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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 425

[CMS-1644-P]

RIN 0938-AS67

Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations--Revised Benchmark Rebased Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations

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. This proposed rule addresses changes to the Shared Savings Program that would modify the program's benchmark rebasing methodology to encourage ACOs' continued investment in care coordination and quality improvement, and identifies publicly available data to support modeling and analysis of these proposed changes. In addition, it would streamline the methodology used to adjust an ACO's historical benchmark for changes in its ACO participant composition, offer an alternative participation option to encourage ACOs to enter performance-based risk arrangements earlier in their participation under the program, and establish policies for reopening of payment determinations to make corrections after financial calculations

have been performed and ACO shared savings and shared losses for a performance year have been determined.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [insert date 60 days after the **date of filing for public inspection** at OFR.]

ADDRESSES: In commenting, please refer to file code CMS-1644-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to **<http://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-1644-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-1644-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC--
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

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

FOR FURTHER INFORMATION CONTACT: Elizabeth November, (410) 786-8084. Email address: 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 Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site 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.

Acronyms

ACO	Accountable Care Organization
BY	Benchmark Year
CBSA	Core Based Statistical Area
CMS	Centers for Medicare & Medicaid Services
CSA	Combined Statistical Area
CY	Calendar Year
DSH	Disproportionate Share Hospital
ESRD	End Stage Renal Disease
FFS	Fee-for-service
GAO	Government Accountability Office
HCC	Hierarchical Condition Category
IME	Indirect Medical Education
MA	Medicare Advantage
MACRA	Medicare Access and CHIP Reauthorization Act of 2015
MedPAC	Medicare Payment Advisory Commission
MLR	Minimum Loss Rate
MSA	Metropolitan Statistical Area
MSR	Minimum Savings Rate

NPI	National Provider Identifier
OACT	Office of the Actuary
PGP	Physician Group Practice
PUF	Public Use File
PY	Performance Year
RIA	Regulatory Impact Analysis
TIN	Taxpayer Identification Number

I. Executive Summary and Background

A. Executive Summary

1. Purpose

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, and encourages investment in infrastructure and redesigned care processes for high quality and efficient health care service delivery. This proposed rule would make changes to the regulations for the Shared Savings Program that were promulgated in November 2011 and June 2015, and codified at 42 CFR Part 425. The goal is to address concerns raised by stakeholders regarding the financial benchmarking methodology, and establish additional options for ACOs to enter performance-based risk arrangements. This proposed rule also seeks to address policies for reopening of payment determinations to make corrections after financial calculations have been performed and ACO shared savings and shared losses for a performance year have been determined. Unless otherwise noted, these changes would be effective 60 days after publication of the final rule. Applicability or

implementation dates may vary, depending on the nature of the policy. Table 1 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 1 – Applicability Dates of Select Provisions of the Proposed Rule

Preamble Section	Section Title/Description	Applicability Date
II.A.2, II.A.3.	Integrating regional factors in resetting ACO benchmarks	Second or subsequent agreement period beginning January 1, 2017 and all subsequent years
II.A.2.e.3.	Use of assignable beneficiaries in calculations based on National FFS expenditures	PY 2017 and subsequent performance years
II.B.	Modification to the methodology for adjusting benchmarks for changes in ACO participant composition	PY 2017 and subsequent performance years
II.C.	An additional participation option that would allow eligible Track 1 ACOs to defer by 1 year their entrance into a performance-based risk model (Track 2 or 3) for their second agreement period	Second agreement period beginning January 1, 2017 and all subsequent years
II.D.	Definitions of circumstances for reopening determinations of ACO shared savings or shared losses to correct financial reconciliation calculations	60 days from publication of the final rule

2. Summary of the Major Provisions

This proposed rule is designed to improve program function and transparency. To achieve these goals, we propose to make the following modifications to the current program:

- Modifying the methodology for rebasing and updating ACO historical benchmarks when an ACO renews its participation agreement for a second or subsequent agreement period to incorporate regional expenditures, thereby making the ACO’s cost target more independent of its historical expenditures and more reflective of FFS spending in its region.

- Modifying the methodology for risk adjustment to account for the health status of the ACO's assigned population in relation to FFS beneficiaries in the ACO's regional service area, and to apply this approach in determining the regional adjustment that is applied to the ACO's rebased historical benchmark.

- Revising the methodology for adjusting ACO benchmarks to account for changes in ACO participant (TIN) composition.

- Adding a participation agreement renewal option to encourage ACOs to enter performance-based risk arrangements earlier in their participation in the Shared Savings Program.

- Defining circumstances under which we would reopen payment determinations to make corrections after the financial calculations have been performed and ACO shared savings and shared losses for a performance year have been determined.

3. Summary of Costs and Benefits

As a result of this proposed rule, the median estimate of the financial impact of the Shared Savings Program for CYs 2017 through 2019 would be net federal savings of \$120 million greater than what would have been saved if no changes were made. Although this is the best estimate of the financial impact of the Shared Savings Program during CYs 2017 through 2019, a relatively wide range of possible outcomes exists. While approximately two-thirds of the stochastic trials resulted in an increase in net program savings, the 10th and 90th percentiles of the estimated distribution show a net increase in costs of \$230 million to net savings of \$490 million, respectively.

Overall, our analysis projects that improvements in the accuracy of benchmark calculations, including through the introduction of a regional adjustment to the ACO's

rebased historical benchmark, are expected to result in increased overall participation in the program. The proposed changes are also expected to improve the incentive for ACOs to invest in effective care management efforts, increase the attractiveness of participation under performance-based risk in Track 2 or 3 for certain ACOs with lower beneficiary expenditures, and result in overall greater gains in savings on FFS benefit claims costs than the associated increase in 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 biased benchmark adjustments due to diagnosis coding intensity shifts. Such monitoring will inform future rulemaking, such as if the Secretary determines that a lower weight should be used in calculating the regional adjustment amount for ACOs' third and subsequent agreement periods.

B. 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 Pub. L. 111-148. Collectively known as the Affordable Care Act, these public laws include a number of provisions designed to improve the quality of Medicare services, support innovation and the establishment of new payment models, better align Medicare payments with provider costs, strengthen Medicare program integrity, and put Medicare on a firmer financial footing.

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 a Shared Savings

Program. This program is a key component of the Medicare delivery system reform initiatives included in the Affordable Care Act and is a new approach to the delivery of health care. The purpose of the Shared Savings Program is to promote accountability for a population of Medicare beneficiaries, improve the coordination of FFS items and services, encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery, and promote higher value care. ACOs that successfully meet quality and savings requirements share a percentage of the achieved savings with Medicare. Consistent with the purpose of the Shared Savings Program, in establishing the program, we focused on developing policies aimed at achieving the three-part aim consisting of: (1) better care for individuals; (2) better health for populations; and (3) lower growth in expenditures.

We published the final rule entitled "Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations" (November 2011 final rule), which appeared in the November 2, 2011 **Federal Register** (76 FR 67802). 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. We anticipated that subsequent rulemaking for the Shared Savings Program would be informed by lessons learned from our experience with the program as well as from testing through the Pioneer ACO Model and other initiatives conducted by the Center for Medicare and Medicaid Innovation (Innovation Center) under section 1115A of the Act.

As of January 1, 2016, over 400 ACOs were participating in the Shared Savings Program. This includes 147 ACOs with 2012 and 2013 agreement start

dates that entered into a new 3-year agreement effective January 1, 2016, to continue their participation in the program. We continue to see strong interest in the program, for instance, as indicated by the 100 ACOs that entered the program for a first agreement period beginning January 1, 2016. See Fact Sheet: CMS Welcomes New Medicare Shared Savings Program (Shared Savings Program) Participants, (January 11, 2016) available online at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-01-11-2.html>. We are gratified by stakeholder interest in this program. In the November 2011 final rule (76 FR 67805), we stated that we intended to assess the policies for the Shared Savings Program and models being tested by the Innovation Center to determine how well they were working and if there were any modifications that would enhance them.

As evidenced by the high degree of interest in participation in the Shared Savings Program, we believe that the policies adopted in the November 2011 final rule are generally well-accepted. However, we identified several policy areas that should be revisited in light of the additional experience we gained during the first two years of program implementation. Therefore, we published a subsequent final rule entitled "Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations" (June 2015 final rule), which appeared in the June 9, 2015 **Federal Register** (80 FR 32692). In that rule, we adopted policies designed to codify existing guidance, reduce administrative burden, and improve program function and transparency in a number of areas, such as eligibility for program participation and data sharing. Additionally, we modified policies related to the financial model, in response to

stakeholder feedback, to encourage greater and continued ACO participation, for example, by offering ACOs the opportunity to continue participating under the one-sided model for a second agreement period, modifying the existing two-sided performance-based risk track (Track 2), and offering an alternative two-sided performance-based risk track (Track 3). 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. We finalized new policies for resetting an ACO's financial benchmark in a second or subsequent agreement period, by integrating the ACO's previous financial performance and equal weighting the historical benchmark years, to encourage ACOs to seek to continue their participation in the program and to address stakeholder concerns about the current benchmark rebasing methodology. We also stated our intention to address other modifications to program rules in future rulemaking in the near term including modifying the methodology for resetting benchmarks by incorporating regional trends and costs.

II. Provisions of the Proposed Regulations

The purpose of this proposed rule is to propose revisions to some key policies of the Shared Savings Program adopted in the November 2011 final rule (76 FR 67802) and modified by the June 2015 final rule (80 FR 32692) including: (1) proposing regulatory changes to the benchmarking methodology that will apply when resetting and updating the benchmark for an ACO's second or subsequent agreement period; (2) proposing a change to the methodology for adjusting an ACO's historical benchmark for changes to the ACO's certified ACO Participant List; (3) proposing a regulatory change to facilitate ACOs' transition to performance-based risk models; and (4) proposing a policy on administrative finality to address the circumstances under which payment determinations

would be reopened to correct financial reconciliation calculations. We seek stakeholders' input regarding these proposed policies, which we believe are important to the continued success of the Shared Savings Program.

A. Integrating Regional Factors when Resetting ACOs' Benchmarks

1. Background on Establishing, Updating, and Resetting the Benchmark

Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established and updated. 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 and updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program, as estimated by the Secretary. Such benchmark shall be reset at the start of each agreement period. In addition to the statutory benchmarking methodology established in section 1899(d) of the Act, section 1899(i)(3) of the Act grants the Secretary the authority to use other payment models, including payment models that would 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.

In the November 2011 final rule, establishing the Shared Savings Program, we adopted policies for establishing, updating and resetting ACO benchmarks at § 425.602.

Under this methodology, we use national FFS spending and trends as part of establishing, updating and resetting ACO-specific benchmarks. Specifically, we currently calculate a benchmark for each ACO using a risk-adjusted average of per capita Parts A and B expenditures for original Medicare FFS beneficiaries who would have been assigned to the ACO in each of the 3 calendar years prior to the start of the agreement period. We trend forward each of the first 2 benchmark years' per capita risk adjusted expenditures to third benchmark year (BY3) dollars based on the national average growth rate in Parts A and B per capita FFS expenditures verified by the CMS Office of the Actuary (OACT). In establishing the benchmark for an ACO's first agreement period, the first benchmark year is weighted 10 percent, the second benchmark year is weighted 30 percent, and the third benchmark year is weighted 60 percent. This weighting creates a benchmark that more accurately reflects the latest expenditures and health status of the ACO's assigned beneficiary population. For each performance year, we adjust for changes in beneficiary characteristics and update the benchmark by the OACT-verified projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original FFS program. In trending forward the historical benchmark, adjusting for changes in beneficiary characteristics, and annually updating the benchmark by growth in national per capita Medicare FFS expenditures, we make calculations for populations of beneficiaries in each of the following Medicare enrollment types: ESRD, disabled, aged/dual eligible, and aged/non-dual eligible. Further, to minimize variation from catastrophically large claims, we truncate an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at a threshold of the 99th percentile of national Medicare FFS expenditures for the applicable Medicare enrollment type (ESRD,

disabled, aged/dual eligible, or aged/non-dual eligible).

Under section 1899(d)(1)(B)(ii) of the Act and § 425.602(c) of the Shared Savings Program regulations, an ACO's benchmark must be reset at the start of each new agreement period. In the June 2015 final rule, we established a policy for resetting ACO benchmarks that accounts for factors relevant to ACOs that have participated in the program for at least one agreement period. This policy is intended to help ensure that the Shared Savings Program remains attractive to ACOs and continues to encourage ACOs to participate in additional agreement periods and to continue to improve their performance, particularly those ACOs that have achieved shared savings. Specifically, we revised § 425.602(c) to specify that in resetting the historical benchmark for ACOs in their second or subsequent agreement period we: (1) weight each benchmark year equally; and (2) make an adjustment to reflect the average per capita amount of savings earned by the ACO in its prior agreement period, reflecting the ACO's financial and quality performance, during that prior agreement period. The additional per capita amount is applied as an adjustment to the ACO's rebased historical benchmark for a number of assigned beneficiaries (expressed as person years) not to exceed the average number of assigned beneficiaries (expressed as person years) under the ACO's prior agreement period. If an ACO was not determined to have generated net savings in its prior agreement period, we do not make any adjustment to the ACO's rebased historical benchmark. We use performance data from each of the ACO's performance years under its prior agreement period in resetting the ACO's benchmark for its second or subsequent agreement period.

We adjust the ACO's historical benchmark for changes during the performance

period in the health status and demographic factors of the ACO's assigned beneficiaries (§ 425.604(a), § 425.606(a), § 425.610(a)), as described in section II.A.3. of this proposed rule. Consistent with section 1899(d)(1)(B)(ii) of the Act, we update the ACO's benchmark annually, 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 described further in section II.A.2.d. of this proposed rule. Additionally, as described further in section II.B. of this proposed rule, we also adjust ACO historical benchmarks annually based on changes to the ACO's certified ACO Participant List.

2. Alternative Approaches to Reset the ACO's Benchmark

a. Overview

In the December 2014 proposed rule, we sought comment on three approaches to account for regional FFS expenditures in ACO benchmarks: (1) use of regional FFS expenditures, instead of national FFS expenditures, to trend forward the most recent 3 years of per beneficiary expenditures for Parts A and B services in order to establish the historical benchmark for each ACO and to update the benchmark during the agreement period; (2) adjusting the ACO's benchmark from its prior agreement period to reflect trends in FFS costs in the ACO's region, effectively holding a portion of the ACO's reset benchmark constant relative to its region; and (3) transitioning ACOs from benchmarks based on their historical costs toward benchmarks based only on regional FFS costs.

Under this approach, an ACO's benchmark would gradually become more independent of the ACO's historical expenditures and gradually more reflective of FFS trends in its region. We also sought comment on a number of technical issues specific to these alternatives, including: how to define an ACO's region, and specifically, the ACO's

regional reference population; how to account for changes in ACO participants from year-to-year and across agreement periods; and considerations related to risk adjusting benchmarks based on regional factors. We also discussed and sought comment on how broadly or narrowly to apply these alternative benchmarking approaches to the program's financial tracks, and the timing for implementing any changes.

Many commenters indicated their support for revising the program's benchmarking methodology to reflect regional cost variation. (See June 2015 final rule (80 FR 32791 through 32796) for a discussion of comments received on and considerations for use of regional factors in establishing, updating and resetting benchmarks.) Of the options to incorporate regional FFS costs in ACO benchmarks, the approach that would transition ACOs to regionally based benchmarks over time seemed to garner the greatest support from commenters. Commenters suggested CMS consider a variety of additional methodologies for revising the program's benchmarks, sometimes offering opposing alternatives. For example, some commenters supported blended approaches, whereby benchmarks would reflect a combination of the ACO's historical costs and regional, national or a combination of regional/national costs. MedPAC offered a vision for both the near and long term evolution of the program's benchmarking methodology. (See letter from Glenn M. Hackbarth, J.D., Chairman, Medicare Payment Advisory Commission to Ms. Marilyn Tavenner, Administrator, Centers for Medicare and Medicaid Services, regarding File code CMS-1461-P (February 2, 2015) (available through www.regulations.gov, comment tracking number 1jz-8gz6-jbt1).) In the short term, we would keep the existing rebasing methodology, but would not rebase an ACO

that met a two-part test,¹ which would leave benchmarks for lower-spending ACOs unchanged. In the longer term, CMS would move ACOs from a benchmark based on the ACO's historical cost experience to a common (equitable), local FFS-based benchmark, where FFS spending is defined to include spending on beneficiaries assigned to ACOs as well as on other beneficiaries in traditional FFS. MedPAC indicated this longer term approach should initially be implemented under the two-sided payment models, phased in over the course of the ACO's second agreement period, but that all ACOs should be transitioned to regional FFS benchmarks by year 2021. On the topic of the pace for transitioning ACOs to regional benchmarks, commenters' suggestions ranged from rapid transition (within the first agreement period) to a slower pace (for example, over the course of 2, 3, 4 or even 5 agreement periods). Several commenters suggested a different pace of transition depending on the ACO's historical costs relative to its market, or the level of experience of the ACO, or an approach under which an ACO could determine its own pace of transitioning to a regional benchmark. One commenter recommended that the changes become effective for all ACOs beginning with the first full performance year after the final rule is published.

Many commenters pointed to the importance of the details of the chosen methodology, for example, the definition of the ACO's region. Some commenters indicated there were insufficient details in the December 2014 proposed rule on the alternative benchmarking approaches or cited their lack of data to analyze the alternatives discussed in order to make an informed and effective recommendation about the options.

¹ MedPAC explained the two-part test: "First, per-capita spending for the ACO (after that spending is adjusted for health care risk and input prices) must be below the national average per-capita FFS spending. Second, per-capita spending for the ACO (risk adjusted) must be below the average FFS spending (risk adjusted) in the ACO's market."

These commenters indicated the need for CMS to perform additional modeling and analytic work on the alternatives discussed in the December 2014 proposed rule, and to share the results of this analysis and put forward detailed proposals on revisions to the benchmarking methodology through additional notice and comment rulemaking. More generally, other commenters requested that CMS provide detailed documentation regarding program calculations and greater access to the underlying data.

In response, we acknowledged the importance of quickly moving to a benchmark rebasing approach that accounts for regional FFS costs and trends in addition to the ACO's historical costs and trends. In the June 2015 final rule, we committed to engaging in additional rulemaking to propose modifications to the Shared Savings Program's methodology for resetting ACO benchmarks. We signaled our anticipated policy direction by outlining an approach to rebasing that would account for regional expenditures and identified additional issues we would need to address in implementing this approach. We discussed a rebasing approach based on a blend of: (1) a regionally trended component, reflecting ACO historical costs for the 3 years preceding its first agreement period that starts in 2017 or a subsequent year, adjusted by a regional trend factor based on changes in regional expenditures for each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) for the most recent year prior to the start of the ACO's new agreement period, and adjusted for changes in the health status and demographic factors of the ACO's assigned beneficiary population in each benchmark year relative to its region; and (2) a rebased component calculated using the current rebasing methodology (based on historical costs from the 3 most recent years prior to the start of the ACO's new agreement period), including equally weighting the

benchmark years but excluding the addition of a portion of savings generated over the same 3 most recent years.

In the June 2015 final rule (80 FR 32796), we specified that the forthcoming proposed rule would provide a detailed discussion of key methodological issues, including: weight of the two benchmark components, risk adjustment, defining an ACO's region, and accounting for changes in ACO participant composition. We indicated that in developing the proposed rule we would take into account broader considerations for the program, including: whether to change the methodology for updating the benchmark; whether to make adjustments to account for ACOs whose costs are relatively high or low in relation to FFS trends in their region or the nation; and how to safeguard against ACOs that may increase their spending to lock in higher benchmarks for future agreement periods.

In the June 2015 final rule we explained that the revised rebasing approach would require tradeoffs among several criteria:

- Strong incentives for ACOs to improve efficiency and to continue participation in the program over the long term.
- Benchmarks which are sufficiently high to encourage ACOs to continue to meet the three-part aim, while also safeguarding the Medicare Trust Funds against the possibility that ACOs' reset benchmarks become overly inflated to the point where ACOs need to do little to maintain or change their care practices to generate savings.
- Generating benchmarks that reflect ACOs' actual costs in order to avoid potential selective participation by (and excessive shared payments to) ACOs with high benchmarks.

In further considering modifications to the benchmarking methodology for this proposed rule, we added the following set of guiding principles:

- **Transparency:** Developed based on identifiable sources of data, and where possible publicly available data and data sets, in order to allow stakeholders to understand and model impacts.
- **Predictability:** Enable ACOs to anticipate their updated benchmark targets and their likely performance under the program.
- **Simplicity:** Methodology can be explained in relatively simple terms and in sufficient detail to be readily understood by ACOs and stakeholders.
- **Accuracy:** Methodology generates benchmarks that are an accurate reflection of the ACOs' expenditures and relevant regional expenditures, and can be accurately implemented and calculated, validated and disseminated in a timely manner.
- **Maintain program momentum and market stability** by providing sufficient notice of methodological changes and phase-in of these changes.

b. Proposals for Regional Definition

(1) Background

The June 2015 final rule indicated that in defining an ACO's region we would consider using Metropolitan Statistical Areas (MSAs) and non-MSA portions of a state, Combined Statistical Areas (CSAs), or another definition of regionally-based statistical areas, or the ACO's county-level service area.

For purposes of this proposed rule, we consider an ACO's region to be synonymous with its service area from which it derives its assigned beneficiaries.

Further, as discussed in this section of the proposed rule, issues related to the definition

of an ACO's regional service area include: (1) the selection of the geographic unit of measure to define this area; (2) identification of the population of beneficiaries to include in this area; and (3) calculation of the FFS expenditures for this area. A fundamental concept underlying our consideration of these issues is that the definition of an ACO's regional service area bear a relationship to the area of residence of the ACO's assigned beneficiaries. In some cases, an ACO's assigned beneficiary population may span multiple geographic boundaries, for example in cases where an ACO provides services to beneficiaries residing in multiple counties within a single state and/or multiple states.

(2) Proposals for Defining the ACO's Regional Service Area

We considered the geographic unit of measure to use in defining an ACO's regional service area for the purpose of determining the corresponding regional FFS expenditures to be used in calculations based on regional spending in the modified approach to establishing, adjusting and updating the ACO's rebased historical benchmark, discussed in this proposed rule. These regional FFS expenditures will be used in determining a regional adjustment to an ACO's rebased historical benchmark and in calculating growth rates of regional spending used in establishing and updating the ACO's rebased historical benchmark, which are described later in this proposed rule. We considered the stability of the definition of the geographic unit of measure, specifically: whether it is a legal or statistical area defined according to uniform national criteria by the U.S. government (for example, by the U.S. Bureau of the Census); whether the area has boundaries that do not change frequently; and CMS' use of the area in other Medicare operations. Core Based Statistical Areas (CBSAs), MSAs, and CSAs are delineated by OMB and are the result of the application of published standards to Census

Bureau data. Other options for defining regional service areas, for example, Hospital Referral Regions as defined by the Dartmouth Institute, may have certain advantages in terms of linking markets together by utilization patterns as opposed to, for example, commuting patterns used by the Census Bureau to define CSAs. However, such definitions are not governmentally maintained, may change over time, and are not otherwise directly utilized for FFS Medicare payment. Of the options considered, definitions of counties, states and territories are the most stable.

We also considered whether the geographic unit is used in other CMS operations. MSAs and rest of state areas are used by CMS for the hospital wage index. Geographic practice cost indices (GPCIs) used to adjust payments for physicians' services are based on 89 Medicare localities, which are either state-wide or combination MSA and rest-of-state areas. There is precedent in the Medicare program for using county-level data to set cost targets for value based purchasing initiatives. CMS used counties to define the service areas of Physician Group Practice (PGP) demonstration sites (a predecessor of CMS' ACO initiatives) and used Parts A and B spending by county as part of setting benchmarks for these organizations. CMS also uses county-level FFS expenditure data, in combination with other adjustments, to establish the benchmarks used for setting local Medicare Advantage (MA) rates. However, under the MA program, special payment areas apply to ESRD enrollees. ESRD payments are determined using State capitation rates for enrollees in dialysis and transplant status (See Medicare Managed Care Manual, Chapter 8 - Payments To Medicare Advantage Organizations, available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c08.pdf>). Currently, CMS produces quarterly and annual reports for Shared Savings Program ACOs that include aggregate

data on distribution of assigned beneficiary residence by county.

We believe county-level data offer a number of advantages over the other options (CBSA, MSA, CSA, State/territory). Counties tend to be stable regional units compared to some alternatives, as the definition of county borders tends not to change. Further, the agency has experience with identifying populations of beneficiaries by county of residence and calculating county-level rates based on their costs. In terms of determining regional costs, smaller areas (such as counties) better capture regional variation in Medicare expenditures, and allow for more customized regional definitions for each ACO, but risk being dominated by expenditures from a single ACO or group of ACOs, which could potentially reduce ACO benchmarks in clustered markets. We can guard against the potential bias from this effect by using a sufficiently large county-based population, as discussed in section II.A.2.b.3. of this proposed rule.

Therefore, we considered developing county FFS rates based on Parts A and B spending by county. We considered the fact that some commenters responding to the December 2014 proposed rule urged CMS to more closely align the Shared Savings Program with MA when adopting a benchmarking approach that accounts for regional costs. For instance, MedPAC's longer term vision for the program's benchmarking methodology included achieving equity among ACOs in a geographic market and rewarding efficiency across payment models, including FFS Medicare, the Shared Savings Program, and MA. Use of county-level FFS data in calculating expenditures for an ACO's regional service area would permit ACOs to be viewed as being on the spectrum between traditional FFS Medicare and MA, a concept some commenters and stakeholders have urged CMS to articulate. Use of county FFS expenditure data, which

are publicly available, would allow for increased transparency in ACO benchmark calculations and would ease ACOs' and stakeholders' access to data for use in modeling and predictive analyses. We would make adjustments to county FFS expenditure data to assure parity between the calculation of these expenditures and calculations of ACO benchmark and performance year expenditures as currently specified under the Shared Savings Program regulations by excluding indirect medical education (IME) payments, disproportionate share hospital (DSH) payments and uncompensated care payments, and by including beneficiary-identifiable payments under a demonstration, pilot or time limited program as discussed in section II.A.2.e. of this proposed rule.

Additionally, consistent with the approach used in MA, we believe the use of state-wide values for the ESRD population is appropriate given the small numbers of ESRD beneficiaries residing in many U.S. counties. Use of values for ESRD beneficiaries at the county level, based on very small numbers, would likely lead to greater instability of county-level expenditures for the ESRD population than for the other larger populations (disabled, aged/dual eligible and aged/non-dual eligible beneficiaries) considered in the program. This concern is particularly acute for ACOs operating in rural areas that tend to be more sparsely populated. We believe use of statewide values, for all ESRD beneficiaries residing in any county within the state, will be more statistically stable.

We propose to determine an ACO's regional service area by the counties of residence of the ACO's assigned beneficiary population. Furthermore, we propose to define regional costs as county FFS expenditures as determined according to the discussion later in this section of the proposed rule and adjusted to assure parity with the

calculation of ACO benchmark and performance year expenditures as specified under the Shared Savings Program regulations (as discussed in greater detail in section II.A.2.e. of this proposed rule). These calculations will be undertaken separately according to the following populations of beneficiaries (identified by Medicare enrollment type): ESRD, disabled, aged/dual-eligible, aged/non-dual eligible. Further, we propose to determine expenditures for ESRD beneficiaries statewide, and apply these amounts consistently to each county within a state. We seek comment on these proposals and on the alternatives for defining the ACO's regional service area, specifically use of CBSA, MSA, CSA or State/territory designations. These proposals are reflected in our proposed addition of a new definition of "ACO's regional service area" to § 425.20 and in a proposed new regulation at § 425.603 describing the calculations that would be used in resetting an ACO's historical benchmark for a second or subsequent agreement period.

(3) Proposals for Establishing the Beneficiary Population Used to Determine Expenditures for an ACO's Regional Service Area

The population that is the basis for calculating regional FFS costs must be sufficiently large to produce statistically stable mean expenditure estimates (avoiding biases that result from small numbers), and must be representative of the demographic mix, health status and cost trends of the beneficiary population within the ACO's regional service area. Therefore, we considered whether the calculation of regional FFS costs for an ACO's regional service area should include or exclude the costs for the ACO's assigned beneficiary population. While including these ACO-assigned beneficiaries results in a larger reference population for calculating regional costs, some stakeholders have expressed concern that doing so will capture the impact of the ACO's efforts to

coordinate care and reduce expenditures for the FFS population it treats and result in relatively lower regional expenditures being used for setting its benchmark.

The following points informed our consideration of this issue:

- Most individual ACO assigned beneficiary populations only make up a small fraction of the FFS beneficiaries in an ACO's regional service area. For example, we found that the rate at which an ACO's assigned population comprised its regional FFS population² ranged from 0.5 percent (minimum) to 57 percent (maximum), with a median of 12 percent.

- In cases where an ACO's assigned population makes up a large portion of the population of its region, removal of the ACO's assigned beneficiaries from the regional FFS population would limit the comparison population and may bias results.

- Removing an ACO's assigned population would add both complexity and volatility to calculations particularly in circumstances where it results in small numbers of beneficiaries remaining in the regional FFS population.

- Including beneficiaries who are not eligible to be assigned to an ACO in the regional FFS population could bias calculations of regional expenditures. For example, including Medicare FFS beneficiaries who have not utilized services ("non-utilizers") in these calculations would result in relatively lower per capita expenditures for the regional FFS population.

