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Ober|Kaler ACO Update

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This is part of Ober|Kaler's comprehensive overview of federal agencies' implementation of the Accountable Care Act's ACO and Shared Savings Program provisions: CMS Proposed ACO Implementing Regulations; Antitrust; Fraud and Abuse; Privacy; Tax-Exempt Organizations.

CMS Proposal Provides Framework for ACO and Shared Savings Program Rules

Recently issued regulations and other notices for comments have given health care providers guidance on how to organize and operate accountable care organizations (ACOs) in order to be eligible to receive payments under Medicare's Shared Savings Program. The Affordable Care Act (ACA), signed into law in March 2010, included incentives for the creation of ACOs. Congress established the ACO Shared Savings Program in the ACA to promote accountability of providers to patient populations and to coordinate services under Medicare as well as to encourage providers to make investments in infrastructure and to design care processes for high-quality, efficient service delivery. Almost a year later on March 31, 2011, several federal agencies (CMS, OIG, DOJ, FTC and IRS) jointly announced the release of proposed rule making and guidance regarding the ACO program. The proposed rule and related guidance is expected to remove the existing legal impediments in the

areas of fraud and abuse, antitrust, tax and privacy to allow for the development of ACOs, and provide guidance on such issues as eligibility to participate, governance, legal structure, quality and privacy.

The three goals stressed under the Shared Savings Program are (1) to provide better care to patients with respect to safety, effectiveness, patient-centeredness, timeliness, efficiency and equity; (2) to provide better health for populations through preventive service and education for issues such an substance abuse and physical inactivity; while (3) decreasing the cost of health care and eliminating waste in the system. CMS seeks to move the health care industry towards this patient-centered care approach by adding patients to the governance structure of ACOs, requiring patient satisfaction data and requiring attention to care coordination issues. ACOs will receive shared savings only if they can meet an extensive list of quality standards related to these goals and show actual savings. In addition to the benefit of shared savings that ACOs will receive, CMS will hold ACOs accountable for losses incurred while participating in the Shared Savings Program.

ACOs are the central element of Medicare's Shared Savings Program. As described more fully below, ACOs can take a variety of forms, but include primary care physicians and other types of providers that provide care to Medicare beneficiaries in a way that will control costs. Achieved savings are shared with the providers and suppliers through the ACO organization when quality metrics are also met. In order to implement the ACO and Medicare Shared Savings Program of the ACA, CMS's proposed regulations deal with a wide range of issues critical to the development of ACOs, including their organizational structure and governance, internal operations, contracting obligations with CMS, reimbursement systems for ACOs under the Medicare Shared Savings Program, and quality reporting and monitoring.

Eligibility, Governance and Leadership

ACOs can take a variety of forms, including joint ventures with hospitals; hospitals with employed physicians and physician group practices. An ACO is a legal entity that is recognized under applicable state law, identified by a taxpayer identification number (TIN) and comprised of an eligible group of ACO participants that come together to coordinate and manage care for Medicare beneficiaries. ACO participants are Medicare-enrolled providers or suppliers of services (i.e., hospital, physician group practice). ACOs also include ACO providers/suppliers who provide services to Medicare beneficiaries, which services are billed to Medicare under a Medicare billing number assigned to an ACO participant (i.e., a physician within a group practice). Only certain types of ACO participants are eligible to form ACOs.

Eligibility

The ACA specified certain ACO participants that are eligible to participate in the Shared Savings Program and granted CMS the authority to include other types of ACO participants. CMS chose to expand the list of eligible

ACO participants beyond the statutory mandate to allow for innovation in possible ACO models and to encourage movement away from the current fee-for-service model with the addition of shared savings incentives. CMS chose this open approach despite concerns that the inclusion of other providers would not produce the efficiencies CMS was attempting to incentivize providers to create. (For example, CMS considered that the inclusion of specialists alongside primary care physicians in an ACO might cause inefficiencies such as duplicative or unnecessary lab testing or imaging, but nevertheless included specialists.) Under the ACA and the proposed CMS rule, ACO participants authorized to form an ACO are:

- ACO professionals in group practice arrangements
- Networks of individual practices of ACO professionals
- Partnerships or joint venture arrangements between hospitals and ACO professionals
- Hospitals employing ACO professionals
- Critical Access Hospitals billing under Method II

CMS specifically discussed the ability of Federally Qualified Health Centers (FQHCs) or Rural Health Centers (RHCs) to form their own ACOs and found that there is a lack of reporting of the data elements needed to assign beneficiaries to an FQHC or RHC as an independent ACO. Medicare, however, recognized the value of these entities, especially in rural areas. Consequently, while they may not form their own ACOs, FQHCs and RHCs may be participants along with other Medicare-enrolled providers (such as SNFs) and suppliers. In addition, in recognition of their importance in the health care system, the proposed rule provides for additional incentives for FQHC and RHC participation in an ACO. CMS is seeking comments on whether other provider types should be eligible to independently participate in the Shared Savings Program.

