DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 414 and 425

[CMS–1701–P]

RIN 0938–AT45

Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success

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

ACTION: Proposed rule.

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 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 in savings and are accountable for repaying shared losses). These proposed 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 proposed rule also would 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.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 16, 2018.

ADDRESSES: In commenting, please refer to file code CMS–1701–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *https://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1701–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1701–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Elizabeth November, (410) 786–8084 or via email at *aco@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov.* Follow the search instructions on that website to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Executive Summary and Background

A. Executive Summary

1. Purpose

Currently, 561 ACOs participate in the Medicare Shared Savings Program (Shared Savings Program). CMS continues 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 proposed rule would make 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 proposed 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). If these changes are finalized, we will continue to monitor the program's ability to reduce healthcare spending and improve care quality to inform future program developments, including whether the program provides beneficiaries with the value and choice demonstrated by other Medicare options such as Medicare Advantage (MA). We also propose changes to address the new requirements of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) (herein referred to as the Bipartisan Budget Act).

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's 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 are 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/shared savingsprogram/* 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, a time-limited model, 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 benefit from waivers of certain federal requirements in connection with their participation in the Shared Savings Program. Even more concerning is the finding that one-sided model ACOs, which are not accountable for sharing in losses, have actually increased Medicare spending relative to their benchmarks. 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.

We believe 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 are proposing 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.

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.*

We believe 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 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. We believe it is necessary to carefully consider each of these factors to create, on balance, sufficient incentives for participation in a voluntary program,

[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.*

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 believe it is necessary 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. The goal of the proposed program redesign is 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 would 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 the same as the Track 1+ Model, which is substantially less than the proposed ENHANCED track). As stakeholders have suggested, we would provide flexibility to allow ACOs that are ready to accelerate their move to higher risk within agreement periods, and enable such ACOs to qualify as Advanced APM entities for purposes of the Quality Payment Program. We would streamline the program and simplify the participation options by retiring Track 1 and Track 2. We would 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 would 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 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.

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 aim 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 are proposing 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 would 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.

Currently, the regional adjustment 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 would 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 would also seek 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 continue to express concerns that the current 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 would 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 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 recent 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 would 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 would 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 would also allow broader access to the program's existing SNF 3-day rule waiver for ACOs under performance-based risk.

Other timely modifications to the program's regulations addressed in this proposed rule, include changes to the program's claims-based assignment methodology and the process for allowing beneficiaries to voluntarily align to ACOs in which the physician or other practitioner they have designated as their primary clinician is an ACO professional, and extending the program's recently finalized policy for addressing extreme and uncontrollable circumstances to performance year 2018 and all subsequent performance years. Further, feedback from the public sought in this rule would inform development of the program's quality measure set to support CMS's Meaningful Measures initiative for reducing provider reporting burden and promoting positive outcomes, and help to identify ways to improve existing data sharing and the quality measure set to address the nation's opioid emergency. Changes to the program's requirements regarding the use of certified electronic health record technology would help ensure Shared Savings Program ACOs are held accountable for using technology that promotes more effective population management and sharing of data among providers, and will ultimately lead to value-based and better care for patients. Lastly, through this proposed rule we seek comment on how Medicare ACOs and the sponsors of stand-alone Part D prescription drug plans (PDPs) could be encouraged to collaborate so as to improve the coordination of pharmacy care for Medicare FFS beneficiaries.

2. Summary of the Major Provisions

This proposed rule would restructure 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 proposed approach, the program's two tracks would be: (i) A BASIC track, offering a path from a one-sided model for eligible ACOs to progressively higher increments of risk and potential reward within a single agreement period, and (ii) 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. This approach includes proposals for 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.

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 propose to offer a July 1, 2019 start date for the first agreement period under the proposed new participation options. This midyear start in 2019 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. We would forgo the application cycle in 2018 for an agreement start date of January 1, 2019. ACOs entering a new agreement period on July 1, 2019, would have the opportunity to participate in the program under agreement periods spanning 5 years and 6 months, with a 6-month first performance year. Additionally, we would offer ACOs with a participation agreement ending on December 31, 2018 an opportunity to extend their current agreement period for an additional 6-month performance year (January 1, 2019–June 30, 2019). These ACOs would then have the opportunity to apply for a new agreement under the BASIC track or ENHANCED track beginning on July 1, 2019.

We propose modifications to the repayment mechanism arrangement requirements applicable to ACOs in performance-based risk tracks, including changes to update these policies to address new participation options under the BASIC track and, in certain circumstances, allow a renewing

ACO to extend the use of its current repayment mechanism into the next agreement period, which would reduce the financial burden of maintaining two concurrent repayment mechanisms. Repayment mechanism arrangements provide CMS assurance that an ACO can repay losses for which it may be liable. The proposed changes include: (1) Adding a provision that could lower the required repayment mechanism amount for BASIC track ACOs in Levels C, D, or E; (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) codifying the required duration of repayment mechanism arrangements; (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 it is sufficient 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 proposed rule would establish regulations in accordance with the Bipartisan Budget Act on the use of 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 would allow 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 proposed rule would also provide 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 would be prohibited, under certain circumstances, from charging beneficiaries for telehealth services, where CMS does not pay for those telehealth services under section 1899(l) 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 propose 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 propose to amend 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 propose policies to expand the role of choice and incentives in engaging beneficiaries in their health care. First, we propose to establish 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 would 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 would 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, we propose modifications to the program's existing policies on voluntary alignment in order to comply with the Bipartisan Budget Act, by allowing beneficiaries to designate a broader range of ACO professionals as their ''primary clinician'' responsible for coordinating their overall care, and providing that we will continue to use a beneficiary's designation to align the beneficiary to the ACO in which their primary clinician participates even if the beneficiary does not continue to receive primary care services from an ACO professional in that ACO. We also seek comment on an alternative beneficiary assignment methodology to make the assignment methodology more patient-centered, and strengthen the engagement of beneficiaries in their health care. Under such an approach, a beneficiary would be assigned to an ACO if the beneficiary ''opted-in'' to the ACO. These selections would be supplemented by voluntary alignment and a modified claims-based assignment methodology. Third, to empower beneficiary choice and further program transparency, we are proposing to revise policies related to beneficiary notifications. Specifically, we propose that ACO participants be required to include information on voluntary alignment in the written notifications they must provide to beneficiaries. ACO participants would be required to provide such notifications during each beneficiary's first primary care visit of each performance year, in addition to having such information posted in the ACO participant's facility and available upon request (as currently required).

We propose new policies for determining 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 propose to revise 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 propose 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 participants' experience with the program. We would 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. Under this proposal, we would 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 that currently apply to particular performance years of a 3-year agreement period, to ensure applicability to ACOs with an agreement period that is not less than 5 years. We also seek to strengthen the program's requirements for monitoring ACOs within an agreement period for poor financial performance and to ensure that ACOs with poor financial performance are not allowed to continue their participation in the program, or to re-enter the program after being terminated, without addressing the deficiencies that resulted in termination.

We propose to update program policies related to termination of ACOs' participation in the program. We propose to reduce 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 seek to modify 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 proposed in this rule. We also propose policies that would 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 propose to restrict eligibility for the BASIC track's glide path to ACOs inexperienced with performance-based risk Medicare ACO initiatives, which we propose to define to include all levels of the BASIC track's glide path. We also propose to 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 would impose payment consequences for early termination by proposing to hold ACOs in two-sided models liable for pro-rated shared losses. This approach would 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 would 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, although we would 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. In these cases, we would 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 propose 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 effects of excessive positive or negative regional adjustment used to establish and reset the benchmark by—

++ Reducing the maximum weight used in calculating the regional adjustment from 70 percent to 50 percent (within the existing phase-in schedule for applying increased weights in calculating the regional adjustment); 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 and downward effects of these adjustments to positive or negative 3 percent over the new agreement period.

This rule also includes proposals for updating the program's policies in a variety of subject areas. We propose to expand the definition of primary care services used in beneficiary assignment to add new codes and revise how we determine whether evaluation and management services were furnished in a SNF. We also propose to extend the policies to address quality performance scoring and determination of shared losses owed by ACOs participating under performance-based risk in the event of extreme or uncontrollable circumstances that were adopted for performance year 2017 to apply for performance year 2018 and subsequent years. We also discuss the potential effects of extreme and uncontrollable circumstances on benchmark year expenditures and the determination of the historical benchmark and seek comment on this issue.

We seek comment on approaches to developing the program's quality measure set in response to the agency's Meaningful Measures initiative as well as to support ACOs and their participating providers/suppliers in addressing opioid utilization within the FFS population. We describe existing sources of program data that may be useful for ACOs to monitor trends in opioid utilization, and solicit comment on suggestions for providing additional aggregate data to ACOs. We also seek comment on quality measures that could be used to assess factors related to opioid utilization, including patient reported outcome measures.

We propose to establish a new program requirement related to the adoption of Certified Electronic Health Record Technology (CEHRT) by eligible clinicians participating in the ACO. Specifically, we propose to require ACOs to certify, upon application to the program and annually thereafter, that the percentage of eligible clinicians participating in the ACO who use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds a specified threshold. For ACOs that are participating in a track (or payment model within a track) that meets the financial risk standard to be an Advanced APM, we further propose to align this requirement with the CEHRT use requirement for Advanced APMs under the Quality Payment Program. In conjunction with this proposal, we propose to discontinue the use of the double-weighted quality measure assessing the percentage of eligible clinicians that successfully meet the Promoting Interoperability Performance Category Base Score (Use of CEHRT, ACO–11) in order to reduce burden and align with the requirements of the Quality Payment Program. We also propose conforming revisions to the CEHRT requirement for Shared Savings

Program ACOs in the Quality Payment Program's regulations under 42 CFR part 414.

Lastly, we seek 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 seek 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.

3. Summary of Costs and Benefits

As detailed in section IV of this proposed rule, the proposed 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 proposed 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 $2.24 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 calendar year (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 mandating that any such voluntary identification will supersede claims-based assignment, and allowing ACOs under certain two-sided models

[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).

to establish CMS-approved beneficiary incentive programs.

II. Provisions of the Proposed Regulations

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 payment under the original Medicare FFS program under Parts A and B in the same manner as they 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 also must 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 our belief 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 and 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 our belief 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, with some commenters suggesting 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 our belief 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 our belief 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 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 of this proposed 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. 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

[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.'').

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 believe 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.

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, we believe a combination of factors affect ACOs' transition to performance-based risk.[5] These factors include:

(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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 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

[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 proposed 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.)

[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).

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 our belief 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 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

[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).

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 our belief 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 1 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 1—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

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. Proposals for Modified Participation Options Under 5-Year Agreement Periods

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 1).

As discussed in detail in the Regulatory Impact Analysis (see section IV. of this proposed rule), our experience with the program indicates

[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-Savin/Performance-Year-2018-Medicare-Shared-Savings-Prog/28n4-k8qs/data.*

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 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. We believe 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 Regulatory Impact Analysis (see section IV. of this proposed rule), 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 believe 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 conclude 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 proposed rule) for both tracks. We believe 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 note 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)). Further, as discussed in section II.D of this proposed rule, we believe 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 will 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 propose 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 propose 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 proposed 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 as described in section II.A.3 of this proposed rule. (Herein, we refer to this participation option for eligible ACOs entering the BASIC track as the BASIC track's glide path, or simply the glide path.)

We propose 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, we believe 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 (as discussed in section II.A.7 of this proposed rule) 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 propose to modify the regulations at §§ 425.600 and 425.610 to designate Track 3 as the ENHANCED track. We propose that all references to the ENHANCED track in the program's regulations would be deemed to include Track 3. Within the preamble of this proposed rule, we intend references to the ENHANCED track to apply to Track 3 ACOs, unless otherwise noted.

As part of the redesign of the program's participation options, we believe it is timely to provide the program's tracks with more descriptive and meaningful names. We believe ''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 design 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 propose that for agreement periods beginning on July 1, 2019, the length of the agreement would be 5 years and 6 months (as discussed in section II.A.7 of this proposed rule). For agreement periods beginning on January 1, 2020, and in subsequent years, the length of the agreement would be 5 years.

Currently, under § 425.20, we define ''agreement period'' to mean the term of the participation agreement, which is 3 performance years unless otherwise specified in the participation agreement. We propose to revise this definition to more broadly mean the term of the participation agreement. Additionally, we propose 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. For consistency, we propose to revise 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.

We also propose 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. In section II.A.5.c of this proposed rule, we discuss 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.

For ACOs entering agreement periods beginning on July 1, 2019, and in subsequent years, we propose 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 proposed rule.

For ACOs entering agreement periods beginning on July 1, 2019, and in subsequent years, we propose 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 discussion in section II.A.4.b.

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

We propose to discontinue Track 2 as a participation option. We propose 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) 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 believe 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 1 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 proposed 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 propose 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 propose 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 and 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 propose 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 believe 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 proposed rule, we are proposing 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.

Modifying the participation options in the Shared Savings Program to offer a new performance-based risk track requires the use of our authority under section 1899(i)(3) of the Act. 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 believe that the BASIC track would provide an additional opportunity for organizations to enter a risk-sharing arrangement and accept greater responsibility for beneficiary care.

This proposed restructuring of participation options, more generally, would help ACOs transition to performance-based risk more quickly than under the program's current design. This proposed rule 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. As described in section II.A.5.c. of this proposed rule, we propose 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). As described in section II.A.7. of this proposed rule, we propose 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 proposed 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 matches the lesser of either the revenue-based or benchmark-based loss sharing limit under the Track 1+ Model.

Further, we believe a significant incentive for ACOs to transition more quickly to the highest level of risk and reward under the BASIC track is 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.

As noted in the Regulatory Impact Analysis (section IV. of this proposed rule), 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, we do not believe that adding the BASIC track as a participation option under the Shared Savings Program would result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology in section 1899(d) (as discussed in the Regulatory Impact Analysis in section IV. of this proposed rule). Further, we believe 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.

This proposed rule includes 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 discussed in the Regulatory Impact Analysis (see section IV. of this proposed rule). As described in the Regulatory Impact Analysis, the elimination of Track 2 as an on-going participation option, the addition of the BASIC track, the benchmarking changes described in section II.D. of this proposed rule, and the proposal in section II.A.7. of this proposed rule 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 calendar year 2019 and then pro-rating these amounts to reflect the shorter performance year, require the use of our authority under section 1899(i) of the Act. These proposed changes to our payment methodology are not 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 will 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.

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

a. Overview

We propose 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. and, as needed, throughout this preamble.

In general, unless otherwise stated, we are proposing 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 proposed rule, we propose to specify in a new section of the regulations at § 425.601). Further, we propose 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 propose 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 propose 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 proposed rule, we are proposing 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 proposed rule, we propose 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 proposed 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 propose 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 proposed 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 proposed 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 this proposed rule, we are proposing 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 2018 and subsequent years. We propose 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 propose 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. We also propose to specify that policies to adjust shared losses for extreme and uncontrollable circumstances would also apply to BASIC track ACOs that are reconciled for a 6-month performance year under § 425.609 or a partial year of performance under § 425.221(b)(2) as a result of early termination as described in section II.E.4 and II.A.6.d of this proposed rule.

b. Proposals for 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 the ACO's 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 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.). 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. We believe that 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 propose the following participation options within the BASIC track.

First, we propose 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 beginning 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 (discussed in section II.A.7. of this proposed rule).

We propose 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 proposed 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 propose 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 propose 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 proposed 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 propose 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, see section II.A.7.). 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 proposed rule).

We believe 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. 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 believe the glide path should provide strong incentives for ACOs to quickly move along the progression towards higher performance-based risk, and therefore prefer 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 are proposing 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 propose 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 propose 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, the phase-in schedule of levels of risk/reward by year would be as follows, and are summarized in comparison to the ENHANCED track in Table 2. 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 proposed 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 the 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 proposed 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 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 2 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. We believe this 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 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 furnishing telehealth services in accordance with 1899(l) of the Act, the SNF 3-day rule waiver (as discussed in section II.B of this proposed rule), and the opportunity to implement a CMS-approved beneficiary incentive program (as discussed in section II.C of this proposed rule).

We propose 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, 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/reward or 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 proposed rule). We propose 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 proposed 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 6 and 7 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.

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

	BASIC Track's Glide Path				ENHANCED track (current track 3)
	Level A & Level B (one-sided model)	Level C (risk/reward)	Level D (risk/reward)	Level E (risk/reward)	
Shared Savings (once MSR met or exceeded).	1st dollar savings at a rate of up to 25% based on quality performance; not to exceed 10% of updated benchmark.	1st dollar savings at a rate of up to 30% based on quality performance, not to exceed 10% of updated benchmark.	1st dollar savings at a rate of up to 40% based on quality performance, not to exceed 10% of updated benchmark.	1st dollar savings at a rate of up to 50% based on quality performance, not to exceed 10% of updated benchmark.	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).	Yes	Yes	Yes	Yes	Yes.
Annual election to enter higher risk? (see section II.A.4.b).	Yes	Yes	No; ACO will automatically transition to Level E at the start of the next performance year.	No; maximum level of risk/reward under the BASIC track.	No; highest level of risk under Shared Savings Program.
Advanced APM status under the Quality Payment Program? [1] [2].	No	No	No	Yes	Yes.

Notes: [1] To be an Advanced APM, an APM must meet the following three criteria: 1. CEHRT criterion: Requires participants to use certified electronic health record technology (CEHRT); 2. Quality Measures criterion: Provides payment for covered professional services based on quality measures comparable to those used in the quality performance category of the Merit-based Incentive Payment System (MIPS); and 3. Financial Risk criterion: Either (1) be a Medical Home Model expanded under CMS Innovation Center authority; or (2) require participating APM Entities to bear more than a nominal amount of financial risk for monetary losses. See, for example Alternative Payment Models in the Quality Payment Program as of February 2018, available at *https://www.cms.gov/Medicare/Quality-Payment-Program/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. BASIC track Level E and the ENHANCED track would meet all three Advanced APM criteria and thus would qualify as Advanced APMs. These preliminary assessments reflect the policies discussed in this proposed rule. CMS will make a final determination based on the policies adopted in the final rule.

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

(3) Calculation of Loss Sharing Limit

As we described earlier in this section, 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 have 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.

Based on CMS's 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). 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 proposed 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 recognize 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 believe these observations from the Track 1+ Model support 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 this proposed 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 are proposing 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 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. 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.

[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).

We also believe 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, we believe that 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 3 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 3—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

We believe that 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's concerns about the complexity of auditing the information reported by ACOs.

We are proposing 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 as described in section II.A.3.b.2 of this proposed rule. 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 seek 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 propose 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 APM incentive payment when the ACO is participating under Level E. For example, for performance years 2019 and 2020, this would be 8 percent. 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 propose 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 proposed 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 4 provides a hypothetical example of the calculation of the loss sharing limit for an ACO participating under Level E of the BASIC track. This example would be relevant, under the proposed policies, for an ACO participating in BASIC track Level E for the performance years beginning on July 1, 2019, and January 1, 2020, 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.

TABLE 4—HYPOTHETICAL EXAMPLE OF LOSS SHARING LIMIT AMOUNTS FOR ACO IN BASIC TRACK LEVEL E

[A] ACO's Total updated benchmark expenditures	[B] ACO Participants' total medicare parts A and B FFS revenue	[C] 8 percent of ACO Participants' total medicare parts A and B FFS revenue ([B] x .08)	[D] 4 percent of ACO's updated benchmark expenditures ([A] x .04)
$93,411,313	$13,630,983	$1,090,479	$3,736,453

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 believe it is important to 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 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.

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

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 proposed rule. In this section, we propose 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. Proposals for Permitting Election of Differing Levels of Risk Within the BASIC Track's Glide Path

We are proposing 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. We believe 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.)

In developing this proposal, 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 to use 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 proposed 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 believe it would be protective of the Trust Funds to restrict ACOs from moving from the BASIC track to the ENHANCED track within their 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 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 proposed 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 (such as the ENHANCED track).

We propose to add a new section of the Shared Savings Program regulations at § 425.226 to govern annual participation elections. Specifically, we propose 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 propose 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 propose 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 propose 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 for a detailed discussion of these requirements.) We propose 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 envision 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 propose 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 July 1, 2019 could elect to enter a higher level of risk/reward within the BASIC

track in advance of the performance year beginning 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 does 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.

c. Proposals for Permitting Annual Election of Beneficiary Assignment Methodology

Section 1899(c)(1) of the Act, as amended by section 50331 of the Bipartisan Budget Act of 2018, provides that the Secretary shall determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on utilization of primary care services furnished by physicians in the ACO and, in the case of performance years beginning on or after January 1, 2019, services provided by a FQHC or RHC. The provisions of section 1899(c) 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 this 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 II.E.2 of this proposed 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 this proposed rule, we are proposing to implement this provision of the Bipartisan Budget Act to provide all ACOs with a choice of prospective assignment for agreement periods beginning July 1, 2019 and in subsequent years. We are also proposing 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 proposed 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 are proposing 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. We believe we are able to begin offering all Shared Savings Program ACOs the opportunity to select their assignment methodology annually, starting with agreement periods beginning July 1, 2019, while meeting the requirements of the Bipartisan Budget Act.

As an approach to meeting the requirements of the Bipartisan Budget Act while building on them to offer greater flexibility, we propose to offer ACOs entering agreement periods in the BASIC track or ENHANCED track, beginning July 1, 2019 and in subsequent years, the option to choose either prospective assignment or preliminary prospective assignment with retrospective reconciliation, prior to the start of their agreement period (at the time of application). We also propose to provide an opportunity for ACOs to switch their selection of beneficiary assignment methodology on an annual basis. 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, we believe 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 proposed rule, we are proposing to discontinue Track 2. Finally, we believe it is appropriate and reasonable to start offering the choice of beneficiary assignment to ACOs in the BASIC track or ENHANCED track for agreement periods beginning July 1, 2019, in order to align with the availability of these two tracks under the proposed redesign of the Shared Savings Program.

We propose 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 propose 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 July 1, 2019, this methodology would apply in the ACO's first performance year (6-month performance year from July 2019–December 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 propose 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 proposed rule. We propose 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 propose 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 propose to make conforming changes to regulations that currently identify assignment methodologies according to program track. Specifically, we propose 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 wish to clarify 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 propose 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 is 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). We continue to believe it is important to maintain symmetry between the benchmark and performance year calculations, and therefore believe it is 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 propose 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 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 seek comment on these proposals.

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

a. Overview

In this section, we describe considerations related to, and proposed policies for, distinguishing among ACOs based on their degree of control over total Medicare Parts A and B FFS expenditures for their assigned beneficiaries by identifying low revenue versus high revenue ACOs, experience of the ACO's legal entity and ACO participants with the Shared Savings Program and performance-based risk Medicare ACO initiatives, and prior performance in the Shared Savings Program. 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 aim to strengthen the following programmatic areas by further policy development.

First, we believe that 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 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 aim 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 before transitioning to the ENHANCED track.

Second, we believe that 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, we believe it is 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 aim to provide a more consistent evaluation of these ACOs' prior performance in the Shared Savings Program at the time of re-application. We also aim 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 believe it is 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 this section, we propose 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; (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; and (3) consideration of 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.

(1) Identifying Low Revenue ACOs and High Revenue ACOs

To define low revenue ACOs and high revenue ACOs for purposes of determining ACO participation options, we believe it is important to consider 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. Elsewhere in this proposed rule, we explain 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 (section IV. of this proposed rule), we describe an approach for differentiating low revenue 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 section IV, 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 and high revenue ACOs.

However, we are concerned 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 believe it is 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 this proposed rule) and the estimated repayment mechanism values for BASIC track ACOs (see section II.A.6.c of this proposed rule), include 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 propose 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 high revenue, while ACOs with a percentage less than the threshold amount would be considered low revenue. In determining the appropriate threshold, we considered our claims-based analysis comparing estimated revenue and benchmark values for Track 1+ Model applicants, as described in section II.A.3. of this proposed rule. We believe 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 believe 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 believe these observations are generalizable and suggest 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 propose to use a 25 percent threshold to determine low revenue 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 propose to add new definitions at § 425.20 for ''low revenue ACO,'' and ''high revenue ACO.''

We propose 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 propose 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 are concerned a lower threshold could categorize ACOs with more moderate revenue as high revenue, for example because of the presence of multi-specialty physician practices or certain rural or safety net providers/suppliers (such as CAHs, FQHCs and RHCs). Categorizing these moderate revenue ACOs as high revenue, 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 are concerned 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 seek 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 low revenue or high revenue is consistent with the proposed 12 month period for determining repayment mechanism amounts (as described in section II.A.6.c of this proposed rule). Such an 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 or high revenue ACO. Additionally, for ACOs with a participant agreement start date of July 1, 2019, we also propose to determine whether the ACO is low revenue or high revenue using expenditure data from the most recent calendar year for which 12 months of data are available.

We note 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 or high revenue ACO. However, 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 seek 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 are especially concerned 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 propose 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 propose 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 propose 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 propose 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 propose 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 propose 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 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. This approach 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 (described elsewhere in this proposed rule) 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/Acute InpatientPPS/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. As described in detail throughout this section of this proposed rule, we believe a revenue-based approach is 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 seek comment on the proposed definitions of ''low revenue ACO'' and ''high revenue ACO''. We also seek comment on the alternatives considered. Specifically, we seek 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 seek comment on the second alternative of differentiating between ACOs based on the size of their assigned population (that is, small versus large ACOs).

(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 this proposed rule, we propose 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. We also propose 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 believe 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 propose 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 believe 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 propose 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 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 as described in section II.A.5.c of this proposed rule.

Therefore, we propose 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 proposed rule (as determined based on whether an ACO is low revenue versus high revenue and inexperienced 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 the 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 described in section II.A.5.c of this proposed rule.

We recognize 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 seek 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 seek 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 seek 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 believe 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'/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 seek 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 believe 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 propose to specify these proposed requirements for low revenue ACOs and high revenue ACOs in revisions to § 425.600, along with other 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 proposed rule. We propose 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 propose 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 seek comment on these proposals.

More generally, we note 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.

(3) Allowing Greater Potential for Reward for Low Revenue ACOs

In this section, we describe and seek comment on several approaches to allowing for potentially greater access to shared savings for low revenue ACOs compared to high revenue ACOs, but do not make any specific proposals at this time. The approaches to rewarding low revenue ACOs discussed in this section recognize the performance trends of low revenue ACOs based on program results and the potential that low revenue ACOs would need additional capital, as a means of encouraging their continued participation in the program.

Although low revenue ACOs generally have control over a smaller share of the total Medicare Parts A and B FFS expenditures for their assigned beneficiaries compared to high revenue ACOs, they have tended to perform better financially than high revenue ACOs, demonstrating their ability to more quickly meet the program's aim of lowering growth in expenditures. High revenue ACOs, in comparison, despite having the advantage of generally controlling a greater share of total Medicare Parts A and B FFS expenditures for their assigned beneficiaries, and having more institutional capacity to affect care processes and better manage care across settings, have demonstrated comparatively poor financial performance.

As previously described in section I of this proposed rule, using the methodology for identifying low revenue and high revenue ACOs described in the Regulatory Impact Analysis (section IV. of this proposed rule), program results for performance year 2016 show that low revenue ACOs outperformed high revenue ACOs, as 41 percent of low revenue ACOs shared savings compared to 23 percent of high revenue ACOs. Among ACOs with four performance years of program results, low revenue ACOs in Track 1 outperformed high revenue ACOs, generating average gross savings of 2.9 percent compared to 0.5 percent for high revenue ACOs. Low revenue ACOs in Track 2 and Track 3 also outperformed high revenue ACOs. The four Track 3 ACOs that owed losses in performance year 2016 were all high revenue. These results suggest high revenue ACOs may be underperforming in containing growth in expenditures, while taking advantage of other aspects of program participation.

We believe low revenue ACOs, identified as proposed previously in this section (that is, 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.

We believe that offering increased potential for low revenue ACOs to earn shared savings would support their success in meeting the program's goals by allowing these organizations to maximize their return on investment, which may be needed to support start-up and operational expenses, and to facilitate their participation in performance-based risk. For example, shared savings payments received by low revenue ACOs could be used to support funding of a repayment mechanism required for their participation in performance-based risk, support meeting the program's quality reporting requirements, or support, when eligible, implementation of an approved beneficiary incentive program as discussed in section II.C.2 of this proposed rule. Any additional incentive would complement previously described proposals that would provide low revenue ACOs a longer pathway to participation under the highest level of risk and potential reward in the ENHANCED track.

One approach we considered would be to allow for a lower MSR for low revenue ACOs in the BASIC track. In section II.A.6.b of this proposed rule, we propose that under Level A and Level B of the BASIC track, under a one-sided model, ACOs with at least 5,000 assigned beneficiaries will have a MSR that varies between 2 percent and 3.9 percent based on the size of the ACO's assigned beneficiary population (which is the same MSR methodology currently used in Track 1). In performance years under a two-sided model of either the BASIC track or the ENHANCED track, we propose to apply a symmetrical MSR/MLR, as chosen by the ACO prior to entering into performance-based risk. As an alternative, to provide a greater incentive for low revenue ACOs, we considered applying a lower MSR during the one-sided model years (Level A and B) for low revenue ACOs that have at least 5,000 assigned beneficiaries for the performance year. For example, 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 this proposed rule.

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. This may be especially important for small ACOs, which would otherwise have MSRs towards the higher end of the range (closer to 3.9 percent, for an ACO with at least 5,000 assigned beneficiaries) for years in which the ACO participates under a one-sided model. However, we do not believe 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, their control over a significant percentage of the 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.

Another approach we considered is to allow for a relatively higher final sharing rate under the first four levels of the BASIC track's glide path for low revenue ACOs. For example, rather than the proposed approach under which the final sharing rate would phase in from a maximum of 25 percent in Level A to a maximum of 50 percent in Level E, 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.

For any policies that would apply differing levels of potential reward to ACOs based on factors such as ACO participants' revenue and expenditures for the ACO's assigned beneficiaries, we prefer an approach under which we would annually re-evaluate whether an ACO is low revenue or high revenue, taking into consideration any changes to the ACO's list of ACO participants or to the providers/suppliers billing through the TINs of the ACO participants that are made during the agreement period. This approach would help ensure, for example, that ACOs do not omit certain institutional providers or other high revenue providers/suppliers from their initial ACO participant list for the purpose of securing their participation in a more favorable financial model, only to subsequently add these organizations to their ACO in subsequent years of the same agreement period.

