

Medicare Shared Savings Program: Accountable Care Organizations (ACO) Final Rule

Key Changes Included Within the Final Rule

In this final rule, CMS noted significant modification, including:

1. *greater flexibility in eligibility to participate in the Shared Savings Program*, which involves modifications to allow critical access hospitals billing under method II, FQHCs, and RHCs to form independent ACOS if they meet specific eligibility criteria. In addition, any Medicare enrolled entities not specified in the statutory definition of eligible entities in section 1899(b)(1)(A)-(D) of the Act can participate in the Shared Savings Program as ACO participants by joining an ACO containing one or more of the organizations eligible to form an ACO.
2. *multiple start dates in 2012* by specifically allowing ACOs to submit to begin participation in the program on April 1 (resulting in an agreement period of 3 performance years with the first performance year of the agreement consisting of 21 months) or July 1 (resulting in an agreement period of 3 years with the first performance year of the agreement consisting of 18 months).
3. *establishment of a longer agreement period for those starting in 2012* in which those periods may extend past the initial 3 year proposal;
4. *greater flexibility in the governance and legal structure of an ACO* by specifically allowing ACOs licensed under Federal or tribal law are eligible to participate in the Shared Savings Program, as well as clarifying that an ACO formed among multiple ACO participants must provide evidence in its application that it is a legal entity separate from any of its ACO participants.;
5. simpler and more streamlined quality performance standards;
6. (6)adjustments to the financial model to increase financial incentives to participate;
7. increased sharing caps;
8. no down-side risk and first-dollar sharing in Track 1;
9. removal of the 25 percent withhold of shared savings;
10. *greater flexibility in timing for the evaluation of sharing savings* (claims run-out reduced to 3 months);
11. greater flexibility in antitrust review;
12. greater flexibility in timing for repayment of losses; and
13. *additional options for participation of Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs)* by specifically allowing these entities to form their own ACOs. In order for this to be possible, in this final rule we are making modifications to the proposed assignment process to recognize the different payment methodologies and claims data that are used by FQHCs and RHCs as compared to the payment methodologies and claims data that are available for physician offices/clinics that are paid under the physician fee schedule. As a result, under the policies established in this final rule, FQHCs and RHCs will be eligible to form ACOs and may also be ACO participants in ACOs formed by other entities. Additionally, Medicare enrolled entities may join independent FQHCs, RHCs, and method II billing CAH ACOs.

General Requirements

Accountability for Beneficiaries.

CMS finalized its policy regarding certification of accountability for beneficiaries described in (76 FR 19544) as proposed without change (§425.100 and 425.204).

Agreement Requirement

CMS finalized its proposal regarding agreements as described previously under §425.208 and §425.210. Further, as described in §425.200, the ACO's agreement period will be for not less than 3 years, consistent with statute, although some agreement periods may be longer than 3 years.

Sufficient number of Primary Care Providers and Beneficiaries

CMS finalized its proposals without change (§425.110).

Identification and Required Reporting on Participating ACO Professionals.

CMS finalized its proposals regarding operational definition of an ACO as a collection of Medicare-enrolled TINs, the obligation of the ACO to identify their ACO participant TINs and NPIs on the application, the obligation of the ACO to update the list, and the required exclusivity of ACO participants upon whom assignment is based without change under sections 425.20, 425.204(5), 425.302(d), 425.306, respectively. CMS clarifies that ACO participants upon which beneficiary assignment is not dependent are not required to be exclusive to a single Medicare Shared Savings Program ACO. This final exclusivity policy extends to the ACO participant TINs of FQHCs, RHCs and ACO participants that include NP, PAs, and specialists upon which beneficiary assignment will be dependent under the revised assignment methodology discussed in section II.E. of this final rule.

Additional comments from the rule in this area:

Not proscriptive in the providers required. CMS does not believe that it should be prescriptive in setting any requirements for the number, type, and location of the providers/suppliers that are included as ACO participants. Unlike managed care models that lock in beneficiaries to a network of providers, beneficiaries assigned to an ACO may receive care from providers and suppliers both inside and outside the ACO. ACOs represent a new model for the care of FFS beneficiaries and for practitioners to focus on coordination of care efforts.

Non-Exclusive ACO providers. Therefore, under our proposal, ACO participants upon which beneficiary assignment was not dependent (for example, acute care hospitals, surgical and medical specialties, RHCs, and FQHCs) would be required to agree to participate in the Medicare ACO for the term of the agreement, but would not be restricted to participation in a single ACO. The point of our proposal was that, for us to appropriately evaluate ACO performance, CMS must evaluate performance based on a patient population unique to the ACO. Therefore, some ACO participants, specifically those that bill for the primary care services on which CMS proposed to base assignment, would have to be exclusive to an ACO, for the purpose of Medicare beneficiary assignment, for the duration of an agreement period. In the absence of such exclusivity and in a situation where an ACO participant is associated with two or more ACOs, it would be unclear which ACO would receive an incentive payment for the participant's efforts on behalf of its

assigned patient population. . . . It does not necessarily require exclusivity of each primary care physician (ACO provider/supplier) whose services are the basis for such assignment. For example, exclusivity of an ACO participant leaves individual NPIs free to participate in multiple ACOs if they bill under several different TINs. Similarly, an individual NPI can move from one ACO to another during the agreement period, provided that he or she has not been billing under an individual TIN. A member of a group practice that is an ACO participant, where billing is conducted on the basis of the group's TIN, may move during the performance year from one group practice into another, or into solo practice, even if doing so involves moving from one ACO to another. This degree of flexibility is, in fact, one reason for our preference to use TINs to identify ACO participants over NPIs.

