**Proposed Changes to the Medicare Shared Savings Program for Accountable Care Organizations**

## Background

As of 2014, more than 330 Accountable Care Organizations (ACOs) agreed to participate in the Medicare Shared Savings Program (MSSP). Net savings for the Medicare program totaled $383 million during the first performance year, while 58 ACOs were awarded $315 million in shared savings.

The Center for Medicare and Medicaid Innovation ("CMMI") established the Pioneer ACO Program for larger, more experienced providers that were willing to take on larger downside risk (and partial capitation) in exchange for greater shares of savings generated, relative to the maximum allowed in the Shared Savings Program.

32 organizations originally enrolled in the Pioneer ACO Program, although several dropped out of the program at various points. In the first performance year, 23 Pioneer ACOs generated $147 million in total Medicare savings.

## ACO Participation & Savings Estimates

- As currently structured (without implementation of any of the proposed changes), the Centers for Medicare and Medicaid Services (CMS) estimates that only 25% of currently-enrolled ACOs would re-enroll in the program for the second 3-year agreement period.
- Based on this low re-enrollment rate, CMS projects that as currently structured, the Shared Savings Program would generate between **$380 million and $1.16 billion** in net federal savings between 2016 and 2018.
- However, CMS estimates that, if finalized, the proposed changes would result in a 90% re-enrollment rate. CMS projects that the higher enrollment in the program would generate increased savings that would offset any savings lost through the proposed rule's relaxing of financial accountability/downside risk standards for ACOs during the second 3-year agreement period.
- Under this new proposed scenario, CMS estimates that Shared Savings Program would generate between **$430 million and $1.65 billion** in net federal savings between 2016 and 2018.

## Updates to ACO Definitions

**CMS proposes the following new definitions:**

- Participation Agreement: the written agreement required under §425.208(a) between the ACO and CMS that, along with the regulations at part 425, governs the ACO's participation.

- ACO Participant Agreement: the written agreement between an ACO and an ACO participant required at § 425.116 in which the ACO participant agrees to participate in, and comply with, the requirements of the Shared Savings Program.

- Assignment Window: the 12-month period used to assign beneficiaries to an ACO.

- **CMS proposes to revise the following existing definitions:**

  - ACO Participant: revises the definition to clarify that an ACO participant is an entity (not a practitioner) identified by a Medicare-enrolled Taxpayer Identification Number ("TIN").

  - ACO Professional: revises the definition to remove the requirement that an ACO professional must be an ACO provider/supplier, and to indicate that an ACO professional is an individual who bills for items/services furnished to Medicare fee-for-service beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant.

  - ACO Provider/Supplier: revises the definition to clarify that an individual or entity is an ACO provider/supplier only when it bills for items and services furnished to Medicare fee-for-service (FFS) beneficiaries during the agreement period under a Medicare billing number assigned to the TIN of an ACO participant and is included on the list of ACO providers/suppliers.

  - Assignment: revises definition to reflect that assignment methodology takes into account claims for primary care services furnished by ACO professionals, not solely claims for primary care services furnished by physicians in ACO.

  - Hospital: CMS proposes to revise the definition of "hospital" to clarify that a Maryland acute care hospital is a "hospital" for purposes of the Shared Savings Program.

**ACO Eligibility Requirements**

CMS proposes to add new requirements for agreements between an ACO and an ACO participant or ACO provider/supplier, including that the agreement must:

- only be an agreement between ACO and the ACO participant;

- be signed on behalf of the ACO and the ACO participant by individuals authorized to bind the ACO and the participant;
- require ACO participant to agree (and ensure provider/suppliers agree) to participate/comply with program rules;
- set forth the ACO participant's rights and obligations in, and representation by, the ACO, including quality reporting and beneficiary notification requirements, and how participation affects inclusion in other Medicare demonstrations;
- describe how the opportunity to receive shared savings or other financial arrangements will encourage the participant to adhere to the ACO's quality assurance and improvement program and evidence-based medicine guidelines;
- require ACO participants to update enrollment information using the Provider Enrollment, Chain and Ownership System ("PECOS"), and to notify the ACO within 30 days after any addition or deletion of an ACO provider/supplier;
- permit the ACO to take remedial action against the ACO participant, and require the participant to take remedial action against its ACO providers/suppliers, including corrective action plans ("CAP"), denial of payments, and termination;
- require completion of a close-out process upon termination/expiration of the ACO's participation agreement that requires the participant to furnish data necessary to complete the annual assessment of the ACO's quality of care and other relevant matters.

The term of agreement must be for at least 1 performance year; and consequences for early termination must be noted.

- For ACOs that contract directly with ACO providers/suppliers, CMS proposes identical requirements but agreements with ACO providers/suppliers would not be required to be for a term of 1 year.

CMS proposes that the ACO must show that its participants/providers/suppliers agreed to comply with program requirements.

CMS proposes that ACO participant agreements must also be submitted when ACO adds participants.

**Sufficient Number of Primary Care Providers and Beneficiaries**

- CMS proposes modifications related to the data used during the application review process to estimate the number of beneficiaries historically assigned in each of the 3 years of the benchmarking period.

- Specifically, CMS proposes that the number of assigned beneficiaries would be calculated for each benchmark year using the assignment methodology set forth in Subpart E of part 425, and in the case of benchmark year 3 ("BY3"), CMS would use the most recent data available with up to a 3-month claims run out to estimate the number of assigned beneficiaries.