Legal Structure

The formation of an ACO by ACO participants as contemplated under the ACA and the proposed CMS rule seems relatively straightforward. Under the ACA and the proposed CMS rule, an ACO must:

- be a legal entity recognized and authorized to conduct business under applicable state law (e.g., a non-profit or for-profit corporation, limited liability company, general or limited partnership)
- hold a taxpayer identification number (TIN)
- have a governing body under which all ACO participants possess proportionate control over the ACO's decision-making process
- be comprised of an eligible group of ACO participants that work together to manage and coordinate care for Medicare beneficiaries

The legal entity can be a corporation, partnership, limited liability company, foundation or any other entity permitted by state law. While the proposed CMS rule recognizes that currently existing legal entities may serve as ACOs, CMS appears to prefer the formation of new, separate legal entities to serve as ACOs due to concerns with the ability to monitor and audit data and to create quality-centered governance which might be jeopardized if other outside providers/suppliers were to participate in the ACO. CMS is requesting comments on whether another method or structure not proposed in the rule would meet the goal of shared governance and sharing of savings.

The ACO may be one legal entity if it is both financially and clinically integrated and at least 75 percent of the control of the entity's governing body is comprised of representatives of the entity. For example, a hospital that employs ACO professionals, which is one of the entity types authorized by the ACA to form ACOs, may be eligible to participate as an ACO in the Shared Savings Program under its existing legal entity. CMS is concerned that ACO formation would be discouraged by the proposed rule's requirement that all ACOs participating in the Shared Savings Program as an ACO must form a separate entity under state law. As such, CMS is soliciting comments on whether this would be a likely outcome of such a requirement.

CMS is also seeking comments on the requirements for the ACO's legal structure and requests comments on other legal structure requirements that may be suitable, especially in light of the fact CMS is trying to encourage not-for-profits to participate in the Shared Savings Program. ACO participants will need to make substantial monetary and other investments in the ACO entity to meet the requirements for data sharing and the like, and to see any return for ownership interests. At this point, the OIG and CMS are seeking comments regarding the impact of the Anti-kickback statute and Stark law with respect to cost and investment for ACO formation and implementation to assist ACOs in determining the appropriate and compliant legal structure for providers seeking to create an ACO.

Governance

Quality reporting is a well-established part of health care governance. That being said, the CMS proposed rule requires that quality be at the center of ACO governance. Specifically, ACO governing bodies must have the authority to promote evidence-based medicine and patient engagement, report on quality and cost measures and coordinate care within the ACOs. In addition, ACO governing bodies must have "broad" responsibility for administrative, fiduciary and clinical operations, and must include Medicare beneficiaries.

Under the proposed rule, the ACO entity would have a separate and unique governing body (board of directors or board of managers, as appropriate) comprised of all ACO participants or their representatives that (1) provides a mechanism for shared governance and decision-making for all ACO participants and (2) has

authority to execute the statutory functions of the ACO. Each ACO participant must have the appropriate proportionate control over governing body decision making, even if that ACO participant would not independently meet the eligibility requirements to form an ACO (e.g., FQHCs, RHCs and other providers/suppliers). Interestingly, CMS has required that Medicare beneficiaries served by the ACO have board representation as long as no immediate family member has a conflict of interest with the ACO.

In developing the governance requirements for ACOs, CMS sought to make the Shared Savings Program accessible to small and rural providers, and therefore expanded its focus beyond large hospitals and hospital systems, who may already have the infrastructure in place to form an ACO. The proposed rule provides that the ACO participants would have not less than 75 percent control of the governing body, leaving the remaining 25 percent for Medicare beneficiaries served by the ACO and, potentially, representatives of entities that are not enrolled in Medicare, but that provide capital and infrastructure necessary to form an ACO entity and to administer the programmatic requirements of the Shared Savings Program. CMS envisioned allowing other non-Medicare enrolled entities, such as health plans and investment companies, to have ownership interest to help fund the infrastructure needed to monitor and report data. CMS is proposing the 75 percent requirement to ensure that the ACO remains “provider-driven” regardless of the inclusion of other entities and to ensure that such entities do not have control over the entity and potentially allow the focus to be taken away from quality and cost efficiencies.

The proposed CMS rule requires “meaningful commitment” by the participants and ACO providers/suppliers, such as human resources or financial investments. The proposed CMS rule requires that each ACO participant have appropriate representation to meet the goals of the Shared Savings Program, but does not specify how representation and control is shared. An ACO participant whose existing entity is structured in accordance with the proposed CMS rule may use its existing board or governing body, if that governing body already has representation by Medicare beneficiaries. Such an ACO would simply provide evidence in its application of the composition of the governing body.

Leadership

The ACO operations may be managed by either an executive, officer, manager or general partner as long as the removal and appointment of such person or entity is under the control of the governing body and such person is able to provide influence related to the clinical practice. In addition, clinical management and oversight must be managed by a “full-time senior-level” state-licensed, board-certified physician medical director who is physically present at the ACO location. The ACO must have a compliance officer who reports to the board and is separate and apart from the ACO’s legal counsel.