Based on this analysis, we concluded that attempting to identify regional FFS expenditures for only non-ACO beneficiaries (or customizing the calculation of regional

² The product of the ACO's proportion of total assigned beneficiaries in a county (in relation to all other counties where its beneficiaries reside), and the percent of the ACO's assigned population comprising the county's FFS population.

FFS expenditures for each ACO by excluding its own beneficiaries) would add significant complexity and create potential bias. Furthermore, excluding the ACO's assigned beneficiaries from the population used to determine regional FFS expenditures may also produce biased results where an ACO tends to serve beneficiaries of a particular Medicare enrollment type, demographic or socio-economic status (for example, ACOs serving largely dual-eligible populations) and when an ACO tends to dominate (serve a large proportion of FFS beneficiaries) in a region. In order to address the latter situation, we considered expanding the scope of an ACO's region (for example, by including adjoining counties) to allow the ACO's regional service area to include a greater mix of beneficiaries who are not assigned to the ACO. However, we believe that this approach may be challenging to apply consistently and accurately given the potential for variation of populations across and within regional areas, and a potentially cumbersome policy to maintain as ACOs continue to develop across the country. In addition, this type of policy would require that we establish a threshold to determine whether an ACO is sufficiently dominant in its region to warrant an expansion of its regional service area. We are concerned that application of such a threshold may encourage ACO decision making based on the ACO's relationship to the threshold (for instance decisions related to an ACO's structure or operations, particularly with respect to its composition of ACO participants and the beneficiaries it serves), either to remain below or exceed the threshold to yield a more favorable benchmark.

Several elements of Shared Savings Program financial calculations are based on expenditures for all Medicare FFS beneficiaries as opposed to the expenditures only for the ACO's assigned beneficiary population, as discussed further in section II.A.2.e. of

this proposed rule. For example, we use all FFS beneficiaries in calculating the following: the growth rates used to trend forward expenditures during the benchmark period; the projected absolute amount of growth in national per capita expenditures for Parts A and B services used to update the benchmark; the completion factors applied to benchmark and performance year expenditures; and the truncation thresholds set at the 99th percentile of national Medicare FFS expenditures. To maintain consistency across program calculations, we considered using all FFS beneficiaries in determining expenditures for the ACO's regional service area. However, we believe that continuing to include expenditures for all FFS beneficiaries would introduce bias into the calculations of the ACO's regional service area expenditures. For one, the overall FFS population will include beneficiaries who are not eligible for assignment to ACOs. In current calculations, we believe this bias is mitigated to some extent by the large size of the national Medicare FFS population. Regional FFS expenditures, calculated based on relatively smaller populations, may be more susceptible to the influence of this bias. For example, in counties where the health status of the overall beneficiary population leads more beneficiaries to be non-utilizers of services a bias in the direction of relatively lower regional expenditures may be more pronounced. On the other hand, a bias in the direction of relatively higher regional expenditures may be more pronounced in counties where there are established patterns of accessing primary care services through specialists who are not the basis for assignment. (We note that recent changes in the assignment algorithm have narrowed the use of services furnished by specialty physicians in the assignment methodology (see 80 FR 32749 through 32754).) Ultimately, such differences could factor more prominently in certain counties that are used to compute an

ACO's regional service area expenditures. Secondly, we believe that these biases may also be more pronounced when calculating the amount of per capita regional FFS expenditures in a particular year as opposed to a factor reflecting change in growth in expenditures across periods in time.

To address this concern, we considered limiting the beneficiary population included for purposes of calculating expenditures for an ACO's regional service area to Medicare FFS beneficiaries who could be considered for assignment to ACOs. As described in greater detail in section II.A.2.e. of this proposed rule, we identify the pool of beneficiaries who are eligible to be assigned to an ACO as those beneficiaries that have received at least one primary care service from a physician in the ACO who is a primary care physician or who has as primary specialty designation included in § 425.402(c) that is utilized in the assignment methodology. We will then use this population of eligible beneficiaries to determine the beneficiaries who will be assigned to an ACO based on the two-step assignment process under § 425.402(b). We considered applying a similar logic to identifying the population of FFS beneficiaries that should be considered in determining expenditures for an ACO's regional service area. That is: if a beneficiary gets at least one primary care service from any Medicare-enrolled physician who is a primary care physician or who has one of the primary specialty designations that are used for purposes of assignment under the Shared Savings Program, the beneficiary would be included in the calculation of expenditures for the ACO's regional service area. We refer to this population as "assignable beneficiaries."

We also considered how to weight the ACO's regional costs in cases where an ACO's assigned population spans multiple counties. ACOs often serve beneficiaries in

multiple counties within a state or across several states, with some ACOs being an aggregation of providers located in different parts of the country. We currently provide ACOs with a quarterly report showing the distribution of the ACO's assigned beneficiary residence by county where the ACO's service area is defined as counties with at least 1 percent of assigned beneficiaries. Based on assignment data from Quarter 1 2015 for all active ACOs in the Shared Savings Program, ACOs served beneficiaries residing in between 2 and 32 counties, with a median of 8 counties served. Given the geographic spread of some ACOs' assigned populations, we believe it will be important to weight an ACO's regional expenditures relative to the proportion of its assigned beneficiaries in each county. Absent this weighting, we could overstate or understate the influence of the expenditures for a county where relatively few or many of an ACO's assigned beneficiaries reside.

Taking these considerations into account, we propose using all assignable beneficiaries, including ACO-assigned beneficiaries, in determining expenditures for the ACO's regional service area in order to ensure sufficiently stable regional mean expenditures. We propose to define the ACO's regional service area to include any county where one or more assigned beneficiaries reside. We also propose to include the expenditures for all assignable FFS beneficiaries residing in those counties in calculating county FFS expenditures by enrollment type that will be used in the ACO's regional cost calculations (discussed in detail in sections II.A.2.c. and II.A.2.d. of this proposed rule). Further, we propose to weight county-level FFS expenditures by 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. These proposals are reflected in the proposed addition of new definitions for “assignable beneficiary” and “ACO’s regional service area” to § 425.20, and in the proposed new regulation at § 425.603.

We believe this proposed approach will result in the most accurate and predictable regional expenditure factor for each ACO. However, we would monitor for cases where an ACO tends to serve a large proportion of FFS beneficiaries in its region, and consider the effect of these circumstances on ACO benchmarks. If warranted, we would explore developing adjustments to the definition of an ACO’s regional service area to account for this circumstance in future rulemaking. We also seek comment on alternatives to proposed use of assignable beneficiaries in establishing the expenditures for an ACO’s regional service area, including use of all Medicare FFS beneficiaries in determining these expenditures.

(4) Proposals for Determining County FFS Expenditures

We considered how to calculate county FFS expenditures for use in factors based on regional FFS expenditures described in this proposed rule. Consistent with proposals described in other sections of this proposed rule, we are proposing the following approach to calculating county FFS expenditures:

- Determine county FFS expenditures based on the expenditures of the assignable population of beneficiaries in each county, where assignable beneficiaries are identified for the 12-month period corresponding to the applicable calendar year (see sections II.A.2.b.3. and II.A.2.e. of this proposed rule). We will make separate expenditure calculations according to the following populations of beneficiaries (identified by Medicare enrollment type): ESRD, disabled, aged/dual-eligible,

aged/non-dual eligible.

- Calculate assignable beneficiary expenditures using the payment amounts included in Part A and B FFS claims with dates of service in the 12-month calendar year for the relevant benchmark or performance year, allowing for a 3-month claims run out and applying a completion factor (see section II.A.2.e.2. of this proposed rule). The completion factor will be calculated based on national FFS assignable beneficiary expenditures (see section II.A.2.e. of this proposed rule).

- ++ These calculations will exclude IME, DSH, and uncompensated care payments (see section II.A.2.e.2. of this proposed rule).

- ++ These calculations will take into consideration individually identifiable payments made under a demonstration, pilot or time limited program (see section II.A.2.e.2. of this proposed rule).

- Truncate a beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile of national Medicare FFS assignable beneficiary expenditures as determined for the relevant year, in order to minimize variation from catastrophically large claims (see section II.A.2.e. of this proposed rule). We would determine truncation thresholds separately for each of the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible).

- Adjust county FFS expenditures for severity and case mix of assignable beneficiaries in the county using prospective CMS- Hierarchical Condition Category (HCC) risk scores (see section II.A.2.e.2. of this proposed rule). We would determine average risk scores separately for each of the four Medicare enrollment types (ESRD, disabled, aged/dual eligible, aged/non-dual eligible).

Consistent with the discussion in section II.A.2.b.2. of this proposed rule, we propose to compute state-level per capita expenditures and average risk scores for the ESRD population in each state and to apply those state-level values to all counties in a state. We believe this approach addresses issues associated with small numbers of ESRD beneficiaries in certain counties that can lead to statistical instability in expenditures for this complex population.

We anticipate making county level data used in Shared Savings Program calculations publicly available annually. For example, a publicly available data file would indicate for each county: average per capita FFS assignable beneficiary expenditures and average risk scores for all assignable beneficiaries by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible). In addition, as described in the regulatory impact analysis section of this proposed rule, we are making publicly available a data file with county-level expenditure and risk score data to support modeling of the proposed changes to the benchmark rebasing methodology.

We propose to include this approach for determining county FFS expenditures in a new regulation at § 425.603. We seek comment on these proposals as well as any additional factors we would need to consider in calculating risk adjusted county FFS expenditures.

c. Proposals for Applying Regional Expenditures to the ACO's Rebased Benchmark

(1) Background

The discussion of benchmark alternatives in the recent rulemaking underscores the array of options for incorporating regional expenditures in ACO benchmarks (see the

December 2014 proposed rule at 79 FR 72839 through 72843; see the June 2015 final rule at 80 FR 32791 through 32796). While we agree with commenters on the benefits of incorporating regional expenditures in rebased benchmarks, we are interested in moving to an alternative rebasing approach that builds on the program's existing benchmarking methodology established under the authority of section 1899(d)(1)(B)(ii) of the Act and codified in the Shared Savings Program regulations at § 425.602. Over 400 ACOs have voluntarily entered the Shared Savings Program under the financial models (Track 1 and Track 2) established in the November 2011 final rule and as modified by the June 2015 final rule (adding a choice of Track 3 for agreement periods beginning January 1, 2016). Further, 147 ACOs with 2012 and 2013 agreement start dates elected to continue their participation in the program for a second 3-year agreement effective January 1, 2016 to which the current methodology for resetting the ACO's benchmark applies (including the rebasing modifications finalized with the June 2015 final rule). The value proposition of the program's financial models, which is largely determined by the methodology used to establish ACO benchmarks, is an important consideration for organizations deciding whether to engage (or continue to engage) in this new approach to the delivery of health care. Therefore, in considering how to incorporate regional expenditures into the benchmarking methodology, we believe that building from the existing benchmarking methodology will help maintain the stability of the program and ultimately result in revised policies that are more easily understood by ACOs and program stakeholders, and more readily implemented by CMS.

Principally, we considered using the Secretary's discretion under section 1899(d)(1)(B)(ii) of the Act to adjust the historical benchmark by "such other factors as

the Secretary determines appropriate” in order to incorporate regional FFS expenditures into the rebased historical benchmark. In this proposed rule we discuss two approaches to calculating an adjustment to an ACO’s rebased historical benchmark to account for regional FFS expenditures for the ACO’s regional service area, and describe how the adjustment would be applied to the rebased historical benchmark

We believe the plain language of section 1899(d)(1)(B)(ii) of the Act demonstrates Congress’ intent that the benchmark established for a Shared Savings Program ACO would reflect the ACO’s historical expenditures in the 3 most recent years prior to the start of the ACO’s agreement period. Congress also recognized that this historical benchmark should be adjusted “for beneficiary characteristics and such other factors as the Secretary determines appropriate.” Therefore, to the extent an ACO’s rebased benchmark continues to be based on the ACO’s historical expenditures in the 3 years preceding the start of the new agreement period, we believe adjusting those historical expenditures to account for regional FFS expenditures for the ACO’s regional service area falls within the Secretary’s discretion to make adjustments to the historical benchmark for “other factors” under section 1899(d)(1)(B)(ii) of the Act.

Currently, CMS makes several adjustments to an ACO’s historical benchmark under the Secretary’s discretion under section 1899(d)(1)(B)(ii) of the Act, including to:

- (1) adjust benchmark year expenditures to exclude IME and DSH payments (§ 425.602(a)(1)(i));
- (2) adjust the historical benchmark for the addition and removal of ACO participants (§ 425.602(a)(8));
- (3) adjust the rebased historical benchmark to account for the average per capita amount of savings generated during the ACO's previous agreement period (§ 425.602(c)(2)(ii));
- and (4) adjust the historical benchmark

for changes in demographics and health status of the ACO's performance year assigned beneficiary population (§§ 425.604(a)(1) through (3), 425.606(a)(1) through (3), 425.610(a)(1) through (3)). For the reasons discussed in the June 2015 final rule, we believe it is appropriate to further adjust ACO historical benchmarks to reflect regional FFS expenditures (see 80 FR 32791 through 32796). Further, in relation to use of regional FFS expenditures in developing the ACO's rebased benchmark, for the reasons discussed in section II.A.2.c.2. of this proposed rule we believe it appropriate to forgo making an additional adjustment to account for savings generated by the ACO in its prior agreement period (see 80 FR 32796).

Table 2 summarizes the proposals discussed in this section of the proposed rule, including the percentage (weight) to be used in calculating the amount of the adjustment for regional FFS expenditures to be applied to the ACO's rebased historical benchmark, using regional (instead of national) trend factors in establishing an ACO's rebased historical benchmark, using regional (instead of national) FFS expenditures to update the ACO's benchmark for each performance year, and the timing of the applicability of the proposed new rebasing methodology.

(2) Proposals for Adjusting the Reset ACO Historical Benchmark to Reflect Regional FFS Expenditures

Our proposal for adjusting an ACO's rebased historical benchmark to reflect regional FFS expenditures for the ACO's regional service area expands on the approaches initially outlined in the June 2015 final rule (see 80 FR 32795 through 32796). The discussion elsewhere in this proposed rule describes two options for calculating the regional FFS adjustment, as well as the calculation of the ACO's rebased

historical benchmark. The first option would be to calculate the adjustment based on a regionally-trended version of the ACO's prior historical benchmark. The second option describes an alternative approach, based on a regional average determined using county FFS expenditures.

Under both options, we would calculate the ACO's rebased historical benchmark using the current rebasing methodology established in the June 2015 final rule under which an ACO's rebased benchmark is calculated based on the 3 years prior to the start of its current agreement period. Consistent with the current policy we would equally weight the 3 benchmark years. However, in trending forward benchmark year (BY) 1 and BY2 expenditures to BY3 dollars, we would use regional growth rates (instead of national growth rates) for Parts A and B FFS expenditures, as discussed in section II.A.2.d. of this proposed rule.

Furthermore, in calculating the ACO's rebased historical benchmark, we would not apply the current adjustment to account for savings generated by the ACO under its prior agreement period. We have observed that for ACOs generating savings, an alternative rebasing methodology that accounts for regional FFS expenditures would generally leave a similar or slightly greater share of measured savings in an ACO's rebased benchmark for its ensuing agreement period. By contrast, for ACOs generating losses, an alternative rebasing methodology that accounts for regional FFS expenditures would tend to carry forward a significant portion of measured losses into their rebased benchmarks and push benchmarks lower than the current rebasing policy. Therefore, in transitioning to a benchmark rebasing methodology that incorporates an adjustment for regional FFS expenditures, we believe it is important to forgo the current adjustment to

account for shared savings generated by the ACO under its prior agreement period. (For further information, see section IV.E. of this proposed rule.)

We considered two options for calculating regional expenditures as an input into an adjustment that we would apply to the ACO's rebased historical benchmark. First, we considered calculating a regionally-trended amount developed using the ACO's historical benchmark from an earlier agreement period adjusted by a regional trend factor based on changes in regional expenditures for each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) for the most recent year prior to the start of the ACO's current agreement period and for changes in health status and demographic factors of the assigned patient population. The calculation of the regionally-trended amount would generally involve the following steps:

- Use the ACO's historical benchmark from a prior agreement period, adjusted to account for ACO Participant List changes. We would use an expenditure ratio to adjust the benchmark for changes in ACO participant (TIN) composition, as described in section II.B. of this proposed rule.

- Risk adjust to reflect changes in the health status of the ACO's assigned beneficiaries from that prior agreement period to the most recent year prior to the start of the new agreement period.

- Trend the historical benchmark to the most recent year prior to the start of the new agreement period based on risk adjusted county FFS expenditures for the ACO's regional service area. As discussed in section II.A.2.b. of this proposed rule, we would determine regional FFS expenditures for an ACO's regional service area, using an approach that weights county expenditures according to the proportion of the ACO's

assigned beneficiaries residing in each county.

- Use weighting to reflect changes in the proportion of each of the four Medicare enrollment types from the prior agreement period to the most recent year prior to the start of the new agreement period. Specifically, we would weight the regionally-trended expenditures by the proportions of the ACO's assigned beneficiaries in each Medicare enrollment type for benchmark year 3 of the ACO's new agreement period.

In the June 2015 final rule (80 FR 32796), we also indicated that we were considering an alternative approach based on regional average spending to transition ACOs to benchmarks based on regional FFS costs. Under this approach, we would calculate a regional FFS adjustment to the ACO's rebased historical benchmark using regional average expenditures. Calculation of regional average expenditures would generally involve the following key steps:

- Calculate risk adjusted regional per capita FFS expenditures using county level Parts A and B expenditures for the ACO's regional service area for each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible); weighted based on the proportion of ACO assigned beneficiaries residing in each county for the most recent benchmark year. We describe the risk adjustment approach that would be used in these calculations to adjust for differences in health status between an ACO and its regional service area in section II.A.3. of this proposed rule.

- Weight the resulting regional expenditures by the proportion of assigned beneficiaries for the most recent benchmark year for each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible).

In comparing the features of the two options, the regionally-trended amount and

regional average expenditures, we believe using regional average expenditures offers a preferred approach. While we believe both options would avoid penalizing ACOs that improve their spending relative to that of their region, the approach of using regional average expenditures would not depend on older historical data in calculations as would be required under the alternative involving calculation of a regionally-trended amount. In general, from an operational standpoint, using a regional average as part of calculating regional FFS expenditures for an ACO's regional service area is anticipated to be easier for ACOs and stakeholders to understand as well as for CMS to implement in comparison to the alternative considered, and would more closely align with the MA rate-setting methodology.

We also considered how the adjustment based on regional FFS expenditures should be applied to the ACO's rebased historical benchmark. Our preferred approach is to use the following steps to adjust the ACO's rebased historical benchmark:

- Calculations of the ACO's rebased historical benchmark and regional average expenditures, as described previously in this section of the proposed rule, would result in average per capita values of expenditures for each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible).
- For each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) we would determine the difference between the per capita regional average amount and the average per capita amount of the ACO's rebased historical benchmark. These values may be positive or negative. For example, for a particular Medicare enrollment type, if the value of the ACO's rebased historical benchmark is greater than the regional average amount, the difference between these

values will be expressed as a negative number.

- Multiply the resulting difference, for each Medicare enrollment type by a percentage determined for the relevant agreement period. The value of this percentage is described in detail later in this section of the proposed rule. 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.

- Add the adjustment to the ACO's rebased historical benchmark, adding the adjustment amount for the Medicare enrollment type to the truncated, trended and risk adjusted average per capita value of ACO's rebased historical benchmark for the same Medicare enrollment type.

- Multiply the 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 of the rebased historical benchmark.

- Sum expenditures across the four Medicare enrollment types to determine the ACO's adjusted rebased historical benchmark.

Therefore, we are proposing to calculate the ACO's rebased benchmark using historical expenditures for the beneficiaries assigned to the ACO in the 3 years prior to the start of its current agreement period, applying equal weights to the benchmark years, but not accounting for shared savings generated by the ACO in its prior agreement period. We propose to adjust the ACO's rebased historical benchmark to reflect risk adjusted regional average expenditures, based on county FFS expenditures determined for the ACO's regional service area. We propose to revise section § 425.602 in order to

limit the scope of the provision to establishing, adjusting, and updating the benchmark for an ACO's first agreement period. We propose to specify in a new regulation at § 425.603 how the benchmark would be reset for a subsequent agreement period, including the proposed methodology for adjusting an ACO's rebased historical benchmark to reflect FFS expenditures in the ACO's regional service area in the ACO's second or subsequent agreement period starting on or after January 1, 2017. Further, we propose to make conforming and clarifying revisions to the provisions of § 425.602, including to: revise the title of the section; remove paragraph (c) from § 425.602 and incorporate this paragraph in the new regulation at § 425.603; and to add a paragraph that describes the adjustments made to the ACO's historical benchmark during an ACO's first agreement period to account for changes in severity and case mix for newly and continuously assigned beneficiaries as presently specified under § 425.604, § 425.606, and § 425.610. We also propose to make a clarifying change to § 425.20, to specify that the acronym "BY" stands for benchmark year.

We seek comment on our proposals and on the alternative approach of using a regionally-trended amount developed from the ACO's historical benchmark for a prior agreement period instead of regional average expenditures to adjust the ACO's rebased historical benchmark. We are particularly interested in comments on the design of the approaches for calculating the regional adjustment to the ACO's rebased historical benchmark described in this section of the proposed rule, as well as any concerns about implementing the proposed regional adjustment.

(3) Proposals for Transitioning to a Higher Weight in Calculating the Adjustment for Regional FFS Expenditures

As discussed in the June 2015 final rule, we considered applying a weight of 70 percent on the regionally-trended component of the rebased benchmark. We explained our initial belief that this weight would serve the goal of providing strong incentives for ACOs to achieve savings and to continue to participate in the Shared Savings Program (see 80 FR 32796). In developing the policies for this proposed rule, we considered both the potential positive and negative consequences of quickly transitioning to use of a greater weight in calculating the regional adjustment to ACOs' rebased historical benchmarks.

We believe placing a greater weight on regional expenditures in adjusting an ACO's historical benchmark will encourage existing low spending ACOs in higher spending and/or higher growth regions to enter and continue their participation in the Shared Savings Program. Stakeholders have expressed concerns that the original rebasing methodology promulgated in the November 2011 final rule, in which an ACO's benchmark is rebased using the ACO's historical expenditures for the most recent 3 years corresponding to its prior agreement period, absent additional adjustment, penalizes an ACO for past achievement of savings by reducing its benchmark for the following agreement period (see 80 FR 32786). In the June 2015 final rule, we expressed our view that the benchmarking methodology should be revised to help ensure that an ACO that has previously achieved success in the program will be rebased under a methodology that encourages its continued participation in the program (see 80 FR 32788). Further, we have noted the importance of quickly moving to a benchmark rebasing approach that

accounts for regional FFS expenditures and trends in addition to the ACO's historical expenditures and trends (see 80 FR 32795 through 32796).

We are also concerned that existing low spending ACOs operating in regions with relatively higher spending and/or higher growth in expenditures may be positioned to generate savings under the proposed methodology because of the regional adjustment to their rebased historical expenditures rather than as a result of actual gains in efficiency, creating an opportunity for arbitrage. In particular, we are concerned about the potential for ACOs to alter their healthcare provider and beneficiary compositions or take other such actions in order to achieve more favorable performance relative to their region without actually changing their efficiency. We anticipate these effects to be more pronounced, the larger the percentage that is applied to the difference between the regional average expenditures for the ACO's regional service area and the ACO's rebased historical expenditures when calculating the regional adjustment. However, we believe there is uncertainty around the magnitude of these possible negative consequences of adjusting the ACO's rebased benchmark based on regional expenditures in the ACO's regional service area which have yet to be observed. We believe these concerns are likely to be outweighed by the benefits of encouraging more efficient care through a benchmark rebasing methodology that encourages continued participation by ACOs that are efficient relative to their regional service area by placing greater weight on regional expenditures when resetting the ACO's benchmark over subsequent agreement periods. The use of a higher percentage in calculating the regional adjustment would create strong incentives for higher spending ACOs to be more efficient relative to their regional service areas while also improving the quality of care provided to their

beneficiaries. Furthermore, this approach will also ensure that ACOs' rebased benchmarks continue to reflect in part their historical spending.

To balance these concerns, we considered a phased approach to transitioning to greater weights in calculating the adjustment amount, expressed as a percentage of the difference between regional average expenditures for the ACO's regional service area and the ACO's rebased historical expenditures. We considered how quickly or slowly to phase-in the maximum weight. Taking the suggestions of some stakeholders, including commenters on the December 2014 proposed rule, such as MedPAC (describing phase-in to a regional benchmark to be completed by 2021, if implemented in 2016) (see 80 FR 32792; see also letter from Glenn M. Hackbarth, J.D., Chairman, Medicare Payment Advisory Commission to Ms. Marilyn Tavenner, Administrator, Centers for Medicare and Medicaid Services, regarding File code CMS-1461-P (February 2, 2015) (available through www.regulations.gov, comment tracking number 1jz-8gz6-jbt1)), we considered increasing the weight used in calculating the adjustment over time, making an ACO's benchmark gradually more reflective of expenditures in its region and less reflective of the ACO's own historical expenditures. We considered a phase-in approach that includes the following features:

- Maintain the current methodology for establishing the benchmark for an ACO's first agreement period in the Shared Savings Program based on the historical expenditures for beneficiaries assigned to the ACO with no adjustment for expenditures in the ACO's regional service area in order to provide continued stability to the program and the momentum for attracting new organizations. As over 400 ACOs have voluntarily entered the program under this methodology we believe the current methodology is an

important part of facilitating entry into the program by organizations located throughout the nation that have differing degrees of experience with accountable care models and have varying provider compositions.

- Increase the percentage used in calculating the regional adjustment amount, applied to the ACO's rebased historical benchmark (determined as specified in this proposed rule), over subsequent agreement periods. For ACOs entering their second agreement period, in calculating the regional adjustment we would take 35 percent of the difference between the ACO's regional service area expenditures and the ACO's rebased historical benchmark expenditures. For ACOs entering their third or subsequent agreement period, the percentage used in this calculation would be set at 70 percent unless the Secretary determines a lower weight should be applied, as specified through future rulemaking.

In making a determination of whether a lower weight should be used in calculating the adjustment, the Secretary would assess what effects the regional adjustment (and other modifications to the program made under this rule) are having on the Shared Savings Program, considering factors such as but not limited to: the effects on net program costs; the extent of participation in the Shared Savings Program; and the efficiency and quality of care received by beneficiaries. As part of this determination, the Secretary may also take into account other factors, such as the effect of implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) on the Shared Savings Program by incentivizing physicians and certain other practitioners to participate more broadly in alternative payment models.

Such a determination could potentially occur in advance of the first application of

this higher percentage. For example, the determination could be made in advance of the agreement period beginning January 1, 2020, which is the start of the third agreement period for ACOs that entered the program in January 2014 and the first group of ACOs to which the revised rebasing methodology discussed in this proposed rule would apply. Any necessary modifications to program policies as a result of the Secretary's determination, such as reducing the long-term weight used in calculating the regional adjustment below 70 percent or making other program changes (for example, refinements to the risk adjustment methodology as described in section II.A.2.e.3. of this proposed rule) would be proposed in future rulemaking, such as through the calendar year (CY) 2020 Physician Fee Schedule rule. Subsequently, we would periodically assess the effects of the regional adjustment over time and address any needed modifications to program policies in future rulemaking.

- As discussed in section II.A.2.f. of this proposed rule, for ACOs that started in the program in 2012 and 2013 and started their second agreement period on January 1, 2016, we would apply this phased approach when rebasing for their third and fourth agreement periods.

We believe this phased approach to moving to a higher percentage in calculating the adjustment for regional expenditures would give ACOs sufficient notice of the transition to benchmarks that reflect regional expenditures. Further, we believe this approach to phasing in the use of a greater percentage to calculate the regional adjustment provides a smoother transition for ACOs to benchmarks reflective of regional FFS expenditures, giving ACOs more time to prepare for this change and therefore ultimately maintaining the stability of ACOs, the Shared Savings Program and the markets where

ACOs operate.

Alternatively, we considered using a percentage set at 50 percent in calculating the regional adjustment amount for ACOs entering their third and subsequent agreement periods (under the phased approach previously described in this section of the proposed rule). We also considered taking a more gradual approach to transitioning to the use of a higher percentage in calculating the adjustment. For instance, in the ACO's second agreement period the percentage used in calculating the regional adjustment would be set at 35 percent; in the ACO's third agreement period the percentage would be set at 50 percent; and in the ACO's fourth and subsequent agreement periods, the percentage would be set at 70 percent unless the Secretary determines a lower weight should be applied, as specified through future rulemaking. However, we prefer an approach which more quickly transitions to the use of a higher percentage in calculating the adjustment, as previously described, over the course of two rebasing periods (for example, the ACO's second and third agreement periods). We believe this faster transition to use of a higher percentage in calculating the adjustment would more quickly create incentives to drive the most meaningful change for ACOs under the Shared Savings Program, including ensuring the program more immediately encourages continued participation by ACOs that are efficient relative to their regional service area.

We also considered an approach that would be similar to the approach to phasing in regional costs described previously, except that we would begin to incorporate some information on an ACO's regional costs during an ACO's initial agreement period, for agreement periods beginning on or after January 1, 2017. In particular, rather than using national trends in FFS expenditures to trend benchmark year expenditures when

establishing the benchmark and to update the benchmark annually during the agreement period, we considered using regional FFS expenditures for both of these purposes for an ACO's first agreement period, similar to the approach we are proposing to use for subsequent agreement periods. We describe and seek comment on related considerations in sections II.A.2.d.2. and II.A.2.d.3. of this proposed rule. Under this alternative, the modified first agreement period benchmarking methodology would apply prospectively to new ACOs entering the program for their first agreement period on or after January 1, 2017. Such an approach has the advantage that it would generate benchmarks that would better measure the factors driving costs for any particular ACO based on the dynamics specific to its regional service area. This approach would also reduce the differences between the benchmarking methodology used in an ACO's first agreement period and the methodology used in subsequent agreement periods, potentially easing the transition between agreement periods. This approach has the potential disadvantage that it would represent a departure from the methodology used for earlier cohorts of ACOs.