- The estimates of the number of assigned beneficiaries would be used during the ACO application review process to determine whether the ACO exceeds the 5,000 assigned beneficiary threshold for each year of the historical benchmark period.

    - If an ACO had at least 5,000 assigned beneficiaries in each of the BYs, it would be deemed to have initially satisfied the eligibility requirement.

- CMS proposes to modify rules to provide greater flexibility to address situations in which an ACO's assigned beneficiary population falls below 5,000 assigned beneficiaries.

    - CMS would specify in its request for a CAP the performance year during which the ACO's assigned population must meet or exceed 5,000 beneficiaries, giving ACOs whose assigned populations fall below 5,000 late in a performance year greater flexibility to address the deficit.

    - CMS would also have the discretion not to impose a CAP when the ACO has already submitted a request to add ACO participants effective at the beginning of the next performance year.

**Identification and Required Reporting of ACO Participants and ACO Providers/Suppliers**

**Certified Lists of ACO Participants and ACO Providers/Suppliers**

- CMS proposes that prior to the start of the agreement period and before each performance year, the ACO must provide CMS with a complete and certified list of ACO participants and their Medicare-enrolled TINs; CMS would use this info to identify individuals/entities affiliated with the ACO participant's TIN in PECOS and then provide the information to the ACO to make any corrections as necessary.

- CMS proposes to require that the ACO report changes in participant and provider/supplier enrollment in PECOS within 30 days.

**Managing Changes to ACO Participants**

- CMS proposes that an ACO must submit a request to CMS to add a new entity to its ACO participant list; if CMS approves, the entity will be added the following performance year.

- CMS proposes that an ACO must notify CMS no later than 30 days after the date of termination of the entity's ACO participant agreement.
- CMS proposes that changes made to the annually certified ACO participant list would result in adjustments to the ACO's historical benchmark, assignment, quality reporting sample, and the obligation of the ACO to report on behalf of eligible professionals for quality initiatives.
    - However, absent unusual circumstances, the removal of a participant during the performance year would not affect certain calculations (i.e., beneficiary assignment, historical benchmark, financial calculations, etc.) for the remainder of the performance year in which the removal becomes effective.

**Managing Changes and Updates**

**Managing Changes to ACO Providers/Suppliers**

- CMS proposes that an ACO may add to the ACO provider/supplier list if it notifies CMS within 30 days after the individual or entity bills for items and services under a billing number assigned to the TIN of an ACO participant.
    - If the ACO provides timely notice, the addition is effective on the date specified in the notice furnished to CMS (but no earlier than 30 days before the date of notice); if the notice is not timely, the addition becomes effective on the date CMS receives notice from the ACO.
- CMS is considering delaying the effective date of additions to the provider/supplier list until after the individuals/entities complete a program integrity screening.
- CMS proposes that to remove an ACO provider/supplier from the list, an ACO must notify CMS no later than 30 days after termination.

**Update of Medicare Enrollment Information**

- CMS proposes to require the ACO to ensure that changes in ACO participant and provider/supplier enrollment are reported in PECOS.

**Significant Changes to an ACO Merged/Acquired Medicare Enrolled Entities**

**Significant Changes to an ACO**

- CMS proposes to specify that a significant change occurs when the ACO is no longer able to meet the eligibility or other program requirements, or when the

number or identity of ACO participants included on the ACO participant list changes by 50% or more during an agreement period.

- Under the proposal, 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 seeks comments on whether to clarify that the ACO's notice of a significant change must be furnished prior to the occurrence of the significant change, and whether ACOs should be required to provide 45 or 60 days' advance notice of a significant change.

**Consideration of Claims Billed by Merged/Acquired Entities**

- CMS proposes to 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 permit ACOs 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.

## Legal Structure and Governance

**Legal Entity and Governing Body**

- CMS proposes to revise the regulations to 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 also proposes that the governing body of the ACO must satisfy three criteria: (1) must be the same as the governing body of the legal entity that is the ACO; (2) for an ACO that comprises multiple ACO participants, must be separate and unique to the ACO and must not be the same as the governing body of any ACO participant; and (3) must satisfy all other requirements set forth in §425.106, including the fiduciary duty requirement.

**Fiduciary Duties of Governing Body Members**

- CMS proposes to clarify that the fiduciary duty owed to an ACO by its governing body members includes the "duty of loyalty" whereby members must act only in the best interests of the ACO and not another individual or entity.

**Composition of the Governing Body**

- CMS proposes to remove the flexibility for ACOs to deviate from the requirement that at least 75% control of an ACO's governing body must be held by ACO participants.

- CMS proposes to prohibit an ACO provider/supplier from being the beneficiary representative on the governing body.

- CMS reiterates that an ACO must have a mechanism for shared governance.

**Leadership and Management Structure**

**Medical Director**

- CMS proposes to remove the requirement that the medical director be an ACO provider/supplier.

    - CMS notes that alternatively, CMS could retain the requirement but permit ACOs to request CMS approval to designate as its medical director a physician who is not an ACO provider/supplier but who is closely associated with the ACO and satisfies all of the other medical director requirements.

- CMS proposes to clarify that the medical director must be physically present on a regular basis "at any clinic, office, or other location of the ACO, ACO participant or ACO provider/supplier."