ACOs will be required to have a quality assurance program and process improvement committee to establish quality, cost effectiveness and process and outcome improvement standards. The ACO must have a physician-directed quality program that establishes internal performance standards and holds the ACO providers/suppliers accountable for meeting these standards to improve quality and reduce costs. The ACO would develop evidence-based medical practice or clinical guidelines and processes to meet the goals of the Shared Savings Program. ACO providers and suppliers who do not meet these guidelines should be subject to remedial action. CMS envisions that these guidelines would be implemented through the use of an electronic health record. In an effort to encourage innovation, CMS is requesting comments on alternatives to these prescriptive leadership and operational requirements.

Contractual Arrangements

The proposed CMS rule contemplates that ACOs will have several contractual arrangements between ACO participants, as well as other providers and suppliers not enrolled in Medicare. These agreements must contain a provision that would allow CMS to audit the contracting party's books and records concerning compliance with the Shared Savings Program. CMS is seeking comments regarding the ability of ACOs to share savings with participants that do not participate in Medicare. CMS is concerned it will not be able to recoup overpayments from non-Medicare participating providers/suppliers contracting with the ACO, and wants to require that all ACO providers/suppliers be bound by the requirements of the Shared Savings Program. For example, CMS could require that all agreements related to the ACO contain a standard contractual provision binding those providers/suppliers so that they have indirect obligations to CMS. CMS is soliciting comments on how to extend the Shared Savings Program requirements under the agreement between CMS and the ACO to all providers/suppliers that have direct and indirect obligations to the ACO.

Application and Agreement

Application

ACOs must complete a detailed application and submit it to CMS for approval before they are able to participate in the Shared Savings Program. This application must include information related to the distribution of sharing of savings and its ability to improve quality, as well information such as a repayment mechanism, governance and legal structure. ACOs also must document in the application how they plan to:

- Promote evidence-based medicine
- Promote beneficiary engagement
- Report internally on quality and cost metrics
- Coordinate care

To allow for flexibility, CMS decided not to be prescriptive in the application process with respect to these goals but left the door open for that in the future. ACOs may need to be more specific in future applications after CMS evaluates its initial approach. CMS will require that extensive documents accompany the application.

After the initial application, ACOs must disclose to CMS whether the ACO, its ACO participants or the ACO providers/suppliers have participated in the Shared Savings Program previously under the same or different name. Similarly, the application must state whether the ACO, its ACO participants or the ACO providers/suppliers are related to another ACO. The ACO must indicate whether the related ACO was terminated or voluntarily withdrew from the Shared Savings Program.

Agreement

If CMS approves an ACO's application, the ACOs must enter into a three-year agreement with CMS to participate in the Shared Savings Program, starting the January 1st following approval of the application or other date stated in the agreement. CMS is seeking comments on how to implement the first year with the January 1, 2012 deadline set by the ACA looming over the process. The 12-month performance period also begins on January 1st of each year, which may cause problems for health care entities who budget on a July 1st fiscal year. If CMS implements changes during the three-year contract period, ACOs will be subject to those changes with the following exceptions:

- eligibility requirements concerning structure and governance
- calculation of sharing rate
- beneficiary assignment

If a statute or regulation changes an ACO's care processes and delivery of care, quality of care, or distribution of shared savings, the ACO will be required to submit a supplement to its original application for approval by CMS. This supplement must detail the changes in process that resulted from the statutory or regulatory change. If the ACO cannot adjust to these changes, it will be terminated from the Shared Savings Program.

Significant Changes in the ACO

During the three-year agreement, an ACO may remove ACO participants but may not add ACO participants. The ACO may add or remove ACO providers/suppliers at any time. ACOs must notify CMS within 30 days prior to any of the following "significant changes" to allow CMS to reevaluate an ACOs eligibility to participate in the Shared Savings Program:

- deviation from its approved application such as a reorganization of the ACO's legal structure or changes in eligibility
- material change as described by the proposed CMS rule
- government-required reorganization as a result of fraud or antitrust concerns

Quality Monitoring and Reporting

The ACA requires HHS to determine appropriate measures to evaluate the quality of care furnished by the ACO, such as measures of clinical processes and outcomes, patient and caregiver experience of care, and utilization. Accordingly, under the proposed rule, ACOs will be required to monitor and report claims review, financial and quality data, as well as submit quarterly and annual reports, perform site visits and conduct patient surveys. Importantly, ACOs that do not meet quality performance thresholds for all proposed quality measures will not be eligible for shared savings, regardless of the extent to which per-capita costs are reduced.

