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healthcare financial management association

ACO Final Rule Fact Sheet - Highlights by Section

Note: Italicized text reflects final rules changes

CMS released a final rule addressing changes to the Medicare Shared Savings Program, including provisions relating to the payment of Accountable Care Organizations (ACOs) participating in the program. Under the Medicare Shared Savings Program, providers of services and suppliers that participate in an ACO continue to receive traditional Medicare Part A and Part B payments, but the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements. This document summarizes the final changes contained in the final rule by section.

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Estimated Net Federal Savings CY16 through CY18 (pgs 32821-32822)

Net Federal Savings:	CY16	CY17	CY18	CY16–CY18
10th Percentile	\$180 million	\$130 million	\$20 million	\$340 million
Median	\$270 million	\$200 million	\$60 million	\$540 million
90th Percentile	\$380 million	\$290 million	\$120 million	\$800 million

Overview of the Medicare Shared Savings Program (pgs 32695)

- Policies adopted in the November 2011 final rule are generally well accepted.
- CMS identified several policy areas for revision in the December 2014 proposed rule.
- The Shared Savings Program must be structured in a way that both encourages new and continued provider participation in the program, and protects beneficiaries with original fee-for-service (FFS) Medicare and Medicare Trust Funds.
- The Shared Savings Program encourages physicians, through eligibility requirements, to include patients in decision-making about health care.

ACO Eligibility Requirements (pgs 32701-32728)

Agreement Requirements (pgs 32701-32705)

- ACO participant agreements are necessary for purposes of program transparency and to ensure an ACO's compliance with program requirements.
- Program rules currently require each ACO participant to commit to the three-year participation agreement that it makes with CMS.
- ACO participant agreements (agreements between the ACO and its participating physicians/physician groups) should include requirement that the agreement must be for at least one performance year and address potential consequences for early termination.
- CMS believes that ACOs will incorporate a requirement that participants and providers/suppliers must provide some prior notice of termination to the ACO.
- ACOs may struggle to incorporate new requirements in time to submit 2016 applications or requests for renewal by applicable deadlines.
- *CMS will not require these changes to be incorporated into any ACO participant agreements that are submitted to CMS for the 2016 performance year.*
- *ACOs that submit requests to add ACO participants for the 2017 performance year will be required to have a corresponding ACO participant agreement that meets new requirements.*

Sufficient Number of Primary Care Providers and Beneficiaries (pgs 32705-32707)

- ACOs must have at least 5,000 assigned beneficiaries.
- ACOs that fall below 5,000 assigned beneficiaries will be allowed to continue in the program, but be issued a warning letter and placed on a corrective action plan (CAP).
 - o While under the CAP, the ACO will remain eligible to share in savings for the performance year in which it fell below the 5,000 level, and the Minimum Savings Rate (MSR) will be adjusted according to the number of assigned beneficiaries determined at time of reconciliation.
- The number of assigned beneficiaries will be calculated for each benchmark year using assignment methodology set forth in part 425 subpart E.
- *In the case of benchmark year 3, CMS will use the most recent data available with up to a three-month claims run-out to estimate the number of assigned beneficiaries.*
- *CMS will specify in its request for a CAP the performance year during which an ACO's assigned population must meet or exceed 5,000 beneficiaries.*
- *CMS will use its discretion regarding whether to impose any remedial measures or to terminate an ACO for failure to satisfy the minimum assigned beneficiary threshold.*

Identification and Required Reporting of ACO Participants and ACO Providers/Suppliers (pgs 32707-32713)

- An ACO is an entity that is identified by a Taxpayer Identification Number (TIN) and composed of one or more Medicare-enrolled TINs associated with ACO participants.

- *Prior to the start of the agreement period, and before each performance year thereafter, an ACO must provide CMS with a complete and certified list of its ACO participants and their Medicare-enrolled TIN.*
- *All individuals and entities currently billing through the Medicare-enrolled TIN identified by an ACO as an ACO participant, must be included on the ACO provider/supplier list.*
- *CMS will provide each ACO with a list of all ACO providers/suppliers NPIs that it has identified in Provider Enrollment, Chain, and Ownership System (PECOS) as associated with each ACO participant's Medicare-enrolled TIN.*
- *An ACO will be required to review the list, make any necessary corrections, and certify lists of all of its ACO participants and ACO providers/suppliers (including their TINs and NPIs) as true, accurate, and complete.*
- *An ACO must submit certified ACO participant and ACO provider/supplier lists at any time, upon CMS request.*
- *An ACO must report changes in its participant and ACO provider/supplier enrollment status in PECOS within 30 days after such changes have occurred.*
- *An ACO is responsible for ensuring its participant or ACO providers/suppliers make the change within the required 30-day time period.*
- *CMS will remove the requirement that the ACO indicate primary care physicians on its application to the program.*

Managing Changes to ACO Participants (pgs 32709-32712)

- *Except for rare instances, such as the cessation of the ACO participant operations or exclusion from the Medicare program, CMS expects ACO participants to remain in the ACO for the entire three-year agreement period.*
- *CMS understands that there are legitimate reasons why the ACO may need to update the list of ACO participants during the three-year agreement period.*
- *An ACO must submit a request to add a new entity to its ACO participant list in the form and manner specified by CMS.*
- *CMS must approve additions to the ACO participant list before they can become effective on January 1 of the following performance year.*
- *An ACO must notify CMS no later than 30 days after termination of an ACO participant agreement.*
- *The notice must be submitted in the form and manner specified by CMS, and include the date of termination of the ACO participant agreement.*
- *ACO participant list changes will result in adjustments to its historical benchmark, assignment, quality reporting sample, and the obligation of the ACO to report on behalf of eligible professionals for certain CMS quality initiatives.*

Managing Changes to ACO Providers/Suppliers (pgs 32712-32713)

- *CMS recognizes that ACO providers/suppliers may terminate affiliation with an ACO participant or affiliate with new or additional Medicare-enrolled TINs (which may or may not be ACO participants) on a frequent basis.*

- *An ACO must notify CMS within 30 days after an individual or entity becomes or ceases to be a Medicare-enrolled provider or supplier that bills for items and services it furnishes to Medicare beneficiaries under a TIN.*

Update of Medicare Enrollment Information (pg 32713)

- *CMS finalized its proposed requirement that ACOs report changes in participant and ACO provider supplier enrollment in PECOs.*

Significant Changes to an ACO (pgs 32713-32714)

- Section 425.214(b) requires an ACO to notify CMS within 30 days of any significant change.
- A significant change occurs when an ACO is no longer able to meet the Shared Savings Program eligibility or program requirements.
- *CMS finalizes the proposal to modify §425.214 to continue to require an ACO to alert it when a significant change occurs.*
- *An ACO's failure to notify CMS of a significant change does not preclude CMS from determining that the ACO has experienced a significant change.*
- *CMS is not finalizing its proposal to specify that a significant change occurs when the number or identity of ACO participants included on the ACO participant list changes by 50 percent or more during an agreement period.*

Consideration of Claims Billed by Merged/Acquired Medicare-Enrolled Entities (pgs 32714-32716)

- The statute and regulations permit ACO participants that form an ACO to use a variety of collaborative organizational structures, including collaborations other than merger.
- To avoid uncertainty and establish a clear and consistent process for the recognition of the claims previously billed by the TINs of acquired entities, CMS proposed to codify the current operational guidance on this topic with minor revisions.
- *CMS will add the option for ACOs to request consideration of claims submitted by the Medicare-enrolled TINs of acquired entities as part of their application, and address the documentation requirements for such requests.*
- *ACOs are permitted to annually request consideration of claims submitted by the TINs of entities acquired through sale or merger upon submission of the ACO's updated list of ACO participants.*
 - o *Detailed information on the manner, format, and timelines for ACOs to submit such requests will be found in operational documents and guidance.*

Legal Structure and Governance (pgs 32716-32717)

- CMS proposed clarifications to rules related to the ACO's legal entity and governing body.
- *CMS finalizes its proposal to remove the reference to "otherwise independent ACO participants" in §425.104(b).*

- *The revised regulation will provide that an ACO formed by "two or more ACO participants, each of which is identified by a unique TIN," must be a legal entity separate from any of its ACO participants.*
- *CMS clarifies that an ACO formed by a single ACO participant may use its existing legal entity and governing body, provided it satisfies the other requirements in §§ 425.104 and 425.106.*
 - o *The ACO's governing body must satisfy three criteria:*
 1. *It must be the same as the governing body of the legal entity that is the ACO.*
 2. *In the case of an ACO that comprises multiple ACO participants, the governing body must be separate and unique to the ACO.*
 3. *The governing body must satisfy all other requirements set forth in §425.106, including the fiduciary duty requirement.*

Fiduciary Duties of Governing Body Members (pgs 32717-32718)