Therefore, we are proposing a phased approach to moving to a higher weight in calculating the regional adjustment, ultimately reaching 70 percent, subject to assessment by the Secretary as discussed previously. We propose to incorporate the following proposed policies regarding the weight to be applied in determining the regional adjustment in a new regulation at § 425.603:

- Calculate the regional adjustment in the ACO's second agreement period by applying a weight of 35 percent to the difference between regional average expenditures for the ACO's regional service area and the ACO's rebased historical benchmark expenditures.

- In the ACO's third and subsequent agreement periods, the percentage used in this calculation would be set at 70 percent unless the Secretary determines a lower weight should be applied as specified through future rulemaking.

We seek comment on our proposed approach to phase in the weight used in calculating the regional adjustment. We are particularly interested in understanding commenters' thoughts and suggestions about the percentage that should be used in calculating the adjustment for regional FFS expenditures. We also seek comment on the alternatives we considered including: (1) limiting the weight used in the calculation of the adjustment to 50 percent (instead of 70 percent) in the ACO's third and subsequent agreement period; (2) a more gradual transition to use of a higher percentage in calculating the adjustment (such as 35 percent in the second agreement period, 50 percent in the third agreement period, and 70 percent in the fourth and subsequent agreement period); and (3) a phase-in approach that uses regional (instead of national) FFS expenditures to trend benchmark year expenditures when establishing and updating the benchmark during an ACO's first agreement period (for agreement periods beginning on or after January 1, 2017). We also seek comment on alternative approaches to address our concerns about selective program participation and arbitrage opportunities that would facilitate our use of a higher percentage in calculating the amount of the adjustment.

d. Proposals for Parity between Establishing and Updating the Rebased Historical Benchmark

(1) Background

In the initial rulemaking to establish the Shared Savings Program, we identified the need to trend forward the expenditures in each of the 3 years making up the historical

benchmark. As explained in earlier rulemaking, because the statute requires the use of the most recent 3 years of per-beneficiary expenditures for Parts A and B services for FFS beneficiaries assigned to the ACO to estimate the benchmark for each ACO, the per capita expenditures for each year must be trended forward to current year dollars before they are averaged using the applicable weights to obtain the benchmark (see 76 FR 19609). In the November 2011 final rule, we finalized an approach under § 425.602(a)(5) for trending forward benchmark expenditures based on national FFS Medicare growth rates for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible, aged/non-dual eligible (76 FR 67924 through 67925). We also explained that making separate calculations for specific groups of beneficiaries – specifically the aged/dual eligible, aged/non-dual eligible, disabled, and ESRD populations – accounts for variation in costs of these groups of beneficiaries, resulting in more accurate calculations (76 FR 67924). We considered using national, State or local growth factors to trend forward historical benchmark expenditures (76 FR 19609 through 19610, 76 FR 67924 through 67925). However, we concluded that using the national growth rate for Parts A and B FFS expenditures as a trend factor for establishing the historical benchmark offered a number of advantages over the alternatives considered, including the following:

- More consistent with the statutory methodology for updating an ACO's benchmark (see 76 FR 19610 and 76 FR 67924).
- Applies a single growth factor to all ACOs, regardless of their size or geographic area; allowing us to move toward establishing a national standard to calculate and measure ACO financial performance (see 76 FR 19610 and 76 FR 67925).

- Appropriately balanced concerns that benchmark trending should encourage participation among providers that are already efficient or operating in low cost regions without unduly rewarding ACOs in high-cost areas (see 76 FR 67925).

We discussed this last point in detail, considering the likely incentives for developing organizations to participate in the program that would result from a policy of using national growth rates to trend forward benchmark expenditures. We explained that the anticipated net effect of using the same trending factor for all ACOs would be to provide a relatively higher expenditure benchmark for low growth/low spending ACOs and a relatively lower benchmark for high growth/high spending ACOs. ACOs in high cost, high growth areas would therefore have an incentive to reduce their rate of growth more to bring their costs more in line with the national average; while ACOs in low cost, low growth areas would have an incentive to continue to maintain or improve their overall lower spending levels (see 76 FR 67925). We also explained that use of the national growth rate could also disproportionately encourage the development of ACOs in areas with historical growth rates below the national average (see 76 FR 19610). These ACOs would benefit from having a relatively higher benchmark, which would increase the chances for shared savings. On the other hand, ACOs in areas with historically higher growth rates above the national average would have a relatively lower benchmark, and might be discouraged from participating in the program (see 76 FR 19610).

In contrast, as we explained in the initial rulemaking to establish the Shared Savings Program, trending expenditures based on State or local area growth rates in Medicare Parts A and B expenditures may more accurately reflect the experience in an

ACO's area and mitigate differential incentives for participation based on location (see 76 FR 19610). We considered, but did not finalize, an option to trend the benchmark by the lower of the national projected growth rate or the State or the local growth rate (see 76 FR 19610 and 76 FR 67925). This option balanced providing a more accurate reflection of local experience with not rewarding historical growth higher than the national average. We believed this method would instill stronger saving incentives for ACOs in both high growth and low growth areas (see 76 FR 19610).

Section 1899(d)(1)(B)(ii) of the Act states that the benchmark shall be updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program, as estimated by the Secretary. Further, the Secretary's authority under section 1899(i)(3) of the Act, for implementing other payment models, allows for alternatives to using national expenditures for updating the benchmark, as long as the Secretary determines the approach improves the quality and efficiency of items and services furnished under Medicare and does not result in additional program expenditures.

In the initial rulemaking, we considered using the flat dollar amount equivalent to the absolute amount of growth in the national FFS expenditures to update the benchmark during an agreement period as specified under section 1899(d)(1)(B)(ii) of the Act. We also considered using our authority under section 1899(i)(3) of the Act to update the benchmark by the lower of the national projected absolute amount of growth in national per capita expenditures and the local/state projected absolute amount of growth in per capita expenditures (see 76 FR 19610 through 19611).

We explained our belief that use of a national update factor was the most

appropriate option in light of the following considerations:

- Congress demonstrated an interest in mitigating some of the regional differences in Medicare spending among ACOs by requiring the use of the flat dollar amount equivalent to the absolute amount of growth in national FFS expenditures to update the benchmark during the agreement period (76 FR 19610).

- ACOs in both high spending, high growth and low spending, low growth areas would have appropriate incentives to participate in the program (76 FR 19611).

In particular, we explained that using a flat dollar increase, which would be the same for all ACOs, provides a relatively higher expenditure benchmark for low growth, low spending ACOs and a relatively lower benchmark for high growth, high spending ACOs. Therefore, ACOs in high spending, high growth areas must reduce their rate of growth more (compared to ACOs in low spending, low growth areas) to bring their costs more in line with the national average (see 76 FR 19610). We also indicated that these circumstances could contribute to selective program participation by ACOs favored by the national flat-dollar update, and ultimately result in Medicare costs from shared savings payments that result from higher benchmarks rather than an ACO's care coordination activities (see 76 FR 19610 through 19611 and 19635).

In contrast, updating the benchmark by the lower of the national projected absolute amount of growth in national per capita expenditures and the local/state projected absolute amount of growth in per capita expenditures could instill strong saving incentives for ACOs in low-growth areas, as well as for ACOs in high-growth areas. Incorporating more localized growth factors reflects the expenditure and growth patterns within the geographic area served by ACO participants, potentially providing a more

accurate estimate of the updated benchmark based on the area from which the ACO derives its patient population (76 FR 19610).

Ultimately, we finalized our policy under § 425.602(b) to update the historical benchmark annually for each year of the agreement period based on the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program. Further, consistent with the final policies for calculating the historical benchmark (among other aspects of the Shared Savings Program's financial models) the calculations for updating the benchmark are made for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible, aged/non-dual eligible (76 FR 67926 through 67927).

In the December 2014 proposed rule, we sought comment on a benchmark rebasing alternative that would use regional FFS expenditures, instead of national FFS expenditures, to develop the historical benchmark trend factors and to update the benchmark during the agreement period (79 FR 72839). We sought comment on using this approach in combination with other alternatives for incorporating regional expenditures into ACO benchmarks, including transitioning ACOs from benchmarks based on their historical expenditures toward benchmarks based on regional FFS expenditures over the course of several agreement periods (79 FR 72841 through 72843). Some commenters were supportive of using a combination of approaches to incorporate regional expenditures into benchmarks. On the issue of which FFS expenditures should be the basis for trending the historical benchmark and updating the benchmark, some commenters expressed support for maintaining the current approach of using only national FFS expenditures, while others suggested using only regional FFS expenditures,

or a combination of factors based on regional and national FFS expenditures (see 80 FR 32794).

More specifically, some commenters encouraged CMS to reflect location-specific changes in Medicare payment rates in the benchmarks by using regional factors (based on regional FFS costs) in establishing and updating ACO-specific benchmarks. Other commenters supporting this approach explained that regional expenditures more accurately reflect the health status of populations (for risk adjustment), differences between rural and urban areas or market/regional differences more generally, and differences in beneficiaries' socioeconomic status. A commenter who supported use of regional costs in updating benchmarks indicated this would better address the effects of churn in the ACO's assigned population, which the commenter explained leads the ACO's population to become less reflective of its historical population and more reflective of its regional population. On the other hand, some commenters encouraged CMS to continue using factors based on national FFS costs to trend and update benchmarks. For example, a commenter expressed concern that using regional FFS expenditures instead of national FFS expenditures in establishing and updating the benchmark may further disadvantage existing low-cost ACOs. Others supported allowing ACOs a choice of either regional and national trends, applying the higher of regional or national trends, or applying regional trends to ACOs in existing high-cost regions and national trends to ACOs in existing low-cost regions. Several commenters offered conflicting views on whether moving to use of regional FFS costs in establishing historical and updated benchmarks would advantage or disadvantage existing low cost providers (80 FR 32792).

In the June 2015 final rule (80 FR 32796), we indicated that we needed to consider further what additional adjustments should be made to the benchmarking methodology when moving to a rebasing approach that accounts for regional FFS trends. These considerations included whether to incorporate regional FFS expenditures in updating an ACO's historical benchmark each performance year or to maintain the current policy under which we update an ACO's benchmark based on the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original FFS program. For instance, the update factor could be based on either regional expenditures or a blend of regional/national FFS expenditures. We also indicated the need to continue to adjust the ACO's historical benchmark for changes in health status and demographic factors of the ACO's assigned beneficiaries during the performance period (as described in section II.A.3 of this proposed rule).

(2) Proposals for Regional Growth Rate as a Benchmark Trending Factor

In considering how to compute an ACO's rebased historical benchmark, we considered replacing the national trend factor that is currently used in trending an ACO's BY1 and BY2 expenditures forward to BY3 with a regional trend factor based on regional FFS expenditures corresponding to the ACO's regional service area. To align with the proposed calculation of the regional FFS expenditures for an ACO's regional service area, we considered the following approach for calculating regional FFS trend factors:

- For each benchmark year, calculate risk adjusted county FFS expenditures for the ACO's regional service area, as described under sections II.A.2.b and II.A.2.e.2 of this proposed rule. As described in section II.A.2.b.4 of this proposed rule, county FFS

expenditures would be determined using total county-level FFS Parts A and B expenditures for assignable beneficiaries, excluding IME, DSH, and uncompensated care payments, but including beneficiary identifiable payments made under a demonstration, pilot or time limited program; regional expenditures would be calculated for each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible);

- For each benchmark year, compute a weighted average of risk adjusted county-level FFS expenditures with weights based on the ACO's regional service area, that is the proportion of an ACO's assigned beneficiaries residing in each county within the ACO's regional service area. Calculations would be done by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) based on the ACO's benchmark year assigned population.

- Compute the average growth rates from BY1 to BY3, and from BY2 to BY3, using the weighted average risk-adjusted county level FFS expenditures for the respective benchmark years, for each Medicare enrollment type.

We would apply these regional trend factors to the ACO's historical benchmark expenditures, which are also adjusted based on the CMS-HCC model, to account for the severity and case mix of the ACO's assigned beneficiaries in each benchmark year.

Using regional trend factors, instead of national trend factors to trend forward expenditures in the benchmark period, would further incorporate regional FFS spending and population dynamics specific to the ACO's regional service area in the ACO's rebased benchmark. We believe there are number of relevant considerations for moving to use of regional trend factors, including the following:

- Regional trend factors would more accurately reflect the cost experience in an

ACO's regional service area compared to use of national trend factors.

- Regional trend factors would reflect the health status of the FFS population that makes up the ACO's regional service area, the region's geographic composition (such as rural versus urban areas), and socio-economic differences that may be regionally related.

- Regional trend factors could better capture location-specific changes in Medicare payments (for example, the area wage index) compared to use of national trend factors.

We also considered how use of regional trend factors in resetting ACO benchmarks could affect participation by relatively high- and low-growth ACOs operating in regions with high and low growth in Medicare FFS expenditures. We anticipate using regional trend factors would result in relatively higher benchmarks for ACOs that are low growth in relation to their region compared to benchmarks for ACOs that are high growth relative to their region. Therefore, use of regional FFS trends could disproportionately encourage the development of and continued participation by ACOs with rates of growth below that of their region. These ACOs would benefit from having a relatively higher benchmark, which would increase their chances for shared savings. On the other hand, ACOs with historically higher rates of growth above the regional average would have a relatively lower benchmark and may be discouraged from participating if they are not confident of their ability to bring their costs in line with costs in their region.

In using regional growth rates specific to an ACO's regional service area and composition (by Medicare enrollment type) we expect to see significant variation in the growth rates between health care markets in different regions of the country and even

between ACOs operating in the same markets. This approach would be a departure from the current methodology that applies a single set of national growth factors calculated for each benchmark year by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible). However, ACOs familiar with the composition of their assigned population and cost trends in their regional service area may find they can more readily anticipate what these trend factors may be. Additionally, stakeholders may find it helpful to observe differences in county FFS expenditures using the data files made publicly available in conjunction with this proposed rule, as described in detail in the regulatory impact analysis section.

Accordingly, we are proposing to replace the national trend factors used for trending an ACO's BY1 and BY2 expenditures to BY3 in calculating an ACO's rebased historical benchmark with regional trend factors derived from a weighted average of risk adjusted FFS expenditures in the counties where the ACO's assigned beneficiaries reside. Further, we propose to calculate and apply these trend factors for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible, aged/non-dual eligible. We propose to incorporate this proposal in a new regulation at § 425.603. We seek comment on this proposed change.

We also considered whether it would be sufficient to incorporate regional FFS expenditures into rebased benchmarks by applying regional trend factors (instead of national trend factors) in establishing the rebased benchmark under the existing rebasing methodology. Therefore, we specifically seek comment on the use of regional trend factors for trending forward an ACO's BY1 and BY2 expenditures to BY3 in establishing and resetting historical benchmarks under the current approach to resetting ACO

benchmarks in § 425.602(c) as an alternative to adopting the proposed approach to adjusting rebased benchmarks to reflect FFS expenditures in the ACO's regional service area, as discussed in section II.A.2.c of this proposed rule. Further, we considered and seek comment on an alternative under which we would apply regional trend factors for trending forward BY1 and BY2 expenditures to BY3 in establishing the benchmark for an ACO's first agreement period under § 425.602(a), allowing this policy to be applied consistently program-wide beginning with an ACO's first agreement period.

(3) Proposals for Updating the Reset Benchmark During the Agreement Period

Section 1899(d)(1)(B)(ii) of the Act states the benchmark shall be updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program, as estimated by the Secretary.

Accordingly, we currently update the historical benchmark annually for each year of the agreement period based on the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program.

We considered using an update factor based on the regional FFS expenditures for the ACO's regional service area to update an ACO's rebased historical benchmark during the ACO's second or subsequent agreement period. This approach would align with our proposal to use regional FFS expenditures in developing the trend factors for the rebased historical benchmark (to trend BY1 and BY2 expenditures to BY3) and our proposal to adjust the ACO's rebased historical benchmark to reflect regional FFS expenditures.

Updating the benchmark based on regional FFS expenditures annually, during the course of the agreement period, would result in a benchmark used to determine shared savings

and losses for a performance year that reflects trends in regional FFS growth for the ACO's regional service area for the corresponding year. As with use of regional trend factors instead of national trend factors (discussed in section II.A.2.d.2. of this proposed rule), we believe calculating the update factor using regional FFS expenditures would 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. Adopting this approach would require our use of authority under section 1899(i)(3) of the Act as it is a departure from the methodology for annually updating the benchmark specified under section 1899(d)(1)(B)(ii) of the Act.

We considered using the following approach to calculate the regional update amount for each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible):

- For each calendar year corresponding to a performance year, calculate risk adjusted county FFS expenditures for the ACO's regional service area, as described under sections II.A.2.b. and II.A.2.e.2. of this proposed rule. As described in section II.A.2.b.4. of this proposed rule, county FFS expenditures would be determined using total county-level FFS Parts A and B expenditures for assignable beneficiaries, excluding IME, DSH, and uncompensated care payments, but including beneficiary identifiable payments made under a demonstration, pilot or time limited program, truncated and risk adjusted for each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible). The ACO's regional service area would be defined based on the ACO's assigned beneficiary population used to perform financial reconciliation for the

relevant performance year.

- Compute a weighted average of risk adjusted county-level FFS expenditures with weights based on the proportion of an ACO's assigned beneficiaries residing in each county of the ACO's regional service area. Calculations would be done by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) based on the ACO's assigned population used to perform financial reconciliation for the relevant performance year. This would result in an update factor for each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible).

We considered whether to calculate a flat dollar equivalent of the projected absolute amount of growth in regional per capita expenditures for Parts A and B FFS services, or whether to calculate the percentage change in growth in regional FFS expenditures for the ACO's regional service area. We discussed issues related to use of a growth rate or a flat dollar amount in the initial rulemaking to establish the Shared Savings Program, including our view that a growth rate would more accurately reflect each ACO's historical experience, but could also perpetuate current regional differences in medical expenditures (see 76 FR 19609 through 19610 and 76 FR 67924). For the reasons discussed in the earlier rulemaking, we believe that using growth rates to determine the annual update would more effectively capture changes in the ACO's regional service area expenditures and changes in the health status of the ACO's population in comparison to the health status of the population of the ACO's regional service area over time. Using a growth rate to update ACOs' benchmarks would also result in proportionately larger updates for higher spending ACOs in the region and lower updates for lower spending ACOs in the region and would strike a balance with the flat-

dollar average regional expenditures used to adjust the ACOs historical benchmark.

We also considered how to apply the update to the ACO's rebased historical benchmark adjusted for expenditures in the ACO's regional service area. To maintain the overall structure of the program's current methodology, and to align with the other proposed revisions to the methodology used to calculate an ACO's rebased historical benchmark described in this proposed rule, the update would be applied after all adjustments are made to the ACO's rebased benchmark. For example, for an ACO in its second or subsequent agreement period, the sequence for adjustments and the application of the update would be as follows:

- Calculate the ACO's rebased historical benchmark using historical expenditures for the beneficiaries assigned to the ACO in the 3 years prior to the start of its current agreement period, using trend factors based on regional FFS expenditures to trend the ACO's BY1 and BY2 expenditures to BY3, and applying equal weights to the benchmark years (as described in sections II.A.2.c. and II.A.2.d.2. of this proposed rule).
- Adjust the ACO's rebased historical benchmark to reflect risk adjusted regional average expenditures based on county FFS expenditures determined for the ACO's regional service area, as described in section II.A.2.c. of this proposed rule.
- As needed, adjust the ACO's rebased historical benchmark to account for changes in ACO participants for the performance year, as described in section II.B. of this proposed rule.
- Adjust the ACO's rebased historical benchmark according to the health status and demographic factors of the ACO's performance year assigned beneficiary population. We would continue to apply the current newly and continuously assigned

risk adjustment methodology, described in detail in section II.A.3. of this proposed rule.

- Update the adjusted rebased historical benchmark using the growth rates in risk adjusted FFS expenditures for the ACO's regional service area for each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible).

The use of an update factor based on regional FFS spending offers different incentives compared to an update factor reflecting only growth in national FFS spending. For instance, accounting for national FFS spending in an ACO's benchmark update, similar to the current methodology for updating ACO benchmarks, would continue to incorporate a national standard in the calculation and measurement of ACO financial performance. This approach would provide a relatively higher expenditure benchmark for low spending ACOs in low growth areas and a relatively lower benchmark for high spending ACOs in high growth areas. In contrast, accounting for changes in regional FFS spending between the benchmark and the performance year by updating the benchmark according to changes in regional FFS expenditures, would ensure that the benchmark continues to reflect recent trends in FFS spending growth in the ACO's region throughout the duration of the ACO's agreement period.

However, we anticipate there being significant variation in annual benchmark updates for individual ACOs, reflecting the cost experience in each ACO's individualized regional service area along with changes in the health status of the population of patients served by the ACO as well as changes in the types of Medicare entitlement status in the ACO's assigned beneficiary population. The update factors are used to account for change in FFS growth. The degree of year-to-year change in expenditures will likely vary in both existing low- and high-growth regions and could also vary significantly from

expectations. In particular, we note our early experience in the program, where the 2012 national FFS growth factors (as used for interim reconciliation for the 2012 starters) showed an overall decrease in expenditures totaling -0.5 percent, and decreases in expenditures for three of four Medicare eligibility types (ESRD, aged/dual eligible, aged/non-dual eligible). Only disabled beneficiaries experienced a growth in expenditures in this timeframe. The resulting negative updates (and corresponding decreases in benchmark values) were surprising to many stakeholders who presumed that the updates would result in benchmark increases.

As discussed previously in this section, it would be necessary to use the discretionary authority in section 1899(i)(3) of the Act to adopt a policy under which we would calculate the benchmark update using regional FFS expenditures. Section 1899(i)(3) of the Act authorizes the Secretary to use other payment models in place of the payment model outlined in section 1899(d) of the Act as long as the Secretary determines these other payment models will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without additional program expenditures. We believe that updating an ACO's rebased historical benchmark based on regional FFS spending, rather than national FFS spending (as is done currently) would have positive effects for the Shared Savings Program and Medicare beneficiaries. As described in the regulatory impact analysis of this proposed rule, the proposed changes to the payment model used in the Shared Savings Program, including updating the ACO's rebased historical benchmark based on regional FFS spending, are anticipated to increase overall participation in the program, improve incentives for ACOs to invest in effective care management efforts, and increase the accuracy of benchmarks in capturing the experience

in an ACO's regional service area compared to the use of national FFS expenditures. Therefore, we believe these changes would result in improved quality of care furnished to Medicare beneficiaries, and greater efficiency of items and services furnished to these beneficiaries, as more ACOs enter and remain in the Shared Savings Program and continue to work to meet the program's three-part aim of better care for individuals, better health for populations and lower growth in expenditures.

We note that section 1899(i)(3)(B) of the Act provides that the requirement that the other payment model not result in additional program expenditures "shall apply . . . in a similar manner as [subparagraph (b) of paragraph (2) of section 1899(i)] applies to the payment model under [section 1899(i)(2)]." Section 1899(i)(2) of the Act provides discretion for the Secretary to use a partial capitation model rather than the payment model described in section 1899(d) of the Act. Section 1899(i)(2)(B) of the Act provides that--

[p]ayments to an ACO for items and services under this title for beneficiaries for a year under the partial capitation model shall be established in a manner that does not result in spending more for such ACO for such beneficiaries than would otherwise be expended for such ACO for such beneficiaries for such year if the model were not implemented, as estimated by the Secretary.

We have not previously addressed this provision in rulemaking. We believe we could use a number of approaches to address this statutory requirement, for example: through an initial estimation that the model does not result in additional expenditures and that spans multiple years of implementation; by a periodic assessment that the model does not result in additional program expenditures; or by structuring the model in a way such that CMS could not spend more for an ACO for such beneficiaries than would otherwise be expended for such ACO for such beneficiaries for such year if the model were not

implemented. However, because section 1899(i)(3)(B) of the Act states only that the requirement that the payment model not result in additional program expenditures must be applied in “a similar manner” to the requirement under section 1899(i)(2)(B) of the Act, we believe we have some discretion to tailor this requirement to the payment framework that is being adopted under the other payment model.

Section 1899(i)(3)(B) of the Act also specifies that the other payment model must not result in additional program expenditures. Section IV.E. of this proposed rule discusses our analysis of this requirement, and our initial assessment of the costs associated with a payment model that includes changes to the manner in which we update the benchmark during an ACO’s agreement period. We compared all current policies and proposed policies to policies that could be implemented under section 1899(d)(1)(B)(ii) of the Act, and assessed that for the period spanning 2017 through 2019 there would be net federal savings. Therefore, we believe that the proposed alternative payment model under section 1899(i)(3) of the Act, which includes using regional FFS expenditures to update an ACO’s rebased historical benchmark and using FFS expenditures of assignable beneficiaries to calculate the national benchmark update for ACOs in their first agreement period and for ACOs that started a second agreement period on January 1, 2016, as discussed in section II.A.2.d.3. of this proposed rule, as well as current policies established using the authority of section 1899(i)(3) of the Act, meets the requirements under section 1899(i)(3)(B) of the Act. We anticipate that the costs of this alternative payment model will be periodically reassessed as part of the impact analysis for subsequent rulemaking regarding the payment models used under the Shared Savings Program. However, in the event we do not undertake additional rulemaking, we intend to

periodically reassess whether a payment model established under authority of section 1899(i)(3) of the Act continues to improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures. If we determine the payment model no longer satisfies the requirements of section 1899(i)(3) of the Act, for example if the alternative payment model results in net program costs, we would undertake additional notice and comment rulemaking to make adjustments to our payment methodology to assure continued compliance with the statutory requirements.

To summarize, we are proposing to include a provision in the proposed new regulation at § 425.603 to specify that for ACOs in their second or subsequent agreement period whose rebased historical benchmark incorporates an adjustment to reflect regional expenditures, the annual update to the benchmark will be calculated as a growth rate that reflects risk adjusted growth in regional per beneficiary FFS spending for the ACO's regional service area. Further, we propose to calculate and apply separate update factors based on risk adjusted regional FFS expenditures for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible, and aged/non-dual eligible. We seek comment on this proposal. We also seek comment on the alternatives considered, including calculating the update factor as the flat dollar equivalent of the projected absolute amount of growth in regional per capita expenditures for Parts A and B FFS services for the ACO's regional service area.

We want to clarify that the current methodology for calculating the annual update will continue to apply in updating an ACO's historical benchmark during its first agreement period, as well as in updating the rebased historical benchmark for the second

agreement period for ACOs that started in the program in 2012 or 2013, and entered their second agreement period on January 1, 2016. That is, for these ACOs, we would continue to update the historical benchmark annually for each year of the agreement period based on the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program. We believe the continued application of an update based on national FFS spending is consistent with the methodology used to establish the benchmarks for these ACOs, particularly the use of trend factors based on national FFS spending to trend an ACO's BY1 and BY2 expenditures to BY3. However, as discussed earlier in this section of this proposed rule, we are seeking comment on the use of trend factors based on regional FFS expenditures, instead of national FFS expenditures, in establishing the benchmark for an ACO's first agreement period (see section II.A.2.d.2. of this proposed rule). Likewise, we considered and seek comment on using regional FFS expenditures, instead of national FFS expenditures, to update an ACO's historical benchmark beginning with its first agreement period.

e. Proposals for Parity Between Calculation of ACO, Regional and National FFS Expenditures

(1) Background

In the November 2011 final rule, we established a methodology for determining ACO benchmark and performance year expenditures for Medicare FFS beneficiaries assigned to the ACO. Under that methodology, we take into account payments made from the Medicare Trust Funds for Parts A and B services for assigned Medicare FFS beneficiaries, including individually beneficiary identifiable payments made under a

demonstration, pilot or time limited program, when computing average per capita Medicare expenditures under the ACO. We exclude IME payments and DSH and uncompensated care payments from both benchmark and performance year expenditures. This adjustment to benchmark expenditures falls under the Secretary's discretion established by section 1899(d)(1)(B)(ii) of the Act to adjust the benchmark for beneficiary characteristics and such other factors as the Secretary determines appropriate. However, section 1899(d)(1)(B)(i) of the Act only provides authority to adjust expenditures in the performance period for beneficiary characteristics and does not provide authority to adjust for "other factors." Therefore, to remove IME and DSH payments from performance year expenditures, we used our authority under section 1899(i)(3) of the Act, which authorizes use of other payment models, in order to make this adjustment (see 76 FR 67920 through 67922). We allow for a 3-month run out of claims data and apply a claims completion factor (percentage), to more accurately determine an ACO's benchmark and performance year expenditures (76 FR 67837 through 67838). To minimize variation from catastrophically large claims we truncate an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile of national Medicare FFS expenditures as determined for each benchmark year and performance year (76 FR 67914 through 67916).