We seek comment on these considerations. We will carefully consider the comments received regarding these options during the development of the final rule, and may consider adopting one or more of these options in the final rule.

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

(1) Overview

In this section of the proposed rule we describe 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 their 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 on whether the ACO is low revenue or high revenue.
- Establishing policies that more clearly differentiate the participation options, and the applicability of program requirements that phase-in over time based on the ACO's and ACO participants' prior experience in the Shared Savings Program or with other Medicare ACO initiatives.

The regulatory background for the proposed policies in this section of the proposed rule includes 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 that are re-entering 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 believe 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) Proposals for Streamlining Regulations

We seek 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 seek 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 propose to define a renewing ACO and an ACO re-entering after termination or expiration of their participation agreement. 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 believe 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 propose to define renewing ACO and re-entering ACO in new definitions in § 425.20.

We propose 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 are also concerned 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 allows for 2 years under a one-sided model for new ACOs only. We are therefore interested in adopting an approach to better identify prior participation and to specify participation options and program requirements applicable to re-entering ACOs.

We propose 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 note that a number of proposed policies depend on the prior participation of an ACO or the experience of its ACO participants. As discussed elsewhere in section II.A of this proposed rule, these include: (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 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 believe 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, we believe that 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 proposed rule. We wish to clarify 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 recognize 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 we believe the most recent experience of the ACO participants in the new ACO is most relevant to determining the applicability of policies to the re-entering ACO. We therefore propose 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 we believe that it will 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 threshold 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 we believe that 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 seek comment on these proposed definitions and on the alternatives considered.

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

We believe it would be useful to revise our regulations to clearly set forth the eligibility requirements and application procedures for renewing ACOs and re-entering ACOs. Therefore, we propose 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 propose 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 proposed in this rule. As discussed elsewhere in this section, we propose 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 proposed 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 proposed rule), the ACO could apply for a SNF 3-day rule waiver (as proposed in section II.B.2.a. of this proposed 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 proposed 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 propose to discontinue (as described in section II.A.2 of this proposed 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 note 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 proposed rule), the effective termination date of its current agreement should be June 30, 2019.

We propose 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 propose 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. 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).

(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 address: (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 perform poorly or to be terminated.

First, we propose modifications to the criterion governing our evaluation of whether the ACO has a history of compliance with the program's quality performance standard. We propose 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 propose 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 are concerned 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 propose 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. In section II.A.7 we propose a 6-month performance year for ACOs that started a first or second agreement period on January 1, 2016, that elect an extension of their agreement period by 6 months from January 1, 2019 through June 30, 2019, and a 6-month first performance year for ACOs entering agreement periods beginning on July 1, 2019. We have also proposed to 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, to June 30, 2019, and from July 1, 2019, to December 31, 2019, as described in section II.A.7 of this proposed 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 propose would be determined 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 believe it is 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 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 BASIC track's glide path on July 1, 2019).

We note 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. 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 propose 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 propose 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 propose 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 proposed rule.

Lastly, we propose 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 propose 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 propose 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 (discussed in this section of this proposed rule) 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. As we discussed previously, we propose to discontinue use of § 425.222. We believe adding a similar requirement to § 425.224 would allow us to more consistently apply policies to renewing and re-entering ACOs. Further, we believe 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 we believe 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 (as discussed in this section of this proposed rule) in determining the eligibility of ACO A to enter a new participation agreement in the program.

(5) Proposed Evaluation Criteria for Determining Participation Options

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, we believe 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 risk 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.

As discussed elsewhere in this section (II.A.5.c of this proposed rule), we are proposing to discontinue application of the policies in § 425.222(a). As a result of this change, we will 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 are concerned 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 are also concerned 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. We believe 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 we believe some restriction is 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 believe it is 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 Physician Group Practice (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 believe it is appropriate to propose 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, we believe that using prior participation by ACO participant TINs in Medicare ACO initiatives along with the prior participation of the ACO legal entity is important when gauging 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's 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 our proposals to differentiate between low revenue and high revenue ACOs, as previously discussed in this section.

Fourth, and lastly, we believe 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.

We prefer 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. 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 propose 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 propose 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 propose 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 propose 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 propose 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 propose 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 are proposing 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 propose 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 propose 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 propose 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 propose 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 includes such other Medicare ACO initiatives involving two-sided risk as may be specified by CMS.

We propose to 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.

As we previously discussed, we are proposing 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 propose to identify all Track 1 ACOs that deferred renewal as being experienced with performance-based risk Medicare ACO initiatives. This includes 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. We believe 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, is necessary to 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 propose to 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.

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 is 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 do not believe that the proposed parameters are 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 propose 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 believe 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 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 are proposed to 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, we believe 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 the ACO's ACO participant list remains relatively unchanged. Second, we believe 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, we believe 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 (if our proposal is finalized), 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 would 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 is not to be overly restrictive, but rather to ensure that ACOs with significant experience with performance-based risk are appropriately placed. While we favor 40 percent for its consistency with the Track 1+ Model requirement, we also seek comment on other numeric thresholds.

As previously discussed in this section, we believe some restriction is 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 believe 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 propose 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 proposed 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 seek comment on this alternative approach.

In summary, in combination with determining an whether ACOs are low revenue versus high revenue, we propose to add 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:

- If an ACO is identified as high revenue, 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.

- If an ACO is identified as low revenue, 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 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 enter the BASIC track Level E (highest level of risk and potential reward) or the ENHANCED track. As discussed in section II.A.3.b of this proposed rule, low revenue ACOs are limited to two agreement periods of participation under the BASIC track.

We propose 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 seek 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 welcome commenters' input on our proposal to assess ACO participants' experience with performance-based risk Medicare ACOs using a 40 percent threshold, and the alternative of employing a threshold other than 40 percent, for example, 30 percent. We welcome 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 welcome 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.

We also believe it is appropriate to 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 note that for purposes of this discussion, we consider 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 propose 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 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) under the proposed approach to applying factors based on regional FFS expenditures beginning with the ACO's first agreement period (see section II.D of this proposed rule). 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 propose 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 propose 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 propose 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 believe 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 propose 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 is 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 is considered to be entering into, for a subset of ACOs, as specified in the provision at § 425.222(c), which we are proposing to discontinue using. We believe this proposed approach ensures 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 helps 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 we believe 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.

We believe 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, mitigate our concerns regarding ACO gaming. We believe 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 the policies discussed elsewhere in this section of the proposed rule for identifying ACOs that are experienced with performance-based risk Medicare ACOs 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 the BASIC track Level E (if an otherwise eligible low revenue ACO) or the ENHANCED track. This mitigates 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 is 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 note that these ACOs' benchmarks would be rebased, which we believe would help to mitigate this concern. We seek 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.

In the June 2016 final rule, we established the phase-in of the weights used in calculating the regional adjustment to the ACO's historical benchmark, for second or subsequent agreement periods beginning in 2017 and subsequent years. As discussed in section II.D of this proposed rule, we propose to use factors based on regional FFS expenditures in calculating an ACO's historical benchmark beginning with an ACO's first agreement period for agreement periods beginning on July 1, 2019, and in subsequent years. We would maintain the phase-in for the regional adjustment weights for ACOs with start dates in the program before July 1, 2019, according to the structure established in the earlier rulemaking (such as using these factors for the first time in resetting benchmarks for the third agreement period for 2012 and 2013 starters). Table 5 includes examples of the phase-in of the proposed 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 proposed approach to differentiating initial entrants, renewing ACOs (including ACOs that renew early), and re-entering ACOs for purposes of policies that phase-in over time.

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

Applicant type	First time regional adjustment used: 35 percent or 25 percent (if spending above region)	Second time regional adjustment used: 50 percent or 35 percent (if spending above region)	Third and subsequent time regional adjustment used: 50 percent weight
New entrant with start date on July 1, 2019.	Applicable to first agreement period starting on July 1, 2019.	Applicable to second agreement period starting in 2025.	Applicable to third agreement period starting in 2030 and all subsequent agreement periods.
Renewing ACO for agreement period starting on July 1, 2019, with initial start date in 2012, 2013, or 2016.	Applicable to third (2012/2013) or second (2016) agreement period starting on July 1, 2019.	Applicable to fourth (2012/2013) or third (2016) agreement period starting in 2025.	Applicable to fifth (2012/2013) or fourth (2016) agreement period starting in 2030 and all subsequent agreement periods.

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

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

As part of the development of these proposals, 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. 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 believe it is no longer 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's ACO participants 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 described in this section, we 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 note 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 believe that our proposal, as discussed in section II.D of this proposed rule, to apply factors based on regional FFS expenditures to ACOs' benchmarks in their first agreement periods addresses 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 decline 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 prefer 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 propose 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.

[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/.*

We seek comment on the proposals described in this section and the alternatives considered. The participation options available to ACOs based on the policies proposed in this section are summarized in Table 6 (low revenue ACOs) and Table 7 (high revenue ACOs).

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

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

TABLE 7—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.

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

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

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

d. Monitoring for Financial Performance

(1) Background

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), (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).

Now that we have additional experience with monitoring ACO financial performance, we believe that 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.

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 believe 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 propose to modify § 425.316 to add a provision for monitoring ACO financial performance. Specifically, we propose 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 propose 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 propose that we may immediately or with advance notice terminate the ACO's participation agreement under § 425.218.

We propose 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. 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 anticipate that the financial performance results for performance years beginning on January 1, 2019 and July 1, 2019, will be available for CMS review in the summer of 2020 and will 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 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, the 2016 results do not take into account ACO participant list changes for these ACOs or rebasing of the ACOs' historical benchmarks for their second agreement period. 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, while experience does not suggest that a large share of ACOs would be affected, we believe that the proposed policy, if adopted, will help to ensure that ACOs are not allowed multiple years of losses without being held accountable for their performance.

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 prefer the proposed approach previously described, because the corridor (MLR threshold above the benchmark) is established to protect ACOs against sharing losses that result from random variation.

As described briefly in section II.A.2 of this proposed rule, ACOs that

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

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 (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. We are concerned 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 believe 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 seek comment on this issue, and on ACOs' use of reinsurance, including their ability to obtain viable reinsurance products covering a Medicare FFS population.

We seek comment on these proposals and related considerations.

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. We propose 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 propose changes to the repayment mechanism requirement to update these policies to address the new participation options included in this proposed 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 propose 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 propose 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 codify 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. In this section, we also propose 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's operations and establishes more equal footing between the risk models. ACOs applying to the Track 1+ Model are 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) Proposals for Timing and Selection of MSR/MLR

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 propose 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 believe these thresholds continue to have importance to protect against savings and losses resulting from random variation, although we describe in section II.A.5.b of this proposed rule our consideration of an alternate approach

that would lower the MSR for low revenue ACOs. Further, 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's operations and establishing more equal footing between the risk models.

Specifically, we propose 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 propose to apply the same variable MSR methodology as is used under § 425.604(b) for Track 1. We propose to specify this variable MSR methodology in a proposed new section of the regulations at § 425.605(b). We also propose to specify in § 425.605(b) the MSR/MLR options for ACOs under two-sided models of the BASIC track, consistent with 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 are proposing to discontinue Track 1, we believe it is 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 propose 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 are also proposing to discontinue Track 2, concurrently with our proposal to discontinue Track 1, we do not believe it is necessary to revise the cross-reference in § 425.606(b)(1)(ii)(C) to the variable MSR methodology under Track 1.

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 believe it is 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, although they will have the opportunity to gain experience with the program, prior to making this selection. This approach would be another means for BASIC ACOs in the glide path to control their level of risk exposure.

Therefore, we propose 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).

(3) Proposals for 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 proposed rule, we are proposing 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 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 § 425.110(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.

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. Based on data available from fourth quarter 2017 program reports, which tend to provide a close approximation of final performance year assignment counts, over 4 percent of ACOs participating in PY 2017 are likely to fall below 5,000 assigned beneficiaries for the performance year, with several likely to be under 1,000.

Consistent with overall program participation trends, most ACOs that have fallen below the 5,000-beneficiary threshold in prior performance years, or that are anticipated to do so for PY 2017, have been 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 below the 5,000-beneficiary threshold that have a fixed MSR/MLR of plus or minus 2 percent or less.

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.

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 static 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 note, 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 8. 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 8. 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 8—DETERMINATION OF MSR BY NUMBER OF ASSIGNED BENEFICIARIES

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

TABLE 8—DETERMINATION OF MSR BY NUMBER OF ASSIGNED BENEFICIARIES—Continued

Number of beneficiaries	MSR (low end of assigned beneficiaries) (percent)	MSR (high end of assigned beneficiaries) (percent)
60,000 +	2.0	2.0

Therefore, we are proposing 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 propose 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 believe this proposal would have a fairly limited reach in terms of number of ACOs impacted, we believe 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. 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 propose 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 fall below the 5,000-beneficiaries threshold which are reconciled for shared savings or losses, as opposed to being limited to ACOs under a CAP as provided in the existing provision at § 425.110(b)(1). Specifically we propose 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 will also distinguish between the policies applicable to determining the MSR/MLR for performance years starting before January 1, 2019, and those that we are proposing to apply for performance years starting in 2019 and subsequent years.

We propose 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 note these 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 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 proposed rule, we propose to specify under a new section of the regulations at § 425.605(b)(1) the range of MSR values that apply under the 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 seek 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 seek commenters' feedback on whether the proposed approach described in this section could improve accountability of ACOs.

We also note that the requirement of section 1899(b)(2)(D) of the Act, for an ACO to have at least 5,000 assigned beneficiaries, continues 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 II.A.6.d of this proposed rule, we are proposing 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.

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 their use; and the duration of the repayment mechanism arrangement.

[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).

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.

The 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.

More generally, 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 believe this approach is 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 proposed 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 lower 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. As noted in our Repayment Mechanism Arrangements Guidance, we believe that this standard would be satisfied by an arrangement that terminates 24 months following the end of the agreement period.

(2) Proposals Regarding 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. We propose 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 believe 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 would 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 lower of the two amounts described previously. We believe this aligns 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 proposed rule. In addition, this approach balances 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 propose 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 are proposing 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 propose 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, 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 propose 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).

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 providers/suppliers enrolled in the ACO 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, 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 propose 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 propose 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 propose 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. If this amount has increased 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 solicit 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 propose that if the estimated amount decreases as a result of the ACO's

change in composition, we will 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, we propose 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 propose 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 propose 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. This proposal protects the financial integrity of the program by ensuring that a renewing ACO will remain capable of repaying losses incurred under its old agreement period.

We propose 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 propose 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 proposed rule.

(3) Proposals Regarding 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 believe modifications to the existing repayment mechanism requirements are 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 believe 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 are proposing 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 are proposing 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 seek comment on these proposals.

(4) Proposal for Repayment Mechanism Duration

We acknowledge that the proposed change to an agreement period of at least 5 years will 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 point 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 will remain 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 propose 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 believe ACOs will be able to work with financial institutions to establish repayment mechanism arrangements that will cover a 5-year agreement period plus a 24-month tail period. This proposed approach is consistent with the program's current guidance.

We propose some exceptions to this general rule. First, we propose 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 believe this may be necessary in rare circumstances to protect the financial integrity of the program.

Second, we believe the duration requirement 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 previously noted, we propose 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 propose 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 are considering 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 proposed rule, renewing ACOs (as we propose 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 recognize 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 are considering 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 solicit comment on whether we should require a longer or shorter extension.

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 seek 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 may specify in the 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 may specify in the final rule). 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 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 believe 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 propose to include similar requirements at § 425.204(f)(6). Specifically, we propose 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 solicit 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.

(5) Proposals Regarding Institutions Issuing Repayment Mechanism Arrangements

We are also proposing 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 propose 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 anticipate 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 welcome commenters' suggestions on these proposed requirements for ACOs regarding the issuing institution for repayment mechanism arrangements.

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.

The current regulations also do not impose any liability for shared losses on two-sided model ACOs that terminate from the program prior to December 31 of a given performance year. 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.

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 are 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, these incentives could have a detrimental effect on the Medicare Trust Funds.

(2) Proposals for Advance Notice of Voluntary Termination

We are 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's 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.

We believe 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 are therefore proposing 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.

(3) Proposals for Payment Consequences of Termination

In this section, we discuss 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 believe 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 recognize that it may 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 do so by providing notice 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 and are also eligible to share in savings. 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 acknowledge the merit of reducing provider uncertainty around Quality Payment Program eligibility, we also recognize that in the early part of the performance year, ACOs have a limited amount of information on which to base termination decisions. 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 to facilitate care management, such as beneficiary-identifiable claims data or payment rule waivers, such as 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 believe that 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, clinicians affiliated with ACOs that terminate with an effective date between March 31 and June 30 would be captured in one or more QP determination snapshots. Clinicians determined to have QP status would lose their status as a result of the termination, and would instead be scored under MIPS using the APM scoring standard.

We propose to conduct financial reconciliation for all ACOs in two-sided models that voluntarily terminate after June 30. We propose 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 will 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 will 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 one 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.

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 are liable for a higher portion of any shared losses that are incurred. This approach also reflects the fact that later-terminating ACOs may have enjoyed 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. Further, 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 propose 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 propose the same methodology as previously described for pro-rating shared losses for voluntarily terminated ACOs would also apply to 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 recognize that this approach may appear to favor CMS, we believe that ACOs expecting to generate savings are less likely to terminate early in the first place. 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 propose 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, with the pro-rated amount reflecting the number of months during the performance year that the ACO was in the program. We propose to apply this policy to ACOs in two-sided models for performance years beginning in 2019 and subsequent performance years.

We also propose to specify in the regulations at § 425.221 the payment consequences of termination during calendar year 2019 for ACOs preparing to enter or participating under agreements beginning July 1, 2019 (see section II.A.7 of this proposed rule).

First, as discussed in detail in section II.A.7 of this proposed rule, we would reconcile ACOs based on the respective 6-month performance year methodology for their participation during a 6-month portion of 2019 in which they are either under a current agreement period beginning prior to 2019, or under a new agreement period beginning July 1, 2019. We propose 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. That is, we would reconcile: ACOs that started a first or second agreement period 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 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, July 1, 2019 through December 31, 2019) we propose 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 calendar year 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 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.

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 enter a new agreement period beginning 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). We propose that ACOs with an effective date of termination of June 30, 2019 that enter a new agreement period beginning July 1, 2019, are 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.

We believe some ACOs may act quickly to enter one of the new participation options made available under the proposed redesign of the program (if finalized). 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, certain ACOs may ultimately realize they are not yet prepared to participate under a new

agreement beginning July 1, 2019 and seek to terminate quickly. 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 (if finalized), we also do not want to unduly bind ACOs that aggressively pursue these new options. We believe the proposed approach provides a means for ACOs to terminate their participation prior to renewing their participation for an agreement period beginning July 1, 2019 or to quickly terminate from a new agreement period beginning July 1, 2019 without the concern of liability for shared losses for a portion of the year.

We also propose to revise the regulations at § 425.221 to streamline and reorganize the provisions in paragraph (b), which we believe is necessary to incorporate these proposed requirements. We seek comment on these proposals and the alternative policies discussed in this section.

7. Participation Options for Agreement Periods Beginning in 2019

a. Overview

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 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).

We believe the considerations that informed our decision to establish alternative start dates at the inception of the Shared Savings Program also are relevant in determining the timing for making the proposed new participation options available. We believe 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 our proposals are 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 propose 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. We anticipate the application cycle for the July 1, 2019 start date would begin in early 2019. We are forgoing the application cycle that otherwise would take place during calendar year 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 proposed rule), and entry into the Track 1+ Model (as further discussed in section II.F of this proposed rule). Although several ACOs that entered initial agreements beginning in 2015 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 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 propose the July 1, 2019 start date as 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. We would therefore anticipate 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 are aware that a delayed application due date for an agreement period beginning in 2019 could affect parties that plan to participate in the Shared Savings Program for performance year 2019 and are relying on the pre-participation waiver. Guidance for affected parties will be posted on the CMS website.

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 twelve 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. We are concerned 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.

Instead, we propose 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, as described in this section. See section II.A.7.b. of this proposed rule for a detailed discussion of this methodology.

Accordingly, our proposed approach for implementing the proposed July 1, 2019 start date would include the following opportunities for ACOs, based on their agreement period start date:

ACOs entering an agreement period beginning on July 1, 2019, would be in a participation agreement for a term of 5 years and 6 months, of which the first performance year would be defined as 6 months (July 1, 2019 through December 31, 2019), and the 5 remaining performance years of the agreement period would each consist of a 12-month calendar year.

ACOs that entered a first or second agreement period with a start date of January 1, 2016, may elect to extend their agreement period for an optional fourth performance year, defined as the 6-month period from January 1, 2019 through June 30, 2019. This election to extend the agreement period is voluntary and an ACO could 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.

We propose that the ACO's voluntary election to extend its agreement period must be made in the form and manner and according to the timeframe established by CMS, and that an ACO executive who has the authority to legally bind the ACO must certify the election. If finalized, we anticipate this election process would begin in 2018 following the publication of the final rule, as part of the annual certification process in advance of 2019 (described in section II.A.7.c.2. of this proposed rule). We note that this optional 6-month agreement period extension is a one-time exception for ACOs with agreements expiring on December 31, 2018 and would not be available to other ACOs that are currently participating in a 3-year agreement in the program, or to future program entrants.

Under the existing provision at § 425.210, the ACO must provide a copy of its participation agreement with CMS to all ACO participants, ACO providers/suppliers, and other individuals and entities involved in ACO governance. Further, all contracts or arrangements between or among the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities must require compliance with the requirements and conditions of the program's regulations, including, but not limited to, those specified in the participation agreement with CMS. An ACO that elects to extend its participation agreement by 6 months must notify its ACO participants, ACO providers/suppliers and other individuals or entities performing functions or services related to ACO activities of this continuation of participation and must require their continued compliance with the program's requirements for the 6-month performance year from January 1, 2019 through June 30, 2019.

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 July 1, 2019. (As discussed in section II.A.5. of this proposed rule, 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 of this proposed rule, an ACO's participation options for the July 1, 2019 start date would depend on whether the ACO is a low revenue or high revenue ACO and the ACO's experience with performance-based risk Medicare ACO initiatives. 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).

As discussed in section II.A.2. of this proposed rule, the proposed modifications to the definition of ''agreement period'' in § 425.20 are intended to broaden the definition to generally refer to the term of the participation agreement. We propose 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, and this election is made in the form and manner and according to the timeframe established by CMS, and certified by an ACO executive who has the authority to legally bind the ACO. For consistency, we also propose minor formatting changes to the existing provision at § 425.200(b)(2) to italicize the header text. We note that as described in section II.A.2. of this proposed rule, we are proposing modifications to § 425.200(b)(3) as part of discontinuing the deferred renewal participation option. In addition, we propose to add a 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 propose to add a provision at § 425.200(b)(5) specifying that, for agreement periods beginning in 2020 and subsequent years, the term of the participation agreement is 5 years.

We also propose to revise 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. We therefore also propose revisions to § 425.200(c) to make necessary formatting changes and specify additional exceptions to the definition of performance year as a 12-month period. Specifically, we propose 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. Similarly, we propose to add a provision 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.

In light of the proposed modifications to § 425.200(c) to establish two 6-month performance years during calendar year 2019, we believe it is also appropriate 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 calendar year 2019.

As an alternative to the proposal to offer an agreement period of 5 years and 6 months beginning 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 proposed rule in connection with 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 would result in more accurate benchmarks and mitigate the effects of reliance on increasingly older historical data as the agreement period progresses. We believe these considerations are 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. 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 calendar year 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, 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 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 calendar year 2019.

We seek comment on these proposals and the related considerations, as well as the alternatives considered.

b. Methodology for Determining Financial and Quality Performance for the 6-Month Performance Years During 2019

(1) Overview

In this section we describe the proposed methodology for determining financial and quality performance for the two 6-month performance years during calendar year 2019: The 6-month performance year from January 1, 2019, to June 30, 2019; and the 6-month performance year from July 1, 2019, to December 31, 2019. We propose to specify the methodologies for reconciling these 6-month performance years during 2019 in a new section of the regulations at § 425.609. Although we propose to use the same overall approach to determining ACO financial and quality performance for these two periods, 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).

We note that ACOs in an agreement period that includes a 12-month performance year 2019 would have the option to terminate their current participation agreements with an effective date of termination of June 30, 2019, and enter a new agreement period beginning on July 1, 2019. We propose to reconcile the performance of these ACOs during the first 6 months of 2019 using the same approach that we are proposing to use to determine performance for the 6-month performance year from January 1, 2019,

through June 30, 2019, for ACOs that started a first or second agreement period on January 1, 2016, that elect to extend their current agreement periods for this 6-month performance year. We propose to specify this approach to determining performance for these ACOs in a new section of the regulations at § 425.609 and in revisions to § 425.221 describing the payment consequences of early termination for ACOs that terminate their participation agreement with an effective termination date of June 30, 2019, and enter a new agreement period beginning July 1, 2019.

After the conclusion of calendar year 2019, CMS would reconcile the financial and quality performance of ACOs that participated in the Shared Savings Program during 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 as discussed elsewhere in this section, 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. We discuss these calculations in detail in section II.A.7.b.2. (for the 6-month period from January 1, 2019 through June 30, 2019) and section II.A.7.b.3. (for the 6-month period from July 1, 2019 through December 31, 2019). Further, we note that this proposed approach to reconciling ACO performance for a 6-month performance year (or performance period) during 2019 would not alter the methodology that would be applied to determine financial performance for ACOs that complete a 12 month performance year corresponding to calendar year 2019.

We note that in discussing these 6-month periods, we use two references, ''6-month performance year'' and ''performance period.'' According to our proposed revisions to § 425.200(c), 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 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''.

Under the proposed policies, we would calculate shared savings or shared losses applicable to an ACO, by comparing the expenditures for the ACO's performance year assigned beneficiaries for calendar year 2019 to the ACO's historical benchmark updated to calendar year 2019. If the difference is positive and is greater than or equal to the MSR and the ACO has met the quality performance standard, the ACO would be eligible for shared savings. If the ACO is in a two-sided model and the difference between the updated benchmark and assigned beneficiary expenditures is negative and is greater than or equal to the MLR (in absolute value terms), the ACO would be liable for shared losses. ACOs would share in first dollar savings and losses based on the applicable final sharing rate or loss sharing rate according to their track of participation for the applicable agreement period, and taking into account the ACO's quality performance for 2019. We would adjust the amount of shared savings for sequestration. We would cap the amount of shared savings at the applicable performance payment limit for the ACO's track and cap the amount of shared losses at the applicable loss sharing limit for the ACO's track. We would then pro-rate 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 (or performance period). This pro-rated amount would be the final amount of shared savings earned or shared losses owed by the ACO for the applicable 6-month performance year (or performance period).

We believe this proposed approach 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 calendar year 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. Deviating from a 12 month reconciliation calculation by using fewer than 12 months of performance year expenditures could interject actuarial biases relative to the benchmark expenditures, which are based on 12 month benchmark years. As a result, we believe this approach to reconciling ACOs based on a 12 month period would protect the actuarial soundness of the financial reconciliation methodology. We also believe 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 will 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 anticipate results with respect to participation during calendar year 2019 would be made available to ACOs in summer 2020. This would allow those ACOs that are eligible to share in savings as a result of their participation in the program during calendar year 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. As discussed in detail in section II.A.7.c.6. of this proposed rule, we propose to provide separate reconciliation reports for each 6-month performance year (or performance period) and would pay shared savings or recoup shared losses separately for each 6-month performance year (or performance period) during 2019 based on these results.

Furthermore, this approach would avoid a more burdensome interim payment process that could accompany an alternative proposal to instead implement, for example, an 18-month performance year from July 1, 2019 to December 31, 2020. Consistent with 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 required, 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 believe 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 calendar year 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 believe 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 believe it is 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 the proposed 6-month performance years (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. We believe 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 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, 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 (section IV. of this proposed rule), we believe this approach would continue to allow for lower growth in Medicare FFS expenditures based on projected participation trends. Therefore, we do 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 believe that the proposed approach to measuring ACO quality performance for a 6-month performance year (or performance period) based on quality data reported for calendar year 2019 maintains 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 believe this 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.

(2) Proposals for Determining Performance for the 6-Month Performance Year From January 1, 2019, Through June 30, 2019

In this section, we describe our proposed approach to determining an ACO's performance for the 6-month performance year from January 1, 2019, through June 30, 2019. These proposed policies would also apply to ACOs that begin a 12-month performance year on January 1, 2019, but 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 (early renewals). Our proposed policies address the following: (1) The ACO participant list that will be used to determine beneficiary assignment; (2) the approach to assigning beneficiaries; (3) the quality reporting period; (4) the benchmark year assignment methodology and the methodology for calculating, adjusting and updating the ACO's historical benchmark; and (5) the methodology for determining shared savings and shared losses. We propose to specify these policies for reconciling the 6-month period from January 1, 2019, through June 30, 2019 in paragraph (b) of a new section of the regulations at § 425.609.

We propose to use the ACO participant list for the performance year beginning January 1, 2019, to determine beneficiary assignment as specified in §§ 425.402 and 425.404, and according to the ACO's track as specified in § 425.400. As discussed in section II.A.7.c of this proposed rule, we propose to allow all ACOs, including ACOs entering a 6-month performance year, to make changes to their ACO participant list in advance of the performance year beginning January 1, 2019.

To determine beneficiary assignment, we propose 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 January 1, 2019 through June 30, 2019, we propose to determine the assigned population using the following assignment windows:

- For ACOs under preliminary prospective assignment with retrospective reconciliation, the assignment window would be calendar year 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. For example, in determining prospective beneficiary assignment for the January 1, 2019 through June 30, 2019 performance year we could use an assignment window from October 1, 2017, through September 30, 2018, to align with the off-set assignment window typically used to determine prospective assignment prior to the start of a calendar year performance year. Beneficiaries would remain prospectively assigned to the ACO at the end of calendar year 2019 unless they

meet any of the exclusion criteria under § 425.401(b) during the calendar year.

We note that this is the same approach that is used to determine assignment under the program's current regulations. Therefore, it would also be used to determine assignment for the performance year beginning on January 1, 2019, for ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019, for purposes of determining their performance during the performance period from January 1, 2019 through June 30, 2019.

