted in the December 2017 IFC (82 FR 60918) that the policies for addressing extreme and uncontrollable circumstances are unlikely to have a significant economic impact on the Shared Savings Program. For purposes of the December 2018 interim final rule with comment, we estimated the impact of these policies by simulating their effect on actual 2016 financial and quality performance results, the most recent available reconciled financial and quality results, for the ACOs participating in the program in performance year 2017 that were potentially impacted by these policies. The total increase in shared savings payments and total reduction in shared loss payments anticipated for ACOs impacted by the policies in this rule in 2017 was estimated to be approximately $3.5 million. Performance year 2017 results were available in August of 2018, and we found that all 11 of the performance-based risk ACOs that owed shared losses received an adjustment, reducing aggregate shared losses by $640,000 to reflect the impact of extreme and uncontrollable circumstances. In addition, 31 ACOs received the mean ACO quality score of 92 percent as a result of having at least 20 percent of their assigned beneficiaries or the ACO's legal entity in a county designated as a natural disaster emergency area.

C. Anticipated Effects

1. Effects on the Medicare Program

a. Background

The Shared Savings Program is a voluntary program operating since 2012 that provides financial incentives for demonstrating quality of care and efficiency gains within FFS Medicare. In developing the policies finalized in this rule, we evaluated the impact of the quality and financial results of the first 4 performance years of the program. We also considered our earlier projections of the program's impacts as described in the November 2011 final rule (see Table 8, 76 FR 67963), the June 2015 final rule (80 FR 32819), and June 2016 final rule (81 FR 38002).

(1) ACO Performance 2012 Through 2016

We have analyzed financial performance from the first four performance years for the Shared Savings Program.[24] Table 14 describes performance year 2016 results for ACOs segmented by track. These results show that in performance year 2016, the 410 Track 1 ACOs spent more on average

[24] The first performance year for the program concluded December 31, 2013, which included a 21-period for April 2012 starters, an 18-month period for July 2012 starters, and a 12-month period for January 2013 starters. Thereafter, results have been determined for the calendar year performance year for 2014 through 2017 for all ACOs that participated in the program for the relevant year. The study conducted for this rule reviewed results through 2016.

relative to their financial benchmarks, resulting in a net loss of $49 million, or $7 per beneficiary. Because these ACOs were in a one-sided shared savings only model, CMS did not recoup any portion of these losses. Further, in performance year 2016, the 6 Track 2 and 16 Track 3 ACOs spent less on average relative to their financial benchmarks. Track 2 ACOs produced net savings of $18 million or $308 per beneficiary, and Track 3 ACOs produced net savings of $14 million or $39 per beneficiary. These results (albeit from a relatively small sample of ACOs that in a number of cases moved to a performance-based risk track only after showing strong performance in a first agreement period under Track 1) indicate that ACOs under performance-based risk were more successful at lowering expenditures in performance year 2016 than ACOs under Track 1.

The same performance year 2016 data also show that ACOs produce a higher level of net savings and more optimal financial performance results the longer they have been in the Shared Savings Program and with additional participation experience. In performance year 2016, 42 percent of ACOs that started participating in the Shared Savings Program in 2012 and remained in the program in 2016 shared in savings and 36 percent of both 2013 and 2014 starters shared in savings. In contrast, 26 percent of 2015 starters shared in savings and 18 percent of 2016 starters shared in savings in performance year 2016.

TABLE 14—PY 2016 RESULTS BY SHARED SAVINGS PROGRAM TRACK

Track	Two-sided Risk?	Number of ACOs Reconciled	Parts A and B Spending Above Benchmark [A]	Parts A and B Spending Below Benchmark [B]	Shared Savings Payments from CMS to ACOs [C]	Shared Loss Payments from ACOs to CMS [D]	Net Effect in Aggregate [A minus B plus C minus D]	Net Effect per Beneficiary per year
Track 1	No	410	$1.021 billion	$1.562 billion	$590 million	$0	$49 million	$7
Track 2	Yes	6	$0	$42 million	$24 million	$0	−$18 million	−$308
Track 3	Yes	16	$25 million	$95 million	$64 million	$9 million	−$14 million	−$39

Table 15 indicates that when analyzing the performance of ACOs in Track 1, which is the track in which the majority of Shared Savings Program ACOs participated as of performance year 2016, it becomes clear that low revenue ACOs are saving CMS money while high revenue ACOs are resulting in additional spending by CMS before accounting for market-wide and potential spillover effects. Low revenue Track 1 ACOs produced net savings of $182 million relative to their benchmarks or $73 per beneficiary, and high revenue Track 1 ACOs produced a net loss of $231 million or $46 per beneficiary. For the purpose of this analysis, an ACO whose ACO participants' Medicare FFS revenue for assigned beneficiaries was less than 10 percent of the ACO's assigned beneficiary population's Parts A and B expenditures, was identified as a ''low revenue ACO,'' while an ACO whose ACO participants' Medicare FFS revenue for assigned beneficiaries was at least 10 percent of the ACO's assigned beneficiary population's Parts A and B expenditures, was identified as a ''high revenue ACO''. Nationally, evaluation and management spending accounts for about 10 percent of total Parts A and B per capita spending. Because ACO assignment focuses on evaluation and management spending, applying a 10 percent limit to identify low revenue ACOs will capture all ACOs that participated in the Shared Savings Program in performance year 2016 that were solely comprised of providers and suppliers billing for physician fee schedule services and generally exclude ACOs with providers and suppliers that bill for inpatient services for their assigned beneficiaries. The use of a threshold of 10 percent of the Parts A and B expenditures for the ACO's assigned beneficiary population to classify ACOs as either ''low revenue'' or ''high revenue'' also showed the most significant difference in performance between the two types of ACOs. We note that this approach differs from the definitions for low revenue ACO and high revenue ACO discussed in section II.A.5.b. and finalized in this final rule. However, our analysis has confirmed that the simpler and more practical policy that we are adopting in this final rule of identifying low revenue ACOs using a 35-percent threshold in terms of the ratio of ACO participants' total Medicare Parts A and B FFS revenue relative to total Medicare Parts A and B expenditures for the ACO's assigned beneficiary population produces a comparable subgroup of ACOs with similarly-elevated average financial performance and ACO participant composition as the methods used in this study, as well as the lower 25 percent threshold proposed in the August 2018 proposed rule.

TABLE 15—PY 2016 RESULTS FOR LOW REVENUE AND HIGH REVENUE TRACK 1 ACOs

Track 1 ACO Composition	Number of ACOs (Total 410)	Parts A and B Spending Above Benchmark [A]	Parts A and B Spending Below Benchmark [B]	Shared Savings Payments from CMS to ACOs [C]	Shared Loss Payments from ACOs to CMS [D]	Net Effect in Aggregate [A minus B plus C minus D]	Net Effect per Beneficiary per Year
Low revenue	188	$339 million	−$863 million	$343 million	$0	−$182 million	−$73
High revenue	222	$682 million	−$698 million	$247 million	$0	$231 million	$46

With respect to ACO quality, the Shared Savings Program's quality measure set includes both process and outcome measures that evaluate preventive care, clinical care for at-risk populations, patient experience of care, and care coordination. ACOs have consistently achieved higher average performance rates compared to group practices reporting similar quality measures. In addition, ACOs that have participated in the program over a longer time period have shown greater improvement in quality performance. For example, across all Shared Savings Program ACOs that reported quality in both performance year 2013 and performance year 2016, average quality performance improved by 15 percent across 25 measures used consistently across the performance years. Further, for performance year 2016, 93 percent of Shared Savings Program ACOs received bonus points for improving quality performance in at least one of the four quality measure domains with an average quality score increase for the applicable domain of 3 percentage points.

Comment: Several commenters expressed support for Track 1 of the Shared Savings Program and the value of one-sided models. Several commenters cited the positive performance of Track 1 ACOs during performance year 2017 and past performance years referencing publically available CMS data and other publically available studies and citing the wide range of potential savings generated by Track 1 ACOs. Several commenters expressed their belief that Shared Savings Program performance should not be measured against ACO benchmarks, as financial benchmarks do not serve as valid counterfactuals and also fail to account for spillover effects, leading to misinterpretations of the value of one-sided models.

A few commenters stated that they believed there is limited evidence available that shows downside risk elicits stronger performance, and one commenter suggested CMS should revise its statements that suggest ACOs participating in Track 1 of the Shared Savings Program have increased spending. A few commenters indicated that as ACOs gain experience with participation in the Shared Savings Program, these experienced ACOs also have demonstrated greater rates of savings, suggesting that ACOs should continue to have additional time to participate in one-sided models and the opportunity for slower transitions to performance-based risk.

Response: We agree with commenters' suggestions that there is value in one-sided models, and we want to reiterate this belief for those commenters who suggested we have not recognized the benefits of participation in a one-sided model. As discussed in detail in this Regulatory Impact Analysis, the program results indicate that ACOs in one-sided models have indeed contributed to significant overall net program savings. We also agree with commenters, that performance in one-sided models should be evaluated using a variety of performance measures, such as comparing ACO markets to non-ACO markets. This type of comparison has shown spending trend reductions supporting the benefits of ACO participation in one-sided models, implying gross savings are likely several times the magnitude measured by program benchmarks. We also agree that ACOs need an opportunity to participate in a one-sided model to gain experience in the Shared Savings Program before moving to performance-based risk, and we believe the glide path provided in the BASIC Track offers the flexibility needed for ACOs to gain experience in the program, while also offering options for ACOs that are ready to accelerate their move to higher risk within an agreement period.

We disagree with commenters that suggested that ACOs should have more time and a slower transition to two-sided models, as we have found ACOs in two-sided models consistently have generated greater savings and have shown higher performance than ACOs in one-sided models, and we believe the glide path provided in the BASIC track strikes the appropriate balance in incentives to improve performance and appropriately transitions ACOs to greater levels of risk and reward.

Comment: Several commenters agreed with the discussion in the August 2018 proposed rule regarding the data that show physician-led ACOs are more successful in producing savings. Some other commenters disagreed with CMS' conclusion that low revenue ACOs (typically physician-led ACOs) perform better than high revenue ACOs (typically ACOs that include a hospital). MedPAC commented that although the August 2018 proposed rule described greater savings relative to benchmarks for low revenue ACOs in 2016, this analysis may not present the full picture because it did not take into account the fact that physician-only ACOs are more common in markets where service use per beneficiary has been historically high. According to MedPAC, even if physician-only ACOs generate some small degree of additional savings on average compared to hospital-based ACOs, the magnitude of these additional savings is not large enough for the Medicare program to favor physician-only ACOs over integrated physician-hospital ACOs for payment purposes. Rather, Medicare should be neutral with respect to the specific configuration of ACOs and their ACO participants and ACO providers/suppliers, and instead design and implement policies to reward the most effective ACOs in a given market.

A few commenters argued that one of CMS' premises for distinguishing between hospital-based and physician-led ACOs is flawed, explaining based on a commenter's own analysis, that at least 20 percent of health system-led ACOs would be designated as

''physician led,'' and more generally that some of the highest performing individual ACOs are hospital-based ACOs.

Response: We believe that factors related to ACO composition, including the relationship between ACO participant revenues and the ACO's benchmark, are reflected in program participation trends and program results, including results from performance years 2016 and 2017. Financial results vary at the ACO level and there are both significant savings and losses represented in the subsets of low and high revenue ACOs, but the finding that low revenue ACOs have higher mean savings is generally consistent even when filtering for specific cohorts of ACOs, specific years of performance, and track selection. Furthermore, the changes we are finalizing in this rule will not preclude high revenue ACOs from succeeding in the program, but instead they will require such ACOs to take a more aggressive path toward performance-based risk—a path that is naturally better suited to entities with higher revenue, as evidenced by the successful participation of high revenue ACOs in Track 2 and Track 3. While early adopters of performance-based risk have included both low revenue ACOs and high revenue ACOs, a larger percentage of high revenue ACOs have elected to participate in two-sided models. For example, in performance year 2017, there were 6 percent more high revenue ACOs participating in Track 2 and Track 3 than in Track 1. However, analyses of performance year 2017 results show that low revenue ACOs continue to have stronger performance overall than high revenue ACOs, and low revenue ACOs in two-sided risk models outperform all other ACOs. While high revenue ACOs with greater experience in the program participating under two-sided models outperformed ACOs with these characteristics in Track 1, high revenue ACOs in two-sided models in their first performance year in the program showed a net loss. Generally, the vast majority of ACOs in two-sided models that have owed shared losses have been high revenue ACOs.

We believe this experience and the program results to date demonstrate that high revenue ACOs generally have a greater capacity to take on higher risk and that higher levels of risk can help serve as catalyst for these organizations to improve quality of care and lower growth in FFS expenditures for their assigned beneficiary populations even more quickly. Further, high revenue ACOs that have not already moved to two-sided risk are not performing as well as low revenue ACOs, although we believe they have the financial means to move to greater risk, and may be taking advantage of program flexibilities that can lead to increased program spending or are not serious about redesigning their care processes to improve quality and lower expenditure growth. As a consequence, we believe high revenue ACOs without a sufficient incentive to change their practice patterns, including through the transition to performance-based risk, may not only lead to higher Medicare spending, but also pose a risk of crowding out participation by low revenue ACOs with stronger potential to improve the quality and efficiency of care delivery.

(2) ACO Market-Wide Effects and Potential Spillover

Analysis of wider program claims data indicates Medicare ACOs have considerable market-wide impact, including significant spillover effects not directly measurable by ACO benchmarks. Whereas spending relative to benchmark (Tables 14 and 15) indicates Shared Savings Program ACOs as a group are not producing net savings for the Medicare FFS program, a study of wider claims data indicates significant net savings are likely being produced. Table 16 includes data through performance year 2016 on the cumulative per capita Medicare FFS expenditure trend (on a price-standardized and risk-adjusted basis) in markets that include Medicare ACOs, including ACOs participating in the Shared Savings Program as well as in the Pioneer and Next Generation ACO Models. Table 16 illustrates that, compared to the results in relation to ACOs' historical benchmarks discussed previously (see Table 14), more savings are likely being generated when both the spillover effects on related populations and the feedback effect of growing ACO participation on the national average FFS program spending growth, which in turn has been used to update ACO benchmarks, are factored in. Table 16 expresses combined market average per capita spending growth since 2011 relative to a baseline FFS per capita trend observed for hospital referral regions continuing to have less than 10 percent of total assignable FFS beneficiaries assigned to Medicare ACOs through 2016. Markets that have been ''ACO active'' longer (defined by the year a market first reached at least 10 percent assignment of assignable FFS beneficiaries to Medicare ACOs) show the greatest relative reduction in average adjusted growth in per capita Medicare FFS spending. Markets that have included Medicare ACOs since 2012, particularly the relatively small subset of 10 hospital referral regions reaching significant ACO participation in risk (defined as at least 30 percent assignment by 2016 to ACOs participating in a Shared Savings Program track or Medicare ACO model with performance-based risk), show the most significant reductions in Medicare FFS spending through 2016.

TABLE 16—AVERAGE ADJUSTED CUMULATIVE PER CAPITA MEDICARE FFS TREND 2011 – 2016 (BY YEAR MARKETS BECOME ACO ACTIVE RELATIVE TO CUMULATIVE TREND FOR MARKETS WITHOUT SIGNIFICANT ACO ACTIVITY)

Markets Grouped	Adjusted Per Capita Change in Spending from Non-ACO Markets					
By ACO Activity	2011	2012	2013	2014	2015	2016
First Active 2016	0.0%	-0.5%	0.0%	-0.5%	-0.3%	-0.5%
First Active 2015	0.0%	-0.2%	0.2%	-0.1%	0.2%	0.1%
National Average	**0.0%**	**-0.3%**	**-0.3%**	**-0.7%**	**-0.7%**	**-1.2%**
First Active 2014	0.0%	-0.5%	-0.3%	-0.5%	-0.7%	-1.5%
First Active 2013	0.0%	0.0%	-0.1%	-1.0%	-1.1%	-1.8%
First Active 2012	0.0%	-0.3%	-0.8%	-1.3%	-1.5%	-2.0%
2012 Subset with Risk	0.0%	-0.9%	-1.9%	-2.5%	-2.9%	-3.4%

Based on an analysis of Medicare Shared Savings Program and Pioneer ACO Model performance data, we observe that the sharpest declines in spending are for post-acute facility services (particularly skilled nursing facility services), with smaller rates of savings (but more dollars saved overall) from prevented hospital admissions and reduced spending for outpatient hospital episodes. These findings become apparent when assessing hospital referral regions both with (>10 percent of assignable Medicare FFS beneficiaries assigned to ACOs in 2012) and without (<10 percent through 2016) a significant portion of assignable Medicare FFS beneficiaries assigned to ACOs. Comparing price-standardized per capita changes in spending from 2011 to 2016, regions with significant ACO penetration yielded larger declines in expenditures in the following areas relative to those without significant ACO penetration: Post-acute care facilities (relative decrease of 9.0 percent), inpatient (1.6 percent relative decrease), and outpatient (3.5 percent relative decrease). These relative decreases were accompanied by declines in evaluation and management services (2.5 percent relative decrease), emergency department (ED) utilization (1.6 percent relative decrease), hospital admissions (1.9 percent decrease), and hospital readmissions (3.5 percent decrease). There also appears to be substitution of higher cost services with lower cost services. For example, during the same period, home health expenditures increased by 5.0 percent and ambulatory surgery center expenditures increased by 1.4 percent, indicating that some beneficiaries could be forgoing care in institutional and inpatient settings in favor of lower cost sites of care.

These findings are supported by outside literature and research. For example, a study conducted by J. Michael McWilliams and colleagues (JAMA, 2017) found that Shared Savings Program ACOs that began participating in 2012 reduced post-acute care spending by 9 percent by 2014.[25] Another study by Ulrika Winblad and colleagues (Health Affairs, 2017) determined that ACO-affiliated hospitals reduced readmissions from skilled nursing facilities at a faster rate than non-ACO-affiliated hospitals through 2013.[26] In addition, a study by John Hsu and colleagues (Health Affairs, 2017) concluded that using care management programs, large Pioneer ACOs generated 6 percent fewer ED visits, 8 percent fewer hospitalizations, and overall 6 percent less Medicare spending relative to a comparison group through 2014.[27]

Assuming Medicare ACOs were responsible for all relative deviations in trend from non-ACO markets produces an optimistic estimate that total combined Medicare ACO efforts potentially reduced total FFS Medicare Parts A and B spending in 2016 by about 1.2 percent, or $4.2 billion (after accounting for shared savings payments but before accounting for the potential impact on MA plan payment). However, it is likely that ACOs are not the only factor responsible for lower spending growth found in early-ACO-active markets. Health care providers in such markets are likely to be more receptive to other models and/or interventions, potentially including the following, for example: (1) Health Care Innovation Award payment and service delivery models funded by the Innovation Center; (2) advanced primary care functionality promoted by other payers, independent organizations like the National Committee for Quality Assurance, and/or through Innovation Center initiatives including the Multi-Payer Advanced Primary Care Practice Demonstration and Comprehensive Primary Care Initiative; and (3) care coordination funded through other Medicare initiatives, including, for example, the Community-based Care Transitions Program. Furthermore, the markets making up the non-ACO comparison group only cover about 10 percent of the national assignable FFS population in 2016 and may offer an imperfect counterfactual from which to estimate ACO effects on other markets.

An alternative (and likely more precise) estimate for the overall Medicare ACO effect on spending through 2016 involves assuming a spillover multiplier mainly for savings on non-assigned beneficiaries whose spending is not explicitly included in benchmark calculations and combining primary and spillover effects to estimate the degree to which ACO benchmarks were reduced by the feedback such efficiency gains would have had on

[25] McWilliams JM, et al. Changes in Postacute Care in the Medicare Shared Savings Program. *JAMA Intern Med.* 2017; 177(4):518–526. doi:10.1001/jamainternmed.2016.9115.

[26] Winblad U, et al. ACO-Affiliated Hospitals Reduced Rehospitalizations from Skilled Nursing Facilities Faster than Other Hospitals. *Health Affairs.* 2017 January; 36(1): 67–73. doi:10.1377/hlthaff.2016.0759.

[27] Hsu J, et al. Bending The Spending Curve By Altering Care Delivery Patterns: The Role Of Care Management Within A Pioneer ACO. *Health Affairs.* 2017 May 1; 36(5):876–884. doi:10.1377/hlthaff.2016.0922.

national average spending growth. Analysis of claims data indicates an average ACO's providers and suppliers provide services to roughly 40 to 50 percent more beneficiaries than are technically assigned to the ACO in a given year. In addition, savings will potentially extend to spending greater than the large claims truncation amount, IME payments, DSH payments, and other pass-through payments that are excluded from ACO financial calculations. Assuming proportional savings accrue for non-assigned beneficiaries and the excluded spending categories, as previously described, supports a spillover savings assumption of 1.6 (that is, 60 cents of savings on non-benchmark spending for every dollar of savings on benchmark spending). Total implied savings, including the assumed spillover savings, suggest that Medicare ACOs were responsible for about 50 percent of the lower spending growth in ACO markets (after becoming ACO active), or roughly 0.5 percent lower total FFS Parts A and B spending in 2016 after accounting for shared savings payments.

The latest results recently published for ACOs participating in a 2017 performance year show continued overall progress in terms of the magnitude of combined program savings relative to combined benchmarks and relative to the net combined dollars returned to ACOs as shared savings payments net of shared loss receipts. For the first time in 2017, ACOs in Track 1 showed combined savings relative to benchmark exceeding the combined dollars returned to such ACOs via shared savings payments. However, the greatest difference in terms of gross savings relative to benchmark outpacing shared savings payments continues to be exhibited by the subgroup of low-revenue ACOs in performance based risk.

There are several other key takeaways from the available evidence and literature regarding the performance of Medicare ACOs, including the following:

Independent Research Finds ACOs Reduce Medicare Trust Fund Outlays. The implications from studying market-level trends described in the previous section are compatible with findings reported by independent researchers. J. Michael McWilliams (JAMA, 2016) found that in 2014, Shared Savings Program ACOs generated estimated program savings of $628 million, or about 2.5 times higher than the savings in relation to participating ACOs' historical benchmarks and nearly twice the total shared savings payments of $341 million.[28] Another study by McWilliams and colleagues (JAMA, 2013) on a commercial ACO initiative, the Alternative Quality Contract, estimated a net 3.4 percent reduction in spending on Medicare beneficiaries due to spillover from a commercial non-Medicare ACO initiative.[29] A study funded by the National Association of Accountable Care Organizations estimated that Shared Savings Program ACOs generated savings of $1.84 billion during through the 2015 performance year, or roughly double the gross savings measured relative to the ACOs' combined benchmark over such period.[30] This research supports the hypothesis that changes in care delivery implemented by Medicare ACO clinicians will, in turn, cause efficiency gains in the wider Medicare FFS population. In another study supporting this hypothesis, Madeleine Phipps-Taylor and Stephen Shortell (NEJM, 2016) conducted a set of case studies which concluded that ACOs were making system and process changes that will improve the value of services provided to all patients, regardless of payer.[31]

Low revenue ACOs (including small and physician-only ACOs) have produced stronger average benchmark savings to date than high revenue ACOs (likely including institutional providers). We also find lower spending growth in the handful of markets that happen to be virtually exclusively populated by low revenue ACOs; however, the sample size of such markets is too small for us to confidently estimate relative performance but does offer some corroboration of the stronger results observed for low revenue ACOs on average relative to their historical benchmarks. Further, evidence suggests that overall payment reform has been associated with little acceleration in consolidation of health care providers that surpasses trends already underway (Post et al., 2017),[32] although there is some evidence of potential defensive consolidation in response to new payment models (Neprash et al., 2017).[33] Anecdotally, ACOs provide physician practices with a way to stay independent and offer a viable alternative to merging with a hospital (Mostashari, 2016).[34]

Generating savings is difficult for ACOs. It may take time as well as trial and error for ACOs to build more efficient care delivery infrastructure. Small absolute savings compound over time in an incremental fashion. This gradual change is evidenced by ACOs' financial performance results to date, which indicate that ACOs produce more net savings the longer they participate in programs such as the Shared Savings Program.