We perform many of these calculations separately for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible, and aged/non-dual eligible. For example, we calculate benchmark and performance year expenditures, determine truncation thresholds, and risk adjust ACO expenditures separately for each of these four Medicare enrollment types. As part of this methodology, we account for

circumstances where a beneficiary is enrolled in a Medicare enrollment type for only a fraction of a year, through a process that results in a calculation of "person years" for a given year. We calculate the number of months that each beneficiary is enrolled in Medicare in each Medicare enrollment type, and divide by 12. When we sum the fraction of the year enrolled in Medicare for all the beneficiaries in each Medicare enrollment type, the result is total person years for the beneficiaries assigned to the ACO.

We apply these policies consistently across the program, as specified in the provisions for establishing, updating and resetting the benchmark under § 425.602, and for determining performance year expenditures under § 425.604 for Track 1 ACOs and under § 425.606 for Track 2 ACOs. Further, in developing Track 3, we determined that it would be appropriate to calculate expenditures consistently program-wide (see 80 FR 32776 through 32777). Accordingly, the provisions in § 425.602 governing establishing, updating, and resetting the benchmark also apply to ACOs under Track 3, and we adopted the same approach for determining performance year expenditures as is used in Track 1 and Track 2 in § 425.610 for Track 3 ACOs.

(2) Proposals for Calculation of Regional FFS Expenditures

As part of our proposal to adjust the historical benchmark to reflect regional FFS expenditures, we believe it is important to calculate FFS expenditures for an ACO's region in a manner consistent with the methodology used to calculate an ACO's benchmark and performance year expenditures. Consistent application of program methodology in calculating FFS expenditures will result in more predictable and stable calculations across the program over time, for example as ACOs transition from a benchmarking methodology that incorporates factors based on national FFS expenditures

to one that incorporates factors based on regional FFS expenditures. In addition, use of an alternative approach to calculating regional FFS expenditures could introduce bias because different types of payments could be included in or excluded from these expenditures, as compared to historical benchmark expenditures and performance year expenditures.

To increase predictability and stability, and avoid this bias, we believe we should follow the same approach in calculating regional FFS expenditures as is used in calculating benchmark and performance year expenditures, for instance by including total Parts A and B FFS claims for the assignable beneficiary population for each county that will be used as the basis for determining expenditures for the ACO's regional service area and using a 3-month claims run out with a completion factor. As explained in previous rulemakings for the Shared Savings Program, we apply a 3-month claims run out and completion factor (expressed as a percentage) so that our calculation of ACO expenditures for a given calendar year reflects the full costs of care furnished to assigned beneficiaries during that year. The decision to use a 3-month claims run out and a completion factor was based on our experience with the submission and processing of Parts A and B claims for services and the inherent lag between when a service is performed and when a claim is submitted for payment (see 76 FR 67837 through 67838; see also 80 FR 32776 through 32777). Currently we use a completion factor that takes into account our experience with the submission of FFS claims nationwide. For instance, since the start of the program (as part of determining ACO benchmarks and the expenditure calculations for the performance years ending December 31, 2013, and December 31, 2014) we have consistently used the same completion factor as a multiplier

applied to total Parts A and B expenditures for an ACO's assigned beneficiaries. We anticipate continuing to use completion factors based on national FFS claims to determine FFS expenditures for an ACO's regional service area, as opposed to calculating county-level claims completion factors. We believe claims completion factors based on national FFS data will continue to accurately reflect the full cost of care furnished to ACO assigned beneficiaries, because these factors are calculated based on a broad population of Medicare FFS beneficiaries and therefore comprehensively reflect billing practices of Medicare providers and suppliers nationally. Applying completion factors based on national FFS claims to regional FFS expenditures also allows us to consistently apply a single set of completion factors across program calculations, further ensuring the comparability of these calculations across the program over time. We are concerned that an alternative approach to calculating completion factors, such as county level completion factors, would add additional complexity without providing additional accuracy. Further, applying region or county-specific completion factors in some calculations and nationally-based completion factors in other calculations, could result in lack of comparability of resulting expenditures.

In the initial rulemaking establishing the Shared Savings Program, we finalized an approach to determining which payments are included in expenditures used in program calculations. Consistent with section 1899(d)(1) of the Act, we take into account payments made from the Medicare Trust Funds for Parts A and B services for assigned Medicare FFS beneficiaries, including individual beneficiary identifiable payments made under a demonstration, pilot or time limited program when computing average per capita Medicare expenditures under the ACO (see 76 FR 67919 through 67920). We also

believe that the calculation of Parts A and B county FFS expenditures used as the basis for calculating the ACO's regional service area expenditures should include individually beneficiary identifiable payments made under a demonstration, pilot or time limited program. Unless these payments are included in the calculation of regional FFS expenditures, these expenditures will be understated compared to ACO benchmark and performance year expenditures. In the November 2011 final rule, we also finalized an approach whereby we exclude IME and DSH payments from program calculations, so as not to create an incentive for ACOs to avoid referrals to hospitals that receive IME and/or DSH payments in an effort to demonstrate savings (see 76 FR 67920 through 67922). Similarly, we believe IME payments and DSH and uncompensated care payments should be excluded from regional FFS expenditures. Absent this adjustment, regional expenditures will overstate payments to providers receiving IME payments and/or DSH and uncompensated care payments, as compared to benchmark and performance year expenditures.

In prior rulemaking for the Shared Savings Program we established policies for truncating an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile of national Medicare FFS expenditures when calculating benchmark and performance year expenditures (see 76 FR 67915 through 67916; see also 80 FR 32776 through 32777). This truncation minimizes variation from catastrophically large claims. To prevent overstatement of the regional FFS expenditures that will be used to adjust an ACO's rebased historical benchmark, we believe it is necessary to apply the same approach to truncating beneficiary expenditures when calculating county FFS expenditures that are used as the basis for determining

expenditures for an ACO's regional service area.

We also risk adjust benchmark expenditures in the Shared Savings Program, to take into account the severity of health status and case mix of assigned beneficiaries, as described in greater detail in section II.A.3.a. of this proposed rule. For example, we use the prospective CMS-HCC model for adjusting benchmark expenditures in establishing the ACO's historical benchmark (see 76 FR 67916 through 67919, and §425.602(a)(3)). Similarly, we would risk adjust county FFS expenditures for severity and case mix of assignable beneficiaries using the prospective CMS-HCC model.

In financial calculations under the Shared Savings Program, we make separate expenditure calculations for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible, and aged/non-dual eligible (see §§ 425.602, 425.604, 425.606, and 425.610). For instance, we use this approach in calculating and truncating benchmark and performance year expenditures, trending historical benchmark expenditures and updating the historical benchmark, and in risk adjusting expenditures. Consistent with this approach, we believe it is important to calculate expenditures for each county used to determine the expenditures for an ACO's regional service area separately for each of these populations of beneficiaries. As described previously in the background for this section of this proposed rule, we use beneficiary person years in calculating expenditures for each Medicare enrollment type. Consistent with this approach, we would also calculate beneficiary person years when determining county FFS expenditures for each Medicare enrollment type.

Taking these considerations into account, we propose to take the following steps in calculating county FFS expenditures used to determine expenditures for an ACO's regional service area:

- Calculate the payment amounts included in Parts A and B FFS claims using a 3-month claims run out with a completion factor. Exclude IME, DSH, and uncompensated care payments. Include individually beneficiary identifiable payments made under a demonstration, pilot or time-limited program.
- Truncate a beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile of national Medicare FFS expenditures as determined for the relevant benchmark or performance year in order to minimize variation from catastrophically large claims.
- Adjust expenditures for severity and case mix using prospective CMS-HCC risk scores.
- Make separate expenditure calculations for each of the following populations of beneficiaries, stated as beneficiary person years: ESRD, disabled, aged/dual eligible, and aged/non-dual eligible.

We propose to incorporate this proposed methodology for calculating county FFS expenditures in a new section of the Shared Savings Program regulations at § 425.603.

We seek comment on this proposed methodology and on any additional factors that should be considered in calculating the expenditures for an ACO's regional service area.

(3) Proposals for Modifying the Calculation of National FFS Expenditures, Completion Factors, and Truncation Thresholds Based on Assignable Beneficiaries

Several elements of the existing Shared Savings Program financial calculations

are based on expenditures for all Medicare FFS beneficiaries regardless of whether they are eligible to be assigned to an ACO, including: the growth rates used to trend forward expenditures during the benchmark period; the projected absolute amount of growth in national per capita expenditures for Parts A and B services used to update the benchmark; the completion factors applied to benchmark and performance year expenditures; and the truncation thresholds set at the 99th percentile of national Medicare FFS expenditures. In calculating these factors based on national FFS expenditures, we take into account Parts A and B expenditures for all Medicare FFS beneficiaries, and exclude IME payments and DSH and uncompensated care payments to align with our methodology for calculating benchmark and performance year expenditures.

Generally, beneficiaries eligible for assignment to Shared Savings Program ACOs are a subset of the larger population of Medicare FFS beneficiaries. In identifying the pool of beneficiaries who can be assigned to an ACO, as a “pre-step” to the two-step assignment process under § 425.402, we determine if a beneficiary received at least one primary care service from a physician within the ACO whose services are used in assignment:

- For performance year 2016 and subsequent performance years, the beneficiary must have received a primary care service, as defined under § 425.20, with a date of service during the 12-month assignment window, as defined under § 425.20.
- The service must have been furnished by a primary care physician as defined under § 425.20 or by a physician with one of the primary specialty designations included in § 425.402(c). Therefore, beneficiaries who have not received any primary care service, or who have only received primary care services from physicians with a primary

specialty code not specified in § 425.402(c) (see 80 FR 32753 through 32754, Table 5-Physician Specialty Codes Excluded From Assignment Step 2), or from non-physician practitioners are excluded from assignment to an ACO.

This pre-step is designed to satisfy the statutory requirement under section 1899(c) of the Act that beneficiaries be assigned to an ACO based on their use of primary care services furnished by physicians (80 FR 32756; § 425.402(a), § 425.402(b)(1)). We use the beneficiary population resulting from the pre-step, referred to as “assignable beneficiaries,” to determine the beneficiaries who will be assigned to an ACO based on the two-step assignment process under § 425.402.

Including beneficiaries ineligible for assignment in calculating factors that are based on the expenditures of the broader FFS population can bias those calculations. There may be differences in the health status and health care cost experience of Medicare beneficiaries excluded from the pre-step compared to those who are eligible for assignment, based on their health conditions and the providers from whom they receive care. Thus, including the expenditures for non-assignable beneficiaries, such as non-utilizers of health care services, can result in lower overall per capita expenditures. These biases may have a more pronounced effect in calculations of regional FFS expenditures, which are based on relatively smaller populations of beneficiaries, as compared to calculations based on the national FFS population. As a result, we are concerned that using expenditures for all Medicare FFS beneficiaries, as opposed to a narrower population of FFS beneficiaries, in calculating certain program elements may introduce a degree of bias in these calculations, particularly for elements based on regional FFS expenditures (as discussed in section II.A.2.b. of this proposed rule).

Therefore, we believe it is timely to reconsider the population that should be used in program calculations for both national and regional FFS populations. Our preferred approach would be to apply a similar logic as is used to identify the population of FFS beneficiaries eligible for assignment as part of the assignment pre-step under § 425.402(b)(1). We would limit the Medicare FFS population used in these program calculations to “assignable” Medicare beneficiaries who meet the following requirements: (1) received at least one primary care service, as defined under § 425.20, with a date of service during the 12-month assignment window; and (2) this primary care service was provided by a primary care physician, as defined under § 425.20, or by a physician with one of the primary specialty designations included in § 425.402(c).

One factor related to calculating expenditures for assignable beneficiaries is the assignment window used to identify this population, with options including: the 12-month period used to assign beneficiaries to Track 1 and 2 ACOs based on a calendar year, and an off-set 12-month period used to assign beneficiaries prospectively to an ACO in Track 3. (See definition of assignment window under § 425.20 and related discussion in the June 2015 final rule at 80 FR 32699.) We believe it is important to calculate regional and national FFS expenditures consistently across the three tracks of the program, so as not to advantage or disadvantage an organization simply on this basis. This consistency would help to ensure a level playing field in markets where multiple ACOs are present, and would also simplify program operations. Accordingly, we are proposing to calculate county FFS expenditures and average risk scores, as well as factors based on national FFS expenditures, using the assignable beneficiary population identified using the assignment window for the 12-month calendar year corresponding to

the benchmark or performance year. This is the same assignment window that is currently used to assign beneficiaries under Track 1 and Track 2. We plan to monitor for observable differences in the health status (for example, as identified by HCC risk scores) and expenditures of the assignable beneficiaries identified using the 12-month calendar year assignment window, as compared to assignable beneficiaries identified using an assignment window that is the off-set 12-month period prior to the benchmark or performance year (for example October through September preceding the calendar year). In the event that we conclude that additional adjustments (for instance as part of risk adjusting county FFS expenditures) are necessary to account for the use of assignable beneficiaries identified using an assignment window that is different from the assignment window used to assign beneficiaries to the ACO, we would address this issue through future rulemaking.

This proposed rule primarily focuses on modifying the methodology for resetting the ACO's historical benchmark for an ACO's second or subsequent agreement period beginning on or after January 1, 2017. As we have indicated elsewhere in this proposed rule (see section II.A.2.d.3. of this proposed rule), while we are proposing to modify the annual update to the ACO's rebased historical benchmark to reflect a regional update, we are not proposing to extend this modification to the benchmark update for ACOs in their first agreement period or for ACOs that started their second agreement period January 1, 2016. We will continue to apply an update based on national FFS expenditures to these ACOs. However, to the extent that we are proposing to change our methodology in order to use only assignable beneficiaries instead of all Medicare FFS beneficiaries in calculating the benchmark update based on national FFS expenditures,

we believe we would need to use the authority under section 1899(i)(3) of the Act to adopt other payment models to implement this proposed change.

Section 1899(d)(1)(B)(ii) of the Act states the benchmark shall be updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program, as estimated by the Secretary. The plain language of section 1899(d)(1)(B)(ii) of the Act demonstrates Congress' intent that the benchmark update be calculated based on growth in expenditures for the national FFS population, as opposed to a subset of this population. Therefore, in order to allow us to use only assignable beneficiaries in determining the amount of growth in per capita expenditures for Parts A and B services for purposes of determining the benchmark update for ACOs in their first agreement period and those ACOs that started a second agreement period on January 1, 2016, it is necessary to rely upon our authority under section 1899(i)(3) of the Act. Section 1899(i)(3) of the Act authorizes the Secretary to use other payment models in place of the payment model outlined in section 1899(d) of the Act as long as the Secretary determines these other payment models will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without additional program expenditures.

For the reasons explained in section II.A.2.d.3 of this proposed rule, we believe using our authority under section 1899(i)(3) of the Act to adopt a payment model that includes calculating the benchmark update for ACOs in their first agreement period and for ACOs that started a second agreement period on January 1, 2016, using national FFS expenditures for assignable beneficiaries, rather than for all FFS beneficiaries, would improve the quality and efficiency of items and services furnished to Medicare

beneficiaries. We believe this approach would increase the accuracy of benchmarks, by determining the national update using a population that more closely resembles the population that could be assigned to ACOs. Further, we believe using assignable beneficiaries across program calculations based on national and regional FFS expenditures will result in factors that are generally more comparable. As a result, these calculations will be more predictable and stable across the program over time, for example as ACOs transition from a benchmarking methodology that incorporates national FFS expenditures to one that incorporates factors based on regional FFS expenditures. Ultimately, we believe this policy could increase overall participation in the program, thereby resulting in more organizations working to meet the program's three-part aim of better care for individuals, better health for populations and lower growth in expenditures.

As explained in section II.A.2.d.3. of this proposed rule, section 1899(i)(3)(B) of the Act also specifies that the other payment model must not result in additional program expenditures. Section IV.E. of this proposed rule discusses our analysis of this requirement, and our initial assessment that for the period spanning 2017 through 2019 there would be net federal savings associated with a payment model under section 1899(i)(3) that includes the proposed changes to the manner in which we update the benchmark during an ACO's agreement period.

Taking these considerations into account, we believe applying a payment methodology that includes calculating the benchmark update consistently based on assignable FFS beneficiaries, instead of all FFS beneficiaries, would meet the requirements under section 1899(i)(3) of the Act that the payment model would improve

the quality and efficiency of items and services furnished to Medicare beneficiaries, without additional program expenditures. However, as discussed in section II.A.2.d.3. of this proposed rule, we intend to revisit this determination periodically. If we determine the payment model no longer satisfies the requirements of section 1899(i)(3) of the Act, for example if the model results in net program costs, we would undertake additional notice and comment rulemaking to make adjustments to the model to assure continued compliance with the statutory requirements. After considering these issues, we are proposing to use the authority under section 1899(i)(3) of the Act to revise the regulation at § 425.602(b)(1) to specify that the annual update to the benchmark will be based on the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program for assignable beneficiaries. We further propose to specify in this provision of the regulations that we will identify assignable beneficiaries for the purpose of calculating the update based on national FFS expenditures using the 12-month calendar year corresponding to the year for which the update is being calculated. We seek comment on these proposals.

We also propose to make conforming changes to the regulations to specify that assignable Medicare FFS beneficiaries, identified based on the 12-month period corresponding to the calendar year for which the calculations are being made, will be used to perform the following calculations: (1) truncation thresholds for limiting the impact of catastrophically large claims on ACO expenditures under § 425.602(a)(4), § 425.604(a)(4), § 425.606(a)(4), § 425.610(a)(4); and (2) growth rates used to trend forward expenditures during the benchmark period under § 425.602(a)(5). We will provide additional information through subregulatory guidance regarding the process for

using assignable beneficiaries to perform these calculations, as well as calculation of the claims completion factor applied under § 425.602(a)(1), § 425.604(a)(5), § 425.606(a)(5), § 425.610(a)(5).

In addition, we propose to specify in a new provision of the Shared Savings Program regulations at § 425.603 that would govern the methodology for resetting, adjusting, and updating an ACO's benchmark for a second or subsequent agreement period that county FFS expenditures will be based on assignable Medicare FFS beneficiaries determined using the 12-month period corresponding to the calendar year for which the calculations are being made.

We propose that regulatory changes regarding use of assignable beneficiaries in calculations based on national FFS expenditures would apply for the 2017 performance year and all subsequent performance years. Under this proposal, these changes would apply to ACOs that are in the middle of an agreement period, specifically ACOs that started their first agreement period in 2015 or 2016 and ACOs that started their second agreement period on January 1, 2016. We would adjust the benchmarks for these ACOs at the start of the first performance year in which these proposed changes apply so that the benchmark for the ACO reflects the use of the same methodology that would apply in expenditure calculations for the corresponding performance year.

We seek comment on these proposals. We also seek comment on whether expenditures for all Medicare FFS beneficiaries should be used to calculate these elements for ACOs in their first agreement period or a second agreement period that started on January 1, 2016, while expenditures for assignable Medicare FFS beneficiaries are used to calculate these elements for the ACO's second and subsequent agreement

period in combination with the use of the assignable beneficiary population to determine expenditures for the ACO's regional service area.

f. Proposed Timing of Applicability of Revised Rebasing and Updating Methodology

In the June 2015 final rule we indicated that the revised rebasing methodology would “apply to ACOs beginning new agreement periods in 2017 or later. ACOs beginning a new agreement period in 2016 would convert to the revised methodology at the start of their third agreement period in 2019” (80 FR 32795). This description did not differentiate between ACOs that started their first agreement period under the Shared Savings Program on January 1, 2016, and ACOs that started in the program in 2012 and 2013 (2012 and 2013 starters) that entered their second agreement period on January 1, 2016.

We considered the following approach, under which the revised rebasing methodology could be applied to new agreement periods beginning on or after January 1, 2017, in a manner that allows for a phase-in to a greater percentage in calculating the regional adjustment (as described in section II.A.2.c.3. of this proposed rule) for all ACOs:

- All ACOs would have the benchmark for their first agreement period set and updated under the methodology under §425.602(a) and (b).
- The 2014, 2015, 2016 starters and subsequent cohorts entering their second agreement periods on or after January 1, 2017, would be rebased under the proposed new methodology for adjusting an ACO's rebased historical benchmark to reflect expenditures in the ACO's regional service area, and the ACO's rebased benchmark would be updated during the agreement period by growth in regional FFS expenditures.

In calculating the regional adjustment to the rebased historical benchmark for an ACO's second agreement period, the percentage applied to the difference between the ACO's regional service area expenditures and ACO's rebased historical benchmark expenditures would be set at 35 percent. In an ACO's third or subsequent agreement period this percentage would be set at 70 percent unless the Secretary determines a lower weight should be applied, as specified through future rulemaking.

- With respect to the 2012 and 2013 starters, who have renewed their agreements for 2016, we would apply the current rebasing methodology, under which we equally weight the benchmark years and account for savings generated during the ACO's prior agreement period, in rebasing their historical benchmark for their second agreement period (beginning in 2016). We would apply the methodology currently specified under § 425.602(b) for updating the benchmark annually for each year of their second agreement period. We would apply the proposed new rebasing policies, including the phase in of the percentage used in calculating the regional adjustment, to these ACOs for the first time in calculating their rebased historical benchmark for their third agreement period (beginning in 2019), as if the ACOs were entering their second agreement period. Accordingly, the 2012 and 2013 starters would have the same transition to the use of a higher percentage in calculating the regional adjustment as all other ACOs.

This approach to phasing in the application of the new methodology for adjusting an ACO's rebased historical benchmark to reflect regional FFS expenditures would give ACOs and other stakeholders greater opportunity to prepare for, understand the effects of and adjust to the application of benchmarks that incorporate regional expenditures.

We are proposing to make these changes applicable to ACOs starting a second or

subsequent agreement period on or after January 1, 2017. Therefore, they would initially apply in resetting benchmarks for the second agreement period for all ACOs other than 2012 and 2013 starters (who entered their second agreement period on January 1, 2016). Further we are proposing that 2012 and 2013 starters would have the same transition to regional adjustments to their rebased historical benchmarks as all other ACOs: in calculating the regional adjustment to the ACO's rebased historical benchmark for its third agreement period (in 2019), the percentage applied to the difference between the ACO's regional service area expenditures and ACO's rebased historical benchmark expenditures would be set at 35 percent; in its fourth or subsequent agreement period this percentage would be set at 70 percent unless the Secretary determines a lower weight should be applied, as specified through future rulemaking. We request comment on this proposed approach to phasing in the application of the revised rebasing and updating methodology.

TABLE 2: CHARACTERISTICS OF CURRENT AND PROPOSED BENCHMARKING APPROACHES

Source of Methodology	Agreement Period	Historical Benchmark Trend factors (Trend BY1, BY2 to BY3)	Adjustment to the historical benchmark for regional FFS expenditures (percentage applied in calculating adjustment)	Adjustment to the historical benchmark for savings in prior agreement period?	Adjustment to the historical benchmark for ACO Participant List changes	Adjustment to historical benchmark for health status and demographic factors of performance year assigned beneficiaries	Update to historical benchmark for growth in FFS spending
Current Methodology	First	National	N/A	N/A	Calculated using benchmark year assignment based on the ACO's certified ACO Participant List for the performance year	Newly assigned beneficiaries adjusted using CMS-HCC model; continuously assigned beneficiaries adjusted using demographic factors alone unless CMS-HCC risk scores result in a lower risk score	National
	Second and subsequent	National	N/A	Yes	Same as methodology for first agreement period	Same as methodology for first agreement period	National
Proposed Rebasing Methodology	Second (third for 2012/2013 starters)	Regional	Yes (35 percent)	No	ACO's rebased benchmark adjusted by expenditure ratio*	No change	Regional
	Third and subsequent (fourth and subsequent for 2012/2013 starters)	Regional	Yes (70 percent unless the Secretary determines a lower weight should be applied, as specified through future rulemaking)	No	Same as proposed methodology for second agreement period	No change	Regional

* Proposed adjustment to the historical benchmark for ACO Participant List changes using an expenditure ratio would be a program-wide change applicable to all ACOs including ACOs in their first agreement period. As part of the proposed rebasing methodology, the regional adjustment to the ACO's rebased historical benchmark would be recalculated based on the new ACO Participant List.

3. Risk Adjustment and Coding Intensity Adjustment

a. Overview

In earlier rulemaking for the Shared Savings Program, we identified several risk adjustment considerations related to use of regional expenditures in resetting ACO benchmarks. In the June 2015 final rule, we specified that the subsequent proposed rule on benchmark rebasing would address the following issues related to risk adjustment: (i) how to refine the program's risk adjustment methodology to account for differences in the mix of beneficiaries assigned to the ACO and in the ACO's region; and (ii) how we might guard against excessive payments as ACOs improve documentation and coding of beneficiary conditions, such as by adjusting ACOs' risk scores for coding intensity or imposing limits on the extent to which an ACO's risk score can rise relative to its region (80 FR 32796). In the December 2014 proposed rule, we acknowledged considerations around the need for normalization of the ACO's assigned beneficiary risk scores among other considerations for additional risk adjustment in developing a rebasing methodology to account for regional expenditures (79 FR 72842).

The Shared Savings Program benchmarking methodology uses the CMS-HCC prospective risk score methodology used by the MA program to adjust expenditures for changes in health status of the population assigned to the ACO. Currently we use CMS-HCC risk scores for an ACO's assigned beneficiary population in risk adjusting the ACO's historical benchmark at the start of its first agreement period, adjusted historical benchmark (based on annual participant list changes during the agreement period) and in rebasing the ACO's benchmark for its second or subsequent agreement period (§ 425.602(a)(3)). Each performance year, we adjust the historical benchmark for

changes during the performance period in the health status and demographic factors of assigned beneficiaries (§ 425.604(a), § 425.606(a), § 425.610(a)). We use CMS-HCC prospective risk scores to adjust the benchmark to take into account changes in severity and case mix for newly-assigned beneficiaries and demographic factors to adjust for changes for beneficiaries continuously assigned to the ACO. However, if the continuously assigned population shows a decline in its CMS-HCC prospective risk scores, we adjust the benchmark to reflect the lower risk score for this population. The risk adjustment methodology applied in determining the updated benchmark each performance year limits the impact of changes in health status, including limiting the impact of ACO coding initiatives undertaken during the agreement period.

We anticipate that using CMS-HCC risk scores for an ACO's assigned beneficiary population in resetting the ACO's benchmark has the potential to benefit ACOs that have systematically engaged in coding initiatives during their prior agreement period. This effect would have been limited in the corresponding performance years due to the application of our current approach to risk adjusting during the agreement period according to the ACO's newly and continuously assigned beneficiary populations. Although initial financial performance results (for the performance years ending December 31, 2013 and 2014) do not show strong evidence that concerns about systematic coding practices by ACOs have materialized, complete data are not yet available to analyze the effect of coding initiatives in the initial rebasing of ACO benchmarks, as initial program entrants (ACOs with 2012 and 2013 agreement start dates) only began their second agreement periods on January 1, 2016.

We received various suggestions for risk adjustment approaches, including

through comments submitted in response to Shared Savings Program proposed rules (see 76 FR 67917 through 67919; 80 FR 32793). For instance, some commenters responding to the December 2014 proposed rule raised the need to revise the program's risk adjustment methodology when moving to an alternative benchmarking methodology that incorporates regional costs. Commenters suggested, for instance: using a regional HCC growth rate or accounting for regional variation in updating the HCC formulas; using a concurrent risk adjustment methodology, and doing so in combination with a demographically adjusted regional FFS cost baseline; creating a risk adjustment factor by comparing the HCC coding between the ACO's assigned beneficiaries and the regional comparison population; following the MA methodology for risk adjustment; and readjusting the risk determination of a population after removing beneficiaries determined ineligible for assignment. Some commenters suggested that CMS not be overly restrictive in applying regional normalization and coding intensity adjustments. Others suggested CMS specifically account for other factors in regional adjustments such as changes in access to care for low-cost populations, and the socio-economic risk profile of beneficiaries. One commenter requested that risk adjustment be based on the ACO's historical performance and not the market's historical performance.

In addition, although the December 2014 proposed rule did not explicitly request comment on the program's existing risk adjustment methodology, many commenters took the opportunity to criticize this aspect of the calculation of ACO benchmarks. Almost all commenters addressing the program's existing risk adjustment methodology suggested that it inadequately captures the risk and cost associated with assigned beneficiaries. Of the alternatives to the current risk adjustment methodology presented by

commenters, many urged CMS to incorporate the full change in HCC risk scores across each performance year (upward and downward adjustment). Some suggested use of regionally-based risk factors. Others suggested that CMS' concerns about upcoding could be addressed through vigilant monitoring or placing a cap on upward risk adjustment growth (for example, relative to a national or regional growth rate). Some urged CMS to continue researching alternative risk adjustment models and consider additional changes to increase the accuracy of the risk adjustment methodology (see 80 FR 32793).

b. Proposals for Risk Adjusting in Determining the Regional Adjustment to the ACO's Rebased Historical Benchmark and Seeking Comment on Approaches for Risk Adjusting Rebased Benchmarks

To balance CMS' concerns regarding ACO coding practices with the recommendations of commenters, we considered an approach whereby we would perform risk adjustment to account for the health status of the ACO's assigned population in relation to FFS beneficiaries in the ACO's regional service area when determining the regional adjustment to the ACO's rebased historical benchmark described in section II.A.2.c. of this proposed rule. Additionally, we considered rigorously monitoring for the impact of coding initiatives on ACO benchmarks and modifying the risk adjustment methodology used in resetting ACO benchmarks as warranted through future rulemaking.