**Other Proposals on Structure**

- CMS proposes to eliminate the provision allowing an ACO to request an exception to the leadership and management requirements related to operations management and clinical management and oversight.

- CMS also proposes to require a program applicant to submit documentation regarding the qualified healthcare professional responsible for the ACO's quality assurance and improvement program.

**Process to Coordinate Care/Pioneer ACO Transition**

**Required Process to Coordinate Care**

- CMS proposes to require an ACO to describe in its application how it will encourage and promote the use of enabling technologies (e.g., electronic health records, telehealth services, etc.) for improving care coordination for beneficiaries.

- CMS proposes to require the applicant to 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 proposes to require that an ACO define and submit performance targets it will use to assess progress of its participants in care coordination.

### Transition of Pioneer ACOs into the Shared Savings Program

- CMS proposes to offer Pioneer ACOs the opportunity to apply to the Shared Savings Program using a condensed application if three criteria are satisfied: (1) the applicant ACO must be the same legal entity as the Pioneer ACO; (2) all of the TINs on the applicant's ACO participant list must have appeared on the "Confirmed Annual TIN/NPI List" (as defined in the Pioneer ACO Model Innovation Agreement with CMS) for the applicant ACO's last full performance year in the Pioneer ACO Model; and (3) the applicant must be applying to participate in a two-sided model.

## Application Deadlines/Renewal of Participation Agreements

### Application Deadlines

- CMS proposes to clarify that CMS approves or denies an application based on: information in the application, any supplemental information in response to a CMS request, and other information available to CMS (including information on the ACO's program integrity history).

- CMS also clarifies the process for requesting supplemental information and specifies that CMS may deny an application if an ACO applicant fails to submit information by specified deadlines.

### Renewal of Participation Agreements

- For ACOs that would like to continue participating after the expiration of their current agreement period, CMS proposes a process for renewing existing participation agreements, rather than requiring submission of a new application.

- An ACO that seeks renewal and was newly formed after March 23, 2010, must agree that CMS can share a copy of its renewal request with the Antitrust Agencies.

- CMS proposes to determine whether to renew a participation agreement based on certain factors including: whether the ACO satisfies the criteria for operating under the selected risk model, the ACO's history of compliance, whether the

ACO has established that it is in compliance, whether the ACO met the quality performance standards, among other requirements.

**Changes to Program Requirements During the 3-Year Agreement**

**Regulatory Changes**

- CMS proposes to modify the requirements to provide that ACOs are subject to all regulatory changes "that become effective during the agreement period" except for regulations on certain specified program areas unless otherwise required by statute.
- Thus, an ACO whose participation agreement is renewed for a second or subsequent agreement period would be subject, beginning at the start of that period, to any regulatory changes regarding ACO structure and governance that became effective during the previous 3 years (that is, during the preceding agreement period).

**Regulatory Changes Related to Beneficiary Assignment**

- CMS proposes to require ACOs to be subject to regulatory changes on beneficiary assignment that are effective during an agreement period.
- CMS could adjust an ACO's benchmark to account for regulatory changes regarding beneficiary assignment methodology that become effective.
- Regulatory changes regarding beneficiary assignment would apply to all ACOs, including ACOs in the middle of an agreement period.

**Provision of Aggregate and Beneficiary Identifiable Data**

**CMS proposes to expand the information made available to ACOs to include certain additional beneficiary identifiable data (subject to HIPAA requirements)**

- CMS proposes to expand the beneficiary identifiable information made available to ACOs to include data elements (name, date of birth, HICN, and sex) for each beneficiary that 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.
- CMS proposes to make available the minimum data set necessary for purposes of the ACO's population-based activities at the following times: (1) at the beginning of the agreement period; (2) at the beginning of each performance year and quarterly thereafter; and (3) in conjunction with the annual reconciliation.

- CMS also proposes to expand the beneficiary identifiable information made available for preliminarily prospectively assigned beneficiaries to include demographic data such as enrollment status, health status information such as risk profile, and chronic condition subgroup, utilization rates of Medicare services such as the use of evaluation and management, hospital, emergency, and post-acute services, including dates and place of service, and expenditure information related to utilization of services.

The proposals to expand data reports would apply ***only*** to ACOs participating in Tracks 1 and 2 (not for proposed Track 3 – as discussed later).

- For Track 3, CMS proposes that ACOs would have access to current beneficiary identifiable data elements under § 425.702(c) for beneficiaries prospectively assigned to the ACO but would not be able to request any information related to other Medicare FFS beneficiaries who receive primary care services that are considered in the assignment process from ACO participants.

**Assignment of Medicare FFS Beneficiaries**

**Existing Beneficiary Assignment Structure**

Currently, CMS assigns beneficiaries to ACOs using a retrospective attribution model in which beneficiaries are assigned ACOs (for the purposes of determining shared savings) at the end of the performance year/period, based on their primary care services utilization during that period.

CMS proposes to clarify that beneficiaries can only be assigned to an ACO if they meet the following criteria:

- Have at least 1 month of Part A and Part B enrollment, and no months of Part A only or Part B only enrollment within the performance year;
- Have no months of Medicare group (private) health plan enrollment in performance year;
- Have not been assigned to any other shared savings initiative;
- Live in the U.S. or U.S. territories.

In order to help ACOs identify which beneficiaries are likely to be assigned to them, CMS provides each ACO its preliminary prospective assigned beneficiaries, based on the previous year's utilization.