Shared savings are not profits. Program experience since 2012 indicates that ACOs make upfront investments in care delivery infrastructure, including data analytics and staffing, with the intent of saving money through improvements in care management and coordination. ACOs that do not achieve savings must still fund these operational costs.

Sustainably rewarding attained efficiency and continued improvement is the central challenge. Therefore, optimizing program design elements for ACO initiatives such as the Shared Savings Program is key to ensuring that both of these goals are attained. Such elements include the methodology used to set and reset the ACO's historical benchmark, the approach used to calculate the ACO's shared savings and/or shared losses, the level of performance-based risk for ACOs, and the methodology for assigning beneficiaries to the ACOs. Striking this balance correctly will foster increased participation in ACO initiatives, which is required to produce higher levels of net savings.

Comment: Several commenters suggested CMS incorporate a broader set of measurement approaches to

[28] McWilliams JM. Changes in Medicare Shared Savings Program Savings From 2013 to 2014. *JAMA*. 2016; 316(16):1711–1713. doi:10.1001/jama.2016.12049.

[29] McWilliams JM, et al. Changes in Health Care Spending and Quality for Medicare Beneficiaries Associated With a Commercial ACO Contract. *JAMA*. 2013; 310(8):829–836. doi:10.1001/jama.2013.276302.

[30] Dobson, A, et al. Estimates of Savings by Medicare Shared Savings Program Accountable Care Organizations. (August 30, 2018); available at *https://www.naacos.com/assets/docs/pdf/Study_of_MSSP_Savings_2012-2015.pdf*

[31] Madeleine Phipps-Taylor & Stephen M. Shortell. ACO Spillover Effects: An Opportunity Not to Be Missed, *NEJM Catalyst* (September 21, 2016); available at *https://catalyst.nejm.org/aco-spillover-effects-opportunity-not-missed/*.

[32] See for example, Brady Post, Tom Buchmueller, and Andrew M. Ryan. Vertical Integration of Hospitals and Physicians: Economic Theory and Empirical Evidence on Spending and Quality. *Medical Care Research and Review*. August 2017. *https://doi.org/10.1177/1077558717727834*. See also, Liaw WR, et al. Solo and Small Practices: A Vital, Diverse Part of Primary Care. *Ann Fam Med*. 2016;14(1):8–15. doi:10.1370/afm.1839.

[33] Neprash HT, Chernew ME & McWilliams JM. Little Evidence Exists to Support the Expectation That Providers Will Consolidate to Enter New Payment Models. *Health Affairs*. 2017; 36(2): 346–354. doi:10.1377/hlthaff.2016.0840.

[34] See for example, Mostashari, F. The Paradox of Size: How Small, Independent Practices Can Thrive in Value-Based Care. *Ann Fam Med*. 2016; 14(1):5–7. doi:10.1370/afm.1899.

determine ACO and Shared Savings Program performance, to better identify spillover and other effects on non-ACO assigned populations. A few commenters believed that improved accuracy in identifying and measuring spillover effects would improve determinations of the overall performance of the Shared Savings Program and better identify actual savings to the Medicare Trust Funds.

Response: We agree with commenters that reviewing the wider impacts and accounting for the spillover effects related to ACO participation in the Shared Savings Program is important, and this was discussed in detail in the Regulatory Impact Analysis for the August 2018 proposed rule. Our analysis of wider program claims data indicates that Medicare ACOs have considerable market-wide impact, including significant spillover effects not directly measurable by ACO benchmarks. Table 16 includes data through PY 2016 on the cumulative per capita Medicare FFS expenditure trend (on a price-standardized and risk-adjusted basis) in markets that include Medicare ACOs, including ACOs participating in the Shared Savings Program as well as in the Pioneer and Next Generation ACO Models. Table 16 illustrates that more savings are likely being generated when both the spillover effects on related populations and the feedback effect of growing ACO participation on the national average FFS program spending growth are factored in. Additionally, analysis of markets that have been ''ACO active'' longer (defined by the year a market first reached at least 10 percent assignment of assignable FFS beneficiaries to Medicare ACOs) shows that these markets have the greatest relative reduction in average adjusted growth in per capita Medicare FFS spending. CMS will continue to use a variety of methods to evaluate the impact of Shared Savings Program participation in future years.

Comment: Several commenters suggested that CMS' statements that ACOs are a potential driver of consolidation in the healthcare industry are not supported by studies or publically available data. One commenter described their belief that consolidation had been occurring before the Shared Savings Program and has generally continued for other reasons, and that the Shared Savings Program may even contribute to greater competition in provider markets, as long as its incentive structure continues to favor lower-revenue organizations. One commenter suggests ACOs provide physician practices with a way to stay independent and offer an alternative to merging with a hospital. One commenter described the program redesign outlined in the August 2018 proposed rule as more complex and expensive than the existing program requirements, and was concerned that it would potentially limit opportunities for smaller companies, such that larger entities will prevail.

Response: As explained earlier in this impact analysis, evidence suggests that overall payment reform has been associated with little acceleration in consolidation of health care providers that surpasses trends already underway (Post et al., 2017) [35], but there is some evidence of potential defensive consolidation in response to new payment models (Neprash et al., 2017) [36]. Anecdotally, ACOs provide physician practices with a way to remain independent and offer a viable alternative to merging with a hospital (Mostashari, 2016).[37] However, we also agree with commenters that additional investigation and research on consolidation is needed.

We disagree with the commenter's suggestion that the program redesign under the ''Pathways to Success'' will encourage larger entities to form, as our incentives for low revenue ACOs will likely continue to support smaller physician-driven organizations to participate in the Shared Savings Program and reduce incentives for consolidation. Rather, we believe that the redesign of the Shared Savings Program offers ACOs of different compositions opportunities to move to value and achieve savings for the Medicare program, while promoting a competitive and accountable marketplace.

Comment: Two commenters disputed CMS' assertion that Shared Savings Program ACOs are not generating significant savings due to ACOs' reluctance to undertake risk. These commenters believe that Shared Savings Program ACOs are improving quality and achieving significantly higher savings for Medicare than CMS originally calculated. One commenter requested that CMS re-examine its data and re-evaluate the effectiveness of the Shared Savings Program. Other commenters expressed disappointment with ACO progress toward significantly improving efficiency of care

Response: We disagree with the assertions made by these commenters that we have underestimated the overall impact of the program. As discussed in detail in this Regulatory Impact Analysis, our analysis of the program indicates that ACOs (the majority of which participated in one-sided Track 1 during our study period) have produced significant overall net program savings as evidenced by reductions in spending trends in ACO markets compared to non-ACO markets, which imply that gross savings from ACO participation in the program are likely at least several times the magnitude measured by program benchmarks. We also note, however, that high revenue ACOs on average are not showing positive net savings relative to their benchmarks. We believe replacing Track 1 with a BASIC track featuring a more gradual, but ultimately quicker, transition to performance-based risk, in conjunction with benchmark refinements, will promote stronger performance by both high revenue and low revenue ACOs remaining in or joining the program.

b. Assumptions and Uncertainties

The changes to the Shared Savings Program finalized in this rule could result in a range of possible outcomes. In assessing the impact of these changes, we considered a number of uncertainties related to determining future participation and performance by ACOs in the Shared Savings Program.

Changes to the existing benchmark calculations described previously will benefit program cost savings by producing benchmarks with improved accuracy (most notably by limiting the effect of the regional benchmark adjustment to positive or negative 5 percent of the national per capita spending amount). However, such savings will be partly offset by increased shared savings payments to ACOs that will benefit from the changes to our benchmarking methodology to incorporate factors based on regional FFS expenditures beginning with the ACO's first agreement period, revise risk adjustment to include up to a 3 percent increase in average HCC risk score over the course of an agreement period, and blend national trend with regional trend when calculating ACO benchmarks. Such trade-offs reflect our intention to strengthen the balance between

[35] See for example, Brady Post, Tom Buchmueller, and Andrew M. Ryan. Vertical Integration of Hospitals and Physicians: Economic Theory and Empirical Evidence on Spending and Quality. *Medical Care Research and Review.* August 2017. *https://doi.org/10.1177/1077558717727834.* See also, Liaw WR, et al. Solo and Small Practices: A Vital, Diverse Part of Primary Care. *Ann Fam Med.* 2016;14(1):8–15. doi:10.1370/afm.1839.

[36] Neprash HT, Chernew ME & McWilliams JM. Little Evidence Exists to Support the Expectation That Providers Will Consolidate to Enter New Payment Models. *Health Affairs.* 2017; 36(2): 346–354. doi:10.1377/hlthaff.2016.0840.

[37] See for example, Mostashari, F. The Paradox of Size: How Small, Independent Practices Can Thrive in Value-Based Care. *Ann Fam Med.* 2016; 14(1):5–7. doi:10.1370/afm.1899.

rewarding ACOs for attainment of efficiency in an absolute sense in tandem with incentivizing continual improvement relative to an ACO's recent baseline.

More predictable relationships, that is, an ACO's knowledge of its costs relative to the FFS expenditures in its region used to adjust its benchmark, can allow risk-averse ACOs to successfully manage significant exposure to performance-based risk. However, the policies we are adopting in this final rule will limit regional adjustments so that they still incentivize low cost ACOs to take on risk while mitigating excessive windfall payments to ACOs that, for a variety of reasons, may be very low cost at baseline. The finalized policies—notably the reduction in the weight used to determine the regional adjustment for high cost ACOs to 15 percent and 25 percent, respectively, in the first 2 agreement periods in which the regional adjustment is applied—also increase the possibility that higher cost ACOs will find a reasonable business case to remain in the program and thereby continue to lower their cost over time.

We also considered the possibility that providers and suppliers will have differing responses to changing financial incentives offered by the program, including for example the varying levels of savings sharing rates and/or loss sharing limits defined for the BASIC and ENHANCED tracks. Participation decisions are expected to continue to be based largely on an ACO's expectation of the effect of rebasing and the regional adjustment on its ability to show spending below an expected future benchmark. We also considered the incentive for ACOs to participate under the highest level of risk and reward in the BASIC track or in the ENHANCED track in order to participate in an Advanced APM for purposes of the Quality Payment Program. Eligible clinicians in an ACO that is participating in an Advanced APM may become Qualifying APM Participants for a year if they receive a sufficient percentage of their payments for Part B covered professional services or a sufficient percentage of Medicare patients through the ACO.

We also gave consideration to the effect on program entry and renewal as a result of discontinuing Track 1 and Track 2, and offering instead the BASIC track (including the glide path for eligible ACOs) and ENHANCED track, including the option for ACOs currently under 3-year agreements for participation in Track 1, Track 2, and Track 3 to terminate their agreement to quickly enter a new agreement period under the BASIC track or the ENHANCED track. For example, if 2014 starters complete a second 3-year agreement period under Track 1 and are eligible to enter the BASIC track's glide path under a one-sided model in 2020, these ACOs could have 7 performance years under a one-sided model. Modeling indicates that while such allowance could slow the transition to risk for some ACOs that might otherwise have enough of a business case to make an immediate transition to performance-based risk, the longer glide path will likely result in greater overall program participation by the end of the projection period and marginally increase overall program savings. We also considered the effect on participation from the final policies that will permit ACOs to change their beneficiary assignment method selection prior to the start of each performance year, and allow ACOs in the BASIC track's glide path the option annually to elect to transition to a higher level of risk and reward within the glide path.

We also considered the potential effects of the final policies to promote participation by low revenue ACOs. By allowing new, low revenue ACOs to enter the BASIC track with several options for progressing under the BASIC track (for example taking 3 years with up to 40 percent sharing in savings without performance-based risk or immediately entering the maximum level of risk and potential reward under such track) and to continue their participation in the BASIC track for a subsequent agreement period (under the highest level of risk and potential reward), the new participation options that we are adopting in this final rule will offer low revenue ACOs a longer period under a more acceptable degree of risk given their revenue constraints, before transitioning to more significant risk exposure under the ENHANCED track.

Low revenue ACOs can still choose to enter the ENHANCED track, and take on additional downside risk in exchange for the opportunity to share in a higher percentage of any savings. Such migration is likeliest for low revenue ACOs expecting a favorable regional adjustment to their rebased historical benchmark. The finalized policy of including the regional adjustment in the methodology for determining an ACO's benchmark for its first agreement period should help provide such ACOs the degree of certainty necessary for earlier election of performance-based risk, while capping the amount of the regional adjustment at positive or negative 5 percent of national per capita expenditures for Parts A and B services for assignable beneficiaries will help CMS to avoid unnecessarily large windfall payments for ACOs that have already been properly incentivized to aggressively participate with a regional adjustment set at the level of the cap.

In addition, we considered related impacts of the changes to the program's benchmarking methodology, as used to establish, adjust, update and reset the ACO's benchmark. For renewing ACOs—especially ACOs that are concerned about competition from operating in a highly competitive ACO market or ACOs that make up a large portion of their market—several changes are likely to help mitigate concerns about the long term business case of the model. Most notably, the use of a regional/national blend to determine the growth rates for the trend and update factors should reduce the degree to which ACO savings (and/or neighboring ACO savings) affect an ACO's own benchmark updates. Furthermore, the final policy of using full HCC risk ratios (with any increase capped at positive 3 percent but uncapped for decreases) regardless of the assignment status of a beneficiary should help to assuage concerns that risk adjustment could adversely affect an ACO that increasingly serves a higher morbidity population in its market.

To best reflect these uncertainties, we continue to utilize a stochastic model that incorporates assumed probability distributions for each of the key variables that will impact participation, changes in care delivery, and the overall financial impact of the Shared Savings Program. The model continues to employ historical baseline variation in trends for groups of beneficiaries assigned using the program's claim-based assignment methodology to simulate the effect of benchmark calculations as described in the June 2016 final rule (81 FR 38005 through 38007). We used several unique assumptions and assumption ranges in the updated model.

To estimate the number of ACOs that will participate in the program, we assumed that up to approximately 250 existing 2018 ACOs will be affected by the changing policies starting with a potential third agreement period beginning on July 1, 2019, or in 2020 or 2021. We also assumed that up to approximately 300 existing 2018 ACOs will be affected by the changing policies starting with a potential second agreement period beginning on July 1, 2019, in 2020, or 2021. In addition, between 20 and 50 new ACOs were assumed to form annually from 2019 through 2028.

We assumed ACO decision making regarding participation will reflect each ACO's updated circumstances including prior year performance as well as expected difference in spending in relation to future anticipated adjusted benchmark spending. Specific related assumptions are as follows:

For one, the potential that existing ACOs will renew under the policies in this final rule are related to expectations regarding the effect of the changes to the regional adjustment on the ACO's rebased benchmark. ACOs expecting adjusted historical benchmarks from 2 to 10 percent higher than actual per capita cost are assumed to select the highest-risk option (Track 3 in the baseline or the ENHANCED track under this final rule); such range is reduced for second or later rebasing under the policies in the final rule to 1 to 5 percent higher than actual per capita cost. Otherwise, ACOs expecting adjusted rebased benchmarks from 0 to 3 percent higher than actual per capita cost are assumed to select the Track 1+ Model (baseline) or Level E of the BASIC track (final rule). ACOs expecting adjusted rebased historical benchmarks from 0 to 5 percent lower than actual per capita cost are expected not to renew unless another agreement in Track 1 is allowed (baseline), or are assumed to have between 15 and 65 percent chance of electing the BASIC track (final rule).

Second, all other renewal decisions are expected to follow the same assumptions as the preceding description except for the following cases. For the baseline scenario, a Track 1 ACO eligible for a second Track 1 agreement period during the projection period that does not otherwise select renewal in Track 3 or the Track 1+ Model will only renew in Track 1 if the ACO had earned shared savings in either of the first 2 years of the existing agreement period or if the ACO anticipates an adjusted historical benchmark no lower than 3 percent below actual cost. For the final rule scenario, an ACO not otherwise choosing the ENHANCED track will only renew in the BASIC track if the following conditions were met: (1) The ACO expects an adjusted historical benchmark no lower than 0 to 3 percent below actual cost; (2) the ACO did not experience a loss in the existing agreement period; and (3) the ACO is low revenue (as high revenue ACOs will be precluded from renewing for a second agreement period in the BASIC track).

Third, we used the following approach to make assumptions about participation decisions for ACOs encountering a shared loss. An adjusted shared loss (L) was calculated by netting out the total expected incentive payments that will be made under the Quality Payment Program to ACO providers/suppliers who are Qualifying APM Participants during the payment year that is 2 years after the performance year for which the ACO is accountable for shared losses. In each trial a random variable (X) was chosen from a skewed distribution ranging from zero to 3 percent of benchmark (mode 1 percent of benchmark) for determining participation decisions affecting years prior to 2023 (alternatively X was sampled from the range zero to 2 percent of benchmark with mode of 0.5 percent of benchmark for participation decisions for 2023 and subsequent years when the incentive to participate in an Advanced APM as a Qualifying APM Participant is reduced). If $L>X$ then the ACO is assumed to drop out. Otherwise, if $L>X/2$ then the ACO is assumed to have a 50 to 100 percent chance of leaving the program. Otherwise, the ACO has a relatively smaller loss ($L<X/2$) and the ACO is assumed to have roughly double the chance of persisting relative to the prior scenario.

Fourth, we used the following approach to make assumptions about the potential that ACOs in the BASIC track will elect early transition to Level E of the BASIC track. An adjusted shared savings (S) was calculated by adding the total potential incentive payments expected under the Quality Payment Program (2 years after the potential transition to Level E) to ACO providers/suppliers who will expect to become Qualifying APM Participants (due to the transition to Level E) to the ACO's most recent shared savings—with such sum expressed as a percentage of benchmark. In each trial a random variable (Y) was chosen from a skewed distribution ranging from 1 to 4 percent of benchmark (mode 2 percent of benchmark). If $S>Y$, then the ACO is assumed to elect immediate transition to Level E of the BASIC track for the following performance year.

Assumptions for ACO effects on claims costs reflect a combination of factors. First, ACO revenue is assumed to be inversely proportional to historical savings achieved prior to implementation of the provisions of this final rule. This is because, as noted earlier, low revenue ACOs (that tend to have low ACO participant Medicare FFS revenue relative to the ACO's benchmark spending) have generally shown stronger financial performance over the first 5 years of the program than high revenue ACOs. For existing low revenue ACOs, baseline savings immediately prior to renewal under the policies in this final rule are estimated to range from 1 to 4 percent of spending accounted for by the program benchmark, with an additional spillover effect on extra-benchmark spending accounting for an additional 25 to 75 percent savings relative to the directly assumed savings on benchmark spending. Conversely, existing high revenue ACOs are assumed to have baseline savings of only 25 percent of the assumed baseline savings for low revenue ACOs, as previously enumerated.

Residual baseline savings are then potentially assumed to gradually diminish if participation ends. Specifically, zero to 100 percent of baseline savings are assumed to erode by the fifth year after an existing ACO drops out of participation as a Medicare ACO.

Alternatively, future savings for each type of ACO are assumed to scale according to the incentive presented by each potential track of participation. Future savings in Track 3 or the ENHANCED track during the projection period for low revenue ACOs are assumed to range from zero to 4 percent of benchmark spending for existing ACOs and 1 to 5 percent of benchmark spending for new ACOs. High revenue ACOs are assumed to have zero to 100 percent of the savings assumed for low revenue ACOs. Ultimate savings are assumed to phase in over 5 to 10 years for all types of ACOs. Savings for the Track 1+ Model or the BASIC track, Levels with downside risk, are assumed to be 50 to 100 percent of the savings assumed for Track 3/ENHANCED track (as previously described). Savings for the BASIC track performance years without downside risk, or Track 1 are assumed to be 30 to 70 percent of the savings assumed for Track 3/ENHANCED track.

We also assumed that selection effects will implicitly include the renewal decisions of ACOs simulated in the model. Further assumptions included the following: (1) The adoption in this final rule of full HCC adjustment (capped at positive 3 percent) allows each ACO to increase its benchmark according to a skewed distribution from -0.5 to 3 percent with mode 0.5 percent (where the lower bound has been marginally decreased to -0.5 percent from the proposed rule assumption of a 0.0 percent to account for our decision not to finalize the proposed floor on downward HCC adjustment in this final rule); and (2) for both the baseline and final rule scenarios, each ACO is assumed to be able to influence its comparable

spending to region by zero to 5 percent (skewed with mode 1 percent) for example via changes in ACO participant TIN composition or other methods to direct assignment in a favorable manner given the financial incentive from the regional adjustment to the benchmark.

Comment: A few commenters stated that CMS has provided no citations or other details as to the source of the data used in the proposed rule. One commenter suggested that in the future CMS should conduct a formal evaluation of the Shared Savings Program, and share the evaluation with stakeholders in advance of rulemaking to aid in the preparation of comments.

Response: CMS makes data publically available on CMS websites in several formats to provide ACOs, providers, and researchers with information to evaluate the Shared Savings Program. CMS provides Public Use Files describing Shared Savings Program Quality and Finance Performance, ACO participation, and Regional FFS expenditures, assignment, and CMS-Hierarchical Condition Category (HCC) prospective risk scores. CMS also makes Research Identifiable Files that include information for every beneficiary assigned to a Shared Savings Program ACO and for all providers participating in a Shared Savings Program ACO, available for a fee through the Research Data Assistance Center (*www.resdac.org*) to researchers who have obtained an appropriate Data Use Agreement. CMS also included summaries of several program evaluations in the Regulatory Impact Analysis for the August 2018 proposed rule. We will continue to consider making additional data and evaluation results publically available during future rulemaking and at such other times as may be appropriate.

c. Detailed Stochastic Modeling Results

A simulation model involving the assumptions and assumption ranges described in the previous section was constructed and a total of 1,000 randomized trials were produced. Table 17 summarizes the annual projected mean impact (projected differences under the changes to the program finalized in this rule relative to the current baseline program) on ACO participation, federal spending on Parts A and B claims, ACO earnings from shared savings net of shared losses, and the net federal impact (effect on claims net of the change in shared savings/shared losses payments). The overall average projection of the impact of the final program changes is approximately $2.9 billion in lower overall federal spending over 10 years from 2019 through 2028 relative to a baseline that assumes the prior program regulations remain in effect through this ten year period. The 10th and 90th percentiles from the range of projected 10-year impacts range from −$5.14 billion to −$680 million in lower spending, respectively. The mean impact is comprised of about −$950 million in lower claims spending, $2.43 billion in reduced shared savings payments, net of shared loss receipts, and approximately $490 million in additional incentive payments made under the Quality Payment Program to additional ACO providers/suppliers expected to become Qualifying APM Participants (mainly for performance years prior to 2023 where the Quality Payment Program incentive made during the corresponding payment year is 5 percent of Physician Fee Schedule revenue).