- *Current regulations require that the governing body members have a fiduciary duty to the ACO and must act consistent with that duty.*
- *CMS finalizes its proposal that the fiduciary duty owed to an ACO by its governing body members includes the duty of loyalty.*

Composition of the Governing Body (pgs 32718-32719)

- *CMS finalizes its proposed modification to state the statutory standard in section 1899(b)(1) of the Act, which requires an ACO to have a "mechanism for shared governance" among ACO participants.*
- *An ACO provider/supplier is prohibited from being the beneficiary representative on the governing body.*
- *While CMS is not finalizing its proposal to remove the flexibility for ACOs to deviate from the requirement that ACO participants must hold at least 75 percent control of an ACO's governing body, it notes that it anticipates permitting such exceptions only in very limited circumstances.*
- *CMS may revisit this issue in future rulemaking.*

Leadership and Management Structure (pgs 32719-32722)

- *CMS is amending §425.108 to provide some additional flexibility regarding qualifications of the ACO medical director.*
 - o *The requirement that the medical director be an ACO provider/supplier will be removed.*
- *CMS will approve applications from innovative ACOs that do not satisfy leadership and management requirements related to operations management and clinical management and oversight.*
- *CMS will require applicants to submit materials at the time of application regarding the ACO's leadership and management team, including the qualified healthcare professional responsible for the ACO's quality assurance and improvement program.*

Required Process to Coordinate Care (pgs 32722-32725)

- CMS will add a new eligibility requirement that an ACO must describe in its application how it will encourage and promote the use of enabling technologies for improving care coordination for beneficiaries.
- Enabling technologies and services may include:
 - o Electronic health records
 - o Health IT tools
 - Population health management
 - Data aggregation and analytic tools
 - o Telehealth services
 - o Remote patient monitoring
 - o Health information exchange services
 - o Other electronic tools to engage patients in their care
- The ACO must agree and require its participants, providers/suppliers, and other individuals or entities performing functions or services related to its activities to comply with all applicable laws, including the Rehabilitation Act of 1973, to ensure access to enabling technologies for individuals with disabilities.
- CMS finalizes its proposal to add a new eligibility requirement which will require an ACO to describe in the application how it will encourage and promote use of enabling technologies for improving care coordination for beneficiaries.
- The applicant must describe how the ACO intends to partner with long-term and post-acute care providers to improve care coordination for the ACO's assigned beneficiaries.
- CMS will not finalize its proposal to add the provision requiring that the ACO define and submit major milestones or performance targets it will use in each performance year to assess progress of ACO participants in implementing the elements required under §425.112(b)(4).

Transition of Pioneer ACOs into the Shared Savings Program (pgs 32722-32728)

- As Pioneer ACOs complete their initial contract period (the agreement is for a minimum of three years with an option to participate for an additional two years), they would have an opportunity to transition into the Shared Savings Program.
- CMS believes it would be appropriate to establish an efficient process to facilitate this transition in a way that minimizes any unnecessary burdens on itself and these ACOs.
- CMS will offer Pioneer ACOs the opportunity to apply to the Shared Savings Program using a condensed application if the following criteria are satisfied:
 - o The applicant ACO must be the same legal entity as the Pioneer ACO.
 - o All of the TINs on the applicant's ACO participant list must have appeared on the "Confirmed Annual TIN/NPI List" for the applicant ACO's last full performance year in the Pioneer ACO Model.
 - o The applicant must be applying to participate in a two-sided model.

- *Any Pioneer ACO transitioning to the Shared Savings Program must apply to participate for an agreement period that would start after its participation in the Pioneer ACO Model has ceased.*
- *Pioneer ACOs transitioning to the Shared Savings Program would be subject to the standard program integrity screening activities and an evaluation of their history of compliance with the requirements of the Pioneer ACO Model.*

Establishing and Maintaining the Participation Agreement with the Secretary (pgs 32728-32732)

Application Deadlines (pg 32728)

- To obtain a determination on whether a prospective ACO meets the requirements to participate in the Shared Savings Program, CMS requires an ACO to submit a complete application in the required form and manner by the established deadline.
- *CMS will approve or deny an application on the basis of the following:*
 - *Information contained in and submitted with the application by a specified deadline*
 - *Any supplemental information submitted in response to CMS's request for information and by a specified deadline*
 - *Other information available to CMS (including information on the ACO's program integrity history)*
 - *Since incomplete applications prevent CMS from making a timely evaluation of whether the ACO satisfies requirements of its regulations, CMS finalizes, as proposed, policies related to application procedures and deadlines:*
 - *It clarifies its process for requesting supplemental information.*
 - *It specifies that it may deny an application if an ACO applicant fails to submit information by specified deadlines.*

Renewal of Participation Agreements (pgs 32729-32730)

- For ACOs that would like to continue participating in the Shared Savings Program after expiration of the current agreement period, CMS proposed a process for renewing their existing participation agreements, rather than requiring submission of a new or condensed application for continued program participation.
- *CMS finalizes policies as proposed regarding the renewal process.*
- *CMS adds new §425.224 to establish procedures for the renewal of participation agreements of ACOs.*
 - *An ACO will be permitted to request a renewal of participation agreement prior to its expiration in a form and manner and by a deadline specified in guidance.*
- *An ACO executive who has the authority to legally bind the ACO must certify that the information contained in the renewal request is accurate, complete, and truthful.*

- *An ACO that seeks renewal of its participation agreement and was newly formed after March 23, 2010, as defined in the Antitrust Policy Statement, must agree that CMS can share a copy of its renewal request with antitrust agencies.*
- *CMS anticipates specifying, in guidance, a timeframe for submission and supplementation of renewal requests that will coincide with deadlines applicable to submission and supplementation of applications by new ACO applicants.*
- *CMS will evaluate an ACO's participation agreement renewal based on all of the following factors:*
 - o *Whether an ACO satisfied the criteria for operating under the selected risk model*
 - o *The ACO's history of compliance with the requirements of the Shared Savings Program*
 - o *Whether the ACO established that it is in compliance with eligibility and other requirements of the Shared Savings Program, including the ability to repay losses, if applicable*
 - o *Whether the ACO met quality performance standards during at least one of the first two years of the previous agreement period*
 - o *Whether an ACO under a two-sided model repaid losses owed to the program that it generated during the first two years of the previous agreement period*
 - o *The results of a program integrity screening of the ACO, its ACO participants, and its ACO providers/suppliers (conducted in accordance with §425.304(b)) quality performance standards during at least one of the first two years of the previous agreement period*
 - o *Whether the ACO under a two-sided model repaid losses owed to the program that it generated during the first two years of the previous agreement period*
 - o *Results of a program integrity screening of the ACO, its ACO participants, and its ACO providers/suppliers*
- CMS approves or denies a renewal request based on the information submitted in the request and other information available to CMS, and notifies the ACO when the request is incomplete or inadequate, to provide an opportunity for the ACO to submit supplemental information to correct the deficiency.
- The ACO must submit both the renewal request and any additional information needed to evaluate the request in the form and manner and by the deadlines specified by CMS.
 - o *CMS will notify each ACO in writing of its determination to approve or deny the ACO's renewal request.*
 - o *If CMS denies the renewal request, the notice will specify the reasons for the denial and inform the ACO of any rights to request reconsideration review.*

Changes to Program Requirements During the Three-Year Agreement

(pgs 32730-32732)

- CMS recognized the potential for changes to the Shared Savings Program regulations that would become effective while participating ACOs are in the middle of an agreement period.
- Therefore, it promulgated a rule to specify under what conditions an ACO would be subject to regulatory changes that become effective after the start of its agreement period.
- *CMS finalized its modification of §425.212(a) to provide that ACOs are subject to all regulatory changes "that become effective during the agreement period," except for regulations regarding certain specified program areas, "unless otherwise required by statute."*
- *An ACO whose participation agreement is renewed for a second or subsequent agreement period will be subject, beginning at the start of that second or subsequent agreement period, to any regulatory changes regarding ACO structure and governance that became effective during the previous three years (that is, during the preceding agreement period).*
- *CMS will remove beneficiary assignment as an exception under §425.212(a).*
 - o *Regulatory changes regarding beneficiary assignment will apply to all ACOs, including those ACOs that are in the middle of an agreement period.*
 - o *Any final policies that affect beneficiary assignment will not apply until the start of the next performance year.*
 - o *Implementing any revisions to the assignment methodology at the beginning of a performance year is reasonable and appropriate, because it will allow CMS to make the necessary programming changes, and will not disrupt the assessment of the ACOs for the current performance year.*

Provision of Aggregate and Beneficiary Identifiable Data (pg 32732-32743)