Proposed Quality Measures

For calculation of the ACO Quality Performance Standards during the first performance period under the ACO agreement, CMS has proposed 65 measures, which are grouped into five "domains":

- Patient/Caregiver Experience (7 measures)
- Care Coordination (16 measures)
- Patient Safety (2 measures)
- Preventative Health (9 measures)
- At-Risk Population/Frail Elderly Health (31 measures)

The 65 proposed measures, their assigned domain, method of submission and other relevant information are compiled in a chart in the preamble to the proposed regulation. Many of the measures are familiar as they are aligned with CMS's current quality initiatives, including the Physician Quality Reporting System (PQRS), Electronic Health Record (EHR) Incentive, and the Hospital Inpatient Quality Reporting Program. CMS anticipates refining and expanding these ACO measures in subsequent program years through additional rulemaking to include other highly prevalent conditions and areas of interest, as well as measures of caregiver experience. CMS seeks comments on the implications of including and excluding the measures proposed, as well as a process for retiring or adjusting the weights of domains and measures over time. In commenting on these proposals, stakeholders should consider the resources and costs associated with collecting data on each measure and their ability to develop the infrastructure necessary to report and improve quality under each measure.

Data Submission Requirements

As indicated, data will be collected through three primary methods: (1) claims data, (2) the Group Practice Reporting Option (GPRO) data collection tool utilized under the PQRS program, and (3) survey instruments. While CMS claims that most of the proposed measures "can be derived from [current] CMS systems and calculated for the assigned patient population the ACO serves," it is clear that quality reporting will be a considerable burden on ACOs. ACOs will be required to report patient-level, clinical data on most of the measures through the GPRO tool, which CMS proposes to build out, refine and upgrade to support clinical data collection and measurement reporting for ACOs. CMS proposes that, for the GPRO measures, CMS will pre-populate the data collection tool with beneficiaries' demographic and utilization information based on Medicare claims data and ACOs will be required to populate remaining fields. Under the proposed rule, CMS will require submission of data related to a sample of at least 411 beneficiaries for each measure set/domain, unless the pool is less than 411 beneficiaries, in which case data on all assigned beneficiaries must be reported.

Similar to its other quality initiatives, CMS will include a data validation process pursuant to which CMS will review a random sample of 30 beneficiaries previously abstracted for each of the measure domains/measure sets. If at the conclusion of a three-phase audit process, the mismatch between the audited charts and the abstracted charts is greater than 10 percent, the ACO will be given the opportunity to correct and resubmit the measures in question. If the mismatch rate still exists, the ACO will not be given credit for meeting the quality target for any measures for which the mismatch rate still exists.

Some GPRO measures rely on ACO attestation rather than the submission of beneficiary data, including those that pertain to HITECH Meaningful Use, the Electronic Prescribing Incentive Program and registry use. These attestations will be validated through CMS data from the EHR Incentive Program and Electronic Prescribing Incentive Program.

Notably, ACOs that fail to report quality measure data accurately, completely and timely may be subject to termination or other sanctions; however, CMS has proposed a number of procedural steps that must occur prior to termination, including a written warning, reevaluation, and an opportunity to resubmit data. Nevertheless, ACOs that exhibit a pattern of inaccurate or incomplete reporting, or that fail to make timely corrections following a notice to resubmit, may be terminated from the program.

Quality Performance Standard Calculation

For the first year of the Shared Savings Program, CMS proposes that an ACO will meet the Quality Performance Standard, and earn either 60 percent (two-sided model) or 50 percent (one-sided model) of the sharable savings, if the ACO completely and accurately reports data on all program measures. For subsequent years, the percent of potential shareable savings will vary based on the ACO's performance on the measures as compared to established benchmarks, which will be developed in future rulemakings. CMS will establish benchmarks and minimum levels based on ACO, fee-for-service and MA data.

CMS is considering two alternative methods for calculating the Quality Performance Standard: (1) a performance score approach that rewards ACOs for better quality with larger percentages of shared savings; and (2) a threshold approach that allows for full shared savings if ACOs meet a minimum threshold. While CMS has proposed regulations regarding the performance score approach, it seeks comments on both alternatives:

Option #1: Performance Score Approach

(1) Each of the 65 measures is subdivided into the 5 domains, as shown above.

(2) For each measure, an ACO can achieve a score of up to 2 points.

- For performance equal to or greater than the minimum attainment level (30th percentile) but less than the performance benchmark (90th percentile), the ACO will receive points on a sliding scale ranging from 1.10 to 1.85 points, based on performance.
- Performance below the attainment level (30th percentile) will yield zero points, while performance at or above the performance benchmark (90th percentile) will yield 2 points.
- For two measures, Measures 35 (diabetes composite) and 52 (coronary artery disease composite), CMS has proposed "all or nothing" scoring pursuant to which an ACO will receive all points only if all criteria are met, and zero points if at least one of the criteria are not met.

(3) CMS will calculate an aggregate score for all measures for each domain, in addition to calculating the percentage of points earned for each domain.

(4) All domains will be weighed equally, regardless of the number of measures within the domain. Thus, CMS will average all domain scores for the ACO to calculate the overall quality score, which will determine the ACO's final sharing rate.

- If, for example, an ACO averaged 90 percent of the quality performance points across all five domains, the ACO would receive 90 percent of the ACO's share of savings. Under the one-sided model, it would be eligible for 90 percent of the potential 50 percent of shared savings, or 45 percent of the total savings generated. Under the two-sided model, the ACO could earn 54 percent of the total savings generated.