TABLE 17—10-YEAR ESTIMATED IMPACT OF FINAL RULE ON ACO PARTICIPATION, SPENDING ON PARTS A AND B CLAIMS, ACO SHARED SAVINGS NET OF LOSSES AND NET FEDERAL IMPACT

(Impact on claims, ACO shared savings, Advanced APM incentive payments, and net federal spending are expressed in $ millions)

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

The overall drop in expected participation is mainly due to the expectation that the program will be less likely to attract new ACO formation in future years as the number of risk-free years available to new ACOs will be reduced from 6 years (two, 3-year agreement periods in current Track 1) to up to 3 years for low revenue ACOs or 2 years for high revenue ACOs in the BASIC track. However, the changes are expected to increase continued participation from existing ACOs, especially those currently facing mandated transition to risk in a third agreement period starting in 2019, 2020, or 2021 under the existing regulations, as well as certain other higher cost ACOs for which the moderated capped regional adjustment will not reduce their benchmark as significantly as prescribed by current regulation.

Relatively small increases in spending in years 2019 through 2021 are largely driven by expectations for more favorable risk adjustment to ACOs' updated benchmarks and a temporary delay in migration of certain existing ACOs to performance-based risk. Savings grow significantly in the out years as a greater share of existing ACOs eventually transition to higher levels of risk and the savings from capping the regional adjustment to the benchmark grow because ACOs would increasingly have become eligible for higher uncapped adjustments under the baseline in the later years of the projection period.

This final rule includes changes from the proposed rule that improve the business case for certain ACOs to renew or join the program. Such changes include higher shared savings rates in certain years of the BASIC track, reduced weights on regional adjustments to benchmarks for ACOs with per capita spending above their region, and the option for new low-revenue ACOs to participate in 3 risk-free years under the BASIC track before moving to BASIC level E for the last 2 years of their first agreement period. Relative to the proposed rule projection, these changes are estimated to increase participation by existing and new ACOs and thereby increase the projected savings on claims to a greater extent than we anticipate overall shared savings payments will grow. Such changes account for most of the difference (roughly $500 million greater net program savings) between the proposed rule projection of $2.24 billion in net savings and the final rule projected net savings of $2.9 billion. The remainder of the difference (about $150 million in increased net program savings) results from our decision not to finalize the proposed negative 3 percent cap on risk adjustment if an ACO's assigned population average HCC risk score declined beyond such point over the course of its agreement period.

The mean projection of $2.9 billion reduced overall federal spending is a reasonable point estimate of the impact of the changes to the Shared Savings Program included in this final rule during the period between 2019 through 2028. However, we emphasize the possibility of outcomes differing substantially from the median estimate, as illustrated by the estimate

distribution. Accordingly, this RIA presents the costs and benefits of this final rule to the best of our ability. As further data emerges and is analyzed, we may improve the precision of future financial impact estimates.

To the extent that the changes to the Shared Savings Program being made through the final rule will result in net savings or costs to Part B of Medicare, revenues from Part B beneficiary premiums will also be correspondingly lower or higher. In addition, because MA payment rates depend on the level of spending within traditional FFS Medicare, savings or costs arising from these changes to the Shared Savings Program will result in corresponding adjustments to MA payment rates. Neither of these secondary impacts has been included in the analysis shown.

Comment: A number of comments highlighted the proposed reduced 25 percent maximum savings sharing rates in certain performance years under the glide path in the BASIC track and/or the use of regional spending to adjust ACO benchmarks in their first agreement period as problematic for generating optimal program participation.

Response: The proposed changes were intended to move more ACOs into performance-based risk and thereby promote stronger efforts to improve the efficiency of care delivery. We have noted other proposed (and now final) changes that many commenters support, like the change in the risk adjustment methodology and the extended 5-year agreement periods, as changes that are expected to help many ACOs to manage such transition successfully. Furthermore, the final rule increases the sharing rate in one-sided models under the BASIC track to 40 percent and in all two-sided models under the BASIC track to 50 percent, thereby improving the incentive for ACOs to begin such transition along the glide path under the BASIC track. Additionally, the final rule moderates the regional adjustment applied in the first and second agreement periods when determining the benchmark for ACOs with average spending higher than their region by reducing the applicable adjustment weight from 25 percent to 15 percent in the first agreement period and from 35 percent to 25 percent in the second agreement period. This change is also anticipated to improve the likelihood a wider mix of ACOs will successfully make the transition to performance-based risk.

Comment: One commenter was concerned by projections that many ACOs would leave the program, and fewer would choose to enter it.

Response: The final rule includes changes that are expected to improve the likelihood of participation from ACOs that may not otherwise have joined the program or renewed their participation, including ACOs already reaching the end of their 6 years of Track 1 participation that would, without the changes in this rule, face higher risk in Track 2 or Track 3 than what will be required under the BASIC track glide path. Other changes including implementing HCC risk adjustment with a 3 percent cap on increases, reducing the weight of the regional adjustment for ACOs that are higher cost than their region, and extending the agreement period from 3 years to 5 years, are expected to offer a more appealing business case for certain ACOs to participate. As a result we are now projecting only 36 fewer ACOs participating by the end of the 10 year projection period compared to the projection of 109 fewer in the proposed rule, and we actually expect higher overall participation in the first half of the projection period when many existing ACOs would have already faced the end of their available time in the one-sided model under Track 1 under the prior participation options.

2. Effects on Beneficiaries

Earlier in this analysis we describe evidence for the Shared Savings Program's positive effects on the efficiency of care delivered by ACO providers/suppliers over the first 5 years of the program. Reduced unnecessary utilization can lead to financial benefits for beneficiaries by way of lower Part B premiums or reduced out of pocket cost sharing or both. Certain beneficiaries may also benefit from the provision of in-kind items and services by ACOs that are reasonably connected to the beneficiary's medical care and are preventive care items or services or advance a clinical goal for the beneficiary. The value of care delivered to beneficiaries also depends on the quality of that care. Evidence indicates there have been incremental improvements in quality of care reported for ACO providers/suppliers. As previously noted in the Background section of this RIA, 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 consistently across PYs 2013 to 2016.

As explained in more detail previously, we believe the changes we are making in this final rule will provide additional incentives for ACOs to improve care management efforts and maintain program participation. In addition, ACOs with low baseline expenditures relative to their region are more likely to transition to and sustain participation in a risk track (either the BASIC track (Level E) or the ENHANCED track) in future agreement periods. Consequently, the changes in this rule will also benefit beneficiaries through greater beneficiary engagement and active participation in their care (via beneficiary incentives) and broader improvements in accountability and care coordination (such as through expanded use of telehealth services and extending eligibility for the waiver of the SNF 3-day rule to all ACOs accepting performance-based risk) than would occur in the absence of these changes. Lastly, we estimate that the net impacts on federal spending, as previously detailed, will correspond to savings to beneficiaries in the form of reductions in Part B premium payments of approximately $380 million over the 10 year projection period through 2028.

We intend to continue to analyze emerging program data to monitor for any potential unintended effect that the use of a regional adjustment (as modified in this final rule) to determine the historical benchmarks for additional cohorts of ACOs could potentially have on the incentive for ACOs to serve vulnerable populations (and for ACOs to maintain existing partnerships with providers and suppliers serving such populations).

3. Effects on Providers and Suppliers

As noted previously, the changes in this final rule aim to improve the ability for ACOs to transition to performance-based risk and provide higher value care. We believe the contemporaneous growth of ACO agreements with other payers is sufficiently mature (and invariably heterogeneous in structure) that it will not be materially affected by the changes to specific features of the Shared Savings Program that we are adopting in this final rule. Although the elimination of Track 1 is expected to ultimately reduce the overall number of ACOs participating in the program, this change might also create opportunities for more effective ACOs to step in and serve the beneficiaries who were previously assigned to other ACOs that leave the program. In addition, other new policies (including changes to HCC risk adjustment, longer 5-year agreement periods, gradual expansion of exposure to risk in the BASIC track, and allowing eligible low revenue ACOs to renew for a second agreement period in Level E of the BASIC track) are expected to increase the number of existing and new ACOs that ultimately make a sustained

transition to performance-based risk. Such transition is expected to help ACOs more effectively engage with their ACO participants and ACO providers/suppliers in transforming care delivery.

Changes to the methodology for making regional adjustments to the historical benchmark are expected to affect ACOs differently depending on their circumstances. Similar to observations described in the June 2016 final rule, certain ACOs that joined the program from a high expenditure baseline relative to their region and that showed savings under the first and/or second agreement period benchmark methodology that did not include a regional adjustment will likely expect lower benchmarks and greater likelihood of shared losses under a methodology that includes a 15 percent weight on the regional expenditure adjustment in the first agreement period in which the adjustment is applied, and higher weights in subsequent agreement periods. Additionally, certain ACOs that joined the program with relatively low expenditures relative to their region might expect significant shared savings payments even if they failed to generate shared savings in their first agreement period prior to the application of the regional adjustment to the benchmark. Limiting the weight of the regional adjustment to the benchmark to 50 percent, reducing the weight for high cost ACOs to 15 percent in the first agreement period and 25 percent in the second agreement period, and capping the adjustment at positive or negative 5 percent of national average per capita FFS spending for assignable beneficiaries, will serve to preserve the incentive for low cost ACOs to maintain participation and accept performance-based risk while also improving the business case for high cost ACOs to continue to participate and drive their costs down toward parity with or even below their regional average. Therefore, the changes to the regional adjustment are expected to increase participation by ACOs in risk tracks by broadening the mix of ACOs with plausible business cases for participation without creating excessive residual windfall payments to ACOs with very low baseline costs or unreasonably punitive decreases to benchmarks for ACOs serving very high cost populations at baseline. The increase in sustained participation in performance-based risk is evidenced by the projection of $490 million in increased incentive payments under the Quality Payment Program to ACO providers/suppliers achieving status as Qualifying APM Participants due to increased ACO participation in risk-based tracks of the Shared Savings Program. Conversely, the projected $2.43 billion in lower overall 10-year shared savings payments to ACOs reflects the prudent limitations that will be placed on the regional adjustment to the benchmark for ACOs that are very low cost relative to their region prior to rebasing.

Several other changes are expected to provide certain ACOs with stronger business cases for participating in the program. Transition to full HCC risk adjustment (capped at positive 3 percent) regardless of beneficiary assignment status is expected to increase the resulting adjusted updated benchmark for the average ACO and better reflect actual shifts in assigned patient morbidity. Blending national with regional trend for ACO benchmark calculations is also expected to mitigate some ACOs' concerns regarding the problem of hyper competition against other ACOs in highly-saturated markets, as well as the potential that large ACOs will drive the regional trend they are ultimately measured against. These factors contribute to the expanded participation expected in performance-based risk and the resulting increase in savings on claims through more efficient care delivery. In this final rule we are making modifications to certain elements of the proposed rule, including increasing the shared savings rates in certain years of the BASIC track and reducing the weight on the regional adjustment for high cost ACOs; such changes are estimated to increase overall program net savings by bolstering participation and thereby reducing claims costs more significantly than the resulting increases in overall shared savings payments to ACOs.

We have made program data available that can help stakeholders evaluate the impact the final rule changes, as previously described, may have on individual ACOs in various markets. The Center for Medicare (CM) has created standard analytical files incorporating factors based on regional FFS expenditures (currently available for CYs 2014, 2015, 2016, and 2017) that specifically tabulate—(1) aggregate expenditure and risk score data for assignable beneficiaries by county; and (2) the number of beneficiaries assigned to ACOs, by county. These public use files can be obtained at the following website *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/SSPACO/SSP_Benchmark_Rebasing.html.*

CM has also created standard analytical files that contain ACO-specific metrics as well as summarized beneficiary and provider information for each performance year of the Shared Savings Program. These files 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 public use files for 2013 through 2017 can be obtained at the following website *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/SSPACO/index.html.*

Comment: Several commenters expressed concern about the potential negative impact on Medicare beneficiaries and entire communities that depend on hospitals and health systems to treat all patients, including uninsured and underinsured populations, of the proposed requirement that high revenue ACOs participate under an accelerated path to performance-based risk. In particular, one commenter explained that not-for-profit providers may be challenged to provide the same level of charity care to their indigent patients under this approach.

Response: We acknowledge the particular challenges faced by safety net providers and the considerations these organizations must weigh in assessing their readiness for program participation in general, and participation under performance-based risk more specifically. We note that all ACO providers/suppliers continue to receive traditional Medicare FFS payments under Parts A and B, and may receive from additional payments the ACO if the ACO meets specified quality and savings requirements of the Shared Savings Program. We have observed that ACOs that serve high rates of dual eligible Medicare and Medicaid beneficiaries have shared savings at higher rate than other ACOs. As a result, we believe the dually eligible Medicare and Medicaid population represents a significant opportunity for ACOs to generate savings through care coordination and quality improvement. We also note that clinicians, including safety net clinicians that participate in Advanced APMs may qualify for incentive payments, which could provide additional resources to safety net providers.

We believe that the combination of policies included as part of the redesign of the Shared Savings Program we are finalizing with this final rule will support ACOs, including ACOs that serve the most complex patients and ACOs with safety net providers as ACO participants, as they transition to

performance-based risk. In particular, we believe the availability of the BASIC track's glide path for ACOs inexperienced with performance-based risk Medicare ACO initiatives, longer agreement periods (of at least 5 years instead of 3-year agreements) which could allow for more predictable historical benchmarks and therefore greater opportunity for ACOs to achieve savings against these benchmarks, a new coding intensity adjustment that permits moderate risk score growth, and lower regional adjustments to historical benchmarks for ACOs that are determined to be higher spending compared to their regional service area will support ACOs as they transition to performance-based risk. Further, additional program flexibilities we are finalizing with this final rule, such as broader access to a SNF 3-day rule waiver and expanded use of telehealth services for eligible ACOs under a two-sided model (see section II.B. of this final rule) could also support care coordination and the delivery of care by safety net providers and the populations they serve.

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. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most physician practices, hospitals, and other providers are small entities either by virtue of their nonprofit status or by qualifying as a small business under the Small Business Administration's size standards (revenues of less than $7.5 to $38.5 million in any 1 year; NAIC Sector–62 series). States and individuals are not included in the definition of a small entity. For details, see the Small Business Administration's website at *http://www.sba.gov/content/small-business-size-standards.* For purposes of the RFA, approximately 95 percent of physicians are considered to be small entities. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the Physician Fee Schedule.

Although the Shared Savings Program is a voluntary program and payments for individual items and services will continue to be made on a FFS basis, we acknowledge that the program can affect many small entities and have developed our rules and regulations accordingly in order to minimize costs and administrative burden on such entities as well as to maximize their opportunity to participate. (For example: Networks of individual practices of ACO professionals are eligible to form an ACO; the use of an MSR under Level A and Level B of the BASIC track, and, if elected by the ACO, under the ENHANCED track and Levels C through E of the BASIC track, that varies by the size of the ACO's population and is calculated based on confidence intervals so that smaller ACOs have relatively lower MSRs; and low revenue ACOs may remain under reduced downside risk in a second agreement period under Level E of the BASIC track).

Small entities are both allowed and encouraged to participate in the Shared Savings Program, provided the ACO has a minimum of 5,000 assigned beneficiaries, thereby potentially realizing the economic benefits of receiving shared savings resulting from the utilization of enhanced and efficient systems of care and care coordination. Therefore, a solo, small physician practice or other small entity may realize economic benefits as a function of participating in this program and the utilization of enhanced clinical systems integration, which otherwise may not have been possible. We believe the policies included in this final rule may further encourage participation by small entities in existing ACOs that may otherwise not find it possible to quickly assume the much higher exposure to downside risk required under the ENHANCED track. Specifically, we believe our policy of allowing eligible low revenue ACOs up to 2 agreement periods in the BASIC track (with the second agreement period at the highest level of risk and potential reward) where downside risk exposure is limited to a percentage of ACO participants' Medicare FFS revenue (capped at a percentage of the ACO's benchmark), and the option for new, low revenue ACOs to participate under one-sided risk for 3 performance years (or 4 performance years in the case of ACOs entering an agreement period beginning on July 1, 2019) in exchange for moving to the highest level of risk and potential reward under the BASIC track for the final two performance years in the agreement period, will support low revenue ACOs by permitting a gradual transition to performance-based risk.

As detailed in this RIA, total expected incentive payments made under the Quality Payment Program to Qualifying APM Participants are expected to increase by $490 million over the 2019 to 2028 period as a result of changes that will increase participation in the Shared Savings Program by certain ACOs and therefore increase the average small entity's earnings from such incentives. We also note that the final policy under which each agreement period will be extended to 5 years (or 6 years for ACOs entering a new agreement period on July 1, 2019) offers greater certainty to ACOs, including small entities, regarding their benchmark as they approach the higher levels of risk required in the higher levels of the BASIC track and under the ENHANCED track.

5. Effect on Small Rural Hospitals

Section 1102(b) of the Act requires us 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, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. Although the Shared Savings Program is a voluntary program, this final rule will have a significant impact on the operations of a substantial number of small rural hospitals. In the proposed rule, we sought comment 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. (We noted that the data currently available on the CMS website, as described in the Effects on Providers and Suppliers section, may be useful for commenters to estimate the effects of the proposed changes for their particular ACO and/or market.) We discuss comments related to the phase-in of regional adjustment weights in section II.D.3 of this final rule.

As discussed in section II.D of this final rule, we are finalizing changes to our regulations such that benchmark adjustments for regional spending are limited to at most a 50 percent weight, with reduced weights in initial agreement periods for ACOs that are high cost relative to their region. The amount of the regional adjustment will be capped for all ACOs at positive or negative 5 percent of national average per capita FFS spending for assignable beneficiaries. Given the variation that can exist across regions, the schedule of weights we are finalizing should recognize efficient rural providers, while providing more time for those rural providers and suppliers that care for high risk patients to come into line with regional spending and move to shared savings. Additionally, in this final rule we are revising our risk adjustment methodology to allow for full HCC risk adjustment (with a

positive 3 percent cap) regardless of beneficiary assignment status and making changes to the benchmarking methodology to provide for the use of a blend of national and regional trends in benchmark calculations. Such changes could help to provide a stronger business case for ACOs built around rural hospitals that may have otherwise been concerned about serving a higher-risk population in their region or driving the local trends in the region against which they will be compared.

In this final rule, we are also making revisions to our original proposal for determining ACO participation options based on a combination of factors (ACO participants' Medicare FFS revenue, and the ACO's experience with performance-based risk Medicare ACO initiatives) to allow use of a higher percentage in determining whether an ACO is a low revenue ACO versus high revenue ACO. As we discuss in section II.A.5.b of this final rule, under this approach we believe more ACOs will be identified as low revenue ACOs and therefore potentially eligible to remain in lower risk for longer, specifically to participate in the BASIC track for up to two, 5-year agreement periods, with the second agreement period in Level E. We believe these changes, in addition to the alternative participation option we are finalizing under which low revenue ACOs, that are legal entities without prior experience in the Shared Savings Program, may elect an additional year under a one-sided model of the BASIC track's glide path prior to transitioning to Level E (the highest level of risk and potential reward in the BASIC track), will provide a gentler pathway to performance-based risk for small, rural and physician-only ACOs.

6. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2018, that is approximately $150 million. This final rule does not include any mandate that will 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. Further, participation in this program is voluntary and is not mandated.

7. Regulatory Review Cost Estimation

We assume all 561 ACOs that participated in the Medicare Shared Savings Program during performance year 2018 will review on average half of this final rule. For example, it is possible that certain ACOs may limit review to issues related only to the BASIC track and not the ENHANCED track or rely on a partnership with a management company, health plan, trade association or other entity that reviews the final rule and advises multiple ACO partners. We used a similar approach to estimate the burden of reviewing the proposed rule. However, we acknowledged that this approach may understate or overstate the costs of reviewing this rule. We welcomed comments on the approach in estimating the number of entities reviewing the rule and the scope of the average review, but did not receive any comments on this issue.

Using the wage information from the Bureau of Labor Statistics for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $107.38 per hour, where the assumed hourly wage of $53.69 has been increased by a factor of 2 to account for fringe benefits.[38] Assuming an average reading speed of 250 words per minute, we estimate it will take approximately 9 hours for the staff to review half of this final rule. For each ACO the estimated cost is $966 (9 hours × $107.38 per hour). Therefore, we estimate the total cost of reviewing this final regulation is approximately $542,000 ($966.42 × 561 ACOs).

8. Other Impacts on Regulatory Burden

We estimate that extending the agreement period to 5 years may reduce certain administrative costs incurred by ACOs. In its review of the Physician Group Practice demonstration, GAO estimated the average entity spent $107,595 on initial startup for administrative processes. We assume roughly one-tenth of such total startup amount will represent the administrative expenses of renewal for an ACO entering a renewed agreement period ($10,760 per ACO). Therefore, we estimate extending the agreement period to 5 years will reduce ACO administrative burden by approximately $6 million over 10 years ($10,760 × 561 ACOs).

As we explained in the Regulatory Impact Analysis for the proposed rule, we did not believe that the proposed policies would otherwise materially impact the burden on ACOs for compliance with the requirements of the Shared Savings Program. We stated that the annual certification and application process would remain comparable to the existing program requirements (setting aside the change to 5-year agreement periods as noted in the previous paragraph). We also anticipate at most a modest additional burden for the modified beneficiary notification requirements under § 425.312, because ACOs and ACO participants will be able to utilize low cost options for notification, including, for example, email or electronic patient portals. To the extent that individual beneficiary notification causes additional beneficiaries to request personalized explanations from ACO representatives or participating providers and suppliers (beyond any such questions that would have arisen under the prior notification requirement), we assume on average 10 percent of assigned beneficiaries, once per agreement period, require five minute conversations that involve an ACO or ACO provider/supplier employee with hourly wage averaging $20, implying a total net added burden of approximately $3.3 million over ten years. We sought comment if stakeholders had reason to believe the proposed changes would materially change the burden of participation in the program that surpassed what we have estimated, as described previously.

Comment: Some comments cited the reduced sharing rates (as low as 25 percent) that were proposed for certain performance years in the BASIC track as problematic for ACOs estimating whether the cost of participation would be worth the potential return. Also cited as a barrier for continued participation was the cost of taking on performance-based risk for ACOs that may not have the experience or capital available for such transition.

Response: Elements of the proposed program redesign that were intended to help ACOs manage the transition to performance-based risk are bolstered by modifications to our original proposals that we are making in this final rule, including increasing the BASIC track maximum sharing rate percentages to 40 percent (Level A and B) and 50 percent (Level C, D, E), respectively, and allowing new legal entities that are determined to be low revenue ACOs participating in the BASIC track's glide path, to elect to remain in a one-sided model for up to 3 performance years (or 4 performance years in the case of ACOs entering an agreement period beginning on July 1, 2019) before transitioning to Level E for the final 2 performance years of their agreement period. Additionally, in this final rule we have increased the threshold used to determine low revenue ACOs (by comparing ACO participants' total Medicare Parts A and B FFS revenue to total Medicare Parts A

[38] Occupational Employment Statistics available online at *https://www.bls.gov/oes/current/oes_nat.htm.*

and B FFS expenditures for the ACO's assigned beneficiaries) from 25 to 35 percent. Increasing the threshold will allow additional ACOs the option to remain in lower levels of performance-based risk for a second agreement period. Additionally, as described in section II.A.6.c. of this final rule, we are finalizing our proposed requirements regarding repayment mechanism arrangement amounts with modifications that are designed to reduce the burden of these arrangements on ACOs participating in Level C, Level D, or Level E of the BASIC track and the ENHANCED track, including any low-revenue ACOs in those tracks. Lastly, the benchmarks for ACOs that are high cost in relation to their region will not be reduced as quickly as originally proposed because a lower regional adjustment weight of 15 percent (compared to the 25 percent weight originally proposed) will be used to calculate the historical benchmark for such an ACO in the first agreement period in which the regional adjustment applies.