TIN Exclusivity. We are therefore finalizing our proposal that each ACO participant TIN is required to commit to an agreement with us. In addition, each ACO participant TIN upon which beneficiary assignment is dependent must be exclusive to one ACO for purposes of the Shared Savings Program. ACO participant TINs upon which beneficiary assignment is not dependent are not required to be exclusive to a single ACO for purposes for the Shared Savings Program. . . We are also providing for consideration of the primary care services provided by specialist physicians, PAs, and NPs in the assignment process subsequent to the identification of the "triggering" physician primary care services. We are therefore also extending our exclusivity policy to these ACO participants. That is, the TINs under which the services of specialists, PAs, and NPs are included in the assignment process would have to be exclusive to one ACO for purposes of the Shared Savings Program.

Eligible participants

CMS finalized its proposals for identifying groups of providers of services and suppliers that may join to form an ACO under §425.102. Specifically, the entities identified in section 1899(b)(1)(A) through (D) of the Act will be able to form ACOs, provided they meet all other eligibility requirements. Additionally, CAHs billing under method II, FQHCs, and RHCs may also form independent ACOs if they meet the eligibility requirements specified in this final rule. In addition, any Medicare enrolled entities not specified in the statutory definition of eligible entities in section 1899(b)(1)(A)-(D) of the Act can participate in the Shared Savings Program as ACO participants by joining an ACO containing one or more of the organizations eligible to form an ACO. Additionally, in response to comments and after further consideration of the available information, CMS has established a process by which primary care services furnished by FQHCs and RHCs will be included in the assignment process, as discussed in section II.E. of the final rule. As a result, FQHCs and RHCs will also be able to form ACOs independently, provided they meet all other eligibility requirements.

Legal Structure and Governance

Legal Entity

CMS finalized its proposal that an ACO must be a legal entity for purposes of all program functions identified in this final rule. CMS is also finalizing commenters' suggestion that ACOs licensed under Federal or tribal law are eligible to participate in the Shared Savings Program. In addition, an ACO

formed among multiple ACO participants must provide evidence in its application that it is a legal entity separate from any of its ACO participants. (§425.104)

Distribution of Shared Savings

CMS finalized its proposals under §425.204(d) without change.

Additional comments from the rule in this area:

We will make any shared savings payments directly to the ACO as identified by its TIN. As explained in the proposed rule, the statute does not specify how shared savings must be distributed, only that the ACO be a legal entity so that the ACO can accept and distribute shared savings. We do not believe we have the legal authority to dictate how shared savings are distributed, however, we believe it would be consistent with the purpose and intent of the statute to require the ACO to indicate as part of its application how it plans to use potential shared savings to meet the goals of the program. Consistent with the discussion found later in this final rule regarding the shared governance of an ACO, we anticipate that ACO participants would negotiate and determine among themselves how to equitably distribute shared savings or use the shared savings to meet the goals of the program.

Governance

An ACO must maintain an identifiable governing body with authority to execute the functions of the ACO as defined in this final rule, including but not limited to, the definition of processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinating care. The governing body must have responsibility for oversight and strategic direction of the ACO, holding ACO management accountable for the ACO's activities. The governing body must have a transparent governing process. The governing body members shall have a fiduciary duty to the ACO and must act consistent with that fiduciary duty. The ACO must have a conflicts of interest policy for the governing body. The ACO must provide for meaningful participation in the composition and control of the ACO's governing body for ACO participants or their designated representatives. (§425.106). CMS will finalize its proposal to require 75 percent control by ACO participants that are Medicare-enrolled TINs. CMS declines, as previously discussed, to require how the voting control will be apportioned among ACO participants.

Additional comments from the rule in this area:

State pre-emption. To clarify, we are not preempting any State laws or State law requirements in this final rule. To the extent that State law affects an ACO's operations, we expect the ACO to comply with those requirements as an entity authorized to conduct business in the State. We do not believe it is necessary to make ACOs attest to do what they otherwise would be required to do under State law.

Composition of the governing body

CMS finalized its proposals that at least 75 percent control of the ACO's governing body must be held by the ACO's participants. The governing body of the ACO must be separate and unique to the ACO in the cases where the ACO comprises multiple, otherwise independent entities that are not under common control (for example, several independent physician group practices). However, the members of the governing body may serve in a similar or complementary manner for a participant in the ACO. Each ACO

should provide for beneficiary representation on its governing body. In cases in which the composition of an ACO's governing body does not meet the 75 percent ACO participant control threshold or include the required beneficiary governing body representation, the ACO must describe why it seeks to differ from the established requirements and how the ACO will involve ACO participants in innovative ways in ACO governance and/or provide for meaningful participation in ACO governance by Medicare beneficiaries. (§425.106).

Leadership and management structure

CMS finalized the requirement that the ACO's operations be managed by an executive, officer, manager, or general partner, whose appointment and removal are under the control of the organization's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency, processes, and outcomes.

In addition, clinical management and oversight must be managed by a senior-level medical director who is one of the ACO's physicians, who is physically present on a regular basis in an established ACO location, and who is a board-certified physician and licensed in one of the States in which the ACO operates.

Processes to Promote Evidence-Based Medicine, Patient Engagement, Reporting, Coordination of Care, and Demonstrating Patient Centeredness

CMS finalized its proposal requiring that in order to be eligible to participate in the Shared Savings Program, the ACO must provide documentation in its application describing its plans to: (1) promote evidence-based medicine; (2) promote beneficiary engagement; (3) report internally on quality and cost metrics; and (4) coordinate care. As part of these processes, an ACO shall adopt a focus on patient-centeredness that is promoted by the governing body and integrated into practice by leadership and management working with the organization's health care teams. These plans must include how the ACO intends to require ACO participants and ACO providers/suppliers to comply with and implement each process (and sub element thereof), including the remedial processes and penalties (including the potential for expulsion) applicable to ACO participants and ACO providers/suppliers for failure to comply. In addition, these plans must describe how such processes will include provisions for internal assessment of cost and quality of care within the ACO and how the ACO would employ these assessments in continuous improvement of the ACO's care practices. (§425.112).