As discussed in section II.A.7.c. of this proposed rule, to determine ACO performance during a 6-month performance year, we propose 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. For early renewal ACOs that terminate their agreement effective June 30, 2019, and enter a new agreement period starting on July 1, 2019, 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 described in section II.A.7.c.4. of this proposed rule, we propose using a different quality measure sampling methodology depending on whether an ACO participates in both a 6-month performance year (or performance period) beginning January 1, 2019 and a 6-month performance year beginning July 1, 2019, or only participates in a 6-month performance year from January 1, 2019 through June 30, 2019.

Consistent with current program policy, we would determine assignment for the benchmark years based on the most recent certified ACO participant list for the ACO effective for the performance year beginning January 1, 2019. This would be the participant list the ACO certified prior to the start of its agreement period unless the ACO has made changes to its ACO participant list during its agreement period as provided in § 425.118(b). If the ACO has made subsequent changes to its ACO participant list, we would recalculate the historical benchmark using the most recent certified ACO participant list. See the 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.*

For the 6-month performance year from January 1, 2019, through June 30, 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 would apply the methodology for establishing, updating and adjusting the ACO's historical benchmark as specified in § 425.602 (for ACOs in a first agreement period) or § 425.603 (for ACOs in a second agreement period), except that data from calendar year 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 calendar year 2019 using the methodology that accounts separately for newly and continuously assigned beneficiaries using prospective HCC risk scores and demographic factors as described under §§ 425.604(a)(1) through (3), 425.606(a)(1) through (3), and 425.610(a)(1) through (3).
- The benchmark would be updated to calendar year 2019 according to the methodology for using growth in national Medicare FFS expenditures for assignable beneficiaries described under § 425.602(b) (for ACOs in a first agreement period) and § 425.603(b) (for ACOs in a second agreement period beginning January 1, 2016), or the methodology for using growth in regional Medicare FFS expenditures described under § 425.603(d) (for ACOs in a second agreement period beginning January 1 of 2017, 2018, or 2019).

We note this approach is already used to adjust and update the historical benchmark each performance year under the program's current regulations. Therefore we would use this same approach to determine the benchmark 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.

For determining performance during the 6-month performance year (or performance period) from January 1, 2019 through June 30, 2019, we would apply the methodology for determining shared savings and shared losses according to the approach specified for the ACO's track under the terms of the participation agreement that was in effect on January 1, 2019: § 425.604 (Track 1), § 425.606 (Track 2) or § 425.610 (Track 3) and, as applicable, the terms of the ACO's participation agreement for the Track 1+ Model authorized under section 1115A of the Act. (See discussion in section II.F of this proposed rule concerning applicability of proposed policies to Track 1+ Model ACOs). However, some exceptions to the otherwise applicable methodology are needed because we are proposing to calculate the expenditures for assigned beneficiaries over the full calendar year 2019 for purposes of determining shared savings and shared losses for the 6-month performance year (or performance period) from January 1, 2019, through June 30, 2019. We propose to use the following steps to calculate shared savings and shared losses:

- Average per capita Medicare expenditures for Parts A and B services for calendar year 2019 would be calculated for the ACO's performance year assigned beneficiary population.
- 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 January 1, 2019, would be used to determine the MSR for Track 1 ACOs 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 is 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 this proposed rule.

++ To qualify for shared savings, the ACO's average per capita Medicare expenditures for its performance year assigned beneficiaries during calendar year 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 calendar year 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 this section of this proposed rule, 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 tracks 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 (or performance period). 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 performance period) or the final amount of shared losses that would be owed by the ACO for the 6-month performance year (or performance period).

We seek comment on these proposals.

(3) Proposals for Determining Performance for the 6-Month Performance Year From July 1, 2019, Through December 31, 2019

In this section, we describe 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 address 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 propose 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 note 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 described in section II.A.7.b.2 of this proposed rule for the 6-month performance year from January 1, 2019 through June 30, 2019. However, 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 propose 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 this proposed rule, 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 propose 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 propose to determine the assigned population using the following assignment windows:

• For ACOs under preliminary prospective assignment with retrospective reconciliation, the assignment window would be calendar year 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. For example, we could use an assignment window from April 30, 2018, through March 31, 2019. 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 calendar year 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 of this proposed rule, to determine ACO performance during either 6-month performance year, we propose 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 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 would apply the methodology for establishing, updating and adjusting the ACO's historical benchmark as specified in proposed § 425.601, except that data from calendar year 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 calendar year 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 discussion in section II.D.2 of this proposed rule.

• The benchmark would be updated to calendar year 2019 according to the methodology described under proposed § 425.601(b) using a blend of national and regional growth rates.

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, some exceptions to the otherwise applicable methodology are needed because we are proposing to calculate the expenditures for assigned beneficiaries over the full calendar year 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 propose to use the following steps to calculate shared savings and shared losses:

• Average per capita Medicare expenditures for Parts A and B services for calendar year 2019 would be calculated for the ACO's performance year assigned beneficiary population. Additionally, when calculating calendar year 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). 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 is 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 this proposed rule.

++ To qualify for shared savings, the ACO's average per capita Medicare expenditures for its performance year assigned beneficiaries during calendar year 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 calendar year 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 this section of this proposed rule, 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 seek comment on these proposals.

c. Applicability of Program Policies to ACOs Participating in a 6-Month Performance Year

In general, unless otherwise stated, we are proposing 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. This would allow routine program operations to continue to apply for ACOs participating under these shorter performance years. Further, it would ensure consistency in the applicability and implementation of our requirements across all program participants, including ACOs participating in 6-month performance years. As we described in section II.A.7.b of this proposed rule, limited exceptions to our policies for determining financial and quality performance are necessary to ensure calculations can continue to be performed on a calendar year basis and using the most relevant data.

In this section, we describe our consideration of program participation options affected by our decision to forgo an application cycle in calendar year 2018 for a January 1, 2019 start date, and the proposal to offer instead an application cycle in calendar year 2019 for a July 1, 2019 start date. We discuss program policies that would need to be modified to allow for the proposed 6-month performance years within calendar year 2019, and related proposals to revise the program's regulations to allow for these modifications.

(1) Unavailability of an Application Cycle for Use of a SNF 3-Day Rule Waiver Beginning January 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, ACOs within a current agreement period under Track 3, or the Track 1+ Model as described in sections II.B.2.a and II.F of this proposed rule, may apply for a SNF 3-day rule waiver, which if approved would begin at the start of their next performance year. As discussed in section II.B.2.a of this proposed rule, we propose to allow the

SNF 3-day rule waiver under the Shared Savings Program to be more broadly available to BASIC track ACOs (under a two-sided model) and ENHANCED track ACOs, regardless of their choice of beneficiary assignment methodology.

In light of our decision to forgo an application cycle in calendar year 2018 for a January 1, 2019 agreement start date, we also would not offer 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 would be the next opportunity for eligible ACOs to begin use of a 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 would extend to ACOs within existing agreement periods in Track 3 that would, under 12 month performance years, not otherwise have the opportunity to apply to begin use of the waiver until January 1, 2020. We believe 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 are not proposing any corresponding revisions to this provision at this time.

(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.

Requirements for this annual certification, and other certifications that occur on an annual basis, continue to apply to all currently participating ACOs in advance of the performance year beginning on January 1, 2019. In the case of ACOs that participate for a portion of calendar year 2019 under one agreement and enter a new agreement period starting on July 1, 2019, 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, to 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, spanning July 1, 2019 to December 31, 2019.

Each ACO certifies 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). The addition of ACO participants must occur prior to the start of the performance year in which these additions become effective. ACO participant must be deleted from the ACO participant list within 30 days after termination of the ACO participant agreement, and such deletion is effective as of the termination date of the ACO participant agreement. Absent unusual circumstances, the ACO participant list that was certified prior to the start of the performance year is used for the duration of the performance year. An ACO's certified ACO participant list for a performance year is used, for example, 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.* These policies would apply for ACOs participating in a 6-month performance year consistent with the terms of the existing regulations.

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

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

The program's current regulations prevent duplication of shared savings payments. 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 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, then: (i) CMS will not consider any services billed through the TIN of the ACO participant when performing assignment for the benchmark or performance year; and (ii) the ACO may be subject to the pre-termination actions set forth in § 425.216, termination under § 425.218, or both.

We note the following examples, regarding ACO participants that submit claims for services that are used assignment, and that are participating in a Shared Savings Program ACO for a 12-month performance year during 2019 (such as a 2017 starter, 2018 starter, or 2015 starter that deferred renewal until 2019).

If the ACO remains in the program under its current agreement past June 30, 2019, these ACO participants would not be eligible to be included on the ACO participant list of another ACO applying to enter a new agreement period under the program beginning on July 1, 2019. An ACO participant in these circumstances could be added to the ACO participant list of a July 1, 2019 starter effective for the performance year beginning on January 1, 2020, if it is no longer participating in the other Shared Savings Program ACO and is not participating in another initiative identified in § 425.114(a).

If an ACO starting a 12-month performance year on January 1, 2019, terminates its participation agreement with an effective date of termination of June 30, 2019, the effective end date of the ACO participants' participation would also be June 30, 2019. Such ACOs that elect to enter a new agreement period beginning on July 1, 2019, can make ACO participant list

changes that would be applicable for their new agreement period. This means that the ACO participants of the terminating ACO could choose to be added to the ACO participant list of another July 1, 2019 starter, effective for the performance year beginning July 1, 2019.

(3) Repayment Mechanism Requirements

ACOs must demonstrate that they have in place an adequate repayment mechanism prior to entering a two-sided model. The repayment mechanism must be in effect for the duration of an ACO's participation in a two-sided model and for 24 months following the conclusion of the agreement period. (See discussion in section II.A.6.c of this proposed rule.)

We note that ACOs that started a first or second agreement period January 1, 2016 in a two-sided model would have in place under current program policies a repayment mechanism arrangement that would cover the 3 years between January 1, 2016 and December 31, 2018 plus a 24-month tail period until December 31, 2020. In the case of an ACO with an agreement period ending December 31, 2018, that extends its agreement for the 6-month performance year from January 1, 2019 through June 30, 2019, we would require the ACO to extend the term of its repayment mechanism so that it would be in effect for the duration of the ACO's participation in a two-sided model plus 24 months following the conclusion of the agreement period (that is, until June 30, 2021). This will allow us sufficient time to perform financial calculations for the 6-month performance year from January 1, 2019 through June 30, 2019 and to use the arrangement to collect shared losses for that performance year, if necessary. This policy is consistent with the policy proposed in section II.A.6.c and at § 425.204(f)(6)(i), which provides that a repayment mechanism must be in effect for the duration of the ACO's participation in a two-sided model plus 24 months following the conclusion of the agreement period.

Consistent with our proposed policy described in section II.A.6.c and § 425.204(f)(4)(iv), a renewing ACO that is under a two-sided model and entering a new agreement period beginning July 1, 2019 would 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. As previously described, we would require the ACO to extend the term of the existing repayment mechanism by an amount of time specified by CMS and, if necessary, to increase the amount of the repayment mechanism to reflect the new repayment mechanism amount.

We are proposing that, for agreement periods beginning on or after July 1, 2019, we would recalculate the amount of the ACO's repayment mechanism before the second and each subsequent performance year in the agreement period, based on the ACO's certified ACO participant list for the relevant performance year. Therefore, for an ACO that enters a new agreement period beginning July 1, 2019, we would calculate the amount of the repayment mechanism for the new agreement period in accordance with our proposed regulation at § 425.204(f)(4). Before the start of performance year 2020, we would recalculate the amount of the ACO's repayment mechanism. Depending on how much the recalculated amount exceeds the existing repayment mechanism amount, we would require the ACO to increase its repayment mechanism amount, consistent with our proposed approach described in section II.A.6.c of this proposed rule and § 425.204(f)(4)(iii).

(4) Proposals for Quality Reporting and Quality Measure Sampling

In order to determine an ACO's quality performance during either 6-month performance year during 2019, we propose 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 calendar year. As we previously described in section II.A.7.b.2 of this proposed rule, 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.

We believe 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 calendar year 2019) in determining the ACO's financial performance. Also, this approach would continue to align the program's quality reporting period with policies under the Quality Payment Program. 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. 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 calendar year 2019) in determining shared savings and shared losses for a 6-month performance year, we believe it is also appropriate to hold ACOs accountable for the quality of the care furnished to their assigned beneficiaries during this same time frame. 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 calendar year 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 described in section II.A.7.c.2. of this proposed rule, ACOs in either 6-

month performance year 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). As discussed in sections II.A.7.b.2 (January 2019–June 2019) and II.A.7.b.3 (July 2019–December 2019), 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 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 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 propose 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 believe the use of the ACO's most recent ACO participant list to assign beneficiaries according to the assignment methodology applicable based on the ACO's most recent participation in the program during 2019 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 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 believe this proposed approach to determining the ACO's quality reporting samples is 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.

We propose to specify the ACO participant lists that would be used in determining the quality reporting samples for measuring quality performance for the 6-month performance years in a new section of the regulations at § 425.609. Specifically we propose to use the following approach to determine the ACO participant list, assignment methodology and assignment window that would be used to generate the quality reporting samples for measuring quality performance of ACOs participating in a 6-month performance year (or performance period) during 2019.

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, to 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 propose 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, to 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, to 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 anticipate 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 it is 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 believe it is 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.

If an ACO extends its participation to the first 6 months of 2019, but does not enter a new agreement period beginning on July 1, 2019, we propose to use the ACO's latest certified participant list (the ACO participant list effective on January 1, 2019) to determine the quality reporting samples for the 2019 reporting period. Beneficiary assignment for purpose of generating the quality reporting samples would be based on the assignment methodology applicable to the ACO during its 6-month performance year from January 1, 2019, through June 30, 2019, under § 425.400, either preliminary prospective assignment or prospective assignment, with excluded beneficiaries removed under § 425.401(b), as applicable. We anticipate 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; and (3) the sample for the CAHPS for ACOs survey would be determined based on the assignment list for calendar year quarter 2. This approach maintains alignment with the assignment windows currently used for establishing quality reporting samples for these measures.

(5) Proposals for Applicability of Extreme and Uncontrollable Circumstances Policies

We propose in section II.E.4 of this proposed rule to extend the policies for addressing the impact of extreme and uncontrollable circumstances on ACO financial and quality performance results for performance year 2017 to performance year 2018 and subsequent years. As specified in section II.E.4, if this proposal is finalized, these policies 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). We also propose that for ACOs that are involuntarily terminated during a 6-month performance year, 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 (according to section II.A.6.d of this proposed rule) and the impact of extreme and uncontrollable circumstances on the ACO (if applicable).

(6) Proposals for Payment and Recoupment for 6-Month Performance Years

We propose to provide separate reconciliation reports for each 6-month performance year, and we would pay shared savings or recoup shared losses separately for each 6-month performance year. Since we propose to perform financial reconciliation for both 6-month performance years during 2019 after the end of calendar year 2019, we anticipate 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 propose to apply the same policies regarding notification of shared savings payment and shared losses, and the timing of repayment of shared losses, to ACOs in 6-month performance years that apply under our current regulations to ACOs in 12-month performance years. We propose 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 propose 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; (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 anticipate results for both 6-month performance years would be available at approximately the same time, 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 withhold from shared savings. See 76 FR 67941 through 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 calendar year 2019. We propose 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 propose 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 believe 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 note 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 propose to specify these policies on payment and recoupment for ACOs in 6-month performance years within calendar year 2019 in a new section of the regulations at § 425.609(e).

(7) Proposals for 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 believe it is 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. We propose a one-time exception to be specified in § 425.600, whereby the automatic advancement policy would not apply to the second performance year for an ACO entering the BASIC track's glide path for an agreement period beginning July 1, 2019. For performance year 2020, the ACO would remain in the same level of the BASIC track's glide path it entered for the 6-month performance year beginning 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.

(8) Interactions With the Quality Payment Program

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 using claims data for services furnished during those dates on which the Advanced APM is actively tested. This means that an 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)). We therefore believe 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.

(9) Proposals for Sharing CY 2019 Aggregate Data With ACOs in 6-month Performance Year From January 2019 Through June 2019

Under the program's current regulations in § 425.702, we share aggregate data with ACOs during the agreement period. This includes providing data at the beginning of each performance year and quarterly during the agreement period. For ACOs that started a first or second agreement period on January 1, 2016, that extend their agreement for an additional 6-month performance year from January 1, 2019, through June 30, 2019, and ACOs that participate in the first 6 months of a 12-month performance year 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 propose to continue to deliver aggregate reports for all four quarters of calendar year 2019 based on the ACO participant list in effect for the first 6 months of the year. This would allow ACOs a more complete understanding of the Medicare FFS beneficiary population that is the basis for reconciliation for the first 6 months of the year. This would allow ACOs to receive data including demographic characteristics and expenditure/utilization trends for their assigned population. We believe 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 who are assigned to the ACO for the 6-month performance year (or performance period) would be compared to the ACO's benchmark (before pro-rating any shared savings or shared losses to reflect the length of the performance year), and maintain consistency with the reports delivered to ACOs that participate in a 12-month performance year 2019. Otherwise, we could be limited to providing ACOs with aggregate reports only for the first and second quarters of 2019, even though the proposed reconciliation would involve consideration of expenditures occurring outside this period during 2019. We propose to specify this policy in revisions to § 425.702.

(10) Proposals for Technical or Conforming Changes To Allow for 6-Month Performance Years

We propose to make certain technical, conforming changes to the following provisions, including additional changes to provisions discussed elsewhere in this proposed rule, to reflect our proposal to add a new provision at § 425.609 to govern the calculation of the financial results for 6-month performance years within calendar year 2019.

We propose that the policies on reopening determinations of shared savings and shared losses to correct financial reconciliation calculations (§ 425.315) would apply with respect to applicable program determinations for performance years within calendar year 2019. We propose to amend § 425.315 to incorporate references to the methodology for determining performance for 6-month performance years within calendar year 2019, as specified in § 425.609.

We propose to add a reference to § 425.609 in § 425.100 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.

In § 425.204(g), we propose to add a reference to § 425.609 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.

In § 425.400(a)(1)(ii), describing the step-wise process for determining beneficiary assignment for each performance year, we propose to also specify that this process would apply to ACOs participating in a 6-month performance year within calendar year 2019, and that assignment would be determined based on the beneficiary's utilization of primary care services during the entirety of calendar year 2019, as specified in § 425.609.

In § 425.400(c)(1)(iv), on the use of certain Current Procedural Terminology (CPT) codes and Healthcare Common Procedure Coding System (HCPCS) codes in determining beneficiary assignment, as proposed to be revised in section II.E.3 of this proposed rule, we propose to further revise the provision to specify that it will be used in determining assignment for performance years starting on January 1, 2019, and subsequent years.

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 propose to specify that these exclusions would occur at the end of calendar year 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.

As part of the proposed revisions to § 425.402(e)(2), which, as described in section II.E.2 of this proposed rule, specifies that beneficiaries who have designated a provider or supplier outside the ACO as responsible for coordinating their overall care will not be added to the ACO's list of assigned beneficiaries for a performance year under the claims-based assignment methodology, we propose to allow the same policy to apply to ACOs participating in a 6-month performance year during calendar year 2019.

In § 425.404(b), on the special assignment conditions for ACOs including FQHCs and RHCs that are used determining beneficiary assignment, we propose to revise the provision to specify its applicability in determining assignment for performance years starting on January 1, 2019, and subsequent performance years.

We also propose 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 calendar year 2019. For clarity and simplicity, we propose 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 calendar year 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 calendar year 2019.

We propose 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 propose 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 calendar year 2019 data in place of performance year data.

B. Fee-for-Service Benefit Enhancements

1. Background

As discussed in earlier rulemaking (for example, 80 FR 32759) and previously in this proposed rule, 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 believe 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 IV. of this proposed 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. We believe that 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. We believe that 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 this proposed rule, we propose modifications to the existing SNF 3-day rule waiver and propose 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 propose to use our authority under section 1899(f) to waive the requirements of section 1834(m)(4)(C)(i) and (ii) 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 propose 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 discussed below.

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). 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. We also continue to believe 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. However, we now believe 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 expanded 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 this proposed rule, we propose 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 this proposed rule, we propose that BASIC track ACOs entering the track's glide path under a one-sided model will be automatically transitioned to a two-sided model during their agreement period and may 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).

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 now believe 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 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 now believe 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 believe 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. We believe 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 propose 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 note 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 a to 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 propose 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, 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 propose 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 propose 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 are proposing 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 are proposing 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 are proposing 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 are not proposing to make the revisions to the SNF 3-day rule waiver applicable for Track 2 ACOs because we are proposing to phase out Track 2, as discussed at section II.A.2 of this proposed 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 II.A.2 of this proposed 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 invite comments on these proposals and related issues.

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.

Next Generation ACOs encouraged CMS to broaden the telehealth waiver under the Next Generation ACO Model to test the use of asynchronous technologies to increase access to care and further support coordination of care for certain dermatology and ophthalmology services. Therefore, effective for 2018, the Telehealth Expansion Benefit Enhancement under the Next Generation ACO Model has been amended to include a waiver of the requirement under section 1834(m)(1) and § 410.78(b) that telehealth services be furnished via a ''interactive telecommunications system'' as that term is defined under § 410.78(a)(3) in order to permit coverage of certain teledermatology and teleophthalmology services furnished using asynchronous technologies.

(2) Provisions of the Bipartisan Budget Act for Telehealth in the Shared Savings Program

Section 50324 of the Bipartisan Budget Act of 2018 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 propose 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 propose 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 propose 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 of this proposed rule, the Shared Savings Program offers two similar, but distinct, assignment methodologies, prospective assignment and preliminary prospective assignment with retrospective reconciliation. We propose to apply these policies regarding payment for telehealth services to ACOs under a two-sided model that participate under the prospective assignment method. We believe 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 welcome comments on our interpretation of this provision.

We propose 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 this proposed rule, we propose 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 propose 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 propose that Medicare would not pay a facility fee when the originating site for a telehealth service is the beneficiary's home.

Further, we propose 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 propose to require that, consistent with section 1899(l)(1)(B) of the Act, the originating site must comply with State licensing requirements.

We propose 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 propose 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,[20] 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.

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

[20] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf.*

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 are proposing 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 propose 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 propose 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 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, 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 propose 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 propose 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.

We note that we are not proposing at this time to establish any waiver of section 1834(m)(1) to permit payment for telehealth services delivered through asynchronous technologies because we do not have sufficient experience with the waiver that is being tested under the Next Generation ACO Model, to inform whether such a waiver would be necessary for purposes of implementing the Shared Savings Program. We may consider this issue further through future rulemaking after we gain additional experience with the use of asynchronous technologies through the Next Generation ACO Model. We welcome 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 use of telehealth services in accordance with section 1899(l) of the Act by track are summarized in Table 9.

TABLE 9—AVAILABILITY OF PROPOSED PAYMENT AND PROGRAM POLICIES TO ACOS BY TRACK

Policy	Policy description	Track 1 (One-sided model; propose to discontinue)	Track 2 (Two-sided model; propose to discontinue)	Track 1+ model (two-sided model)	BASIC track (proposed new track)	ENHANCED track (proposed; current track 3 financial model)
Telehealth Services furnished in accordance with § 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 under preliminary prospective assignment).	N/A (because under preliminary prospective assignment).	Proposed requirements for performance year 2020 and onward (prospective assignment) [1].	Proposed requirements for performance year 2020 and onward, applicable for performance years under a two-sided model (prospective assignment).	Proposed requirements for performance year 2020 and onward (prospective assignment)
SNF 3-Day Rule 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).	Proposed for performance years beginning on July 1, 2019 and subsequent years, eligible for performance years under a two-sided model (prospective or preliminary prospective assignment).	Proposed for performance years beginning on July 1, 2019 and subsequent years (prospective or preliminary prospective assignment)

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 proposed rule.

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

C. Providing Tools To Strengthen Beneficiary Engagement

1. 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 the agency's 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, Congress recently passed section 50341 of the Bipartisan Budget Act of 2018, which amends section 1899 of the Act, to allow 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 are proposing policies 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 are proposing to revise policies related to beneficiary notifications. Specifically, we propose 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 are seeking 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

We believe that patient engagement is an important part of motivating and encouraging more active participation by beneficiaries in their health care. We believe 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 note 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.*

We believe that the 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 § 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 § 425.304, 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 mentioned 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 § 425.304(a)(2). 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, 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 § 425.304(a)(2), provided that the requirements of § 425.304(a)(2) 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 § 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 proposed, are satisfied. We emphasize 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 § 425.304(a)(2) (including the previously mentioned examples), stakeholders have advocated that ACOs be permitted to offer a more flexible, expanded range of beneficiary incentives that are not currently allowable under § 425.304. In particular, stakeholders seek 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, 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 adds 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 adds 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 adds 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. Proposals for Beneficiary Incentive Programs

In order to implement the changes set forth in section 1899(b)(2) and (m) of the Act, we are proposing 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 our proposed policy, we have 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 address each of these considerations in this 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 this proposed rule, we are proposing 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 risk 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. 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 propose 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. 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. The ACO could, however, start a beneficiary incentive program on January 1, 2020 (assuming it renews its agreement).

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 believe 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. For example, 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, 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 believe 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 propose 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 would provide additional information regarding the application on our website.

We propose 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 propose 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. This 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 proposed rule).

An ACO would be required to operate its beneficiary incentive program effective at the beginning of the performance year following CMS's 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).

An ACO with an approved beneficiary incentive program application would be permitted to operate its beneficiary incentive program for any consecutive performance year if it complies with certain certification requirements. Specifically, an ACO that seeks to continue to offer its beneficiary incentive program beyond the initial 12-month or 18-month term (as previously discussed) would 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. 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. CMS would provide further information regarding the annual certification process through subregulatory guidance.

In addition to the application and certification requirements previously described, we are considering 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 solicit comments on this issue.

With respect to who may receive an incentive payment, 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 note 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 this proposed rule, we propose 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, 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 policy regarding which ACOs may establish a beneficiary incentive program, 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 may 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 mirror 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. This means that 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, 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 propose to incorporate a $20 incentive payment limit into the regulation. We also propose 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 believe it is necessary to round the updated maximum incentive payment amount to the nearest whole dollar. We have reflected this policy in our proposed regulations text. We would post the updated maximum payment amount on the Shared Savings Program website and/or in a guidance regarding beneficiary incentive programs.

We also propose 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, 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, an ACO may 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 are of equal monetary value.

Furthermore, as required by section 1899(m)(2)(D)(iii) of the Act, we propose 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 propose to require that each incentive payment be ''made no later than 30 days after a qualifying service is furnished to such a beneficiary.''

We have considered the individuals and entities that should be permitted to offer incentive payments to beneficiaries under a beneficiary incentive program. We note 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 believe this requirement is 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 are therefore proposing to require that the ACO legal entity, and not ACO participants or ACO providers/suppliers, furnish the incentive payments directly to beneficiaries. We seek 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 believe it is 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 propose 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 have 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 believe 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 propose 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. An ACO that establishes a beneficiary incentive program would be required to maintain and make available such records in accordance with § 425.314(b). In addition to these record retention proposals, we expect any ACO that establishes a beneficiary incentive program to update its compliance plan (as required under § 425.300(b)(2)), to address any finalized regulations that address beneficiary incentive programs.

Furthermore, we propose 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 propose 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 believe these requirements are necessary to reduce the likelihood of undue influence resulting in inappropriate steering of beneficiaries to specific products or providers/suppliers. We seek comments on this issue.

We also propose 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 propose 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 propose 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 believe 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 seek comments on all of our proposed program integrity requirements.

In addition, we are proposing 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 are also proposing 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 propose 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 have included this 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 believe 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 are therefore proposing this policy at § 425.304(c)(7). We solicit 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 propose 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 are also proposing 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 note 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 welcome 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 § 425.304(c)(4)(i)) to support such an evaluation of beneficiary incentive programs. We note, however, that we do not want to discourage participation by imposing overly burdensome data management requirements on ACOs. We therefore seek comment on reporting requirements for ACOs that are approved to establish a beneficiary incentive program.

In addition, we note 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). 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 are considering whether beneficiaries should be notified of the availability of a beneficiary incentive program. Because beneficiary incentives may be subject to abuse, we believe it is necessary, and we have proposed, to prohibit the advertisement of a beneficiary incentive program. We are 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 by this proposed rule in section II.C.3.a., all ACO participants are required to notify beneficiaries that their ACO providers/suppliers are participating in the Shared Savings Program. We solicit 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 seek 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 note 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 propose 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 propose 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 note that this proposed policy would require reporting for the 6-month performance year that begins on July 1, 2019. We seek 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 are proposing 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 10.

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

Policy	Policy description	Track 1 (one-sided model; propose to discontinue)	Track 2 (two-sided model; propose to discontinue)	Track 1+ model (two-sided model)	BASIC track (proposed new track)	ENHANCED track (proposed; current track 3 financial model)
Beneficiary Incentive Program.	Requires ACOs that establish a beneficiary incentive program to provide an incentive payment to each assigned beneficiary (prospective or preliminary prospective) for each qualifying service received.	N/A	Proposed beginning July 1, 2019 and for subsequent performance years (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).

d. Clarification of Existing Rules

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 propose a technical change to the title and structure of § 425.304. Specifically, we are proposing 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 propose 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).''

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/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 previously discussed, 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 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 can login to MyMedicare.gov and 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, 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,[21] and specifically on the voluntary alignment process.[22]

(2) Proposed Revisions

We are revisiting 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. We have also proposed changes in response to section 50331 of the Bipartisan Budget Act of 2018, 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 addition, 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. While there are many sources of information on the program that are available to beneficiaries, 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.

We also considered methods of notification that would better ensure that beneficiaries receive the comprehensive notification at the point of care. The current 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. Although standardized written notices must be made available upon request, we are concerned that few beneficiaries, or others who accompany beneficiaries to their medical appointments, may initiate request for this information. In turn, beneficiaries may not have the information they need to make informed decisions about their health care and their data.

Finally, we considered how to minimize burden on the ACO providers/suppliers that would provide the notification. We seek 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 are proposing to modify § 425.312(a) to require additional content for beneficiary notices. We propose 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 propose 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 this 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 propose 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 propose to require ACO participants to use a template notice that we would prepare and make available to ACOs. 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, 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. The CMS-developed template notice would also 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. 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 § 425.312(b)(2).