Importantly, only primary care services are used for determining beneficiary assignment, through the following two step process:

Step One:

- If beneficiary received at least one primary care service by a primary care physician during performance year, and allowed charges for primary care services furnished by the ACO's participants are greater than allowed charges for primary care 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.

Step Two:

- If beneficiary did not receive any primary care services from a primary care physician during performance year, but beneficiary received at least one primary care service from a non-primary care physician participating in the ACO, and received more primary care services from ACO professionals (including physicians from any specialty, NPs, PAs, and CNSs) at the ACO than he/she received from professionals of any other ACO or non-ACO practice, then the beneficiary will be assigned to the ACO.

**Changes to the Definition of Primary Care Services**

Under current rules, only the following services are included as "primary care services" for the purposes of ACO beneficiary assignment:

- physician office/hospital outpatient visit (HCPCS Codes 99201-99215); nursing facility/home health care initiation visits (99304-99340; other visits to a patient home (99341-99350); Welcome to Medicare visit (G0402); and annual wellness visits (G0438, G0439).

CMS proposes to add transitional care management services (HCPCS Codes 99495-99496) and chronic care management services (HCPCS Code GXXX1) to the definition. CMS also proposes to include primary services furnished by ACO-participating NPs, PAs, and CNSs in Step 1 of the beneficiary assignment methodology, so long as the beneficiary has also received a primary care service from a primary care physician that is participating in the ACO.

CMS proposes to exclude primary care services performed by certain specialty physicians from inclusion in "Step 2" calculation of primary care service utilization for the purposes of beneficiary assignment (see Table 3).

CMS also requests comments on an option for replacing the current two step assignment methodology with a new one step assignment process in which the plurality of primary care services provided by the physicians listed in Tables 1 and 2, and the non-physician practitioners in Table 4, would all be considered in a single step.

### Exclusion of Specialty Physician-Provided Primary Care Services

**Table 1—CMS Physician Specialty Codes That Would Continue to Be Included In Assignment Step 1**

| Code | Specialty Name |
|---|---|
| 01 | General Practice |
| 08 | Family Practice |
| 11 | Internal Medicine |
| 38 | Geriatric Medicine |

**Table 2—CMS Physician Specialty Codes That Would Continue To Be Included In Assignment Step 2**

| Code | Specialty Name |
|---|---|
| 03 | Allergy/Immunology |
| 06 | Cardiology |
| 10 | Gastroenterology |
| 13 | Neurology |
| 16 | Obstetrics/Gynecology |
| 17 | Hospice and Palliative Care |
| 23 | Sports Medicine |
| 25 | Physical Medicine and Rehabilitation |
| 29 | Pulmonary Disease |
| 37 | Pediatric Medicine |
| 39 | Nephrology |
| 44 | Infectious Disease |
| 46 | Endocrinology |
| 66 | Rheumatology |
| 70 | Multispecialty Clinic or Group Practice |
| 82 | Hematology |
| 83 | Hematology/Oncology |
| 84 | Preventive Medicine |
| 90 | Medical Oncology |
| 98 | Gynecology/Oncology |

| Table 3—CMS Physician Specialty Codes That Would Be Excluded from Assignment Step 2 | |
|---|---|
| Code | Specialty Name |
| 02 | General Surgery |
| 04 | Otolaryngology |
| 05 | Anesthesiology |
| 07 | Dermatology |
| 09 | Interventional Pain Management |
| 12 | Osteopathic Manipulative Therapy |
| 14 | Neurosurgery |
| 18 | Ophthalmology |
| 20 | Orthopedic Surgery |
| 21 | Cardiac Electrophysiology |
| 22 | Pathology |
| 24 | Plastic and Reconstructive Surgery |
| 26 | Psychiatry |
| 27 | Geriatric Psychiatry |
| 28 | Colorectal Surgery |
| 30 | Diagnostic Radiology |
| 33 | Thoracic Surgery |
| 34 | Urology |
| 36 | Nuclear Medicine |
| 40 | Hand Surgery |
| 72 | Pain Management |
| 76 | Peripheral Vascular Disease |
| 77 | Vascular Surgery |
| 78 | Cardiac Surgery |
| 79 | Addiction Medicine |
| 81 | Critical Care (Intensivists) |
| 85 | Maxillofacial Surgery |
| 86 | Neuro-psychiatry |
| 91 | Surgical Oncology |
| 92 | Radiation Oncology |
| 93 | Emergency Medicine |
| 94 | Interventional Radiology |
| 99 | Unknown Physician Specialty |
| C0 | Sleep Medicine |

| Table 4—CMS Non-Physician Specialty Codes That Would Be Included In Assignment Step 1 | |
|---|---|
| Code | Specialty Name |
| 01 | General Practice |
| 08 | Family Practice |
| 11 | Internal Medicine |
| 38 | Geriatric Medicine |

### Other Beneficiary Assignment Issues

For primary care services provided by physicians practicing in Federally Qualified Health Centers ("FQHCs") and Rural Health Clinics ("RHCs"), CMS previously used FQHC/RHC attestation information both for purposes of determining whether a beneficiary was "assignable" to an ACO and also for purposes of assigning beneficiaries to the ACO under Step 1.

CMS proposes to use this attestation information only for purposes of determining whether a beneficiary is assignable to an ACO—referred to as an assignment "pre-step" for FQHC or RHC beneficiaries.