We propose to adjust for differences in health status between an ACO and its regional service area in a given year, in determining the regional adjustment to the ACO's rebased historical benchmark. For example, we would compute for each Medicare enrollment type a measure of risk-adjusted regional expenditures that would account for differences in HCC risk scores of the ACO's assigned beneficiaries and the average HCC

risk scores in the ACO's regional service area. We believe this approach would account for differences in health status between the ACO's assigned population and the broader FFS population in the ACO's regional service area. It would also capture differences in coding intensity efforts applied to the ACO's assigned population and the FFS population in the ACO's regional service area. We propose to include this risk adjustment approach in the revised benchmark rebasing methodology under a new provision of the Shared Savings Program regulations at § 425.603.

While we anticipate the proposed approach would serve as a partial coding intensity adjustment, it may not fully adjust for differential coding intensity by the ACO relative to its region. In other words, this would not adjust for intensive coding practices of the ACO that are above and beyond the coding practices occurring generally in the ACO's region. For this reason, we plan to rigorously monitor for the impact of coding initiatives on ACO benchmarks and, if warranted, would undertake further rulemaking to modify the risk adjustment methodology to further limit ACOs from generating higher benchmarks simply through systematic coding practices. The combined approach of adjusting for an ACO's risk relative to its region while engaging in further rigorous monitoring is also in alignment with certain comments received in response to the December 2014 proposed rule, including comments recommending that CMS compare an ACO's HCC coding with that of a regional comparison population and avoid being overly restrictive in applying coding intensity adjustments (see 80 FR 32793).

We believe the combined approach of proposing to adjust for an ACO's risk relative to that of its region in determining the regional adjustment to the ACO's rebased historical benchmark, while engaging in further rigorous monitoring, is reasonable given

the lack of strong evidence to date that ACOs are engaging in more intensive coding practices and given a number of factors that we believe would mitigate the potential impact of coding intensity on ACO financial calculations, including the following:

- The program's current policy for performance year reconciliation under which the ACO's benchmark is risk adjusted using HCC scores for the newly assigned population, but any upward adjustment for the continuously assigned population is limited to demographics, appears to mitigate the impact of ACO coding initiatives.
- CMS is fully transitioning in 2016 to a new HCC model that markedly reduces the model's sensitivity to subjectively coded severity levels for key chronic conditions.
- ACOs are less susceptible to coding practices, for instance, compared to MA plans, for several reasons including the following: (1) ACOs can be comprised of entities with little influence over the coding practices at other facilities or settings (a point made by commenters responding to the December 2014 proposed rule (see 80 FR 32793)); and (2) unlike MA plans, ACOs cannot submit supplemental diagnosis codes.
- Routine changes in the assignment of beneficiaries to the ACO would tend to reduce the potential disparity in coding intensity between the ACO and its region. As a result of normal changes in beneficiary assignment from year to year, beneficiaries whose risk scores were subject to ACO coding initiatives in one year may no longer be assigned to the ACO in the next year. These changes in the ACO's assigned population may serve to mitigate the effect of coding initiatives by preventing the ACO from being able to systematically apply coding intensity efforts across a static population year after year. In addition, under the proposals described in section II.A.2. of this proposed rule, regional FFS expenditures would reflect the coding intensity efforts (or lack thereof) within the

ACO's regional service area, including the ACO's own coding intensity initiatives.

- Many ACOs tend to be clustered in similar regions, meaning coding intensity efforts in such regions would also be felt by the region's wider population as a whole, further reducing the potential impact of coding intensity for ACOs relative to their region. Similarly, ACOs serve a wider population than just their assigned beneficiaries which leads to spillover of any coding shifts to the wider region; when many ACOs are clumped together geographically these spillover effects can be further amplified.

However, we considered several alternatives that might be employed in the future to limit the impacts of intensive coding while still accounting for changes in health status within an ACO's assigned beneficiary population.

One alternative we considered would be to apply the methodology currently used to adjust the ACO's benchmark annually to account for the health status and demographic factors of the ACO's performance year assigned beneficiaries (according to newly and continuously assigned populations) when rebasing the ACO's historical benchmark. Under this approach, newly assigned beneficiaries would always receive full HCC risk adjustment, whereas continuously assigned beneficiaries would receive either HCC or demographic risk adjustment, depending on whether average HCC risk scores were rising or falling. We believe this approach would more significantly limit ACOs from generating higher benchmarks simply through systematic coding practices, compared to the current risk adjustment methodology that accounts for the CMS-HCC scores of all assigned beneficiaries in rebasing, or the approaches proposed in this section. An advantage of this alternative is that it is already part of the current benchmarking methodology and is familiar to ACOs and stakeholders, and would be

relatively easy for CMS to implement.

We have also considered ultimately moving to a coding intensity adjustment similar to the methodology used in the MA program which relies on an analysis of populations of beneficiaries who remained in MA for two consecutive reference years, and whose diagnoses all came from MA, referred to as stayers. For a full description of the MA approach see “Advance Notice of Methodological Changes for Calendar Year (CY) 2010 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies,” February 20, 2009, available online at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/Advance2010.pdf>. Under this approach we would develop a coding intensity adjustment by looking at risk score changes over time for beneficiaries assigned to the ACO for at least two consecutive prospective risk adjustment data years (similar to the population referred to as stayers under the MA methodology) relative to the greater FFS population. One advantage of this approach is that CMS has several years of experience with the methodology used under the MA program. Further, this approach would measure the degree of coding intensity and adjust accordingly. However, before implementing an approach similar to the one used in the MA program, we would need to conduct additional analyses, using Shared Savings Program data spanning several program years, including future years.

We seek comment on the proposals to risk adjust to account for the health status of the ACO’s assigned population in relation to FFS beneficiaries 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, and to specify this approach under a new

provision of the Shared Savings Program regulations at § 425.603. If this approach is finalized, we would rigorously monitor for the impact of coding initiatives on ACO benchmarks and make necessary refinements to the program's risk adjustment methodology through future rulemaking if program results show adverse impacts due to increased coding intensity. We also seek comment on alternatives considered that might be employed in the future to limit the impacts of intensive coding while still accounting for changes in health status within an ACO's assigned beneficiary population, including: (1) apply the methodology currently used to adjust the ACO's benchmark annually to account for the health status and demographic factors of the ACO's performance year assigned beneficiaries (according to newly and continuously assigned populations) when rebasing the ACO's historical benchmark; or (2) develop a coding intensity adjustment by looking at risk score changes over time for beneficiaries assigned to the ACO for at least two consecutive prospective risk adjustment data years (similar to the population referred to as stayers under the MA methodology) relative to the greater FFS population.

We note that these proposed changes would not apply in calculating the benchmarks for ACOs in their first agreement period, or in establishing and updating the rebased historical benchmark for the second agreement period for ACOs that started in the program in 2012 and 2013 and started a new agreement period on January 1, 2016. Rather, we will continue to use CMS-HCC risk scores for the ACO's assigned beneficiary population in risk adjusting the ACO's historical benchmark at the start of the agreement period.

Further, for all ACOs, we will continue to use the current methodology to adjust the ACO's benchmark annually to account for the health status and demographic factors

of the ACO's performance year assigned beneficiaries (according to the newly and continuously assigned populations).

B. Adjusting Benchmarks for Changes in ACO Participant (TIN) Composition

1. Overview

In the initial rulemaking establishing the Shared Savings Program, we acknowledged that the addition or removal of ACO participants or ACO providers/suppliers (identified by TINs and NPIs, respectively) during the term of an ACO's participation agreement could affect a number of different aspects of the ACO's participation in the Shared Savings Program. In the November 2011 final rule, we included the regulation at § 425.214(a)(3), which specified that the ACO's benchmark, risk scores, and preliminary prospective assignment may be adjusted to reflect changes in ACO participants or ACO providers/suppliers at CMS' discretion. Following the issuance of the November 2011 final rule, we issued subregulatory guidance further describing how the agency would use this discretion to make adjustments to reflect changes in ACO participants. See "Changes in ACO participants and ACO providers/suppliers during the Agreement Period" available online at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Updating-ACO-Participant-List.html> (last modified November 16, 2015). This guidance explains:

After acceptance into the program and upon execution of the participation agreement with CMS, the ACO must certify the completeness and accuracy of its list of ACO participants. We set the ACO's historical benchmark at the start of the agreement period based on the assigned population in each of the three benchmark years by using the ACO Participant List certified by the ACO. The ACO must submit a new certified ACO Participant List at the start of each new performance year.

CMS will adjust the ACO's historical benchmark at the start of a performance year if the ACO Participant List that the ACO certified at the start of that performance year differs from the one it certified at the start of the prior performance year. We will use the updated certified ACO Participant List to assign beneficiaries to the ACO in the benchmark period (the 3 years prior to the start of the ACO's agreement period) in order to determine the ACO's adjusted historical benchmark. As a result of changes to the ACO's certified ACO Participant List, we may adjust the historical benchmark upward or downward. We'll use the new certified list of ACO participants and the adjusted benchmark for the new performance year's assignment, quality measurement and sampling, reports for the new performance year, and financial reconciliation. We will provide ACOs with the adjusted Historical Benchmark Report.

In the June 2015 final rule we amended the Shared Savings Program regulations to incorporate portions of the subregulatory guidance (80 FR 32707 through 32712) at § 425.118(b)(3)(i). This provision specifies that CMS annually adjusts an ACO's assignment, historical benchmark, the quality reporting sample, and the obligation of the ACO to report on behalf of eligible professionals that bill under the TIN of an ACO participant for certain CMS quality initiatives to reflect the addition or deletion of entities from the list of ACO participants that is submitted to CMS before the start of a performance year in accordance with § 425.118(a). Further, § 425.118(b)(3)(ii) specifies that absent unusual circumstances, CMS does not make adjustments during the performance year to the ACO's assignment, historical benchmark, performance year financial calculations, the quality reporting sample, or the obligation of the ACO to report on behalf of eligible professionals that bill under the TIN of an ACO participant for certain CMS quality initiatives to reflect the addition or deletion of entities from the ACO Participant List that become effective during the performance year. CMS has sole discretion to determine whether unusual circumstances exist that would warrant such adjustments. Because we added a new provision at § 425.118 that addresses the

adjustments that CMS will make to reflect changes in an ACO's list of ACO participants, we removed the reference to CMS' discretion to adjust the benchmark under § 425.214(a)(3). The June 2015 final rule also codified the subregulatory policies allowing for consideration of claims billed under merged and acquired Medicare-enrolled TINs for purposes of beneficiary assignment and establishing the ACO's benchmark (§§ 425.204(g), 425.118(a)(2)).

During the program's initial performance years, we experienced a high volume of change requests from ACOs, both adding and removing ACO participants. With each new performance year an ACO has the opportunity to request the addition of new ACO participants and to make other changes to its ACO Participant List resulting in a new certified ACO Participant List as required under § 425.118(a). Prospective additions must be vetted through CMS' screening process which reviews the TINs for program integrity concerns, Medicare enrollment requirements, and participation in other Medicare shared savings initiatives. ACOs may delete ACO participants from their ACO Participant List at any time during the performance year and are required to notify CMS within 30 days after the termination of an ACO participant agreement (§ 425.118(b)(2)).

When we adjust historical benchmarks during the agreement period to account for changes in beneficiary assignment arising from ACO Participant List changes, the benchmark period (the 3 years prior to the start of the ACO's agreement period) remains the same. For instance, if an ACO with an agreement start date of January 1, 2013, added ACO participants for its second performance year (2014), then the adjustments made to the historical benchmark to reflect the ACO's certified ACO Participant List for performance year two would have been based on the same 3 benchmark years (2010,

2011, and 2012) originally used to calculate the historical benchmark for the ACO based on the ACO Participant List it certified when it entered the program at the start of its first performance year. As a result of this methodology, if an ACO certifies revisions to its ACO Participant List for its second and third performance years, it is necessary for us to adjust the historical benchmark to reflect the changes made to the ACO Participant List for the second performance year, and to make further adjustments to reflect the changes made for the third performance year.

Changes in the ACO participant TINs that compose ACOs are also relevant to determining beneficiary assignment across all ACOs participating in the program. A beneficiary is assigned to an ACO if the beneficiary received the plurality of his or her primary care services (measured in allowed charges) from ACO professionals billing under the TINs of ACO participants in the ACO rather than outside the ACO (such as from ACO professionals billing under the TINs of ACO participants in other ACOs or from individual providers or provider organizations that are not participating in an ACO). We perform the assignment process for ACOs simultaneously, regardless of whether they have had an ACO Participant List change. To determine where a beneficiary got the plurality of his or her primary care services, we compare the total allowed charges for each beneficiary for primary care services provided by the ACO (in total for all ACO participants) to the allowed charges for primary care services provided by ACO participants in other ACOs and by non-ACO providers and suppliers. See "Medicare Shared Savings Program: Shared Savings and Losses and Assignment Methodology Specifications" available online at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Financial-and-Assignment-Specifications.html>

(see version 4 dated December 2015 applicable beginning Performance Year 2016, and version 3 dated December 2014 applicable for Performance Years prior to 2016). In the case where a beneficiary is receiving primary care services from ACO participants in multiple ACOs or from both ACO participants and non-ACO providers and suppliers, the composition of each ACO is important in determining whether the beneficiary is assigned to an ACO at all, and in determining to which ACO (among several) the beneficiary may be assigned.

In summary, in making adjustments to the historical benchmarks for ACOs within an agreement period to account for ACO Participant List changes, the historical benchmark period remains constant, but beneficiary assignment reflects the influence of ACO Participant List changes. Under this methodology, the historical benchmarks for ACOs with ACO Participant List changes from one performance year to the next continue to reflect the ACOs' historical costs in relation to the current composition of the ACO. Changes to an ACO's list of ACO participants will result in changes to the ACO's assigned beneficiary population which can affect the proportion of an ACO's assigned population in each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible), assigned beneficiary expenditures, and risk adjustment. Further, the historical benchmark will be adjusted to remove the historical claims experience of any ACO participant TINs that have been deleted from the ACO Participant List, unless the TIN has merged with or been acquired by another ACO participant TIN as reported to CMS by the ACO.

In accordance with these policies, we adjusted the historical benchmarks for 162 of 220 ACOs (74 percent) with 2012 and 2013 start dates for the 2014 performance year

to reflect changes in ACO participants. For the 2015 performance year, we adjusted benchmarks for 245 of 313 ACOs (78 percent) with 2012, 2013 or 2014 start dates to reflect changes in ACO participants. Among the ACOs that made TIN changes effective for performance year 2015, the mean percentage change in historical benchmark value was -0.3 percent and the magnitude of the change for most ACOs was between -2 percent and +2 percent.

While the current methodology ensures that a benchmark that has been adjusted based on changes in the ACO's participant composition accurately reflects benchmark year assignment using the most recent certified ACO Participant List, a primary drawback is that this methodology is operationally burdensome. To adjust benchmarks to account for ACO Participant List changes made by ACOs for each new performance year we must repeat the assignment process for all 3 benchmark years for each starter cohort. For example, in order to adjust benchmarks for 2012, 2013, and 2014 starters making ACO Participant List changes for the 2015 performance year we had to perform the assignment process for 5 different benchmark years: 2009, 2010, 2011, 2012, and 2013. The operational burden associated with the current methodology will increase further as Track 3 ACOs enter the program. Track 3 ACOs have an offset assignment window based on the most recent 12-month period preceding the relevant calendar year for which data are available (for example, the period spanning October – September prior to the start of the benchmark year) whereas the assignment window for Track 1 and 2 ACOs is based on the 12-month calendar year that corresponds to the benchmark year. Therefore, with the first ACOs starting their participation under Track 3 on January 1, 2016, we now have to perform two assignment runs for each benchmark year.

2. Proposed Revisions

In light of the operational burden of adjusting benchmarks to reflect changes in ACO participants under the current policy, and the considerations associated with our proposal to adopt a benchmark rebasing methodology that requires additional calculations, we considered alternative approaches to streamline calculations of adjusted historical benchmarks. Under these alternatives, we would start with the historical benchmark based on the ACO's certified ACO Participant List for the most recent prior performance year and make adjustments to the benchmark using expenditures from a single reference year—for example, the third benchmark year (BY3) of the current agreement period—for which beneficiary assignment has been performed using both the ACO Participant List for the most recent prior performance year and the new ACO Participant List for the current performance year. This approach would allow us to adjust the benchmark to reflect changes in the ACO participants while reducing the number of benchmark years for which assignment would need to be redetermined based on the new ACO Participant List. Under this approach, where we would adjust the benchmark determined based on the ACO's list of ACO participants for the most recent prior performance year, there would be a cumulative effect of the adjustment in the case where an ACO certifies changes to its ACO Participant List effective for the second and third performance years of the agreement period. However, the number of cumulative adjustments would be limited and, further, we believe that applying adjustments to the benchmark determined based on the certified ACO Participant List for the most recent prior performance year in all cases enhances the simplicity of the approach.

Calculations for the adjustment would be made in relation to three populations of

beneficiaries assigned to the ACO in the reference year:

- Stayers: beneficiaries assigned to an ACO using both the ACO Participant List for the most recent prior performance year and the new ACO Participant List.

- Joiners: beneficiaries who are assigned to the ACO using the new ACO Participant List but not the ACO Participant List for the most recent prior performance year.

- Leavers: beneficiaries who are assigned to the ACO using the ACO Participant List for the most recent prior performance year but not the new ACO Participant List.

Calculation of the adjusted historical benchmark would include the following steps for each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible):

- Calculate a stayer component: multiply an ACO's historical benchmark by a ratio of average per capita reference year expenditures for stayers to average per capita reference year expenditures for stayers and leavers combined. This ratio may adjust the benchmark upward or downward depending on the relative expenditures and person years of the stayers and leavers.

- Calculate a joiner component: determine average per capita reference year expenditures for joiners.

- Combine the stayer and joiner components: obtain the overall adjusted benchmark for each enrollment type by taking a weighted average of the stayer and joiner components where each component's weight is its relative share of the total number of assigned beneficiaries, identified as stayers or joiners (respectively), based on the new Participant List.

- Once the preceding three steps have been completed for each Medicare enrollment type: Calculate a single weighted average per capita adjusted historical benchmark. We will sum the product of the benchmark expenditures for each Medicare enrollment type and the ACO's proportion of assigned beneficiaries for the corresponding Medicare enrollment type. We will determine the proportion of assigned beneficiaries by Medicare enrollment type during the reference year based on the assigned beneficiary population determined using the new ACO Participant List.

- In conjunction with the proposals to adjust an ACO's rebased historical benchmark to account for regional expenditures, we would also redetermine the regional adjustment to account for changes to the ACO's certified ACO Participant List. In addition to the steps described previously, we would redetermine the ACO's regional service area during the reference year based on the residence of the ACO's assigned beneficiaries for the reference year determined using the new ACO Participant List. We would also use this assigned population to determine the ACO's proportion of beneficiaries by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) to be used in calculating the regional adjustment. We would redetermine the regional adjustment, using the approach described previously under section II.A.2.c. of this proposed rule. In calculating the regional adjustment, we would adjust for differences between the health status during the reference year of the ACO's assigned beneficiaries determined using the new ACO Participant List and the population of assignable beneficiaries in the ACO's regional service area.

We believe that this approach offers the right balance between approximating the accuracy of the current methodology for adjusting historical benchmarks (which requires

performing beneficiary assignment for all 3 of an ACO's historical benchmark years with the new ACO Participant List) and operational ease. Initial modeling suggests that benchmarks calculated using this alternative methodology are highly correlated with those calculated using the current methodology.

We also examined a second alternative under which we would calculate the average per capita expenditures for leavers in the reference year and use this value, along with the relative person years for leavers and stayers, to impute average per capita reference year expenditures for stayers from the historical benchmark. The imputed expenditures for stayers would then be combined with average per capita reference year expenditures for joiners to obtain the overall adjusted benchmark. This second alternative, in addition to being more complex to compute and explain, does not consistently improve the accuracy of the calculations compared to the first alternative. For example, initial modeling indicates this approach can produce a phenomenon whereby ACOs with large numbers of high cost leavers (in relation to their stayer and joiner populations) actually retained relatively high benchmarks under this adjustment, which was an unanticipated result. Further, we have concerns about the reliability and predictability of imputed data, on which this approach depends.

We believe that several clarifications to the application of the preferred first alternative methodology are important. First, in the case where an ACO's new ACO Participant List yields zero assigned beneficiaries who are identified as stayers, we would apply the current methodology for adjusting the historical benchmark for ACO Participant List changes. That is, in such cases, we would calculate the ACO's average per capita historical benchmark based on assignment for each of the 3 benchmark years

prior to the start of the ACO's agreement period using the new ACO Participant List. Second, the ACO Participant List for the performance year would be used to identify the counties of residence for the ACO's assigned beneficiaries in order to determine the ACO's regional service area for the purpose of calculating the regional benchmark update, as discussed in section II.A.2.d. of this proposed rule.

We considered whether to apply the preferred alternative methodology for adjusting the historical benchmark for ACO Participant List changes for all ACOs beginning with an ACO's first agreement period, or only for ACOs in a second or subsequent agreement period as part of the revised rebasing methodology. We believe that applying a single policy for adjusting historical benchmarks for changes in ACO participants to all ACOs participating in the program would provide operational consistency and stability to the program and its participants.

Therefore, we propose to replace the current approach for calculating adjusted historical benchmarks for ACOs that make ACO Participant List changes with an approach that adjusts an ACO's historical benchmark using a ratio that is based on expenditures for the ACO's beneficiaries assigned using both the ACO Participant List for the new performance year and the ACO Participant List for the most recent prior performance year (stayers) and expenditures for the ACO's beneficiaries assigned using only the ACO Participant List for the ACO's most recent prior performance year (stayers and leavers) for the same reference year. We propose to define the reference year as benchmark year 3 of the ACO's current agreement period. This figure would then be combined with reference year expenditures for beneficiaries assigned using only the ACO Participant List for the new performance year (joiners) to obtain the overall

adjusted benchmark. Calculations of the adjustment would be made, and applied to the historical benchmark, for each of the following populations of beneficiaries, according to Medicare enrollment type: ESRD, disabled, aged/dual eligible, and aged/non-dual eligible. We propose to apply this adjustment to the ACO's historical benchmark determined based the ACO's certified ACO Participant List for the most recent prior performance year. We propose to apply this new approach program wide as we believe it will address operational inefficiencies in the calculation of adjusted historical benchmarks under the current approach while still providing an accurate adjustment to reflect changes in ACO participants. We also propose that in the event an ACO's new ACO Participant List results in zero stayers, we would continue to apply the current methodology for adjusting the ACO's historical benchmark for ACO Participant List changes. We propose to incorporate this adjustment to the historical benchmark for ACOs in their first agreement period and those ACOs that started a second agreement period on January 1, 2016, by adding a paragraph to § 425.602. In addition, we propose to specify that the adjustment would apply to the ACO's rebased historical benchmark in a new provision of the Shared Savings Program regulations at § 425.603. We also propose to add definitions for "stayers", "joiners" and "leavers" to § 425.20.

We seek comment on this proposed approach to adjusting ACO historical benchmarks for changes in ACO participants and any modifications to our proposed approach that may be needed. We welcome comments on alternatives to applying the adjustment to the ACO's historical benchmark determined based on the ACO's certified ACO Participant List for the most recent prior performance year, such as applying the proposed adjustment to the historical benchmark established for the first performance

year of the ACO's agreement period. Further, we seek commenters' suggestions on the anticipated interactions between the proposed approach to adjusting ACO historical benchmarks using an expenditure ratio and the rebasing alternatives discussed previously in this proposed rule.

C. Facilitating Transition to Performance-Based Risk

1. Overview

As discussed in the December 2014 proposed rule (79 FR 72815 through 72816), we believe that in order for the Shared Savings Program to be effective and sustainable over the long term, we need to further strengthen our efforts to transition the Shared Savings Program to a two-sided performance-based risk program in which ACOs share in both savings and losses. Although we are encouraged by stakeholder interest in the Shared Savings Program, ACOs have been cautious in choosing to enter performance-based risk arrangements. Only a small number of ACOs have agreed to participate under the program's performance-based risk track (Track 2) established in the November 2011 final rule. Therefore, in the June 2015 final rule, we established a new performance-based risk track at §425.610, referred to as Track 3, and made other program revisions (see 80 FR 32694 and 32695 for a summary) to encourage ACOs to accept performance-based risk arrangements. We also indicated in the June 2015 final rule (80 FR 32695) that we intended to consider other modifications to program rules in future rulemaking in the near term to improve ACO willingness to take on performance-based risk. Accordingly, in addition to the proposals to integrate regional factors when resetting ACO benchmarks which are discussed in section II.A. of this proposed rule, we continued to consider whether other revisions might also be appropriate to provide ACOs

with additional flexibilities to support them as they transition to performance-based risk.

Currently, for its initial agreement period, 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. ACOs entering the program under the one-sided shared savings model (Track 1) that meet eligibility criteria may continue their participation under this model for a second 3-year agreement period as specified under § 425.600(b).

Stakeholders and ACOs have suggested a variety of options to address their concerns about some of the current agreement period related policies. For example, as discussed in the June 2015 final rule (80 FR 32763), some commenters responding to the December 2014 proposed rule supported allowing ACOs initially participating under Track 1 to extend their first agreement period by 1, 2 or 3 years, under certain circumstances, to gain additional experience before starting their second agreement period under a performance-based risk track. Under such an option in which ACOs are allowed to choose voluntarily to have a longer agreement period under Track 1, stakeholders requested that we also maintain an ACO's original historical benchmark as it gains additional experience before moving to performance-based risk. These stakeholders explained that this approach would facilitate ACOs' transition to two-sided performance-based risk arrangements. We did not adopt these suggestions for the reasons discussed in the June 2015 final rule (80 FR 32763). However, based on our experience with the first group of ACOs eligible for renewal for 2016 in which nearly all such ACOs applied to remain in Track 1 for an additional agreement period, we have further considered these issues.

2. Proposed Revisions

We further considered these stakeholder suggestions and whether it would be appropriate to offer an additional option to encourage ACOs to move more quickly from the one-sided shared savings model to a performance-based risk model when renewing their agreements. To respond to stakeholder concerns and to provide additional support for ACOs that are willing to accept performance-based risk arrangements, we are proposing to add a participation option that would allow eligible Track 1 ACOs to defer by 1 year their entrance into a performance-based risk model (Track 2 or 3) by extending their first agreement period under Track 1 for a fourth performance year. ACOs that would be eligible to elect this proposed new participation option would be those ACOs eligible to renew for a second agreement period under Track 1 but instead are willing to move to a performance-based risk track 2 years earlier, after continuing under Track 1 for 1 additional year. This option would assist ACOs in transitioning to a two-sided risk track when they need only one additional year in Track 1 rather than a full 3-year agreement period in order to prepare to accept performance-based risk. The additional year could allow such ACOs to further develop necessary infrastructure to meet the program's goals, such as further developing their care management services, adopting additional mechanisms for measuring and improving quality performance, finalizing implementation and testing of electronic medical records, and performing data analytics. This option would be available to Track 1 ACOs whose first agreement period is scheduled to end on or after December 31, 2016. Under this proposal, ACOs that elect this new participation option would continue under their first agreement period for a fourth year, deferring benchmark rebasing as well as deferring entrance to a two-sided

risk track if they are approved for renewal.

More specifically, we are proposing to provide an additional option for ACOs participating under Track 1 to apply to renew for a second agreement period under a two-sided track (Track 2 or Track 3) under the renewal process specified at § 425.224. If the ACO's renewal request is approved, the ACO would be able to defer entering the new agreement period under a performance-based risk track for 1 year. Further, as a result of this deferral, we would also defer rebasing the ACO's benchmark for 1 year. At the end of this fourth performance year under Track 1, the ACO would transition to the selected performance-based risk track for a 3-year agreement period. Accordingly, we are proposing to amend the participation agreement requirements at § 425.200 to provide that an ACO that defers entering its new agreement period will be able to continue participating under its first agreement for an additional year (for an agreement period that would total 4 years).

An ACO electing this option would still be required to undergo the renewal process specified at § 425.224 prior to the end of its initial agreement (PY 3) and meet all other renewal requirements including the requirement that the ACO demonstrate that it is capable of repaying shared losses as required to enter a performance-based risk track. Because the ACO would be committing under the renewal application to transition to a performance-based risk track following completion of PY 4 under Track 1, the ACO would be required to demonstrate as part of its renewal application that it has established an adequate repayment mechanism as specified at § 425.204(f) to assure CMS of its ability to repay losses for which it may be liable during the new agreement period. We propose to make this option available to Track 1 ACOs whose first agreement period is

scheduled to end on or after December 31, 2016. Therefore, if finalized, this option would be available to ACOs with 2014 start dates seeking to renew their participation agreement in order to enter their second agreement period beginning in 2017. Under this proposal, we would update the ACO's benchmark as specified at § 425.602(b) for performance year 4 of the initial participation agreement. However, we would defer resetting the benchmark as specified at proposed § 425.603 until the beginning of the ACO's second agreement period (that is, the ACO's first agreement period under the selected performance-based risk track). The benchmark would be reset under the policies in place for that time period including any regional adjustment, as described in this proposed rule, if finalized. Also, we propose that the quality performance standard that would apply for performance year 4 of the initial participation agreement would be the same as for the ACO's performance year 3, consistent with § 425.502(a)(2). Specifically, we propose that during the fourth performance year of the ACO's first agreement period, the ACO must continue to report all measures and the ACO will be assessed on performance based on the quality performance standard in place for the third performance year of the ACO's first agreement period.

In addition, under this proposal, if a Track 1 ACO finishing its initial agreement period chooses to elect this option during the renewal of its participation in the Shared Savings Program, the ACO would be required to transition to the selected performance-based risk track at the end of the fourth performance year under Track 1. The term of the second agreement period would be 3 performance years.