Option #2: Quality Threshold Approach

(1) If any ACO performs at or above the CMS-established minimum quality threshold (50th percentile), the ACO would retain the full shared risk savings percentage (50 percent for one-sided risk, 60 percent for two-sided risk).

(2) If the ACO fails to meet the threshold, it would not be eligible for shared savings.

Both approaches have benefits and drawbacks. The performance score approach would permit an ACO to retain some of the shared savings at a lower threshold of achieving the 30th percentile, but full shared savings would not kick in unless the ACO meets or exceeds the 90th percentile. The quality threshold approach would allow for full shared savings at the 50th percentile, but it provides for no shared savings under that threshold. CMS has not provided specific proposals regarding how it will utilize the "most currently available data source[s]" to determine the benchmark thresholds, so it is difficult to determine, at this time, how readily a particular ACO would be able to meet the established benchmarks and threshold. As we have seen in other quality initiatives, it is likely that some measures will become "topped out" where virtually all providers are performing at or near 100 percent and there is little measureable variance between providers. In such circumstances, a few errant cases can drastically skew a provider's score in comparison to other providers. The proposed rule does not discuss how CMS will deal with this issue. Of course, for the first performance period, an ACO will retain its full shared risk savings (50 percent for one-sided risk, 60 percent for two-sided risk) for merely reporting on all measures within all domains.

CMS seeks comments regarding the pros and cons of each approach, and solicits comments on alternatives for blending the two approaches. With respect to the quality performance approach, CMS requests comments on its proposal to weigh all domains equally, which it believes incentivizes ACOs to address quality across the continuum of care, as opposed to an approach weighing all of the individual measures equally or in accordance with their clinical importance. CMS also invites comments on its proposal to require ACOs to report on 100 percent of the measures during the first performance period and has considered, alternatively, whether it should allow ACOs to report on a subset of measures based on their level of readiness, including organizational and systems capacity, to participate in the Shared Savings Program. In commenting on these

proposals, potential ACO participants should consider their current organization and systems capabilities in collecting and reporting data on the proposed measures, as well as their capabilities for dedicating staff and resources to improving quality, to meet thresholds and benchmarks yet to be established by CMS.

Incorporation of the Physician Quality Reporting System

CMS proposes to require "eligible professionals" (i.e., physicians, nurse practitioners, physical or occupational therapists, etc.) to submit data for purposes of the PQRS incentive through the ACO on the quality measures proposed for the Shared Savings Program. Accordingly, eligible professionals within an ACO who satisfactorily report the quality measures during the first performance period would qualify under the Shared Savings Program for a PQRS incentive equal to 0.5 percent of the ACO's eligible professionals' total estimated Medicare Part B PFS-allowed charges for covered professional services furnished.

Public Reporting

In the name of transparency, ACOs will be responsible for public reporting in a standardized format to be determined by CMS, as follows:

- name and location
- primary contact
- participating providers of services and suppliers
- identification of participants in joint ventures between ACO professionals and hospitals
- identification of the representatives on its governing body
- associated committees and committee leadership
- quality performance standard scores
- shared savings or losses information, including the amount of shared savings received by the ACO or losses owed to CMS
- total proportion of shared savings that was distributed among the ACO participants

The public reporting requirement would be included within the ACO's three-year agreement. CMS seeks comments on these proposals, including recommendations regarding whether the ACOs should be required to make the information publicly available, or whether ACOs should report to CMS, which would in turn make the information available.

Assignment of Beneficiaries

An ACO must agree to have at least 5,000 beneficiaries assigned to it. CMS is seeking comments related to meeting this 5,000 beneficiary threshold. Under the proposed CMS rule, ACOs that fall under 5,000

beneficiaries would not be automatically terminated but instead would receive a notice from CMS and be placed on corrective action. In response to this corrective action, the ACO must indicate its plan to add more primary care providers to increase, in turn, the number of beneficiaries assigned to the ACO. The ACO would receive the shared savings available for the year it was placed on corrective action, but if the 5,000 beneficiary threshold is not met by the end of the following year, the ACO will not be eligible for shared savings for that year and CMS will terminate the ACO's participation agreement. CMS is requesting comments on other options for dealing with ACOs with less than 5,000 beneficiaries.

Patients are assigned to an ACO based on their use of primary care physicians. In determining how to implement beneficiary assignment, CMS reviewed various issues:

- an operational definition of ACO in order to distinguish among ACOs
- a definition of *primary care services*
- a determination of whether to assign beneficiaries prospectively or retrospectively
- a determination of the proportion of primary care services necessary for a beneficiary to be assigned to a particular ACO

Prior to discussing any of these issues, however, CMS goes to great lengths to explain that while beneficiaries technically are "assigned" to an ACO according to the language of the statute, CMS prefers to view the process as "alignment" rather than "assignment" because beneficiaries retain "complete freedom of choice" in the physicians and other practitioners and suppliers from whom they receive services. As is described in more detail below, however, beneficiaries whose primary care physicians are part of an ACO are by definition counted in the shared savings of the ACO. The only way a beneficiary can "opt out" of an ACO is to find a primary care physician who is not participating in an ACO.