- If a beneficiary is identified as an "assignable" beneficiary in the assignment pre-step, then CMS would 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 primary care services from the ACO under Step 1.

CMS also proposes that that when considering services furnished by physicians in Electing Teaching Amendment ("ETA") hospitals in the assignment methodology, CMS would use the amount payable under the PFS for the specified HCPCS code as a proxy for the amount of the allowed charges for the service.

**Proposed Changes to Transition from Track 1 to Track 2**

CMS proposes to modify its rules to allow ACOs to remain in Track 1 during the second 3-year agreement period in certain instances.

- The proposal would require that all Track 1 ACOs transition to Track 2 by the end of the second 3-year agreement period, although Track 1 ACOs would still have the option to transition to Track 2 after the first 3-year agreement period.
- Track 1 ACOs would have the option to remain in Track 1 for the second 3-year agreement period, so long as:

(1) They meet criteria for ACO agreement renewal (discussed above), including acceptable quality performance and achievement in becoming eligible to share in savings during at least one of the first two performance years of the initial 3-year agreement period; and

(2) In at least one of the first two performance years of the previous agreement period, the ACO did not generate losses in excess of a percentage equivalent to the ACO's MSR percentage (referred to by CMS as the "negative MSR")."

- In exchange for this flexibility, CMS proposes to reduce the maximum sharing rate for by 10 percentage points for ACOs that remain in Track 1 for a second 3-year agreement period. As a result, the maximum sharing rate for these ACOs will be 40% for the second agreement period.
- In order to make Track 2 more attractive to current Track 1 ACOs (particularly smaller ACOs), CMS proposes to alter the MSR and the MLR rules for Track 2 ACOs.
- Specifically, CMS proposes to allow Track 2 MSRs and MLRs to vary based on the size of the ACO, in a similar manner as MSRs vary under Track 1:

**Table 6 – Proposed Minimum Savings Rate and Minimum Loss Rate for Track 2**

| Number of Beneficiaries | MSR/MLR (low end of assigned beneficiaries) | MSR/MLR (high end of assigned beneficiaries) |
|---|---|---|
| 5,000 - 5,999 | 3.9% | 3.6% |
| 6,000 - 6,999 | 3.6% | 3.4% |
| 7,000 - 7,999 | 3.4% | 3.2% |
| 8,000 - 8,999 | 3.2% | 3.1% |
| 9,000 - 9,999 | 3.1% | 3.0% |
| 10,000 - 14,999 | 3.0% | 2.7% |
| 15,000 - 19,999 | 2.7% | 2.5% |
| 20,000 – 49,999 | 2.5% | 2.2% |
| 50,000 – 59,999 | 2.2% | 2.0% |
| 60,000 + | 2.0% | |

**Proposed Establishment of "Track 3"**

- Establishing a "Track 3" ACO Process
    - CMS proposes to add a Track 3 for ACOs that are ready to accept higher levels of financial risk than the risk level under Track 2, in exchange for higher shared savings opportunities. The benefits for Track 3 ACOs would include:
        - allowance for prospective beneficiary assignment; eligibility for higher sharing rates and higher shared savings caps; alternative changes to annual per beneficiary benchmarks; and potential waivers from various Medicare rules that limit beneficiary eligibility for certain post-acute care services.
- Prospective Assignment for Track 3 ACOs
    - CMS proposes to implement a prospective assignment methodology for Track 3 that uses the same stepwise assignment methodology to assign beneficiaries in Track 3 used in Track 1 and Track 2.
    - Track 3 bases its prospective assignment on primary care utilization from the previous year, in a similar way CMS uses for establishing "preliminary prospectively assigned beneficiary" lists for Track 1 and Track 2, except that the list would be the definitive list of assigned beneficiaries for the performance year, with no changes other than eliminating beneficiaries that cease to qualify for assignment to any ACO.
    - CMS proposes the same beneficiary eligibility criteria as Track 1 and Track 2, with the exception that CMS is removing the "Not assigned to any other shared savings initiative" criteria for Track 3.

- CMS proposes to base prospective beneficiary assignment on the most recent 12 months for which primary care utilization data are available, and which would be off-set from the calendar year.

- CMS proposes that once a beneficiary is prospectively assigned to Track 3, the beneficiary will not be eligible for assignment to a different ACO.

**Per Beneficiary Benchmark for Track 3 ACOs**

**Determining the Per Beneficiary Benchmark for Track 3**

- CMS proposes to establish the historical per beneficiary spending benchmark for Track 3 ACOs by determining the beneficiaries that would have been prospectively assigned to the ACO during each of the three most recent years prior to the start of the agreement period and basing the benchmark year assignment on a 12-month assignment window offset from the calendar year prior to the start of each benchmark.

- CMS would still determine the Parts A and B fee-for-service expenditures for each calendar year, whether it is a benchmark year or a performance year, using a 3-month claims run out with a completion factor for these prospectively assigned beneficiaries.

- CMS would also exclude Indirect Medical Education ("IME") and Disproportionate Share Hospital ("DSH") payments from the benchmarks and performance year expenditures.

**Risk-Adjusting the Updated Benchmark for Track 3**

- CMS proposes minor modifications to the risk adjustment methodology used in Tracks 1 and 2 to account for Track 3's prospective beneficiary assignment methodology.

- For Track 3, CMS proposes to use an off-set 12 month period prior to the relevant performance or benchmark year (rather than the "prior calendar year") to prospectively assign beneficiaries.