If such an ACO subsequently decides during the fourth performance year that it no longer wants to transition to the performance-based risk track it selected in its

application for a second agreement period, then the currently established close-out procedures and payment consequences of early termination under § 425.221 would apply. For example, if the ACO voluntarily terminates its agreement under § 425.221(a), effective December 31 of its fourth performance year, and completes all required close-out procedures, then as specified by § 425.221(b), the ACO would be eligible to share in any shared savings for its fourth performance year.

However, we believe it would be appropriate under this proposed participation option to provide some incentive for ACOs to honor their commitment to participate early in a performance-based risk track. Therefore, we are proposing that if an ACO that has been approved for an extension of its initial agreement period terminates its participation agreement prior to the start of the first performance year of the second agreement period, then the ACO would be considered to have terminated its participation agreement for the second agreement period under § 425.220. Such an ACO would not be eligible to participate in the Shared Savings Program again until after the date on which the term of that second agreement period would have expired if the ACO had not terminated its participation, consistent with § 425.222.

We would further note that if an ACO that goes on to participate under a two-sided track under this proposed option voluntarily terminates its agreement during its second agreement period, then the currently established close-out procedures and payment consequences of early termination under § 425.221 would apply. If an ACO terminates its agreement under its selected performance-based risk track and subsequently decides to reapply to participate in the Shared Savings Program, then the requirements under § 425.222 for re-application after termination would apply. For

example, consistent with our current policy, such an organization would be required to apply to participate under a two-sided model and would have to wait the duration of its remaining agreement period before reapplying.

In developing this proposal to support our policy goal of providing additional flexibility to ACOs that are considering transitioning to two-sided risk, we considered an alternative approach that might achieve the same goal. Specifically, we considered an alternative option that would permit the ACO to transition to a two-sided risk track during a subsequent 3-year agreement period under Track 1, instead of extending the first agreement period for an additional year. Under this alternative approach, we would allow the ACO to remain in Track 1 for the first performance year of the second 3-year agreement period. The ACO would then be required to transition to Track 2 or 3 for the final 2 performance years of the agreement period. An ACO choosing this option would be required to satisfy all the requirements for a performance-based risk track at the time of renewal, including the requirement that the ACO demonstrate that it is capable of repaying shared losses as required to enter a performance-based risk track. Under this approach, we would rebase the ACO's benchmark as provided under proposed § 425.603, effective for the first year of the second 3-year agreement period. Further, we would calculate shared savings for the first year of the second 3-year agreement period under the one-sided model as specified at § 425.604. During the second and third performance years of the second agreement period we would calculate shared savings and shared losses, as applicable, under either Track 2 (as determined at § 425.606) or Track 3 (as determined at § 425.610). We did not elect to propose this alternative option because we believe there could be a stronger incentive for some ACOs to transition to two-sided

performance-based risk if we were to defer resetting the ACO's benchmark until the beginning of the ACO's second agreement period. Additionally, the alternative approach could raise concerns about risk selection since an ACO could participate for the first performance year of the second agreement period under this alternative, learn midway through the second performance year that its expenditures for the first performance year were below the negative MSR, and withdraw from the program before being subjected to reconciliation under performance-based risk.

We welcome comments on this proposal and the alternative approach, as well as on other possible alternatives to provide flexibility and encourage ACOs to enter into and honor their participation agreements under performance-based risk tracks, and any related issues.

D. Administrative Finality: Reopening Determinations of ACO Savings or Losses to Correct Financial Reconciliation Calculations, and a Conforming Change

1. Overview

ACOs enter into agreements with CMS to participate in the Shared Savings Program, under which ACOs that meet quality performance requirements and reduce the Medicare Parts A and B expenditures for their assigned beneficiaries below their benchmark by a specified margin are eligible to share a percentage of savings with the Medicare program. Further, ACOs participating under a two-sided track, whose Medicare Parts A and B expenditures for their assigned beneficiaries exceed their benchmarks by a specified margin, are liable for sharing losses with CMS. After each performance year (PY), CMS calculates whether an ACO has generated shared savings by comparing its actual expenditures for its assigned beneficiaries in the PY with its

updated benchmark. Savings are generated if actual Medicare Parts A and B expenditures for assigned beneficiaries are less than the updated benchmark expenditures and shared with the ACO if they exceed the ACO's minimum savings rate, and the ACO meets the minimum quality performance standards and otherwise maintains its eligibility to participate in the Shared Savings Program. For an ACO in a two-sided track, losses are generated if actual Medicare Parts A and B expenditures for assigned beneficiaries are greater than the updated benchmark expenditures and the ACO is liable for shared losses if the losses exceed the ACO's minimum loss rate.

To date, we have announced 2 years of financial performance results for ACOs participating in the Shared Savings Program, in Fall 2014 for 220 ACOs with 2012 and 2013 start dates for PY 1 (concluding December 31, 2013), and in August 2015 for 333 ACOs with 2012, 2013 and 2014 start dates for PY 2014. Several months after the release of PY 1 financial reconciliation results and shared savings payments to eligible ACOs, we discovered that there was an issue with one of the source input data fields used in the final financial reconciliation calculations that we ultimately determined resulted in an estimated 5 percent overstatement of PY 1 shared savings payments to ACOs and an understatement of shared losses. The issue did not result in understated PY 1 shared savings payments or overstated PY 1 shared loss recoupments for any ACO.

When we calculate total Medicare Parts A and B FFS expenditures for assigned beneficiaries for purposes of establishing ACO benchmarks and determining performance year results, we make an adjustment to remove IME payments and DSH payments, including uncompensated care payments. We identified an issue in the source data for Quarter 4 of CY 2013 that caused some cancellation claims for uncompensated care to be

incorrectly signed (plus sign instead of a minus sign) in the national claim data repository used to calculate ACO benchmarks and performance year results. The outcome of the sign error was that the amounts deducted from total CY 2013 expenditure calculations were doubled for claims that were canceled and resubmitted, which ultimately led to ACO total expenditures for PY1 being understated in the final reconciliation for PY1 (that is, for the performance year ending December 31, 2013). As a result, the PY 1 shared savings payments were overstated for some ACOs and shared losses were understated for some other ACOs. The impact on individual ACOs varied depending on the extent to which services provided to the ACO's assigned beneficiaries were furnished by providers that receive DSH payments.

The financial reconciliation calculation/methodology and the amount of shared savings an ACO might earn, including all underlying financial calculations, are not appealable. That is, the determination of whether an ACO is eligible for shared savings under section 1899(d), and the amount of such shared savings, as well as the underlying financial calculations are precluded from administrative and judicial review under section 1899(g)(4) of the Act and § 425.800(a)(4). However, under § 425.314(a)(4), if as a result of any inspection, evaluation, or audit, it is determined that the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO has been calculated in error, CMS reserves the right to reopen the initial determination and issue a revised initial determination. (See also the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Reconsideration-Review-Process-Guidance.pdf>).

Thus far, we have not further specified, either through regulations or program

guidance, the actions that we would take under circumstances when we identify an error in a prior payment determination, such as the error that occurred in the calculation of PY 1 shared savings and shared losses. We have considered what actions we believe would be appropriate for addressing issues with the financial reconciliation calculations underlying the initial determination of ACO shared savings and shared losses in situations such as the data source error that occurred for PY 1, or a final agency determination under § 425.804 or § 425.806, if an error were discovered after a request for reconsideration of the initial determination. In considering this issue, we reviewed existing, analogous provisions within the Medicare program (such as § 405.980 and § 405.986 regarding reopening of initial determinations of claims under the original Medicare program, § 405.1885 regarding reopening of intermediary determinations of program reimbursement under the original Medicare program, and § 423.346 regarding reopening of payment determinations under Medicare Part D).

We are concerned that adopting wholesale one of these existing reopening processes, including all of the associated timeframes, may not be appropriate for the Shared Savings Program. For example, many ACOs have indicated that they intend to quickly reinvest some of any future shared savings they might receive to provide additional staff training, hire additional staff and make other infrastructure improvements to further improve the quality of care for Medicare beneficiaries and reduce unnecessary costs. We believe such investments may be critical so that ACOs can innovate further to achieve even greater cost savings. Shared savings payments also can support an ACO's ongoing operational costs, which we previously estimated to be an average of \$0.86 million for an ACO participating in the Shared Savings Program (80 FR 32827). For

example, shared savings payments support infrastructure (such as IT solutions) and process development, staffing, population management, care coordination, quality reporting and improvement, and patient education (80 FR 32767). We believe that ACOs may be reluctant to make the necessary investments to enable them to further improve the quality of care for Medicare beneficiaries and achieve greater cost savings if they might be required to unexpectedly pay back some or all of their shared savings payments. Further, ACOs could be reluctant to participate in two-sided performance-based risk tracks, if after receiving a payment determination they might subsequently be required to pay additional amounts for shared losses.

We are concerned that the current uncertainty regarding the timeframes and other circumstances in which we would reopen a payment determination to correct financial calculations under the Shared Savings Program could introduce financial uncertainty which could seriously limit an ACO's ability to invest in additional improvements to increase quality and efficiency of care. This uncertainty could also limit an ACO's ability to get a clean opinion from its financial auditors, which could, for example, harm the ACO's ability to obtain necessary capital for additional program improvements. This could be especially challenging for ACOs seeking to enter or continue under a two-sided performance-based risk track since under the requirements at § 425.204(f)(2), such an ACO must, as part of its application for a two-sided performance-based risk track, demonstrate its ability to repay shared losses to the Medicare program, which it may do by placing funds in escrow, obtaining a surety bond, establishing a line of credit (as evidenced by a letter of credit that the Medicare program can draw upon), or establishing a combination of such repayment mechanisms, that will ensure its ability to repay the

Medicare program. These arrangements can often require that an ACO and/or its financial supporters make an assessment of the ACO's level of financial risk for possible repayments. Uncertainty over past financial results could significantly affect an ACO's ability to obtain and maintain these arrangements with financial institutions, and thus discourage ACOs from participating in the Shared Savings Program under two-sided performance-based risk tracks. We are particularly concerned that this could discourage ACOs from moving more quickly from the one-sided shared savings track to a performance-based risk track when renewing their agreements.

We considered an approach under which we would always reopen a determination of ACO shared savings or shared losses to correct any issue that might arise with respect to a financial calculation. Under this approach, we would correct for any and all issues (for example, a source data error or computational error), even for relatively minor errors having little impact on ACO financial results, that are identified within four years after the release of final financial reconciliation results. We are concerned that this approach of correcting even very minor errors might result in significant operational burdens for ACOs and CMS, including multiple financial reconciliation re-runs and off-cycle payment/recoupment activities that could have the potential for significant and unintended operational consequences, and could jeopardize the certainty of performance results for both ACOs and CMS. As noted earlier in this section, this approach, which includes a relatively broad scope and extended timeframe for reopening, could introduce financial uncertainty that could limit an ACO's ability to invest in additional improvements to increase quality and efficiency of care. This uncertainty could also limit an ACO's ability to get a clean opinion from its financial auditors and/or to obtain funds

from lenders or investors.

We also considered whether to adopt a policy under which we would never correct for errors after performing the financial calculations and making initial determinations of ACO shared savings and shared losses. By establishing such definitive administrative finality following notification of any applicable performance-based payments or loss recoupments, both ACOs and CMS would be better able to anticipate that such performance-based payments or loss recoupments would not be subject to subsequent revision. Financial calculations and shared savings payments or shared loss recoupments would not be subject to future reopening, and ACOs would be able to plan future transactions, issue financial reports, and plan for contingencies in reliance on the fact that those payment determinations were closed. However, we believe it would be appropriate to reopen financial calculations in certain circumstances, such as in the case of fraud or similar fault as defined at § 405.902, or for errors with a significant impact on the computation of ACOs' shared savings/shared losses. Therefore, we believe it would be appropriate to allow for corrections, under certain circumstances and within a defined timeframe, after financial calculations have been performed and the determination of ACO shared savings and shared losses has been made. In the following section we further discuss the rationale and the details of our proposed finality policy for financial calculations and shared savings payments or shared loss recoupments.

2. Proposed Revisions

a. Circumstances for Reopening Initial Determinations and Final Agency Determinations of ACO Shared Savings or Shared Losses to Correct Financial Reconciliation Calculations

It is longstanding policy in the Medicare program that a determination may be reopened at any time if it was procured by fraud or “similar fault,” (see, for example, § 405.980(b)(3); 74 FR 65296, 65313 (December 9, 2009)). Further, under the Shared Savings Program regulations at § 425.314(a)(4), if as a result of any inspection, evaluation, or audit, it is determined that the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO has been calculated in error, CMS reserves the right to reopen the initial determination and issue a revised initial determination. We believe it would be appropriate to define the circumstances under which we would reopen a payment determination to make corrections after the financial calculations have been performed and ACO shared savings and shared losses determined, absent evidence of fraud or similar fault. In developing the proposals in this section, we considered the following issues: (1) the type of issue/error that we would correct; (2) the timeframes for reopening a payment determination; and (3) whether we should establish a materiality threshold as an indicator of a material effect on shared savings and shared losses that would warrant a correction, and if so, at what level.

First, we are proposing that CMS would have discretion to reopen a payment determination at any time in the case of fraud or “similar fault,” as defined in § 405.902. Second, we are proposing that in certain circumstances we would reopen a payment determination for good cause. For consistency and to decrease program complexity, we

believe it would be reasonable and appropriate to base the definition of good cause for purposes of the Shared Savings Program on the definition of good cause used elsewhere in the Medicare FFS program. We propose to follow the same approach to reopening for good cause as applies to the reopening of Parts A and B claims determinations under § 405.986. Specifically, we propose that CMS will have the discretion to reopen a payment determination, within 4 years after the date of notification to the ACO of the initial determination of shared savings or shared losses for the relevant performance year, if there is good cause. We propose that good cause may be established if there is new and material evidence that was not available or known at the time of the payment determination, and which may result in a different conclusion, or if the evidence that was considered in making the payment determination clearly shows on its face that an obvious error was made at the time of the payment determination.

New and material evidence or an obvious error could come to CMS' attention through a variety of means, such as identification by CMS through CMS program integrity reviews or audits, identification through audits conducted by independent federal oversight entities such as the Office of the Inspector General (OIG) or the Government Accountability Office (GAO). CMS program integrity reviews and audits would include reviews and audits conducted by CMS' contractors. We believe it would be appropriate to establish a 4-year time period (that is, 4 years from initial notification of the payment determination) for reopenings for good cause to provide sufficient time to initiate, complete, and evaluate errors through CMS program integrity reviews or audits by oversight entities like OIG or GAO. A timeline for reopenings for good cause that is too short could undermine the ability of CMS to address significant issues raised through

such program integrity initiatives or audits. Therefore, we believe that it would be appropriate to establish a 4-year timeframe for reopening Shared Savings Program payment determinations for good cause. In developing the proposed time period for reopenings, we considered alternative approaches in which we would provide for either shorter or longer time periods for reopenings for good cause. We chose not to propose these alternative time periods for good cause. A shorter time period might provide more financial certainty for ACOs but could make it difficult for CMS to make corrections based on program integrity reviews or audits by OIG or GAO. Similarly, a longer time period might make it feasible for CMS to make additional corrections based on program integrity reviews or audits by OIG or GAO, but could provide less financial certainty for ACOs.

We propose that good cause would not be established by changes in substantive law or interpretative policy. A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or CMS general instruction, whether made in response to judicial precedent or otherwise, would not be a basis for reopening a payment determination under this section. Further, we propose CMS has sole discretion to determine whether good cause exists for reopening a payment determination under this section. Under the proposal, the determination of whether an error was made, whether a correction would be appropriate based on these proposed criteria, and the timing and manner of any correction would be within the sole discretion of CMS. We do not intend to propose an exhaustive list of potential issues that would or would not constitute good cause, but do intend to provide additional subregulatory guidance on this issue if this policy is finalized as proposed. As one example, we do not believe it would be an error constituting good

cause for reopening of a payment determination if an ACO identified a claims anomaly such as a participating provider who submitted claims to its Medicare contractor either earlier or later than it had typically submitted claims previously and which therefore might impact the ACO's total expenditures. Likewise, we do not believe that good cause would be established by a request to reopen a claims payment determination based upon a third party payer's error in making a payment determination when Medicare processed the claim in accordance with the information in its system of records or on the claim form. We would also note that good cause would not be established by a reconsideration, appeal, or other administrative or judicial review of any determinations precluded under § 425.800.

When determining whether to reopen for good cause, we would also consider whether the error is material and thus warrants a correction by reviewing the nature and particular circumstances of the error. Under this proposal, we would not reopen a payment determination to consider, or otherwise consider as part of a reopening, additional claims information submitted following the end of the 3-month claims run out and the use of the completion factor. We would continue to use claims submitted prior to the end of the 3-month claims run out with a completion factor to calculate an ACO's per capita expenditures for each performance year, consistent with §§ 425.604(a)(5), 425.606(a)(5) and 425.610(a)(5). Also, consistent with established policy, under this proposed policy, we would not reopen a determination if an ACO's ACO participants submitted additional claims or submitted corrected claims after the 3-month claims run out period following the end of the performance year. As discussed in the November 2011 final rule (76 FR 67837 through 67838), in establishing this policy we focused on

balancing the need for timely payment determinations and the benefits of utilizing the most complete data in calculating both the quality metrics and the shared savings reconciliation. We continue to believe that a 3-month run out of claims data aids in ensuring success for ACOs by allowing prompt shared savings payments to eligible ACOs, enabling them to offset the initial startup and/or ongoing operational costs which would in turn allow the ACOs to remain financially viable and enable them to make additional investments to further improve quality of care and decrease costs, while any decrease in the accuracy as a result of the use of a 3-month run out versus a longer time period is mitigated by the application of a completion factor.

Corrections for errors for good cause could in some circumstances introduce additional program complexities with unanticipated consequences. For example, changes to beneficiary assignment could affect the calculation of shared savings and losses for multiple ACOs. Therefore, in order to provide an opportunity for CMS to consider updated information and make other adjustments to payments determinations across all ACOs, and to minimize program disruptions for ACOs resulting from multiple reopenings, we will, to the extent feasible, make corrections in a unified reopening (as opposed to multiple reopenings) to correct errors for a given performance year. In addition, we will consider other ways to reduce operational burdens for both ACOs and CMS that could result from making payment adjustments. For example, during the 4-year time period from notification of the initial payment determination for reopenings due to good cause, if we determine that a correction needs to be made for a performance year's results, we would seek to potentially adjust shared savings payments to the ACO or shared loss recoupments from the ACO for a subsequent performance year. To

illustrate, if an ACO that generated shared savings for the second performance year of its agreement period owed CMS money based on a correction made to the payment determination for the prior performance year, we might be able to deduct the amount owed prior to making the current year shared savings payments (subject to the general requirement, discussed elsewhere, for ACOs to repay monies owed to CMS within 90 days of notification of the obligation).

In addition, we have evaluated how we might consider materiality when determining whether to reopen for good cause in the case of CMS technical errors. We do not intend to propose specific criteria for determining materiality but we would provide additional information for ACOs through subregulatory guidance, as appropriate. For example, in the case of technical errors by CMS such as CMS data source file errors and CMS computational errors, we would consider limiting reopenings of payment determinations under the Shared Savings Program to issues/errors that have a material effect on the net amount of ACO shared savings and shared losses computed for the applicable performance year for all ACOs, and thus warrant a correction due to the magnitude of the error. Establishment of such a threshold for making financial corrections to address errors in the determination of shared savings payments or shared loss recoupments could reduce the likelihood of there being multiple financial reconciliation re-runs for errors that do not significantly affect the financial performance calculations. The general requirement under the Shared Savings Program is that ACOs are required to make payment in full to CMS of all amounts owed within 90 days of their receipt of notification. Numerous off cycle adjustments to address technical errors that do not have a material effect on the total amount of ACO shared savings and shared

losses computed for the applicable performance year could be disruptive and administratively burdensome for both ACOs and CMS, and could discourage ACOs from participating in the Shared Savings Program.

Accordingly, in considering when to reopen an error for good cause, we intend to strike a careful balance between important Medicare program integrity concerns that payments be made timely and accurately under the Shared Savings Program with our desire to minimize unnecessary operational burdens for ACOs and CMS, and to support the ACOs' ability to invest in additional improvements to increase quality and efficiency of care. To achieve this careful balance in objectives, for reopenings to address CMS technical errors, we may consider whether the error satisfies a materiality threshold, such as 3 percent of the total amount of net shared savings and shared losses for all ACOs for the applicable performance year. We would expect to provide additional information about how we may consider the materiality of an error in subregulatory guidance, if we finalize this policy as proposed. To illustrate, under such an approach, we could exercise our discretion to reopen the financial reconciliation for a performance year if we determined that a correction to address a CMS technical error would affect total net shared savings and shared losses (that is, the amount of shared savings after the amount of shared losses has been subtracted) for all ACOs for the affected performance year by 3 or more percent. We may consider a higher threshold, such as 5 percent, or a lower threshold, such as 1 or 2 percent. However, based on a review of guidance from the GAO for financial audits of federal entities, we believe that 3 percent could be a reasonable threshold for "material effect." The GAO guidance was developed to assist auditors in assessing material effect for planning the audit scope for federal entities to

ensure that financial statement audits achieve their intended outcomes of providing enhanced accountability over taxpayer-provided resources. This guidance has been used for a number of years by GAO financial auditors for performing financial statement audits of federal entities. (See the GAO website at http://www.gao.gov/special.pubs/01765G/vol1_complete.pdf.) Although ACOs are not federal entities, we believe it would be reasonable to consider the GAO guidance in developing a material effect threshold across all ACOs. The Shared Savings Program is a relatively large federal program administered within HHS, including over 400 ACOs (as of January 1, 2016). Accordingly, we believe that the GAO guidance on federal entity audits, while not directly applicable, provides a relevant and appropriate resource in considering a materiality threshold for reopening certain payment determinations under the Shared Savings Program.

We also initially considered applying a materiality threshold for each ACO rather than applying a materiality threshold to total net shared savings and shared losses for all ACOs. We recognize that in some situations an individual ACO might prefer to have a different materiality threshold, or might prefer that we always correct CMS technical errors that favor the individual ACO. However, we do not believe that applying a materiality threshold, such as 3 percent, to the financial results for each ACO, or applying a lower (or no) materiality threshold for reopenings for CMS technical errors, would achieve the desired level of administrative finality for the Shared Savings Program given that there currently are over 400 ACOs in the program, and correction for CMS technical errors would sometimes favor an individual ACO and sometimes not. We also do not believe it would be appropriate to establish a finality policy to only correct errors that

favor the individual ACO. We believe it would be appropriate to limit reopenings to correct CMS technical errors that more widely affect the program rather than reopening determinations for specific issues for each of the hundreds of ACOs participating in the Shared Savings Program absent evidence of fraud or similar fault, or good cause established by evidence of other errors. Otherwise, as noted earlier in this section, a relatively broad scope and extended timeframe for reopening could introduce financial uncertainty that could limit ACOs' ability to invest in additional improvements to increase quality and efficiency of care.

Finally, we note that the current requirements for ACO repayment of shared losses after notification of the initial determination of shared losses would not be affected by any proposals in this section. As described under § 425.606(h)(3) (Track 2) and § 425.610(h)(3) (Track 3), if an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification. These current requirements would continue to apply for repayment by ACOs for shared losses. For example, an ACO would not be able to delay recoupment of any payments required under § 425.606(h)(3) or § 425.610(h)(3) by notifying CMS of a possible error that could merit reopening. Instead, if we determined that a correction should be made, we would subsequently adjust shared savings and shared losses for the applicable performance year based on the correction, and we would add any amount owed to the ACO, as determined through the reopening, prior to making any current year shared savings payments for which the ACO is eligible.

Therefore, after considering these issues, we are proposing to revise § 425.314 to remove (a)(4) and add a new paragraph (e) to specify the circumstances under which we

would reopen a payment determination under §§ 425.604(f), 425.606(h), 425.610(h), 425.804, or 425.806. Specifically, we are proposing that, if CMS determines that the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO has been calculated in error, CMS may reopen the earlier payment determination and issue a revised initial determination. We propose that a payment determination may be reopened: (1) at any time in the case of fraud or similar fault, as defined in §405.902; or (2) not later than 4 years after the date of notification to the ACO of the initial determination of shared savings or shared losses for the relevant performance year, for good cause. We propose that good cause may be established when there is new and material evidence of an error or errors, that was not available or known at the time of the payment determination and may result in a different conclusion, or the evidence that was considered in making the payment determination clearly shows on its face that an obvious error was made at the time of the payment determination. Good cause would not be established by a change of legal interpretation or policy by CMS in a regulation, CMS ruling or CMS general instruction, whether made in response to judicial precedent or otherwise. We have sole discretion to determine whether good cause exists for reopening a payment determination under this section. Also, good cause would not be established by a reconsideration, appeal, or other administrative or judicial review of any determinations precluded under §425.800.

Under the proposal, the determination of whether an error was made, whether a correction would be appropriate based on these proposed criteria, and the timing and manner of any correction would be made would be within the sole discretion of CMS. If CMS determines that the reopening criteria are met, CMS would recompute the financial

results for all ACOs affected by the error or errors. In light of this policy proposal, we would not reopen and revise the PY 1 payment determinations solely affected by the data source error described previously because we so far have not specified, either through regulations or program guidance, the criteria CMS would apply in determining whether to reopen a payment determination. However, we would reopen and revise these PY 1 payment determinations for other errors satisfying the proposed criteria for reopening for good cause or for fraud or similar fault.

We believe this proposal would offer a flexible, balanced approach, providing additional certainty for ACOs as to whether they are eligible for shared savings payments, or required to repay a portion of losses under risk-based tracks, and the amount of any such shared savings or shared losses. ACOs would thus be better able to plan future financial transactions and investments to further improve the quality of beneficiary health care and reduce costs, issue financial reports, and plan for contingencies in reliance on the fact that those payments are closed after the period for reopening has lapsed, in the absence of fraud or similar fault. We acknowledge that from year to year, corrections could sometimes advantage individual ACOs and sometimes disadvantage individual ACOs. We anticipate that, over time, this approach would not likely have a biased effect on ACOs or Medicare expenditures since the impact of reopenings over time would be equally likely to increase/decrease net shared savings and losses.

In addition, we note that nothing in this proposal would limit the scope of the preclusion of administrative and judicial review under § 425.800. However, we propose to amend § 425.800(a)(4), expressly to include a revised initial determination in the list of determinations that are precluded from administrative and judicial review. We invite

comments on this proposal, including the proposed criteria for reopening, on alternative approaches for defining the time period for reopenings of payment determinations, on the criteria for establishing good cause, whether the time period for reopenings for good cause should be longer or shorter than 4 years, and on any other criteria that we should consider for the final rule to address issues related to financial reconciliation calculations and the determination of ACO shared savings and shared losses.

b. Conforming Change

As discussed earlier in the overview for this section, the determination of whether an ACO is eligible for shared savings, and the amount of such shared savings, and the limit on the total amount of shared savings as well as the underlying financial calculations are excluded from administrative and judicial review under section 1899(g) of the Social Security Act. Accordingly, in the November 2011 final rule establishing the Shared Savings Program, we adopted the regulation at § 425.800 to preclude administrative and judicial review of the determination of whether an ACO is eligible for shared savings and the amount of shared savings under Track 1 and Track 2 (§ 425.800(a)(4)), and the limit on total amount of shared savings that may be earned under Track 1 and Track 2 (§ 425.800(a)(5)). In the June 2015 final rule, we amended the Shared Savings Program regulations by adding a new provision at § 425.610 to establish a new performance-based risk option (Track 3) that includes prospective beneficiary assignment and a higher sharing rate. However, in the June 2015 final rule we inadvertently did not also update the regulation at § 425.800 to include references to determinations under §425.610 (Track 3) in the list of determinations under this part for which there is no reconsideration, appeal, or other administrative or judicial review.

Therefore, we are proposing a conforming change to amend § 425.800 to add determinations under § 425.610 (Track 3) to the list of determinations under § 425.800 (a)(4) and (a)(5) for which there is no reconsideration, appeal, or other administrative or judicial review.

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. Proposed changes are focused on calculations for resetting the financial benchmark for an ACO's second or subsequent agreement period, thereby fulfilling a goal communicated in the Shared Savings Program June 2015 final rule (80 FR 32692) to propose a method for taking into account regional expenditures when resetting an ACO's financial benchmark for a second or subsequent agreement period.

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), 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.

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

The Shared Savings Program is a voluntary program involving an innovative mix of financial incentives for demonstrating quality of care and efficiency gains within FFS Medicare. As a result, the changes to the Shared Savings Program proposed in this rule could result in a range of possible outcomes. While evaluation of the program's overall impact to date is ongoing, the quality and financial results of the first 2 performance years are within the range originally projected for the program in the November 2011 final rule (see Table 8, 76 FR 67963). Also, at this point, we have seen no evidence of selective ACO participation that would systematically bias overall program performance as measured by ACO benchmarks.

In the June 2015 final rule, we established a policy for rebasing an ACO's

financial benchmark for a second or subsequent agreement period by weighting each benchmark year equally and taking into account savings generated by the ACO in the previous agreement period. We also discussed potential future modifications to the rebasing methodology that would account for regional FFS expenditures and remove the policy of adding savings generated by the ACO in the previous agreement period. After further analysis, in this proposed rule, we propose an alternative approach that would adjust the ACO's reset benchmark by a percentage of the difference between the ACO's regional service area average per capita expenditure amount and the ACO's rebased historical benchmark amount (described in section II.A.2.c. of this proposed rule). Under the proposed phased approach to using a higher percentage in calculating the adjustment for regional expenditures (described in section II.A.2.c.3. of this proposed rule): in the ACO's second agreement period the percentage used in calculating the regional adjustment would be set at 35 percent; in the ACO's third agreement period and subsequent agreement periods, the percentage would be set at 70 percent unless the Secretary determines a lower weight should be applied, as specified through future rulemaking. This proposed approach would weaken the link between an ACO's performance in prior agreement periods and its benchmark in subsequent agreement periods. These changes are intended to strengthen the incentives for ACOs to invest in infrastructure and care redesign necessary to improve quality and efficiency and meet the goals of the Shared Savings Program.