Comment: We received several comments suggesting that CMS does not fully recognize the administrative and upfront investment required to participate in the Shared Savings Program. One commenter urged CMS to allow ACOs additional time under a one-sided model in order to ensure that they have an opportunity in which to earn a return on their initial investments. One commenter suggested CMS place a proportionate emphasis on both quality and financial improvements when evaluating when ACOs are ready to undertake additional risk and allow time for ACOs to experience a return on initial investments.

Response: We acknowledge that ACOs make upfront investments such as in care delivery infrastructure, data analytics and staffing, with the intent of saving money through improvements in care management and coordination. In developing our policies for the Shared Savings Program, including the new policies we are adopting in this final rule, we have sought to minimize costs and administrative burden as well as to maximize opportunities to participate. For example, we estimate that extending the agreement period to 5 years may reduce certain administrative costs incurred by ACOs. Additionally, we expect certain other policies will help to offset upfront investments and bolster the business case for ACOs to continue participation in the Shared Savings Program, including the ability for ACO providers/suppliers to qualify for Advanced APM incentive payments, the application of a positive adjustment to the ACO's benchmark if its spending is below regional spending, and the use of risk adjustment methodology that allows for limited upward adjustments if the average HCC risk score rises for the ACO assigned population.

D. Alternatives Considered

A particularly significant element of the changes to the benchmarking methodology included in this final rule is the final policy that limits the effect of regional adjustments on rebased ACO historical benchmarks via a cap of positive or negative 5 percent of national average per capita FFS expenditures for assignable beneficiaries. If the final policy were amended to remove this cap then shared savings payments to low cost ACOs and selective participation decisions would increase the cost of the final rule by roughly $4.4 billion such that the estimated $2.9 billion savings relative to current regulation baseline (as estimated for this final rule in the previous sections) would instead be projected as a $1.5 billion cost.

Another alternative considered would have been to push back the first agreement periods under the proposed new participation options and all other applicable changes to a January 1, 2020 start date. This would avoid the complexity of a July 1, 2019 midyear start date. ACOs otherwise eligible to renew their participation in the program in 2019 would be offered a 1-year extension under their current agreement periods. This alternative would have had differing impacts on federal spending.

Forgoing the proposed July 1, 2019 start date and providing for the next available start date of January 1, 2020, would have likely marginally increased spending on claims through a combination of factors. In addition, this approach would have delayed, by 6 months, the transition into performance-based risk for certain ACOs whose current agreement periods will end on December 31, 2018. Forgoing the proposed July 1, 2019 start date likely also would have caused a temporary increase in overall shared savings payments to such ACOs during 2019 because of the additional year lag between the historical baseline expenditures and the 2019 performance year expenditures under the extended agreement period. However, this alternative would also have had a slightly greater effect in reducing Federal spending in later years through a combination of factors. Under this approach, the third historical benchmark year of the subsequent agreement period for such ACOs would have been CY 2019 rather than CY 2018, as will be the case under the finalized July 1, 2019 start date. The use of historical expenditures from 2017 through 2019, rather than 2016 through 2018, to determine the benchmark for these ACOs would have marginally reduced the cumulative variation affecting benchmark accuracy in 2024, the final year of these ACOs' first agreement period under the policies in this final rule. We would have also anticipated a reduction in incentive payments made under the Quality Payment Program in 2021 (which are based on participation by eligible clinicians in Advanced APMs during 2019) by delaying the transition to performance-based risk for certain ACOs to 2020 instead of July 1, 2019.

We also considered the potential impact of adopting the alternative beneficiary assignment methodology that was discussed in the proposed rule, under which ACOs would be allowed to elect a beneficiary opt-in based assignment methodology supplemented by a modified claims-based assignment methodology for beneficiaries who have received the plurality of their primary care and at least seven primary care services, from one or more ACO professionals in the ACO during the applicable assignment window and voluntary alignment. However, significant uncertainties potentially impacting the program in offsetting ways made projecting the impact difficult, and we chose not to adopt a beneficiary opt-in assignment methodology at this time. Although it is possible that ACOs electing such methodology could more effectively target care management to more engaged and/or needier subpopulations of patients, it is also possible that such targeting could deter ACOs from deploying more comprehensive care delivery reform across a wider mix of patients served by ACO providers/suppliers. It is also unclear if many ACOs would see value in a more restrictive assignment approach as they may be hesitant to voluntarily reduce their overall number of assigned beneficiaries and consequently lower their total benchmark spending and the magnitude of potential shared savings. Furthermore, it is not currently empirically possible to determine if the potential method for adjusting benchmark expenditures that was described in the proposed rule would provide sufficient accuracy in setting spending targets or if it could be vulnerable to higher claims variation and/or bias because of the selective

nature of beneficiaries who opt in, voluntarily align, or meet the modified claims-based assignment criteria in order to be assigned to the ACO. Such uncertainties and challenges may be likely to dissuade ACOs from electing such alternative assignment methodology over the existing options rooted in a broader claims-based assignment methodology supplemented by voluntary alignment, which current experience shows generally duplicates assignment for a subset of beneficiaries that would have been assigned via the existing claims-based assignment methodology. We note that although some commenters supported a hybrid assignment approach using opt-in and claims-based assignment (often confusing opt-in with the current voluntary alignment process), most commenters disagreed with this approach. Most of the commenters raised operational and administrative concerns in recruiting beneficiaries and putting in place the systems (both IT support systems and personnel) to support this approach. If few ACOs were to elect this potential alternative assignment methodology then the impact on program spending would also be minimal.

E. Compliance With Requirements of Section 1899(i)(3)(B) of the Act

Certain policies, including both existing policies and the new policies we are adopting in this final rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished to Medicare FFS beneficiaries. Section 1899(i)(3)(B) of the Act requires that such other payment model must not result in additional program expenditures. Policies falling under the authority of section 1899(i)(3) of the Act include—(1) performance-based risk; (2) refining the calculation of national expenditures used to update the historical benchmark to reflect the assignable subpopulation of total FFS enrollment; (3) updating benchmarks with a blend of regional and national trends as opposed to the national average absolute growth in per capita spending; (4) reconciling the two 6-month performance years during 2019 based on expenditures for all of CY 2019, and pro-rating any resulting shared savings or shared losses; and (5) adjusting performance year expenditures to remove IME, DSH, and uncompensated care payments.

A comparison was constructed between the projected impact of the payment methodology that incorporates all changes and a hypothetical baseline payment methodology that excludes the elements described previously that require section 1899(i)(3) of the Act authority—most importantly performance-based risk in the ENHANCED track and Levels C, D, and E of the BASIC track and updating benchmarks using a blend of regional and national trends. The hypothetical baseline was assumed to include adjustments allowed under section 1899(d)(1)(B)(ii) of the Act including the up to 50 percent weight used in calculating the regional adjustment to the ACO's rebased historical benchmark, as finalized in this rule (depending on the number of rebasings and the direction of the adjustment), capped at positive or negative 5 percent of national average per capita FFS expenditures for assignable beneficiaries. The stochastic model and associated assumptions described previously in this section were adapted to reflect a higher range of potential participation given the perpetually sharing-only incentive structure of the hypothetical baseline model. Such analysis estimated approximately $4 billion greater average net program savings under the alternative payment model that includes all policies that require the authority of section 1899(i)(3) of Act than will be expected under the hypothetical baseline in total over the 2019 to 2028 projection period. The alternative payment model, as finalized in this rule, is projected to result in greater savings on benefit costs and reduced net payments to ACOs. In the final projection year, the alternative payment model is estimated to have 10 percent greater savings on benefit costs, 15 percent lower spending on net shared savings payments to ACOs, with 39 percent reduced overall ACO participation compared to the hypothetical baseline model.

Participation in performance-based risk in the ENHANCED track and the higher levels of the BASIC track is assumed to improve the incentive for ACOs to increase the efficiency of care for beneficiaries (similar to the assumptions used in the modeling of the impacts, described previously). Such added savings are partly offset by lower participation associated with the requirement to transition to performance-based risk. Despite the higher maximum sharing rate of 75 percent in the ENHANCED track under the alternative payment model under section 1899(i)(3) of the Act, relative to the 50 percent maximum sharing rate assumed for the single one-sided risk track under the hypothetical baseline, shared savings payments are expected to be reduced relative to the hypothetical baseline because of lower expected participation resulting from the elimination of Track 1, more accurate benchmarks due to the incorporation of regional factors into the calculation of benchmark updates for all ACOs, and the cap on the regional benchmark adjustment of positive or negative 5 percent of the national average per capita FFS spending amount for assignable beneficiaries.

We will reexamine this projection in the future to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied. In the event that we later determine that the payment model established under section 1899(i)(3) of the Act no longer meets this requirement, we will undertake additional notice and comment rulemaking to make adjustments to the payment model to assure continued compliance with the statutory requirements.

F. Accounting Statement and Table

As required by OMB Circular A–4 under Executive Order 12866, in Table 18, we have prepared an accounting statement showing the change in—(1) net federal monetary transfers; (2) shared savings payments to ACOs net of shared loss payments from ACOs; and (3) incentive payments made under the Quality Payment Program to additional ACO providers/suppliers expected to become Qualifying APM Participants from 2019 to 2028 who would not have been expected to achieve such status absent the changes we are adopting in this final rule.

TABLE 18—ACCOUNTING STATEMENT ESTIMATED IMPACTS (CYs 2019–2028)

Category	Primary Estimate	Minimum Estimate	Maximum Estimate	Source Citation (RIA, preamble, etc.)
Transfers From the Federal Government to ACOs				
Annualized monetized: Discount rate: 7%	-230.7 million	57.2 million	-510.6 million	Table 17
Annualized monetized: Discount rate: 3%	-263.6 million	32.7 million	-553.4 million	

Notes: Negative values reflect reduction in federal net cost resulting from care management by ACOs. Estimates may be a combination of benefits and transfers. To the extent that the incentives created by Medicare payments change the amount of resources society uses in providing medical care, the more accurate categorization of effects will be as costs (positive values) or benefits/cost savings (negative values), rather than as transfers.

G. Regulatory Reform Analysis Under Executive Order 13771

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. The modifications in this final rule are expected to primarily have effects on transfers via lower claims spending and shared savings outlays as described previously in this regulatory impact analysis. However these modifications are also anticipated to marginally reduce the administrative burden on participating ACOs by roughly $2.16 million over 10 years (as detailed previously in this RIA) which corresponds to an annualized net cost savings of $126,000 when discounted at 7 percent relative to year 2016; therefore this final rule, will be considered a deregulatory action under Executive Order 13771.

H. Conclusion

The analysis in this section, together with the remainder of this preamble, provides a regulatory impact analysis. As a result of this final rule, the median estimate of the financial impact of the Shared Savings Program for CYs 2019 through 2028 will be net federal savings of $2.9 billion greater than the expected savings if no changes were made. Although this is the best estimate of the financial impact of the Shared Savings Program during CYs 2019 through 2028, a relatively wide range of possible outcomes exists. While a small fraction of trials projected significant increases in program spending, over 90 percent of the stochastic trials resulted in significant overall spending decreases over 10 years, with the 10th and 90th percentiles of the estimated distribution showing a net decrease in spending of $680 million and $5.14 billion, respectively.

Overall, our analysis projects that faster transition from one-sided model agreements—tempered by the option for eligible ACOs of a gentler exposure to downside risk calculated as a percentage of ACO participants' total Medicare Parts A and B FFS revenue and capped at a percentage of the ACO's benchmark—can affect broader participation in performance-based risk in the Shared Savings Program and reduce overall claims costs. A second key driver of estimated net savings is the reduction in shared savings payments from the new limitation on the amount of the regional adjustment to the ACO's historical benchmark. Such reduction in overall shared savings payments is projected to result despite the benefit of higher net adjustments expected for a larger number of ACOs from the use of a simpler HCC risk adjustment methodology, the blending of national and regional trends for benchmark calculations, and longer 5-year agreement periods that allow ACOs a longer horizon from which to benefit from efficiency gains before benchmark rebasing.

Therefore, the final changes are expected to improve the incentive for ACOs to invest in effective care management efforts, increase the number of ACOs participating under performance-based risk by discontinuing Track 1 and Track 2, and offering instead a BASIC track (which includes a glide path from a one-sided model to performance-based risk for eligible ACOs) or the ENHANCED track (based on the current design of Track 3), reduce the number of ACOs with poor financial and quality performance (by eliminating Track 1, requiring faster transition to performance-based risk, limiting high revenue ACOs to 1 agreement period in the BASIC track and low revenue ACOs to 2 agreement periods in the BASIC track (second agreement period at Level E), and increasing the monitoring of ACO financial performance), and result in greater overall gains in savings on FFS benefit claims costs while decreasing expected shared savings payments to ACOs.

We intend to monitor emerging results for ACO effects on claims costs, changing participation (including risk for increased costs due to high performing ACOs selecting to participate in a track (or a payment model within a track) with greater rewards), and unforeseen bias in benchmark adjustments due to diagnosis coding intensity shifts.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

VI. Effective Date Exception

According to 5 U.S.C. 801, a major rule may be effective 60 days after the date of publication in the **Federal Register** which allows for Congressional review, unless there is good cause for an earlier effective date under section 808(2). Good cause can be found when the procedures within section 801 are impracticable, unnecessary, or contrary to the public interest, in which case the rule shall take effect at a time as determined by the Federal agency promulgating the rule.

In this final rule we are finalizing a July 1, 2019 agreement start date for the redesigned participation options. This allows ACOs whose agreement periods expire December 31, 2018 and who extended their agreement for a 6-month performance year from January 1, 2019, through June 30, 2019, to renew for a new agreement period beginning July 1, 2019 to continue their participation in the program without interruption.

CMS will offer an application cycle for a one-time new agreement period

start date of July 1, 2019. To ensure ACOs have sufficient time to apply, and for CMS to adequately review these applications, the application cycle activities must begin in January 2019 with a notice of intent to apply, and application submission must occur by February 22, 2019.

Allowing for the final policies to become effective 60 days after the publication of this final rule would provide ACOs with less time to submit their applications and correct deficiencies, contract their provider networks, and establish repayment mechanisms. We may need to delay and shorten the application review period, allowing less time for applicants to correct deficiencies and bring their organizations into compliance with new program rules and requirements. This delay as a result of a March 1, 2019 effective date would be impracticable because it could prevent ACOs whose agreement periods expire June 30, 2019 from completing the renewal process and as a result may leave no other option for these organizations than to conclude their participation in the program.

We also acknowledged that a delayed application due date for an agreement period beginning in 2019 could affect parties planning to participate in the Shared Savings Program for performance year 2019 and that are relying on the pre-participation waiver.

As a result we find the delay in the effective date of the rule until March 1, 2019 to be impracticable and unnecessary. We therefore find there is good cause for an exception to the effective date to be 45 days from the date of publication in the **Federal Register**.

List of Subjects in 42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 425 as set forth below:

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 1. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

■ 2. Section 425.20 is amended by adding in alphabetical order definitions for ''Experienced with performance-based risk Medicare ACO initiatives'', ''High revenue ACO'', ''Inexperienced with performance-based risk Medicare ACO initiatives'', ''Low revenue ACO''; ''Performance-based risk Medicare ACO initiative'', ''Re-entering ACO'', and ''Renewing ACO'' to read as follows:

§ 425.20 Definitions.

* * * * *

Experienced with performance-based risk Medicare ACO initiatives means an ACO that CMS determines meets the criteria in either paragraph (1) or (2) of this definition.

(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 as defined under this section, or that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e).

(2) Forty percent or more of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, as defined under this section, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e), in any of the 5 most recent performance years prior to the agreement start date.

* * * * *

High revenue ACO means an ACO whose total Medicare Parts A and B fee-for-service revenue of its ACO participants based on revenue for the most recent calendar year for which 12 months of data are available, is at least 35 percent of the total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries based on expenditures for the most recent calendar year for which 12 months of data are available.

* * * * *

Inexperienced with performance-based risk Medicare ACO initiatives means an ACO that CMS determines meets all of the following:

(1) The ACO is a legal entity that has not participated in any performance-based risk Medicare ACO initiative as defined under this section, and has not deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e).

(2) Less than 40 percent of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, as defined under this section, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e), in each of the 5 most recent performance years prior to the agreement start date.

Low revenue ACO means an ACO whose total Medicare Parts A and B fee-for-service revenue of its ACO participants based on revenue for the most recent calendar year for which 12 months of data are available, is less than 35 percent of the total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries based on expenditures for the most recent calendar year for which 12 months of data are available.

* * * * *

Performance-based risk Medicare ACO initiative means, for purposes of this part, an initiative implemented by CMS that requires an ACO to participate under a two-sided model during its agreement period, including the following options and initiatives:

(1) Participation options within the Shared Savings Program as follows:

(i) BASIC track (Levels A through E).

(ii) ENHANCED track.

(iii) Track 2.

(2) The Innovation Center ACO models under which an ACO accepts risk for shared losses as follows:

(i) Pioneer ACO Model.

(ii) Next Generation ACO Model.

(iii) Comprehensive ESRD Care Model two-sided risk tracks.

(iv) Track 1+ Model.

(3) Other initiatives involving two-sided risk as may be specified by CMS.

* * * * *

Re-entering ACO means 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, as defined in this section, that previously participated in the program and is applying to participate in the program after a break in participation, because it is either—

(i) An ACO whose participation agreement expired without having been renewed; or

(ii) 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.

Renewing ACO means 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.

* * * * *

§ 425.100 [Amended]

■ 3. Section 425.100 is amended—

■ a. In paragraph (b) by removing the phrase ''under § 425.604, § 425.606, § 425.609 or § 425.610'' and adding in its place the phrase ''under § 425.604, § 425.605, § 425.606, § 425.609 or § 425.610''; and

■ b. In paragraph (c) by removing the phrase ''under § 425.606, § 425.609 or § 425.610'' and adding in its place the phrase ''under § 425.605, § 425.606, § 425.609 or § 425.610''.

■ 4. Section 425.110 is amended by revising paragraph (b) to read as follows:

§ 425.110 Number of ACO professionals and beneficiaries.

* * * * *

(b) If at any time during the performance year, an ACO's assigned population falls below 5,000, the ACO may be subject to the actions described in §§ 425.216 and 425.218.

(1) While under a CAP, the ACO remains eligible for shared savings and liable for shared losses.

(2) If the ACO's assigned population is not at least 5,000 by the end of the performance year specified by CMS in its request for a CAP, CMS terminates the participation agreement and the ACO is not eligible to share in savings for that performance year.

(3) In determining financial performance for an ACO with fewer than 5,000 assigned beneficiaries, the MSR/MLR is calculated as follows:

(i) For ACOs with a variable MSR and MLR (if applicable), the MSR and MLR (if applicable) are set at a level consistent with the number of assigned beneficiaries.

(ii) For performance years starting before July 1, 2019, for ACOs with a fixed MSR/MLR, the MSR/MLR remains fixed at the level consistent with the choice of MSR and MLR that the ACO made at the start of the agreement period.

(iii) For performance years starting on July 1, 2019 and in subsequent years, for ACOs that selected a fixed MSR/MLR at the start of the agreement period or prior to entering a two-sided model during their agreement period, the MSR/MLR is calculated as follows:

(A) The MSR/MLR is set at a level based on the number of beneficiaries assigned to the ACO.

(*1*) The MSR is the same as the MSR that would apply in a one-sided model under § 425.604(b) (for Track 2 ACOs) or § 425.605(b)(1) (for BASIC track and ENHANCED track ACOs) and is based on the number of assigned beneficiaries.

(*2*) The MLR is equal to the negative MSR.

(B) The MSR and MLR revert to the fixed level previously selected by the ACO for any subsequent performance year in the agreement period in which the ACO's assigned beneficiary population is 5,000 or more.

§ 425.118 [Amended]

■ 5. Section 425.118 is amended in paragraph (b)(1)(iii) by removing the phrase ''screening performed under § 425.304(b)'' and adding in its place the phrase ''screening performed under § 425.305(a)''.

■ 6. Section 425.200 is amended—

■ a. By revising the heading for paragraph (b)(3), and revising paragraph (b)(3)(ii);

■ b. By adding paragraphs (b)(4) and (5);

■ c. By adding paragraph (c)(3);

■ d. By redesignating paragraphs (e)(1)(i) through (v) as paragraphs (e)(1)(ii) through (vi); and

■ e. By adding a new paragraph (e)(1)(i).

The revisions and additions read as follows:

§ 425.200 Participation agreement with CMS.

* * * * *

(b) * * *

(3) *For 2017 and 2018.** * *

(ii) The term of the participation agreement is 3 years, except for an ACO whose first agreement period in Track 1 began in 2014 or 2015, in which case the term of the ACO's initial agreement period under Track 1 (as described under § 425.604) may be extended, at the ACO's option, for an additional year for a total of 4 performance years if the conditions specified in paragraph (e) of this section are met.

(4) *For 2019.* (i) The start date is January 1, 2019, and the term of the participation agreement is 3 years for ACOs whose first agreement period began in 2015 and who deferred renewal of their participation agreement under paragraph (e) of this section; or

(ii) The start date is July 1, 2019, and the term of the participation agreement is 5 years and 6 months.

(5) *For 2020 and subsequent years.* (i) The start date is January 1 of that year; and

(ii) The term of the participation agreement is 5 years.

(c) * * *

(3) For an ACO that entered an agreement period with a start date of July 1, 2019, the ACO's first performance year of the agreement period is defined as the 6-month period between July 1, 2019, and December 31, 2019.

* * * * *

(e) * * *

(1) * * *

(i) The ACO's first agreement period in the Shared Savings Program under Track 1 began in 2014 or 2015.

* * * * *

■ 7. Section 425.202 is amended by adding introductory text after the heading of paragraph (b) to read as follows:

§ 425.202 Application procedures.

* * * * *

(b) *Condensed application form.* For determining eligibility for agreement periods beginning before July 1, 2019:

* * * * *

■ 8. Section 425.204 is amended—

■ a. By revising paragraph (f); and

■ b. In paragraph (g) introductory text by removing the phrase ''under § 425.602'' and adding in its place the phrase ''under § 425.601, § 425.602, or § 425.603''.

The revision reads as follows:

§ 425.204 Content of the application.

* * * * *

(f) *Assurance of ability to repay.* (1) An ACO must have the ability to repay all shared losses for which it may be liable under a two-sided model.

(2) An ACO that will participate in a two-sided model must establish one or more of the following repayment mechanisms in an amount and by a deadline specified by CMS in accordance with this section:

(i) An escrow account with an insured institution.

(ii) A surety bond from a company included on the U.S. Department of Treasury's List of Certified Companies.

(iii) A line of credit at an insured institution (as evidenced by a letter of credit that the Medicare program can draw upon).