- Thus, the reference period for determining whether a beneficiary is "newly" or "continuously" assigned would be the most recent prior prospective assignment window (the off-set 12 months) before the assignment window for the current performance year.

**Final Sharing/Loss Rate and Performance Payment/ Loss Recoupment under Track 3**

- CMS proposes to set the sharing rate under Track 3 at 75% (to reflect the greater degree of risk borne by Track 3 participants), and to increase the shared loss rate to a maximum of 75% (to retain symmetry within the model, comparable to Track 2).
- The Track 3 performance payment limit would not exceed 20% of the ACO's updated benchmark, and the amount of shared losses for which an ACO may be liable could not exceed 15% of its updated benchmark in each year of the ACO's 3-year arrangement.
- ACOs with high quality performance would not be permitted to reduce the percentage of shared losses for which they would be responsible for each year of the agreement period below 40%.

**MSR and MLR in Track 3**

- CMS proposes to apply the same fixed 2% MSR and MLR that currently apply to Track 2 to Track 3 ACOs;
- CMS would consider setting both the MSR and MLR to 1% instead of 2% or remove the MSR and MLR entirely;
- ACOs would be subject to normal variation around their benchmark so that they would be held responsible for all losses when performance year expenditures were above the benchmark, in addition to sharing in any savings if performance year expenditures fell below the benchmark.

**Below is a chart showing all of CMS' proposed changes to Tracks 1, 2 and 3**

**TABLE 7. SHARED SAVINGS FINANCIAL MODEL OVERVIEW**

| | Track 1; One-Sided Risk Model | | Tracks 2 and 3: Two-Sided Risk Models | | |
|---|---|---|---|---|---|
| **Issue** | **Current** | **Proposed** | **Current Track 2** | **Proposed Track 2** | **Proposed Track 3** |
| Transition to Two Sided Model | First agreement period under one sided model. Subsequent agreement periods under two-sided model | Remove requirement to transition to two-sided model for a second agreement period. | ACOs may elect Track 2 without completing a prior agreement period under a one-sided model. Once elected, ACOs cannot go into Track 1 for subsequent agreement periods. | No change | Same as Track 2 |
| Assignment | Preliminary prospective assignment for reports; retrospective assignment for financial reconciliation | No change | Preliminary prospective assignment for reports; retrospective assignment for financial reconciliation | No change | Prospective assignment for reports and financial reconciliation |
| Benchmark | Reset at the start of each agreement period | Seeking comment on alternative methodology | Same as Track 1 | Seeking comment on alternative methodology | Same as Tracks 1 and 2 and seeking comment on alternative methodology |

| | Track 1; One-Sided Risk Model | | Tracks 2 and 3: Two-Sided Risk Models | | |
|---|---|---|---|---|---|
| **Issue** | **Current** | **Proposed** | **Current Track 2** | **Proposed Track 2** | **Proposed Track 3** |
| Adjustments for health status and demographic changes | Historical benchmark expenditures adjusted based on CMS-HCC model.<br>Updated historical benchmark adjusted relative to the risk profile of the performance year.<br>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. | No change | Same as Track 1. | No change | Same as Tracks 1 and 2. |
| Adjustments for IME and DSH | IME and DSH excluded from benchmark and performance year expenditures. | No change | Same as Track 1 | No change | Same as Tracks 1 and 2 |
| Other payment adjustments | Include other payment adjustments included in Part A and B claims such as, geographic payment adjustments and Hospital Value-Based Purchasing payments, in benchmark and performance year | Seeking comment on other technical adjustments | Same as Track 1 | Seeking comment on other technical adjustments | Same as Tracks 1 and 2 |

| | Track 1; One-Sided Risk Model | | Tracks 2 and 3: Two-Sided Risk Models | | |
|---|---|---|---|---|---|
| **Issue** | **Current** | **Proposed** | **Current Track 2** | **Proposed Track 2** | **Proposed Track 3** |
| | expenditures | | | | |
| Quality Sharing Rate | Up to 50 percent based on quality performance | Up to 50 percent based on quality performance for first agreement period, reduced by 10 percentage points for each subsequent agreement period under the one-sided model | Up to 60 percent based on quality performance | No change | Up to 75 percent based on quality performance |
| Minimum Savings Rate | 2.0 percent to 3.9 percent depending on number of assigned beneficiaries. | No change | Fixed 2.0 percent | 2.0 percent to 3.9 percent depending on number of assigned beneficiaries | Fixed 2.0 percent |
| Minimum Loss Rate | Not applicable | No change | Fixed 2.0 percent | 2.0 percent to 3.9 percent depending on number of assigned beneficiaries | Fixed 2.0 percent |
| Performance Payment Limit | 10 percent | No change | 15 percent | No change | 20 percent |

| | Track 1; One-Sided Risk Model | | Tracks 2 and 3: Two-Sided Risk Models | | |
|---|---|---|---|---|---|
| **Issue** | **Current** | **Proposed** | **Current Track 2** | **Proposed Track 2** | **Proposed Track 3** |
| Shared Savings | First dollar sharing once MSR is met or exceeded. | No change | Same as Track 1. | No change | Same as Tracks 1 and 2. |
| Shared Loss Rate | Not applicable | No change | One minus final sharing rate applied to first dollar losses once minimum loss rate is met or exceeded; shared loss rate not to exceed 60 percent | No change | One minus final sharing rate applied to first dollar losses once minimum loss rate is met or exceeded; shared loss rate may not be less than 40 percent or exceed 75 percent |
| Loss Sharing Limit | Not applicable | No change | Limit on the amount of losses to be shared in phases in over 3-years starting at 5 percent in year 1; 7.5 percent in year 2; and 10 percent in year 3 and any subsequent year. Losses in excess of the annual limit would not be shared. | No change | 15 percent. Losses in excess of the annual limit would not be shared. |