- ACOs should have, or should work toward having, processes in place to independently identify and produce data they believe are necessary to best evaluate the health needs of their patient population, improve health outcomes, monitor provider/supplier quality of care and patient experience of care, and produce efficiencies in utilization of services.
- Access to beneficiary identifiable information would provide ACOs with a more complete picture about the care their assigned beneficiaries receive, both within and outside the ACO.
- *CMS has made a set of Shared Savings Program research identifiable files available through the Research Data Assistance Center (Redact) web site at: <http://www.resdac.org/news/shared-savings-program-aco-researchidentifiable/files/2015/01-0>*

Aggregate Data Reports and Limited Identifiable Data (pgs 32734-32737)

- *CMS will expand data made available to ACOs for preliminary, prospectively attributed beneficiaries, to include:*

- Demographic data
 - Health status information
 - Utilization rates
 - Expenditure information related to utilization of services
- *In addition to the four data elements (name, date of birth, HICN, and sex) that it currently makes available for preliminarily prospectively assigned beneficiaries, it will expand the beneficiary identifiable information that is made available under existing §425.702(c)(1) to include the following data elements for each beneficiary who has a primary care service visit with an ACO participant that bills for primary care services that are considered in the assignment process in the most recent 12-month period:*
 - Name
 - Date of birth
 - HICN
 - Sex
- *Although CMS finalizes its proposal to make available health status information, such as risk profile and chronic condition subgroup, it does not intend to release beneficiary identifiable HCC risk score data to ACOs participating in the Shared Savings Program.*
- *CMS does not intend to release contact information for individual beneficiaries.*
- *Existing requirements will continue to apply to aggregate reports generated for PY15, which will include any quarterly reports or annual reconciliation reports for PY15 generated during CY16.*
- *The new requirements will apply to reports that are generated for PY16, including any PY16 reports that are generated in CY15 or CY17.*
- *For ACOs in Tracks 1 and 2, CMS is expanding the list of beneficiaries for which data are made available under §425.702(c)(1) to include all the beneficiaries who had a primary care service visit during the previous 12 months with an ACO participant that submits claims for primary care services considered in the assignment process*
- *CMS will articulate the data elements associated with the minimum data set in operational guidance and update as needed to reflect changes in the minimum data necessary for ACOs to perform healthcare operations activities.*
- *For Track 3 ACOs, the beneficiary identifiable data included in reports made available under §425.702(c) will be limited to the ACO's prospectively assigned beneficiaries.*

Claims Data Sharing and Beneficiary Opportunity to Decline Claims Data Sharing
 (pg 32737-32743)

- *CMS proposed and finalizes a policy under Tracks 1 and 2 to make beneficiary identifiable claims data available in accordance with applicable law on a monthly basis for beneficiaries who are either preliminarily prospectively assigned to the ACO or who have received a primary care service from an ACO participant upon whom assignment is based during the most recent 12-month period.*
- *CMS will begin sharing beneficiary identifiable claims data with ACOs participating under Tracks 1 and 2 that request claims data on beneficiaries who are included on their preliminary prospective assigned beneficiary list, or who have received a*

- primary care service from an ACO participant upon whom assignment is based during the most recent 12-month period, at the start of the ACO's agreement period, provided all other requirements for claims data sharing under the Shared Savings Program and HIPAA regulations are met.*
- *CMS finalizes its proposal that it will share beneficiary identifiable claims data with ACOs participating under Track 3 that request beneficiary identifiable claims data on beneficiaries who are included on their prospectively assigned beneficiary list*
 - *These changes are effective Jan. 1, 2016, in order to give ACOs in the middle of their three-year participation agreements some time to make necessary adjustments in light of new rules.*
 - *ACOs will need some time to finalize collection and notification to CMS of any beneficiary notifications mailed prior to November 1. The timing will also coincide with a new cohort of ACOs and the issuance of the 2016 Medicare & You Handbook that will notify beneficiaries of the opportunity to decline claims data sharing through 1-800 Medicare*
 - *CMS finalizes its proposed modifications to §425.708 to reflect the streamlined process by which beneficiaries may decline claims data sharing.*
 - o *Beneficiaries must be notified in writing by Medicare regarding the Shared Savings Program, and given the opportunity to decline claims data sharing in accordance with §425.708, and by the ACO participant at the point of care that their ACO providers/suppliers are participating in the Shared Savings Program and the opportunity to decline data sharing in accordance with §425.312.*
 - *CMS believes healthcare providers should already be providing information that describes how a beneficiary's health information may be used and disclosed and is protected under the HIPAA Privacy Rule.*
 - *The information contained in the Medicare & You Handbook and the signs containing information regarding claims data sharing posted in ACO participant facilities will prompt beneficiaries to ask questions and engage with their providers concerning their provider's participation in an ACO and the beneficiary's opportunity to decline data sharing.*
 - *ACO participants are required to use CMS-approved template language to notify beneficiaries regarding participation in an ACO and the opportunity to decline data sharing.*
 - *CMS will honor any beneficiary request to decline claims data sharing that is received under §425.708 until such time as the beneficiary may reverse his or her claims data sharing preference to allow data sharing.*
 - *These changes are effective Nov. 1, 2015, to:*
 - o *Enable ACOs that choose to mail notifications under the current requirements to mail notifications to beneficiaries up until the end of October*
 - o *Permit the 30-day window for ACOs to receive notifications from beneficiaries that choose to decline claims data sharing*
 - o *Give ACOs one last opportunity to notify CMS, in turn, of "beneficiaries" preferences in December 2015*

Assignment of Medicare FFS Beneficiaries (pgs 32743-32758)

- In the November 2011 final rule, CMS finalized the methodology that it currently uses to assign beneficiaries to ACOs for the purposes of the Shared Savings Program.
- *Under this section of the final rule, CMS summarizes certain key policies and methodological issues to provide background for several revisions to the assignment methodology that it proposed based on its initial experiences with the program and questions from stakeholders.*

Basic Criteria for a Beneficiary to be Assigned to an ACO (pgs 32744-32746)

- In the proposed rule, CMS outlined criteria that a beneficiary must meet in order to be eligible to be assigned to a participating ACO.
- It proposed the criteria under which a beneficiary would be eligible to be assigned to a participating ACO, for a performance year or benchmark year.
- *CMS finalizes its proposal to codify the criteria that a beneficiary must meet in order to be eligible to be assigned to an ACO.*
- *A beneficiary will be eligible to be assigned to an ACO, for a performance year or benchmark year, if the beneficiary meets all of the following criteria during the assignment window:*
 - o *Has at least 1 month of Part A and Part B enrollment and does not have any months of Part A only or Part B only enrollment*
 - o *Does not have any months of Medicare group (private) health plan enrollment*
 - o *Is not assigned to any other Medicare shared savings initiative*
 - o *Lives in the U.S. or U.S. territories and possessions as determined based on most recent available data in CMS's beneficiary records regarding the beneficiary's residence at the end of the assignment window*
- *CMS also finalizes its proposal to add a new provision to the regulations outlining these criteria.*
- *If a beneficiary meets all of criteria, then it will be eligible to be assigned to an ACO in accordance with two-step beneficiary assignment methodology in §425.402 and §425.404*

Definition of Primary Care Services (pgs 32746-32748)

- Effective Jan. 1, 2014, CPT codes 99201 through 99205 and 99211 through 99215 are no longer recognized for payment under OPPS.
 - o Under OPPS, outpatient hospitals have been instructed to use HCPCS code G0493 instead.
- This coding change under OPPS affects Electing Teaching Amendment (ETA) operational processes under the Shared Savings Program.
- CMS needs to reconsider its ETA hospital-related proposal, and intends to address this issue in future rulemaking.
- *CMS will update the definition of primary care services at §425.20 to include both TCM codes (CPT codes 99495 and 99496), and the CCM code (CPT code 99490).*
- *These codes will be included in its beneficiary assignment methodology.*

- *Any future revisions to the definition of primary care service codes will be made through the annual PFS rulemaking process.*

Consideration of Physician Specialties and Non-Physician Practitioners in the Assignment Process (pg 32748)

- After identifying all patients who had a primary care service with a physician who is an ACO professional, CMS employs a step-wise assignment process that occurs in the following two steps:
 - o *Step 1:* First, CMS adds up allowed charges for primary care services billed by primary care physicians through TINs of ACO participants in the ACO. Then, it adds up allowed charges for primary care services furnished by primary care physicians that are billed through other Medicare-enrolled TINs (or through a collection of ACO participant TINs in case of another ACO). If allowed charges for services furnished by ACO participants are greater than allowed charges for services furnished by participants in any other ACO or by any non-ACO participating Medicare-enrolled TIN, then the beneficiary is assigned to the ACO in the first step of the assignment process.
 - o *Step 2:* Applies only for beneficiaries who have not received any primary care services from a primary care physician. CMS assigns the beneficiary to an ACO in this step if a beneficiary received at least one primary care service from a physician participating in an ACO, and more primary care services (measured by Medicare allowed charges) from ACO professionals (physician regardless of specialty, nurse practitioner (NP), physician assistant (PA) or clinical nurse specialist (CNS)) at the ACO than from ACO professionals in any other ACO or solo practice/group of practitioners identified by a Medicare-enrolled TIN or other unique identifier, as appropriate, that is unaffiliated with any ACO.