(3) An ACO that will participate under a two-sided model of the Shared Savings Program must submit for CMS approval documentation that it is capable of repaying shared losses that it may incur during its agreement period, including details supporting the adequacy of the repayment mechanism.

(i) An ACO participating in Track 2 must demonstrate the adequacy of its repayment mechanism at such times as requested by CMS.

(ii) An ACO entering an agreement period in Levels C, D, or E of the BASIC track or the ENHANCED track 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.

(iii) An ACO entering an agreement period in Level A or Level B of the BASIC track 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, and at such other times as requested by CMS.

(iv) An ACO that has submitted a request to renew its participation agreement must submit as part of the renewal request documentation demonstrating the adequacy of the repayment mechanism that could be used to repay any shared losses incurred for performance years in the next agreement period. The repayment mechanism applicable to the new agreement period may be the same repayment mechanism currently used by the ACO, provided that the ACO submits documentation establishing that the amount and duration of the existing repayment mechanism have been revised to comply with paragraphs (f)(6)(i) and (ii) of this section.

(4) CMS calculates the amount of the repayment mechanism as follows:

(i) For a Track 2 ACO, the repayment mechanism amount must be equal to at least 1 percent of the total per capita Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries, based on expenditures used to calculate the benchmark for the applicable agreement period, as estimated by CMS at the time of application.

(ii) For a BASIC track or ENHANCED track ACO, the repayment mechanism amount must be equal to the lesser of the following:

(A) One percent of the total per capita Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available.

(B) Two percent of the total Medicare Parts A and B fee-for-service revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available.

(iii) For agreement periods beginning on or after July 1, 2019, CMS recalculates the ACO's repayment mechanism amount before the second and each subsequent performance year in the agreement period in accordance with this section based on the certified ACO participant list for the relevant performance year.

(A) If the recalculated repayment mechanism amount exceeds the existing repayment mechanism amount by at least 50 percent or $1,000,000, whichever is the lesser value, CMS notifies the ACO in writing that the amount of its repayment mechanism must be increased to the recalculated repayment mechanism amount.

(B) Within 90 days after receipt of such written notice from CMS, the ACO must submit for CMS approval documentation that the amount of its repayment mechanism has been increased to the amount specified by CMS.

(iv) In the case of an ACO that has submitted a request to renew its participation agreement and wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period, the amount of the repayment mechanism must be equal to the greater of the following:

(A) The amount calculated by CMS in accordance with paragraph (f)(4)(ii) of this section.

(B) The repayment mechanism amount that the ACO was required to maintain during the last performance year of the participation agreement it seeks to renew.

(5) After the repayment mechanism has been used to repay any portion of shared losses owed to CMS, the ACO must replenish the amount of funds available through the repayment mechanism within 90 days.

(6) The repayment mechanism must be in effect for the duration of the ACO's participation under a two-sided model plus 12 months following the conclusion of the agreement period, except as otherwise specified in this section.

(i) For an ACO that is establishing a new repayment mechanism to meet this requirement, the repayment mechanism must satisfy one of the following criteria:

(A) The repayment mechanism covers the entire duration of the ACO's participation under a two-sided risk model plus 12 months following the conclusion of the agreement period.

(B) The repayment mechanism covers a term of at least the first two performance years in which the ACO is participating under a two-sided model and provides for automatic, annual 12-month extensions of the repayment mechanism such that the repayment mechanism will eventually remain in effect for the duration of the agreement period plus 12 months following the conclusion of the agreement period.

(ii) For a renewing ACO that wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period, the existing repayment mechanism must be amended to meet one of the following criteria.

(A) The duration of the existing repayment mechanism is extended by an amount of time that covers the duration of the new agreement period plus 12 months following the conclusion of the new agreement period.

(B) The duration of the existing repayment mechanism is extended, if necessary, to cover a term of at least the first two performance years of the new agreement period and provides for automatic, annual 12-month extensions of the repayment mechanism such that the repayment mechanism will eventually remain in effect for the duration of the new agreement period plus 12 months following the conclusion of the new agreement period.

(iii) CMS may require the ACO to extend the duration of the repayment mechanism if necessary to ensure that the ACO fully repays CMS any shared losses for each of the performance years of the agreement period.

(iv) The repayment mechanism may be terminated at the earliest of the following conditions:

(A) The ACO has fully repaid CMS any shared losses owed for each of the performance years of the agreement period under a two-sided model.

(B) CMS has exhausted the amount reserved by the ACO's repayment mechanism and the arrangement does not need to be maintained to support the ACO's participation under the Shared Savings Program.

(C) 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.

* * * * *

§ 425.220 [Amended]

■ 9. Section 425.220 is amended in paragraph (a) by removing the phrase ''60 days'' and adding in its place the phrase ''30 days''.

■ 10. Section 425.221 is amended by revising paragraph (b) to read as follows:

§ 425.221 Close-out procedures and payment consequences of early termination.

* * * * *

(b) *Payment consequences of early termination.* (1) *Receipt of shared savings.* (i) Except as set forth in paragraph (b)(3)(i) of this section, an ACO that terminates its participation agreement under § 425.220 is eligible to receive shared savings for the performance year during which the termination becomes effective only if all of the following conditions are met:

(A) CMS designates or approves an effective date of termination of the last calendar day of the performance year.

(B) The ACO has completed all close-out procedures by the deadline specified by CMS.

(C) The ACO has satisfied the criteria for sharing in savings for the performance year.

(ii) If the participation agreement is terminated at any time by CMS under § 425.218, the ACO is not eligible to receive shared savings for the performance year during which the termination becomes effective.

(2) *Payment of shared losses.* (i) Except as set forth in paragraph (b)(3)(i) of this section, for performance years beginning before July 1, 2019, an ACO under a two-sided model is not liable for any shared losses if its participation agreement is terminated effective before the last calendar day of a performance year.

(ii) Except as set forth in paragraph (b)(3)(ii) of this section, for performance years beginning on July 1, 2019 and subsequent performance years, an ACO under a two-sided model is liable for a pro-rated share of any shared losses, as calculated in paragraph (b)(2)(iii) of this section, if its participation agreement is terminated effective before the last calendar day of a performance year.

(A) An ACO under a two-sided model that terminates its participation agreement under § 425.220 with an effective date of termination after June 30th of a 12-month performance year is liable for a pro-rated share of any shared losses determined for the performance year during which the termination becomes effective.

(B) An ACO under a two-sided model whose participation agreement is terminated by CMS under § 425.218 is liable for a pro-rated share of any shared losses determined for the performance year during which the termination becomes effective.

(iii) The pro-rated share of losses described in paragraph (b)(2)(ii) of this section is calculated as follows:

(A) In the case of a 12-month performance year, the shared losses incurred during the 12 months of the performance year are multiplied by the quotient equal to the number of months of participation in the program during the performance year, including the month in which the termination was effective, divided by 12.

(B) In the case of a 6-month performance year beginning July 1, 2019, the shared losses incurred during CY 2019 are multiplied by the quotient equal to the number of months of participation in the program during the performance year, including the month in which the termination was effective, divided by 12.

(3) *Exceptions.* (i) An ACO starting a 12-month performance year on January 1, 2019, that terminates its participation agreement with an effective date of termination of June 30, 2019, and that enters a new agreement period beginning on July 1, 2019, is eligible for pro-rated shared savings or liable for pro-rated shared losses for the 6-month period from January 1, 2019, through June 30, 2019, as determined in accordance with § 425.609.

(ii) An ACO under a two-sided model that terminates its participation agreement under § 425.220 during the 6-month performance year beginning July 1, 2019, with an effective date of termination prior to the last calendar day of the performance year is not liable for shared losses incurred during the performance year.

■ 11. Section 425.222 is amended by revising the section heading and paragraphs (a), (b), and (c) introductory text to read as follows:

§ 425.222 Eligibility to re-enter the program for agreement periods beginning before July 1, 2019.

(a) For purposes of determining the eligibility of a re-entering ACO to enter an agreement period beginning before July 1, 2019, the ACO may participate in the Shared Savings Program again only after the date on which the term of its original participation agreement would have expired if the ACO had not been terminated.

(b) For purposes of determining the eligibility of a re-entering ACO to enter an agreement period beginning before July 1, 2019, an ACO whose participation agreement was previously terminated must demonstrate in its application that it has corrected the deficiencies that caused it to be terminated from the Shared Savings Program and has processes in place to ensure that it remains in compliance with the terms of the new participation agreement.

(c) For purposes of determining the eligibility of a re-entering ACO to enter an agreement period beginning before July 1, 2019, an ACO whose participation agreement was previously terminated or expired without having been renewed may re-enter the program for a subsequent agreement period.

* * * * *

■ 12. Section 425.224 is amended—

■ a. By revising the section heading and paragraph (a);

■ b. By revising paragraph (b) heading and paragraphs (b)(1) introductory text and (b)(1)(ii);

■ c. By removing paragraphs (b)(1)(iv) and (v);

■ d. By redesignating paragraphs (b)(1)(iii) and (vi) as paragraphs (b)(1)(iv) and (v);

■ e. By adding a new paragraph (b)(1)(iii);

■ f. By revising newly redesignated paragraphs (b)(1)(iv) and (v);

■ g. In paragraph (b)(2) introductory text by removing the phrase ''Renewal requests'' and adding in its place the phrase ''Applications'';

■ h. In paragraph (b)(2)(i) by removing the phrase ''renewal request'' and adding in its place the phrase ''application''; and

■ i. In paragraphs (c)(1) and (2) introductory text by removing the phrase ''renewal request'' and adding in its place the phrase ''application''.

The revisions and addition read as follows:

§ 425.224 Application procedures for renewing ACOs and re-entering ACOs.

(a) *General rules.* A renewing ACO or a re-entering ACO may apply to enter a new participation agreement with CMS for participation in the Shared Savings Program.

(1) In order to obtain a determination regarding whether it meets the requirements to participate in the Shared Savings Program, the ACO must submit a complete application in the form and manner and by the deadline specified by CMS.

(2) An ACO executive who has the authority to legally bind the ACO must certify to the best of his or her knowledge, information, and belief that the information contained in the application is accurate, complete, and truthful.

(3) An ACO that seeks to enter a new participation agreement under the Shared Savings Program and was newly formed after March 23, 2010, as defined in the Antitrust Policy Statement, must agree that CMS can share a copy of its application with the Antitrust Agencies.

(4) The ACO must select a participation option in accordance with the requirements specified in § 425.600. Regardless of the date of termination or expiration of the participation agreement, a renewing ACO or re-entering ACO that was previously under a two-sided model, or a one-sided

model of the BASIC track's glide path (Level A or Level B), may only reapply for participation in a two-sided model.

(b) *Review of application.* (1) CMS determines whether to approve a renewing ACO's or re-entering ACO's application based on an evaluation of all of the following factors:

* * * * *

(ii) The ACO's history of noncompliance with the requirements of the Shared Savings Program, including, but not limited to, the following factors:

(A)(*1*) For an ACO that entered into a participation agreement for a 3-year period, we consider whether the ACO failed to meet the quality performance standard during 1 of the first 2 performance years of the previous agreement period.

(*2*) For an ACO that entered into a participation agreement for a period longer than 3 years, we consider whether the ACO failed to meet the quality performance standard in either of the following:

(*i*) In 2 consecutive performance years and was terminated as specified in § 425.316(c)(2).

(*ii*) For 2 or more performance years of the previous agreement period, regardless of whether the years are in consecutive order.

(B) For 2 performance years of the ACO's previous agreement period, regardless of whether the years are in consecutive order, whether the average per capita Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiary population exceeded its updated benchmark by an amount equal to or exceeding either of the following:

(*1*) The ACO's negative MSR, under a one-sided model.

(*2*) The ACO's MLR, under a two-sided model.

(C) Whether the ACO failed to repay shared losses in full within 90 days as required under subpart G of this part for any performance year of the ACO's previous agreement period in a two-sided model.

(D) For an ACO that has participated in a two-sided model authorized under section 1115A of the Act, whether the ACO failed to repay shared losses for any performance year as required under the terms of the ACO's participation agreement for such model.

(iii) Whether the ACO has demonstrated in its application that it has corrected the deficiencies that caused any noncompliance identified in paragraph (b)(1)(ii) of this section to occur, and any other factors that may have caused the ACO to be terminated from the Shared Savings Program, and has processes in place to ensure that it remains in compliance with the terms of the new participation agreement.

(iv) Whether the ACO has established that it is in compliance with the eligibility and other requirements of the Shared Savings Program to enter a new participation agreement, including the ability to repay losses by establishing an adequate repayment mechanism under § 425.204(f), if applicable.

(v) The results of a program integrity screening of the ACO, its ACO participants, and its ACO providers/suppliers (conducted in accordance with § 425.305(a)).

* * * * *

■ 13. Section 425.226 is added to subpart C to read as follows:

§ 425.226 Annual participation elections.

(a) *General.* This section applies to ACOs in agreement periods beginning on July 1, 2019, and in subsequent years. Before the start of a performance year, an ACO may make elections related to its participation in the Shared Savings Program, as specified in this section, effective at the start of the applicable performance year and for the remaining years of the agreement period, unless superseded by a later election in accordance with this section.

(1) *Selection of beneficiary assignment methodology.* An ACO may select the assignment methodology that CMS employs for assignment of beneficiaries under subpart E of this part. An ACO may select either of the following:

(i) Preliminary prospective assignment with retrospective reconciliation, as described in § 425.400(a)(2).

(ii) Prospective assignment, as described in § 425.400(a)(3).

(2) *Selection of BASIC track level.* An ACO participating under the BASIC track in the glide path may select a higher level of risk and potential reward, as provided in this section.

(i) An ACO participating under the BASIC track's glide path may elect to transition to a higher level of risk and potential reward within the glide path than the level of risk and potential reward that the ACO would be automatically transitioned to in the applicable year as specified in § 425.605(d)(1). The automatic transition to higher levels of risk and potential reward within the BASIC track's glide path continues to apply to all subsequent years of the agreement period in the BASIC track.

(ii) An ACO transitioning to a higher level of risk and potential reward under paragraph (a)(2)(i) of this section must meet all requirements to participate under the selected level of performance-based risk, including both of the following:

(A) Establishing an adequate repayment mechanism as specified under § 425.204(f).

(B) Selecting a MSR/MLR from the options specified under § 425.605(b).

(b) *Election procedures.* (1) All annual elections must be made in a form and manner and according to the timeframe established by CMS.

(2) ACO executive who has the authority to legally bind the ACO must certify the elections described in this section.

■ 14. Section 425.304 is revised to read as follows:

§ 425.304 Beneficiary incentives.

(a) *General.* (1) Except as set forth in this section, or as otherwise permitted by law, ACOs, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are prohibited from providing gifts or other remuneration to beneficiaries as inducements for receiving items or services from or remaining in, an ACO or with ACO providers/suppliers in a particular ACO or receiving items or services from ACO participants or ACO providers/suppliers.

(2) Nothing in this section shall be construed as prohibiting an ACO from using shared savings received under this part to cover the cost of an in-kind item or service or incentive payment provided to a beneficiary under paragraph (b) or (c) of this section.

(b) *In-kind incentives.* ACOs, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities may provide in-kind items or services to Medicare fee-for-service beneficiaries if all of the following conditions are satisfied:

(1) There is a reasonable connection between the items and services and the medical care of the beneficiary.

(2) The items or services are preventive care items or services or advance a clinical goal for the beneficiary, including adherence to a treatment regime, adherence to a drug regime, adherence to a follow-up care plan, or management of a chronic disease or condition.

(3) The in-kind item or service is not a Medicare-covered item or service for the beneficiary on the date the in-kind item or service is furnished to the beneficiary.

(c) *Monetary incentives*—(1) *General.* For performance years beginning on July 1, 2019 and for subsequent performance years, an ACO that is participating under Track 2, Levels C, D, or E of the BASIC track, or the ENHANCED track may, in accordance with this section, establish a beneficiary incentive program to provide monetary incentive payments to Medicare fee-for-service beneficiaries who receive a qualifying service.

(2) *Application procedures.* (i) To establish or reestablish a beneficiary incentive program, an ACO must submit a complete application in the form and manner and by a deadline specified by CMS.

(ii) CMS evaluates an ACO's application to determine whether the ACO satisfies the requirements of this section, and approves or denies the application.

(iii) If an ACO wishes to make a material change to its CMS-approved beneficiary incentive program, the ACO must submit a description of the material change to CMS in a form and manner and by a deadline specified by CMS. CMS will promptly evaluate the proposed material change and approve or reject it.

(3) *Beneficiary incentive program requirements.* An ACO must begin to operate its approved beneficiary incentive program beginning on July 1, 2019 or January 1 of the relevant performance year.

(i) *Duration.* (A) Subject to the termination provision at paragraph (c)(7) of this section, an ACO must operate its approved beneficiary incentive program for an initial period of 18 months in the case of an ACO approved to operate a beneficiary incentive program beginning on July 1, 2019, or 12 months in the case of an ACO approved to operate a beneficiary incentive program beginning on January 1 of a performance year.

(B) For each consecutive year that an ACO wishes to operate its beneficiary incentive program after the CMS-approved initial period, it must certify all of the following by a deadline specified by CMS:

(*1*) Its intent to continue to operate the beneficiary incentive program for the entirety of the relevant performance year.

(*2*) That the beneficiary incentive program meets all applicable requirements.

(ii) *Beneficiary eligibility.* A fee-for-service beneficiary is eligible to receive an incentive payment under a beneficiary incentive program if the beneficiary is assigned to the ACO through either of the following:

(A) Preliminary prospective assignment, as described in § 425.400(a)(2).

(B) Prospective assignment, as described in § 425.400(a)(3).

(iii) *Qualifying service.* For purposes of this section, a qualifying service is a primary care service (as defined in § 425.20) with respect to which coinsurance applies under Part B, if the service is furnished through an ACO by one of the following:

(A) An ACO professional who has a primary care specialty designation included in the definition of primary care physician under § 425.20.

(B) An ACO professional who is a physician assistant, nurse practitioner, or certified nurse specialist.

(C) A FQHC or RHC.

(iv) *Incentive payments.* (A) An ACO that establishes a beneficiary incentive program must furnish an incentive payment for each qualifying service furnished to a beneficiary described in paragraph (c)(3)(ii) of this section in accordance with this section.

(B) Each incentive payment made by an ACO under a beneficiary incentive program must satisfy all of the following conditions:

(*1*) The incentive payment is in the form of a check, debit card, or a traceable cash equivalent.

(*2*) The value of the incentive payment does not exceed $20, as adjusted annually by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year, rounded to the nearest whole dollar amount.

(*3*) The incentive payment is provided by the ACO to the beneficiary no later than 30 days after a qualifying service is furnished.

(C) An ACO must furnish incentive payments in the same amount to each eligible Medicare fee-for-service beneficiary without regard to enrollment of such beneficiary in a Medicare supplemental policy (described in section 1882(g)(1) of the Act), in a State Medicaid plan under title XIX or a waiver of such a plan, or in any other health insurance policy or health benefit plan.

(4) *Program integrity requirements*—(i) *Record retention.* An ACO that establishes a beneficiary incentive program must maintain records related to the beneficiary incentive program that include the following:

(A) Identification of each beneficiary that received an incentive payment, including beneficiary name and HICN or Medicare beneficiary identifier.

(B) The type and amount of each incentive payment made to each beneficiary.

(C) The date each beneficiary received a qualifying service, the corresponding HCPCS code for the qualifying service, and identification of the ACO provider/supplier that furnished the qualifying service.

(D) The date the ACO provided each incentive payment to each beneficiary.

(ii) *Source of funding.* (A) An ACO must not use funds from any entity or organization outside of the ACO to establish or operate a beneficiary incentive program.

(B) An ACO must not directly, through insurance, or otherwise, bill or otherwise shift the cost of establishing or operating a beneficiary incentive program to a Federal health care program.

(iii) *Beneficiary notifications.* An ACO or its ACO participants shall notify assigned beneficiaries of the availability of the beneficiary incentive program in accordance with § 425.312(b).

(iv) *Marketing prohibition.* Except for the beneficiary notifications required under this section, the beneficiary incentive program is not the subject of marketing materials and activities, including but not limited to, an advertisement or solicitation to a beneficiary or any potential patient whose care is paid for in whole or in part by a Federal health care program (as defined at 42 U.S.C. 1320a–7b(f)).

(5) *Effect on program calculations.* CMS disregards incentive payments made by an ACO under paragraph (c) of this section in calculating an ACO's benchmarks, estimated average per capita Medicare expenditures, and shared savings and losses.

(6) *Income exemptions.* Incentive payments made under a beneficiary incentive program are not considered income or resources or otherwise taken into account for purposes of either of the following:

(i) Determining eligibility for benefits or assistance (or the amount or extent of benefits or assistance) under any Federal program or under any State or local program financed in whole or in part with Federal funds.

(ii) Any Federal or State laws relating to taxation.

(7) *Termination.* CMS may require an ACO to terminate its beneficiary incentive program at any time for either of the following:

(i) Failure to comply with the requirements of this section.

(ii) Any of the grounds for ACO termination set forth in § 425.218(b).

■ 15. Section 425.305 is added to read as follows:

§ 425.305 Other program safeguards.

(a) *Screening of ACO applicants.* (1) ACOs, ACO participants, and ACO providers/suppliers are reviewed during the Shared Savings Program application process and periodically thereafter with regard to their program integrity history, including any history of Medicare program exclusions or other sanctions and affiliations with individuals or entities that have a history of program integrity issues.

(2) ACOs, ACO participants, or ACO providers/suppliers whose screening reveals a history of program integrity issues or affiliations with individuals or entities that have a history of program integrity issues may be subject to denial of their Shared Savings Program applications or the imposition of additional safeguards or assurances against program integrity risks.

(b) *Prohibition on certain required referrals and cost shifting.* ACOs, ACO participants, and ACO providers/suppliers are prohibited from doing the following:

(1) Conditioning the participation of ACO participants, ACO providers/suppliers, other individuals or entities performing functions or services related to ACO activities in the ACO on referrals of Federal health care program business that the ACO, its ACO participants, or ACO providers/suppliers or other individuals or entities performing functions or services related to ACO activities know or should know is being (or would be) provided to beneficiaries who are not assigned to the ACO.

(2) Requiring that beneficiaries be referred only to ACO participants or ACO providers/suppliers within the ACO or to any other provider or supplier, except that the prohibition does not apply to referrals made by employees or contractors who are operating within the scope of their employment or contractual arrangement to the employer or contracting entity, provided that the employees and contractors remain free to make referrals without restriction or limitation if the beneficiary expresses a preference for a different provider, practitioner, or supplier; the beneficiary's insurer determines the provider, practitioner, or supplier; or the referral is not in the beneficiary's best medical interests in the judgment of the referring party.

■ 16. Section 425.308 is amended by revising paragraph (b)(6) and adding paragraph (b)(7) to read as follows:

§ 425.308 Public reporting and transparency.

* * * * *

(b) * * *

(6) Use of payment rule waivers under § 425.612, if applicable, or telehealth services under § 425.613, if applicable, or both.

(7) Information about a beneficiary incentive program established under § 425.304(c), if applicable, including the following, for each performance year:

(i) Total number of beneficiaries who received an incentive payment.

(ii) Total number of incentive payments furnished.