In order to identify an ACO from an operational perspective, CMS has decided to collect the TINs of the ACO participants, which will be provided by all ACOs. These sets of TINs, which would include a physician group practice's TIN as well as perhaps a hospital's TIN, then can be linked to an individual specialty code by CMS. To assign beneficiaries, CMS would look to the primary care services received from physicians whose TINs are assigned to a particular ACO. Further, primary care physicians could participate in only one ACO, in order that beneficiaries can be appropriately assigned. Other physicians and health care providers can participate in more than one ACO. To further assist in the assignment process, CMS will require ACOs to identify the NPIs for all ACO professionals, with a list that separately identifies physicians who provide primary care as defined by CMS.

The assignment of beneficiaries to ACOs based on their utilization of primary care services in accordance with the ACA requires a determination of what services constitute *primary care services*. The ACA does not specify how CMS is to make this determination, however. Accordingly, CMS reviewed three options before proposing a method for defining *primary care services*: (1) assignment based on a predetermined set of primary care services; (2) assignment based on predetermined services and a predefined group of primary care providers; and (3) assignment of beneficiaries in a "step-wise" fashion (i.e., identify primary care physicians and then specialists providing these same services).

Using the "primary care services" method would require assignment based on the evaluation and management codes that are defined as primary care services within the ACA, and the codes related to the annual wellness visit and the Welcome to Medicare benefit. This straightforward option provides for the greatest amount of beneficiaries assigned to ACOs in professional shortage areas. However, the drawback to this approach is that a patient may be assigned to a specialist rather than a primary care physician, and CMS makes clear that the intent of the Medicare Shared Savings Program is to benefit, first and foremost, primary care physicians.

CMS evaluated a second option whereby beneficiaries would be assigned to physicians designated as primary care physicians. While the statute includes both physicians and non-physician practitioners as ACO professionals, beneficiaries are assigned based only on utilization of primary care physician services. CMS defines *primary care physicians* as those who provide primary care services and who are designated as internal medicine, general practice, family practice, or geriatric medicine physicians. CMS's only concern with this option is that it would exclude services provided by specialists and thereby could reduce the number of potential beneficiaries in an ACO. CMS chose to propose this option in the regulations.

The third option CMS considered, but did not choose, was to assign beneficiaries in a "step-wise fashion." Under this method, beneficiaries would be assigned first by their primary care physician and then by those specialists who provide primary care services to patients who do not see a primary care physician. CMS found fault with this option because it would be more complicated and would limit specialists for whom a beneficiary was assigned to participating in a single ACO.

A separate hotly debated issue is whether beneficiaries would be assigned prospectively (prior to the performance year) or retrospectively (after the performance year). Under a prospective methodology, CMS would base assignment of beneficiaries on their utilization data for prior years. Many have argued that it is essential to have beneficiaries assigned prospectively in order to manage the care of those patients. It is also important to have targets and goals that can only be developed if the ACO patient population is known at the beginning of the performance year. Using this method would also require year-end retrospective adjustment for

patients who came to or left an ACO in the middle of the year. Using a retrospective methodology, CMS argues, is necessary as there is about 25 percent variation in the treating physicians of Medicare beneficiaries from year to year. Accordingly, prospective assignment would be less accurate than retrospective assignment. Retrospective assignment "appropriately holds the ACO accountable for the actual population it cared for during the performance year." Further, CMS is hoping that the ACO program will change care coordination for all patients, not just those assigned to the ACO, which it believes will occur more readily if all patients are treated equally and the ACO does not know which patients will ultimately drive the amount of shared savings to be received. While CMS found merit in both the prospective and retrospective approaches to the assignation of beneficiaries, CMS has proposed the retrospective approach and has requested comments in that regard. CMS also notes that while beneficiaries are to be retrospectively assigned for purposes of calculating shared savings, ACOs will be able to receive aggregate patient data for their "expected assigned population" during the benchmark period.

Finally, because beneficiaries are able to see any physician they choose, CMS found it necessary to determine how to assign a beneficiary who receives services from more than one primary care physician. CMS weighed whether to assign beneficiaries based on a plurality approach or a majority approach. CMS believed that using a majority approach could reduce the number of beneficiaries assigned to any ACO. Further, given that many beneficiaries see more than one primary care physician, a majority rule would be too strict a standard, thus perhaps curbing the development and sustainability of ACOs. Accordingly, CMS has proposed a plurality rule for assignment of beneficiaries, under which a beneficiary will be assigned to an ACO when that individual receives more primary care from the ACO than from any other provider. CMS has requested comments on whether there should be a minimum number of primary care services provided by an ACO before a beneficiary is assigned to that ACO.