Including Primary Care Services Furnished by Non-Physician Practitioners in Step 1 (pg 32748-32749)

- *CMS will include claims for primary care services furnished by NPs, PAs, and CNSs under step 1 of the assignment process, after having identified beneficiaries who received at least one primary care service by a physician participating in the ACO.*
- *The current methodology will continue to be used for PY15, including reconciliation, while the new methodology will be used for operations related to PY16.*
- *CMS is retaining rules for the current methodology under §425.402(a) and the methodology that will be applicable for performance years beginning in 2016 has been designated under §425.402(b).*

Excluding Services Provided by Certain Physician Specialties from Step 2 (pgs 32749-32754)

- CMS proposed to exclude services provided by certain physician specialties from step 2 of the assignment process. The proposal was made partly to address stakeholder concerns that by including such claims in step 2 of the assignment process, the ACO participant TINs that submit claims for services furnished by certain specialists are

limited to participating in only one ACO because of the exclusivity requirement under the regulations.

- The net effect of the proposal would be to exclude certain claims from determining the ACO's assigned population.
- *CMS is modifying its proposal to exclude services provided by certain physician specialties based on public comment, as follows:*
 - o *To include pediatric medicine (specialty code 37) in step 1 assignment*
 - o *To include osteopathic manipulative medicine (specialty code 12) and psychiatry specialties (specialty codes 26, 27, 79, 86) in step 2 assignment*
 - o *To exclude allergy and immunology (specialty code 03), gastroenterology (specialty code 10), hospice and palliative medicine (specialty code 17), infectious diseases (specialty code 44), rheumatology (specialty code 66), and interventional cardiology (C3) from step 2 assignment.*
- *Please see the following tables in the appendix for specialty-specific detail:*
 - o *Table 2 from the final rule (Appendix 1 of this document) shows the CMS physician specialty codes that are included in step 1 under the final policy.*
 - o *Table 3 from the final rule (Appendix 2 of this document) shows the CMS specialty codes for NPs, PAs, and CNSs that are included in beneficiary assignment step 1 under the final policy.*
 - o *Table 4 from the final rule (Appendix 3 of this document) lists the physician specialties that are included in step 2 under the final policy.*
 - o *Table 5 from the final rule (Appendix 4 of this document) lists the physician specialties that are excluded from the beneficiary assignment methodology under step 2 under the final policy.*
 - *Services furnished by these physician specialties are also excluded for the purposes of determining if a beneficiary has received a primary care service from a physician who is an ACO professional, which under §425.402(a) is a precondition for assignment to an ACO.*
- *CMS will add a new paragraph to identify the physician specialty designations that will be considered in step 2 of the assignment process, with the noted modifications.*
- *CMS will clarify that each ACO participant who submits claims for primary care services used to determine the ACO's assigned population must be exclusive to one Shared Savings Program ACO.*
- *The current assignment methodology will continue to be used for PY15, including the final retrospective reconciliation which will occur in mid-2016.*
- *The new methodology will be used for operations related to PY16, including during application review for ACOs that are applying or renewing for a 2016 start date.*

Other Assignment Methodology Considerations (pgs 32754-32755)

- CMS considered whether it might be preferable, after excluding the specialties listed in Table 3 of the proposed rule from step 2 of the assignment process, to further simplify beneficiary assignment by establishing an assignment process that involves only a single step in which the plurality of primary care services provided by the physicians listed in

Tables 1 and 2 of the proposed rule, and non-physician practitioners in Table 4 of the proposed rule, would all be considered in a single step.

- Because a one-step assignment methodology could also introduce additional instability into the assignment process, CMS did not propose to combine the two steps used under the current assignment methodology.
- Although CMS did not propose this change, it sought comments as to whether it would be preferable, after excluding the physician specialties listed in Table 3 from the assignment process, to further simplify the assignment methodology by establishing an assignment process that involves only a single step.
- CMS agreed with commenters that it is appropriate to continue to maintain the current two-step assignment process at this time.

Assignment of Beneficiaries to ACOs that include Federally Qualified Health Centers, Rural Health Clinics, Critical Access Hospitals, and Electing Teaching Amendment Hospitals (pg 32755)

- These types of providers may submit claims for physician and other professional services when certain requirements are met, but do not submit claims through the standard Part B claims payment system.
 - Accordingly, CMS established operational processes so that it can consider claims for professional services submitted by these providers in the process for assigning beneficiaries to ACOs.
- Assignment of Beneficiaries to ACOs that Include FQHCs and RHCs (pg 32755-32756)
 - *CMS finalizes its proposal to amend §425.404 to use FQHC/RHC physician attestation information only for purposes of determining whether a beneficiary is eligible to be assigned to an ACO.*
 - *If a beneficiary is identified as "assignable," then CMS will use claims for primary care services furnished by all ACO professionals submitted by the FQHC or RHC to determine whether the beneficiary received a plurality of his or her primary care services from the ACO under Step 1.*
 - *CMS refers to this determination as the assignment "pre-step," which 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.*
 - Assignment of Beneficiaries to ACOs that Include CAHs (pg 32756)
 - Method II CAH claims that include professional services require special processing because they are submitted as part of institutional claims.
 - CMS developed operational procedures that allow these claims to be considered in the assignment process under §425.402.
 - *CMS did not make any new proposals regarding the use of services billed by method II CAHs in the assignment process, but included this discussion in the proposed rule to promote understanding of its processes.*

- *CMS will continue including claims for primary care services billed by method II CAHs in the beneficiary assignment process under §425.402 using established procedures.*
- Assignment of Beneficiaries to ACOs that Include ETA Hospitals (pg 32757)
- Since the December 2014 proposed rule was issued, new information has been released about how clinic visits are billed under OPPS, effective Jan. 1, 2014, which affects operational processes for considering ETA hospital claims in the assignment methodology for the Shared Savings Program because under OPPS, outpatient hospitals, including ETA hospitals, now report these services using HCPCS code, G0463, instead of CPT codes in the range 99201 through 99205, and 99211 through 99215.
- *CMS will further consider the operational processes necessary in order to allow ETA hospital outpatient claims to continue to be considered in assignment methodology, and will address these issues in future rulemaking.*

Applicability Date for Changes to the Assignment Algorithm (pgs 32757-32758)

- *CMS finalizes its proposal to adjust all benchmarks at the start of the first performance year in which the new assignment rules are applied so that the benchmark for the ACO reflects use of the same assignment rules as will apply in performance year.*
- *Additionally, CMS will not retroactively apply the new beneficiary assignment methodology to a previous performance year.*
- *When conducting the final retrospective reconciliation of beneficiary assignment for PY15 during mid-2016, CMS will use the assignment methodology that was applicable at the start of 2015.*

Shared Savings and Losses (pgs 32758-32812)

- In the November 2011 final rule establishing the Shared Savings Program, CMS created two tracks from which ACOs could choose to participate:
 - One-sided risk model (Track 1) that incorporates statutory payment methodology under section 1899(d) of the Act
 - Two-sided model (Track 2) that is also based on the payment methodology under section 1899(d) of the Act, but incorporates performance-based risk using the authority under section 1899(i)(3) of the Act to use other payment models
- Under the one-sided model, ACOs qualify to share in savings but are not responsible for losses.
- Under two-sided model, ACOs qualify to share in savings with an increased sharing rate, but also must take on risk for sharing in losses.
- CMS required that ACOs participating in Track 1 during their first agreement period must transition to Track 2 for all subsequent agreement periods.
- In the December 2014 proposed rule, CMS reiterated its intent to continue to encourage ACOs' forward movement up the ramp from the one-sided model to performance-based risk.