Overlap with CMS Innovation Center Shared Savings Initiative

Duplication in Participation in the Shared Savings Programs

CMS identified several current initiatives in which ACO participants receive shared savings such that they would be prohibited from participation in the Shared Savings Program: Independence at Home, the MHCQ IHIE and NCCCN demonstrations, MAPCP arrangements involving shared savings, PGP Transition demonstration, the Care Management for High-Cost Beneficiaries Demonstrations, and the Pioneer ACO Model through the Innovation Center. CMS recognizes, however, that there may be other demonstrations or programs that will be implemented or expanded as a result of the Affordable Care Act, some in the near future. CMS will update its list of duplicative shared savings efforts periodically to inform prospective Shared Savings Program participants and as part of the application. Additionally, CMS is finalizing a proposal to implement a process for ensuring that savings associated with beneficiaries assigned to an ACO participating in the Shared Savings Program are not duplicated by savings earned in another Medicare program or demonstration involving shared savings. Specifically,

applications for participation in the Shared Savings Program will be reviewed carefully to assess for overlapping TINs. TINs that are already participating in another Medicare program or demonstration involving shared savings will be prohibited from participating in the Medicare Shared Savings Program. An ACO application that contains TINs that are already participating in another Medicare program or demonstration involving shared savings will be rejected.

If the other program or demonstration involving shared savings does not assign beneficiaries based upon the TINs of the health care providers from whom they receive care, but uses an alternate beneficiary assignment methodology, CMS will work with the developers of the respective demonstrations and initiatives to devise an appropriate method to ensure no duplication in shared savings payment. For example, billing TINs who are participating in the Pioneer ACO Model would be prohibited from also participating in the Shared Savings Program. Additionally, since the Pioneer ACO Model may begin before the Shared Savings Program and assigns beneficiaries prospectively, CMS will work with the Innovation Center to ensure no beneficiaries used to determine shared savings are assigned to both (§425.114).

Transition of the PGP Demonstration Sites into the Shared Savings Program. CMS finalized its proposals without change (§425.202). Thus, the PGP sites will not be permitted to participate concurrently in the Shared Savings Program.

Overlap with the Innovation Center Shared Savings Models

CMS finalized its proposal to exclude Pioneer ACO Model participants from participation in the Shared Savings Program. Additionally, since the Pioneer ACO Model may begin before the Shared Savings Program and will and assign beneficiaries prospectively, CMS will work with the Innovation Center to ensure no beneficiaries used to determine shared savings are assigned to both (§425.114).

Establishing the Agreement with the Secretary

Options for the Start Date of the Performance Year

As specified in §425.200, for the first year of the Shared Savings Program (CY 2012), ACOs will be afforded the flexibility to submit to begin participation in the program on April 1 (resulting in an agreement period of 3 performance years with the first performance year of the agreement consisting of 21 months) or July 1 (resulting in an agreement period of 3 years with the first performance year of the agreement consisting of 18 months). During all calendar years of the agreement period, including the partial year associated with both the April 1, 2012 and July 1, 2012 start dates, the eligible providers participating in an ACO that meets the quality performance standard but does not generate shareable savings will qualify for a PQRS incentive payment (as described in sections II.F. of this final rule and §425.504).

Timing and Process for Evaluating Shared Savings

Based upon CMS' review of the public comments received on the proposed policy, CMS is finalizing a policy, under §425.602, §425.604, and §425.606 of using 3-months of claims run-out data, with the application of an appropriate completion percentage, to calculate the benchmark and per capita expenditures for the performance year. CMS will monitor ACO providers and suppliers for any deliberate delay in submission of claims that would result in an unusual increase in the claims incurred during the performance year, but submitted after, the 3 month run-out period immediately following each

performance year, and as discussed in section II.H. of this final rule, will consider such deliberate behavior grounds for termination.

New program Standards Established During the Agreement Period

Under §425.212 CMS will finalize its proposal that ACOs be held responsible for all regulatory changes in policy, with the exception of: eligibility requirements concerning the structure and governance of ACOs, calculation of sharing rate, and beneficiary assignment. However, CMS will modify its proposal to allow ACOs the flexibility to voluntarily terminate their agreement in those instances where regulatory standards are established during the agreement period which the ACO believes will impact the ability of the ACO to continue to participate in the Shared Savings Program.

Managing significant Changes to the ACO During the Agreement Period

Under §425.214, CMS is modifying its proposal so that ACO participants and ACO providers/suppliers may be added and subtracted over the course of the agreement period. ACOs must notify us of the change within 30 days of these additions/subtractions of ACO participants or providers/suppliers. Additionally, in the event of "significant changes", which is defined as an event that occurs resulting in an ACO being unable to meet the eligibility or program requirements of the Shared Savings Program, the ACO must also notify us within 30 days. Such changes may necessitate, for example, adjustments to the ACO's benchmark, but allow the ACO to continue participating in the Shared Savings Program. Such changes may also cause the ACO to no longer meet eligibility, for example, losing a large primary care practice could cause the ACO assignment to fall below 5,000, and result in termination of the agreement.

Coordination with Other Agencies

Waivers of CMP, Anti-Kickback, and Physician Referral Laws

Comments received in response to the April 2011 proposed rule directed toward the joint CMS and DHHS OIG solicitation will be responded to in the interim final rule with comment period. CMS encourages reader review of the interim final rule.

IRS Guidance Relating to Tax-Exempt Organizations Participating in ACOs

CMS also received comments relating to the tax treatment of ACOs. Tax issues are within the jurisdiction of IRS, not CMS. Accordingly, those issues are not addressed in this Final Rule but it has shared the relevant comments with IRS.

Antitrust Policy Statement

See later in rule.