We believe 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 believe 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 believe 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 seek 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 seek comment on whether a beneficiary should receive the written notice at the beneficiary's first primary care visit of the performance year, or

[21] Accountable Care Organizations & You, available at *https://www.medicare.gov/Pubs/pdf/11588-Accountable-Care-Organizations-FAQs.pdf.*

[22] 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.*

during the beneficiary's first visit of the performance year with any ACO participant. We also seek comment on whether there are alternative media for disseminating the beneficiary notice that may be less burdensome on ACOs, such as dissemination via email.

In addition, we solicit comment on whether the template notice should include other information outlining ACO activities that may be related to or affect a Medicare FFS beneficiary. Such activities may 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 welcome feedback on the format, content, and frequency of this 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 may place on ACO participants. More specifically, we welcome 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 are also taking this opportunity to add 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 seek 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 are also proposing technical changes to the title and structure of § 425.312. For example, we are proposing to replace the title of § 425.312 with ''Beneficiary notifications.''

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, we believe 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 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.E.2, we have recently implemented a voluntary alignment process (which we are proposing to refine based on requirements in the Bipartisan Budget Act), 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, 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. We believe 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. These issues are addressed in the following discussion.

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 note 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 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.*) 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 they 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 believe this provision would authorize CMS to conduct oversight regarding ACOs' records documenting the beneficiaries who received such a notification and the beneficiary responses.

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 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 are 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. We believe 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.6.b of this proposed 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 is 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 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. We note that 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 order to meet this requirement under an opt-in based assignment methodology, we are 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 are 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 the proposed 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 are 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 believe 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, including the proposed revisions to provisions at §§ 425.400, 425.401, 425.402 and 425.404 as discussed in sections II.E.2 and II.E.3 of this proposed rule (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 are 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 this section, 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 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.

For ACOs electing to participate under an opt-in based assignment methodology, we would assign beneficiaries to the ACO using a hybrid approach that would be 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 note that this threshold of seven primary care services is 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 believe it could be appropriate to establish such 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 seek 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 proposed in section II.A.4.c. of this proposed 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 believe that the 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 that 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.6.3. of this proposed 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 believe 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.

Under opt-in based assignment, we anticipate that 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 chose 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, beneficiary spends time in and receives care in different parts of the country during the year (sometimes referred to as being a ''snowbird''), or the beneficiary receives care from a tertiary care facility that is geographically distant from his or her home. Further, this approach is in line with the expanded telehealth policies discussed in section II.B of this proposed rule under which certain geographic and other restrictions would be removed. We welcome 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. 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 proposed 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.

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 what is proposed in section II.D 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 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 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 presume this is 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 is 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 would monitor the effects of this policy to determine if it is effective in addressing the differences in characteristics between the population assigned for 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 were 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 January 1, 2020 and concluding December 31, 2024, and a beneficiary opted in and was assigned for 2023 and remained opted in and assigned for 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 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.

In section II.D. of this proposed rule, we propose 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 are 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 believe 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 note 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 (see section IV.D of this 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. Although for some policies we can draw upon our initial experience with implementing voluntary alignment. We believe the approach to adjusting benchmarks to address an opt-in based assignment methodology, as discussed in this proposed rule, could address our concerns about the comparability of benchmark and performance year populations. If such a policy were 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.

If we were to establish an opt-in based assignment methodology, we anticipate that we would also 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 would emphasize 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 are soliciting 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 welcome 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 seek comment on whether this minimum threshold for use in determining modified claims-based assignment should be set at a higher or lower. We also welcome comments on an appropriate methodology for establishing and adjusting an ACO's historical benchmark under an opt-in based assignment methodology. Further, we seek comment on how to treat opt-in beneficiaries when rebasing the historical benchmark for renewing ACOs. Additionally, we welcome 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.

We have 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 seek 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.

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.

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, 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 wish to encourage ACOs to take on higher levels of risk, we considered the importance of adopting a balanced risk adjustment methodology that provides ACOs with some protection against decreases in risk scores.

Our preferred approach would 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 11 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 11—HYPOTHETICAL DATA ON APPLICATION OF AGREEMENT PERIOD CAP ON PY TO BY3 RISK RATIO

Medicare enrollment type	BY3 renormalized CMS–HCC risk score	PY renormalized CMS–HCC risk score	Risk ratio before applying cap	Final risk ratio
ESRD	1.031	1.054	1.022	1.022
Disabled	1.123	1.074	0.956	0.970
Aged/dual eligible	0.987	1.046	1.060	1.030
Aged/non-dual eligible	1.025	1.001	0.977	0.977

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.

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 suggests 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, we believe 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 believe 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 preferred approach would also limit large decreases in CMS–HCC prospective risk scores across all assigned beneficiaries. We believe that such a balanced approach would provide ACOs with a greater incentive to assume performance-based risk than under 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 believe that this approach, which mirrors one of the risk adjustment methodologies tested in the Next Generation ACO Model, has a significant advantage over the current Shared Savings Program policy in that it is 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 choice of 3 percent as the preferred level for the symmetrical cap is 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 proposed 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.7). 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 believe that a 3 percent cap on changes in CMS–HCC risk scores is 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 are 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 are 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 are proposing 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 proposed rule, the cap would represent the maximum change in risk scores for the agreement period between BY3 and calendar year 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 seek comment on this proposal, including the level of the cap.

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 proposed 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 proposed rule, we discuss proposals designed to mitigate these concerns.

b. Proposals To Apply 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. 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 above reasons, we are proposing 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 will apply for ACOs in their second or subsequent agreement period, including all policies proposed in this 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 calendar year 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 proposed in section II.A.7 of this proposed 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 favor maintaining the existing weights, which we believe are more accurate because they capture the ACO's most recent experience in the benchmark period.

We propose to add a new provision at § 425.601 to the regulations that will describe how we will establish, adjust, update and reset historical benchmarks using factors based on regional FFS expenditures for all ACOs for agreement periods beginning on July 1, 2019 and in subsequent years. We seek comment on this proposal.

c. Proposals for 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.

We have revaluated the effects of the regional adjustment as part of the regulatory impact analysis required for this proposed rule (see section IV) and have also taken into consideration our experience in applying the regional adjustment under the policies established in the June 2016 final rule. While we continue 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 are concerned that, if unaltered, the regional adjustment will have unintended consequences and adverse effects on ACO incentives as discussed in the Regulatory Impact Analysis (section IV).

By design, the regional adjustment results in more generous benchmarks for ACOs that spend below their regions. As noted in section II.D.3.b of this proposed rule, 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. Preliminary results for ACOs that renewed for a second agreement period starting in 2018 show a similar share of ACOs receiving a positive adjustment and one ACO seeing an adjustment of over 10 percent. As the weight applied to the regional adjustment increases, we are concerned that the benchmarks for the ACOs with the lowest spending relative to their region will become overly inflated to the point where they will 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.

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 show slightly smaller negative adjustments, on average, we are 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, will 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 are proposing 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 believe that 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 are proposing 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 wish 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 proposed 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. 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 under the current benchmarking methodology that enters its third agreement period upon renewal would be subject to a weight of 50 or 35 percent. By contrast, if the same ACO had terminated during its second agreement period and subsequently re-enters the program, the ACO would continue to face a weight of 35 or 25 percent until the start of its subsequent 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 would 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.

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 believe that using 50 percent as the maximum weight is 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 wish to note 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 new rebasing methodology, which were calculated using the lowest weights under the current phase-in schedule, we are 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 believe that limiting regional adjustments for ACOs that are particularly low- or high-cost relative to their regions, will 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 are thus also proposing 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 believe that defining the cap based on national per capita expenditures offers 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 believe 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, we believe 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.

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 expenditure for that enrollment type in the same manner that we currently apply the uncapped regional adjustment. Table 12 provides an illustrative example of how the final adjustment would be determined.

TABLE 12—HYPOTHETICAL DATA ON APPLICATION OF CAP TO REGIONAL ADJUSTMENT AMOUNT

Medicare enrollment type	Uncapped adjustment	National assignable FFS expenditure	5 percent of national assignable FFS expenditure	Final adjustment
ESRD	$4,214	$81,384	$4,069	$4,069
Disabled	−600	11,128	556	−556
Aged/dual eligible	788	16,571	829	788
Aged/non-dual eligible	−367	9,942	497	−367

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. This is 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. 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 will only reduce the magnitude of the adjustment for a particular enrollment type if the original uncapped value of the adjustment is relatively large. This is not necessarily the case under the aggregate approach, where adjustments for all enrollment types, large or small, will be reduced if the aggregate regional adjustment exceeds the aggregate cap.

We believe 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, will help to reduce windfall gains to low-spending ACOs and will also help to reduce the incentive for higher spending ACOs to leave the program by limiting the negative adjustments these ACOs will experience. We anticipate that the proposed cap on the regional adjustment will 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 expect 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 believe 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 are proposing 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 are proposing 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 are proposing to apply weights of 50 percent and 35 percent for lower and

higher spending ACOs, respectively. For the third or subsequent agreement period, we are proposing 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 are proposing 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 this section are included in the proposed new provision 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 are seeking comment on these proposals, as well as the alternative capping methodology considered. We are also seeking comment on the proposed timeline for application of these proposals.

d. Proposals for 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, we acknowledge 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 (see 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, 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 MA 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 this section 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 proposed 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 because 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 are proposing 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 suggests 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.

We are also concerned 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 favor 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. One drawback of this approach relative to the blended approaches previously described is that it treats 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.

As we have 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 propose 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 propose to use a blend of national and regional update factors, computed as described in this section, to update the historical benchmark to the performance year (or to calendar year 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 this 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 wish to make 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, should our proposal in section II.A.4.c be finalized, the weight that is 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, 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 this title and the alternative methodology would result in program expenditures equal to or lower than those that would result under the statutory payment model.

By combining a national component that is more independent of an ACO's own experience with a regional component that captures location-specific trends, we believe that 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 believe 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 (section IV. of this proposed rule), we project that this proposed approach, in combination with other changes to the statutory payment model proposed elsewhere in this 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 propose 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 calendar year 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 this 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 this section 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 are included in the proposed new provision at § 425.601, which would govern the determination of historical benchmarks for all ACOs. We seek comment on these proposals, as well as the alternatives considered, including incorporating national trends at the county rather than regional level or using national trend factors for ACOs with penetration in their regional service area exceeding a certain threshold.

4. Technical Changes To Incorporate References to Benchmark Rebasing Policies

We are also proposing 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 are also proposing 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 propose 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.

E. Updating Program Policies

1. Overview

This section addresses various proposed revisions to the Shared Savings Program designed to update program policies. We propose to revise our regulations governing the assignment process in order to align our voluntary alignment policies with the requirements of section 50331 of the Bipartisan Budget Act of 2018 and to update the definition of primary care services. We also propose to extend the policies that we recently adopted for ACOs impacted by extreme and uncontrollable circumstances during 2017 to 2018 and subsequent performance years. We also solicit comment on considerations related to supporting ACOs' activities to address the national opioid crisis and the agency's meaningful measures initiative. We propose to discontinue use of the quality performance measure that assesses an ACO's eligible clinicians' level of adoption of CEHRT and propose instead that ACOs annually certify that the percentage of eligible clinicians participating in the ACO using CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds certain thresholds. Lastly, we seek comment 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.

2. Revisions to Policies on Voluntary Alignment

a. Background

Section 50331 of the Bipartisan Budget Act of 2018 amended section 1899(c) of the Act (42 U.S.C. 1395jjj(c)) to add a new paragraph (2)(B) that requires the Secretary, for performance year 2018 and each subsequent performance year, to permit a Medicare FFS beneficiary to voluntarily identify an ACO professional as the primary care provider of the beneficiary for purposes of assigning such beneficiary to an ACO, if a system is available for electronic designation. A voluntary identification by a Medicare FFS beneficiary under this provision supersedes any claims-based assignment otherwise determined by the Secretary. Section 50331 also requires the Secretary to establish a process under which a Medicare FFS beneficiary is notified of his or her ability to designate a primary care provider or subsequently to change this designation. An ACO professional is defined under section 1899(h) of the Act as a physician as defined in section 1861(r)(1) of the Act and a practitioner described in section 1842(b)(18)(C)(i) of the Act.

We believe that section 50331 requires certain revisions to our current beneficiary voluntary alignment policies in § 425.402(e). Prior to enactment of the Bipartisan Budget Act of 2018, section 1899(c) of the Act required that beneficiaries be assigned to an ACO based on their use of primary care services furnished by a physician as defined in section 1861(r)(1) of the Act, and beginning January 1, 2019, services provided in RHCs/FQHCs. In order to satisfy this statutory requirement, we currently require that a beneficiary receive at least one primary care service during the beneficiary assignment window from an ACO professional in the ACO who is a physician with a specialty used in assignment in order to be assigned to the ACO (see § 425.402(b)(1)). As currently provided in § 425.404(b), for performance year 2019 and subsequent performance years, for purposes of the assignment methodology in § 425.402, CMS treats a service reported on an FQHC/RHC claim as a primary care service performed by a primary care physician. After identifying the beneficiaries who have received a primary care service from a physician in the ACO, we use a two-step, claims-based methodology to assign beneficiaries to a particular ACO for a calendar year (see § 425.402(b)(2) through (4)). In the CY 2017 PFS final rule (81 FR 80501 through 80510), we augmented this 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'' they believe is responsible for coordinating their overall care using MyMedicare.gov, a secure online patient portal. MyMedicare.gov contains a list of all of the Medicare-enrolled practitioners who appear on the Physician Compare website and beneficiaries may choose any practitioner present on Physician Compare as their primary clinician.

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 as defined under § 425.20 or a physician with one of the primary specialty designations included in § 425.402(c) (see § 425.402(e)). Such beneficiaries will be added prospectively to the ACO's list of assigned beneficiaries for the subsequent performance year, superseding any assignment that might have otherwise occurred under the claims-based methodology. Further, beneficiaries may change their designation at any time through *MyMedicare.gov;* the new choice will be incorporated when we perform assignment for the subsequent performance year. Beneficiaries who designate a provider or supplier outside an ACO, who is a primary care physician, a physician with a specialty designation that is considered in the assignment methodology, or a nurse practitioner, physician assistant, or clinical nurse specialist, as responsible for coordinating their overall care will not be added to an ACO's list of assigned beneficiaries, even if they would otherwise meet the criteria for claims-based assignment.

b. Proposals

Section 1899(c) of the Act, as amended by section 50331 of the Bipartisan Budget Act of 2018, requires the Secretary to permit a Medicare FFS beneficiary to voluntarily identify an ACO professional as their primary care provider for purposes of assignment to an ACO. Under our current methodology, a beneficiary may select any practitioner who has a record on the Physician Compare website as their primary clinician; however, we will only assign the beneficiary to an ACO if they have chosen a practitioner who is a primary care physician (as defined at § 425.20), a physician with one of the primary specialty designations included in § 425.402(c), or a nurse practitioner, physician assistant, or clinical nurse specialist. Therefore, we propose to modify our current voluntary alignment policies at § 425.402(e)(2)(iii) to provide that we will assign a beneficiary to an ACO based upon their selection of any ACO professional, regardless of specialty, as their primary clinician. Under this proposal, a beneficiary may select a practitioner with any specialty designation, for example, a specialty of allergy/immunology or surgery, as their primary care provider and be eligible for assignment to the ACO in which the practitioner is an ACO professional. Specifically, we propose to revise § 425.402(e)(2)(iii) to remove the requirement that the ACO professional designated by the beneficiary be a primary care physician as defined at § 425.20, a physician with a specialty designation included at § 425.402(c), or a nurse practitioner, physician assistant, or clinical nurse specialist. In addition, the provision at § 425.402(e)(2)(iv) addresses beneficiary designations of clinicians outside the ACO as their primary clinician. The current policy at § 425.402(e)(2)(iv) provides that a beneficiary will not be assigned to an ACO for a performance year if the beneficiary has designated a provider or supplier outside the ACO who is a primary care physician as defined at § 425.20, a physician with a specialty designation included at § 425.402(c), or a nurse practitioner, physician assistant, or clinical nurse specialist as their primary clinician responsible for coordinating their overall care. Consistent with the proposed revisions to § 425.402(e)(2)(iii) to incorporate the requirements of section 50331 of the Bipartisan Budget Act, we propose to revise § 425.402(e)(2)(iv) to indicate that if a beneficiary designates any provider or supplier outside the ACO as their primary clinician responsible for coordinating their overall care, the beneficiary will not be added to the ACO's list of assigned beneficiaries for a performance year.

Section 1899(c) of the Act, as amended by section 50331 of the Bipartisan Budget Act of 2018, requires the Secretary to allow a beneficiary to voluntarily align with an ACO, and does not impose any restriction with respect to whether the beneficiary has received any services from an ACO professional (see section 1899(c)(2)(B)(i) of the Act). We also believe the requirement in section 1899(c)(2)(B)(iii) of the Act that a beneficiary's voluntary identification shall supersede any claims-based alignment is consistent with eliminating the requirement that the beneficiary have received a service from an ACO professional in order to be eligible to be assigned an ACO. Therefore, we propose to remove the requirement at § 425.402(e)(2)(i) that a beneficiary must have received at least one primary care service from an ACO professional who is either a primary care physician or a physician with a specialty designation included in § 425.402(c) within the 12 month assignment window in order to be assigned to the ACO. Under this proposal, a beneficiary who selects a primary clinician who is an ACO professional, but who does not receive any services from an ACO participant during the assignment window, will remain eligible for assignment to the ACO. We believe this approach reduces burden on beneficiaries and their practitioners by not requiring practitioners to provide unnecessary care during a specified period of time in order for a beneficiary to remain eligible for assignment to the ACO. Consistent with this proposal, we propose to remove § 425.402(e)(2)(i) in its entirety.

We note that, under this proposal, if a beneficiary does not change their primary clinician designation, the beneficiary will remain assigned to the ACO in which that practitioner participates during the ACO's entire agreement period and any subsequent agreement periods under the Shared Savings Program, even if the beneficiary no longer seeks care from any ACO professionals. Because a beneficiary who has voluntarily identified a Shared Savings Program ACO professional as their primary care provider will remain assigned to the ACO regardless of where they seek care, this proposed change could also impact assignment under certain Innovation Center models in which overlapping beneficiary assignment is not permitted. Although we believe our proposed policy is consistent with the requirement under section 1899(c)(2)(B)(iii) of the Act that a voluntary identification by a beneficiary shall supersede any claims-based assignment, we also believe it could be appropriate, in limited circumstances, to align a beneficiary to an entity participating in certain specialty and disease-specific Innovation Center models, such as the CEC Model. CMS implemented the CEC Model to test a new system of payment and service delivery that CMS believes will lead to better health outcomes for Medicare beneficiaries living with ESRD, while lowering costs to Medicare Parts A and B. Under the model, CMS is working with groups of health care providers, dialysis facilities, and other suppliers involved in the care of ESRD beneficiaries to improve the coordination and quality of care that these individuals receive. We believe that an ESRD beneficiary, who is otherwise eligible for assignment to an entity participating in the CEC Model, could benefit from the focused attention on and increased care coordination for their ESRD available under the CEC Model. Such a beneficiary could be disadvantaged if they were unable to receive the type of specialized care for their ESRD that would be available from an entity participating in the CEC Model. Furthermore, we believe it could be difficult for the Innovation Center to conduct a viable test of a specialty or

disease-specific model, if we were to require that beneficiaries who have previously designated an ACO professional as their primary clinician remain assigned to the Shared Savings Program ACO under all circumstances. Currently, the CEC Model completes its annual PY prospective assignment lists prior to the Shared Savings Program in order to identify the beneficiaries who may benefit from receiving specialized care from an entity participating in the CEC Model. Additionally, on a quarterly basis, a beneficiary may be assigned to the CEC Model who was previously assigned to a Track 1 or Track 2 ACO.

As a result, we believe that in some instances it may be necessary for the Innovation Center to use its authority under section 1115A(d)(1) of the Act to waive the requirements of section 1899(c)(2)(B) of the Act solely as necessary for purposes of testing a particular model.

Therefore, we are proposing to create an exception to the general policy that a beneficiary who has voluntarily identified a Shared Savings Program ACO professional as their primary care provider will remain assigned to the ACO regardless of where they seek care. Specifically, we propose that we would not assign such a beneficiary to the ACO when the beneficiary is also eligible for assignment 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 Secretary that a waiver under section 1115A(d)(1) of the Act of the requirement in section 1899(c)(2)(B) of the Act is necessary solely for purposes of testing the model. Under this proposal, if a beneficiary selects a primary clinician who is a Shared Savings Program ACO professional and the beneficiary is also eligible for alignment to a specialty care or disease specific 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 that a waiver of the requirement in section 1899(c)(2)(B) is necessary solely for purposes of testing the Model, the Innovation Center or its designee would notify the beneficiary of their alignment to an entity participating in the model. Additionally, although such a beneficiary may still voluntarily identify his or her primary clinician and may seek care from any clinician, the beneficiary would not be assigned to a Shared Savings Program ACO even if the designated primary clinician is a Shared Savings Program ACO professional.

We would include a list of any models that meet these criteria on the Shared Savings Program website, to supplement the information already included in the beneficiary assignment reports we currently provide to ACOs (as described under § 425.702(c)), so that ACOs can know why certain beneficiaries, who may have designated an ACO professional as their primary clinician, are not assigned to them. Similar information would also be shared with 1–800–MEDICARE to ensure that Medicare customer service representatives are able to help beneficiaries who may be confused as to why they are not aligned to the ACO in which their primary clinician is participating.

Section 1899(c)(2)(B)(ii) of the Act, as amended by section 50331 of the Bipartisan Budget Act, requires the Secretary to establish a process under the Shared Savings Program through which each Medicare FFS beneficiary is notified of the ability to identify an ACO professional as his or her primary care provider and informed of the process that may be used to make and change such identification. We intend to implement section 1899(c)(2)(B)(ii) of the Act under the beneficiary notification process at § 425.312. In addition, we plan to use the beneficiary notification process under § 425.312 to address the concern that beneficiary designations may become outdated. Specifically, we propose to require ACO participants to use a CMS-developed template notice that encourages beneficiaries to check their designation regularly and to update their designation when they change care providers or move to a new area. We discuss our beneficiary notification processes further in section II.C.3.a of this proposed rule.

We propose to apply these modifications to our policies under the Shared Savings Program regarding voluntary alignment beginning for performance years starting on January 1, 2019, and subsequent performance years. We propose to incorporate these new requirements in the regulations by redesignating § 425.402(e)(2)(i) through (iv) as § 425.402(e)(2)(i)(A) through (D), adding a paragraph heading for newly redesignated § 425.402(e)(2)(i), and including a new § 425.402(e)(2)(ii).

We note that as specified in § 425.402(e)(2)(ii) a beneficiary who has designated an ACO professional as their primary clinician must still be eligible for assignment to an ACO by meeting the criteria specified in § 425.401(a). These criteria establish the minimum requirements for a beneficiary to be eligible to be assigned to an ACO under our existing assignment methodology, and we believe it is appropriate to impose the same basic limitations on the assignment of beneficiaries on the basis of voluntary alignment. We do not believe it would be appropriate, for example, to assign a beneficiary to an ACO if the beneficiary does not reside in the United States, or if the other eligibility requirements are not met.

We request comments on our proposals to implement the new requirements governing voluntary alignment under section 50331 of the Bipartisan Budget Act of 2018. We also seek comment on our proposal to create a limited exception to our proposed policies on voluntary alignment to allow a beneficiary to be assigned to an entity participating in a model tested or expanded under section 1115A of the Act when certain criteria are met. In addition, we welcome comments on how we might increase beneficiary awareness and further improve the electronic process through which a beneficiary may voluntarily identify an ACO professional as their primary care provider through My.Medicare.gov for purposes of assignment to an ACO.

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

a. Background

Section 1899(c)(1) of the Act, as amended by the 21st Century Cures Act and the Bipartisan Budget Act of 2018, provides that for performance years beginning on or after January 1, 2019, the Secretary shall assign beneficiaries to an ACO based on their utilization of primary care services provided by a physician and all services furnished by RHCs and FQHCs. However, the statute does not specify which kinds of services may be considered primary care services for purposes of beneficiary assignment. We established the initial list of services that we considered to be primary care services in the November 2011 final rule (76 FR 67853). In that final rule, we indicated that we intended to monitor this issue and would consider making changes to the definition of primary care services to add or delete codes used to identify primary care services, if there were sufficient evidence that revisions were warranted. We have updated the list of primary care service codes in subsequent rulemaking to reflect additions or modifications to the codes that have been recognized for payment under the Medicare PFS, as summarized in the CY 2018 PFS proposed rule (82

FR 34109 and 34110). Subsequently, in the CY 2018 PFS final rule, we revised the definition of primary care services to include three additional chronic care management service codes, 99487, 99489, and G0506, and four behavioral health integration service codes, G0502, G0503, G0504 and G0507 (82 FR 53212 and 53213). These additions are effective for purposes of performing beneficiary assignment under § 425.402 for performance year 2019 and subsequent performance years.

Accounting for these recent changes, we define primary care services in § 425.400(c) for purposes of assigning beneficiaries to ACOs under § 425.402 as the set of services identified by the following HCPCS/CPT codes:

CPT codes:

(1) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(2) 99304 through 99318 (codes for professional services furnished in a Nursing Facility, excluding services furnished in a SNF which are reported on claims with place of service code 31).

(3) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(4) 99341 through 99350 (codes for evaluation and management services furnished in a patients' home).

(5) 99487, 99489 and 99490 (codes for chronic care management).

(6) 99495 and 99496 (codes for transitional care management services).

HCPCS codes:

(1) G0402 (the code for the Welcome to Medicare visit).

(2) G0438 and G0439 (codes for the Annual Wellness Visits).

(3) G0463 (code for services furnished in electing teaching amendment hospitals).

(4) G0506 (code for chronic care management).

(5) G0502, G0503, G0504 and G0507 (codes for behavioral health integration).

As discussed in the CY 2018 PFS final rule, a commenter recommended that CMS consider including the advance care planning codes, CPT codes 99497 and 99498, in the definition of primary care services in future rulemaking (82 FR 53213). We indicated that we would consider whether CPT codes 99497 and 99498 or any additional existing HCPCS/CPT codes should be added to the definition of primary care services in future rulemaking for purposes of assignment of beneficiaries to ACOs under the Shared Savings Program. In addition, effective for CY 2018, the HCPCS codes for behavioral health integration G0502, G0503, G0504 and G0507 have been replaced by CPT codes 99492, 99493, 99494, 99484 (82 FR 53078).

CPT codes 99304 through 99318 are used for reporting evaluation and management services furnished by physicians and other practitioners in a skilled nursing facility (reported on claims with POS code 31) or a nursing facility (reported on claims with POS code 32). Based on stakeholder input, we finalized a policy in the CY 2016 PFS final rule (80 FR 71271 through 71272) effective for performance year 2017 and subsequent performance years, to exclude services identified by CPT codes 99304 through 99318 from the definition of primary care services for purposes of the beneficiary assignment methodology when the claim includes the POS code 31 modifier designating the services as having been furnished in a SNF. We established this policy to recognize that SNF patients are shorter stay patients who are generally receiving continued acute medical care and rehabilitative services. Although their care may be coordinated during their time in the SNF, they are then transitioned back into the community to the primary care professionals who are typically responsible for providing care to meet their true primary care needs. We continue to believe that it is appropriate for SNF patients to be assigned to ACOs based on care received from primary care professionals in the community (including nursing facilities), who are typically responsible for providing care to meet the true primary care needs of these beneficiaries. ACOs serving special needs populations, including beneficiaries receiving long term care services, and other stakeholders have recently suggested that we consider an alternative method for determining operationally whether services identified by CPT codes 99304 through 99318 were furnished in a SNF. Instead of indirectly determining whether a beneficiary was a SNF patient when the services were furnished based on physician claims data, these stakeholders suggest we more directly determine whether a beneficiary was a SNF patient based on SNF facility claims data. These stakeholders have recommended that CMS use contemporaneous SNF Medicare facility claims to determine whether a professional service identified by CPT codes 99304 through 99318 was furnished in a SNF and thus should not be used for purposes of the beneficiary assignment methodology under § 425.402. Specifically, these stakeholders suggest that we determine whether services identified by CPT codes 99304 through 99318 were furnished in a SNF by determining whether the beneficiary also received SNF facility services on the same date of service.

In this rule we propose to make changes to the definition of primary care services in § 425.400(c) to add new codes and to revise how we determine whether services identified by CPT codes 99304 through 99318 were furnished in a SNF.

b. Proposed Revisions

Based on feedback from ACOs and our further review of the HCPCS and CPT codes currently recognized for payment under the PFS, we believe it would be appropriate to amend the definition of primary care services to include certain additional codes. Specifically, we propose to revise the definition of primary care services in § 425.400(c) to include the following HCPCS and CPT codes: (1) Advance care planning service codes, CPT codes 99497 and 99498, (2) administration of health risk assessment service codes, CPT codes 96160 and 96161, (3) prolonged evaluation and management or psychotherapy service(s) beyond the typical service time of the primary procedure, CPT codes 99354 and 99355, (4) annual depression screening service code, HCPCS code G0444, (5) alcohol misuse screening service code, HCPCS code G0442, and (6) alcohol misuse counseling service code, HCPCS code G0443. In addition, in the recent CY 2019 PFS proposed rule (see 83 FR 35841 through 35844) CMS proposed to create three new HCPCS codes to reflect the additional resources involved in furnishing certain evaluation and management services: (1) GPC1X add-on code, for the visit complexity inherent to evaluation and management associated with certain primary care services, (2) GCG0X add-on code, for visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or interventional pain management-centered care, and (3) GPRO1, an additional add-on code for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure. We believe it would be appropriate to include these codes in the definition of primary care services under the Shared Savings Program because these codes are used to bill for services that are similar to services that are already included in the list of primary care codes at § 425.400(c). We

also expect that primary care physicians, nurse practitioners, physician assistants, and clinical nurse specialists frequently furnish these services as part of their overall management of a patient. As a result, we believe that including these codes would increase the accuracy of the assignment process by helping to ensure that beneficiaries are assigned to the ACO or other entity that is actually managing the beneficiary's care.