Modifications to the Existing Payment Tracks (pgs 32759-32761)

- *CMS finalizes certain modifications to program policies to encourage ACOs to enter performance-based risk arrangements.*
- *Modifications respond to commenters' recommendations for improving the financial incentives under the program and allow ACOs a range of options with respect to features of tracks they may select from.*
- In the November 2011 final rule, CMS established policies to encourage ACOs not only to enter the program, but also to progress to increased risk based on the belief that payment models where ACOs bear a degree of financial risk have the potential to induce more meaningful systematic change in the behavior of providers and suppliers.
- In the December 2014 proposed rule, CMS revisited its policies related to Tracks 1 and 2 in order to smooth the on ramp for organizations participating in the Shared Savings Program.
 - o First, CMS proposed to remove the requirement at §425.600(b) for Track 1 ACOs to transition to Track 2 after their first agreement period.
 - o Second, CMS proposed to modify the financial thresholds under Track 2 to reduce the level of risk that ACOs must be willing to accept.
- CMS explained that it believes there are a number of advantages to smoothing the on ramp by implementing these proposed policies
- *Although CMS is not adopting additional suggestions recommended by some commenters in the rule, it will further consider these suggestions and may propose additional revisions to encourage ACOs to enter performance-based risk arrangements through future notice and comment rulemaking.*
- *Following is a discussion of these modifications:*

Transition from the One-sided to Two-sided Model (pgs 32761-32764)

- *CMS finalizes its proposal to permit ACOs to participate in an additional 3-year agreement period under Track 1, for a total of two agreement periods under the one-sided model.*

Eligibility Criteria for Continued Participation in Track 1 (pgs 32764-32766)

- CMS proposed to make the option of participating in Track 1 for a second agreement period available to only those Track 1 ACOs that:
 1. Meet the criteria established for ACOs seeking to renew agreements, including demonstrating to CMS that they met the quality performance standard during at least one of the first two years of the previous agreement period
 2. Did not generate losses in excess of negative MSR in at least one of the first two performance years of the previous agreement period.
- *The general criteria described in section II.C.3. of the final rule apply to all renewing ACOs, including Track 1 ACOs applying for a second agreement period under the one-sided model.*
- *Under §425.224(b), CMS will evaluate an ACO's participation agreement renewal based on all of the following factors:*
 - *Whether the ACO satisfies the criteria for operating under the selected risk model*

- *The ACO's history of compliance with the requirements of the Shared Savings Program*
- *Whether the ACO has established that it is in compliance with eligibility and other requirements of the Shared Savings Program, including ability to repay losses, if applicable*
- *Whether the ACO met quality performance standards during at least one of the first two years of the previous agreement period*
- *For an ACO under a two-sided model, whether the ACO has repaid losses owed to the program that it generated during the first two years of the previous agreement period*
- *The results of a program integrity screening of the ACO, its ACO participants, and its ACO providers/suppliers (conducted in accordance with §425.304(b))*
- *CMS is not finalizing any additional financial performance criteria for determining eligibility for Track 1 ACOs to continue under the one-sided model for a second agreement period.*

Maximum Sharing Rate for ACOs in a Second Agreement Period under Track 1
(pgs 32766-32767)

- As part of its proposal to allow ACOs to participate in a second agreement period under the one-sided model, CMS proposed to reduce the sharing rate by 10 percent for ACOs in a second agreement period under Track 1 to make staying in the one-sided model less attractive than moving forward along the risk continuum.
- CMS also considered other variations and options for allowing ACOs additional time in the one-sided model.
- *CMS is not finalizing, as proposed, to reduce the maximum sharing rate during an ACO's second agreement period under Track 1.*
- *An ACO participating under Track 1 for a second agreement period that meets all the requirements for receiving shared savings payments under the one-sided model will receive a shared savings payment of up to 50 percent of all savings, as determined on the basis of its quality performance.*

Eligibility for Continued Participation in Track 1 by Previously Terminated ACOs
(pgs 32767-32769)

- *CMS finalizes its proposed changes to §425.222(c) to permit previously terminated Track 1 ACOs to reapply under the one-sided or two-sided model, and to differentiate between whether the ACO will be applying for its first or second agreement period under Track 1 based on when it terminated its previous agreement.*
- *CMS finalized these changes, but is making additional revisions to clarify the treatment of previously terminated Track 1 ACOs that were in their second agreement period at the time of termination.*
- *CMS is not modifying the current policy that prohibits an ACO whose prior agreement under Track 2 was terminated from applying to participate under Track 1.*

Modifications to the Track 2 Financial Model (pgs 32769-32771)

- CMS proposed to modify the financial model under Track 2 for ACOs choosing this two-sided option to further encourage ACOs to accept increased performance-based risk.
- CMS proposed to retain existing features of Track 2 with the exception of modifying the threshold that Track 2 ACOs must meet or exceed in order to share in savings (minimum savings rate (MSR)) or losses (minimum loss rate (MLR)) from the current flat 2 percent to vary based upon the size of the ACO's assigned beneficiary population, as determined based on the methodology for setting the MSR under the one-sided model in §425.604(b) as shown in Table 8 (pg 32811) of the rule.
- *CMS will retain existing features of Track 2, with the exception of revising §425.606(b) to allow ACOs entering Track 2 for agreement periods beginning January 2016 or later a choice among several options for establishing their MSR/MLR:*
 1. *0 percent MSR/MLR*
 2. *Symmetrical MSR/MLR in a 0.5 percent increment between 0.5 – 2.0 percent*
 3. *Symmetrical MSR/MLR that varies based on the ACO's number of assigned beneficiaries according to the methodology established under the one-sided model*

Creating Options for ACOs that Participate in Risk-Based Arrangements (pg 32771-32772)

- CMS proposed to develop a new risk-based Track 3 based on current payment methodology under Track 2, but would also incorporate some different elements that may make it more attractive for entities to accept increased performance-based risk.
- CMS proposed certain discrete features for Track 3 that differentiate it from Track 2.
- CMS proposed to make modifications to the beneficiary assignment methodology, sharing rate, and performance payment and loss sharing limits.
- *CMS finalized Track 3 with features that distinguish it from Tracks 1 and 2.*

A discussion of CMS's final actions on its proposed policies related to the creation of Track 3 follows.

Prospective versus Retrospective Assignment in Track 3 (pgs 32772-32774)

- In the November 2011 final rule that established the Shared Savings Program, CMS adopted a preliminary prospective assignment model with retrospective reconciliation because it would provide ACOs with adequate information to redesign their care processes while also encouraging ACOs to standardize these care processes for all Medicare FFS beneficiaries instead of focusing care management activities on a small subset of their FFS population.
- In the December 2014 proposed rule, CMS discussed the use of prospective alignment in the Pioneer ACO Model, where beneficiaries are aligned to Pioneer ACOs prior to the start of each performance year.
- Under the Pioneer ACO Model, the list of prospectively aligned beneficiaries is reconciled at the end of the year to exclude certain beneficiaries from the list, for example, beneficiaries who were not eligible for alignment during the performance year.

- However, no new beneficiaries are added to the list.
- This prospective assignment methodology would use the same stepwise assignment methodology to assign beneficiaries to ACOs in Track 3 as is used to assign beneficiaries to ACOs participating under Track 1 and Track 2.
- The major difference would be that beneficiaries would be assigned to Track 3 ACOs prospectively, at the start of the performance year, and there would be no retrospective reconciliation resulting in the addition of new beneficiaries at the end of the performance year.
- *CMS finalizes its proposal to codify at §425.400(a)(3) a prospective assignment methodology that would use the stepwise assignment methodology under §425.402 to assign beneficiaries to ACOs in Track 3.*
- *Although beneficiaries will be assigned prospectively to Track 3 ACOs, the assignment methodology will be the same as is used to assign beneficiaries to ACOs participating under Track 1 and Track 2, with limited exceptions such as assignment window.*

Exclusion Criteria for Prospectively Assigned Beneficiaries (pgs 32774-32775)

- CMS proposed to perform a limited reconciliation where beneficiaries would only be removed from the prospective assignment list at the end of the year if they were not eligible for assignment at that time under the criteria in proposed §425.401(b).
- *CMS finalizes its proposed policy of excluding beneficiaries from the prospective assignment list for an ACO participating under Track 3, who meet exclusion criteria, as specified at §425.401(b), at the end of a performance or benchmark year.*
- *CMS is adopting a modification to this policy under which it will also perform this exclusion on a quarterly basis during each performance year, and incorporate these exclusions into quarterly reports provided to Track 3 ACOs.*
- *CMS will use recently available assignment data when determining the ACO's quality reporting sample.*

Timing of Prospective Assignment (pgs 32775-32776)

- *CMS finalizes its proposal regarding the timing of beneficiary assignment under Track 3, and will base prospective assignment on a 12-month assignment window (off-set from the calendar year) prior to the start of the performance year.*
- *In addition, an "assignment window" will be defined at §425.20 as the 12-month period used to assign beneficiaries to an ACO.*

Interactions between Prospective and Retrospective Assignment Models (pgs 32776)

- In the December 2014 proposed rule, CMS explained that because there are markets with multiple Medicare ACOs, there would likely be interactions between the prospective assignment for Track 3 ACOs and preliminary prospective assignment with retrospective reconciliation for Track 1 and Track 2 ACOs.
- *CMS finalizes the policy that once a beneficiary is prospectively assigned to a Track 3 ACO for a benchmark or performance year, the beneficiary will not be eligible for assignment to a different ACO, even if the beneficiary chose to receive a plurality of*

primary care services from ACO professionals in that ACO during the relevant benchmark or performance year.