(iii) HCPCS codes associated with any qualifying service for which an incentive payment was furnished.

(iv) Total value of all incentive payments furnished.

(v) Total of each type of incentive payment (for example, check or debit card) furnished.

* * * * *

■ 17. Section 425.310 is amended by revising paragraph (c)(3) to read as follows:

§ 425.310 Marketing requirements.

* * * * *

(c) * * *

(3) Comply with § 425.304 regarding beneficiary incentives.

* * * * *

■ 18. Section 425.312 is amended by revising the section heading and paragraph (a) and adding paragraph (b) to read as follows:

§ 425.312 Beneficiary notifications.

(a) *Notifications to fee-for-service beneficiaries.* (1) An ACO shall ensure that Medicare fee-for-service beneficiaries are notified about all of the following in the manner set forth in paragraph (a)(2) of this section:

(i) That each ACO participant and its ACO providers/suppliers are participating in the Shared Savings Program.

(ii) The beneficiary's opportunity to decline claims data sharing under § 425.708.

(iii) Beginning July 1, 2019, the beneficiary's ability to, and the process by which, he or she may identify or change identification of the individual he or she designated for purposes of voluntary alignment (as described in § 425.402(e)).

(2) Notification of the information specified in paragraph (a)(1) of this section must be carried out through the following methods:

(i) By an ACO participant posting signs in its facilities and, in settings in which beneficiaries receive primary care services, making standardized written notices available upon request.

(ii) During the performance year beginning on July 1, 2019 and each subsequent performance year, by an ACO or ACO participant providing each beneficiary with a standardized written notice prior to or at the first primary care visit of the performance year in the form and manner specified by CMS.

(b) *Beneficiary incentive program notifications.* (1) Beginning July 1, 2019, an ACO that operates a beneficiary incentive program under § 425.304(c) shall ensure that the ACO or its ACO participants notify assigned beneficiaries of the availability of the beneficiary incentive program, including a description of the qualifying services for which an assigned beneficiary is eligible to receive an incentive payment (as described in § 425.304(c)).

(2) Notification of the information specified in paragraph (b)(1) of this section must be carried out by an ACO or ACO participant during each relevant performance year by providing each assigned beneficiary with a standardized written notice prior to or at the first primary care visit of the performance year in the form and manner specified by CMS.

* * * * *

■ 19. Section 425.314 is amended by adding paragraph (a)(4) and revising paragraph (b)(1) to read as follows:

§ 425.314 Audits and record retention.

(a) * * *

(4) The ACO's operation of a beneficiary incentive program.

(b) * * *

(1) To maintain and give CMS, DHHS, the Comptroller General, the Federal Government or their designees access to all books, contracts, records, documents, and other evidence (including data related to Medicare utilization and costs, quality performance measures, shared savings distributions, information related to operation of a beneficiary incentive program, and other financial arrangements related to ACO activities) sufficient to enable the audit, evaluation, investigation, and inspection of the ACO's compliance with program requirements, quality of services performed, right to any shared savings payment, or obligation to repay losses, ability to bear the risk of potential losses, and ability to repay any losses to CMS.

* * * * *

§ 425.315 [Amended]

■ 20. Section 425.315 is amended in paragraph (a)(1)(ii) by removing the phrase ''§ 425.604(f), § 425.606(h), § 425.609(e) or § 425.610(h)'' and adding in its place the phrase ''§ 425.604(f), § 425.605(e), § 425.606(h), § 425.609(e) or § 425.610(h)''.

■ 21. Section 425.316 is amended by adding paragraph (d) to read as follows:

§ 425.316 Monitoring of ACOs.

* * * * *

(d) *Monitoring ACO financial performance.* (1) For performance years beginning on July 1, 2019 and subsequent performance years, CMS determines whether the Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries for the performance year 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.

(2) If the Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries for the performance year exceed the ACO's updated benchmark as specified in paragraph (d)(1) of this section, CMS may take any of the pre-termination actions set forth in § 425.216.

(3) If the Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries for the performance year exceed the ACO's updated benchmark as specified in paragraph (d)(1) of this section for another performance year of the agreement period, CMS may immediately or with advance notice terminate the ACO's participation agreement under § 425.218.

■ 22. Section 425.400 is amended—

■ a. By revising the headings for paragraphs (a)(2) and (3);

■ b. In paragraph (a)(3)(i) by removing the phrase ''under Track 3''; and

■ c. By adding paragraph (a)(4).

The revisions and addition read as follows:

§ 425.400 General.

(a) * * *

(2) *Preliminary prospective assignment with retrospective reconciliation.* * * *

(3) *Prospective assignment.* * * *

(4) *Assignment methodology applied to ACO.* (i) For agreement periods beginning before July 1, 2019, the applicable assignment methodology is determined based on track as specified in § 425.600(a).

(A) Preliminary prospective assignment with retrospective reconciliation as described in paragraph (a)(2) of this section applies to Track 1 and Track 2 ACOs.

(B) Prospective assignment as described in paragraph (a)(3) of this section applies to Track 3 ACOs.

(ii) For agreement periods beginning on July 1, 2019 and in subsequent years, an ACO may select the assignment methodology that CMS employs for assignment of beneficiaries under this subpart.

(A) An ACO may select either of the following:

(*1*) Preliminary prospective assignment with retrospective reconciliation, as described in paragraph (a)(2) of this section.

(*2*) Prospective assignment, as described in paragraph (a)(3) of this section.

(B) This selection is made prior to the start of each agreement period, and may be modified prior to the start of each performance year as specified in § 425.226.

* * * * *

§ 425.401 [Amended]

■ 23. Section 425.401 is amended in paragraph (b) introductory text by removing the phrase ''or at the end of CY 2019 as specified in § 425.609(b)(1)(ii)'' and adding in its place the phrase ''or at the end of CY 2019 as specified in § 425.609(b)(1)(ii) and (c)(1)(ii)''.

■ 24. Section 425.402 is amended by revising paragraph (e)(3)(i) to read as follows:

§ 425.402 Basic assignment methodology.

* * * * *

(e) * * *

(3) * * *

(i) Offering anything of value to the Medicare beneficiary as an inducement to influence the Medicare beneficiary's decision to designate or not to designate an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section. Any items or services provided in violation of paragraph (e)(3) of this section are not considered to have a reasonable connection to the medical care of the beneficiary, as required under § 425.304(b)(1).

* * * * *

§ 425.502 [Amended]

■ 25. Section 425.502 is amended in paragraph (e)(4)(v) by removing the phrase ''in the third year of the previous agreement period'' and adding in its place the phrase ''in the last year of the previous agreement period''.

■ 26. Section 425.600 is amended—

■ a. In paragraph (a) introductory text by removing the phrase ''For its initial agreement period, an ACO'' and adding in its place ''An ACO'';

■ b. By revising paragraphs (a)(1), (2) and (3);

■ c. By adding paragraph (a)(4);

■ d. By revising paragraphs (b) introductory text and (c); and

■ e. By adding paragraphs (d), (e) and (f).

The revisions and additions read as follows:

§ 425.600 Selection of risk model.

(a) * * *

(1) *Track 1.* For agreement periods beginning before July 1, 2019, an ACO in Track 1 operates under the one-sided model (as described under § 425.604) for the agreement period.

(2) *Track 2.* For agreement periods beginning before July 1, 2019, an ACO in Track 2 operates under a two-sided model (as described under § 425.606), sharing both savings and losses with the Medicare program for the agreement period.

(3) *ENHANCED track.* An ACO in the ENHANCED track operates under a two-sided model (as described under § 425.610), sharing both savings and losses with the Medicare program for the agreement period. For purposes of this part, all references to the ENHANCED track are deemed to include Track 3.

(4) *BASIC track.* For agreement periods beginning on July 1, 2019, and in subsequent years, an ACO in the BASIC track operates under either a one-sided model or a two-sided model (as described under § 425.605), either sharing savings only or sharing both savings and losses with the Medicare program, as specified in this paragraph (a)(4).

(i) *Levels of the BASIC track's glide path*—(A) *Phase-in of levels of the risk and reward.* Under the BASIC track's glide path, the level of risk and potential reward phases in over the course of the agreement period in the following order:

(*1*) *Level A.* The ACO operates under a one-sided model as described under § 425.605(d)(1)(i).

(*2*) *Level B.* The ACO operates under a one-sided model as described under § 425.605(d)(1)(ii).

(*3*) *Level C.* The ACO operates under a two-sided model as described under § 425.605(d)(1)(iii).

(*4*) *Level D.* The ACO operates under a two-sided model as described under § 425.605(d)(1)(iv).

(*5*) *Level E.* The ACO operates under a two-sided model as described under § 425.605(d)(1)(v).

(B) *Glide path progression.* (*1*) Experience in Track 1. (*i*) Except for an ACO that previously participated in Track 1 under paragraph (a)(1) of this section or a new ACO identified as a re-entering ACO because more than 50 percent of its ACO participants have recent prior experience in a Track 1 ACO, an ACO eligible to enter the BASIC track's glide path as determined

under paragraphs (d)(1)(i) and (d)(2)(i) of this section may elect to enter its agreement period at any of the levels of risk and potential reward available under paragraphs (a)(4)(i)(A)(*1*) through (*5*) of this section.

(*ii*) An ACO that previously participated in Track 1 under paragraph (a)(1) of this section or a new ACO identified as a re-entering ACO because more than 50 percent of its ACO participants have recent prior experience in a Track 1 ACO may elect to enter its agreement period at any of the levels of risk and potential reward available under paragraphs (a)(4)(i)(A)(*2*) through (*5*) of this section.

(*2*) Automatic advancement. Unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i), the ACO is automatically advanced to the next level of the BASIC track's glide path at the start of each subsequent performance year of the agreement period, if a higher level of risk and potential reward is available under the BASIC track.

(*i*) Exception for ACO entering the BASIC track's glide path for an agreement period beginning on July 1, 2019. The automatic advancement does not apply at the start of the second performance year for an ACO entering the BASIC track's glide path for an agreement period beginning on July 1, 2019. For performance year 2020, the ACO remains in the same level of the BASIC track's glide path that it entered for the July 1, 2019 through December 31, 2019 performance year, unless the ACO chooses to advance more quickly in accordance with § 425.226(a)(2)(i). The ACO is automatically advanced to the next level of the BASIC track's glide path at the start of performance year 2021 and all subsequent performance years of the agreement period.

(*ii*) Exception for new legal entity identified as a low revenue ACO. An exception is available for a low revenue ACO that is a new legal entity and is not identified as a re-entering ACO that enters the BASIC track's glide path at Level A under paragraph (a)(4)(i)(A)(*1*) of this section, and is automatically advanced to Level B under paragraph (a)(4)(i)(A)(*2*) of this section for performance year 2 (or performance 3 in the case of ACOs entering an agreement period beginning on July 1, 2019). Prior to the automatic advancement of the ACO to Level C under paragraph (a)(4)(i)(A)(*3*) of this section, the ACO may elect to remain in Level B under paragraph (a)(4)(i)(A)(*2*) of this section for performance year 3 (performance year 4 in the case of ACOs entering an agreement period beginning on July 1, 2019). In the case of an ACO that elects to remain in Level B for an additional performance year pursuant to the second sentence of paragraph (a)(4)(i)(B)(*2*)(*ii*) of this section, the ACO is automatically advanced to Level E under paragraph (a)(4)(i)(A)(*5*) of this section at the start of performance year 4 (or performance year 5 in the case of ACOs entering an agreement period beginning on July 1, 2019).

(*iii*) Prior to entering performance-based risk, an ACO must meet all requirements to participate under performance-based risk, including establishing an adequate repayment mechanism as specified under § 425.204(f) and selecting a MSR/MLR from the options specified under § 425.605(b).

(*3*) If the ACO fails to meet the requirements to participate under performance-based risk under paragraph (a)(4)(i)(B)(*2*)(*iii*) of this section, the agreement is terminated.

(*4*) If, in accordance with § 425.226(a)(2)(i), the ACO elects to transition to a higher level of risk and reward available under paragraphs (a)(4)(i)(A)(*3*) through (*5*) of this section, then the automatic transition to levels of higher risk and reward specified in paragraph (a)(4)(i)(B)(*2*) of this section applies to all subsequent performance years of the agreement period.

(ii) *Agreement period under Level E of the BASIC track.* If an ACO enters the BASIC track and is ineligible to participate under the glide path described in paragraph (a)(4)(i) of this section, as determined under paragraph (d) of this section, Level E as described in paragraph (a)(4)(i)(A)(*5*) of this section applies to all performance years of the agreement period.

(b) For agreement periods beginning before July 1, 2019, ACOs may operate under the one-sided model for a maximum of 2 agreement periods. An ACO may not operate under the one-sided model for a second agreement period unless the—

* * * * *

(c) For agreement periods beginning before July 1, 2019, an ACO experiencing a net loss during a previous agreement period may reapply to participate under the conditions in § 425.202(a), except the ACO must also identify in its application the cause(s) for the net loss and specify what safeguards are in place to enable the ACO to potentially achieve savings in its next agreement period.

(d) For agreement periods beginning on July 1, 2019, and in subsequent years, CMS determines an ACO's eligibility for the Shared Savings Program participation options specified in paragraph (a) of this section as follows:

(1) If an ACO is identified as a high revenue ACO, the ACO is eligible for the participation options indicated in paragraph (a) of this section as follows:

(i) If the ACO is determined to be inexperienced with performance-based risk Medicare ACO initiatives, the ACO may enter either the BASIC track's glide path at any of the levels of risk and potential reward available under paragraphs (a)(4)(i)(A)(*1*) through (*5*) of this section, except as provided in paragraph (a)(4)(i)(B) of this section, or the ENHANCED track under paragraph (a)(3) of this section.

(ii) If the ACO is determined to be experienced with performance-based risk Medicare ACO initiatives:

(A) The ACO may enter the ENHANCED track under paragraph (a)(3) of this section except as provided in paragraph (d)(1)(ii)(B) of this section.

(B) An ACO in a first or second agreement period beginning in 2016 or 2017 identified as experienced with performance-based risk Medicare ACO initiatives based on participation in the Track 1+ Model may renew for a consecutive agreement period beginning on July 1, 2019, or January 1, 2020 (respectively), under either the BASIC track Level E under paragraph (a)(4)(i)(A)(*5*) of this section, or the ENHANCED track under paragraph (a)(3) of this section.

(2) If an ACO is identified as a low revenue ACO, the ACO is eligible for the participation options indicated in paragraph (a) of this section as follows:

(i) If the ACO is determined to be inexperienced with performance-based risk Medicare ACO initiatives, the ACO may enter either the BASIC track's glide path at any of the levels of risk and potential reward available under paragraphs (a)(4)(i)(A)(*1*) through (*5*) of this section, except as provided in paragraph (a)(4)(i)(B) of this section, or the ENHANCED track under paragraph (a)(3) of this section.

(ii) If the ACO is determined to be experienced with performance-based risk Medicare ACO initiatives, the ACO may enter under either the BASIC track Level E under paragraph (a)(4)(i)(A)(*5*) of this section, except as provided in paragraph (d)(3) of this section, or the ENHANCED track under paragraph (a)(3) of this section.

(3) Low revenue ACOs may participate under the BASIC track for a maximum of two agreement periods. A low revenue ACO may only participate in the BASIC track for a second agreement period if it satisfies either of the following:

(i) The ACO is the same legal entity as a current or previous ACO that previously entered into a participation agreement for participation in the BASIC track only one time.

(ii) For a new ACO identified as a re-entering ACO, the ACO in which the majority of the new ACO's participants were participating previously entered into a participation agreement for participation in the BASIC track only one time.

(e) CMS monitors low revenue ACOs identified as experienced with performance-based risk Medicare ACO initiatives, during an agreement period in the BASIC track, for changes in the revenue of ACO participants that would cause the ACO to be considered a high revenue ACO and ineligible for participation in the BASIC track. If the ACO meets the definition of a high revenue ACO (as specified in § 425.20)—

(1) The ACO is permitted to complete the remainder of its current performance year under the BASIC track, but is ineligible to continue participation in the BASIC track after the end of that performance year if it continues to meet the definition of a high revenue ACO; and

(2) CMS takes compliance action as specified in §§ 425.216 and 425.218, up to and including termination of the participation agreement, to ensure the ACO does not continue in the BASIC track for subsequent performance years of the agreement period if it continues to meet the definition of a high revenue ACO.

(f) For agreement periods beginning on July 1, 2019, and in subsequent years, CMS determines the agreement period an ACO is entering for purposes of applying program requirements that phase-in over multiple agreement periods, as follows:

(1) An ACO entering an initial agreement period is considered to be entering a first agreement period in the Shared Savings Program.

(2) A re-entering ACO is considered to be entering a new agreement period in the Shared Savings Program as follows—

(i) An ACO whose participation agreement expired without having been renewed re-enters the program under the next consecutive agreement period in the Shared Savings Program;

(ii) An ACO whose participation agreement was terminated under § 425.218 or § 425.220 re-enters the program at the start of the same agreement period in which it was participating at the time of termination from the Shared Savings Program, beginning with the first performance year of that agreement period; or

(iii) A new ACO identified as a re-entering ACO enters the program in an agreement period that is determined based on the prior participation of the ACO in which the majority of the new ACO's participants were participating.

(A) If the participation agreement of the ACO used in this determination expired without having been renewed or was terminated, the agreement period of the re-entering ACO is determined in accordance with paragraph (f)(2)(i) or (ii) of this section, as applicable.

(B) If the ACO used in this determination is currently participating in the program, the new ACO is considered to be entering into the same agreement period as this currently participating ACO, beginning with the first performance year of that agreement period.

(3) A renewing ACO is considered to be entering the next consecutive agreement period in the Shared Savings Program.

(4) For purposes of this paragraph (f), program requirements that phase in over multiple agreement periods are as follows:

(i) The quality performance standard as described in § 425.502(a).

(ii) The weight used in calculating the regional adjustment to the ACO's historical benchmark as described in § 425.601(f).

(iii) The use of equal weights to weight each benchmark year as specified in § 425.601(e).

■ 27. Section 425.601 is added to read as follows:

§ 425.601 Establishing, adjusting, and updating the benchmark for agreement periods beginning on July 1, 2019, and in subsequent years.

(a) *Computing per capita Medicare Part A and Part B benchmark expenditures for an ACO's first agreement period.* For agreement periods beginning on July 1, 2019, and in subsequent years, in computing an ACO's historical benchmark for its first agreement period under the Shared Savings Program, CMS determines the per capita Parts A and B fee-for-service expenditures for beneficiaries that would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period using the ACO participant TINs identified before the start of the agreement period as required under § 425.118(a) and the beneficiary assignment methodology selected by the ACO for the first performance year of the agreement period as required under § 425.226(a)(1). CMS does all of the following:

(1) Calculates the payment amounts included in Parts A and B fee-for-service claims using a 3-month claims run out with a completion factor.

(i) This calculation excludes indirect medical education (IME) and disproportionate share hospital (DSH) payments.

(ii) This calculation includes individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(2) Makes separate expenditure calculations for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(3) Adjusts expenditures for changes in severity and case mix using prospective HCC risk scores.

(4) Truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries identified for the 12-month calendar year corresponding to each benchmark year in order to minimize variation from catastrophically large claims.

(5) Trends forward expenditures for each benchmark year (BY1 and BY2) to the third benchmark year (BY3) dollars using a blend of national and regional growth rates.

(i) To trend forward the benchmark, CMS makes separate calculations for expenditure categories for each of the following populations of beneficiaries:

(A) ESRD.

(B) Disabled.

(C) Aged/dual eligible Medicare and Medicaid beneficiaries.

(D) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(ii) National growth rates are computed using CMS Office of the Actuary national Medicare expenditure data for each of the years making up the historical benchmark for assignable beneficiaries identified for the 12-month calendar year corresponding to each benchmark year.

(iii) Regional growth rates are computed using expenditures for the ACO's regional service area for each of the years making up the historical benchmark as follows:

(A) Determine the counties included in the ACO's regional service area based on the ACO's assigned beneficiary population for the relevant benchmark year.

(B) Determine the ACO's regional expenditures as specified under paragraphs (c) and (d) of this section.

(iv) The national and regional growth rates are blended together by taking a weighted average of the two. The weight applied to the—

(A) National growth rate is calculated as the share of assignable beneficiaries in the ACO's regional service area for BY3 that are assigned to the ACO in BY3, as calculated in paragraph (a)(5)(v) of this section; and

(B) Regional growth rate is equal to 1 minus the weight applied to the national growth rate.

(v) CMS calculates the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO by doing all of the following:

(A) Calculating the county-level share of assignable beneficiaries that are assigned to the ACO for each county in the ACO's regional service area.

(B) Weighting the county-level shares according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries residing in the county in relation to the ACO's total number of assigned beneficiaries.

(C) Aggregating the weighted county-level shares for all counties in the ACO's regional service area.

(6) Restates BY1 and BY2 trended and risk adjusted expenditures using BY3 proportions of ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(7) Weights each year of the benchmark for an ACO's initial agreement period using the following percentages:

(i) BY3 at 60 percent.

(ii) BY2 at 30 percent.

(iii) BY1 at 10 percent.

(8) Adjusts the historical benchmark based on the ACO's regional service area expenditures, making separate calculations for the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. CMS does all of the following:

(i) Calculates an average per capita amount of expenditures for the ACO's regional service area as follows:

(A) Determines the counties included in the ACO's regional service area based on the ACO's BY3 assigned beneficiary population.

(B) Determines the ACO's regional expenditures as specified under paragraphs (c) and (d) of this section for BY3.

(C) Adjusts for differences in severity and case mix between the ACO's assigned beneficiary population and the assignable beneficiary population for the ACO's regional service area identified for the 12-month calendar year that corresponds to BY3.

(ii) Calculates the adjustment as follows:

(A) Determines the difference between the average per capita amount of expenditures for the ACO's regional service area as specified under paragraph (a)(8)(i) of this section and the average per capita amount of the ACO's historical benchmark determined under paragraphs (a)(1) through (7) of this section, for each of the following populations of beneficiaries:

(*1*) ESRD.

(*2*) Disabled.

(*3*) Aged/dual eligible for Medicare and Medicaid.

(*4*) Aged/non-dual eligible for Medicare and Medicaid.

(B) Applies a percentage, as determined in paragraph (f) of this section.

(C) Caps the per capita dollar amount for each Medicare enrollment type (ESRD, Disabled, Aged/dual eligible Medicare and Medicaid beneficiaries, Aged/non-dual eligible Medicare and Medicaid beneficiaries) calculated under paragraph (a)(8)(ii)(B) of this section at a dollar amount equal to 5 percent of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary.

(*1*) For positive adjustments, the per capita dollar amount for a Medicare enrollment type is capped at 5 percent of the national per capita expenditure amount for the enrollment type for BY3.

(*2*) For negative adjustments, the per capita dollar amount for a Medicare enrollment type is capped at negative 5 percent of the national per capita expenditure amount for the enrollment type for BY3.

(9) For the second and each subsequent performance year during the term of the agreement period, the ACO's benchmark is adjusted in accordance with § 425.118(b) for the addition and removal of ACO participants or ACO providers/suppliers, for a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), or both. To adjust the benchmark, CMS does the following:

(i) Takes into account the expenditures of beneficiaries who would have been assigned to the ACO under the ACO's most recent beneficiary assignment methodology selection in any of the 3 most recent years prior to the start of the agreement period using the most recent certified ACO participant list for the relevant performance year.