CMS also reviewed methods for counting the number of services that a beneficiary receives to determine which ACO provided a plurality of services, including counting by number of services or by charges. One benefit to counting charges rather than number of services is that it is unlikely that a "tie breaker" would ever be needed. Further, counting charges would assign the beneficiary to the ACO that provided the highest intensity and complexity of primary care services, rather than the ACO that saw the patient the most.

Beneficiaries will not receive notification of the ACO to which they have been assigned. Rather, CMS will develop educational materials to provide to beneficiaries so that they understand care coordination and management under ACOs. Further, all ACO facilities will be required to post signs that indicate the facilities' participation in an ACO, that give patients the opportunity to opt-out of data sharing or that explain that patients

who do not want to take part in the ACO are free to seek primary care services from a physician who does not participate in an ACO.

Although the health care industry has attempted to provide patient-focused evidence-based care to patients, the current fee-for-service model incentivizes volumes and through-put rather than containing costs and focusing on quality. For example, ACOs are encouraged to create safety nets for patients who may need reminders for appointments and tests.

Shared Savings Determination

ACO participants will continue to receive reimbursement under the original Medicare fee-for-service payment system. However, ACO participants are also eligible to receive payment for shared Medicare savings provided that the ACO meets the established quality performance standards and achieves cost savings against a benchmark of expected average per-capita Medicare fee-for-service expenditures.

Alternative Payment Models

The ACA authorizes HHS to select any payment model that it determines will improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures. Consequently, CMS evaluated several payment models that could be used to implement the Shared Savings Program.

CMS initially considered a pure one-sided shared savings approach. A primary benefit of this approach is that it has the potential to attract a large number of participants to the program and introduce value-based purchasing broadly to providers and suppliers. In addition, a model with no downside risk might also attract smaller group participation. CMS rejected this approach, however, because it feared that a one-sided model would not create a sufficiently strong incentive to improve the efficiency of health care delivery. In response to this concern, CMS also considered a risk-based option that would provide greater potential rewards for greater risk-sharing responsibility.

Under the proposed rule, CMS adopted a hybrid approach that combines some of the elements of a one-sided model with a risk-based approach. The key advantage of the hybrid approach is that it will enable smaller or less-experienced organizations to gain experience with risk models while also providing opportunities for experienced ACOs to share in both losses and greater potential rewards. ACOs participating in the Shared Savings Program thus can enroll in one of two tracks:

Under Track 1, ACOs enter into a three-year agreement with CMS in which the ACO is not responsible for any portion of the losses incurred above the expenditure target in the first two years of participation. The ACO is still eligible to share in any savings realized during the first two years. In the third year, however, the agreement automatically changes to a two-sided model in which the ACO shares in potential losses as well as savings. After the initial three-year agreement, ACOs would be required to enter into a two-sided arrangement by participating in Track 2.

Under Track 2, ACOs enter into a three-year agreement with CMS in which the ACO shares in both losses and savings in every year of participation. To incentivize more-experienced ACOs to join Track 2, the two-sided model offers higher shared savings rates than the one-sided model.

Shared Savings Methodology

An ACO is eligible to receive payment of shared savings only if "the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark…." To determine and appropriately share savings with ACOs, therefore, CMS must make several determinations as part of the shared savings methodology.

In the discussion that follows, it can be assumed that the features of the one-sided and two-sided model are identical unless otherwise noted. In general, CMS proposed the same eligibility requirements and methodologies for both models, including the same eligibility criteria, beneficiary assignment methodology, benchmark and update methodology, quality performance standards, data reporting requirements, data-sharing provisions, monitoring for avoidance of at-risk beneficiaries, and transparency requirements.

Establishing and Updating the Benchmark

In order to implement the Shared Savings Program, CMS was first required to establish an expenditure benchmark. The ACA provides that HHS will "estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per-beneficiary expenditures for parts A and B services for Medicare fee-for-service beneficiaries assigned to the ACO." The benchmark is thus essentially a surrogate measure for what the Medicare fee-for-service Parts A and B expenditures would have been in the absence of the ACO.

CMS considered two approaches to meeting the statutory language for estimating the benchmark. Under both approaches, the benchmark is derived from prior expenditures of assigned beneficiaries and adjusted for certain beneficiary characteristics, and other factors CMS deems appropriate, and updated by the projected

absolute amount of growth in national per-capita expenditures. Both approaches would also reset the benchmark at the beginning of each agreement period. The two approaches differ markedly, however, based upon the beneficiary populations that would be used to determine the ACO's benchmark. Although Option 1 has been incorporated in the proposed rule, CMS is soliciting comments on both proposed options. Specifically, CMS wonders how each approach might (1) affect the willingness of ACOs or particular types of ACOs to participate in the Shared Savings Program, (2) create incentives to seek or avoid certain types of beneficiaries, and (3) impact Medicare expenditures.