Coordinating the Shared Savings Program Applications with Antitrust Agencies

In sum, CMS is modifying its proposal. CMS finds that the voluntary expedited review approach discussed previously, coupled with the Antitrust Agencies' traditional law enforcement authority and CMS' collaborative efforts to share data and information with the Antitrust Agencies, will allow ACOs a reasonable opportunity to obtain guidance regarding their antitrust risk in an expedited fashion, while also providing appropriate safeguards so that potential or actual anticompetitive harm can be identified and remedied. CMS is finalizing the policies at §425.202. However, the agency will continue to review these policies and adjust them accordingly as it gains more experience with the Shared Savings Program.

Provision of Aggregate and Beneficiary Identifiable Data

Data sharing

No major changes.

Sharing Aggregate Data

CMS finalized without change its proposals related to sharing of aggregate data (see part 425 subpart H in regulatory text of this final rule).

Identification of Historically Assigned Beneficiaries

CMS is finalizing its proposal to provide the ACO with a list of beneficiary names, dates of birth, sex, and HICN derived from the beneficiaries whose data was used to generate the preliminary prospective aggregate reports (Subsection H). CMS is modifying its proposal to provide similar information in conjunction with each quarterly aggregated data report, based upon the most recent 12 months of data, consistent with the time frame listed in the proposed rule.

Sharing Beneficiary Identifiable Claims Data

No major changes.

Giving Beneficiaries the Opportunity to Decline Data Sharing

CMS will finalize its proposal in 425.704, to allow ACOs to request beneficiary identifiable data on a monthly basis. Additionally, CMS is modifying this proposal in §425.708 to allow the ACO the option of contacting beneficiaries from the list of preliminarily prospectively assigned beneficiaries in order to notify them of the ACO's participation in the program and their intent to request beneficiary identifiable data. If, after a period of 30 days from the date the ACO provides such notification, neither the ACO nor CMS has received notification from the beneficiary to decline data sharing, the ACOs would be able to request beneficiary identifiable data. The ACO would be responsible for repeating the notification and opportunity to decline sharing information during the next face-to-face encounter with the beneficiary in order to ensure transparency, beneficiary engagement, and meaningful choice. CMS notes that if a beneficiary declines to have their claims data shared with the ACO, this does not preclude physicians from sharing medical record information as allowed under HIPAA amongst themselves, for example, a referring primary care physician providing medical record information to a specialist.

Assignment of Medicare Fee-for-Service Beneficiaries

Assignment of Medicare Fee-for-Service Beneficiaries

CMS is finalizing its proposed policies concerning the eligibility of Medicare FFS beneficiaries for assignment to an ACO under the Shared Savings Program. Specifically, as required by the statute, and consistent with the definition of Medicare fee-for-service beneficiary in §425.20, under §425.400(a) only individuals enrolled in the original Medicare fee-for-service program under parts A and B, and not enrolled in an MA plan under Part C, an eligible organization under section 1876 of the Act, or a PACE program under section 1894 of the Act, can be assigned to an ACO.

Definition of Primary Care Services

CMS is finalizing its proposal to define "primary care services" in § 425.20 as the set of services identified by the following HCPCS codes: 99201 through 99215, 99304 through 99340, 99341 through 99350, the Welcome to Medicare visit (G0402), and the annual wellness visits (G0438 and G0439) as primary care services for purposes of the Shared Savings Program. In addition, CMS will establish a cross-walk for these codes to certain revenue center codes used by FQHCs (prior to January 1, 2011) and RHCs so that their services can be included in the ACO assignment process.

Consideration of Physician Specialties in the Assignment Process

Under §425.402, after identifying all patients that had a primary care service with a physician who is an ACO provider/supplier in an ACO, CMS will employ a stepwise approach as the basic assignment methodology. Under this approach, beneficiaries are first assigned to ACOs on the basis of utilization of primary care services provided by primary care physicians. Those beneficiaries who are not seeing any primary care physician may be assigned to an ACO on the basis of primary care services provided by other physicians. This final policy thus allows consideration of all physician specialties in the assignment process. CMS describes this step-wise approach in greater detail later in this final rule, after further addressing other related issues, including consideration of primary care services furnished by non-physician practitioners, such as NPs and PAs. As also discussed later in this final rule, CMS will also consider only the specific procedure and revenue codes designated in this final rule in the assignment process.

Consideration of Services Furnished by Non-Physician Practitioners in the Assignment Process

Therefore, under §425.402 of this final regulation CMS is adopting the following step-wise process for beneficiary assignment. CMS' final step-wise assignment process takes into account the two decisions that CMS has just described: (1) its decision to base assignment on the primary care services of specialist physicians in the second step of the assignment process; and (2) its decision also to take into account the plurality of all primary care services provided by ACO professionals in determining which ACO is truly responsible for a beneficiary's primary care in second step of the assignment process. CMS' final step-wise assignment process will thus occur in the following two steps, after identifying all patients that received a primary care service from a physician who is a provider/supplier in the ACO (and who are thus eligible for assignment to the ACO under the statutory requirement to base assignment on "utilization of primary care services"):

Step 1: CMS will identify beneficiaries who had received at least one physician primary care service from a primary care physician who is a provider/supplier in an ACO. In this step, a beneficiary can be assigned to an ACO only if he or she has received at least one primary care service from a primary care physician who is an ACO provider/supplier in the ACO during the most recent year (for purposes of preliminary prospective assignment, as discussed later in this final rule), or the performance year (for purposes of final retrospective assignment). If this condition is met, the beneficiary will be assigned to the ACO if the allowed charges for primary care services furnished by primary care physicians who are providers/suppliers of that ACO are greater than the allowed charges for primary care services furnished by primary care physicians who are providers/suppliers of other ACOs, and greater than the allowed charges for primary care services provided by primary care physicians who are unaffiliated with any ACO (identified by Medicare-enrolled TINs or other unique identifiers, as appropriate).