The following provides additional information about the HCPCS and CPT codes that we are proposing to add to the definition of primary care services:

Advance care planning (CPT codes 99497 and 99498): Effective January 1, 2016, CMS pays for voluntary advance care planning under the PFS (80 FR 70955 through 70959). See CMS, Medicare Learning Network, ''Advance Care Planning'' (ICN 909289, August 2016), available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/AdvanceCarePlanning.pdf.* Advance care planning enables Medicare beneficiaries to make important decisions that give them control over the type of care they receive and when they receive it. Medicare pays for advance care planning either as a separate Part B service when it is medically necessary or as an optional element of a beneficiary's Annual Wellness Visit. We believe it would be appropriate to include both Advance Care Planning codes 99497 and 99498 in the definition of primary care services under the Shared Savings Program because the services provided as part of advance care planning include counseling and other evaluation and management services similar to the services included in Annual Wellness Visits and other evaluation and management service codes that are already included in the list of primary care codes.

Administration of health risk assessment (CPT codes 96160 and 96161): In the CY 2017 PFS final rule (81 FR 80330 through 80331), CMS added two new CPT codes, 96160 and 96161, to the PFS, effective for CY 2017, to be used for payment for the administration of health risk assessment. These codes are ''add-on codes'' that describe additional resource components of a broader service furnished to the patient that are not accounted for in the valuation of the base code. For example, if a health risk assessment service were administered during a physician office visit, then the physician would bill for both the appropriate office visit code and the appropriate health risk assessment code. We believe it would be appropriate to include CPT codes 96160 and 96161 in the definition of primary care services because these add-on codes frequently represent additional practice expenses related to office visits for evaluation and management services that are already included in the definition of primary care services.

Prolonged evaluation and management or psychotherapy service(s) beyond the typical service time of the primary procedure (CPT codes 99354 and 99355): These two codes are also ''add-on codes'' that describe additional resource components of a broader service furnished in the office or other outpatient setting that are not accounted for in the valuation of the base codes. Code 99354 is listed on a claim to report the first hour of additional face-to-face time with a patient and code 99355 is listed separately for each additional 30 minutes of face-to-face time with a patient beyond the time reported under code 99354. Codes 99354 and 99355 would be billed separately in addition to the base office or other outpatient evaluation and management or psychotherapy service. (See Medicare Claims Processing Manual Chapter 12, Sections 30.6.15.1 Prolonged Services With Direct Face-to-Face Patient Contact Service (Codes 99354–99357) available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf;* also see CMS, MLN Matters, Prolonged Services (Codes 99354–99359) (Article Number MM5972, Revised March 7, 2017), available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm5972.pdf.*) Although we do not currently include prolonged services codes CPT code 99354 and 99355 on our list of primary care services, based on further review we believe it would be appropriate to include them on our list of primary care services to more accurately assign beneficiaries to ACOs based on all the allowed charges for the primary care services furnished to beneficiaries. We note that the definitions of codes 99354 and 99355 also include prolonged services for certain psychotherapy services, which are not currently included on our list of primary care services. Therefore, we propose to include the allowed charges for CPT code 99354 and 99355, for purposes of assigning beneficiaries to ACOs, only when the base code is also on the list of primary care services.

Annual depression screening (HCPCS code G0444), alcohol misuse screening (HCPCS code G0442), and alcohol misuse counseling (HCPCS code G0443): Effective October 14, 2011, all Medicare beneficiaries are eligible for annual depression screening and alcohol misuse screening. (See CMS Manual System, Screening for Depression in Adults (Transmittal 2359, November 23, 2011) available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2359CP.pdf* and see CMS, MLN Matters, Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse (Article Number MM7633, Revised June 4, 2012), available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm7633.pdf*). Although these three codes have been in use since before the implementation of the Shared Savings Program in 2012, based on further review of these services, we believe that it would be appropriate to consider these services in beneficiary assignment. Annual depression screening may be covered if it is furnished in a primary care setting that has staff-assisted depression care supports in place to assure accurate diagnosis, effective treatment, and follow-up. Alcohol misuse screening and counseling are screening and behavioral counseling interventions in primary care to reduce alcohol misuse. All three of these codes include screening and counseling services similar to counseling and other evaluation and management services included in the codes already on the list of primary care codes.

In the recent CY 2019 PFS proposed rule (see 83 FR 35841 through 35844)), CMS proposed to create three new HCPCS G-codes as part of a broader proposal to simplify the documentation requirements and to more accurately pay for services represented by CPT codes 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient). All three of these codes are ''add-on codes'' that describe additional resource components of a broader service furnished to the patient that are not accounted for in the valuation of the base codes.

HCPCS code GPC1X is intended to capture the additional resource costs, beyond those involved in the base evaluation and management codes, of providing face-to-face primary care services for established patients. HCPCS code GPC1X would be billed in addition to the base evaluation and management code for an established patient when the visit includes primary care services. In contrast, new HCPCS code GCG0X is an add-on code intended to reflect the

complexity inherent to evaluation and management services associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology, and interventional pain management-centered care. We believe it would be appropriate to include both proposed new HCPCS codes GCG0X and GPC1X in our definition of primary care services because they represent services that are currently included in CPT codes 99201 through 99215, which are already included in the list of primary care codes in § 425.400(c).

Finally, proposed new HCPCS code GPRO1 (prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure, in the office or other outpatient setting requiring direct patient contact beyond the usual service; 30 minutes) is modeled on CPT code 99354, a prolonged services code discussed earlier in this section which we are proposing to add to our list of primary care services. HCPCS code GPRO1 is intended to reflect prolonged evaluation and management or psychotherapy service(s) of 30 minutes duration beyond the typical service time of the primary or base service, whereas existing CPT code 99354 reflects prolonged services of 60 minutes duration. As is the case for code 99354, code GPRO1 would be billed separately in addition to the base office or other outpatient evaluation and management or psychotherapy service. We believe it would be appropriate to include proposed HCPCS code GPRO1 on our list of primary care services for the same reasons we are proposing to add CPT code 99354 to our list of primary care services. Because the proposed definition of HCPCS code GPRO1 also includes prolonged services for certain psychotherapy services, which are not currently included on our list of primary care services, we propose to include the allowed charges for HCPCS code GPRO1, for purposes of assigning beneficiaries to ACOs, only when the base code is also on the list of primary care services.

We propose to include these codes in the definition of primary care services when performing beneficiary assignment under § 425.402, for performance years starting on January 1, 2019, and subsequent years. We note, however, that our proposal to include the three proposed new ''add-on codes'', GPC1X, GCG0X, and GPRO1, is contingent on CMS finalizing its proposal to create these new codes for use starting in 2019.

As previously discussed in section II.E.3.a, ACOs and other stakeholders have expressed concerns regarding our current policy of identifying services billed under CPT codes 99304 through 99318 furnished in a SNF by using the POS modifier 31. We continue to believe it is appropriate to exclude from assignment services billed under CPT codes 99304 through 99318 when such services are furnished in a SNF. However, we agree with stakeholders that it might increase the accuracy of beneficiary assignment for these vulnerable and generally high cost beneficiaries if we were to revise our method for determining whether services identified by CPT codes 99304 through 99318 were furnished in a SNF to focus on whether the beneficiary also received SNF facility services on the same day. We believe it would be feasible for us to directly and more precisely determine whether services identified by CPT codes 99304 through 99318 were furnished in a SNF by analyzing our facility claims data files rather than by using the POS modifier 31 in our professional claims data files. Operationally, we would exclude professional services claims billed under CPT codes 99304 through 99318 from use in the assignment methodology when there is a SNF facility claim in our claims files with dates of service that overlap with the date of service for the professional service. Therefore, we propose to revise the regulation at § 425.400(c)(1)(iv)(A)(*2*), effective for performance years starting on January 1, 2019 and subsequent performance years, to remove the exclusion of claims including the POS code 31 and in its place indicate more generally that we would exclude services billed under CPT codes 99304 through 99318 when such services are furnished in a SNF.

Under our current process, if CMS's HCPCS committee or the American Medical Association's CPT Editorial Panel modifies or replaces any of the codes that we designate as primary care service codes in § 425.400(c), we must revise the primary care service codes listed in § 425.400(c) as appropriate through further rulemaking before the revised codes can be used for purposes of assignment. As noted previously, effective for CY 2018, the HCPCS codes for behavioral health integration G0502, G0503, G0504 and G0507 have been replaced by CPT codes 99492, 99493, 99494 and 99484. Therefore, consistent with our current process, we propose to revise the primary care service codes in § 425.400(c)(1)(iv) to replace HCPCS codes G0502, G0503, G0504 and G0507 with CPT codes 99492, 99493, 99494 and 99484 for performance years starting on January 1, 2019, and subsequent performance years.

We note that the regulations text at § 425.400(c)(1)(iv) includes brief descriptions for the HCPCS codes that we have designated as primary care service codes, but does not include such descriptions for the CPT codes that we have designated as primary care service codes. For consistency, we are proposing a technical change to the regulations at § 425.400(c)(1)(iv)(A) to also include descriptions for the CPT codes. We also note that one of the Chronic Care Management (CCM) codes, CPT code 99490, is inadvertently listed in the regulations text at § 425.400(c)(1)(iv)(A)(*6*) along with the codes for Transitional Care Management (TCM) services. We are proposing a technical change to the regulations to move CPT code 99490 up to § 425.400(c)(1)(iv)(A)(*5*) with the other CCM codes.

We welcome comments on the new codes we are proposing to add to the definition of primary care services used for purposes of assigning beneficiaries to Shared Savings Program ACOs. In addition, we seek comments on our proposal to revise our method for excluding services identified by CPT codes 99304 through 99318 when furnished in a SNF. We also seek comments on the other proposed technical changes to § 425.400(c)(1)(iv). We also welcome comments on any additional existing HCPCS/CPT codes that we should consider adding to the definition of primary care services in future rulemaking.

4. Extreme and Uncontrollable Circumstances Policies for the Shared Savings Program

a. Background

Following the 2017 California wildfires and Hurricanes Harvey, Irma, Maria and Nate, stakeholders expressed concerns that the effects of these types of disasters on ACO participants, ACO providers/suppliers, and the assigned beneficiary population could undermine an ACO's ability to successfully meet the quality performance standards, and adversely affect financial performance, including, in the case of ACOs under performance-based risk, increasing shared losses. To address these concerns, we published an interim final rule with comment period titled Medicare Program; Medicare Shared Savings Program: Extreme and Uncontrollable Circumstances Policies for Performance Year 2017 (hereinafter referred to as the Shared Savings Program IFC) that appeared in the

Federal Register on December 26, 2017 (82 FR 60912). In the Shared Savings Program IFC, we established policies for addressing ACO quality performance scoring and the determination of the shared losses owed by ACOs participating under performance-based risk tracks for ACOs that were affected by extreme or uncontrollable circumstances during performance year 2017. The policies adopted in the Shared Savings Program IFC were effective for performance year 2017, including the applicable quality data reporting period for the performance year. We have considered the comments received to date on the Shared Savings Program IFC in developing the policies in this proposed rule for 2018 and subsequent years.

The extreme and uncontrollable circumstances policies established in the Shared Savings Program for performance year 2017 align with the policies established under the Quality Payment Program for the 2017 MIPS performance period and subsequent MIPS performance periods (see CY 2018 Quality Payment Program final rule with comment, 82 FR 53780 through 53783 and Quality Payment Program IFC, 82 FR 53895 through 53900). In particular, in the Shared Savings Program IFC (82 FR 60914), we indicated that we would determine whether an ACO has 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 or the ACO's legal entity is located in such an area. 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 a Federal Emergency Management Agency (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).

Because ACOs may face extreme and uncontrollable circumstances in 2018 and subsequent years, we believe it is appropriate to propose to extend the policies adopted in the Shared Savings Program IFC for addressing ACO quality performance scoring and the determination of the shared losses owed for ACOs affected by extreme or uncontrollable circumstances to performance year 2018 and subsequent performance years. In addition, in the Shared Savings Program IFC, we indicated that we planned to observe the impact of the 2017 hurricanes and wildfires on ACOs' expenditures for their assigned beneficiaries during performance year 2017, and might revisit the need to make adjustments to the methodology for calculating the benchmark in future rulemaking. We consider this issue further in the discussion that follows.

b. Proposed Revisions

The financial and quality performance of ACOs located in areas subject to extreme and uncontrollable circumstances could be significantly and adversely affected. Disasters may have several possible effects on ACO quality and financial performance. For instance, displacement of beneficiaries may make it difficult for ACOs to access medical record data required for quality reporting, as well as, reduce the beneficiary response rate on survey measures. Further, for practices damaged by a disaster, the medical records needed for quality reporting may be inaccessible. We also believe that disasters may affect the infrastructure of ACO participants, ACO providers/suppliers, and potentially the ACO legal entity itself, thereby disrupting routine operations related to their participation in the Shared Savings Program and achievement of program goals. The effects of a disaster could include challenges in communication between the ACO and its participating providers and suppliers and in implementation of and participation in programmatic activities. Catastrophic events outside the ACO's control can also increase the difficulty of coordinating care for patient populations, and due to the unpredictability of changes in utilization and cost of services furnished to beneficiaries, may have a significant impact on expenditures for the applicable performance year and the ACO's benchmark in the subsequent agreement period. These factors could jeopardize ACOs' ability to succeed in the Shared Savings Program, and ACOs, especially those in performance-based risk tracks, may reconsider whether they are able to continue their participation in the program.

Because widespread disruptions could occur during 2018 or subsequent performance years, we believe it is appropriate to have policies in place to change the way in which we assess the quality and financial performance of Shared Savings Program ACOs in any affected areas. Accordingly, we propose to extend the automatic extreme and uncontrollable circumstances policies under the Shared Savings Program that were established for performance year 2017 to performance year 2018 and subsequent performance years. Specifically, we propose that the Shared Savings Program extreme and uncontrollable circumstances policies for performance year 2018 and subsequent performance years would apply when we determine that an event qualifies as an automatic triggering event under the Quality Payment Program. As we discussed in the Shared Savings Program IFC (82 FR 60914), we believe it is also appropriate to extend these policies to encompass the quality reporting period, unless the reporting period is extended, because if an ACO is unable to submit its quality data as a result of a disaster occurring during the quality data submission window, we would not have the quality data necessary to measure the ACO's quality performance for the performance year. For example, if an extreme and uncontrollable event were to occur in February 2019, which we anticipate would be during the quality data reporting period for performance year 2018, then the extreme and uncontrollable circumstances policies would apply for quality data reporting and quality performance scoring for performance year 2018, if the reporting period is not extended. We do not believe it is 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 the applicable performance year. Accordingly, we also propose that the policies regarding quality reporting would apply with respect to the determination of the ACO's quality performance in the event that an extreme and uncontrollable event occurs during the applicable quality data reporting period for a performance year and the reporting period is not extended. However, we note 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 that performance year, we do not believe it would be appropriate to make an adjustment to shared losses in the event an extreme or uncontrollable event occurs during the quality data reporting period.

(1) Modification of Quality Performance Scores for all ACOs in Affected Areas

As we explained in the Shared Savings Program IFC (82 FR 60914 through 60916), 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, for 2017, we established a policy for determining when an ACO, which may have ACO participants and ACO providers/suppliers located in multiple geographic areas, would qualify for the automatic extreme and uncontrollable circumstance policies for the determination of quality performance. Specifically, we adopted a policy for performance year 2017 of determining whether an ACO has been affected by extreme and uncontrollable circumstances by determining whether 20 percent or more of the ACO's assigned beneficiaries resided in counties designated as an emergency declared area in the performance year, as determined under the Quality Payment Program as discussed in the Quality Payment Program IFC (82 FR 53898) or the ACO's legal entity is located in such an area. For 2017, we adopted a policy under which the location of an ACO's legal entity is determined based on the address on file for the ACO in CMS's ACO application and management system. 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 for 2017 because, as we stated in the Shared Savings Program IFC, we believe the 20 percent threshold provides 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 indicated that we believe the 20 percent threshold ensures 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 noted that it is possible that some ACOs that have fewer than 20 percent of their assigned beneficiaries residing in affected areas may have a legal entity that is located in an emergency declared area. Consequently, their ability to quality report may be equally impacted because the ACO legal entity may be unable to collect the necessary information from the ACO participants or experience infrastructure issues related to capturing, organizing, and reporting the data to CMS. We stated that if less than 20 percent of the ACO's assigned beneficiaries reside in an affected area and the ACO's legal entity is not located in a county designated as an affected area, then we believe that there is unlikely to be a significant impact upon the ACO's ability to report or on the representativeness of the quality performance score that is determined for the ACO. For performance year 2017, we will 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, these ACOs will 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.

In the Shared Savings Program IFC, we modified the quality performance standard specified under § 425.502 by 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 also modified § 425.502(e)(4) to specify that an ACO receiving the mean Shared Savings Program ACO quality score for performance year 2017 based on the extreme and uncontrollable circumstances policies is not eligible for bonus points awarded based on quality improvement in that year because quality data will not be available to determine if there was improvement from year to year.

In the Shared Savings Program IFC, we established policies with respect to quality reporting and quality performance scoring for the 2017 performance year. In anticipation of any future extreme and uncontrollable events, we believe it is appropriate to propose to extend these policies, with minor modifications, to subsequent performance years as well. In order to avoid confusion and reduce unnecessary burdens on affected ACOs, we propose to align our policies for 2018 and subsequent years with policies established for the Quality Payment Program in final rule with comment period, entitled CY 2018 Updates to the Quality Payment Program (82 FR 53568). Specifically, we propose to apply determinations made under the Quality Payment Program with respect to whether an extreme and uncontrollable circumstance has occurred and the identification of the affected geographic areas and the applicable time periods. Generally, in line with the approach taken for 2017 in the Quality Payment Program IFC (82 FR 53897), we anticipate that the types of events that would be considered an automatic triggering event would be events designated as a Federal Emergency Management Agency (FEMA) major disaster or a public health emergency declared by the Secretary, but CMS will review each situation on a case-by-case basis. We also propose that CMS 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. Additionally, we propose to determine an ACO's legal entity location based on the address on file for the ACO in CMS's ACO application and management system.

In the Shared Savings Program IFC, we established a policy for performance year 2017 under which we will determine the percentage of the ACO's assigned population that was affected by a disaster based on the final list of beneficiaries assigned to the ACO for the performance year. We begin producing the final list of assigned beneficiaries after allowing for 3 months of claims run out following the end of a performance year. However, the quality reporting period ends before the 3-month claims run out period ends. Therefore, we are concerned that if, for future performance years, we continue to calculate the percentage of affected beneficiaries based on the ACO's final

list of assigned beneficiaries, it would not be operationally feasible for us to notify an ACO as to whether it meets the 20 percent threshold prior to the end of the quality reporting period because the final list of assigned beneficiaries is not available until after the close of the quality reporting period. We now believe it would be appropriate to base this calculation on the list of assigned beneficiaries used to generate the Web Interface quality reporting sample, which would be available with the quarter three program reports, generally in November of the applicable performance year (or calendar year for the 6-month performance year (or performance period) from January 1, 2019, through June 30, 2019). Under this timeline, we would be able to notify ACOs earlier as to whether they exceed the 20 percent threshold, and ACOs could then use this information to decide whether to report quality data for the performance year. Therefore, for performance year 2018 and subsequent performance years, we are proposing to determine the percentage of an ACO's assigned beneficiaries that reside in an area affected by an extreme and uncontrollable circumstance using the list of assigned beneficiaries used to generate the Web Interface quality reporting sample. We believe we can use this assignment list report regardless of the date(s) the natural disaster occurred. The assignment list report provides us with a list of beneficiaries who have received the plurality of their primary care services from ACO professionals in the ACO at a specific point in time. As this is the list that is used to determine the quality reporting sample, we believe it is appropriate to use the same list to determine how many of the ACO's beneficiaries reside in an area affected by a disaster, such that the ACO's ability to report quality data could be compromised. We propose to revise § 425.502(f) to reflect this proposal for performance year 2018 and subsequent years. We welcome comments on this proposal

In the Shared Savings Program IFC (82 FR 60916), we described the policies under the MIPS APM scoring standard that would apply for performance year 2017 for MIPS eligible clinicians in an ACO that did not completely report quality. The existing tracks of the Shared Savings Program (Track 1, Track 2 and Track 3), and the Track 1+ Model are MIPS APMs under the APM scoring standard.[23] If finalized, we expect the proposed BASIC track and ENHANCED track (based on Track 3) would similarly be considered MIPS APMs under the APM scoring standard. For purposes of the APM scoring standard, MIPS eligible clinicians in an ACO that has been affected by an extreme and uncontrollable circumstance and does not report quality for a performance year, and therefore, receives the mean ACO quality score under the Shared Savings Program, would have the MIPS quality performance category reweighted to zero percent resulting in MIPS performance category weighting of 75 percent for the Promoting Interoperability performance category and 25 percent for Improvement Activities performance category under the APM scoring standard per our policy at § 414.1370(h)(5)(i)(B). In the event an ACO that has been affected by an extreme and uncontrollable circumstance is able to completely and accurately report all quality measures for a performance year, and therefore receives the higher of the ACO's quality performance score or the mean quality performance score under the Shared Savings Program, we would not reweight the MIPS quality performance category to zero percent under the APM scoring standard. Additionally, unless otherwise excepted, the ACO participants will receive a Promoting Interoperability (PI) (formerly called Advancing Care Information (ACI)) performance category score under the APM scoring standard based on their reporting, which could further increase their final score under MIPS.

We propose to revise § 425.502(f) to extend the policies established for performance year 2017 to performance year 2018 and subsequent performance years. Specifically, we propose that for performance year 2018 and subsequent performance years, including the applicable quality data reporting period for the performance year if the reporting period is not extended, in the event that we determine that 20 percent or more of an ACO's assigned beneficiaries, as determined using the list of beneficiaries used to generate the Web Interface quality reporting sample, reside 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 is 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 quality performance score for all Shared Savings Program ACOs for the applicable performance year.
- If the ACO is able to completely and accurately report all quality measures, we would use the higher of the ACO's quality performance score or the mean quality performance score for all Shared Savings Program ACOs. If the ACO's quality performance score is used, the ACO would also be eligible for quality improvement points.
- If the ACO receives the mean Shared Savings Program quality performance score, the ACO would not be eligible for bonus points awarded based on quality improvement during the applicable performance year.
- If an ACO receives the mean Shared Savings Program ACO quality performance 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 would 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. Under this approach, the comparison will continue to be between consecutive years of quality reporting, but these years may not be consecutive calendar years.

Additionally, we propose to address the possibility that ACOs that have a 6-month performance year (or performance period) during 2019 may be affected by extreme and uncontrollable circumstances. As described in section II.A.7 of this proposed rule, we are proposing to use 12 months of data, based on the calendar year, to determine quality performance for the two 6-month performance years during 2019 (from January 2019 through June 2019, and from July 2019 through December 2019). We are also proposing to use this same approach to determine quality performance for ACOs that start a 12-month performance year on January 1, 2019, and then elect to voluntarily terminate their participation agreement with an effective termination date of June 30, 2019, and enter a new agreement period starting on July 1, 2019. Accordingly, we believe it is necessary to account for disasters occurring in any month(s) of calendar year 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

[23] 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.*

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. For example, assume that an ACO participates in the Shared Savings Program for a 6-month performance year from January 1, 2019, through June 30, 2019, and does not continue its participation in the program for a new agreement period beginning July 1, 2019. Further assume that we determine that 20 percent or more of the ACO's assigned beneficiaries, as determined using the list of beneficiaries used to generate the Web Interface quality reporting sample, reside in an area that is affected by an extreme and uncontrollable circumstance, as determined under the Quality Payment Program, in September 2019. The ACO's quality performance score for the 2019 reporting period would be adjusted according to the policies in § 425.502(f).

We propose to specify the applicability of the alternative scoring methodology in § 425.502(f) to the 6-month performance years (or the 6-month performance period) within calendar year 2019 in the proposed new section of the regulations at § 425.609 that describes the methodology for determining an ACO's financial and quality performance for the two 6-month performance years (or the 6-month performance period) during 2019.

(2) Mitigating Shared Losses for ACOs Participating in a Performance-Based Risk Track

In the Shared Savings Program IFC (82 FR 60916) we modified the payment methodology for performance-based risk tracks for performance year 2017, established under the authority of section 1899(i) of the Act, to mitigate shared losses owed by ACOs affected by extreme and uncontrollable circumstances. Under this approach, we will reduce the ACO's shared losses, if any, determined to be owed for performance year 2017 under the existing methodology for calculating shared losses in the Shared Savings Program regulations at 42 CFR part 425 subpart G 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 reside in an area affected by an extreme and uncontrollable circumstance. For performance year 2017, we will 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 reside in the disaster area. In this scenario, we would adjust the ACO's losses in the following manner: $\$100{,}000 - (\$100{,}000 \times 0.25 \times 0.25) = \$100{,}000 - \$6{,}250 = \$93{,}750$. The policies for performance year 2017 are specified in paragraph (i) in § 425.606 for ACOs under Track 2 and § 425.610 for ACOs under Track 3.

We believe it is appropriate to continue to apply these policies in performance year 2018 and subsequent years to address stakeholders' concerns that ACOs participating under a performance-based risk track 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 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 believe ACOs that are participating in performance-based risk tracks may reconsider whether they are able to continue their participation in the Shared Savings Program under a performance-based risk track. The approach we adopted for performance year 2017 in the Shared Savings Program IFC, and which we are proposing to continue for performance year 2018 and subsequent years, balances 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 portion of their final assigned beneficiary population that was outside the area affected by the disaster. Consistent with the policy adopted for performance year 2017 in the Shared Savings Program IFC, we believe it is appropriate to continue to use the final assignment list report for the performance year for purposes of this calculation. This final assignment list report will be available at the time we conduct final reconciliation and provides the most complete information regarding the extent to which an ACO's assigned beneficiary population was affected by a disaster.

Additionally, we propose to also address the possibility that ACOs that have a 6-month performance year during 2019 may be affected by extreme and uncontrollable circumstances. As described in section II.A.7 of this proposed rule, we are proposing to use 12 months of expenditure data, based on the calendar year, to perform financial reconciliation for the two 6-month performance years during 2019 (from January 2019 through June 2019, and from July 2019 through December 2019). Accordingly, for ACOs participating in a 6-month performance year during 2019, we believe it is necessary to account for disasters occurring in any month(s) of calendar year 2019, regardless of whether the ACO is actively participating in the Shared Savings Program at the time of the disaster. This proposal applies to ACOs participating under a 6-month performance year during calendar year 2019, that would be reconciled based on their financial performance during the entire 12-month calendar year 2019 (as described in section II.A.7 of this proposed rule and in the proposed provision at § 425.609). This proposal also applies to ACOs that start a 12-month performance year on January 1, 2019, and then elect to voluntarily terminate their participation agreement with an effective termination date of June 30, 2019, and enter a new agreement period starting on July 1, 2019. Consistent with § 425.221(b)(3)(i), we would reconcile these ACOs for the performance period from January 1, 2019, through June 30, 2019, based on their financial performance during the entire 12-month calendar year 2019, according to the methodology in the proposed provision at § 425.609.

For ACOs with a 6-month performance year (or performance period) that are affected by an extreme or uncontrollable circumstance during calendar year 2019, we propose 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. For example, assume that: A disaster was declared for October 2019 through December 2019; an ACO is being reconciled for its participation during the performance year (or performance period) from January 1, 2019, through June 30, 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 × 0.25 × 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 × 0.5 = $46,875.

This proposed approach to mitigate shared losses for ACOs that may be affected by extreme and uncontrollable circumstances would also apply 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 (as described in section II.A.6 of this proposed rule and in the proposed revisions to § 425.221(b)(2)). We note that according to the proposed policies in section II.A.6.d of this proposed rule, an ACO under a two-sided model that voluntarily terminates its participation agreement under § 425.220 during a 6-month performance year 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. For ACOs that are involuntarily terminated from a 6-month performance year, pro-rated shared losses for the 6-month performance year would be determined based on assigned beneficiary expenditures for the full calendar year 2019 (as described in section II.A.7 of this proposed rule) and then pro-rated to account for the partial year of participation prior to involuntary termination.

We acknowledge 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 may also be affected by extreme and uncontrollable circumstances. In this case, we propose 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 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 × 0.25 × 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 × 0.25 = $23,437.50.

Therefore, we propose to amend §§ 425.606(i) and 425.610(i) to extend the policies regarding extreme and uncontrollable circumstances that were established for performance year 2017 to performance year 2018 and subsequent years. In section II.A.3.a of this proposed rule, we discuss our proposal that these policies for addressing the impact of extreme and uncontrollable circumstances on ACO financial performance would also apply to BASIC track ACOs under performance-based risk. These proposals are reflected in the proposed new provision at § 425.605(f). We also propose 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 will 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 address 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)(3)(i). In addition, we are proposing to include a provision at § 425.609(d) to provide that the policies on extreme and uncontrollable circumstances would apply to the determination of shared losses for ACOs participating in a 6-month performance year during 2019.

We note that to the extent that our proposal to extend the policies adopted in the Shared Savings Program IFC to 2018 and subsequent performance years constitutes a proposal to change the payment methodology for 2018 after the start of the performance year, we believe that consistent with section 1871(e)(1)(A)(ii) of the Act, and for the reasons discussed in this section of this proposed rule, it would be contrary to the public interest not to propose to establish a policy under which we would have the authority adjust the shared losses calculated for ACOs in Track 2 and Track 3 for performance year 2018 to reflect the impact of any extreme or uncontrollable circumstances that may occur during the year.

These proposed policies would not change the status of those payment models that meet the criteria to be Advanced APMs under the Quality Payment Program (see § 414.1415). Our proposed policies would reduce the amount of shared losses owed by ACOs affected by a disaster, but the overall financial risk under the payment model would not change and participating ACOs would still remain at risk for an amount of shared losses in excess of the Advanced APM generally applicable nominal amount standard. Additionally, these policies would not prevent an eligible clinician from satisfying the requirements to become a QP for purposes of the APM Incentive Payment (available for payment years through 2024) or higher physician fee schedule updates (for payment years beginning in 2026) under the Quality Payment Program.

We also want to emphasize that all ACOs would continue to be entitled to share in any savings they may achieve for a performance year. ACOs in all tracks of the program will continue to receive shared savings payments, if any, as determined under subpart G of the regulations. The calculation of savings and the determination of shared savings payment amounts for a performance year would not be affected by the proposed policies to address extreme and uncontrollable circumstances, except that the quality performance score for an affected ACO may be adjusted as described in this section of this proposed rule.