(ii) Redetermines the regional adjustment amount under paragraph (a)(8) of this section, according to the ACO's assigned beneficiaries for BY3 resulting from the ACO's most recent certified ACO participant list, the ACO's beneficiary assignment methodology selection under § 425.226(a)(1) for the relevant performance year, or both.

(10) The historical benchmark is further adjusted at the time of reconciliation for a performance year to account for changes in severity and case mix of the ACO's assigned beneficiary population as described under §§ 425.605(a), 425.609(c), and 425.610(a).

(b) *Updating the benchmark.* For all agreement periods beginning on July 1, 2019, and in subsequent years, CMS updates the historical benchmark annually for each year of the agreement period using a blend of national and regional growth rates.

(1) To update the benchmark, CMS makes separate calculations for expenditure categories for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) National growth rates are computed using CMS Office of the Actuary national Medicare expenditure data for BY3 and the performance year for assignable beneficiaries identified for the 12-month calendar year corresponding to each year.

(3) Regional growth rates are computed using expenditures for the ACO's regional service area for BY3 and the performance year, computed as follows:

(i) Determine the counties included in the ACO's regional service area based on the ACO's assigned beneficiary population for the year.

(ii) Determine the ACO's regional expenditures as specified under paragraphs (c) and (d) of this section.

(4) The national and regional growth rates are blended together by taking a weighted average of the two. The weight applied to the—

(i) National growth rate is calculated as the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO for the applicable performance year as specified in paragraph (a)(5)(v) of this section; and

(ii) Regional growth rate is equal to 1 minus the weight applied to the national growth rate.

(c) *Calculating county expenditures.* For all agreement periods beginning on July 1, 2019, and in subsequent years, CMS does all of the following to determine risk adjusted county fee-for-service expenditures for use in calculating the ACO's regional fee-for-service expenditures:

(1)(i) Determines average county fee-for-service expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area, where assignable beneficiaries are identified for the 12-month calendar year corresponding to the relevant benchmark or performance year.

(ii) Makes separate expenditure calculations for each of the following populations of beneficiaries:

(A) ESRD.

(B) Disabled.

(C) Aged/dual eligible Medicare and Medicaid beneficiaries.

(D) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Calculates assignable beneficiary expenditures using the payment amounts included in Parts A and B fee-for-service claims with dates of service in the 12-month calendar year for the relevant benchmark or performance year, using a 3-month claims run out with a completion factor. The calculation—

(i) Excludes IME and DSH payments; and

(ii) Considers individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(3) Truncates a beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries identified for the 12-month calendar year that corresponds to the relevant benchmark or performance year, in order to minimize variation from catastrophically large claims.

(4) Adjusts fee-for-service expenditures for severity and case mix of assignable beneficiaries in the county using prospective HCC risk scores. The calculation is made according to the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(d) *Calculating regional expenditures.* For all agreement periods beginning on July 1, 2019, and in subsequent years, CMS calculates an ACO's risk adjusted regional expenditures by—

(1) Weighting the risk-adjusted county-level fee-for-service expenditures determined under paragraph (c) of this section according to the ACO's proportion of assigned beneficiaries in the county, determined by the number of the ACO's assigned beneficiaries in the applicable population (according to Medicare enrollment type) residing in the county in relation to the ACO's total number of assigned beneficiaries in the applicable population (according to Medicare enrollment type) for the relevant benchmark or performance year for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries;

(2) Aggregating the values determined under paragraph (d)(1) of this section for each population of beneficiaries (according to Medicare enrollment type) across all counties within the ACO's regional service area; and

(3) Weighting the aggregate expenditure values determined for each population of beneficiaries (according to Medicare enrollment type) under paragraph (d)(2) of this section by a weight reflecting the proportion of the ACO's overall beneficiary population in the applicable Medicare enrollment type for the relevant benchmark or performance year.

(e) *Resetting the benchmark.* (1) An ACO's benchmark is reset at the start of each subsequent agreement period.

(2) For second or subsequent agreements periods beginning on July 1, 2019, and in subsequent years, CMS establishes, adjusts, and updates the rebased historical benchmark in accordance with paragraphs (a) through (d) of this section with the following modifications:

(i) Rather than weighting each year of the benchmark using the percentages provided in paragraph (a)(7) of this section, each benchmark year is weighted equally.

(ii) For a renewing ACO or re-entering ACO whose prior agreement period benchmark was calculated according to § 425.603(c), to determine the weight used in the regional adjustment calculation described in paragraph (f) of this section, CMS considers the agreement period the ACO is entering into according to § 425.600(f) in combination with either of the following—

(A) The weight previously applied to calculate the regional adjustment to the ACO's benchmark under § 425.603(c)(9) in its most recent prior agreement period; or

(B) For a new ACO identified as a re-entering ACO, CMS considers the weight previously applied to calculate the regional adjustment to the benchmark under § 425.603(c)(9) in its most recent prior agreement period of the ACO in which the majority of the new ACO's participants were participating previously.

(f) *Phase-in of weights used in regional adjustment calculation.* (1) The first time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have lower spending than the ACO's regional service area.

(ii) Using 15 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have higher spending than the ACO's regional service area.

(2) The second time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area.

(ii) Using 25 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

(3) The third time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to

have lower spending than the ACO's regional service area.

(ii) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

(4) The fourth or subsequent time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment to the historical benchmark using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark.

(5) To determine if an ACO has lower or higher spending compared to the ACO's regional service area, CMS does the following:

(i) Multiplies the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's historical benchmark for each population of beneficiaries (ESRD, Disabled, Aged/dual eligible Medicare and Medicaid beneficiaries, Aged/non-dual eligible Medicare and Medicaid beneficiaries) as calculated under either paragraph (a)(8)(ii)(A) or (e) of this section by the applicable proportion of the ACO's assigned beneficiary population (ESRD, Disabled, Aged/dual eligible Medicare and Medicaid beneficiaries, Aged/non-dual eligible Medicare and Medicaid beneficiaries) for BY3 of the historical benchmark.

(ii) Sums the amounts determined in paragraph (f)(4)(i) of this section across the populations of beneficiaries (ESRD, Disabled, Aged/dual eligible Medicare and Medicaid beneficiaries, Aged/non-dual eligible Medicare and Medicaid beneficiaries).

(iii) If the resulting sum is a net positive value, the ACO is considered to have lower spending compared to the ACO's regional service area. If the resulting sum is a net negative value, the ACO is considered to have higher spending compared to the ACO's regional service area.

(iv) If CMS adjusts the ACO's benchmark for the addition or removal of ACO participants or ACO providers/suppliers during the term of the agreement period or a change to the ACO's beneficiary assignment methodology selection as specified in paragraph (a)(9) of this section, CMS redetermines whether the ACO is considered to have lower spending or higher spending compared to the ACO's regional service area for purposes of determining the percentage in paragraphs (f)(1) and (2) of this section used in calculating the adjustment under either paragraph (a)(8) or (e) of this section.

(g) *July 1, 2019 through December 31, 2019 performance year.* In determining performance for the July 1, 2019 through December 31, 2019 performance year described in § 425.609(c), CMS does all of the following:

(1) When adjusting the benchmark using the methodology set forth in paragraph (a)(10) of this section and § 425.609(c), CMS adjusts for severity and case mix between BY3 and CY 2019.

(2) When updating the benchmark using the methodology set forth in paragraph (b) of this section and § 425.609(c), CMS updates the benchmark based on growth between BY3 and CY 2019.

■ 28. Section 425.602 is amended—

■ a. By revising the section heading and paragraph (a) introductory text;

■ b. In paragraph (a)(1)(ii)(B) by removing the phrase ''For agreement periods beginning in 2018 and subsequent years'' and adding in its place the phrase ''For agreement periods beginning in 2018''; and

■ c. In paragraphs (a)(4)(ii) and (a)(5)(ii) by removing the phrase ''For agreement periods beginning in 2017 and subsequent years'' and adding in its place the phrase ''For agreement periods beginning in 2017 and 2018''.

The revisions read as follows:

§ 425.602 Establishing, adjusting, and updating the benchmark for an ACO's first agreement period beginning on or before January 1, 2018.

(a) *Computing per capita Medicare Part A and Part B benchmark expenditures.* For agreement periods beginning on or before January 1, 2018, in computing an ACO's fixed historical benchmark that is adjusted for historical growth and beneficiary characteristics, including health status, CMS determines the per capita Parts A and B fee-for-service expenditures for beneficiaries that would have been assigned to the ACO in any of the 3 most recent years prior to the agreement period using the ACO participants' TINs identified at the start of the agreement period. CMS does all of the following:

* * * * *

■ 29. Section 425.603 is amended—

■ a. By revising the section heading;

■ b. In paragraph (c) introductory text by removing the phrase ''For second or subsequent agreement periods beginning in 2017 and subsequent years'' and adding in its place the phrase ''For second or subsequent agreement periods beginning in 2017, 2018 and on January 1, 2019'';

■ c. In paragraph (c)(1)(ii)(B) by removing the phrase ''For agreement periods beginning in 2018 and subsequent years'' and adding in its place the phrase ''For agreement periods beginning in 2018 and on January 1, 2019'';

■ d. In paragraphs (d) introductory text and (e) introductory text by removing the phrase ''For second or subsequent agreement periods beginning in 2017 and subsequent years'' and adding in its place the phrase ''For second or subsequent agreement periods beginning in 2017, 2018 and on January 1, 2019'';

■ e. In paragraph (e)(2)(ii)(B) by removing the phrase ''For agreement periods beginning in 2018 and subsequent years'' and adding in its place the phrase ''For agreement periods beginning in 2018 and on January 1, 2019''; and

■ f. In paragraph (f) introductory text by removing the phrase ''For second or subsequent agreement periods beginning in 2017 and subsequent years'' and adding in its place the phrase ''For second or subsequent agreement periods beginning in 2017, 2018, and on January 1, 2019''.

The revision reads as follows:

§ 425.603 Resetting, adjusting, and updating the benchmark for a subsequent agreement period beginning on or before January 1, 2019.

* * * * *

■ 30. Section 425.604 is amended—

■ a. In paragraph (a) introductory text by removing the phrase ''under § 425.602'' and adding in its place the phrase ''under § 425.602 or § 425.603'';

■ b. In paragraph (a)(3) introductory text by removing the phrase ''described in § 425.602(a)'' and adding in its place the phrase ''described in § 425.602(a) or § 425.603(c)''; and

■ c. In paragraph (b) by revising the table.

The revision reads as follows:

§ 425.604 Calculation of savings under the one-sided model.

* * * * *

(b) * * *

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

* * * * *

■ 31. Section 425.605 is added to read as follows:

§ 425.605 Calculation of shared savings and losses under the BASIC track.

(a) *General rules.* For each performance year, CMS determines whether the estimated average per capita Medicare Parts A and B fee-for-service expenditures for Medicare fee-for-service beneficiaries assigned to the ACO are above or below the updated benchmark determined under § 425.601. In order to qualify for a shared savings payment under the BASIC track, or to be responsible for sharing losses with CMS, an ACO's average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for the performance year must be below or above the updated benchmark, respectively, by at least the minimum savings or loss rate under paragraph (b) of this section.

(1) CMS uses an ACO's prospective HCC risk score to adjust the benchmark for changes in severity and case mix in the assigned beneficiary population between BY3 and the performance year.

(i) Positive adjustments in prospective HCC risk scores are subject to a cap of 3 percent.

(ii) This cap is the maximum increase in risk scores for each agreement period, such that any positive adjustment between BY3 and any performance year in the agreement period cannot be larger than 3 percent.

(2) In risk adjusting the benchmark as described in § 425.601(a)(10), CMS makes separate adjustments for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(3) To minimize variation from catastrophically large claims, CMS truncates an assigned beneficiary's total annual Medicare Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare Parts A and B fee-for-service expenditures as determined for the applicable performance year for assignable beneficiaries identified for the 12-month calendar year corresponding to the performance year.

(4) CMS uses a 3-month claims run out with a completion factor to calculate an ACO's per capita expenditures for each performance year.

(5) Calculations of the ACO's expenditures include the payment amounts included in Medicare Parts A and B fee-for-service claims.

(i) These calculations exclude indirect medical education (IME) and disproportionate share hospital (DSH) payments.

(ii) These calculations take into consideration individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program.

(6) In order to qualify for a shared savings payment, the ACO's average per capita Medicare Parts A and B fee-for-service expenditures for the performance year must be below the applicable updated benchmark by at least the minimum savings rate established for the ACO under paragraph (b) of this section.

(b) *Minimum savings or loss rate.* (1) For ACOs under a one-sided model of the BASIC track's glide path, as specified under paragraphs (d)(1)(i) and (ii) of this section, CMS uses a sliding scale, based on the number of beneficiaries assigned to the ACO under subpart E of this part, to establish the MSR for the ACO as follows:

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

(2) Prior to entering a two-sided model of the BASIC track, the ACO must select the MSR/MLR. For an ACO making this selection as part of an application for, or renewal of, participation in a two-sided model of the BASIC track, the selection applies for the duration of the agreement period under the BASIC track. For an ACO making this selection during an agreement period, as part of the application cycle prior to entering a two-sided model of the BASIC track, the selection applies for the remaining duration of the applicable agreement period under the BASIC track.

(i) The ACO must choose from the following options for establishing the MSR/MLR:

(A) Zero percent MSR/MLR.

(B) Symmetrical MSR/MLR in a 0.5 percent increment between 0.5 and 2.0 percent.

(C) Symmetrical MSR/MLR that varies, based on the number of beneficiaries assigned to the ACO under subpart E of this part. The MSR is the same as the MSR that would apply under paragraph (b)(1) of this section for an ACO under a one-sided model of the BASIC track's glide path, and is based on the number of assigned beneficiaries. The MLR under the BASIC track is equal to the negative MSR.

(ii) The ACO selects its MSR/MLR as part of one the following:

(A) Application for, or renewal of, program participation in a two-sided model of the BASIC track.

(B) Election to participate in a two-sided model of the BASIC track during an agreement period under § 425.226.

(C) Automatic transition from Level B to Level C of the BASIC track's glide path under § 425.600(a)(4)(i).

(D) Automatic transition from Level B to Level E of the BASIC track's glide path under § 425.600(a)(4)(i)(B)(*2*)(*ii*).

(3) To qualify for shared savings under the BASIC track, an ACO's average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for the performance year must be below its updated benchmark costs for the year by at least the MSR established for the ACO.

(4) To be responsible for sharing losses with the Medicare program, an ACO's average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for the performance year must be above its updated benchmark costs for the year by at least the MLR established for the ACO.

(c) *Qualification for shared savings payment.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the minimum quality performance standards established under § 425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) *Levels of risk and potential reward.* (1) The following levels of risk and potential reward apply to an ACO in the BASIC track, as permitted under § 425.600(d).

(i) *Level A (one-sided model)*—(A) *Final sharing rate.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level A, receives a shared savings payment of up to 40 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(i)(B) of this section).

(B) *Performance payment.* (*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, the final sharing rate specified in paragraph (d)(1)(i)(A) of this section applies to an ACO's savings on a first dollar basis.

(*2*) The amount of shared savings an eligible ACO receives under the BASIC track, Level A, may not exceed 10 percent of its updated benchmark.

(ii) *Level B (one-sided model)*—(A) *Final sharing rate.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level B, receives a shared savings payment of up to 40 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(ii)(B) of this section).

(B) *Performance payment.* (*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, the final sharing rate specified in paragraph (d)(1)(ii)(A) of this section applies to an ACO's savings on a first dollar basis.

(*2*) The amount of shared savings an eligible ACO receives under the BASIC track, Level B, may not exceed 10 percent of its updated benchmark.

(iii) *Level C (two-sided model)*—(A) *Final sharing rate.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level C, receives a shared savings payment of up to 50 percent of all the savings under the updated benchmark,

as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(iii)(B) of this section).

(B) *Performance payment.* (*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, the final sharing rate specified in paragraph (d)(1)(iii)(A) of this section applies to an ACO's savings on a first dollar basis.

(*2*) The amount of shared savings an eligible ACO receives under the BASIC track, Level C may not exceed 10 percent of its updated benchmark.

(C) *Shared loss rate.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined based on a fixed 30 percent loss sharing rate.

(D) *Loss recoupment limit.* (*1*) Except as provided in paragraph (d)(1)(iii)(D)(*2*) of this section, the amount of shared losses for which an eligible ACO is liable may not exceed 2 percent of total Medicare Parts A and B fee-for-service revenue of the ACO participants in the ACO.

(*2*) Instead of the revenue-based loss recoupment limit determined under paragraph (d)(1)(iii)(D)(*1*) of this section, the loss recoupment limit for the ACO is 1 percent of the ACO's updated benchmark as determined under § 425.601, if the amount determined under paragraph (d)(1)(iii)(D)(*1*) of this section exceeds the amount that is 1 percent of the ACO's updated benchmark as determined under § 425.601.

(iv) *Level D (two-sided model)*—(A) *Final sharing rate.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level D, receives a shared savings payment of up to 50 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(iv)(B) of this section).

(B) *Performance payment.* (*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, the final sharing rate specified in paragraph (d)(1)(iv)(A) of this section applies to an ACO's savings on a first dollar basis.

(*2*) The amount of shared savings an eligible ACO receives under the BASIC track, Level D, may not exceed 10 percent of its updated benchmark.

(C) *Shared loss rate.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined based on a fixed 30 percent loss sharing rate.

(D) *Loss recoupment limit.* (*1*) Except as provided in paragraph (d)(1)(iv)(D)(*2*) of this section, the amount of shared losses for which an eligible ACO is liable may not exceed 4 percent of total Medicare Parts A and B fee-for-service revenue of the ACO participants in the ACO.

(*2*) Instead of the revenue-based loss recoupment limit determined under paragraph (d)(1)(iv)(D)(*1*) of this section, the loss recoupment limit for the ACO is 2 percent of the ACO's updated benchmark as determined under § 425.601, if the amount determined under paragraph (d)(1)(iv)(D)(*1*) of this section exceeds the amount that is 2 percent of the ACO's updated benchmark as determined under § 425.601.

(v) *Level E (two-sided model)*—(A) *Final sharing rate.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level E, receives a shared savings payment of up to 50 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(v)(B) of this section).

(B) *Performance payment.* (*1*) If an ACO qualifies for savings by meeting or exceeding the MSR, the final sharing rate specified in paragraph (d)(1)(v)(A) of this section applies to an ACO's savings on a first dollar basis.

(*2*) The amount of shared savings an eligible ACO receives under the BASIC track, Level E, may not exceed 10 percent of its updated benchmark.

(C) *Shared loss rate.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined based on a fixed 30 percent loss sharing rate.

(D) *Loss recoupment limit.* (*1*) Except as provided in paragraph (d)(1)(v)(D)(*2*) of this section, the amount of shared losses for which an eligible ACO is liable may not exceed the percentage, as specified in § 414.1415(c)(3)(i)(A) of this chapter, of total Medicare Parts A and B fee-for-service revenue of the ACO participants in the ACO.

(*2*) Instead of the revenue-based loss recoupment limit determined under paragraph (d)(1)(v)(D)(*1*) of this section, the loss recoupment limit for the ACO is 1 percentage point higher than the percentage, as specified in § 414.1415(c)(3)(i)(B) of this chapter, based on the ACO's updated benchmark as determined under § 425.601, if the amount determined under paragraph (d)(1)(v)(D)(*1*) of this section exceeds this percentage of the ACO's updated benchmark as determined under § 425.601.

(2) Level E risk and reward as specified in paragraph (d)(1)(v) of this section applies to an ACO eligible to enter the BASIC track that is determined to be experienced with performance-based risk Medicare ACO initiatives as specified under § 425.600(d).

(e) *Notification of savings and losses.* (1) CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due.

(2) CMS provides written notification to an ACO of the amount of shared losses, if any, that it must repay to the program.

(3) If an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

(f) *Extreme and uncontrollable circumstances.* The following adjustment is made in calculating the amount of shared losses, after the application of the shared loss rate and the loss recoupment limit.

(1) CMS determines the percentage of the ACO's performance year assigned beneficiary population affected by an extreme and uncontrollable circumstance.

(2) CMS reduces the amount of the ACO's shared losses by an amount determined by multiplying the shared losses by the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance, and the percentage of the ACO's assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance.

(i) For an ACO that is liable for a pro-rated share of losses under § 425.221(b)(2)(ii), the amount of shared losses determined for the performance year during which the termination becomes effective is adjusted according to this paragraph (f)(2).

(ii) [Reserved]

(3) CMS applies determinations made under the Quality Payment Program with respect to—

(i) Whether an extreme and uncontrollable circumstance has occurred; and

(ii) The affected areas.

(4) CMS has sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred and the percentage of the ACO's assigned beneficiaries residing in the affected areas.

(g) *July 1, 2019 through December 31, 2019 performance year.* Shared savings or shared losses for the July 1, 2019 through December 31, 2019 performance year are calculated as described in § 425.609.

■ 32. Section 425.606 is amended—

■ a. In paragraph (a) introductory text by removing the phrase ''under § 425.602'' and adding in its place the phrase ''under § 425.602 or § 425.603'';
■ b. In paragraph (a)(3) introductory text by removing the phrase ''described in § 425.602(a)'' and adding in its place the phrase ''described in § 425.602(a) or § 425.603(c)'';
■ c. In paragraph (g) introductory text by removing the phrase ''under § 425.602'' and adding in its place the phrase ''under § 425.602 or § 425.603''; and
■ d. By adding paragraph (i)(2)(i), and reserved paragraph (i)(2)(ii).

The additions read as follows:

§ 425.606 Calculation of shared savings and losses under Track 2.

* * * * *

(i) * * *

(2) * * *

(i) For an ACO that is liable for a pro-rated share of losses under § 425.221(b)(2)(ii) or (b)(3)(i), the amount of shared losses determined for the performance year during which the termination becomes effective is adjusted according to this paragraph (i)(2).

(ii) [Reserved]

* * * * *

■ 33. Section 425.609 is amended by:
■ a. Revising the section heading and paragraphs (b) introductory text and (b)(2);
■ b. Adding paragraph (c); and
■ c. Revising paragraphs (d)(1), and (e).

The revisions and addition read as follows:

§ 425.609 Determining performance for 6-month performance years during CY 2019.

* * * * *

(b) *January 2019 through June 2019.* For ACOs participating in a 6-month performance year from January 1, 2019, through June 30, 2019, under § 425.200(b)(2)(ii)(B) and for ACOs eligible for pro-rated shared savings or liable for pro-rated shared losses in accordance with § 425.221(b)(3)(i) for the performance period from January 1, 2019, through June 30, 2019, CMS reconciles the ACO for the period from January 1, 2019, through June 30, 2019, after the conclusion of CY 2019, based on the 12-month calendar year and pro-rates shared savings or shared losses to reflect the ACO's participation from January 1, 2019, through June 30, 2019. CMS does all of the following to determine financial and quality performance:

* * * * *

(2) Uses the ACO's quality performance for the 2019 reporting period to determine the ACO's quality performance score as specified in § 425.502.

(i) The ACO participant list finalized for the first performance year of the ACO's agreement period beginning on July 1, 2019, is used to determine the quality reporting samples for the 2019 reporting year for the following ACOs:

(A) An ACO that extends its participation agreement for a 6-month performance year from January 1, 2019, through June 30, 2019, under § 425.200(b)(2)(ii)(B), and enters a new agreement period beginning on July 1, 2019.