Determining Benchmark and Performance Year Expenditures under Track 3
(pgs 32776-32777)

- *CMS finalizes its proposal for calculating historical benchmarks for Track 3 ACOs, by determining benchmark year expenditures for Track 3 ACOs using calendar year expenditures for prospectively assigned beneficiaries.*
- *The proposal allows a three-month claims run out, excluding Indirect Medical Education and Disproportionate Share Hospital payments, and considers individually beneficiary-identifiable payments made under a demonstration, pilot or time-limited program.*

Risk Adjusting the Updated Benchmark for Track 3 ACOs (pgs 32777-32778)

- Under Track 1 and Track 2, the risk adjustment methodology differentiates between newly and continuously assigned beneficiaries.
- CMS proposed to apply the same general risk adjustment methodology in Track 3, but to make certain refinements to its definitions of newly and continuously assigned beneficiaries at §425.20 to be consistent with its proposed prospective assignment approach for Track 3.
- CMS also proposed to replace the reference to “most recent prior calendar year” with a reference to “the assignment window for the most recent prior benchmark or performance year.”
- For Track 3, the reference period for determining whether a beneficiary is newly or continuously assigned would be the most recent prior prospective assignment window (the 12 months off set from the calendar year) before the assignment window for the current performance year.
- The reference period for determining whether, under Track 1 or 2, a beneficiary is newly or continuously assigned would continue to be the most recent prior assignment window (the most recent calendar year).
- *CMS finalizes its proposed risk adjustment methodology for updating the historical benchmark for Track 3 ACOs.*
- *CMS will also modify definitions of newly and continuously assigned beneficiaries to ensure they are consistent with prospective assignment under Track 3 and remain relevant to preliminary prospective assignment with retrospective reconciliation under Tracks 1 and 2.*

Final Sharing/Loss Rate and Performance Payment/Loss Recoupment Limit Under Track 3 (pgs 32778-32779)

- ACOs that meet all requirements for receiving shared savings payments under the one-sided (Track 1) model can qualify to receive a shared savings payment of up to 50 percent of all savings under its updated benchmark, not to exceed 10 percent of its updated benchmark, as determined on the basis of its quality performance.

- A Track 2 ACO can receive shared savings payment of up to 60 percent of all savings under its updated benchmark, not to exceed 15 percent of its updated benchmark.
- CMS considered options for increasing ACO participation in a performance-based risk track by improving the attractiveness of the final sharing rate and the performance payment limit in a risk model.
- *CMS finalized the following modifications in order to implement a new two-sided risk option, Track 3:*
 - *Applying a shared savings rate of up to 75 percent in conjunction with accepting risk for up to 75 percent of all losses, depending on quality performance similar to Track 2 ACOs*
 - *Not permitting Track 3 ACOs with high quality performance to reduce percentage of shared losses below 40 percent.*
 - *Applying a performance payment limit such that shared savings do not exceed 20 percent of the Track 3 ACO's updated benchmark, and a loss recoupment limit of 15 percent of the Track 3 ACO's updated benchmark*

Minimum Savings Rate and Minimum Loss Rate in Track 3 (pgs 32779-32780)

- CMS proposed to apply the same fixed MSR and MLR of 2 percent under Track 3, as was originally established for Track 2 under the November 2011 final rule
- *CMS finalizes the same MSR/MLR methodology for ACOs in both Track 2 and 3.*
- *Under this methodology, ACOs may select a symmetrical MSR/MLR to apply throughout the course of their agreement period from a set of options.*
- *Track 3 ACOs would have the opportunity to select a symmetrical MSR/MLR prior to the start of their agreement period, as part of their initial program application or agreement renewal application.*
 - o *No modifications to this selection would be permitted during the course of this agreement period.*
- *CMS finalizes an MSR/MLR methodology for Track 3 that will allow ACOs to choose among several options for establishing their symmetrical MSR/MLR:*
 - *0 percent MSR/MLR*
 - *Symmetrical MSR/MLR in a 0.5 percent increment between 0.5 – 2.0 percent*
 - *Symmetrical MSR/MLR that varies based on the ACO's number of assigned beneficiaries according to the methodology established under the one-sided model*

Monitoring for Gaming and Avoidance of At-Risk Beneficiaries (pgs 32780-32781)

- In the December 2014 proposed rule, CMS explained it has taken steps to minimize incentives for gaming by retaining other Shared Savings Program policies and procedures, such as risk-adjusting expenditures and monitoring ACOs to ensure they are not engaging in gaming or avoidance of at-risk beneficiaries.

- Its proposal to exclude only those beneficiaries that no longer meet eligibility criteria for assignment to an ACO should reduce the probability of attempts by an ACO to "cherry pick" or avoid at-risk beneficiaries.
- *CMS will monitor closely the implementation of prospective assignment and the effect of performance-based risk on ACOs, and if it identifies concerns, it may revise its policies in these areas in future rulemaking.*

Modifications to Repayment Mechanism Requirements (pg 32781)

- The November 2011 final rule established a requirement that ACOs applying to participate in the two-sided model must establish a repayment mechanism to assure CMS that they can repay losses for which they may be liable.
- As discussed below, the final rule incorporates several changes proposed in December.

Amount and Duration of the Repayment Mechanism (pgs 32781-32783)

- The practical impact of the current rule is to require ACOs to create and maintain two separate repayment mechanisms for two consecutive performance years, which doubles the amount of repayment mechanism during overlapping time periods between the start of a new performance year and the settlement of the previous performance year.
- *CMS finalizes its proposal to require an ACO that enters two-sided model to establish a repayment mechanism once at beginning of a three-year agreement period.*
- *CMS notes that the repayment mechanisms established by these ACOs are types of repayment mechanisms that CMS is retaining under this final rule.*
- *ACOs are expected to maintain existing repayment mechanisms in accordance with terms set forth in the repayment mechanisms for performance year (PY) 2014 and 2015.*
- *Should these ACOs choose to renew their participation agreements for a second agreement period beginning Jan. 1, 2016, they will only need to establish a repayment mechanism once at the beginning of their new three-year agreement period.*
- *Under the new requirements, ACOs must demonstrate that they would be able to repay shared losses incurred at any time within the agreement period, and for a reasonable period of time after the end of each agreement period (the "tail period").*
- *An ACO must demonstrate the adequacy of its repayment mechanism and maintain the ability to repay 1 percent of the ACO's total per capita Medicare Parts A and B FFS expenditures for its assigned beneficiaries based on the expenditures used to establish the benchmark for the applicable agreement period, as estimated by CMS at the time of application or participation agreement renewal.*
- *CMS finalizes the requirement that if an ACO uses its repayment mechanism to repay any portion of shared losses owed to CMS, it must promptly replenish the amount of funds required to be available through the repayment mechanism within 90 days.*

Permissible Repayment Mechanisms (pgs 32783-32785)

- Under current rules, ACOs may demonstrate the ability to repay shared losses by obtaining reinsurance, placing funds in escrow, obtaining surety bonds, establishing line of credit, or establishing another appropriate repayment mechanism that will ensure their ability to repay the Medicare program.
- *The final rule eliminated reinsurance as a repayment mechanism for shared losses.*
- *Moving forward, an ACO may demonstrate the ability to repay shared losses owed by placing funds in escrow, obtaining surety bonds, establishing a line of credit, or by using a combination of these mechanisms.*

Methodology for Establishing, Updating, and Resetting the Benchmark (pgs 32785-32786)

- The HHS Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available three years of per beneficiary expenditures for parts A and B services for Medicare FFS beneficiaries assigned to the ACO.
- In the December 2014 proposed rule, CMS considered whether modifying the methodology used for establishing, updating, and resetting ACO benchmarks to account for factors relevant to ACOs that have participated in the program for 3 or more years would help ensure that the Shared Savings Program remains attractive to ACOs and continues to encourage ACOs to improve performance, particularly those that have achieved shared savings.
- The comments received on the issues were carefully considered in developing policies in the final rule, as well as in arriving at the decision to pursue further rulemaking to make additional changes to the benchmarking methodology in the near future.

Modifications to the Rebasing Methodology (pgs 32786-32791)

- In the December 2014 proposed rule, CMS discussed the possible implications of using the current benchmarking methodology when resetting the ACO's benchmark for its second or subsequent agreement period.
- To address concerns raised by stakeholders related to resetting benchmarks, CMS considered revising the methodology to equally weight benchmark years and account for shared savings earned by an ACO in its prior agreement period, as a way to encourage ongoing participation by successful ACOs and improve the incentive to achieve savings.
- CMS is revising §425.602(c) to specify that in resetting the historical benchmark for ACOs in their second or subsequent agreement, it will weight each benchmark year equally.
- In the December 2014 proposed rule, CMS sought comment on a methodology for resetting ACO benchmarks that would account for shared savings earned by an ACO in its prior agreement period as a way to encourage continued participation by successful ACOs and improve the incentive to achieve savings.