(3) Determination of Historical Benchmarks for ACOs in Affected Areas

In the Shared Savings Program IFC, we sought comment on how to address the impact of extreme and uncontrollable circumstances on the expenditures for an ACO's assigned beneficiary population for purposes of determining the benchmark (82 FR 60917). As we explained in the Shared Savings Program IFC (82 FR 60913), the impact of disasters on an ACO's financial performance could be unpredictable as a result of changes in utilization and cost of services furnished to the Medicare beneficiaries it serves. In some cases, ACO

participants might be unable to coordinate care because of migration of patient populations leaving the impacted areas. On the other hand, patient populations remaining in impacted areas might receive fewer services and have lower overall costs to the extent that healthcare providers are unable to reopen their offices because they lack power and water, or have limited access to fuel for operating alternate power generators. Significant changes in costs incurred, whether increased or decreased, as a result of an extreme or uncontrollable circumstance may 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. An 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. Likewise, a decrease in expenditures for a particular calendar year would result in a lower benchmark value when the same calendar year is used to determine the ACO's historical benchmark.

While considering options for adjusting ACOs' historical benchmarks to account for disasters occurring during a benchmark year, we considered the effect that the proposed regional factors, that are discussed in section II.D.3 might have on the historical benchmarks for ACOs located in a disaster area. After review, we believe that when regional factors are applied to an ACO's historical benchmark, the regional factors would inherently adjust for variations in expenditures from year to year, and thus would also adjust for regional variations in expenditures related to extreme and uncontrollable circumstances. For example, assume that an ACO experienced a reduction in beneficiary expenditures in performance year 2017 because a portion of its assigned beneficiaries resided in counties that were impacted by a disaster. Then, also assume expenditures returned to their previously higher level in 2018 and this ACO subsequently renewed its ACO participation agreement in 2020. In 2020, when the ACO's historical benchmark would be reset (rebased), the expenditures for 2017 (now a historical benchmark year) would be subject to a higher regional trend factor because expenditures increased back to the expected level in 2018, which would increase the 2017 benchmark year expenditures. Additionally, this ACO could also have its historical benchmark increased even further as a result of its performance compared to others in its region, as reflected in the regional adjustment to the ACO's historical benchmark. In contrast, consider an ACO that experienced an increase in beneficiary expenditures in performance year 2017 because a portion of its assigned beneficiaries resided in counties that were impacted by a disaster. Then, assume expenditures returned to their previously lower level in 2018 and this ACO renewed its ACO participation agreement in 2020. In 2020, when the ACO's historical benchmark would be reset, the expenditures for 2017 would be subject to a lower regional trend factor because expenditures decreased back to the expected level in 2018, which would decrease the 2017 benchmark year expenditures. Additionally, this ACO could also have its historical benchmark decreased further as a result of its performance compared to others in its region, as reflected in the regional adjustment to the ACO's historical benchmark.

Our expectation that the proposed regional factors that would be used to establish an ACO's historical benchmark would also adjust for variations in expenditures related to extreme and uncontrollable circumstances is supported by a preliminary analysis of data for areas that were affected by the disasters that occurred in performance year 2017. Our analysis of the data showed that, as a result of the disasters in these areas, expenditure trends for the performance year appeared below projections. For these areas, the expenditures began to increase after the disaster incident period ended, but expenditures were still below expectations for the year. Based on the expenditure trends beginning to return to expected levels after the disaster period, it would be reasonable to expect that expenditures would continue to increase to expected levels in 2018. This difference between the lower than expected levels of expenditures in 2017 and a return to expected expenditures in 2018, would result in a higher regional trend factor being applied to 2017 expenditures when they are used to determine an ACO's historical benchmark.

In considering whether it might be necessary to make an additional adjustment to ACOs' historical benchmarks to account for expenditure variations related to extreme and uncontrollable circumstances, we considered an approach where we would adjust the historical benchmark by reducing the weight of expenditures for beneficiaries who resided in a disaster area during a disaster period and placing a correspondingly larger weight on expenditures for beneficiaries residing outside the disaster area during the disaster period. Such an approach would be expected to proportionally increase the historical benchmark for ACOs that experienced a decrease in expenditures, and conversely proportionally decrease the historical benchmark for ACOs that experienced an increase in expenditures for their assigned beneficiaries who were impacted by a disaster. Under this approach, for each of the historical benchmark years, we would identify each ACO's assigned beneficiaries who had resided in a disaster area during a disaster period. The portion of expenditures for these assigned beneficiaries that was impacted by the disaster would be removed from the applicable historical benchmark year(s). The removal of these expenditures from the historical benchmark year(s) would allow the historical benchmark calculations to include only expenditures that were not impacted by the disaster. We believe this methodology for calculating benchmark expenditures would adjust for expenditure increases or decreases that may occur as a result of impacts related to a disaster.

If we were to implement such an adjustment to the historical benchmark, we believe it would be appropriate to avoid making minor historical benchmark adjustments for an ACO that was not significantly affected by a disaster by establishing a minimum threshold for the percentage of an ACO's beneficiaries located in a disaster area. Based on data from 2017, quarter 3, over 80 percent of ACOs had less than 50 percent of their assigned beneficiaries residing in disaster counties, with over 75 percent having less than 10 percent of their assigned beneficiaries residing in disaster counties. Based on this data, we believe a minimum threshold of 50 percent of assigned beneficiaries residing in disaster counties could be an appropriate threshold for the adjustment to historical benchmarks because historical benchmarks are calculated based on the ACO's entire assigned beneficiary population in each benchmark year, rather than a sample as is used for quality reporting.

However, we are concerned that this methodology for calculating an adjustment might not be as accurate as the inherent adjustment that would result from applying regional factors when resetting the benchmark and may

impact other expected expenditure variations occurring in the impacted areas. For example, if an additional disaster adjustment were to be applied, it might have unintended impacts when expenditure truncation is applied, it might inappropriately weight and not account for expected variations in expenditures between areas that were and were not impacted by the disaster, and it might compound effects that have already been offset by the regional adjustment. In addition, the expenditures, as adjusted, may not be representative of the ACO's actual performance and aggregate assigned beneficiary population during the benchmark period.

In summary, we believe the regional factors that we are proposing to apply as part of the methodology for determining an ACO's historical benchmark would reduce the expenditures in a historical benchmark year when they are greater than expected (relative to other historical benchmark years) as a result of a disaster and conversely increase expenditures in a historical benchmark year when they are below the expected amount. For these reasons, we believe that the proposal in section II.D.3 of this proposed rule to apply regional factors when determining ACOs' historical benchmarks, starting with an ACO's first agreement period for agreement periods starting on July 1, 2019, and in subsequent years, would be sufficient to address any changes in expenditures during an ACO's historical benchmark years as a result of extreme and uncontrollable circumstances, and an additional adjustment, such as the method discussed previously in this section would not appear to be necessary. However, we will continue to evaluate the impact of the 2017 disasters on ACOs' assigned beneficiary expenditures, and we intend to continue to consider whether it might be appropriate to make an additional adjustment to the historical benchmark to account for expenditures that may have increased or decreased in a historical benchmark year as a result of an extreme or uncontrollable circumstance.

We welcome comments on these issues, including whether it is necessary to adjust ACOs' historical benchmarks to account for extreme and uncontrollable circumstances that might occur during a benchmark year, and appropriate methods for making such benchmark adjustments. We would also note that the proposal in section II.D.3 of this proposed rule to apply regional factors to determine ACOs' historical benchmarks would apply starting with an ACO's first agreement period for agreement periods starting on July 1, 2019, and in subsequent years and would therefore have no effect on benchmarks for ACOs in a first agreement period starting before July 1, 2019. Accordingly, we welcome comments on whether and how an adjustment should be made for ACOs whose benchmarks do not reflect these regional factors.

We invite comments on the policies being proposed for assessing the financial and quality performance of ACOs affected by an extreme or uncontrollable circumstance during performance year 2018 and subsequent years, including the applicable quality data reporting period for the performance year, unless the reporting period is extended. We believe these policies would reduce burden and financial uncertainty for ACOs, ACO participants, and ACO providers/suppliers affected by future catastrophes, and will also align with existing Medicare policies in the Quality Payment Program. We also invite comments on any additional areas where relief may be helpful or other ways to mitigate unexpected issues that may arise in the event of an extreme and uncontrollable circumstance.

5. Program Data and Quality Measures

In this section, we solicit comments on possible changes to the quality measure set and modifications to program data shared with ACOs to support CMS's Meaningful Measures initiative and respond to the nation's opioid misuse epidemic. As part of the Meaningful Measures initiative, we are focusing the agency's efforts on updating quality measures, reducing regulatory burden, and promoting innovation (see CMS Press Release, CMS Administrator Verma Announces New Meaningful Measures Initiative and Addresses Regulatory Reform; Promotes Innovation at LAN Summit, October 30, 2017, available at *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-10-30.html).* Under the Meaningful Measures initiative, we are working towards assessing performance on only those core issues that are most vital to providing high-quality care and improving patient outcomes, with an emphasis on outcome-based measures, reducing unnecessary burden on providers, and putting patients first. When we developed the quality reporting requirements under the Shared Savings Program, we considered the quality reporting requirements under other initiatives, such as the Physician Quality Reporting System (PQRS) and Million Hearts Initiative, and consulted with the measures community to ensure that the specifications for the measures used under the Shared Savings Program are up-to-date and reduce reporting burden.

Since the Shared Savings Program was first established in 2012, we have not only updated the quality measure set to reduce reporting burden, but also to focus on more meaningful outcome-based measures. The most recent updates to the Shared Savings Program quality measure set were made in the CY 2017 PFS Final Rule (81 FR 80484 through 80489) to adopt the ACO measure recommendations made by the Core Quality Measures Collaborative, a multi-stakeholder group with the goal of aligning quality measures for reporting across public and private stakeholders in order to reduce provider reporting burden. Currently, more than half of the 31 Shared Savings Program quality measures are outcome-based, including:

- Patient-reported outcome measures collected through the CAHPS for ACOs Survey that strengthen patient and caregiver experience;
- Outcome measures supporting care coordination and effective communication, such as unplanned admission and readmission measures; and
- Intermediate outcome measures that address the effective treatment of chronic disease, such as hemoglobin A1c control for patients with diabetes and control of high blood pressure.

It is important that the quality reporting requirements under the Shared Savings Program align with the reporting requirements under other Medicare initiatives and those used by other payers in order to minimize the need for Shared Savings Program participants to devote excessive resources to understanding differences in measure specifications or engaging in duplicative reporting. We seek comment, including recommendations and input on meaningful measures, on how we may be able to further advance the quality measure set for ACO reporting, consistent with the requirement under section 1899(b)(3)(C) of the Act that the Secretary seek to improve the quality of care furnished by ACOs by specifying higher standards, new measures, or both.

One particular area of focus by the Department of Health and Human Services is the opioid misuse epidemic. The Centers for Disease Control and Prevention (CDC) reports that the number of people experiencing chronic pain lasting more than 3 months is estimated to include 11 percent of the adult population. According to a 2016

CDC publication, 2 million Americans had opioid use disorder (OUD) associated with prescription opioids in 2014 (*https://www.cdc.gov/drugoverdose/prescribing/guideline.html*). Since the implementation of Medicare Part D in 2006 to cover prescription medications, the Medicare program has become the largest payer for prescription opioids in the United States (Zhou et al, 2016; *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4955937/*). Safe and effective opioid prescribing for older adults is of particular importance because misuse and abuse of opioids can lead to increased adverse events in this population (for example, increased falls, fractures, hospitalization, ER visits, mortality), especially given the high prevalence of polypharmacy in the elderly. Polypharmacy is the simultaneous use of multiple drugs by a single patient, for one or more conditions, which increases the risk of adverse events. For example, a study by MedPAC found that some beneficiaries who use opioids fill more than 50 prescriptions among 10 drug classes annually (*http://www.medpac.gov/docs/default-source/reports/chapter-5-polypharmacy-and-opioid-use-among-medicare-part-d-enrollees-june-2015-report-.pdf?sfvrsn=0,* MedPAC, 2015).

As part of a multifaceted response to address the growing problem of overuse and abuse of opioids in the Part D program, CMS adopted a policy in 2013 requiring Medicare Part D plan sponsors to implement enhanced drug utilization review. Between 2011 through 2014, there was a 26 percent decrease or 7,500 fewer Medicare Part D beneficiaries identified as potential opioid over-utilizers which may be due, at least in part, to these new policies. On January 5, 2017, CMS released its Opioid Misuse Strategy. This document outlines CMS's strategy and the array of actions underway to address the national opioid misuse epidemic and can be found at *https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/CMS-Opioid-Misuse-Strategy-2016.pdf.*

We aim to align our policies under the Shared Savings Program with the priorities identified in the Opioid Misuse Strategy and to help ACOs and their participating providers and suppliers in responding to and managing opioid use, and are therefore considering several actions to improve alignment. Specifically, we are considering what information regarding opioid use, including information developed using aggregate Medicare Part D data, could be shared with ACOs. We are also considering the addition of one or more measures specific to opioid use to the ACO quality measures set. The potential benefits of such policies would be to focus ACOs on the appropriate use of opioids for their assigned beneficiaries and support their opioid misuse prevention efforts.

First, we are considering what information, including what aggregated Medicare Part D data, could be useful to ACOs to combat opioid misuse in their assigned beneficiary population. We recognize the importance of available and emerging resources regarding the opioid epidemic at the federal, state, and local level, and intend to work with our federal partners to make relevant resources available in a timely manner to support ACOs' goals and activities. We will also continue to share information with ACOs highlighting Federal opioid initiatives, such as the CDC Guideline for Prescribing Opioids for Chronic Pain (*https://www.cdc.gov/drugoverdose/prescribing/guideline.html*), which reviews the CDC's recommended approach to opioid prescribing, and the Surgeon General's report on Substance Use and Addiction, Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health, (*https://addiction.surgeongeneral.gov/*) which focuses on educating and mobilizing prescribers to take action to end the opioid epidemic by improving prescribing practices, informing patients about the risks of and resources for opioid addiction, and encouraging health care professionals to take a pledge to end the opioid crisis. We will also continue to highlight information about the opioid crisis and innovations for opioid treatment and prevention strategies in ACO learning system webinars. These webinars provide the forum for peer-to-peer sharing, such as the webinar held last year on Community Approaches to Preventing Opioid-Related Overdoses and Deaths, which included speakers from State and community organizations.

Although we recognize that not all beneficiaries assigned to Shared Savings Program ACOs have Part D coverage, we believe a sufficient number do have Part D coverage to make aggregate Part D data regarding opioid use helpful for the ACOs. As an example, we have found the following information for performance year 2016:

- Approximately 70 percent of beneficiaries assigned to ACOs participating in the Shared Savings Program had continuous Part D coverage.
- For assigned beneficiaries with continuous Part D enrollment, almost 37 percent had at least one opioid prescription. This percentage ranged from 10.6 percent to 58.3 percent across ACOs.
- The mean number of opioid medications filled per assigned beneficiary (with continuous Part D coverage) varied across ACOs, ranging from 0.3 to 4.5 prescriptions filled, with an average of 2.1 prescriptions filled.
- The number of opioid prescriptions filled for each assigned beneficiary with at least one opioid prescription filled varied across ACOs and ranged from 2.6 to 8.4 prescriptions, with an average of 5.5 opioid prescriptions filled.

ACOs currently receive as part of the monthly claims and claims line feed data Part D prescription drug event (PDE) data on prescribed opioids for their assigned beneficiaries who have not opted out of data sharing. We encourage ACOs to use this beneficiary-level data in their care delivery practices.

We also seek suggestions for other types of aggregate data related to opioid use that could be added for informational purposes to the aggregate quarterly and annual reports CMS provides to ACOs. The aim would be for ACOs to utilize this additional information to improve population health management for assigned beneficiaries, including prevention, identifying anomalies, and coordinating care. The type of aggregate data should be highly relevant for a population-based program at the national level and have demonstrated value in quality improvement initiatives. We are particularly interested in high impact aggregate data that would reflect gaps in quality of care, patient safety, multiple aspects of care, and drivers of cost. We aim to provide aggregate data that have validity for longitudinal analysis to enable both ACOs and the Shared Savings Program to trend performance across time and monitor for changes. Aggregate data on both processes and outcomes are appropriate, provided that the data are readily available. Types of aggregate data that we have begun to consider, based on the information available from prescription drug event records for assigned beneficiaries enrolled in Medicare Part D, include filled prescriptions for opioids (percentage of the ACO's assigned beneficiaries with any opioid prescription, number of opioid prescriptions per opioid user), number of beneficiaries with a concurrent prescription of opioids and benzodiazepines; and number of beneficiaries with opioid prescriptions above a certain daily Morphine Equivalent Dosage threshold. Second, we are seeking comments on measures

that can be added to the quality measure set for the purpose of addressing the opioid epidemic and addiction, more generally. We seek comment on measures related to various aspects of opioid use, such as prevention, pain management, or opioid use disorder treatment, and on measures related to addiction. In particular, we are considering the following relevant NQF-endorsed measures, with emphasis on Medicare individuals with Part D coverage who are 18 years or older without cancer or enrolled in hospice:

- NQF #2940 Use of Opioids at High Dosage in Persons Without Cancer: Analyzes the proportion (XX out of 1,000) of Medicare Part D beneficiaries 18 years or older without cancer or enrolled in hospice receiving prescriptions for opioids with a daily dosage of morphine milligram equivalent (MME) greater than 120 mg for 90 consecutive days or longer.
- NQF #2950 Use of Opioids from Multiple Providers in Persons Without Cancer: Analyzes the proportion (XX out of 1,000) of Medicare Part D beneficiaries 18 years or older without cancer or enrolled in hospice receiving prescriptions for opioids from four (4) or more prescribers AND four (4) or more pharmacies.
- NQF #2951 Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer: Analyzes the proportion (XX out of 1,000) of Medicare Part D beneficiaries 18 years or older without cancer or enrolled in hospice with a daily dosage of morphine milligram equivalent (MME) greater than 120 mg for 90 consecutive days or longer, AND who received opioid prescriptions from four (4) or more prescribers AND four (4) or more pharmacies.

In addition, we seek input on potential measures for which data are readily available, such as measures that might be appropriately calculated using Part D data, and that capture performance on outcomes of appropriate opioid management. Comments on measures that are not already NQF endorsed should include descriptions of reliability, validity, benchmarking, the population in which the measure was tested, along with the data source that was used, and information on whether the measure is endorsed and by what organization. We recognize that measures of the various aspects of opioid use may involve concepts related to integrated, coordinated, and collaborative care, including as applicable for co-occurring and/or chronic conditions, as well as measures that reflect the impact of interventions on patient outcomes, including direct and indirect patient outcome measures. We also seek comment on opioid-related measures that would support effective measurement alignment of substance use disorders across programs, settings, and varying interventions.

6. Promoting Interoperability

Consistent with the call in the 21st Century Cures Act for interoperable access, exchange, and use of health information, the final rule entitled, 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications (2015 Edition final rule) (80 FR 62601) under 45 CFR part 170 [24] focuses on the 2015 Edition of health IT certification criteria that support patient care, patient participation in care delivery, and electronic exchange of interoperable health information. The 2015 Edition final rule, which was issued on October 16, 2015, is expected to improve interoperability by adopting new and updated vocabulary and content standards for the structured recording and exchange of health information and to facilitate the accessibility and exchange of data by including enhanced data export, transitions of care, and application programming interface capabilities. These policies are relevant to assessing the use of CEHRT under the Quality Payment Program and other value based payment initiatives.

Under the Shared Savings Program, section 1899(b)(2)(G) of the Act requires participating ACOs to define processes to report on quality measures and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies. Consistent with the statute, ACOs participating in the Shared Savings Program are required to coordinate care across and among primary care physicians, specialists, and acute and post-acute providers and suppliers and to have a written plan to encourage and promote the use of enabling technologies for improving care coordination, including the use of electronic health records and electronic exchange of health information (§ 425.112(b)(4)). Additionally, since the inception of the program in 2012, CMS has assessed the level of CEHRT use by certain clinicians in the ACO as a double-weighted quality measure (Use of Certified EHR Technology, ACO–11) as part of the quality reporting requirements for each performance year. For the 2018 performance year, we will use data derived from the Quality Payment Program's Promoting Interoperability performance category to calculate the percentage of eligible clinicians participating in an ACO who successfully meet the Advancing Care Information Performance Category Base Score for purposes of ACO–11. Because the measure is used in determining an ACO's quality score and for determining shared savings or losses under the Shared Savings Program, all eligible clinicians participating in Shared Savings Program ACOs must submit data for the Quality Payment Program's Advancing Care Information performance category, including those eligible clinicians who are participating in Shared Savings Program tracks that have been designated as Advanced APMs and who have met the QP threshold or are otherwise not subject to the MIPS reporting requirements.

In contrast, some alternative payment models tested by the Innovation Center, require all participants to use CEHRT even though certain tracks within those Models do not meet the financial risk standard for designation as Advanced APMs, such as the Oncology Care Model (one-sided risk arrangement track) and the Comprehensive End-Stage Renal Disease Care (CEC) Model (non-LDO one-sided risk arrangement track).[25] The primary rationale for this requirement is to promote CEHRT use by eligible clinicians and organizations participating in APMs by requiring them to demonstrate a strong commitment to the exchange of health information, regardless of whether they are participating in an APM that meets the criteria to be designated as an Advanced APM. Additionally, under the Quality Payment Program, an incentive payment will be made to certain Qualifying APM Participants (QPs) participating in Advanced APMs. Beginning in 2017, an eligible clinician can become a QP for the year by participating sufficiently in an Advanced APM during the QP performance period. Eligible clinicians who are QPs for a year receive a lump sum APM incentive payment for payment years from 2019 through 2024, and are excluded from the MIPS reporting requirements for the performance year and the MIPS payment adjustment for the payment year. In the CY 2017 Quality Payment Program final rule (81 FR 77408) we finalized the criteria that define an

[24] For more information, see: *https://www.healthit.gov/sites/default/files/understanding-certified-health-it-2.pdf.*

[25] See list of 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.*

Advanced APM based on the requirements set forth in sections 1833(z)(3)(C) and (D) of the Act. An Advanced APM is an APM that, among other criteria, requires its participants to use CEHRT. In the CY 2017 Quality Payment Program final rule, we established that Advanced APMs meet this requirement if the APM either (1) requires at least 50 percent of eligible clinicians in each participating APM Entity, or for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT to document and communicate clinical care to their patients or other health care providers; or (2) for the Shared Savings Program, applies a penalty or reward to an APM Entity based on the degree of the use of CEHRT of the eligible clinicians in the APM Entity (§ 414.1415(a)(1)(i) and (ii)). In the CY 2017 PFS final rule, we updated the title and specifications of EHR quality measure (ACO–11) to align with the Quality Payment Program criterion on CEHRT use in order to ensure that certain tracks under the Shared Savings Program could meet the criteria to be Advanced APMs. Specifically, we revised the ACO–11 measure to assess ACOs on the degree of CEHRT use by eligible clinicians participating in the ACO in order to align with the Quality Payment Program. Performance on the measure is determined by calculating the percentage of eligible clinicians participating in the ACO who successfully meet the Promoting Interoperability Performance Category Base Score.

In light of our additional experience with the Shared Savings Program, our desire to continue to promote and encourage CEHRT use by ACOs and their ACO participants and ACO providers/suppliers, and our desire to better align with the goals of the Quality Payment Program and the criteria for participation in certain alternative payment models tested by the Innovation Center, as previously noted, we believe it would be appropriate to amend our regulations related to CEHRT use and the eligibility requirements for ACOs to participate in the Shared Savings Program. Specifically, we propose to add a requirement that all ACOs demonstrate a specified level of CEHRT use in order to be eligible to participate in the Shared Savings Program. Additionally, we propose that, as a condition of participation in a track, or a payment model within a track, that meets the financial risk standard to be an Advanced APM, ACOs must certify that the percentage of eligible clinicians participating in the ACO who use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the threshold required for Advanced APMs as defined under the Quality Payment Program (§ 414.1415(a)(1)(i)). In conjunction with this proposed new eligibility requirement, we propose to retire the EHR quality measure (ACO–11) related to CEHRT use, thereby reducing reporting burden, effective for quality reporting for performance years starting on January 1, 2019, and subsequent performance years. In addition, consistent with our proposal to align with the Advanced APM criterion on use of CEHRT, we propose to apply the definition of CEHRT under the Quality Payment Program (§ 414.1305), including any subsequent updates to this definition, for purposes of the Shared Savings Program.

First, we are proposing that for performance years starting on January 1, 2019, and subsequent performance years ACOs in a track or a payment model within a track that does not meet the financial risk standard to be an Advanced APM must attest and certify upon application to participate in the Shared Savings Program, and subsequently, as part of the annual certification process, that at least 50 percent of the eligible clinicians participating in the ACO use CEHRT to document and communicate clinical care to their patients or other health care providers. ACOs would be required to submit this certification in the form and manner specified by CMS.

This proposed requirement aligns with the requirements regarding CEHRT use in many alternative payment models being tested by the Innovation Center (as previously noted). Additionally, we note that at the time of application, ACOs must have a written plan to use enabling technologies, such as electronic health records and other health IT tools, to coordinate care (§ 425.112(b)(4)(i)(C)). Over the years, successful ACOs have impressed upon us the importance of ''hitting the ground running'' on the first day of their participation in the Shared Savings Program, rather than spending the first year or two developing their care processes. We believe that requiring ACOs that are entering a track or a payment model within a track that does not meet the financial risk standard to be an Advanced APM to certify that at least 50 percent of the eligible clinicians participating in the ACO use CEHRT aligns with existing requirements under the Shared Saving Program and many Innovation Center alternative payment models and encourages participation by organizations that are more likely to meet the program goals. In addition, we believe such a requirement would also promote greater emphasis on the importance of CEHRT use for care coordination. Finally, we note that in the CY 2019 PFS proposed rule, we proposed to increase the threshold of CEHRT use required for APMs to meet criteria for designation as Advanced APMs under the Quality Payment Program to 75 percent (see 83 FR 35990). Given the proposals for updates and modifications to the Shared Savings Program tracks found elsewhere in this proposed rule, as well as the proposals under the Quality Payment Program, we believe it is important that only those ACOs that are likely to be able to meet or exceed the threshold designated for Advanced APMs should be eligible to enter and continue their participation in the Shared Savings Program. Because of this, and also our desire to align requirements as explained in more detail later in this section, we also considered whether to propose to require all Shared Savings Program ACOs, including ACOs in tracks or payment models within tracks that would not meet financial criteria to be designated as Advanced APMs, to meet the 75 percent threshold proposed under the Quality Payment Program.

We propose changes to the regulations at § 425.204(c) (to establish the new application requirement) and § 425.302(a)(3)(iii) (to establish the new annual certification requirement). We also propose to add a new provision at § 425.506(f)(1) to indicate that for performance years starting on January 1, 2019, and subsequent performance years, all ACOs in a track or a payment model within a track that does not meet the financial risk standard to be an Advanced APM must certify that at least 50 percent of their eligible clinicians use CEHRT to document and communicate clinical care to their patients or other health care providers. We note that this proposal, if finalized, would not affect the previously-finalized provisions for MIPS eligible clinicians reporting on the Promoting Interoperability (PI) performance category under MIPS. In other words, MIPS eligible clinicians who are participating in ACOs would continue to report as usual on the Promoting Interoperability performance category. We welcome comment on these proposed changes. We also seek comment on whether the percentage of CEHRT use should be set at a level higher than 50 percent for ACOs in a track or a payment model within a track that does not meet the financial risk standard to be an Advanced APM given

that average ACO performance on the Use of Certified EHR Technology measure (ACO–11) has substantially exceeded 50 percent, with ACOs reporting that on average roughly 80 percent of primary care physicians in their ACOs meet meaningful use requirements,[26] suggesting that a higher threshold may be warranted now or in the future. Additionally, a higher threshold percentage (such as 75 percent) would align with the proposed changes to the CEHRT use requirement under the Quality Payment Program in the CY 2019 PFS proposed rule.

Further, for ACOs in tracks or models that meet the financial risk standard to be Advanced APMs under the Quality Payment Program, we propose to align the proposed CEHRT use threshold with the criterion on use of CEHRT established for Advanced APMs under the Quality Payment Program. Although we believe it would be ideal for all ACOs to meet the same CEHRT thresholds to be eligible for participation in the Shared Savings Program, we recognize that there may be reasons why it may be desirable for ACOs in tracks or payment models within a track that do not meet the financial risk standard for Advanced APMs to have a different threshold requirement for CEHRT use than more sophisticated ACOs that are participating in tracks or payment models that qualify as Advanced APMs under the Quality Payment Program. For example, we note that in order for an APM to meet the criteria to be an Advanced APM under the Quality Payment Program, it must currently require at least 50 percent of eligible clinicians in each participating APM entity to use CEHRT to document and communicate clinical care to their patients or other health care providers (in addition to certain other criteria). However, we have proposed to increase this threshold level under the Quality Payment Program to 75 percent of eligible clinicians in each participating Advanced APM entity, as part of the CY 2019 PFS proposed rule, as previously noted. Therefore, for performance years starting on January 1, 2019, and subsequent performance years for Shared Savings Program tracks (or payment models within tracks) that meet the financial risk standard to be an Advanced APM, we propose to align the CEHRT requirement with the Quality Payment Program Advanced APM CEHRT use criterion at § 414.1415(a)(1)(i). Specifically, we propose that such ACOs would be required to certify that they meet the higher of the 50 percent threshold proposed for ACOs in a track (or a payment model within a track) that does not meet the financial risk standard to be an Advanced APM or the CEHRT use criterion for Advanced APMs under the Quality Payment Program at § 414.1415(a)(1)(i). We believe that requiring these ACOs to meet the higher of the 50 percent threshold proposed for ACOs in a track (or a payment model within a track) that does not meet the financial risk standard to be an Advanced APM or the CEHRT use criterion for Advanced APMs will ensure alignment of eligibility requirements across all Shared Savings Program ACOs, while also ensuring that if the CEHRT use criterion for Advanced APMs is higher than 50 percent, those Shared Savings Program tracks (or payment models within a track) that meet the financial risk standard to be an Advanced APM would also meet the CEHRT threshold established under the Quality Payment Program. We anticipate that for performance years starting on January 1, 2019, the tracks (or payment models within tracks) that would be required to meet the CEHRT threshold designated at § 414.1415(a)(1)(i) would include Track 2, Track 3, and the Track 1+ Model, and for performance years starting on July 1, 2019, they would include the BASIC track, Level E, and the ENHANCED track. ACOs in these tracks (or a payment model within such a track) would be required to attest and certify that the percentage of the eligible clinicians in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the level of CEHRT use specified under the Quality Payment Program regulation at § 414.1415(a)(1)(i). Although this proposal may cause Shared Savings Program ACOs in different tracks (or different payment models within the same track) to be held to different requirements regarding CEHRT use, we believe it is appropriate to ensure not only that ACOs that are still new to participation in the Shared Savings Program are not excluded from the program due to a requirement that a high percentage of eligible clinicians participating in the ACO use CEHRT, but also that eligible clinicians in ACOs further along the risk continuum have the opportunity to participate in an Advanced APM for purposes of the Quality Payment Program.