Step 2: This step would consider only beneficiaries who have not received any primary care services from a primary care physician either inside or outside the ACO. Under this step a beneficiary will be assigned to an ACO only if he or she has received at least one primary care service from any physician (regardless of specialty) in the ACO during the most recent year (for purposes of preliminary prospective assignment), or the performance year (for purposes of final retrospective assignment). If this condition is met, the beneficiary will be assigned to an ACO if the allowed charges for primary care services furnished by ACO professionals who are ACO providers/suppliers of that ACO (including specialist physicians, NPs, PAs, and CNSs), are greater than the allowed charges for primary care services furnished by ACO professionals who are ACO providers/suppliers of each other ACO, and greater than the allowed charges for primary care services furnished by any other physician, NP, PA, or CNS, (identified by Medicare-enrolled TINs or other unique identifiers, as appropriate) who is unaffiliated with any ACO.

Assignment of Beneficiaries to ACOs that Include FQHCs and/or RHCs

In §425.404, CMS is modifying the policy that it proposed in response to comments to establish a beneficiary assignment process that will allow primary care services furnished in FQHCs and RHCs to be considered in the assignment process for any ACO that includes an FQHC and/or RHC. (These changes to the assignment process will also allow FQHCs and RHCs to form ACOs independently, without the participation of other types of eligible entities.) Operationally CMS will assign beneficiaries to ACOs that include FQHCs/RHCs in a manner consistent with how CMS will assign beneficiaries to other ACOs based on primary care services performed by physicians as previously described.

CMS will require that an ACO that include FQHCs and/or RHCs to provide it, through an attestation, with a list of the physician NPIs that provide direct patient primary care services in an FQHC or RHC. This attestation will be part of the application process for all ACOs that include FQHCs and/or RHCs as ACO participants. CMS will then use the combination of the ACO's TINs (or other unique identifiers, where appropriate) and these NPIs provided to CMS through the attestation process to identify beneficiaries who receive a primary care service in an FQHC or RHC from a physician, and to assign those beneficiaries to the ACO if they received the plurality of their primary care services, as determined based on allowed charges for the HCPCS codes and revenue center codes listed in the definition of primary care services, from ACO providers/suppliers.

Prospective vs. Retrospective Beneficiary Assignment to Calculate Eligibility for Shared Savings

Under §425.400 of this final regulation, CMS is revising its proposed policy to provide for prospective assignment of beneficiaries to ACOs in a preliminary manner at the beginning of a performance year based on most recent data available. Assignment will be updated quarterly based on the most recent 12 months of data. Final assignment is determined after the end of each performance year based on data from that year. CMS is also finalizing a proposal that beneficiary assignment to an ACO is for purposes of determining the population of Medicare FFS beneficiaries for whose care the ACO is accountable, and for determining whether an ACO has achieved savings, and in no way diminishes or restricts the rights of beneficiaries assigned to an ACO to exercise free choice in determining where to receive health care services. Beneficiaries assigned to ACOs under the Shared Savings Program retain their full rights as Medicare fee-for-service beneficiaries to seek and receive services from the physicians and other medical practitioners of their choice. No exclusions or restrictions based on health conditions or similar factors will be applied in the assignment of Medicare FFS beneficiaries. CMS is also finalizing its proposal to determine assignment to an ACO under the Shared Savings Program based on a statistical determination of a beneficiary's utilization of primary care services, rather than on a process of

enrollment or "voluntary selection" by beneficiaries. The specific methodology (the "step-wise" approach) is described in §425.402. In that methodology, CMS is also finalizing its proposal to assign beneficiaries to no more than one ACO.

Majority vs. Plurality Rule for Beneficiary Assignment

In §425.402, CMS finalized its proposal to adopt a plurality of primary care services, defined in terms of allowed charges, as the basis for assignment. However, it is modifying the way in which the agency will calculate that plurality in order to apply it in the two-step assignment process, as described previously.

Quality and Other Reporting Requirements

Measures to Assess the Quality of Care Furnished by an ACO

After considering commenter concerns, CMS has finalized 33 of the 65 proposed quality measures. The measures include a mix of both process and outcome measures, including patient experience of care, although CMS intends to move to more outcomes-based measures and fewer process measures over time. Of the 33 measures, only 23 are scoreable, as the measures as part of the patient experience survey modules are scored as 1 measure and the all or nothing diabetes and CAD measures are scored as 1 measure each.

CMS states that it has removed those measures that were perceived as redundant, operationally complex, or burdensome. Those that remain focus on priority areas and are areas of high prevalence and high cost in the Medicare population, and also align with measures in other programs. CMS notes that it intends to use claims and administrative data to monitor the quality of care furnished by ACOs in an effort to identify patterns of avoiding at-risk beneficiaries and misuse, underuse, and overuse of services over time.

As ACOs will be accountable for all care received by their assigned beneficiary population, quality measures will reflect the care assigned beneficiaries receive from ACO providers and non-ACO providers. CMS will use claims data submitted by the ACO providers/suppliers as well as from providers outside the ACO in determining measure numerators and denominators.

CMS also explains that ACOs will also be required to comply with any measures updates made in future rulemaking as clinical guidelines change and as other programs update their measure requirements. CMS notes that, as it gains experience with the program and develops better understanding of the types of measures that are most important to assess the quality of care furnished by this new type of entity, it will add or remove measures from the Shared Savings Program.

Specific to risk-adjustment, CMS notes that risk adjustment is included for a number of the proposed measures and that other measures include specific exclusions for patients, such as those in hospice, who may not benefit from an action targeted by the measure. CMS explains that ACO payments are specifically linked to accurate reporting and that the quality performance standard must be met in order for an ACO to be considered eligible for shared savings, which CMS expects will provide a strong incentive for complete and accurate reporting. However, rather than transition all measures from pay for reporting to pay for performance in the second performance year of the ACO agreement period as proposed, CMS will transition only a portion of the measures to pay for performance in the second performance year, and then all but one of the measures to pay for performance in the third

performance year. CMS may audit the quality measures data ACOs enter into the GPRO web interface by requiring the ACO to share beneficiary medical record information with CMS.