Further, a key modification to the benchmark rebasing methodology would be to refine certain calculations that currently rely on national FFS expenditures and corresponding trends so that they would instead be determined according to county FFS

trends observed in each ACO's unique assignment-weighted regional service area. Annual average per capita costs would be tabulated for assignable FFS beneficiaries in each county. For each ACO a regional weighted average expenditure would be found by applying ACO assigned-beneficiary weights to the average expenditures tabulated for each county. Changes in an ACO's regional service area average per capita expenditures (and relative risk reflected in associated HCC risk scores) would define a regional trend specific to each ACO's region. This regional trend would be utilized in two specific areas of the existing benchmark methodology to replace the: (1) national expenditure trend in calculations establishing the ACO's rebased historical benchmark; and (2) existing national "flat dollar" growth amount for updating the rebased historical benchmark for each performance year.

By replacing the national average FFS expenditure trend and "flat dollar" update with trends observed for county level FFS assignable beneficiaries in each ACO's unique assignment-weighted regional service area, benchmark calculations would be better structured to account for exogenous trend factors particular to each ACO's region and the pool of potentially-assignable beneficiaries therein (for example, higher trend due to a particularly acute flu season or an unusually large area wage index adjustment or change).

Although the policy would have mixed effects - increasing or decreasing benchmarks for ACOs in various circumstances - an overall increase in program savings would likely result from taking into account service-area trends in benchmark calculations. In some cases lower benchmarks would be produced, preventing shared savings payments to certain ACOs for whom national average trends and updates would

have provided higher updated benchmarks. For other ACOs, such a policy would be more sensitive to regional circumstances outside of the ACO's control causing higher trends for the ACO's service area. In such cases, a higher benchmark could improve program cost savings by reducing the likelihood the ACO would choose to drop out of the program because a shared loss would otherwise have been assessed because of exogenous factors unrelated to the ACO's changes in care delivery.

In addition, applying the regional trend as a percentage (rather than "flat dollar") when updating the benchmark to a performance year basis is anticipated to further reduce program costs by improving the accuracy of updated benchmarks, particularly for ACOs that have historical benchmarks significantly below or above average. The November 2011 final rule discussed the risk that large nominal "flat dollar" growth updates could compound over an agreement period to excessively inflate benchmarks for ACOs with relatively low historical benchmark cost and could lead to predictable bias and resulting cost for selective participation in the program (76 FR 67964). Such risk has not materialized in program experience to date, largely due to the historically low national program trend used to update ACO benchmarks through the first 3 years of the program. However, the per capita trend for the Medicare FFS program is anticipated to be higher in future years associated with the period governed by this proposed rule in contrast to the relatively moderate growth in cost experienced over the first 3 years of the program's implementation³. The proposed changes to the methodology for updating the benchmark would apply regional trends to update ACO benchmarks and therefore prevent the

³ Traditional fee-for-service Medicare Part A and B annual per capita cost trend is expected to reach approximately 5 percent in 2019, as detailed in the 2017 Medicare Advantage Early Preview accessible at: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/EarlyPreview2017GrowthRates.pdf>

increased program cost the current update methodology risks by employing an average "flat dollar" update that compounds over the 3 years in an ACO's agreement period.

Program participation and ACO beneficiary assignment are not homogeneously distributed geographically. ACOs tend to have service areas overlapping those of other ACOs in the same urban or suburban market(s). Therefore, to the extent that ACOs produce significant reductions in expenditures, a greater proportion of such savings would affect ACO-service-area trends than the average effect felt at the national program level, effectively reducing the average ACO's updated benchmark compared to what the use of a national trend alone would have produced. While such effect has the potential to reduce program costs by reducing net shared savings payments it could be seen as a disadvantage to participating organizations in "ACO-heavy regions" that manage to broadly increase efficiency at the overall regional market level⁴. However, on the whole, we anticipate this effect to be a reasonable trade-off that would not prevent an overall improvement in the incentive for ACOs to improve efficiency in care delivery in the context of periodic benchmark rebasing as a result of the policies proposed in this proposed rule.

Additionally, we anticipate significant program savings would result from the proposal to remove the current policy in which savings generated in the previous agreement period would be taken into account when resetting the benchmark in an ACO's second or subsequent agreement period. This proposed rule would modify the

⁴ Similarly, certain regions may be targeted for care delivery reforms, for example certain Center for Medicare and Medicaid Innovation models. A downward bias on an ACO's benchmark could be felt to the extent that such activity reduces expenditures for beneficiaries in the ACO's region but not in a proportional way within the ACO's assigned population. Such scenarios are more likely when competing models are specifically targeted for beneficiaries not assigned to an ACO.

methodology used to rebase ACO benchmarks for agreement periods beginning in 2017 and subsequent years. In other words, the current rebasing methodology would apply to ACOs that entered a second or subsequent agreement period prior to 2017.

Changes to the existing benchmark calculations described previously would therefore benefit program cost savings by producing rebased benchmarks with improved accuracy (for example, reflecting regional trends rather than national average trends and ‘flat dollar’ updates) and of somewhat lower per capita cost on average (due to no longer adding a portion of savings to the baseline and because of oversampling ACO populations in regional trend calculations). However, such savings would be partly offset by increasing shared savings payments to ACOs benefiting from our proposal to adjust the rebased historical benchmark with a portion of the difference between the ACO’s regional service area average per capita expenditure amount and the ACO’s rebased historical benchmark amount. Such trade-off reflects the intention of our proposal to strengthen the reward for attainment of efficiency in an absolute sense, complementing the existing program’s focus on rewarding improvement relative to an ACO’s recent baseline.

Making a regional adjustment to the ACO’s rebased historical benchmark would strengthen an ACO’s incentives to generate and maintain efficient care delivery over the long run by weakening the link between an ACO’s prior performance and its future benchmark. This adjustment is expected to marginally increase program participation in agreement periods where risk (Track 2 or 3) is mandatory for an ACO since a significant portion of ACOs will have knowledge that a favorable baseline expenditure comparison to their FFS region will mitigate their risk of being assessed a shared loss in a subsequent

agreement period. It is also expected to reduce the frequency with which ACOs in Track 2 or 3 drop out of the program during an agreement period because such ACOs will have somewhat greater certainty regarding the extent to which savings achieved in the prior agreement period would continue to be reflected in a rebased benchmark that incorporates a regional adjustment.

However, more predictable relationships, that is, an ACO's knowledge of its costs relative to FFS expenditures in its region, also creates risk of added cost to the Shared Savings Program by way of-- (1) increasing shared savings payments to ACOs exhibiting expenditures significantly below their region at baseline especially in cases where such differences are related to factors exogenous to efficiency in the delivery of care (where shared savings payments could be further inflated by increased selection of Track 3 over Track 2); (2) potentially losing participation from ACOs with expenditures high above their region at baseline - reducing the opportunity to impact beneficiary populations with the greatest potential for improvements in the cost and quality of care;⁵ and (3) from structural shifts by ACOs in ways that would reduce assignment of relatively high cost beneficiaries and increase assignment of relatively healthy populations or shift the geography of their service area to similarly effect a more favorable benchmark adjustment.

In addition to the uncertainty with respect to the relationship of the potential

⁵ Early program results indicate that ACOs with expenditures significantly above their risk-adjusted FFS regional average have produced greater than average reductions in expenditures than ACOs with low baseline expenditures relative to their region; however it is not yet evident that such early savings achieved for such relatively high cost populations are likely to grow to an extent that their expenditures would reach parity with their region. If the regional adjustment results in unattainable benchmarks for ACOs serving at-risk populations then the program would likely exhibit decreasing participation from providers serving populations where the greatest potential for savings through management would otherwise be present and therefore we would expect significantly lower savings for the program than currently anticipated.

offsetting effects noted previously, there remains broader uncertainty as to the number of ACOs that will participate in the program (especially under performance-based risk in Track 2 or Track 3), provider and supplier response to financial incentives offered by the program, interactions with other value based models and programs from CMS and other payers, and the ultimate effectiveness of the changes in care delivery that may result as ACOs work to improve the quality and efficiency of patient care. Certain ACOs that have achieved shared savings in their first agreement period may find that they receive significantly lower benchmarks under the proposed revisions (especially in cases where regional expenditures are much lower than expenditures for the ACO's assigned beneficiary population). Other ACOs may seek to maximize sharing in savings by selecting Track 3 if they have assigned beneficiaries with significantly lower expenditures at baseline relative to their region. These uncertainties continue to complicate efforts to assess the financial impacts of the Shared Savings Program and result in a wide range of potential outcomes regarding the net impact of the changes in this proposed rule on Medicare expenditures.

To best reflect these uncertainties, we continue to utilize a stochastic model that incorporates assumed probability distributions for each of the key variables that will affect the overall financial impact of the Shared Savings Program. A summary of assumptions and assumption ranges utilized in the model includes the following:

- Approximately 100, 100, and 200 ACOs will consider renewing in 2017, 2018, and 2019, respectively.

- ACOs will choose not to renew if--

- ++ Under the current policy: The ACO's gross loss in the prior performance year

was 5 percent or greater; or

++ Under the proposed policies: The ACO's gross loss would be 3 percent or greater in the prior performance year after accounting for the expected effect of the revised rebasing methodology (for example, considering differences between the ACO's spending and that of its region) and adjusting for ACO participant changes which result in baseline cost reduction of 2 percent on average (see discussion elsewhere in this proposed rule).

In either scenario, the thresholds are calibrated to approximate the level of baseline loss an ACO would correlate to an expected shared loss from its rebased benchmark. The magnitude of the loss is roughly equal to the revenue ACO participating physicians may have gained from the 5 percent incentive payment available under MACRA⁶ that is potentially available to physicians and certain other practitioners in certain ACOs for participation in the program; the policies included in this proposed rule are assumed to result in a lower tolerance for renewal after a prior agreement period loss because the proposed regional adjustment to the rebased benchmark is expected to be more consistent from year to year whereas the current rebasing methodology would be expected to generate a higher benchmark reflecting to a greater degree the actual spending from the prior agreement period that led to the prior loss. However, ACOs that do renew under the policies included in this proposed rule would be more likely to remain in the program for the entire agreement period because the benchmark adjustment improves the likelihood that favorable changes to the methodology for rebasing the benchmark that led the ACO

⁶ Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established new incentives to encourage physicians and certain other practitioners to participate in alternative payment models; pending rulemaking, such incentive payments may equate to approximately 5 percent of physician fee schedule revenue to eligible professionals participating in certain qualifying ACOs

to renew its agreement would continue to be evidenced in future performance years.

- Renewing ACO will choose higher risk in Track 3 if--

++ Under the current policies: The ACO's gross savings in prior performance year are 4 percent or greater; or

++ Under the proposed policies: The ACO's prior performance year gross savings adjusted by regional expenditures would be 2 percent or greater.

In either scenario, similar to the renewal assumption, policies included in the proposed rule offer greater certainty that adjusted prior performance will correlate to future performance and therefore the threshold for selecting Track 3 is lower than what is assumed for baseline scenario.

- Marginal gross savings would increase by between 0.0 percent to 1.0 percent for ACOs selecting higher performance-based risk in Track 3 and between 0.0 percent to 0.2 percent for all ACOs due to the adjusted rebasing methodology. These ranges were chosen to encompass a range of relative savings rates observed for performance-based risk accepted by ACOs participating in the Pioneer ACO Model relative to Shared Savings Program ACOs, the vast majority of which have elected to participate under the one-sided shared savings model (Track 1).

- ACOs experiencing a loss during the rebased agreement period are assumed to drop out prior to the second or third performance year if a shared loss from the prior performance year exceeds 2 percent. While Pioneer ACO Model experience would predict a lower tolerance for remaining in the program after a loss, 2 percent was chosen to approximate the incentive payment under MACRA likely to be made available to physicians and certain other practitioners participating in ACOs in Track 2 and Track 3,

which was not available to participants in Pioneer ACOs.

- ACOs make adjustments to their ACO Participant Lists that reduce their cost relative to region by approximately 2 percent on average. This assumption is based on empirical analysis of 2015 ACO Participant List change requests and resulting impact on ACO baseline expenditures due to changes in assignment; the magnitude of bias is assumed to be greater for ACOs starting higher than their corresponding regional average expenditures and/or with a relatively small assigned beneficiary population and lower for ACOs starting below regional average expenditures and/or with a relatively large assigned beneficiary population.

- ACOs achieve a mean quality score of 80 percent (based on analysis of Shared Savings Program ACO quality scores in 2013 and 2014).

- ACO savings have a diluted impact on regional expenditures and trends according to ACO assignment saturation of FFS beneficiary population in the market.

Assumptions for ACO baseline costs, including variations in trends for ACOs and their relationship to their respective regions were determined by analyzing existing ACO and corresponding regional expenditures back to 2009, the first benchmark year used for the first wave of ACOs that entered the program in 2012. (Note associated data for the 2012 through 2014 time period is being released in conjunction with this proposed rule to assist commenters in modeling implications of the proposals.) The empirical time series data were randomly extrapolated to form baseline time series data through the end of the rebased agreement period by applying growth rates to ACOs and their regions by randomly sampling empirical growth rates for ACOs (and their respective regions) with similar characteristics in terms of size and relative cost to region.

Using a Monte Carlo simulation approach, the model randomly draws a set of extrapolated ACO baseline trends and specific values for each variable, reflecting the expected covariance among variables, and calculates the program's financial impact based on the specific set of assumptions. We repeated the process for a total of 1,000 random trials, tabulating the resulting individual cost or savings estimates to produce a distribution of potential outcomes that reflects the assumed probability distributions of the incorporated variables.

Table 3 details our estimate of the 3-year net impact of the proposed policy changes on FFS net benefit claims costs, net shared savings payments to ACOs, and the resulting impact on net Federal cost. Projected impacts are detailed for the first 3 cohorts of ACOs that would be renewing agreements under the proposed changes, renewing respectively for agreement periods starting in 2017, 2018, and 2019. During these agreement periods, a 35 percent weight would be placed on the benchmark expenditure adjustment for regional FFS expenditures. In such agreement periods, total savings from the proposed changes to the methodology for calculating and trending expenditures during the benchmark period in order to establish and update the benchmark, as well as anticipated savings from marginally increased program participation and improved incentives for creating efficiency, are expected to be greater than the increase in cost of net shared savings payments due to selective participation in response to adjustments that are predictably significant (either favorable or unfavorable) upon examination of how expenditures for the ACO's historically assigned beneficiary population compare to the ACO's regional service area expenditure level at baseline. For this reason the net Federal impact is projected to be a savings (that is, a negative change in net Federal cost) for the

first 3 years for each renewing cohort, and correspondingly a \$120 million net Federal savings for the first 3 calendar years of the projection window, 2017 through 2019. Such median impact on net Federal cost results from a projected increase in savings on net benefit claims costs of \$370 million partially offset by a \$250 million increase in net shared savings payments to ACOs. The last two rows of Table 3 enumerate the range of potential net Federal cost impacts our modeling projected, specifically the 10th percentile of simulation outcomes (a \$230 million net Federal increase in cost) and the 90th percentile (\$490 million net Federal savings). Overall, approximately two-thirds of trials resulted in combined net Federal savings over 2017 to 2019.

TABLE 3: ESTIMATED 3-YEAR IMPACT OF PROPOSED CHANGES (INCLUDING 35 PERCENT WEIGHT USED IN DETERMINING REGIONAL ADJUSTMENT AMOUNT) ON NET BENEFIT COSTS, NET PAYMENTS TO ACOs, AND OVERALL NET FEDERAL COSTS CYs 2017 THROUGH 2019

(Impacts are Median Results Unless Otherwise Noted)

	Calendar Year	2017	2018	2019	3-Year Total
Impact on Net Claims Costs (\$Million)	ACOs Renew 2017	-60	-60	-70	-190
	ACOs Renew 2018		-60	-60	-120
	ACOs Renew 2019			-60	-60
	All ACO Total	-60	-120	-190	-370
Impact on Net Shared Savings Pay (\$Million)	ACOs Renew 2017	40	30	30	100
	ACOs Renew 2018		40	30	70
	ACOs Renew 2019			80	80
	All ACO Total	40	70	140	250
Overall Impact on Net Federal Costs (\$Million)	ACOs Renew 2017	-20	-30	-40	-90
	ACOs Renew 2018		-20	-30	-50
	ACOs Renew 2019			20	20
	All ACO Total	-20	-50	-50	-120
	Low (10th %-ile)	20	50	160	230
High (90th %-ile)	-70	-160	-260	-490	

The stochastic model and resulting financial estimates were prepared by the CMS

Office of the Actuary (OACT). The median result of \$120 million increase in savings in net Federal cost is a reasonable "point estimate" of the impact of the proposed changes to the Shared Savings Program during the period between 2017 through 2019. 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 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 Shared Savings Program would result in corresponding adjustments to MA payment rates. Neither of these secondary impacts has been included in the analysis shown.

a. Effects of the Proposed Rule in Subsequent Agreement Periods

For an ACO's third agreement period (that is, second rebased agreement period, for example the 3-year period covering 2020 through 2022 for ACOs renewing for a second agreement period in 2017) we are proposing that the weight on the adjustment to the benchmark for regional FFS expenditures be increased from the 35 percent applicable in the first renewed agreement period to 70 percent. Increasing the weight of the adjustment reduces the strength of the link between an ACO's effect on the cost of care

for its assigned beneficiaries and the benchmark calculated for an ensuing agreement period. Weakening this link may increase the incentive for ACOs to make investments in care delivery reforms because resulting potential savings would be more likely to be rewarded over multiple agreement periods rather than being ‘baked’ back into the benchmark at the next rebasing. On the other hand, efficiency gains would need to be significantly greater than those currently achieved by the ACOs participating in the program to result in budget neutrality by sufficiently offsetting increased shared savings payments to ACOs favored by a regional adjustment with 70 percent weight. As discussed in the preamble, we are proposing to set the weight on the regional adjustment at 70 percent for the third and subsequent agreement periods unless the Secretary determines a lower weight should be applied, as specified through future rulemaking. This determination, which could be made in advance of the agreement period beginning January 1, 2020, may be based on an assessment of the effects of the regional adjustment (and other modifications to the program made under this rule) on the Shared Savings Program such as: the effects on net program costs; the extent of participation in the Shared Savings Program; and the efficiency and quality of care received by beneficiaries.

ACOs demonstrate a wide range of differences in expenditures relative to risk adjusted expenditure levels for their region (for the sample of roughly 200 ACOs that started in the program in 2012 or 2013 the percentage by which ACO per capita expenditures exceed or are exceeded by their respective risk-adjusted regional per capita expenditures varies with a standard deviation of approximately 10 percent).

Transitioning to a 70 percent weight to calculate the regional adjustment effectively down-weights the savings generated by the changes we are proposing to make to the

existing benchmark calculation, since an ACO's benchmark would have increased dependence on the regional FFS expenditures and correspondingly a decreasing dependence on the historical expenditures for the ACO. At the same time, increasing the weight used to calculate the regional adjustment could result in selective participation and increases in shared savings payments to ACOs that have low beneficiary expenditures at baseline. If that were to happen, the overall anticipated cost of net shared savings payments would rise and outweigh the anticipated potential gains from additional care management and associated improvements in net benefit costs spurred by the improved incentives for efficiency generated by partially delinking ACO benchmarks from their own historical costs.

An element of the proposed regional adjustment which becomes apparent when reviewing the accompanying data files and the performance of ACOs in 2013 and 2014 (for those roughly 200 ACOs that started in 2012 and 2013) is that ACOs that are above or below the regional service area expenditure amount used to adjust their rebased benchmark in 1 year tend to have a similar bias in the following year. Placing a 100 percent weight on the regional service area expenditure amount illustrates this. Of the 50 ACOs that were the furthest below their estimated regional service area expenditure level in 2013, all were at least 10 percent below and their average expenditures were roughly 15 percent below the expenditures for the region. In the subsequent year, 2014, none of these ACOs exceeded its regional service area expenditure level, and the average expenditure difference only moved by about 2 percentage points. Similar yet less glaring results occur in those ACOs above their regional service area expenditure level, with the 50 ACOs the furthest above their

regional service area expenditure level having costs an average of approximately 10 percent above the regional service area expenditure level in 2013 – an average difference for the group that only moved by about 2 percentage points the following year.

Of the approximately 150 ACOs that were more than 0.5 percent below their regional service area expenditure level, only about 10 percent were above their regional service area expenditure level in the following year. Again, ACOs above their regional service area expenditure level follow a similar pattern, though less drastic. Of the ACOs above their regional service area expenditure level by more than 0.5 percent, approximately 25 percent performed below their regional service area expenditure level in the following year. Notwithstanding the potential for behavioral changes, this illustrates that for a significant portion of existing ACOs, there is evidence of a bias when compared to their regional service area expenditure level and that bias is likely to be predictable over time. We have accounted for cost associated with program selection for ACOs favored by such bias and considered attrition in participation by ACOs disfavored by such bias. However for some ACOs of the latter condition, it may take multiple years to sufficiently redesign their care delivery processes in order to generate savings substantial enough to offset high expenditures relative to their region at baseline. We note that this analysis is based on data from the first two years of program operations, and longer term effects may emerge to mitigate bias for certain ACOs with high expenditures at baseline.

Additionally, the passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established new incentives to encourage providers to participate in alternative payment models. Paying for value and incentivizing better care coordination

and integration is a top priority for us, and we have been implementing policies that encourage a shift towards paying for value instead of volume. MACRA provides additional tools to encourage care integration and value-based payment. Although implementation of MACRA is ongoing and many details are still to be proposed and finalized through rulemaking, the incentives created by MACRA could result in increased market pressure on providers to participate in ACOs. This may lower the risk of selective participation and potentially lead to higher expected net Federal savings.

Emerging data will be monitored in order to provide additional information for updating projections as part of the proposed use of a higher percentage (70 percent) in calculating the regional adjustment amount for ACOs entering a third or subsequent agreement period. For example, if ACOs respond by generating new efficiencies in care beyond those that are anticipated, and/or potential selective participation responses are lower than expected, then a 70 percent weight could potentially be associated with revised expectations regarding net costs or net savings. However, it is also possible that gains in efficiency will fail to materialize and/or selective participation and other behavioral responses will increase cost beyond the level that is currently anticipated, in such scenario we would consider further rulemaking as necessary to protect the Medicare Trust Funds (for example, in order to apply a lower percent weight in calculating the regional adjustment amount). To help further develop and potentially improve this analysis, we request comment on the aspects of the rule that may incentivize behavior that will affect participation in the program and potential shared savings. We specifically request data and methodology suggestions for modeling interactions between ACO payment parameters, anticipated responses to incorporating regional adjustments and

trends into the benchmark.

b. Further Considerations

The proposed rule would introduce regional expenditure trends and a regional adjustment to the rebased historical benchmark that would include prospective HCC risk adjustment to ensure trending and the regional adjustment appropriately account for differences in risk between an ACO's assigned beneficiary population and its regional service area assignable beneficiary population. Current program experience supports the hypothesis that the current approach of applying conditional reliance on demographic risk ratios for a continuously-assigned subset of beneficiaries for purposes of adjusting the historical benchmark to a performance year basis provides a reasonable balance between accounting for changes in risk of the population and limiting the risk that coding intensity shifts would artificially inflate ACO benchmarks. The proposal would retain this current policy for adjusting the historical benchmark to a performance year basis.

However, for the proposed changes involving the use of regional expenditure trends (to trend forward the benchmark years and to update the ACO's rebased historical benchmark) and the adjustment to the rebased benchmark for expenditures in the ACO's regional service area, we are not proposing to interject an additional explicit policy for limiting coding intensity sensitivity at this time (beyond what is described in section II.A.3. of this proposed rule), but would rely on the difference between the average prospective HCC scores for the ACO's assigned beneficiary population and its regional service area assignable beneficiary population. Regional trend calculations for the rebased historical base years are expected to mitigate the risk of sensitivity to potential coding intensity efforts by ACO providers/suppliers for several reasons. The benchmark

years for the new agreement period correspond to performance years from a prior agreement period where incentives for coding intensity changes were already actively limited by the continuously assigned demographic alternative calculation. In addition, coding intensity shifts that are uniform over a prior agreement period would not affect the trending of historical expenditures from the first 2 years to the third year of such period because such historical adjustments are only sensitive to risk score changes between the first 2 years and the third year of such baseline period. The CMS prospective HCC model has been updated for 2016 in ways that reduce its sensitivity to subjective coding levels for chronic conditions that are known to have historically accounted for differences in coding levels for MA beneficiaries relative to FFS Medicare. Lastly, ACOs tend to neighbor each other in markets where any ACO coding intensity shifts would then likely drive similar market-wide effects (including effects from market spillover affecting diagnosis codes submitted for patients receiving care from ACO providers/ suppliers but who are not ultimately assigned to an ACO) that would tend to net out any coding shifts in the calculation of risk scores relative to the ACO's region. This final consideration also offers a degree of reassurance that the calculation of the adjustment reflecting the difference between an ACO's expenditures relative to its region would be less likely to be materially biased by ACO coding intensity shifts.

If the new benchmark rebasing methodology proposed in this rule is adopted, we intend to carefully monitor emerging program data to assess whether the overall benchmark methodology as revised remains appropriately balanced between sensitivity to real changes in assigned population risk and protection from making shared savings payments due to potential coding intensity shifts. Of particular concern for close

monitoring (and potential future rulemaking changes, if necessary) are the unique circumstances related to the use of a prospective beneficiary assignment methodology in Track 3 and the associated benchmark calculations for Track 3 ACOs. Prospective assignment creates an overlap between the claims considered for purposes of determining beneficiary assignment to the ACO and the period in which diagnosis submissions from claims are utilized for calculating a beneficiary's prospective HCC score for the year during which the beneficiary will be assigned to the ACO. A related area for monitoring is whether regional FFS expenditures tabulated at a county level for assignable beneficiaries determined using the assignment methodology used in Track 1 and Track 2 would provide an unbiased comparison to a beneficiary population assigned under the prospective assignment methodology for Track 3. For these reasons, monitoring will consider the potential necessity to undertake rulemaking in order to make adjustments to regional calculations for Track 3 ACOs to avoid biasing the results.

2. Effects on Beneficiaries

As explained in more detail previously, we believe the proposed changes would provide additional incentive 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 (Tracks 2 or 3) in future agreement periods. Consequently, the changes in this rule will also benefit beneficiaries through broader improvements in accountability and care coordination (such as through the use of the waiver of the 3-day stay SNF rule by Track 3 ACOs) than would occur under current regulations.

Additionally, we intend to continue to analyze emerging program data to monitor

for any potential unintended effect that the introduction of a regional adjustment to the ACO's rebased historical benchmark 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). Further refinements that could be addressed in future rulemaking if monitoring ultimately revealed such problems could include reducing the percentage applied to the adjustment to the benchmark for regional expenditures, introducing additional adjustments (for example, enhancements or complements to the prospective HCC risk model) to control for exogenous factors impacting an ACO's costs relative to its region, or otherwise modifying the benchmark calculation to improve the balance between rewarding attainment and improvement in the efficiency and quality of care delivery for the full spectrum of beneficiaries enrolled in FFS Medicare.

3. Effects on Providers and Suppliers

The proposed shift from adding prior agreement period savings to an ACO's rebased baseline (as provided in the June 2015 final rule for ACOs renewing for a second agreement period starting in 2016) to an adjustment reflecting 35 percent of the difference between the ACO's regional service area average per capita expenditure amount and the ACO's rebased historical benchmark amount is anticipated to provide an additional incentive for ACOs to make investments to improve care coordination. At the same time, such change in methodology also shifts the benchmark policy focus from rewarding improvement in trend relative to an ACO's original baseline to an incentive that places more weight on attainment of efficiency – how an ACO compares in absolute expenditures to its region. Certain ACOs that joined the program from a high

expenditure baseline relative to their region and that showed savings under the first agreement period benchmark methodology will 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 may now expect significant shared savings payments even if they failed to generate shared savings in their first agreement period under the existing benchmark methodology.

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 Web site 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 Track 1, and, if elected by the ACO, under Tracks 2 and 3 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 eligible ACOs may remain under the one-sided model for a second agreement period.)

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 proposals to facilitate the transition to performance-based risk (see section II.C. of this proposed rule) and to streamline the adjustment to the benchmark for changes in the ACO participant composition (see section II.B. of this proposed rule), may further encourage participation by small entities. For example, smaller entities (among others) that are risk averse but ready to transition to a performance-based risk track may elect the option (if finalized) that would defer by one year their entrance into a two-sided model. Once under a two-sided model, ACOs will have the opportunity for greater reward compared to participation under the one-sided model although they will be at risk for shared losses. Additionally, the proposed

approach to adjusting for changes in ACO participant composition could provide greater stability to the benchmark calculations over time, particularly for ACOs with relatively smaller numbers of assigned beneficiaries.