We propose to add a new provision to the regulations at § 425.506(f)(2) to establish the CEHRT requirement for performance years starting on January 1, 2019, and subsequent performance years for ACOs in a track or a payment model within a track that meets the financial risk standard to be an Advanced APM under the Quality Payment Program. These ACOs would be required to certify that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the higher of 50 percent or the threshold for CEHRT use by Advanced APMs at § 414.1415(a)(1)(i). We seek comment on this proposal. We also seek comment on whether we should apply the same standard regarding CEHRT use across all Shared Savings Program ACOs, including ACOs participating in tracks or payment models within tracks that do not meet the financial risk standard to be designated as Advanced APMs, specifically Track 1 and the proposed BASIC track, Levels A through D, or maintain the proposed 50 percent requirement for these ACOs as they gain experience on the glide path to performance-based risk.

As a part of these proposals to require ACOs to certify that a specified percentage of their eligible clinicians use CEHRT, CMS reserves the right to monitor, assess, and/or audit an ACO's compliance with respect to its certification of CEHRT use among its participating eligible clinicians, consistent with §§ 425.314 and 425.316, and to take compliance actions (including warning letters, corrective action plans, and termination) as set forth at §§ 425.216 and 425.218 when ACOs fail to meet or exceed the required CEHRT use thresholds. Additionally, we propose to adopt for purposes of the Shared Savings Program the same definition of ''CEHRT'' as is used under the Quality Payment Program. We propose to amend § 425.20 to incorporate a definition of CEHRT consistent with the definition at § 414.1305, including any subsequent updates or revisions to that definition. Consistent with this proposal and to ensure alignment with the requirements regarding CEHRT use under the Quality Payment Program, we also propose to amend § 425.20 to incorporate the definition of ''eligible clinician'' at § 414.1305 that applies under the Quality Payment Program.

Additionally, if the proposal to introduce a specified threshold of CEHRT use as an eligibility requirement for participation in the Shared Savings

[26] This estimate is based on calculations of primary care physician CEHRT use prior to the changes made to ACO–11 to align with the Quality Payment Program, which became effective for quality reporting for performance year 2017.

Program is finalized, we believe this new requirement should replace the current ACO quality measure that assesses the Use of Certified EHR Technology (ACO–11). The proposed new eligibility requirement, which would be assessed through the application process and annual certification, would help to meet the goals of the program and align with the approach used in other MIPS APMs. Moreover, the proposed new requirement would render reporting on the Use of Certified EHR Technology quality measure unnecessary in order for otherwise eligible tracks (and payments models within tracks) to meet the Advanced APM criterion regarding required use of CEHRT under § 414.1415(a)(1)(i). As a result, continuing to require ACOs to report on this measure would introduce undue reporting burden on eligible clinicians that meet the QP threshold and would otherwise not be required to report the Promoting Interoperability performance category for purposes of the Quality Payment Program. Therefore, we are proposing to remove the Use of Certified EHR Technology measure (ACO–11) from the Shared Savings Program quality measure set, effective with quality reporting for performance years starting on January 1, 2019, and subsequent performance years. We propose corresponding changes to the regulation at § 425.506. As previously noted, the removal of the Use of Certified EHR Technology measure (ACO–11) from the quality measure set used under the Shared Savings Program, if finalized, would not affect policies under MIPS for reporting on the Promoting Interoperability performance category and scoring under the APM Scoring Standard for MIPS eligible clinicians in MIPS APMs. In other words, eligible clinicians subject to MIPS (such as eligible clinicians in BASIC track, Levels A through D, Track 1, and other MIPS eligible clinicians who are required to report on the Promoting Interoperability performance category for purposes of the Quality Payment Program) would continue to report as usual on the Promoting Interoperability performance category. However, data reported for purposes of the Promoting Interoperability performance category under MIPS would not be used to assess the ACO's quality performance under the Shared Savings Program. We welcome public comment on the proposal to remove the quality measure on Use of Certified EHR Technology (ACO–11) from the Medicare Shared Savings Program measure set, effective for quality reporting for performance years starting on January 1, 2019, and subsequent years.

Finally, as discussed previously in this section, in the CY 2017 Quality Payment Program final rule, CMS finalized a separate Advanced APM CEHRT use criterion that applies for the Shared Savings Program at § 414.1415(a)(1)(ii). To meet the Advanced APM CEHRT use criterion under the Shared Savings Program, a penalty or reward must be applied to an APM Entity based upon the degree of CEHRT use among its eligible clinicians. We believed that this alternative criterion was appropriate to assess the Advanced APM CEHRT use requirement under the Shared Savings Program because at the time a specific level of CEHRT use was not required for participation in the program (81 FR 77412).

We now believe that that our proposal to impose specific CEHRT use requirements on ACOs participating in the Shared Savings Program would eliminate the need for the separate CEHRT use criterion applicable to the Shared Savings Program APMs found at § 414.1415(a)(1)(ii). If the previously described proposals are finalized, ACOs seeking to participate in a Shared Savings Program track (or payment model within a track) that meets the financial risk standard to be an Advanced APM would be required to demonstrate that the percentage of eligible clinicians in the ACO using CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the higher of 50 percent or the percentage specified in the CEHRT use criterion for Advanced APMs at § 414.1415(a)(1)(i). As a result, a separate CEHRT use criterion for APMs under the Shared Savings Program would no longer be necessary.

We therefore propose to revise the separate Shared Savings Program CEHRT use criterion at § 414.1415(a)(1)(ii) so that it applies only for QP Performance Periods under the Quality Payment Program prior to 2019. We seek comment on this proposal.

7. 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 providers and Part D sponsors.

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 (HIPAA).

We seek 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 seek 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 seek 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 seek 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.

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

1. Background

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 have previously noted that 55 Shared Savings Program Track 1 ACOs entered into the Track 1+ Model beginning 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 a 3-year agreement in the Model.

To enter the model, ACOs approved to participate are required to agree to the terms and conditions of the model by executing a Track 1+ Model Participation Agreement. See *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 its authority under section 1115A(d)(1) of the Act, CMS has waived certain provisions of law 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.

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 note 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

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 renew their participation in the Track 1+ Model for an agreement period start date of 2018, 2019, or 2020. The 2018 application cycle is closed, and as discussed elsewhere in this proposed rule, 55 ACOs began participating in the Track 1+ Model on January 1, 2018. As discussed in section II.A.7 of this proposed rule, 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 would similarly not offer a start date of January 1, 2019, for participation in the Track 1+ Model.

In addition, we have also 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) as offered in the Track 1+ Model and to also 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. If the proposed approach to adding the BASIC track is 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.

Existing Track 1+ Model ACOs would 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, depending upon whether the ACO is low revenue or high revenue (as described in section II.A.5 of this proposed rule). Additionally, as discussed in section II.A.7.c.1 of this proposed rule, ACOs would not have the opportunity to apply to use a SNF 3-day rule waiver starting on January 1, 2019, under our decision to forgo an annual application cycle for a January 1, 2019 start date in the Shared Savings Program and the proposal that the next available application cycle would occur in advance of a July 1, 2019 start date in the Shared Savings Program. An exception to the January 1 start date for use of a SNF 3-day rule waiver would similarly be made 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.

In making this decision to discontinue future application cycles for the Track 1+ Model, we considered the high level of participation in the Track 1+ Model in its first performance year. This high level of interest in the model indicates a positive response to its design, and therefore we believe we have met an important goal of testing the Track 1+ Model. As we previously described in section II.A.1 of this proposed rule, the availability of the Track 1+ Model

significantly increased the number of ACOs participating under a two-sided risk model in connection with their participation in the Shared Savings Program, with over half of the 101 Shared Savings Program ACOs that have elected to take on performance-based risk opting to participate in the Track 1+ Model starting in 2018, the Model's first year. We will evaluate the quality and financial performance of Track 1+ Model ACOs and consider the results of this evaluation in the development of future policies for the Shared Saving Program.

Further, as discussed in section II.A of this proposed rule, we have incorporated lessons learned from our initial experience with the Track 1+ Model into the design of the proposed BASIC track. This includes offering a payment model within the BASIC track (Level E) that includes the same level of risk and potential reward as available under the Track 1+ Model. We have also proposed a repayment mechanism estimation methodology based on our experience with the Track 1+ Model, to allow 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. We believe offering both the BASIC track and the Track 1+ Model would create unnecessary redundancy in participation options within CMS's Medicare ACO initiatives.

3. Applicability of Proposed Policies to Track 1+ Model ACOs Through Revised Program Regulations or Revisions to Track 1+ Model Participation Agreements

We believe a comprehensive discussion of the applicability of the proposed policies to Track 1+ Model ACOs would allow these ACOs to better prepare for their future years of participation in the program and the Track 1+ Model. 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.

Unless specified otherwise, the proposed changes to the program's regulations that are applicable to Shared Savings Program ACOs within a current agreement period would 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 proposed changes to those regulations would 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 proposed policies would apply to Track 1+ Model ACOs, if finalized:

- Changes to the repayment mechanism requirements (other than the proposed provisions regarding calculation of the repayment mechanism amount at § 425.204(f)(4)), which would be applicable with the effective date of the final rule (section II.A.6.c). We believe these proposed requirements are similar to the requirements under which Track 1+ Model ACOs established their repayment mechanisms, such that no revision to these arrangements would be required, in the event the proposed policies are finalized. Further, consistent with the proposed changes to the repayment mechanism requirements, we note that Track 1+ Model ACOs that seek to renew their Shared Savings Program agreement would be permitted to use their existing repayment mechanism arrangement to support their continued participation in the Shared Savings Program under a two-sided model in their next agreement period, provided that the amount and duration of the repayment mechanism arrangement are updated as specified by CMS.
- The requirement to notify beneficiaries regarding voluntary alignment and to provide a standardized written notice at the first primary care visit of each performance year (section II.C.3.a.2). If finalized, the proposed policy would be applicable for the performance year beginning on July 1, 2019, and subsequent performance years.
- Revisions to voluntary alignment policies (section II.E.2). If finalized, the proposed policies would be applicable for the performance year beginning on January 1, 2019, and subsequent performance years.
- Revisions to the definition of primary care services used in beneficiary assignment (section II.E.3.b). If finalized, the proposed policy would be applicable for the performance year beginning on January 1, 2019, and subsequent performance years.
- Discontinuation of quality measure ACO–11; requirement to attest at the time of application and as part of the annual certification that a specified percentage of the ACO's eligible clinicians use CEHRT (section II.E.6). If finalized, the proposed policy would be applicable for the performance year beginning on January 1, 2019, and subsequent performance years.

We would also seek to apply the following proposed policies to Track 1+ Model ACOs, although to do so would require 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).
- Revising the MSR/MLR to address small population sizes (section II.A.6.b.3).
- Payment consequences of early termination for ACOs under performance-based risk (section II.A.6.d).
- Annual certification that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the higher of 50 percent or the threshold established under § 414.1415(a)(1)(i) (section II.E.6). This certification would be required to ensure the Track 1+ Model continues to meet the CEHRT criterion for qualification as an Advanced APM for purposes of the Quality Payment Program.
- For ACOs that started a first or second Shared Savings Program participation agreement on January 1, 2016, and entered the Track 1+ Model on January 1, 2018, and that elect to extend their Shared Savings Program participation agreement for the 6-month performance year from January 1, 2019 through June 30, 2019 (as described in section II.A.7 of this proposed rule):

++ Consistent with the policy proposed in section II.A.7.c.3 and § 425.204(f)(6), the ACO would be required to extend its repayment mechanism so that it ends 24 months after the end of the agreement period (June 30, 2021).

++ We would determine performance for the 6-month performance year from January 1, 2019 through June 30, 2019, according to the approach specified in a proposed new section of the regulations at § 425.609(b), applying the financial methodology for calculating shared losses specified in the ACO's Track 1+ Model Participation Agreement.

++ We would continue to share aggregate report data with the ACO for the entire calendar year 2019, consistent with the proposed approach described in section II.A.7.c.9, and the terms of the

ACO's Track 1+ Model Participation Agreement.

• Extreme and uncontrollable circumstances policies for determining shared losses for performance years 2018 and subsequent years, consistent with the policies specified in §§ 425.610(i) (section II.E.4) and 425.609(d) (section II.A.7.c.5) for ACOs that elect to extend their Shared Savings Program participation agreement for the 6-month performance year from January 1, 2019 through June 30, 2019.

• Certain requirements related to the use of telehealth services beginning on January 1, 2020, as provided under section 1899(l) of the Act (section II.B.2.b.2). As previously described, the Bipartisan Budget Act of 2018 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 would be appropriate to apply the same requirements under the Track 1+ Model with respect to the use of telehealth services that would apply to other Shared Savings Program ACOs that are applicable ACOs for purposes of section 1899(l) of the Act. This would ensure consistency across program operations, payments, and beneficiary protection requirements for Track 1+ Model ACOs and other Shared Savings Program ACOs with respect to the use of telehealth services.

We seek comment on these considerations, and any other issues that we may not have discussed related to the effect of the proposed policies on ACOs that entered the Track 1+ Model beginning in 2018. We note that these ACOs will complete their participation in the Track 1+ Model by no later than December 31, 2020 (for ACOs that entered the model at the start of a 3-year agreement period), or sooner in the case of ACOs that entered the model at the start of their second or third performance year within their current 3-year agreement period.

G. Summary of Proposed Timing of Applicability

Applicability or implementation dates may vary, depending on the policy, and the timing specified in the final rule. Unless otherwise noted, the proposed changes would be effective 60 days after publication of the final rule. Table 13 lists the anticipated applicability date of key changes in this proposed 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.

TABLE 13—APPLICABILITY DATES OF SELECT PROVISIONS OF THE PROPOSED 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 years beginning in 2019 and subsequent years.
II.A.6.b.2	Timing of election of MSR/MLR	Agreement periods starting on or after July 1, 2019.
II.A.6.b.3	Modifying the MSR/MLR to address small population sizes	Performance years beginning in 2019 and subsequent years.
II.A.6.c.3	Annual recalculation of repayment mechanism amounts	Agreement periods starting on or after July 1, 2019.
II.A.6.d	Payment consequences of early termination for ACOs under performance-based risk.	Performance years beginning in 2019 and subsequent years.
II.A.7	Participation options for agreement periods beginning in 2019	January 1, 2019 effective date for extension of existing agreement period for a 6-month fourth performance year, if elected by ACOs that started a first or second agreement period on January 1, 2016. One-time, July 1, 2019 agreement start date; 6-month first performance year.
II.B.2.a	Availability of the SNF 3-day rule waiver for eligible ACOs under performance-based risk under either prospective assignment or preliminary prospective assignment.	July 1, 2019 and subsequent performance years, for eligible ACOs applying for, or currently approved for, a SNF 3-day rule waiver. Not available to Track 2 ACOs.
II.B.2.a	Eligible CAHs and hospitals operating under a swing-bed agreements permitted to partner with eligible ACOs as SNF affiliates.	July 1, 2019, and subsequent performance years.

TABLE 13—APPLICABILITY DATES OF SELECT PROVISIONS OF THE PROPOSED RULE—Continued

Preamble section	Section title/description	Applicability date
II.B.2.b	Telehealth services furnished under section 1899(l)	Performance year 2020 and subsequent years for services furnished by physicians and practitioners billing through the TIN of an ACO participant in an applicable ACO.
II.C.2	Implementation of approved beneficiary incentive programs	July 1, 2019, and subsequent performance years.
II.C.3.a.2	New content and timing for beneficiary notifications	Performance year beginning on July 1, 2019, and subsequent years.
II.D.2.b	Benchmarking Methodology Refinements: Risk adjustment methodology for adjusting historical benchmark each performance year.	Agreement periods starting on or after July 1, 2019.
II.D.3.b	Benchmarking Methodology Refinements: Application of regional factors to determine the benchmark for an ACO's first agreement period.	Agreement periods starting on or after July 1, 2019.
II.D.3.c	Benchmarking Methodology Refinements: Modifying the regional adjustment..	Agreement periods starting on or after July 1, 2019.
II.D.3.d	Benchmarking Methodology Refinements: Modifying the methodology for calculating growth rates used in establishing, resetting, and updating the benchmark.	Agreement periods starting on or after July 1, 2019.
II.E.2	Modifications to voluntary alignment requirements	Performance years beginning in 2019 and subsequent years.
II.E.3	Revisions to the definition of primary care services used in beneficiary assignment.	Performance years beginning in 2019 and subsequent years.
II.E.4	Extreme and uncontrollable circumstances policies for the Shared Savings Program.	Performance year 2018 and subsequent years.
II.E.6	Addition of an interoperability criterion (use of CEHRT) to determine eligibility for program participation.	Performance years beginning in 2019 and subsequent years.
II.E.6	Discontinued use of quality measure ACO–11	Performance years beginning in 2019 and subsequent years.

III. 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 proposed rule need not be reviewed by the Office of Management and Budget.

IV. Regulatory Impact Analysis

A. Statement of Need

This proposed rule is necessary in order to make certain payment and policy changes to the Medicare Shared Savings Program established under section 1899 of the 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 proposed policies is summarized in the statement of the rule's purpose in section I of this proposed rule and described in greater detail throughout the discussion of the proposed policies in section II of this proposed rule. As we have previously explained in this proposed 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 generating losses (and therefore increasing Medicare spending) while receiving 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 proposed redesign of the Shared Savings Program, ACOs of different compositions, and levels of experience with the accountable care model could continue to participate in the program, but the proposals included in this proposed rule would put the program on a path towards achieving a more measureable move to value and achieve savings for the Medicare program, while promoting a competitive and accountable marketplace.

In summary, this proposed rule would 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 proposes to extend the length of ACOs' agreement periods from 3 to 5 years as well as to 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 mitigating the effects of factors based on regional FFS expenditures on ACO benchmarks more generally. These proposed 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 under the program's current regulations.

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 proposing 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;

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; and offer the opportunity for Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider with such a voluntary identification superseding claims-based assignment. Additionally, this proposed rule would expand 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 intend to forgo the application cycle in 2018 for an agreement start date of January 1, 2019, and instead propose to offer a July 1, 2019 start date. This midyear start in 2019 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. Additionally, ACOs with a participation agreement ending on December 31, 2018, would have an opportunity to extend their current agreement period for an additional 6-month performance year and 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, would 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 proposed rule includes the proposed methodology for determining ACO financial performance for these two, 6-month performance years during CY 2019.

Further, this proposed rule would make other timely updates to the program's regulations, for consistency with other changes in program policies or Medicare policies more generally, such as: (1) Modifying the definition of primary care services used in beneficiary assignment to add new codes and revising how we determine whether evaluation and management services were furnished in a SNF; (2) extending policies previously adopted for performance year 2017 to performance year 2018 and subsequent years to address quality performance scoring and the determination of shared losses (under two-sided models) in the event of extreme or uncontrollable circumstances; and (3) promoting interoperability in Medicare by establishing a new Shared Savings Program eligibility requirement related to adoption of CEHRT by an ACO's eligible clinicians, while discontinuing use of the existing quality measure on use of CEHRT.

B. Overall Impact

We examined the impacts of this 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.

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 if the full set of proposals in this rule were finalized to the expected outcomes under current regulations. We provide our analysis of the expected costs of the proposed 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 IV.E. of this proposed rule.

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 proposed policies, 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 four performance years of financial performance results available for the Shared Savings Program.[27] Table 14 describes performance year 2016

[27] 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 2016 for all ACOs that participated in the program for the relevant year. Performance year 2017 results are not available at the time of publication of this proposed rule.

results for ACOs segmented by track. These results show that in performance year 2016, the 410 Track 1 ACOs spent more on average 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 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 − B + C − 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 enrollee, and high revenue Track 1 ACOs produced a net loss of $231 million or $46 per enrollee. 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 would capture all ACOs that participated in the Shared Savings Program in performance year 2016 that were solely comprised of providers and suppliers billing physician fee schedule services and generally exclude ACOs with providers and suppliers that bill 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 proposed definitions for low revenue ACO and high revenue ACO discussed in section II.A.5.b. of this proposed rule. However, our analysis has confirmed that the simpler and more practical proposed policy for identifying low revenue ACOs using a 25-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 physician-based ACO participant composition.

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	Parts A and B spending below benchmark [A]	Shared savings payments from CMS to ACOs [B]	Shared loss payments from ACOs to CMS [C]	Net effect in aggregate [A − B + C − D] [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.

(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.[28] 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.[29] 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.[30]

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 that ACO benchmarks were reduced by the feedback such efficiency gains would have on 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 would 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, would imply 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.

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.[31] 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.[32] This research supports the hypothesis that changes in delivery implemented by Medicare ACO clinicians would 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 would improve the value of services provided to all patients, regardless of payer.[33]

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),[34] although there is some evidence of potential defensive consolidation in response to new payment models (Neprash et al., 2017).[35] Anecdotally, ACOs provide physician practices with a way to stay independent and offer a viable alternative to merging with a hospital (Mostashari, 2016).[36]

[28] 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.

[29] 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.

[30] 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.

[31] 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.

[32] 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.

[33] 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/.*

[34] 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.

[35] Neprash HT, Chernew ME & McWilliams JM. Little Evidence Exists to Support the Expectation That Providers Would Consolidate to Enter New Payment Models. *Health Affairs.* 2017; 36(2): 346–354. doi:10.1377/hlthaff.2016.0840.

[36] See for example, Mostashari, F. The Paradox of Size: How Small, Independent Practices Can Thrive

Continued

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 would foster increased participation in ACO initiatives, which is required to produce higher levels of net savings.

b. Assumptions and Uncertainties

The changes to the Shared Savings Program proposed in this rule could result in a range of possible outcomes. 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 would 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 would be partly offset by increased shared savings payments to ACOs benefiting from our proposal to apply the methodology incorporating factors based on regional FFS expenditures beginning with the ACO's first agreement period, revising risk adjustment to include up to a 3 percent increase in average HCC risk score over the course of an agreement period, and blending national trend with regional trend when calculating ACO benchmarks. Such trade-offs reflect the intention of our proposal to strengthen the balance between 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 proposed policy would 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 proposed policy also increases the possibility that higher cost ACOs would 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 would 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 proposed 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 be considered an Advanced APM Entity for purposes of the Quality Payment Program. Eligible clinicians in an ACO that is an Advanced APM Entity 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 would 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 proposals to permit ACOs to change their beneficiary assignment method selection prior to the start of each performance year, to 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, and to offer a July 1, 2019 start date (including the proposed extension of an existing agreement period through June 30, 2019).

We also considered the potential effects of policies proposed to promote participation by low revenue ACOs as follows. By allowing low revenue ACOs to enter the BASIC track (potentially immediately entering the maximum level of risk and potential reward under such track) and continue their participation in the BASIC track for a subsequent agreement period (under the highest level of risk and potential reward), the proposal would 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 proposal to include 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 regional adjustment at positive or negative 5 percent of national per capita expenditures for Parts A and B services for assignable beneficiaries helps CMS avoid unnecessarily large windfall payments for ACOs that would have

in Value-Based Care. *Ann Fam Med.* 2016; 14(1):5–7. doi:10.1370/afm.1899.

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 proposed 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 proposed 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 proposal to use full HCC risk ratios (capped at positive or negative 3 percent) 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 inside of 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 would 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 would participate in the program, we assumed that up to approximately 250 existing 2018 ACOs would be affected by the proposed 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 would be affected by the proposed 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 would 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 would renew under the policies in the proposed rule would be related to expectations regarding the effect of the proposed 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 the proposed rule); such range is reduced for second or later rebasing under the policies in the proposed 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 BASIC track, Level E (proposed). ACOs expecting adjusted rebased historical benchmarks from zero 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 zero and 50 percent chance of electing the BASIC track (proposed).

Second, all other renewal decisions would 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 would 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 proposed scenario, an ACO not otherwise choosing the ENHANCED track would 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 would be precluded from renewing 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 would 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 would elect early transition to the BASIC track, Level E. 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 would 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 the BASIC track, Level E 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 new 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 proposed 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, Level E, 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, Levels C and D, or Track 1 are assumed to be 30 to 70 percent of the savings assumed for Track 3/ENHANCED track. Lastly, savings for the BASIC track, Levels A and B, are assumed to be 20 to 60 percent of the savings assumed for Track 3/ENHANCED track.

We also assumed that selection effects would implicitly include the renewal decisions of ACOs simulated in the model. Further assumptions included the following: (1) The proposed adoption of full HCC adjustment (capped at positive or negative 3 percent) allows each ACO to increase its benchmark according to a skewed distribution from zero to 3 percent (mode 0.5 percent); and (2) for both the baseline and proposed 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.

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 proposed changes to the program 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 proposed program changes is approximately $2.24 billion in lower overall federal spending over 10 years from 2019 through 2028. The 10th and 90th percentile from the range of projected 10 year impacts range from −$4.43 billion in lower spending to $0.09 billion in higher spending, respectively. The mean impact is comprised of about $0.51 billion in lower claims spending, $2.17 billion in reduced shared savings payments, net of shared loss receipts, and approximately $0.44 billion 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 PROPOSED RULE ON ACO PARTICIPATION, SPENDING ON PARTS A AND B CLAIMS, ACO SHARED SAVINGS NET OF LOSSES AND NET FEDERAL IMPACT

(Impact on claims, ACO shared savings, Advanced APM incentive payments, and net federal spending are expressed in $ millions)

Performance Year	ACO Participation	Claims	ACO Net Earnings	Federal Impact Before APM Incentives	Advanced APM Incentives to QPs	Net Federal Impact
2019	-20	60	60	120	0	120
2020	-33	80	40	120	0	120
2021	-49	50	20	70	0	70
2022	-29	20	-150	-130	70	-60
2023	-17	-40	-200	-240	130	-110
2024	-21	-110	-160	-280	220	-60
2025	-90	-160	-290	-450	0	-450
2026	-109	-190	-400	-590	30	-560
2027	-107	-150	-500	-650	0	-650
2028	-109	-80	-570	-650	-10	-660
10-Year Total		**-510**	**-2,170**	**-2,680**	**440**	**-2,240**
Low (10th Percentile)		-2,140	-4,310	-4,840	110	-4,430
High (90th Percentile)		1,040	270	-440	740	90

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 would be reduced from 6 years (two, 3-year agreement periods in current Track 1) to 2 years in the BASIC track, which also has reduced attractiveness with a lower 25 percent maximum sharing rate during the 2 risk-free years. 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 capped regional adjustment would 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.

The mean projection of $2.24 billion reduced overall federal spending is a reasonable point estimate of the impact of the proposed changes to the Shared Savings Program 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 proposed rule to the best of our ability. To help further develop and potentially improve this analysis, we request comment on the aspects of the rule that may incentivize behavior that could affect participation in the program and potential shared savings payments. As further data emerges and is analyzed, we may improve the precision of future financial impact estimates.

To the extent that proposed changes to the Shared Savings Program will result in net savings or costs to Part B of Medicare, revenues from Part B beneficiary premiums would also be correspondingly lower or higher. In addition, because MA payment rates depend on the level of spending within traditional FFS Medicare, savings or costs arising from the proposed changes to the Shared Savings Program would result in corresponding adjustments to MA payment rates. Neither of these secondary impacts has been included in the analysis shown.

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 five 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 performance years 2013 to 2016.

As explained in more detail previously, we believe the proposed changes would 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 would 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 under current regulations. Lastly, we estimate that the net impacts on federal spending, as previously detailed, would correspond to savings to beneficiaries in the form of reductions in Part B premium payments of approximately $310 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 by the proposed 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, changes in this proposed 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 would not be materially affected by the proposed changes to specific features of the Shared Savings Program; however, we seek comment if stakeholders disagree with such assumption, as we would want to consider impacts on other payers and patient populations, if evidenced, as part of the development of the policies to be included in the final rule. Although the proposed elimination of Track 1 is expected to ultimately reduce the overall number of ACOs participating in the program, this proposed 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 proposed policies (including changes to HCC risk adjustment, longer five 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 the BASIC track under Level E) 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.

Proposed 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 would likely expect lower benchmarks and greater likelihood of shared losses under a methodology that includes a 35 percent weight on the regional expenditure adjustment. 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 and capping the adjustment at positive or negative 5 percent of national average per capita FFS spending for assignable beneficiaries would 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 proposed 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 cost 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 $440 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 $2.17 billion in lower overall 10-year shared savings payments to ACOs reflects the prudent limitations that would 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 or negative 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 would 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.

We have made program data available that can help stakeholders evaluate the impact the proposed 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, and 2016) 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 2016 can be obtained at the following website *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/SSPACO/index.html.*

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 BASIC track, Levels C through E, 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 the BASIC track, Level E.)

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 proposed rule, such as the proposal to allow low revenue ACOs up to 2 agreement periods in 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 provider/supplier revenue (capped at a percentage of the ACO's benchmark), 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.