With respect to patient experience, CMS believes that patients' perception of their care experience reflects important aspects of the quality of the care they receive but may not be adequately captured by other measures. Therefore CMS has finalized the use of the Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS) survey and have agreed to pay for the first two years of the survey in 2012 and 2013. Starting in 2014, ACOs participating in the Shared Savings Program must select a survey vendor (from a list of CMS-certified vendors) and will pay that vendor to administer the survey and report results using standardized procedures developed by CMS. CMS will develop and refine these standardized procedures over the next 18 to 24 months.

In addition, CMS intends to add an Access to Specialists module in order to emphasize the importance of specialty care for patients served by the ACO. CMS maintains that this action will complement the programs focus on care coordination and its monitoring activities to ensure ACOs are not engaged in practices to avoid at risk patients.

Requirements for Quality Measures Data Submission by ACOs

CMS has finalized its proposal to use survey based measures, claims and administrative data based measures, and the GPRO web interface as a means of ACO quality data reporting for certain measures. CMS also states that it will retain the right to validate the data ACOs enter into the GPRO web interface.

Specific to reporting periods, CMS states that all quality measures will have a 12-month, calendar year reporting period, regardless of ACO start date, and that additional information about the specifications will be made shortly in a sub-regulatory guidance.

Quality Performance Standards

CMS recognized that achieving the quality performance standard on 33 out of 33 measures would be challenging, particularly in the early years. To that end, CMS has modified its proposed requirement to state that ACOs must achieve the quality performance standard on 70 percent of the measures in each domain. Failure to meet this requirement will prompt the ACO to be placed on a corrective action plan. Underperformance in the following year would cause CMS to terminate the agreement with the ACO.

This approach would allow an ACO to fail one or more individual measures in each domain measure and still earn shared savings. However, in any year that an ACO scores a zero for an entire measure domain, it would not be eligible to share in any savings generated. ACOs that exhibit a pattern of inaccurate or incomplete reporting or fail to make timely corrections following notice to resubmit quality data may be terminated from the program, and would therefore be disqualified from sharing in savings.

In addition, 100 percent reporting of the quality measures in the first year of the Shared Savings Program will result in an ACO earning 50 or 60 percent of shareable savings, depending on whether the ACO is in the one-sided or two-sided model. For future performance periods, the percent of potential shareable savings will vary based on the ACO's performance on the measures as compared with the measure benchmarks as CMS phases in the pay for performance measures.

CMS has also established minimum attainment level for each measure at a national flat 30 percent or the national Medicare FFS or MA 30th percentile level of performance. ACOs will have to score at or above the minimum attainment level in order to receive any credit for reporting the quality measure.

Finally, CMS finalized its proposal to scoring individual measures in each domain in pay for performance years. Based on their level of performance on each measure an ACO would earn a corresponding number of points, and the total points earned for measures in each domain would be summed and divided by the total points available for that domain to produce an overall domain score of the percentage of points earned versus points available.

CMS will weight each of the 4 measure domains (patient/caregiver experience, care coordination/patient safety, preventive health, and at-risk population) equally at 25 percent for purposes of determining an ACO's overall quality performance score, which will ultimately be applied to the maximum sharing rate under either the one-sided or two-sided model to determine the ACOs final sharing rate for purposes of determining its shared savings payment or share of losses.

Reporting Requirements Related to the PQRS and Electronic Health Records Technology

CMS finalized its proposal to incorporate PQRS reporting requirements and incentive payment under the Shared Savings Program. Specifically, CMS finalized the use of the GPRO web interface, as proposed, as well as its proposal that EPs that are ACO providers/suppliers constitute a group practice under their ACO participant TIN for purposes of qualifying for a PQRS incentive under the Shared Savings Program. Therefore, an ACO, on behalf of its EPs, is required to satisfactorily submit quality data on the GPRO quality measures. EPs within an ACO may qualify for a PQRS incentive under the Shared Savings Program only as a group practice and not individuals. ACO participants and ACO providers/suppliers also may not seek to qualify for the PQRS incentive under traditional PQRS, outside of the Shared Savings Program.

In addition, CMS intends that reporting on the GPRO quality measures under the Shared Savings Program will also fulfill the reporting requirements for purposes of avoiding the payment adjustment under section 1848(a) of the Act that begins in 2015, which CMS will discuss in detail in a future rulemaking.

EPs within an ACO participant TIN that satisfactorily report the ACO GPRO measures during the reporting period will qualify under the Shared Savings Program for a PQRS incentive equal to 0.5 percent of the Secretary's estimate of total Medicare Part B PFS allowed charges for covered professional services furnished by the ACO's EPs during the first reporting period.

Also, ACO participant TINs in ACOs that meet the satisfactory reporting requirements will still be eligible for a PQRS incentive payment under the Shared Savings Program, even if the ACO does not generate shareable savings for the Shared Savings Program.

ACOs are eligible to qualify for the PQRS incentive under the Shared Savings Program to the extent that they contain EPs; however, not all ACO participants will necessarily be eligible for the PQRS incentive under the Shared Savings Program. In addition, and similar to traditional PQRS, an EP cannot qualify for the PQRS incentive as both a group and as an individual under the same TIN.

While EPs in ACOs may still separately participate in the EHR Incentive Program or eRx Incentive Program, CMS did not finalize its proposal to require that at least 50 percent of an ACO's primary care physicians be determined to be "meaningful EHR users" by the start of the second performance year in order to continue participation in the Shared Savings Program. Instead CMS has doubled weight the quality measure "Percent of PCPs who Successfully Qualify for an EHR Incentive Program Payment," to stress the importance of EHR adoption among ACOs.

Finally, CMS has aligned the Shared Savings Program quality measures reporting requirements with those in other programs, to the extent possible.