As detailed in this RIA, total median shared savings payments net of shared losses are expected to increase by \$250 million over the 2017 to 2019 period as a result of changes that will increase benchmarks for certain ACOs participating in the Shared Savings Program and therefore increase the average small entity's shared savings revenue. However, the impact on any single small entity may depend on its relationship to costs calculated for the counties comprising its regional service area. We seek comment from individual providers, including small entities, regarding the changes proposed with special focus on the impact of the adjustment to the benchmark to reflect regional FFS expenditures, again noting for commenters that county level data are being made available in conjunction with this proposed rule to allow them to analyze such differences in cost for individual ACOs and their regions.

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 will 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 trend

calculations and adjustments for ACOs that include rural hospitals as ACO participants will be made in order to reflect FFS costs and trends in the ACO's regional service area. Overall, we expect the average ACO to receive greater shared savings revenue under the proposed changes (\$250 million greater net sharing anticipated over 2017 through 2019). However, the impact on individual ACOs and their participating small rural hospitals may differ from the program average. We seek comment from small rural hospitals on the proposed changes with special focus on the impact of the adjustment to the benchmark to reflect regional FFS expenditures, again noting for commenters that county level data being made available in conjunction with this proposed rule to allow them to analyze such differences in cost for individual ACOs and their regions.

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 2015, that is approximately \$144 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 \$144 million in any 1 year. Further, participation in this program is voluntary and is not mandated.

D. Alternatives Considered

As indicated in the June 2015 final rule (see 80 FR 32795 through 32796), and as discussed previously in section II.A.2.c. of this proposed rule, we also considered an alternative method for establishing benchmarks for subsequent agreement periods that would incorporate regional trends. Under such method we would apply the regional

trend to inflate an ACO's historical benchmark from the prior (that is, first) agreement period to represent expenditures expected for the most recent base year preceding the ACO's subsequent agreement period. This approach would therefore be delinked from an ACO's performance over the prior agreement period (except to the extent an ACO's assigned population impacts its wider regional trend) – improving the incentive for ACOs to invest in efforts to improve efficiency. In contrast to the methodology for calculating a regional adjustment proposed in this rule, it would also retain sensitivity to baseline costs demonstrated by beneficiaries assigned to the ACO in the prior agreement period, potentially mitigating concerns regarding certain types of program selection and possibly providing a more incremental transition for ACOs familiar with the existing program benchmark methodology.

Specifically it was estimated that blending an ACO's rebased benchmark with its prior (first) historical benchmark inflated by a regional trend would produce an overall budget neutral change in net program cost for the subsequent agreement period if the blending were accomplished via a 70 percent weight on an ACO's trended prior benchmark and a 30 percent weight on its rebased benchmark. While such blend would reasonably be expected to result in an improvement in program incentives for ACOs to generate new efficiencies in care delivery despite rebasing concerns, other considerations impacted the decision to ultimately propose the different approach detailed in this proposed rule.

Primarily, program experience to date indicates that many ACOs make significant changes to their provider composition over the course of an agreement period. Attempting to lock-in a first historical benchmark that would be trended to form

70 percent of the historical benchmark for future agreement periods would invariably be complicated and in many cases biased by changes in provider composition made years after the ACO's first entry into the program. Such operational complications and potential biases would invariably grow in magnitude for subsequent agreement periods, necessitating modifications to future rebasing, for example by reducing the weight on the regionally-trended component of the benchmark or requiring the regionally trended component always to be sourced from the rebased benchmark from the prior agreement period – changes that would likely dampen the incentive for ACOs to make significant investments in redesigning care in efficient ways. Furthermore, the rebasing methodology proposed in this proposed rule has the comparative advantage of linking the regional adjustment to an ACO's historical expenditures to its region's contemporary standardized cost as opposed to the level of cost (and associated efficiency) that happened to be exhibited in an ACO's prior historical benchmark period. Therefore, it was determined that the proposed approach generally offers a less complicated and more consistent and equitable mechanism for adjusting ACO rebased benchmarks to reflect regional expenditures over the long term.

E. Compliance with Requirements of Section 1899(i)(3)(B) of the Act

As previously discussed in this proposed rule, certain proposals 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) requires that such other payment model must not result in additional program expenditures. Collectively, current and proposed policies falling under authority of section 1899(i)(3) of the Act include:

performance-based risk, refining the calculation of national expenditures used to update the historical benchmark to use the assignable subpopulation of total FFS enrollment, updating benchmarks with regional trends as opposed to national average absolute growth in per capita spending, and 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 proposed 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 Tracks 2 and 3 and updating benchmarks using regional trends. The hypothetical baseline was assumed to include adjustments allowable under section 1899(d)(1)(B)(ii) of the Act including the provision from the June 2015 final rule whereby an ACO's rebased benchmark might include an adjustment reflecting a portion of savings measured during the ACO's prior agreement period and the 35 percent weight used in calculating the regional adjustment to the ACO's rebased historical benchmark proposed in this rule. The stochastic model and associated assumptions described previously in this section were adapted to reflect the agreement period spanning 2017 through 2019 for roughly 100 ACOs expected to renew in 2017. Such analysis estimated approximately \$130 million greater average net program savings under the alternative payment model that includes all proposed changes than expected under the hypothetical baseline in total over the 2017 to 2019 agreement period cycle. Furthermore, approximately 78 percent of stochastic trials resulted in greater or equal net program savings. The proposals were projected to result in both greater savings on benefit costs and net payments to ACOs.

Participation in performance-based risk under Track 2 and Track 3 is assumed to improve the incentive for ACOs to increase the efficiency of care for beneficiaries (similar to as assumed 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. Correspondingly, net shared savings payments are also expected to be greater under the proposed alternative payment model under section 1899(i)(3) of the Act than under the hypothetical baseline, mainly driven by the higher sharing rates and potentially lower minimum savings requirements in Track 2 and Track 3, but partly offset mainly by lower benchmarks resulting from the removal of the policy adopted in the June 2015 final rule of adding a portion of savings to the rebased benchmark, the use of more-accurate regional benchmark updates, and new shared loss revenue.

Additionally, we also projected a lower net federal savings of approximately \$15 million would result from using the hypothetical baseline described previously but forgoing the adjustment to account for a portion of savings generated during the ACO's prior agreement period. We believe the proposed removal of this adjustment for savings generated in the ACO's prior agreement period would enable us to place a greater weight on the amount of the regional adjustment in the future, while not over crediting or penalizing an ACO for its prior performance (discussed in section II.A.2.c. of this proposed rule). This alternative hypothetical baseline (that does not account for savings generated in the ACO's prior agreement period) more closely resembles the future hypothetical baseline that would be used in our analysis of the application of a higher weight in calculating the regional adjustment in subsequent agreement periods (if the policies described in this proposed rule are finalized).

Relative savings projected for the ACOs starting a second agreement period in 2017 participation cycle are reasonably assumed to be proportional for ACOs starting a second agreement period in 2018 and 2019 because the assumptions and parameters would be the same or similar. Accordingly, the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures is therefore satisfied for the period 2017 through 2019. As discussed in sections II.A.2.d.3. and II.A.2.e.3. of this proposed rule, 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, taking into account, for example, increasing the weight placed on the regional adjustment to an ACO's rebased historical benchmark, which is proposed to increase to 70 percent for an ACO's third and subsequent agreement period (unless the Secretary determines a lower weight should be applied, as specified through future rulemaking). In the event that we conclude 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 4, 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) the aggregate cost of ACO operations for ACO participants and ACO providers/suppliers from 2017 to 2019 that are associated with the provisions of this

proposed rule as compared to baseline.

**TABLE 4: ACCOUNTING STATEMENT ESTIMATED IMPACTS
(CYs 2017–2019)**

Category	Primary Estimate	Minimum Estimate	Maximum Estimate	Source Citation (RIA, preamble, etc.)
Transfers From the Federal Government to ACOs				
Annualized monetized: Discount rate: 7%	- 39.3 million	73.5 million	-159.1 million	Table 3
Annualized monetized: Discount rate: 3%	-39.7 million	75.3 million	-161.5million	
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. Publicly Available Data to Facilitate Modeling of Proposed Changes

We believe several sources of data will facilitate ACOs and other stakeholders in modeling the proposed changes to the benchmark rebasing methodology that include calculations using factors of regional FFS spending. Concurrent with the issuance of this proposed rule, we are making the following new data files available for select calendar years through the Shared Savings Program website at www.cms.gov/sharedsavingsprogram/:

- Files containing average county FFS expenditures, CMS-HCC prospective risk scores and person-years for assignable beneficiaries by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) for 2012, 2013, and 2014.
- Files containing the total number of assigned beneficiaries for each ACO for each county where at least 1 percent of the ACO's assigned beneficiaries reside for 2012, 2013, and 2014.

These files can be accessed under the Statutes/Regulations/Guidance section of the Shared Savings Program's website, see <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Statutes-Regulations-Guidance.html>.

A listing of all publicly available Shared Savings Program ACO data and ACO performance data sources maintained by CMS is available through the Shared Savings Program website (see the guide titled "Medicare Shared Savings Program Publicly available ACO data and ACO performance data sources maintained by CMS" available online at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html>). The most comprehensive data sets that include specific data used in determining financial reconciliation for performance year 1

(ending December 31, 2013) and performance year 2014 are the Shared Savings Program Accountable Care Organizations Public Use Files (PUFs). For each ACO (identified by ACO name) the PUFs contain: financial and quality performance data (including quality score, final sharing rate, Minimum Savings Rate/Minimum Loss Rate, benchmark, and the same data provided through the program's Performance Year results dataset available through Data.CMS.gov regarding the calculation of savings/losses); data on demographic characteristics of the ACO's assigned beneficiary population; ACO-level data on expenditure and utilization metrics; and data on the ACO's provider/supplier composition. Additionally, the performance year 2014 PUF includes variables not included in the PUF for the first performance year, including: state(s) where beneficiaries reside; average expenditures for populations of beneficiaries by enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) for benchmark years 1, 2, 3; average HCC risk scores in the performance year and benchmark years 1, 2, 3 for populations of beneficiaries by enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible); average historical expenditure benchmark; and number of assigned beneficiaries by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) in the performance year. (Note the existing 2013 PUF displays aggregate 18 or 21 month data for ACOs with start dates in April 2012 or July 2012 whereas the new data files to support modeling of this proposed rule include data on a calendar year basis, including data for 2013.)

Combining data from existing PUFs and the new data files will allow one or more years of comparison between risk-adjusted per capita expenditures for an ACO's assigned beneficiaries and the corresponding risk-adjusted expenditures for the ACO's

regional service area, however the specific year or years of available comparison depend on the ACO's start date. For example, it will be possible to use the new data files to estimate the BY2, BY3 and PY1 (respectively CYs 2012, 2013, and 2014) risk standardized regional FFS costs by Medicare enrollment type for ACOs that started January 1, 2014 and then make a piecewise comparison to corresponding ACO assigned population standardized per capita costs by Medicare enrollment type for such years using the existing 2014 PUF data.

While we believe the release of the new data files in conjunction with existing 2014 PUF data will provide a reasonable overall dataset for illustrating relationships that exist between a representative sample of ACOs in terms of their expenditures and trends relative to their risk-adjusted county-weighted FFS regional service area expenditures and trends, we note that precision in such comparison for any single ACO may be limited because the datasets are not exhaustive. For example, as noted previously, assignment data for an ACO are not shown for counties with less than 1 percent of the ACO's overall assigned beneficiary population in the given year, and ACO assignment is not broken out by Medicare enrollment type at the county level.

We note that aside from these data files published and maintained by CMS, there are possibly other sources of data that would inform analyses of the proposed changes to the benchmarking methodology described in this proposed rule. For example, individual ACOs may have access to additional data, specific to their organization and experience in the communities in which they operate, that may further enable them to model the potential impacts of the proposed changes on their organization.

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 2017 through 2019 would be net federal savings of \$120 million greater than what would have been saved if no changes were made. Although this is the best estimate of the financial impact of the Shared Savings Program during CYs 2017 through 2019, a relatively wide range of possible outcomes exists. While approximately two-thirds of the stochastic trials resulted in an increase in net program savings, the 10th and 90th percentiles of the estimated distribution show a net increase in costs of \$230 million to net savings of \$490 million, respectively.

Overall, our analysis projects that improvements in the accuracy of benchmark calculations, including through the introduction of a regional adjustment to the ACO's rebased historical benchmark, are expected to result in increased overall participation in the program. The proposed changes are also expected to improve the incentive for ACOs to invest in effective care management efforts, increase the attractiveness of participation under performance-based risk in Track 2 or 3 for certain ACOs with lower beneficiary expenditures, and result in overall greater gains in savings on FFS benefit claims costs than the associated increase in 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 biased benchmark adjustments due to diagnosis coding intensity shifts. Such monitoring will inform future rulemaking such as if the Secretary determines that a lower weight should

be used in calculating the regional adjustment amount for ACOs' third and subsequent agreement periods.

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 in 42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 425 as set forth below:

PART 425--MEDICARE SHARED SAVINGS PROGRAM

1. The authority citation, for part 425 is revised 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. Amend § 425.20 by adding in alphabetical order definitions for "ACO's regional service area", "Assignable beneficiary", "BY", "Joiners", "Leavers", and "Stayers" to read as follows:

§ 425.20 Definitions.

* * * * *

ACO's regional service area means all counties where one or more beneficiaries assigned to the ACO reside.

* * * * *

Assignable beneficiary means a Medicare fee-for-service beneficiary who receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c).

* * * * *

BY stands for benchmark year.

* * * * *

Joiners means beneficiaries who were not assigned to the ACO for the preceding performance year but become assigned to the ACO for the current performance year when the certified ACO participant list for the current performance year, as required under § 425.118, is taken into account.

Leavers means beneficiaries who were assigned to the ACO for the preceding performance year, but are no longer assigned to the ACO for the current performance year when the certified ACO participant list for the current performance year, as required under § 425.118, is taken into account.

* * * * *

Stayers means beneficiaries who were assigned to the ACO for the preceding performance year and remain assigned to the ACO for the current performance year when

the certified ACO participant list for the current performance year, as required under § 425.118 is taken into account.

* * * * *

3. Amend §425.200 as follows:

A. In paragraph (b)(2) by removing the phrase "all subsequent years" and adding in its place the phrase "through 2016".

B. By adding paragraph (b)(3).

C. By adding paragraph (e).

The additions read as follows:

§ 425.200 Participation agreement with CMS.

* * * * *

(b) * * *

(3) For 2017 and all subsequent years—

(i) The start date is January 1 of that year; and

(ii) The term of the participation agreement is 3 years, except the term of an 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.

* * * * *

(e) Optional fourth year. (1) To qualify for a fourth performance year as described in paragraph (b)(3)(ii) of this section, the ACO must meet all of the following conditions:

(i) Is currently participating in its first agreement period under Track 1.

(ii) Has requested renewal of its participation agreement in accordance with § 425.224.

(iii) Has selected a two-sided model (as described under § 425.606 or § 425.610 of this part) in its renewal request.

(iv) Has requested an extension of its current agreement period and a 1-year deferral of the start of its second agreement period in a form and manner specified by CMS.

(v) CMS approves the ACO's renewal, extension, and deferral requests.

(2) An ACO that is approved for renewal, extension, and deferral that terminates its participation agreement before the start of the first performance year of the second agreement period is--

(i) Considered to have terminated its participation agreement for the second agreement period under §425.220; and

(ii) Not eligible to participate in the Shared Savings Program again until after the date on which the term of that second agreement period would have expired if the ACO had not terminated its participation, consistent with § 425.222.

4. Amend § 425.314 as follows:

A. By removing paragraph (a)(4).

B. By adding paragraph (e).

The additions reads as follows:

§ 425.314 Audits and record retention.

* * * * *

(e) Reopenings. (1) If CMS determines that the amount of shared savings due to

the ACO or the amount of shared losses owed by the ACO has been calculated in error, CMS may reopen the initial determination or a final agency determination under subpart I of this part and issue a revised initial determination:

(i) At any time in the case of fraud or similar fault as defined in § 405.902; or
(ii) Not later than 4 years after the date of the notification to the ACO of the initial determination of savings or losses for the relevant performance year under §425.604(f), § 425.606(h), or § 425.610(h), for good cause.

(2) Good cause may be established when--

(i) There is new and material evidence that was not available or known at the time of the payment determination and may result in a different conclusion; or

(ii) The evidence that was considered in making the payment determination clearly shows on its face that an obvious error was made at the time of the payment determination.

(3) A change of legal interpretation or policy by CMS in a regulation, CMS ruling or CMS general instruction, whether made in response to judicial precedent or otherwise, is not a basis for reopening a payment determination under this section.

(4) CMS has sole discretion to determine whether good cause exists for reopening a payment determination under this section.

5. Amend § 425.602 as follows:

A. Revise the section heading.

B. Redesignate paragraph (a)(4) as paragraph (a)(4)(i).

C. In newly redesignated paragraph (a)(4)(i) by removing the phrase "Truncates an assigned" and adding in its place the phrase "For performance years before 2017,

truncates an assigned".

- D. Add paragraph (a)(4)(ii).
- E. Revise paragraph (a)(5)
- F. Add paragraphs (a)(8)(i) and (ii).
- G. Add paragraph (a)(9).
- H. Revise paragraphs (b)(1) and (2).
- I. Remove paragraph (c).

The revisions and additions read as follows:

§ 425.602 Establishing, adjusting, and updating the benchmark for an ACO's first agreement period.

(a) * * *

(4) * * *

(ii) For the 2017 performance year and all subsequent performance years, 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)(i) For performance years before 2017–

(A) Using CMS Office of the Actuary national Medicare expenditure data for each of the years making up the historical benchmark, determines national growth rates and trends expenditures for each benchmark year (BY1 and BY2) to the third benchmark year (BY3) dollars.

(B) To trend forward the benchmark, CMS makes separate calculations for

expenditure categories for each of the following populations of beneficiaries:

- (1) ESRD.
- (2) Disabled.
- (3) Aged/dual eligible Medicare and Medicaid beneficiaries.
- (4) Aged/non-dual eligible Medicare and Medicaid beneficiaries.
- (ii) For the 2017 and all subsequent performance years—

(A) Using CMS Office of the Actuary national Medicare expenditure data for each of the years making up the historical benchmark, determines national growth rates for assignable beneficiaries identified for the 12-month calendar year corresponding to each benchmark year, and trends expenditures for each benchmark year (BY1 and BY2) to the third benchmark year (BY3) dollars.

(B) To trend forward the benchmark, CMS makes separate calculations for expenditure categories for each of the following populations of beneficiaries:

- (1) ESRD.
- (2) Disabled.
- (3) Aged/dual eligible Medicare and Medicaid beneficiaries.
- (4) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

* * * * *

- (8) * * *

(i) For performance years before 2017, the benchmark is adjusted to take into account the expenditures for beneficiaries who would have been assigned to the ACO in any of the 3 most recent years prior to the agreement period using the most recent certified ACO participant list for the relevant performance year.

(ii) For the 2017 performance year and all subsequent performance years, the benchmark is adjusted to account for changes in the certified ACO participant list during the term of the agreement period.

(A) To adjust the benchmark, CMS does the following:

(1) Calculates a stayer component using an expenditure ratio of average per capita expenditures for stayers to stayers and leavers combined, using BY3 as a reference year. CMS makes separate expenditure calculations 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) Calculates a joiner component using average per capita expenditures for joiners, using BY3 as a reference year. CMS makes separate expenditure calculations 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) Combines the stayer component described in paragraph (a)(8)(ii)(A)(1) of this section and the joiner component described in paragraph (a)(8)(ii)(A)(2) of this section.

(4) Calculates a single weighted average per capita adjusted historical benchmark from separate expenditure calculations 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.

(B) In the event no stayers are identified to complete the calculation as described in paragraph (a)(8)(ii)(A) of this section, CMS calculates an adjusted historical benchmark for the ACO as described in paragraph (a)(8)(i) of this section.

(9) The historical benchmark is further adjusted at the time of reconciliation for a performance year to account for changes in severity and case mix 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) * * *

(1) For performance years before 2017, CMS updates the historical benchmark annually for each year of the agreement period based on the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program.

(i) CMS updates the fixed benchmark by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program using data from CMS' Office of the Actuary.

(ii) To update the benchmark, CMS makes expenditure calculations for separate 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.

(2) For the 2017 performance year and all subsequent performance years, CMS updates the historical benchmark annually for each year of the agreement period based on the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program for assignable beneficiaries identified for the 12-month calendar year corresponding to the year for which the update is calculated.

(i) CMS updates the fixed benchmark by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program for assignable beneficiaries identified for the 12-month calendar year corresponding to the year for which the update is being calculated using data from CMS' Office of the Actuary.

(ii) To update the benchmark, CMS makes expenditure calculations for separate 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.

6. Add § 425.603 to read as follows:

§ 425.603 Resetting, adjusting, and updating the benchmark for a subsequent

agreement period.

(a) An ACO's benchmark is reset at the start of each subsequent agreement period.

(b) For ACOs entering into a second agreement period in 2016, CMS establishes, adjusts, and updates the rebased historical benchmark in accordance with § 425.602(a) and (b) with the following modifications:

(1) Rather than weighting each year of the benchmark using the percentages provided at § 425.602(a)(7), each benchmark year is weighted equally.

(2) An additional adjustment is made to account for the average per capita amount of savings generated during the ACO's previous agreement period. The adjustment is limited to the average number of assigned beneficiaries (expressed as person years) under the ACO's first agreement period.

(c) For ACOs entering into a second or subsequent agreement period in 2017 and subsequent years, CMS establishes the rebased historical benchmark by determining the per capita Parts A and B fee-for-service expenditures for beneficiaries who would have been assigned to the ACO in any of the 3 most recent years before the agreement period using the certified ACO participant list submitted before the start of the agreement period as required under § 425.118. 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. The calculation --

(i) Excludes IME and DSH payments; and

(ii) Considers individually beneficiary identifiable payments made under a demonstration, pilot or time limited program.

(2) Makes separate expenditure calculations 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) 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 regional growth rates based on expenditures for the ACO's regional service area as determined under paragraphs (e) and (f) of this section, making separate expenditure calculations 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.

(6) Restates BY1 and BY2 trended and risk-adjusted expenditures in BY3

proportions 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.
- (7) Weights each benchmark year equally.
- (8) The benchmark is adjusted to account for changes in the certified ACO

participant list during the term of the agreement period.

- (i) To adjust the benchmark, CMS does the following:

(A) Calculates a stayer component using an expenditure ratio of average per capita expenditures for stayers to stayers and leavers combined, using BY3 as a reference year. CMS makes separate expenditure calculations for each of the following populations of beneficiaries:

- (1) ESRD.
- (2) Disabled.
- (3) Aged/dual eligible Medicare and Medicaid beneficiaries.
- (4) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(B) Calculates a joiner component using average per capita expenditures for joiners, using BY3 as a reference year. CMS makes separate expenditure calculations for each of the following populations of beneficiaries:

- (1) ESRD.
- (2) Disabled.
- (3) Aged/dual eligible Medicare and Medicaid beneficiaries.

(4) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(C) Combines the stayer component described in paragraph (c)(8)(i)(A) of this section and the joiner component described in paragraph (c)(8)(i)(B) of this section.

(D) Calculates a single weighted average per capita adjusted historical benchmark from separate expenditure calculations for each of the following populations of beneficiaries:

(1) ESRD.

(2) Disabled.

(3) Aged/dual eligible Medicare and Medicaid beneficiaries.

(4) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(ii) In the event no stayers are identified to complete the calculation as described in paragraph (c)(8)(i) of this section, CMS calculates an adjusted historical benchmark for the ACO as described in § 425.602(a)(8)(i).

(iii) CMS redetermines the regional adjustment amount under paragraph (c)(9) of this section, according to the ACO's assigned beneficiaries for BY3 resulting from the most recent certified ACO participant list for the relevant performance year.

(9) 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 (e) and (f) of this section for BY3.

(C) Adjusts for differences in severity and case mix between the ACO's assigned beneficiary population and the ACO's regional service area that includes assignable beneficiaries identified for the 12-month calendar year that corresponds to the relevant benchmark year.

(ii) Calculates the adjustment as follows:

(A) Determines the difference between the ACO's regional service area average per capita expenditure amount as specified under paragraph (c)(9)(i) of this section and the average per capita amount of the ACO's rebased historical benchmark determined under paragraphs (c)(1) through (8) of this section, for each of the following populations of beneficiaries:

(1) ESRD.

(2) Disabled.

(3) Aged/dual eligible Medicare and Medicaid beneficiaries.

(4) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(B) Applies a percentage, determined as follows:

(1) The first time an ACO's benchmark is rebased using the methodology described under paragraph (c) of this section, CMS calculates the regional adjustment using 35 percent of the difference between the ACO's regional service area average per capita expenditure amount and the ACO's rebased historical benchmark amount.

(2) The second or subsequent time that an ACO's benchmark is rebased using the

methodology described under this paragraph (c), CMS calculates the regional adjustment to the historical benchmark using 70 percent of the difference between the ACO's regional service area average per capita regional expenditure amount and the ACO's rebased historical benchmark amount, unless the Secretary determines a lower weight should be applied.

(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 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).

(d) CMS updates the rebased historical benchmark under paragraph (c) of this section, annually for each year of the agreement period by the growth in the ACO's regional service area expenditures by doing all of the following:

(1) Determining the counties included in the ACO's regional service area based on the ACO's assigned beneficiary population used to determine financial reconciliation for the relevant performance year.

(2) Determining growth rates based on expenditures for counties in the ACO's regional service area calculated under paragraphs (e) and (f) of this section, for each performance year.

(3) Updating the benchmark by making separate calculations 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.

(e) For ACOs entering into a second or subsequent agreement period in 2017 and 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, 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.

(iii) The calculation for ESRD beneficiaries is based on the aggregation of expenditures statewide, and applied consistently to each county within a State.

(2) Calculates assignable beneficiary expenditures using the payment amounts included in Part 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 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.

(i) The calculation is made according to 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) The calculation for ESRD beneficiaries is based on the aggregation of expenditures and prospective CMS- HCC risk scores statewide, and applied consistently to each county within a State.

(f) For ACOs entering into a second or subsequent agreement period in 2017 and subsequent years, CMS does all of the following to calculate an ACO's regional expenditures using risk-adjusted county fee-for-service expenditures determined according to paragraph (e) of this section:

(1) Weights resulting county expenditures by the ACO's proportion of assigned

beneficiaries 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.
- (iii) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(2) Weights county-level fee-for-service expenditures by 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, to determine regional fee-for-service expenditures 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.

7. Amend § 425.604 as follows:

A. In paragraphs (a)(1) and (2), remove each time it appears the phrase "adjust for changes" and add in its place the phrase "adjust the benchmark for changes."

B. In paragraph (a)(3) introductory text, remove the phrase "In adjusting for health status" and add in its place the phrase "In adjusting the benchmark for health status".

C. Redesignate paragraph (a)(4) as paragraph (a)(4)(i).

D. In newly redesignated paragraph (a)(4)(i) by remove the phrase "To minimize

variation" and add in its place the phrase "For performance years before 2017 to minimize variation".

E. Add paragraph (a)(4)(ii).

The addition reads as follows:

§425.604 Calculation of savings under the one-sided model.

(a) * * *

(4) * * *

(ii) For the 2017 and all subsequent performance years to minimize variation from catastrophically large claims, CMS 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 the performance year.

* * * * *

8. Amend § 425.606 as follows:

A. In paragraphs (a)(1) and (2), remove each time it appears the phrase "adjust for changes" and add in its place the phrase "adjust the benchmark for changes. "

B. In paragraph (a)(3) introductory text, remove the phrase "In adjusting for health status" and add in its place the phrase "In adjusting the benchmark for health status. "

C. Redesignate paragraph (a)(4) as paragraph (a)(4)(i).

D. In newly redesignated paragraph (a)(4)(i), remove the phrase "To minimize variation" and add in its place the phrase "For performance years before 2017 to minimize variation".

E. Add paragraph (a)(4)(ii).

The addition reads as follows:

§425.606 Calculation of shared savings and losses under Track 2.

(a) * * *

(4) * * *

(ii) For the 2017 performance years and all subsequent performance years to minimize variation from catastrophically large claims, CMS 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 the performance year.

* * * * *

9. Amend § 425.610 as follows:

A. In paragraphs (a)(1) and (2), remove each time it appears the phrase "adjust for changes" and add in its place the phrase "adjust the benchmark for changes. "

B. In paragraph (a)(3) introductory text, remove the phrase "In adjusting for health status" and add in its place the phrase "In adjusting the benchmark for health status. "

C. Redesignating paragraph (a)(4) as paragraph (a)(4)(i).

D. In newly redesignated paragraph (a)(4)(i), remove the phrase "To minimize variation" and add in its place the phrase "For performance years before 2017 to minimize variation".

E. Add paragraph (a)(4)(ii).

The addition reads as follows:

§ 425.610 Calculation of shared savings and losses under Track 3.

(a) * * *

(4) * * *

(ii) For the 2017 and all subsequent performance years to minimize variation from catastrophically large claims, CMS 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 the performance year.

* * * * *

10. Amend § 425.800 as follows:

A. In paragraph (a)(4) by—

i. Removing the phrase "The determination of whether" and adding in its place the phrase "The initial determination or revised initial determination of whether".

ii. Removing the phrase "including the determination" and adding in its place the phrase "including the initial determination or revised initial determination".

iii. Removing the cross-reference "§425.602, §425.604, and § 425.606" and adding in its place the cross-reference "§§ 425.602, 425.604, 425.606, and 425.610".

B. In paragraph (a)(5) by removing the cross-reference "§425.604 and 425.606" and adding in its place "§§ 425.604, 425.606, and 425.610".

Dated: December 16, 2015.

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Dated: December 21, 2015.

Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

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