## Ways to Encourage ACO Participation in Performance-Based Risk Arrangements

**Payment Requirements and Program Requirements that May Need to be Waived in Order to Carry out the Shared Savings Program**

CMS is proposing to waiver several requirements in the proposed Track 3 model in order to encourage ACO participation in performance-based risk rrrangements. CMS is seeking comments in each of the following categories:

- The skilled nursing facility (SNF) 3-day rule as required under Track 2. CMS believes greatest savings in a two-sided risk track would be achieved by eliminating, where appropriate, the entire prior hospital stay and allowing direct admission to a SNF.
- The Home Health Homebound requirement. Participating ACOs would have to demonstrate capacity and infrastructure necessary to identify and clinically manage non-homebound beneficiaries and would have to have a 3+ star rating under the CMS 5-Star Quality Rating System.
- A very narrow provision for referrals to post-acute care settings 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 Condition of Participation at § 482.43 that implement this requirement.
- The "originating site" requirements for telehealth to limit telehealth payment to services furnished within specific types of geographic areas or specify the particular sites at which the eligible telehealth individual must be located at the time the service.

**Other Options for Improving the Transition to Two-Sided Performance-Based Risk Options**

**Beneficiary Attestation**

- CMS notes (but does not propose) that they could offer a "beneficiary attestation" process to ACOs that participate under two-sided risk financial arrangements.
- Under a similar Pioneer ACO demonstration (after which this would be modeled), beneficiaries confirm a care relationship with a provider and are aligned to his/ her Pioneer ACO for the following performance year, regardless of whether or not ACO-participating practitioners rendered the plurality of the beneficiary's primary care services during the performance year.
- CMS would revise its regulations as necessary to protect beneficiaries from undue coercion or influence in connection with whether or not they choose to attest.

CMS requests comments on whether it would be appropriate to offer a beneficiary attestation process to ACOs that choose to participate in the MSSP under two-sided risk financial arrangements. CMS is interested in receiving comments and suggestions on a wide variety of

policy and operational issues related to beneficiary attestation. **Step-Wise Progression for ACOs to Take on Performance-Based Risk**

- It is not possible under current regulations for some ACO providers/suppliers to participate in Track 1, while others—billing through the same TIN—participate under Track 2.
- CMS seeks suggestions for a framework that would permit providers/suppliers within a single organization to accept varying degrees of risk; specifically the relative merits of allowing MSSP ACOs to split their ACO participants into different tracks, or split provider/suppliers billing through a given TIN so that a subset may participate in a track that offers a higher sharing rate in exchange for taking on greater risk.
- Participating ACOs would be subject to several requirements, including:
    - Must have 5,000 assigned beneficiaries and meet other eligibility/governance requirements to participate in the program, and have completed a full agreement period under Track 1;
    - Must submit a "segmented list" of ACO participants to CMS that would participate under a performance-based risk track.

CMS requests comments on these options and other considerations for permitting organizations to move forward to performance-based risk in a step-wise manner. CMS specifically seeks comment on ways to mitigate selection bias when considering these options. **Modifications to Repayment Mechanism Requirements**

- **Amount and Duration of the Repayment Mechanism**
    - CMS proposes to establish a single repayment mechanism to cover the entire 3-year agreement period and a "reasonable period of time after" to be later established.
    - CMS also proposes an ACO demonstrate the adequacy of its repayment mechanism and maintain the ability to repay 1% of Medicare Part A and B FFS expenditures used to establish the benchmark for the applicable agreement period, as estimated by CMS.
    - If the repayment mechanism is used to repay any portion of shared losses owed to CMS, the ACO must replenish funds within 60 days.
- **Permissible Repayment Mechanisms**
    - CMS proposes to remove the option for ACOs to demonstrate their ability to pay using reinsurance or an alternative mechanism. Thus, CMS proposes to revise its

rule at § 425.204(f)(2) to indicate that an ACO may demonstrate its 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**

**Establishing, Updating, and Resetting the Benchmark**

The Department of Health and Human Services establishes benchmarks for each agreement period for each ACO using the most recent available 3 years of per beneficiary expenditures for Parts A and B for FFS beneficiaries assigned to the ACO.

- 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.
- Benchmarks have been very low in recent years, reflecting historically low cost growth in the FFS environment. CMS anticipates that the trend for ACOs participating in MSSP will be similar to the trend for sites in the Physician Group Practice ("PGP") demonstration, with more organizations generating savings as they gain experience.

- Under current methodologies, CMS weights benchmark expenditures at 60% for benchmark year 3 ("BY3"), 30% for BY2, and 10% for BY1, to ensure that the benchmark more accurately reflects the latest expenditure and health status of the ACO's assigned beneficiary population.
    - Alternatively, CMS is considering weighing the benchmark years equally, ascribing a weight of one-third to each benchmark year.
        - CMS notes this would more gradually lower benchmarks of ACOs that perform well in their first agreement period.
        - CMS expresses concern that this approach may be less accurate since it may not sufficiently account for an ACO's most recent historical cost experience but could encourage greater participation or encourage ACOs to achieve greater shared savings.