Shared Savings and Losses

CMS has finalized its proposal to offer ACOs a choice of two tracks: *shared savings only* under Track 1, and *shared savings and losses* under Track 2. Track 1 will be a shared savings only model for the duration of the ACO's first agreement period. ACOs electing Track 2 will be under the two-sided model for the duration of their first agreement period. All ACOs must participate in the two-sided model in agreement periods subsequent to the initial agreement period. ACOs that experience a net loss during their first agreement period will also be able to apply and participate in a subsequent agreement period, so long as they identify in their application the cause(s) for the net loss and to specify what safeguards are in place to enable the ACO to potentially achieve savings in its next agreement period. CMS will monitor closely this aspect of the program, and may revise its policy future rulemaking.

Shared Savings and Losses Determination

CMS will establish an ACO's initial benchmark based on the Parts A and B FFS expenditures of beneficiaries who would have been assigned to the ACO in any of the 3 years prior to the start of the ACO's agreement period using the ACO participants' TINs identified at the start of the agreement period. Benchmark expenditures will be calculated by categorizing beneficiaries in cost categories, which will apply to all ACOs. CMS will also truncate an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for each benchmark and performance year; weight the most recent year of the benchmark, BY3, at 60 percent, BY2 at 30 percent and BY1 at 10 percent; and reset the benchmark at the start of each agreement period.

Adjusting the Benchmark and Actual Expenditures

CMS will risk adjust an ACO's historical benchmark expenditures using the CMS Hierarchal Condition Category (CMS-HCC) model. CMS will make additional risk adjustments to performance year assigned beneficiaries instead of capping growth in risk adjustments during the term of the agreement at zero percent. For newly assigned beneficiaries, CMS will annually update an ACO's CMS-HCC prospective risk scores, to take into account changes in severity and case mix. CMS will use demographic factors to adjust for severity and case mix for the continuously assigned population relative to the historical benchmark. Should the assigned population shows a decline in its CMS-HCC prospective risk scores, CMS will lower the risk score for this population and the ACO's updated benchmark will be restated in the appropriate performance year risk relative to the risk profile of the performance year assigned beneficiaries. Additional adjustments will be made for ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

With respect to coding, CMS will monitor and evaluate the issue of more complete and accurate coding for future rule making and to use an audit process to assure the appropriateness of ACO coding practices and to adjust ACO risk scores. CMS will also monitor HCC scores for beneficiaries assigned in the prior year that are not assigned in the current performance year, and may make a more explicit adjustment for this population in future rule making.

CMS will include all Parts A and B expenditures, with the exception of IME and DSH adjustments, in the calculation of the benchmark and performance year expenditures.

Updating the Benchmark

CMS will update the benchmark by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program using data from CMS' Office of the Actuary. Further, in updating the benchmark, CMS will make calculations for separate cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible and aged/non-dual eligible.

Determining Shared Savings

Minimum Savings Rate (MSR)

CMS intends to use a sliding scale, based on the size of the ACO's assigned population, to establish the MSR for ACOs participating under the one-sided model. CMS will apply a flat 2 percent MSR to all ACOs participating under the two-sided model.

Quality Performance Sharing Rate

Again, ACOs under the one-sided model can earn up to 50 percent of total savings based on quality performance and ACOs under the two-sided model can earn up to 60 percent of total savings based on quality performance.

Additional Shared Savings Payments

CMS will not use a sliding scale-based increase in the shared savings rate for ACOs that include an FQHC or RHC as an ACO participant, nor will it provide additional financial incentives, beyond those established for quality performance, for the care of dual eligible beneficiaries or other factors related to the composition of the ACO or its activities, nor will the final rule include a preference for ACOs participating in similar arrangements with other payers.

Net Sharing Rate

CMS will allow for sharing on first dollar savings for ACOs under the one-sided model once savings meet or exceed the MSR. Similarly, CMS will allow sharing on a first dollar savings for ACOs under the two-sided model once savings meet or exceed the MSR.

Performance Payment Limits

CMS will raise the payment limit from 7.5 percent to 10 percent of an ACO's updated benchmark for ACOs under the one-sided model and to raise the payment limit from 10 percent to 15 percent of an ACO's updated benchmark for ACOs that elect the two-sided model.

Calculating Sharing in Losses

The shared losses methodology will mirror the shared savings methodology, comprised of: a formula for calculating shared losses based on the final sharing rate, use of a MLR to protect against losses resulting from random variation and a loss sharing limit to provide a ceiling on the amount of losses an ACO would be required to repay.

Minimum Loss Rate

CMS will apply a MLR for the two-sided model. To be responsible for sharing losses with the Medicare program, an ACO's average per capita Medicare expenditures for the performance year must exceed its updated benchmark costs for the year by at least 2 percent. Once losses meet or exceed the MLR, an ACO would be responsible for paying the percentage of excess expenditures, on a first dollar basis, up to the proposed annual limit on shared losses.

Shared Loss Rate

The shared loss rate for an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark will be determined based on the inverse of its final sharing rate based on quality performance (that is, 1 minus the shared savings rate). In addition, an ACO's shared loss rate will be subject to a cap of 60 percent consistent with the maximum rate for sharing savings.

Limits on Shared Losses

The amount of shared losses for which an eligible ACO is liable may not exceed the following percentages of its updated benchmark: 5 percent in the first performance year of participation in a two-sided model under the Shared Savings Program, 7.5 percent in the second performance year, and 10 percent in the third performance year. In addition, and as a result of CMS' decision to eliminate the requirement for ACOs under the one-sided model to accept risk in their third performance year, CMS did not finalize a provision regarding the limits on shared losses for ACOs transitioning from the one-sided to two-sided model.

Repayment of Shared Losses

With respect to repayment, CMS will allow ACOs flexibility to specify their preferred method for repaying potential losses, and how that would apply to ACO participants and ACO providers/suppliers.