As detailed in this RIA, total expected incentive payments made under the Quality Payment Program to Qualifying APM Participants are expected to increase by $440 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 proposal to extend each agreement period to at least 5 years offers greater certainty to ACOs, including small entities, regarding their benchmark as they approach the higher levels of risk required in the later years 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 proposed rule would have a significant impact on the operations of a substantial number of small rural hospitals. We have proposed changes to our regulations such that benchmark adjustments for regional spending are limited to at most a 50 percent weight and are capped at positive or negative 5 percent of national average per capita FFS spending for assignable beneficiaries. Additionally we have proposed to blend national and regional trend in benchmark calculations, and have proposed allowing full HCC risk adjustment with a positive or negative 3 percent cap regardless of beneficiary assignment status. Such changes could help 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 against which they would be compared. We seek 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. (See the Effects on Providers and Suppliers section for a description of data currently available on the CMS website that may be useful for commenters to estimate the effects of such proposed changes for their particular ACO and/or market.)

6. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2018, that is approximately $150 million. This proposed rule does not include any mandate that would result in spending by state, local or tribal governments, in the aggregate, or by the private sector in the amount of $150 million in any 1 year. Further, participation in this program is voluntary and is not mandated.

7. Regulatory Review Cost Estimation

We assume all 561 ACOs currently participating in the Medicare Shared Savings Program will review on average half of this proposed 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 proposed rule and advises

multiple ACO partners. However, we acknowledge that this assumption may understate or overstate the costs of reviewing this rule. We welcome any comments on the approach in estimating the number of entities reviewing the proposed rule and the scope of the average review.

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 $107.39 per hour, where the assumed hourly wage of $53.69 has been increased by a factor of 2 to account for fringe benefits.[37] Assuming an average reading speed of 200 words per minute, we estimate it would take approximately 6 hours for the staff to review half of this proposed rule. For each ACO the estimated cost is $644.34 (6 hours × $107.39 per hour). Therefore, we estimate the total cost of reviewing this proposed regulation is approximately $361,500 ($644.34 × 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 would 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 would reduce ACO administrative burden by approximately $6 million over 10 years ($10,760 × 561 ACOs).

We do not believe that the proposals included in this proposed rule would otherwise materially impact the burden on ACOs for compliance with the requirements of the Shared Savings Program. The annual certification and application process would remain comparable to the existing program (setting aside the change to five year agreement periods as noted in the previous paragraph). However, we seek comment if stakeholders have reason to believe the proposed changes would materially change the burden of participation in the program beyond what we have estimated, as described previously.

[37] Occupational Employment Statistics available online at *https://www.bls.gov/oes/current/oes_nat.htm.*

D. Alternatives Considered

A particularly significant element of the proposed changes to the benchmarking methodology included in this proposed rule is the proposal to limit 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 proposal were amended to remove this cap then shared savings payments to low cost ACOs and selective participation decisions would increase the cost of the proposed rule by roughly $5 billion such that the estimated $2.24 billion savings relative to current regulation baseline (as estimated for the proposed rule in the previous sections) would instead be projected as a $2.75 billion cost.

Another alternative considered would be to push back the first agreement periods under the proposed new participation options and all other applicable proposed 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 one year extension under their current agreement periods. This alternative would have 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 likely marginally increase spending on claims through a combination of factors. This approach would delay, by 6 months, the transition into performance-based risk for certain ACOs whose current agreement periods will end on December 31, 2018. We also would anticipate a temporary increase in overall shared savings payments to such ACOs during the one year extension in 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 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 be CY 2019 rather than CY 2018, as would be the case under the proposed 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 marginally reduce the cumulative variation affecting benchmark accuracy in 2024, the final year of these ACOs' first agreement period under the policies in this proposed rule. We would also anticipate 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.

Overall, it is estimated that the shift to a January 1, 2020 start date for new agreement periods under the proposed changes, combined with a 1-year extension of the existing agreement period for most ACOs otherwise expected to enter a new agreement period in 2019, would reduce overall Federal spending by approximately an additional $100 million relative to the estimated $2.24 billion reduction in spending estimated for the proposal to offer a July 1, 2019 start date for new agreement periods under the proposed changes.

We also considered the potential impact of the alternative of allowing ACOs 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 make projecting the impact of such proposal difficult. 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 is 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 regardless via the existing claims-based assignment methodology. 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 proposed new policies described in this proposed 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 proposed 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 $3 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 would be expected under the hypothetical baseline in total over the 2019 to 2028 projection period. The alternative payment model, as proposed 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 14 percent greater savings on benefit costs, 9 percent lower spending on net shared savings payments to ACOs, with 46 percent reduced overall ACO participation compared to the hypothetical baseline model.

Participation in performance-based risk in the ENHANCED track and the later years 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 would 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 proposed changes.

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%.	−168.9 million	103.3 million	−427.6 million	Table 17.

TABLE 18—ACCOUNTING STATEMENT ESTIMATED IMPACTS—Continued

[CYs 2019–2028]

Category	Primary estimate	Minimum estimate	Maximum estimate	Source citation (RIA, preamble, etc.)
Annualized monetized: Discount rate: 3%.	−199.8 million	78.9 million	−466.0 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 would 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 proposed modifications in this proposed 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 $5.67 million over 10 years (as detailed previously in this RIA); therefore this proposed rule, if finalized, would 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 proposed rule, the median estimate of the financial impact of the Shared Savings Program for CYs 2019 through 2028 would be net federal savings of $2.24 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 roughly 89 percent of the stochastic trials resulted in an overall increase in net program savings over 10 years, the 10th and 90th percentiles of the estimated distribution show a net increase in costs by $0.09 billion and a net decrease in costs by $4.43 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 proposed 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 proposed 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 one 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 cost due to selective changes in participation), and unforeseen bias in benchmark adjustments due to diagnosis coding intensity shifts.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

List of Subjects

42 CFR Part 414

Administrative practice and procedure, Biologics, Drugs, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

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 proposes to amend 42 CFR parts 414 and 425 as set forth below:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

■ 2. Section 414.1415(a)(1)(ii) is revised to read as follows:

§ 414.1415 Advanced APM criteria.

(a) * * *

(1) * * *

(ii) For QP Performance Periods prior to 2019, for the Shared Savings Program, apply a penalty or reward to an APM Entity based on the degree of the use of

CEHRT of the eligible clinicians in the APM Entity.

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 1. The authority citation for part 425 continues to read as follows:

Authority: Secs. 1102, 1106, 1871, and 1899 of the Social Security Act (42 U.S.C. 1302, 1306, 1395hh, and 1395jjj).

■ 2. Section 425.20 is amended—

■ a. By revising the definition of ''Agreement period'';

■ b. By adding in alphabetical order definitions for ''Certified Electronic Health Record Technology (CEHRT)'', ''Eligible clinician'', ''Experienced with performance-based risk Medicare ACO initiatives'', ''High revenue ACO'', ''Inexperienced with performance-based risk Medicare ACO initiatives'', and ''Low revenue ACO'';

■ c. By revising the definition of ''Performance year''; and

■ d. By adding in alphabetical order definitions for ''Performance-based risk Medicare ACO initiative'', ''Re-entering ACO'', and ''Renewing ACO''.

The revisions and additions read as follows:

§ 425.20 Definitions.

* * * * *

Agreement period means the term of the participation agreement.

* * * * *

Certified Electronic Health Record Technology (CEHRT) has the same meaning given this term under § 414.1305 of this chapter.

* * * * *

Eligible clinician has the same meaning given this term under § 414.1305 of this chapter.

* * * * *

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 25 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 25 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 year means 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.

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 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 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 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 January 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 in 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 paragraph (a);

■ b. By revising the heading of paragraph (b);

■ c. By removing paragraph (b)(2) introductory text, adding a heading for paragraph (b)(2), and revising paragraph (b)(2)(ii);

■ d. By removing paragraph (b)(3) introductory text, adding a heading for paragraph (b)(3), and revising paragraph (b)(3)(ii);

■ e. By adding paragraphs (b)(4) and (5);

■ f. By revising paragraphs (c) and (d);

■ g. By redesignating paragraphs (e)(1)(i) through (v) as paragraphs (e)(1)(ii) through (vi); and

■ h. By adding a new paragraph (e)(1)(i).

The revisions and additions read as follows:

§ 425.200 Participation agreement with CMS.

(a) *General.* In order to participate in the Shared Savings Program, an ACO must enter into a participation agreement with CMS for a period of not less than the number of years specified in this section.

(b) *Agreement period.* * * *

(2) *For 2013 and through 2016.* * * *

(ii) The term of the participation agreement is 3 years unless all of the following conditions are met to extend the participation agreement by 6 months:

(A) The ACO entered an agreement period starting on January 1, 2016.

(B) The ACO elects to extend its agreement period until June 30, 2019.

(*1*) The ACO's election to extend its agreement period is made in the form and manner and according to the timeframe established by CMS; and

(*2*) An ACO executive who has the authority to legally bind the ACO must certify the election described in paragraph (b)(2)(ii)(B) of this section.

(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) *Performance year.* The ACO's performance year under the participation agreement is the 12 month period beginning on January 1 of each year during the term of the participation agreement unless otherwise noted in its participation agreement, and except as follows:

(1) For an ACO with a start date of April 1, 2012, or July 1, 2012, the ACO's first performance year is defined as 21 months or 18 months, respectively.

(2) 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 under paragraph (b)(2)(ii)(B) of this section, the ACO's fourth performance year is the 6-month period between January 1, 2019, and June 30, 2019.

(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.

(d) *Submission of measures.* For each performance year of the agreement period, ACOs must submit measures in the form and manner required by CMS according to § 425.500(c), and as applicable according to §§ 425.608 and 425.609.

(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 paragraph (b) introductory text to read as follows:

§ 425.202 Application procedures.

* * * * *

(b) * * * For determining eligibility for agreement periods beginning before July 1, 2019:

* * * * *

■ 8. Section 425.204 is amended—

■ a. By adding paragraph (c)(7);

■ b. By revising paragraph (f); and

■ c. In paragraph (g) introductory text by removing the phrase ''under § 425.602,'' and adding in its place the phrase ''under § 425.601, § 425.602, § 425.603 or § 425.609,''.

The addition and revision read as follows:

§ 425.204 Content of the application.

* * * * *

(c) * * *

(7) The ACO must certify, in a form and manner specified by CMS, that the

percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage specified by CMS at § 425.506(f).

* * * * *

(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 or the ENHANCED track must demonstrate the adequacy of its repayment mechanism prior to the start of each agreement period in which it takes risk and at such other times as requested by CMS.

(ii) An ACO entering an agreement period in Levels C, D, or E of the BASIC 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)(4)(iv) and (f)(6)(ii) of this section.

(4) CMS calculates the amount of the repayment mechanism as follows:

(i) For a Track 2 or ENHANCED track 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 for the most recent calendar year for which 12 months of data are available.

(ii) For a BASIC 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 10 percent or $100,000, whichever is the lesser value, CMS notifies the ACO 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 either paragraph (f)(4)(i) or (ii) of this section, as applicable.

(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 in a two-sided model plus 24 months following the conclusion of the agreement period, except as follows:

(i) 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.

(ii) In the case of 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 duration of the existing repayment mechanism must be extended by an amount of time specified by CMS and must be periodically extended thereafter upon notice from CMS.

(iii) 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 one of the following:

(*1*) December 31st for a 12-month performance year.

(*2*) December 31st for a 6-month performance year starting on July 1, 2019.

(*3*) June 30th for a 6-month performance year starting on January 1, 2019.

(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.* Except as set forth in paragraphs (b)(3)(i) and (ii) of this section, for performance years beginning in 2019 and subsequent performance years, an ACO under a two-sided model is liable for a pro-rated share of any shared losses as follows if its participation agreement is terminated effective before the last day of a performance year:

(i) 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.

(ii) 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 paragraphs (b)(2)(i) and (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 during 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 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 a 6-month performance year 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 425.302 is amended—

■ a. In paragraph (a)(3)(i) by removing the phrase ''requirements; and'' and adding in its place the phrase ''requirements;'';

■ b. In paragraph (a)(3)(ii) by removing the phrase ''owed to CMS.'' and adding in its place the phrase ''owed to CMS; and''; and

■ c. Adding paragraph (a)(3)(iii).

The addition reads as follows:

§ 425.302 Program requirements for data submission and certifications.

(a) * * *

(3) * * *

(iii) That the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the applicable percentage specified by CMS at § 425.506(f).

* * * * *

■ 15. 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.

(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 a 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 both 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 with retrospective reconciliation, 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.

(*4*) The incentive payment is not offered as part of 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)).

(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.

(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).

■ 16. 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.

■ 17. 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.

* * * * *

■ 18. 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.

* * * * *

■ 19. 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) An ACO participant must notify Medicare fee-for-service beneficiaries at the point of care about all of the following:

(1) Its ACO providers/suppliers are participating in the Shared Savings Program.

(2) The beneficiary's opportunity to decline claims data sharing under § 425.708.

(3) Beginning July 1, 2019, the beneficiary's 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 (as described in § 425.402(e)).

(b) Notification of the information specified in paragraph (a) of this section must be carried out by an ACO participant through all of the following methods:

(1) Posting signs in its facilities and, in settings in which beneficiaries receive primary care services, making standardized written notices available upon request.

(2) Beginning July 1, 2019, providing each beneficiary with a standardized written notice at the first primary care visit of each performance year in the form and manner specified by CMS.

* * * * *

■ 20. 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]

■ 21. Section 425.315 is amended in paragraph (a)(1)(ii) by removing the phrase ''§ 425.604(f), § 425.606(h) 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)''.

■ 22. 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 in 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.

■ 23. Section 425.400 is amended—

■ a. In paragraph (a)(1)(ii) by adding before the period, ''and, with respect to ACOs participating in a 6-month performance year during CY 2019, during the entirety of CY 2019 as specified in § 425.609'';

■ b. By revising the headings for paragraphs (a)(2) and (3);

■ c. In paragraph (a)(3)(i) by removing the phrase ''under Track 3'';

■ d. By adding paragraph (a)(4);

■ e. By revising paragraphs (c)(1)(iv) introductory text, (c)(1)(iv)(A), (c)(1)(iv)(B) introductory text, and (c)(1)(iv)(B)(*5*); and

■ f. By adding paragraphs (c)(1)(iv)(B)(*6*) through (*10*).

The revisions and additions 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 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.

* * * * *

(c) * * *

(1) * * *

(iv) For performance years starting on January 1, 2019, and subsequent performance years as follows:

(A) CPT codes:

(*1*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*2*) 99304 through 99318 (codes for professional services furnished in a nursing facility; services identified by these codes furnished in a SNF are excluded).

(*3*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*4*) 99341 through 99350 (codes for evaluation and management services furnished in a patients' home for claims identified by place of service modifier 12).

(*5*) 99487, 99489 and 99490 (codes for chronic care management).

(*6*) 99495 and 99496 (codes for transitional care management services).

(*7*) 99497 and 99498 (codes for advance care planning).

(*8*) 96160 and 96161 (codes for administration of health risk assessment).

(*9*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)).

(*10*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(B) HCPCS codes:

* * * * *

(*5*) G0444 (codes for annual depression screening service).

(*6*) G0442 (code for alcohol misuse screening service).

(*7*) G0443 (code for alcohol misuse counseling service).

(*8*) GPC1X (add-on code, for visit complexity inherent to evaluation and management associated with primary medical care services).

(*9*) GCG0X (add-on code, for visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or interventional pain management-centered care).

(*10*) GPRO1 (add-on code, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)).

■ 24. Section 425.401 is amended by revising paragraph (b) introductory text to read as follows:

§ 425.401 Criteria for a beneficiary to be assigned to an ACO.

* * * * *

(b) A beneficiary is excluded from the prospective assignment list of an ACO that is participating under prospective assignment under § 425.400(a)(3) at the end of a performance or benchmark year and quarterly during each performance year consistent with § 425.400(a)(3)(ii), or at the end of CY 2019 as specified in § 425.609(b)(1)(ii) and (c)(1)(ii), if the beneficiary meets any of the following criteria during the performance or benchmark year:

* * * * *

■ 25. Section 425.402 is amended by revising paragraphs (e)(2) and (e)(3)(i) to read as follows:

§ 425.402 Basic assignment methodology.

* * * * *

(e) * * *

(2) Beneficiaries are added to the ACO's list of assigned beneficiaries if all of the following conditions are satisfied:

(i) For performance year 2018:

(A) The beneficiary must have had at least one primary care service during the assignment window as defined under § 425.20 with a physician who is an ACO professional in the ACO who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in paragraph (c) of this section.

(B) The beneficiary meets the eligibility criteria established at § 425.401(a) and must not be excluded by the criteria at § 425.401(b). The exclusion criteria at § 425.401(b) apply for purposes of determining beneficiary eligibility for alignment to ACOs under all tracks based on the beneficiary's designation of an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section.

(C) The beneficiary must have designated an ACO professional who is a primary care physician as defined at § 425.20, a physician with a specialty designation included at paragraph (c) of this section, or a nurse practitioner, physician assistant, or clinical nurse specialist as responsible for coordinating their overall care.

(D) If a beneficiary has designated a provider or supplier outside the ACO who is a primary care physician as

defined at § 425.20, a physician with a specialty designation included at paragraph (c) of this section, or a nurse practitioner, physician assistant, or clinical nurse specialist, as responsible for coordinating their overall care, the beneficiary is not added to the ACO's list of assigned beneficiaries under the assignment methodology in paragraph (b) of this section.

(ii) For performance years starting on January 1, 2019, and subsequent performance years:

(A) The beneficiary meets the eligibility criteria established at § 425.401(a) and must not be excluded by the criteria at § 425.401(b). The exclusion criteria at § 425.401(b) apply for purposes of determining beneficiary eligibility for alignment to an ACO based on the beneficiary's designation of an ACO professional as responsible for coordinating their overall care under paragraph (e) of this section, regardless of the ACO's assignment methodology selection under § 425.400(a)(4)(ii).

(B) The beneficiary must have designated an ACO professional as responsible for coordinating their overall care.

(C) If a beneficiary has designated a provider or supplier outside the ACO as responsible for coordinating their overall care, the beneficiary is not added under the assignment methodology in paragraph (b) of this section to the ACO's list of assigned beneficiaries for a 12-month performance year or the ACO's list of assigned beneficiaries for a 6-month performance year, which is based on the entire CY 2019 as provided in § 425.609.

(D) The beneficiary is not assigned 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.

(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).

* * * * *

§ 425.404 [Amended]

■ 26. Section 425.404 is amended in paragraph (b) by removing the phrase ''For performance year 2019 and subsequent performance years'' and adding in its place the phrase ''For performance years starting on January 1, 2019, and subsequent performance years''.

■ 27. Section 425.502 is amended—

■ a. 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'';

■ b. In paragraph (e)(4)(vi) by removing the phrase ''For performance year 2017'' and adding in its place the phrase ''For performance year 2017 and subsequent performance years'';

■ c. By adding a new paragraph (e)(4)(vii);

■ d. By revising paragraph (f) introductory text;

■ e. By redesignating paragraphs (f)(1) and (2) as paragraphs (f)(2)(i) and (ii);

■ f. By adding a new paragraph (f)(1);

■ g. By adding a new paragraph (f)(2) introductory text;

■ h. In newly redesignated paragraph (f)(2)(i) by removing the phrase ''for performance year 2017'' and adding in its place the phrase ''for the relevant performance year'';

■ i. By removing paragraph (f)(4); and

■ j. By redesignating paragraph (f)(5) as paragraph (f)(4).

The revisions and additions read as follows:

§ 425.502 Calculating the ACO quality performance score.

* * * * *

(e) * * *

(4) * * *

(vii) For performance year 2017 and subsequent performance years, if an ACO receives the mean Shared Savings Program ACO quality score under paragraph (f) of this section, in the next performance year for which the ACO receives a quality performance score based on its own quality reporting, quality improvement is measured based on a comparison between the performance in that year and the most recently available prior performance year in which the ACO reported quality.

(f) *Extreme and uncontrollable circumstances.* For performance year 2017 and subsequent performance years, including the applicable quality data reporting period for the performance year if the quality reporting period is not extended, CMS uses an alternative approach to calculating the quality score for ACOs affected by extreme and uncontrollable circumstances instead of the methodology specified in paragraphs (a) through (e) of this section as follows:

(1) CMS determines the ACO was affected by an extreme and uncontrollable circumstance based on either of the following:

(i) Twenty percent or more of the ACO's assigned beneficiaries reside in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance.

(A) Assignment is determined under subpart E of this part.

(B) In making this determination for performance year 2017, CMS uses the final list of beneficiaries assigned to the ACO for the performance year. For performance year 2018 and subsequent performance years, CMS uses the list of assigned beneficiaries used to generate the Web Interface quality reporting sample.

(ii) The ACO's legal entity is located in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance. An ACO's legal entity location is based on the address on file for the ACO in CMS' ACO application and management system.

(2) If CMS determines the ACO meets the requirements of paragraph (f)(1) of this section, CMS calculates the ACO's quality score as follows:

* * * * *

■ 28. Section 425.506 is amended—

■ a. In paragraph (b) by removing the phrase ''As part of the quality performance score'' and adding in its place the phrase ''For performance years 2012 through 2018, as part of the quality performance score'';

■ b. In paragraph (c) by removing the phrase ''Performance on this measure'' and adding in its place the phrase ''For performance years 2012 through 2018, performance on this measure'';

■ c. In paragraph (e) introductory text by removing the phrase ''For 2017 and subsequent years'' and adding in its place the phrase ''For 2017 and 2018''; and

■ d. By adding paragraph (f).

The addition reads as follows:

§ 425.506 Incorporating reporting requirements related to adoption of certified electronic health record technology.

* * * * *

(f) For performance years starting on January 1, 2019, and subsequent performance years, ACOs in a track or a payment model within a track that—

(1) Does not meet the financial risk standard to be an Advanced APM must certify annually and at the time of application that the percentage of eligible clinicians participating in the

ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds 50 percent; or

(2) Meets the financial risk standard to be an Advanced APM must certify annually and at the time of application that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the higher of 50 percent or the threshold established under § 414.1415(a)(1)(i) of this chapter.

■ 29. 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)(A) 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)(*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*) 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, except as provided in paragraph (a)(4)(i)(B)(*2*)(*i*) of this section.

(*i*) 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.

(*ii*) 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).

(*iii*) 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.

(*iv*) 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*)(*ii*) 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) 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, the ACO may enter 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 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).

■ 30. 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 CMS–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 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 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 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.

(3) The third 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.

(4) 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 BY 3 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.

■ 31. 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 on January 1, 2019'';

■ 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, 2018 and on January 1, 2019''; and

■ d. By adding paragraph (c).

The revisions and addition read as follows:

§ 425.602 Establishing, adjusting, and updating the benchmark for an ACO's first agreement period beginning on or before January 1, 2019.

(a) *Computing per capita Medicare Part A and Part B benchmark expenditures.* For agreement periods beginning on or before January 1, 2019, 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:

* * * * *

(c) *January 1, 2019 through June 30, 2019 performance year.* In determining performance for the January 1, 2019 through June 30, 2019 performance year described in § 425.609(b) CMS does all of the following:

(1) When adjusting the benchmark using the methodology set forth in paragraph (a)(9) of this section and § 425.609(b), 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(b), CMS updates the benchmark based on growth between BY3 and CY 2019.

■ 32. 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'';

■ 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''; and

■ g. By adding paragraph (g).

The revision and addition reads as follows:

§ 425.603 Resetting, adjusting, and updating the benchmark for a subsequent agreement period beginning on or before January 1, 2019.

* * * * *

(g) In determining performance for the January 1, 2019 through June 30, 2019 performance year described in § 425.609(b) CMS does all of the following:

(1) When adjusting the benchmark using the methodology set forth in paragraph (c)(10) of this section and § 425.609(b), CMS adjusts for severity and case mix between BY3 and CY 2019.

(2) When updating the benchmark using the methodology set forth in paragraph (d) of this section and § 425.609(b), CMS updates the benchmark based on growth between BY3 and CY 2019.

■ 33. 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)'';

■ c. In paragraph (b) by revising the table; and

■ d. By adding paragraph (g).

The revision and addition read 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

* * * * *

(g) *January 1, 2019 through June 30, 2019 performance year.* Shared savings for the January 1, 2019 through June 30, 2019 performance year are calculated as described in § 425.609.

■ 34. 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) Negative adjustments in prospective HCC risk scores are subject to a cap of negative 3 percent.

(iii) These caps are the maximum change in risk scores for each agreement period, such that the adjustment between BY3 and any performance year in the agreement period cannot be larger than 3 percent in either direction.

(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).

(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) An ACO eligible to enter the BASIC track's glide path as specified under § 425.600(d) may elect to enter its agreement period at any of the levels of risk and potential reward under paragraphs (d)(1)(i) through (v) of this section, with the exception that an ACO that previously participated in Track 1 under § 425.600(a)(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, may elect to enter its agreement period at any of the levels of risk and potential reward available under paragraphs (d)(1)(ii) through (v) of this section.

(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 25 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 25 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 30 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 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)(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), 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.

■ 35. 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'';

■ d. In paragraph (i) introductory text by removing the phrase ''For performance year 2017'' and adding in its place the phrase ''For performance year 2017 and subsequent performance years'';

■ e. In paragraph (i)(1) remove the phrase ''2017''; and

■ f. By adding paragraph (i)(2)(i), reserved paragraph (i)(2)(ii), and paragraph (j).

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) 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]

* * * * *

(j) *January 1, 2019 through June 30, 2019.* Shared savings or shared losses for the January 1, 2019 through June 30, 2019 performance year are calculated as described in § 425.609.

■ 36. Section 425.609 is added to read as follows:

§ 425.609 Determining performance for 6-month performance years during CY 2019.

(a) *General.* An ACO's financial and quality performance for a 6-month performance year during 2019 are determined as described in this section.

(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 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 after the conclusion of CY 2019 for the period from January 1, 2019, through June 30, 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:

(1) Uses the ACO participant list in effect for the performance year beginning January 1, 2019, to determine beneficiary assignment, using claims for the entire calendar year, as specified in §§ 425.402 and 425.404, and according to the ACO's track as specified in § 425.400.

(i) For ACOs under preliminary prospective assignment with retrospective reconciliation the assignment window is CY 2019.

(ii) For ACOs under prospective assignment—

(A) Medicare fee-for-service beneficiaries are 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; 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.

(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 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.

(3) Uses the methodology for calculating shared savings or shared losses applicable to the ACO under the terms of the participation agreement that was in effect on January 1, 2019.

(i) The ACO's historical benchmark is determined according to either § 425.602 (first agreement period) or § 425.603 (second agreement period) except as follows:

(A) The benchmark is adjusted for changes in severity and case mix between BY 3 and CY 2019 using the methodology that accounts separately for newly and continuously assigned beneficiaries using prospective HCC risk scores and demographic factors as described under §§ 425.604(a)(1) through (3), 425.606(a)(1) through (3), and 425.610(a)(1) through (3).

(B) The benchmark is updated to CY 2019 according to the methodology described under § 425.602(b), § 425.603(b), or § 425.603(d), based on whether the ACO is in its first or second agreement period, and for an ACO in a second agreement period, the date on which that agreement period began.

(ii) The ACO's financial performance is determined based on the track the ACO is participating under during the performance year starting on January 1, 2019 (§ 425.604, § 425.606 or § 425.610), 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 (b)(1) of this section.

(B) Expenditures calculated in paragraph (b)(3)(ii)(A) of this section are compared to the ACO's updated benchmark determined according to paragraph (b)(3)(i) of this section.

(C)(*1*) The ACO's performance year assigned beneficiary population identified in paragraph (b)(1) of this section is used to determine the MSR for Track 1 ACOs 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 (b)(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 January 1, 2019 (§ 425.604, § 425.606 or § 425.610) and paragraph (b)(3)(ii)(C)(*1*) of this section.

(*ii*) Meet the minimum quality performance standards established under § 425.502 and according to paragraph (b)(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 January 1, 2019 (§ 425.606 or § 425.610) and paragraph (b)(3)(ii)(C)(*1*) of this section.

(D) For an ACO that meets all the requirements to receive shared savings payment under paragraph (b)(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 January 1, 2019 (§ 425.604, § 425.606 or § 425.610), is applied to all savings under the updated benchmark specified under paragraph (b)(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 (b)(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 period from January 1, 2019, through June 30, 2019.

(E) For an ACO responsible for shared losses under paragraph (b)(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 January 1, 2019 (§ 425.606 or § 425.610), is applied to all losses under the updated benchmark specified under paragraph (b)(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 (b)(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 period from January 1, 2019, through June 30, 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 after the conclusion of CY 2019 for the period from July 1, 2019, through December 31, 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) Medicare fee-for-service beneficiaries are 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; 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 BY 3 and CY 2019 based on growth in prospective HCC risk scores, subject to a symmetrical cap of positive or negative 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 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) *Extreme and uncontrollable circumstances.* For ACOs affected by extreme and uncontrollable circumstances during CY 2019—

(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

(2) In determining the ACO's quality performance score for the 2019 quality reporting period, CMS uses the alternative scoring methodology specified in § 425.502(f).

(e) *Notification of savings and losses.* 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:

(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.

(4) 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.

■ 37. 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 all instances of the phrase ''Track 3'' and, in each instance, 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. In paragraph (i) introductory text by removing the phrase ''For performance year 2017'' and adding in its place the phrase ''For performance year 2017 and subsequent performance years'';

■ h. In paragraph (i)(1) by removing the phrase ''2017''; and

■ i. By adding paragraph (i)(2)(i), reserved paragraph (i)(2)(ii), and paragraphs (j) and (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) Negative adjustments in prospective HCC risk scores are subject to a cap of negative 3 percent.

(iii) These caps are the maximum change in risk scores for each agreement period, such that the adjustment between BY3 and any performance year in the agreement period cannot be larger than 3 percent in either direction.

(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) 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]

* * * * *

(j) *January 1, 2019 through June 30, 2019 performance year.* Shared savings or shared losses for the January 1, 2019 through June 30, 2019 performance year are calculated as described in § 425.609.

(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.

■ 38. 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.

■ 39. 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.

■ 40. Section 425.702 is amended—

■ a. By revising paragraphs (c)(1)(ii)(A) introductory text, (c)(1)(ii)(B) introductory text and (c)(1)(ii)(C); and

■ b. By adding paragraph (d).

The revisions and addition 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.

* * * * *

(d) For an ACO eligible to be reconciled under § 425.609(b), CMS shares with the ACO quarterly aggregate reports as provided in paragraphs (b) and (c)(1)(ii) of this section for CY 2019.

■ 41. 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.

* * * * *

■ 42. 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: June 11, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 28, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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