**Modifications to Shared Savings Benchmarks Under Consideration**

- Accounting: CMS is considering accounting for an ACO's shared savings during its prior agreement period, so that a second or subsequent benchmark incorporates an ACO's share of savings for those ACOs that received shared savings payments under the prior agreement period.

- CMS believes that doing so may address concerns expressed by some stakeholders that under the existing benchmarking methodology achieving savings may sometimes be financially unattractive for ACOs because of the potential impact on their benchmarks in future agreement periods.

- Use of Regional Factors: Instead of using national FFS expenditure data to trend expenditures in setting the historical benchmark, and to update the benchmark for each performance year, CMS is considering using regional FFS expenditure data, calculating the ACO's regional expenditure trend and update factors according to cost experience of a reference population.

- Alternative Methodology: *Holding Historical Costs Constant to Region.* CMS is considering a new methodology for resetting benchmarks, and a variety of potential approaches to it, that would hold the ACO's historical per assigned beneficiary spending constant relative to its local market so that improvements in efficiency achieved during an agreement period would not lower its benchmark for a subsequent period.

- Alternative Methodology: *Transition to Benchmarks Based Only on Regional FFS Costs Over Multiple Agreement Periods.* CMS is considering transitioning ACOs from benchmarks based on their historical costs toward benchmarks based only on regional FFS costs over the course of multiple agreement periods – an approach suggested by MedPAC and others – making ACO benchmarks gradually more independent of past performance and more dependent on success in being more cost efficient relative to its local market.

**Seeking Comment on Benchmarking Alternatives**

- CMS seeks comment on all of its considerations to modify or adjust the methodology for establishing, updating and resetting ACO benchmarks, and their applicability, in particular:

    - Using combinations of approaches;

    - How broadly or narrowly to apply alternative approaches to program's tracks;

    - Timing of any regional versus national FFS expenditure change, and whether a revision should be used to determine the benchmark that will apply during the 2016 performance year for all ACOs;

    - Criteria for determining comparison or reference group for using regional FFS data;

    - Addressing concerns about risk adjustment, including the possible use of regional normalization or coding intensity adjustments;

- How if at all to handle payment differences and changes under Medicare FFS.

**Additional Program Requirements and Beneficiary Protections**

**Proposed Changes to Reporting, Termination, Enforcement and Reconsideration**

- CMS proposes several refinements and clarifications to current policies on:
    - CMS proposes to require that each ACO maintain a dedicated webpage on which the ACO must publicly report of certain organizational information to include:
        - key clinical and administrative leaders;
        - the type of ACO participants or combinations of ACO participants;
        - performance on all quality measures used to asses ACO performance.
    - Termination of the participation agreement §§ 425.218 and 425.220
        - CMS proposes to permit termination for failure to timely comply with requests for documents or submitting false or fraudulent data; to implement certain close out procedures upon termination or non-renewal, and payment consequences upon termination (ACOs that terminate prior to December 31 would not qualify for shared savings).
    - Enforcement of ACO compliance with quality performance standards § 425.316(c)
    - Reconsideration review procedures §§ 425.802 and 425.804
        - CMS proposes to permit only on-the-record reviews of reconsideration requests and to modify and clarify that the reconsideration process allows both ACOs and CMS to submit one brief each in support of its position.

**Regulatory Impact Analysis**

**Summary of Impacts**

**TABLE 9: ALTERNATIVE SCENARIO ASSUMING ALL PROPOSED CHANGES ESTIMATED NET FEDERAL SAVINGS, COSTS AND BENEFITS, CYs 2016 THROUGH 2018**

| | CY 2016 | CY 2017 | CY 2018 | CYs (2016-2018) |
|---|---|---|---|---|
| **Net Federal Savings** | | | | |
| 10th Percentile | $190 million | $150 million | $80 million | $430 million |
| Median | $380 million | $350 million | $280 million | $1,010 million |
| 90th Percentile | $590 million | $570 million | $510 million | $1650 million |
| **ACO Shared Savings** | | | | |
| 10th Percentile | $90 million | $150 million | $220 million | $470 million |
| Median | $140 million | $210 million | $280 million | $630 million |
| 90th Percentile | $200 million | $280 million | $350 million | $820 million |
| **ACO Shared Losses** | | | | |
| 10th Percentile | $0 million | $0 million | $0 million | $10 million |
| Median | $10 million | $20 million | $0 million | $30 million |
| 90th Percentile | $30 million | $40 million | $20 million | $70 million |
| **Costs** | The estimated aggregate average start-up investment and 3-year operating costs is $562 million. The total estimated start-up investment costs average $30 million, with ongoing costs averaging $181 million, for the anticipated mean baseline participation of 210 ACOs. | | | |
| **Benefits** | Improved healthcare delivery and quality of care and better communication to beneficiaries through patient-centered care. | | | |

Note that the percentiles for each individual year do not necessarily sum to equal the corresponding percentiles estimated for the total 3-year impact in the column labeled CYs 2016 through 2018, due to the annual and overall distributions being constructed independently. Also, the cost estimates for this table reflect our assumptions for increased ACO participation as well as changes in the mix of new and continuing ACOs.