ACOs under the two-sided model will be required to demonstrate that it has established a repayment mechanism. One-sided model ACOs requesting interim payment must make a similar demonstration at the time of application. CMS will determine the adequacy of an ACO's repayment mechanism prior to the start of each year under the two-sided model. As proposed, the repayment mechanism must be sufficient to ensure repayment of potential losses equal to at least 1 percent of total per capita Medicare Parts A and B fee-for-service expenditures for assigned beneficiaries based either on expenditures for the most recent performance year or expenditures used to establish the benchmark. If an ACO's repayment mechanism does not enable CMS to fully recoup the losses for a given performance year, CMS will not carry forward unpaid losses into subsequent performance years and agreement periods.

In addition, if an ACO incurs shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

Withholding Performance Payments

CMS has eliminated the 25 percent withhold and the related proposed provision concerning forfeiture of the 25 percent withhold in the event of early termination from the program.

Determining First Year Performance for ACOs beginning April 1 or July 1, 2012

For ACOs with start dates of April 1 or July 1, 2012, reconciliation for the first performance year will occur after the completion of the ACO's first performance year, defined as 21 months for April 1 starters and 18 months for July 1 starters. ACOs must indicate in their application whether they are requesting an interim payment calculation. ACOs that opt for interim payment during their first performance year must demonstrate as part of their application that they have an adequate repayment mechanism in place, consistent with the requirements for two-sided model ACOs. ACOs that generate shared losses under the interim payment calculation must repay such losses within 90 days of notification of losses. Further, any monies determined to be owed by an ACO after first year reconciliation, whether as a result of additional shared losses or an overpayment of shared savings, must be repaid to CMS, in full, within 90 days of receipt of notification.

Additional Program Requirements and Beneficiary Protections

Beneficiary Protections

ACO participants are required to post signs in their facilities indicating their associated ACO provider's/supplier's participation in the Shared Savings Program and to make available standardized written notices developed by CMS to Medicare FFS beneficiaries whom they serve. The standardized written notices must be furnished in settings in which fee-for-service beneficiaries are receiving primary care services.

Additionally, ACOs may choose to provide notification of their participation to the beneficiaries who appear on the preliminary prospective assignment list and quarterly assignment lists.

Also, to minimize beneficiary confusion and reduce burden on ACOs and its ACO providers/suppliers, if an ACO is no longer participates ACOs will not be required to provide beneficiaries notice that the ACO, its ACO participants and its ACO providers/suppliers will no longer be participating in the Shared Savings Program.

CMS explains that it intends to report ACO quality performance GPRO measures on Physician Compare along with the performance of all other PQRS group practices. However, this is contingent upon the final policies regarding public reporting under the PQRS, which will be announced in the CY 2012 Physician Fee Schedule final rule that will be issued later this year. Additional guidance will be made available to ACO's regarding public reporting of the quality performance scores.

Program Monitoring

CMS finalized its proposal to monitor ACO performance and ensure program integrity by undertaking an audit if CMS determines it is necessary. CMS retains the right to terminate an ACO if it is found to have been avoiding at-risk beneficiaries or those who are underperforming on quality performance standards.

Program Integrity Requirements

As it relates to compliance plans, an ACO may coordinate and streamline compliance efforts with those of its ACO participants and ACO providers/suppliers. Compliance plans must be updated periodically to reflect changes in law, including new regulations regarding mandatory compliance plan requirements of the Affordable Care Act. In addition, "probable" violations of law should be reported to law enforcement. Finally, CMS explains that legal counsel to the ACO and the compliance officer must be different individuals. ACOs may use their current compliance officer, who must report directly to the ACO's governing body, provided that the compliance officer is not legal counsel to the existing organization and meets other requirements outlined in the rule.

CMS also finalized its requirement to prohibit ACOs, their ACO participants, their ACO providers/suppliers, from conditioning participation in the ACO on referrals of Federal health care program business to the ACO, its ACO participants, or its ACO providers/suppliers for services they know or should know are being provided to beneficiaries who are not assigned to the ACO. CMS has modified the final rule to prohibit limiting or restricting referrals of patients to ACO participants or ACO providers/suppliers within the same ACO, except that the prohibition does not apply to referrals made by employees or contractors who are operating within the scope of their employment or contractual arrangement to the employer or contracting entity, provided that the employees and contractors remain free to make referrals without restriction or limitation if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner,

or supplier; or the referral is not in the patient's best medical interests in the judgment of the referring party.

Terminating an ACO Agreement

CMS explains that it may terminate an ACO's agreement for non-compliance with the requirements of the Shared Savings Program, which includes maintaining eligibility. Examples include termination for avoidance of at-risk beneficiaries, failure to meet quality performance standards as previously described. CMS also retains the right to terminate an ACO's agreement immediately for violations CMS determine are more serious.

CMS states that it will work with ACOs where appropriate to understand why the noncompliance occurred and work to develop an effective CAP. In addition, and consistent with CMS' proposal to terminate an ACO in the event sanctions or other actions are taken against an ACO, its ACO participants, its ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities, by an accrediting organization, or by a State, Federal, or local government agency, an ACO agreement may be terminated if its providers are excluded by the OIG or have their privileges to participate in Medicare revoked.

Demonstrating meaningful beneficiary participation is a requirement for eligibility and as such, failure to adequately notify beneficiaries of participation in the program would constitute grounds for terminating the ACO.

In addition, if an ACO has violated the antitrust laws or the fraud and abuse authorities (except to the extent these laws are waived by the Secretary under section 1899(f) of the Act), the ACO's eligibility to participate in the Shared Savings Program will have to be reassessed by CMS.

Finally, ACOs may voluntarily terminate and will be required to provide CMS and all of its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities with a 60-day notice of its decision to terminate its participation in the Shared Savings Program. ACOs that terminate their participation agreement early will not share in any savings for the performance year during which it notifies CMS of its decision to terminate the participation agreement because it failed to complete the entire performance year by which CMS calculates shared savings payments (§425.316(c)(5)). ACO's would not be required to notify beneficiaries of the ACO's decision to withdraw from the Shared Savings Program, nor would it be required to forfeit its mandatory proposed 25 percent withhold of shared savings if its agreement is terminated before the term is completed.