- *CMS is revising §425.602(c) to specify that in resetting the historical benchmark for ACOs in their second or subsequent agreement, it will weight each benchmark year equally.*
- *CMS is also revising the title of provision 425.602 to clarify that it contains policies relevant to the original calculation of the benchmark at the start of an ACO's first agreement period and to the updates to the benchmark that are made during the agreement period and resetting the benchmark at the start of each subsequent agreement period.*
- *In resetting the historical benchmark for ACOs entering their second agreement period, CMS will make an adjustment to reflect the average per capita amount of savings earned by the ACO in its first agreement period, reflecting the ACO's financial and quality performance, and number of assigned beneficiaries, during that agreement period.*
- *CMS is only adding back the ACO's portion of the shared savings, not the total savings generated.*
- *The additional per capita amount will be applied 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 first agreement period.*
- *If an ACO was not determined to have generated net savings in its first agreement period, CMS will not make any adjustment to the ACO's rebased historical benchmark.*
- *CMS will use performance data from each ACO's performance years under its first agreement period in resetting the ACO's benchmark under its second agreement period.*
- *For ACOs with April 1, 2012, and July 1, 2012, agreement start dates that will be entering their second agreement period in 2016, CMS will use calendar year 2013 data from the performance year 1 final financial reconciliation for these ACOs, to align with the same 12-month period for the corresponding benchmark year in performing this calculation.*
- *CMS will continue to issue a preliminary benchmark to an ACO, close to the start of the ACO's subsequent agreement period, based on available data.*
- *CMS will then issue a final historical benchmark once it has the data needed to determine the ACO's financial and quality performance for its third performance year under its prior agreement and complete benchmark calculation.*

Use of Regional Factors in Establishing, Updating, and Resetting Benchmarks (pgs 32791-32796)

- *As discussed in the December 2014 proposed rule, stakeholders expressed concern that the existing benchmarking methodology does not sufficiently account for the influence of cost trends in the surrounding region or local market on the ACO's financial performance, and does not suitably encourage ACOs to achieve and maintain savings.*
- *CMS finalizes modifications to the benchmark rebasing methodology, to include equally weighting the ACO's historical benchmark years, and accounting for savings generated in*

the ACO's first agreement period when setting the ACO's benchmark for its second agreement period.

- *Recognizing 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, CMS intends to propose and seek comment on the components of and procedures for calculating a regionally trended, rebased benchmark through a proposed rule to be issued later this summer.*
- *The current final rule does not take further action to incorporate regional factors into the benchmark.*
- *A forthcoming proposed rule will provide details of CMS's considerations and preferred methodology.*

Technical Adjustments to the Benchmark and Performance Year Expenditures

(pgs 32796-32799)

- When computing the average per capita Medicare expenditures for an ACO during both the benchmark period and performance years, CMS considers all Parts A and B expenditures, including payments made under a demonstration, pilot or time-limited program, with the exception of IME and DSH adjustments, which are excluded from these calculations.
- With the exception of adjustments to account for IME and DSH payments, CMS ultimately declined to make any adjustments to account for various differences in payment rates among providers and suppliers in the initial final rule.
- CMS excluded IME and DSH payments from both benchmark and performance year expenditure calculations.
- *CMS is not making additional technical adjustments to its current policy on calculation of benchmark and performance year expenditures, but intends to continue to evaluate these issues and may revisit the in future rulemaking.*

Ways to Encourage ACO Participation in Performance-Based Risk Arrangements

(pgs 32799-32880)

- Under the current Medicare FFS system, providers have a financial incentive to increase their volume of services.
- As a result, many current Medicare regulations are designed to prevent overuse of services and the resulting increase in Medicare spending in this context.
- CMS considered what additional flexibilities could be offered to encourage ACO participation in performance-based risk arrangements, including waiving certain Medicare Program rules.
- In the proposed rule, CMS discussed offering a variety of waivers to MSSP participants. Below is a discussion of each waiver and its status as a result of the final rule

Payment Requirements and Other Program Requirements that May Need to be Waived in Order to Carry out the Shared Savings Program (pgs 32880-32808)

- The proposed rule sought comments on the following specific waivers of payment and other program rules that would implicate the waiver authority under section 1899(f) of the Act:
 - o SNF Three-Day Rule – CMS sought comment on whether waiver of the three-day SNF rule was necessary for purposes of implementing two-sided performance based risk models under the Shared Savings Program. *CMS is adopting a new provision to provide for a waiver of the SNF 3-day rule for ACOs that participate in Track 3. Specifically, CMS will waive the requirement for a three-day inpatient hospital stay prior to provision of Medicare-covered post-hospital extended care services for beneficiaries prospectively assigned to ACOs that participate in Track 3. This waiver will be effective on or after Jan. 1, 2017, and all ACOs participating under Track 3 or applying to participate under Track 3 will be eligible to apply for the waiver. For purposes of this waiver, an eligible ACO under the Shared Savings Program is an ACO that has elected to participate in Track 3 and has been approved by CMS as having demonstrated that it has the capacity to identify and manage patients who would be either directly admitted to a SNF or admitted to a SNF after an inpatient hospitalization of fewer than three days.*
 - o Billing and Payment for Telehealth Services – CMS sought comment on an option that would waive originating site requirements that limit telehealth payment to services furnished within specific types of geographic areas or in an entity participating in a federal telemedicine demonstration project approved as of Dec. 31, 2000. *CMS intends to initially focus on further development and testing of waiver of billing and payment requirements for telehealth services through the Next Generation ACO Model. A telehealth waiver will be available to ACOs no earlier than Jan. 1, 2017, after notice and comment and rulemaking*
 - o Homebound Requirement Under the Home Health Benefit – CMS sought comment on whether a waiver of the homebound requirement under section 1899(f) of the Act is necessary in order to carry out the Shared Savings Program. Specifically, it sought comment on an option that would offer an ACO participating under Track 3 the opportunity to provide home health services to non-homebound beneficiaries that are prospectively assigned to the ACO, and requested additional comment on related implementation issues.
 - o Waivers for Referrals to Post-acute Care Settings - As a condition of participation (CoP) in Medicare, a hospital must have in effect a discharge planning process that applies to all patients. Hospital discharge planning is a process that involves determining the appropriate post-hospital discharge destination for a patient; identifying what the patient requires for a smooth and safe transition from the hospital to his or her discharge destination; and beginning the process of meeting the patient's identified post-discharge needs. CMS sought comment on

whether it is necessary to waive the requirement that a hospital “not specify or otherwise limit the qualified provider which may provide post-hospital home services” and the portions of the hospital discharge planning CoP that implement this requirement, using its waiver authority under section 1899(f) of the Act for ACOs participating in two-sided risk tracks under the Shared Savings Program.

- *With the exception of the waiver of the SNF three-day rule, CMS needs additional time to assess whether any of the waivers discussed in the proposed rule or suggested by commenters are necessary for the operation of the Shared Savings Program. CMS will consider this issue further and will carefully examine lessons learned regarding the waivers that are being tested as part of Innovation Center Models, and in the event that it determines that additional waivers are necessary to carry out the Shared Savings Program, it will propose them in future rulemaking.*

Other Options for Improving the Transition to Two-Sided Performance-Based Risk Arrangements (pgs 32808-32812)

- In the proposed rule, CMS solicited comment on other options that could be implemented independent of waiver authority to support ACO efforts to increase quality and decrease costs under two-sided performance-based risk arrangements:
 - o *Beneficiary Attestation* – Beneficiaries are required to be assigned to an ACO participating in the Shared Savings Program based on the beneficiary’s utilization of primary care services rendered by physicians participating in the ACO. Thus, beneficiary choice, as indicated by their utilization of primary care service furnished by physicians who are ACO professionals in the ACO, determines beneficiary assignment to an ACO under the Shared Savings Program. Although CMS did not make any specific proposals related to beneficiary attestation, it welcomed comments on whether it would be appropriate to offer a beneficiary attestation process to ACOs that choose to participate in the Shared Savings Program under two-sided risk financial arrangements. *CMS expects to propose to implement beneficiary attestation for purposes of beneficiary assignment under Shared Savings Program beginning Jan. 1, 2017, in the 2017 Physician Fee Schedule (PFS) rulemaking. This timeline will allow for further development and testing of this approach through the Pioneer and Next Generation ACO Model, and development of appropriate safeguards against abusive or coercive marketing associated with beneficiary attestation. Until it gains additional operational experience, CMS anticipates limiting beneficiary attestation process to ACOs participating under Tracks 2 or 3.*
 - o *Solicitation of Comment on a Step-Wise Progression for ACOs to Take on Performance-Based Risk* – Under the current Shared Savings Program rules, an ACO may not include an entity on its list of ACO participants unless all ACO providers/suppliers billing through the entity’s Medicare enrolled TIN have

agreed to participate in the program and comply with the program rules. Furthermore, it is not possible under the current regulations for some ACO providers/ suppliers to participate in Track 1, while other ACO providers/suppliers that may be more ready to accept performance-based risk participate under Track 2. In the proposed rule, CMS noted that some stakeholders have commented that requiring all ACO providers/suppliers billing through an ACO participant TIN to participate in the same risk track could deter some ACOs from entering higher risk arrangements (Tracks 2 or 3) if they do not believe that all of the ACO providers/suppliers billing through a given ACO participant TIN are prepared to operate under high levels of risk. CMS did not propose to change regulations in order to allow providers and suppliers billing through the same ACO participant TIN to participate in different tracks under the Shared Savings Program, but expressed interest in stakeholder opinion on the issue, and sought comment on what options the program might consider in the future to encourage organizations to participate in the program while permitting providers and suppliers within that organization to accept varying degrees of risk. *CMS will explore operational processes to develop a methodology that would permit ACOs to split ACO participants or ACO providers/suppliers into two different risk tracks while also ensuring appropriate beneficiary protections. It may revisit this approach in future rulemaking as infrastructure evolves to support this new alternative*