(B) An ACO that participates in the program for the first 6 months of a 12-month performance year during 2019 and is eligible for pro-rated shared savings or liable for pro-rated shared losses in accordance with § 425.221(b)(3)(i).

(ii) The ACO's latest certified ACO participant list is used to determine the quality reporting samples for the 2019 reporting year for an ACO that extends its participation agreement for the 6-month performance year from January 1, 2019, through June 30, 2019, under § 425.200(b)(2)(ii)(B), and does not enter a new agreement period beginning on July 1, 2019.

* * * * *

(c) *July 2019 through December 2019.* For ACOs entering an agreement period beginning on July 1, 2019, the ACO's first performance year is from July 1, 2019, through December 31, 2019, as specified in § 425.200(c)(3). CMS reconciles the ACO for the period from July 1, 2019, through December 31, 2019, after the conclusion of CY 2019, based on the 12-month calendar year and pro-rates shared savings or shared losses to reflect the ACO's participation from July 1, 2019, through December 31, 2019. CMS does all of the following to determine financial and quality performance:

(1) Uses the ACO participant list in effect for the performance year beginning on July 1, 2019, to determine beneficiary assignment, using claims for the entire calendar year, consistent with the methodology the ACO selected at the start of its agreement period under § 425.400(a)(4)(ii).

(i) For ACOs under preliminary prospective assignment with retrospective reconciliation the assignment window is CY 2019.

(ii) For ACOs under prospective assignment—

(A) The assignment window is the same as the assignment window that applies under paragraph (b)(1)(ii)(A) of this section for ACOs under prospective assignment for the 6-month performance year from January 1, 2019, through June 30, 2019; and

(B) Beneficiaries remain prospectively assigned to the ACO at the end of CY 2019 if they do not meet any of the exclusion criteria under § 425.401(b) during the calendar year.

(2) Uses the ACO's quality performance for the 2019 reporting period to determine the ACO's quality performance score as specified in § 425.502. The ACO participant list finalized for the first performance year of the ACO's agreement period beginning on July 1, 2019, is used to determine the quality reporting samples for the 2019 reporting year for all ACOs.

(3) Uses the methodology for calculating shared savings or shared loses applicable to the ACO for its first performance year under its agreement period beginning on July 1, 2019.

(i) The ACO's historical benchmark is determined according to § 425.601 except as follows:

(A) The benchmark is adjusted for changes in severity and case mix between BY3 and CY 2019 based on growth in prospective HCC risk scores, subject to a cap of positive 3 percent as described under § 425.605(a)(1) or § 425.610(a)(2).

(B) The benchmark is updated to CY 2019 according to the methodology described under § 425.601(b).

(ii) The ACO's financial performance is determined based on the track the ACO is participating under during the performance year starting on July 1, 2019 (§ 425.605 (BASIC track) or § 425.610 (ENHANCED track)), unless otherwise specified. In determining ACO financial performance, CMS does all of the following:

(A) Average per capita Medicare Parts A and B fee-for-service expenditures for CY 2019 are calculated for the ACO's performance year assigned beneficiary population identified in paragraph (c)(1) of this section.

(B) Expenditures calculated in paragraph (c)(3)(ii)(A) of this section are compared to the ACO's updated benchmark determined according to paragraph (c)(3)(i) of this section.

(C)(*1*) The ACO's performance year assigned beneficiary population identified in paragraph (c)(1) of this section is used to determine the MSR for ACOs in BASIC track Level A or Level B, and the variable MSR/MLR for ACOs in a two-sided model that selected this option at the start of their agreement period. In the event a two-sided model ACO selected a fixed MSR/MLR at the start of its agreement period, and the ACO's performance year assigned population identified in paragraph (c)(1) of this section is below 5,000 beneficiaries, the MSR/MLR is determined based on the number of

assigned beneficiaries as specified in § 425.110(b)(3)(iii).

(*2*) To qualify for shared savings an ACO must do all of the following:

(*i*) Have average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for CY 2019 below its updated benchmark costs for the year by at least the MSR established for the ACO based on the track the ACO is participating under during the performance year starting on July 1, 2019 (§ 425.605 or § 425.610) and paragraph (c)(3)(ii)(C)(*1*) of this section.

(*ii*) Meet the minimum quality performance standards established under § 425.502 and according to paragraph (c)(2) of this section.

(*iii*) Otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(*3*) To be responsible for sharing losses with the Medicare program, an ACO's average per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiary population for CY 2019 must be above its updated benchmark costs for the year by at least the MLR established for the ACO based on the track the ACO is participating under during the performance year starting on July 1, 2019 (§ 425.605 or § 425.610) and paragraph (c)(3)(ii)(C)(*1*) of this section.

(D) For an ACO that meets all the requirements to receive a shared savings payment under paragraph (c)(3)(ii)(C)(*2*) of this section—

(*1*) The final sharing rate, determined based on the track the ACO is participating under during the performance year starting on July 1, 2019 (§ 425.605 or § 425.610), is applied to all savings under the updated benchmark specified under paragraph (c)(3)(i) of this section, not to exceed the performance payment limit for the ACO based on its track; and

(*2*) After applying the applicable performance payment limit, CMS pro-rates any shared savings amount determined under paragraph (c)(3)(ii)(D)(*1*) of this section by multiplying the amount by one-half, which represents the fraction of the calendar year covered by the July 1, 2019 through December 31, 2019 performance year.

(E) For an ACO responsible for shared losses under paragraph (c)(3)(ii)(C)(*3*) of this section—

(*1*) The shared loss rate, determined based on the track the ACO is participating under during the performance year starting on July 1, 2019 (§ 425.605 or § 425.610), is applied to all losses under the updated benchmark specified under paragraph (c)(3)(i) of this section, not to exceed the loss recoupment limit for the ACO based on its track; and

(*2*) After applying the applicable loss recoupment limit, CMS pro-rates any shared losses amount determined under paragraph (c)(3)(ii)(E)(*1*) of this section by multiplying the amount by one-half, which represents the fraction of the calendar year covered by the July 1, 2019 through December 31, 2019 performance year.

(d) * * *

(1) In calculating the amount of shared losses owed, CMS makes adjustments to the amount determined in paragraph (b)(3)(ii)(E)(*1*) or (c)(3)(ii)(E)(*1*) of this section, as specified in § 425.605(f), § 425.606(i), or § 425.610(i), as applicable; and

* * * * *

(e) *Notification of savings and losses.* (1) CMS notifies the ACO of shared savings or shared losses separately for the January 1, 2019 through June 30, 2019 performance year (or performance period) and the July 1, 2019 through December 31, 2019 performance year, consistent with the notification requirements specified in §§ 425.604(f), 425.605(e), 425.606(h), and 425.610(h), as applicable:

(i) CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due.

(ii) CMS provides written notification to an ACO of the amount of shared losses, if any, that it must repay to the program.

(iii) If an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

(2) If an ACO is reconciled for both the January 1, 2019 through June 30, 2019 performance year (or performance period) and the July 1, 2019 through December 31, 2019 performance year, CMS issues a separate notice of shared savings or shared losses for each performance year (or performance period), and if the ACO has shared savings for one performance year (or performance period) and shared losses for the other performance year (or performance period), CMS reduces the amount of shared savings by the amount of shared losses.

(i) If any amount of shared savings remains after completely repaying the amount of shared losses owed, the ACO is eligible to receive payment for the remainder of the shared savings.

(ii) If the amount of shared losses owed exceeds the amount of shared savings earned, the ACO is accountable for payment of the remaining balance of shared losses in full.

■ 34. Section 425.610 is amended—

■ a. By revising the section heading;

■ b. In paragraph (a) introductory text by removing the phrase ''under § 425.602'' and adding in its place the phrase ''under § 425.601, § 425.602 or § 425.603'' and by removing the phrase ''Track 3'' and adding in its place the phrase ''the ENHANCED track'';

■ c. By revising paragraph (a)(1) through (3);

■ d. In paragraph (b)(1)(iii) by removing the phrase ''Track 3'' each time it appears and adding in its place the phrase ''the ENHANCED track'' and by removing the phrase ''§ 425.604(b)'' and adding in its place the phrase ''either § 425.604(b) (for ACOs entering an agreement period on or before January 1, 2019) or § 425.605(b)(1) (for ACOs entering an agreement period on July 1, 2019, and in subsequent years)'';

■ e. In paragraphs (b)(2), (d), (e)(2) by removing the phrase ''Track 3'' and adding in its place the phrase ''the ENHANCED track'';

■ f. In paragraph (g) by removing the phrase ''under § 425.602'' and adding in its place the phrase ''under § 425.601, § 425.602 or § 425.603'';

■ g. By adding paragraph (i)(2)(i), and reserved paragraph (i)(2)(ii); and

■ h. By adding paragraph (k).

The revisions and additions read as follows:

§ 425.610 Calculation of shared savings and losses under the ENHANCED track.

(a) * * *

(1) Risk adjustment for ACOs in agreement periods beginning on or before January 1, 2019. CMS does the following to adjust the benchmark each performance year:

(i) *Newly assigned beneficiaries.* CMS uses an ACO's prospective HCC risk score to adjust the benchmark for changes in severity and case mix in this population.

(ii) *Continuously assigned beneficiaries.* (A) CMS uses demographic factors to adjust the benchmark for changes in the continuously assigned beneficiary population.

(B) If the prospective HCC risk score is lower in the performance year for this population, CMS adjusts the benchmark for changes in severity and case mix for this population using this lower prospective HCC risk score.

(2) Risk adjustment for ACOs in agreement periods beginning on July 1, 2019, and in subsequent years. CMS uses an ACO's prospective HCC risk score to adjust the benchmark for changes in severity and case mix in the assigned beneficiary population between BY3 and the performance year.

(i) Positive adjustments in prospective HCC risk scores are subject to a cap of 3 percent.

(ii) This cap is the maximum increase in risk scores for each agreement period, such that any positive adjustment between BY3 and any performance year in the agreement period cannot be larger than 3 percent.

(3) In risk adjusting the benchmark as described in §§ 425.601(a)(10), 425.602(a)(9) and 425.603(c)(10), CMS makes separate adjustments for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

* * * * *

(i) * * *

(2) * * *

(i) For an ACO that is liable for a pro-rated share of losses under § 425.221(b)(2)(ii) or (b)(3)(i), the amount of shared losses determined for the performance year during which the termination becomes effective is adjusted according to this paragraph (i)(2).

(ii) [Reserved]

* * * * *

(k) *July 1, 2019 through December 31, 2019 performance year.* Shared savings or shared losses for the July 1, 2019 through December 31, 2019 performance year are calculated as described in § 425.609.

■ 35. Section 425.612 is amended—

■ a. By revising paragraphs (a)(1) introductory text and (a)(1)(ii)(A);

■ b. By redesignating paragraphs (a)(1)(ii)(B) through (G) as paragraphs (a)(1)(ii)(C) through (H);

■ c. By adding new paragraph (a)(1)(ii)(B);

■ d. By revising paragraphs (a)(1)(iii)(A), (a)(1)(iv), and (a)(1)(v) introductory text;

■ e. Redesignating paragraphs (a)(1)(v)(A) through (C) as paragraphs (a)(1)(v)(C) through (E);

■ f. Adding new paragraphs (a)(1)(v)(A) and (B);

■ g. Revising newly redesignated paragraph (a)(1)(v)(D); and

■ h. By adding paragraphs (a)(1)(vi) and (f).

The revisions and additions read as follows:

§ 425.612 Waivers of payment rules or other Medicare requirements.

(a) * * *

(1) *SNF 3-day rule.* For performance year 2017 and subsequent performance years, CMS waives the requirement in section 1861(i) of the Act for a 3-day inpatient hospital stay prior to a Medicare-covered post-hospital extended care service for eligible beneficiaries assigned to ACOs participating in a two-sided model and as provided in paragraph (a)(1)(iv) of this section during a grace period for beneficiaries excluded from prospective assignment to an ACO in a two-sided model, who receive otherwise covered post-hospital extended care services furnished by an eligible SNF that has entered into a written agreement to partner with the ACO for purposes of this waiver. Eligible SNFs include providers furnishing SNF services under swing bed agreements. All other provisions of the statute and regulations regarding Medicare Part A post-hospital extended care services continue to apply. ACOs identified under paragraph (a)(1)(vi) of this section may request to use the SNF 3-day rule waiver for performance years beginning on July 1, 2019, and in subsequent years.

* * * * *

(ii) * * *

(A) In the case of a beneficiary who is assigned to an ACO that has selected preliminary prospective assignment with retrospective reconciliation under § 425.400(a)(2), the beneficiary must appear on the list of preliminarily prospectively assigned beneficiaries at the beginning of the performance year or on the first, second, or third quarterly preliminary prospective assignment list for the performance year in which they are admitted to the eligible SNF, and the SNF services must be provided after the beneficiary first appeared on the preliminary prospective assignment list for the performance year.

(B) In the case of a beneficiary who is assigned to an ACO that has selected prospective assignment under § 425.400(a)(3), the beneficiary must be prospectively assigned to the ACO for the performance year in which they are admitted to the eligible SNF.

* * * * *

(iii) * * *

(A) Providers eligible to be included in the CMS 5-star Quality Rating System must have and maintain an overall rating of 3 or higher.

* * * * *

(iv) For a beneficiary who was included on the ACO's prospective assignment list or preliminary prospective assignment list at the beginning of the performance year or on the first, second, or third quarterly preliminary prospective assignment list for the performance year, for an ACO for which a waiver of the SNF 3-day rule has been approved under paragraph (a)(1) of this section, but who was subsequently removed from the assignment list for the performance year, CMS makes payment for SNF services furnished to the beneficiary by a SNF affiliate if the following conditions are met:

(A)(*1*) The beneficiary was prospectively assigned to an ACO that selected prospective assignment under § 425.400(a)(3) at the beginning of the applicable performance year, but was excluded in the most recent quarterly update to the assignment list under § 425.401(b), and the beneficiary was admitted to a SNF affiliate within 90 days following the date that CMS delivered the quarterly exclusion list to the ACO; or

(*2*) The beneficiary was identified as preliminarily prospectively assigned to an ACO that has selected preliminary prospective assignment with retrospective reconciliation under § 425.400(a)(2) in the report provided under § 425.702(c)(1)(ii)(A) at the beginning of the performance year or for the first, second, or third quarter of the performance year, the SNF services were provided after the beneficiary first appeared on the preliminary prospective assignment list for the performance year, and the beneficiary meets the criteria to be assigned to an ACO under § 425.401(a)(1) and (2).

(B) But for the beneficiary's removal from the ACO's assignment list, CMS would have made payment to the SNF affiliate for such services under the waiver under paragraph (a)(1) of this section.

(v) The following beneficiary protections apply when a beneficiary receives SNF services without a prior 3-day inpatient hospital stay from a SNF affiliate that intended to provide services under a SNF 3-day rule waiver under paragraph (a)(1) of this section, the SNF affiliate services were non-covered only because the SNF affiliate stay was not preceded by a qualifying hospital stay under section 1861(i) of the Act, and in the case of a beneficiary where the ACO selected one of the following:

(A) Prospective assignment under § 425.400(a)(3), the beneficiary was not prospectively assigned to the ACO for the performance year in which they received the SNF services, or was prospectively assigned but was later excluded and the 90-day grace period, described in paragraph (a)(1)(iv)(A) of this section, has lapsed.

(B) Preliminary prospective assignment with retrospective reconciliation under § 425.400(a)(2), the beneficiary was not identified as preliminarily prospectively assigned to

the ACO for the performance year in the report provided under § 425.702(c)(1)(ii)(A) at the beginning of the performance year or for the first, second, or third quarter of the performance year before the SNF services were provided to the beneficiary.

* * * * *

(D) CMS makes no payments for SNF services to a SNF affiliate of an ACO for which a waiver of the SNF 3-day rule has been approved when the SNF affiliate admits a FFS beneficiary who was not prospectively or preliminarily prospectively assigned to the ACO prior to the SNF admission or was prospectively assigned but was later excluded and the 90-day grace period under paragraph (a)(1)(iv)(A) of this section has lapsed.

* * * * *

(vi) The following ACOs may request to use the SNF 3-day rule waiver:

(A) An ACO participating in performance-based risk within the BASIC track under § 425.605.

(B) An ACO participating in the ENHANCED track under § 425.610.

* * * * *

(f) *Waiver for payment for telehealth services.* For performance year 2020 and subsequent performance years, CMS waives the originating site requirements in section 1834(m)(4)(C)(i) and (ii) of the Act and makes payment for telehealth services furnished to a beneficiary, if the following conditions are met:

(1) The beneficiary was prospectively assigned to an ACO that is an applicable ACO for purposes of § 425.613 at the beginning of the applicable performance year, but the beneficiary was excluded in the most recent quarterly update to the prospective assignment list under § 425.401(b).

(2) The telehealth services are provided by a physician or practitioner billing under the TIN of an ACO participant in the ACO within 90 days following the date CMS delivers the quarterly exclusion list to the ACO.

(3) But for the beneficiary's exclusion from the ACO's prospective assignment list, CMS would have made payment to the ACO participant for such services under § 425.613.

■ 36. Section 425.613 is added to subpart G to read as follows:

§ 425.613 Telehealth services.

(a) *General.* Payment is available for otherwise covered telehealth services furnished on or after January 1, 2020, by a physician or other practitioner billing through the TIN of an ACO participant in an applicable ACO, without regard to the geographic requirements under section 1834(m)(4)(C)(i) of the Act, in accordance with the requirements of this section.

(1) For purposes of this section:

(i) An applicable ACO is an ACO that is participating under a two-sided model under § 425.600 and has elected prospective assignment under § 425.400(a)(3) for the performance year.

(ii) The home of the beneficiary is treated as an originating site under section 1834(m)(4)(C)(ii) of the Act.

(2) For payment to be made under this section, the following requirements must be met:

(i) The beneficiary is prospectively assigned to the ACO for the performance year in which the beneficiary received the telehealth service.

(ii) The physician or practitioner who furnishes the telehealth service must bill under the TIN of an ACO participant that is included on the certified ACO participant list under § 425.118 for the performance year in which the service is rendered.

(iii) The originating site must comply with applicable State licensing requirements.

(iv) When the originating site is the beneficiary's home, the telehealth services must not be inappropriate to furnish in the home setting. Services that are typically furnished in an inpatient setting may not be furnished as a telehealth service when the originating site is the beneficiary's home.

(v) CMS does not pay a facility fee when the originating site is the beneficiary's home.

(b) *Beneficiary protections.* (1) When a beneficiary who is not prospectively assigned to an applicable ACO or in a 90-day grace period under § 425.612(f) receives a telehealth service from a physician or practitioner billing through the TIN of an ACO participant participating in an applicable ACO, CMS makes no payment for the telehealth service to the ACO participant.

(2) In the event that CMS makes no payment for a telehealth service furnished by a physician or practitioner billing through the TIN of an ACO participant, and the only reason the claim was non-covered is because the beneficiary is not prospectively assigned to the ACO or in the 90-day grace period under § 425.612(f), all of the following beneficiary protections apply:

(i) The ACO participant must not charge the beneficiary for the expenses incurred for such service.

(ii) The ACO participant must return to the beneficiary any monies collected for such service.

(iii) The ACO may be required to submit a corrective action plan under § 425.216(b) for CMS approval. If the ACO is required to submit a corrective action plan and, after being given an opportunity to act upon the corrective action plan, the ACO fails to implement the corrective action plan or demonstrate improved performance upon completion of the corrective action plan, CMS may terminate the participation agreement as specified under § 425.216(b)(2).

(c) *Termination date for purposes of payment for telehealth services.* (1) Payment for telehealth services under paragraph (a) of this section does not extend beyond the end of the applicable ACO's participation agreement.

(2) If CMS terminates the participation agreement under § 425.218, payment for telehealth services under paragraph (a) of this section is not made with respect to telehealth services furnished beginning on the date specified by CMS in the termination notice.

(3) If the ACO terminates the participation agreement, payment for telehealth services under paragraph (a) of this section is not made with respect to telehealth services furnished beginning on the effective date of termination as specified in the written notification required under § 425.220.

(d) *Monitoring of telehealth services.* (1) CMS monitors and audits the use of telehealth services by the ACO and its ACO participants and ACO providers/suppliers, in accordance with § 425.316.

(2) CMS reserves the right to take compliance action, up to and including termination of the participation agreement, as specified in §§ 425.216 and 425.218, with respect to an applicable ACO for non-compliance with program requirements, including inappropriate use of telehealth services.

■ 37. Section 425.702 is amended by revising paragraphs (c)(1)(ii)(A) introductory text, (c)(1)(ii)(B) introductory text and (c)(1)(ii)(C) to read as follows:

§ 425.702 Aggregate reports.

* * * * *

(c) * * *

(1) * * *

(ii) * * *

(A) For an ACO participating under preliminary prospective assignment with retrospective reconciliation as specified under § 425.400(a)(2), the following information is made available regarding preliminarily prospectively assigned beneficiaries and beneficiaries that received a primary care service during the previous 12 months from one of the ACO participants that submits

claims for primary care services used to determine the ACO's assigned population under subpart E of this part:

* * * * *

(B) For an ACO participating under preliminary prospective assignment with retrospective reconciliation as specified under § 425.400(a)(2), information in the following categories, which represents the minimum data necessary for ACOs to conduct health care operations work, is made available regarding preliminarily prospectively assigned beneficiaries:

* * * * *

(C) The information under paragraphs (c)(1)(ii)(A) and (B) of this section is made available to ACOs participating under prospective assignment as specified under § 425.400(a)(3), but is limited to the ACO's prospectively assigned beneficiaries.

* * * * *

■ 38. Section 425.704 is amended by revising paragraph (d)(1) to read as follows:

§ 425.704 Beneficiary-identifiable claims data.

* * * * *

(d) * * *

(1) For an ACO participating under—

(i) Preliminary prospective assignment with retrospective reconciliation as specified under § 425.400(a)(2), the beneficiary's name appears on the preliminary prospective assignment list provided to the ACO at the beginning of the performance year, during each quarter (and in conjunction with the annual reconciliation) or the beneficiary has received a primary care service from an ACO participant upon whom assignment is based (under subpart E of this part) during the most recent 12-month period; or

(ii) Prospective assignment as specified under § 425.400(a)(3), the beneficiary's name appears on the prospective assignment list provided to the ACO at the beginning of the performance year.

* * * * *

■ 39. Section 425.800 is amended—

■ a. In paragraph (a)(4) by removing the phrase ''under §§ 425.602, 425.604, 425.606, and 425.610'' and adding in its place the phrase ''in accordance with section 1899(d) of the Act, as implemented under §§ 425.601, 425.602, 425.603, 425.604, 425.605, 425.606, and 425.610'';

■ b. In paragraph (a)(5) by removing the phrase ''established under §§ 425.604, 425.606, and 425.610'' and adding in its place the phrase ''established under §§ 425.604, 425.605, 425.606, and 425.610''; and

■ c. By adding paragraph (a)(7).

The addition reads as follows:

§ 425.800 Preclusion of administrative and judicial review.

(a) * * *

(7) The termination of a beneficiary incentive program established under § 425.304(c).

* * * * *

Dated: December 14, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: December 18, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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