Additional Program Requirements and Beneficiary Protections (pgs 32812-32819)

Public Reporting and Transparency (pg 32813)

- For purposes of the Shared Savings Program, each ACO is currently required at §425.308 to publicly report certain organizational and other information.
- Currently, CMS recommends that ACOs publicly report the specified information in a standardized format that it has made available to ACOs through guidance at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO-Public-Reporting-Guidance.pdf>
- In the December 2014 proposed rule, CMS proposed to modify the public reporting requirements set forth at §425.308.
- CMS also proposed to require that each ACO maintain a dedicated web page on which the ACO must publicly report this specified information.
- Additionally, an ACO would have to report the address of the webpage on which it discloses the information and apprise CMS of changes to that website address in the form and manner that it has specified.
- *CMS finalizes its proposed policies reflected in §425.308.*
- *An ACO must maintain a dedicated webpage on which the ACO must publicly report information listed in paragraph (b) using a template specified by CMS.*

- *CMS made a technical correction at §425.308(b) to add the word "publicly" to clarify that the information reported using the template must be publicly available.*
- *Each ACO must report to CMS the address of the web page on which it discloses information and apprise it of changes to that website address in the form and manner specified by CMS in operational guidance.*
- *Information reported on an ACO's public reporting webpage in the standardized format specified by CMS will not be subject to marketing review and approval.*
- *ACOs must publicly identify and list key clinical and administrative leaders within their organization.*
- *ACOs must publicly report the types of ACO participants or combinations of ACO participants that form the ACO.*
- *Each ACO must publicly report its performance on all quality measures.*
- *ACOs are required to publicly report their use of any waivers under §425.612, if applicable.*
- *CMS will publicly report ACO-specific information, including information the ACO is required to publicly report under §425.308, as necessary to support program goals and transparency.*

Terminating Program Participation (pg 32815)

- CMS proposed several modifications to the regulations related to termination of a participation agreement.

Grounds for Termination (pgs 32815-32816)

- CMS proposed to modify the grounds for termination to specifically include the failure to comply with CMS requests for submission of documents and other information by the CMS-specified deadline.
- As explained in the December 2014 proposed rule, the submission of those documents by the specified due date is important for program operations.
- ACOs are obligated to repay shared savings payments to which they are not entitled, including, by way of example only, any overpayment to the ACO based on the submission of false or fraudulent data.
- *CMS is finalizing its proposals related to terminating program participation.*

Close-Out Procedures and Payment Consequences of Early Termination (pgs 32816-32817)

- CMS proposed to add new §425.221 to address close-out procedures and payment consequences of early termination.
- CMS believed it was important to establish an orderly close-out process when an ACO's participation agreement is terminated.
- *CMS will terminate an ACO agreement for failure to comply with requests for information and documentation by the due date specified.*
- *An ACO agreement will be terminated for submission of false or fraudulent data.*
- *ACOs are obligated to repay shared savings payments to which they are not entitled, including any overpayment received.*

- *An ACO whose participation agreement is terminated prior to its expiration either voluntarily or by CMS must implement close-out procedures regarding the following in a form, manner, and deadline specified by CMS:*
 - o *Notice to ACO participants of termination*
 - o *Record retention*
 - o *Data sharing*
 - o *Quality reporting*
 - o *Beneficiary continuity of care*
- *Close-out procedures also apply to ACOs that have elected not to renew their agreements upon expiration of the participation agreement.*
- *Any ACO that fails to complete close-out procedures in the form and manner and by the deadline specified by CMS will not be eligible for shared savings.*
- *An ACO whose participation agreement is voluntarily terminated will qualify for shared savings for the performance year during which the termination becomes effective, if:*
 - o *The effective date of termination is December 31*
 - o *The ACO completes its close-out process for the performance year in which termination becomes effective by a date specified by CMS*
 - o *The ACO has satisfied criteria for sharing in savings for performance year*
- *The ACO must specify in its termination notice, and CMS must approve, a termination effective date of December 31 for the current performance year.*
- *The opportunity to share in savings for performance year does not extend to an ACO that terminates its participation agreement with an effective date prior to December 31 or to an ACO that CMS terminates.*

Reconsideration Review Process (pgs 32817-32818)

- To date, all reconsideration review requests have been on-the-record reviews
- In the December 2014 proposed rule, CMS explained that it believes that on-the-record reviews are fair to both parties.
- *CMS finalizes its proposal to permit only on-the-record reviews of reconsideration requests.*
- *The reconsideration review process permits the ACO and CMS to submit one brief each in support of their respective positions by the deadline established by the CMS reconsideration official.*
- *Submission of additional briefs or evidence is at the sole discretion of the reconsideration official.*

Monitoring ACO Compliance with Quality Performance Standards (pgs 32818-32819)

- CMS proposed several technical revisions to clarify its administrative enforcement authority when ACOs fail to meet the quality reporting requirements.
- *CMS is removing redundant sections of the regulation text (§425.316(c)(3) and (c)(4))*
- *CMS finalizes its proposal to redesignate §425.316(c)(5) as §425.316(c)(3), and to make changes to indicate the ACO must report "accurately, completely, and timely" to emphasize the importance of timely submission of measures and to conform to language elsewhere in the program rules.*

Appendix 1 - CMS Physician Specialty Codes Included in Step 1

**TABLE 2—SPECIALTY CODES
INCLUDED IN ASSIGNMENT STEP 1**

Code	Specialty Name
01	General Practice
08	Family Practice
11	Internal Medicine
37	Pediatric Medicine
38	Geriatric Medicine

Appendix 2 – CMS Specialty Codes for NPs, PAs, and CNSs Included in Beneficiary Assignment Step 1

**TABLE 3-- CMS NON-PHYSICIAN SPECIALTY CODES
INCLUDED IN ASSIGNMENT STEP 1**

Code	Specialty Name
50	Nurse practitioner
89	Clinical nurse specialist
97	Physician assistant

Appendix 3 - Physician Specialties Included in Step 2

**TABLE 4-- PHYSICIAN SPECIALTY CODES –
INCLUDED IN ASSIGNMENT STEP 2**

Code	Specialty Name
06	Cardiology
12	Osteopathic manipulative medicine
13	Neurology
16	Obstetrics/gynecology
23	Sports medicine
25	Physical medicine and rehabilitation
26	Psychiatry
27	Geriatric psychiatry
29	Pulmonary disease
39	Nephrology
46	Endocrinology
70	Multispecialty clinic or group practice
79	Addiction medicine
82	Hematology
83	Hematology/oncology
84	Preventive medicine
86	Neuro-psychiatry
90	Medical oncology
98	Gynecology/oncology

Appendix 4 - Physician Specialties Excluded from the Beneficiary Assignment Methodology under Step 2

TABLE 5 -- PHYSICIAN SPECIALTY CODES EXCLUDED FROM ASSIGNMENT STEP 2

Code	Specialty Name
02	General surgery
03	Allergy/immunology
04	Otolaryngology
05	Anesthesiology
07	Dermatology
09	Interventional pain management
10	Gastroenterology
14	Neurosurgery
17	Hospice and Palliative Care
18	Ophthalmology
20	Orthopedic surgery
21	Cardiac electrophysiology
22	Pathology
24	Plastic and reconstructive surgery
28	Colorectal surgery
30	Diagnostic radiology
33	Thoracic surgery
34	Urology
36	Nuclear medicine
40	Hand surgery
44	Infectious disease
66	Rheumatology
72	Pain management
76	Peripheral vascular disease
77	Vascular surgery
78	Cardiac surgery
81	Critical care (intensivists)
85	Maxillofacial surgery
91	Surgical oncology

Appendix 4 - Physician Specialties Excluded from the Beneficiary Assignment Methodology under Step 2 - Continued

Code	Specialty Name
92	Radiation oncology
93	Emergency medicine
94	Interventional radiology
99	Unknown physician specialty
C0	Sleep medicine
C3	Interventional Cardiology