Option #1

Under Option 1, CMS will estimate the benchmark for an ACO using the Parts A and B fee-for-service expenditures of beneficiaries *who would have been assigned* to the ACO in each of the three years prior to the start of an ACO's agreement period using the ACO participants' TINs. To minimize variations from catastrophically large claims, CMS will truncate an assigned beneficiary's total annual Parts A and B fee-for-service per-capita expenditures at the 99th percentile as determined for each benchmark year. Based on these data, CMS will then estimate a fixed benchmark that is adjusted for overall growth and beneficiary characteristics, including health status, using prospective HCC adjustments. The benchmark would then be updated annually during the agreement period based on the absolute amount of growth in national per-capita expenditures for Parts A and B services under the original Medicare fee-for-service program.

An ACO's assigned beneficiary population could diverge from the benchmark population if an ACO's population or composition of providers/suppliers changes over time. Consequently, some of the beneficiaries whose expenditures would be included in the benchmark under this approach would not be reflected in the population assigned to the ACO during the years of the ACO agreement period, which could potentially affect the comparability of performance measurement. It is also possible that this benchmark approach could provide undesirable incentives to seek and/or avoid specific beneficiaries during the agreement period so that average expenditures would more likely be less than the benchmark established using historical averages. If requested by an ACO, CMS will provide the ACO with aggregated data and information on beneficiaries that would historically have been assigned to the ACO and, as a result, have a likelihood of being assigned during the agreement period.

Option #2

In response to some of the concerns raised about benchmarking under Option 1, Option 2 establishes the benchmark based on the Parts A and B fee-for-service expenditures of the beneficiaries who are actually assigned to the ACO during each performance year, with the expenditures being those incurred in the three years immediately preceding the ACO's agreement period for those assigned beneficiaries. As was

the case under Option 1, these data would then be adjusted for overall growth and beneficiary characteristics, including health status, using prospective HCC adjustments. The benchmark would then be updated annually during the agreement period based on the absolute amount of growth in national per-capita expenditures for Parts A and B services under the original Medicare fee-for-service program.

This approach requires additional adjustments to the benchmark if a beneficiary does not have three full years of immediately-prior Medicare eligibility (i.e., a beneficiary who is not 68 years old in their first year assigned to the ACO) or if an assigned beneficiary dies during an agreement year. CMS is considering several possible adjustment mechanisms, and has solicited other approaches that could be considered.

Adjusting the Benchmark and Average Per-Capita Expenditures for Beneficiary Characteristics

The ACA mandates that the characteristics of the beneficiaries assigned to an ACO be taken into account when estimating an ACO's benchmark and its expenditures during the agreement period. This requirement helps to ensure that quality and efficiency in the delivery of health care services are the basis for sharing savings under the Shared Savings Program. The relative health status of beneficiaries is a key characteristic that must be taken into account in order to foster an environment in which ACOs are encouraged to effectively coordinate care for beneficiaries with complex illnesses. CMS considered two basic options for risk adjusting average per-capita expenditures in order to reflect beneficiary characteristics.

One option is to consider only patient demographic factors, such as age, sex, and Medicaid status, without considering diagnostic information. A second approach is to incorporate diagnostic information, specifically the CMS-HCC prospective risk adjustment model, which uses demographic variables and beneficiaries' prior year diagnoses to develop risk scores that are then applied to their current-year expenditures. When using a risk adjustment model that incorporates diagnostic data, however, risk scores can be affected by changes in the health status of beneficiaries or by changes in coding intensity and the mix of specialists and providers furnishing care. Consequently, ACOs could have an incentive to code more fully or intensely because of the potential impact on performance payments. Under a risk-adjustment methodology that incorporates diagnostic information, therefore, ACOs could achieve apparent cost savings through coding changes rather than improved delivery of care.

CMS has considered several possible ways to account for the upward trend in risk scores. For example, CMS considered normalization factors and coding intensity adjustments, as well as an annual cap on allowable risk-score growth for each ACO. Although a model that uses beneficiary demographic factors alone to risk adjust would avoid this issue, CMS elected to adjust Medicare expenditures using the CMS-HCC model because it

more accurately predicts health care expenditures than the demographic-only model. In addition, CMS notes that incorporating diagnostic data into the risk-adjustment model will incentivize ACOs to maintain complete and accurate medical documentation, which could garner enhanced data for use in population management, care coordination, and quality improvement.

To combat the incentive for ACOs to game the Shared Savings System by coding more fully or intensely, CMS proposes to calculate a single benchmark risk score for each ACO based on the ACO's historically assigned beneficiary population. This approach ostensibly should avoid any distortion due to changed coding practices since the risk score is based on a period in which providers and suppliers did not have the same incentive to increase coding. CMS has solicited comments on its proposed approach, and specifically seeks comments on alternative approaches such as the MA "new enrollee" demographic risk adjustment model or applying a coding intensity cap on annual growth in the risk scores of an ACO's assigned beneficiary population.

Technical Adjustments to the Benchmark: Impact of IME and DSH

The ACA states that the Shared Savings Benchmark "shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate…." As CMS observes, several factors in the Medicare fee-for-service payment systems – including the indirect medical education (IME) adjustment and the disproportionate share hospital (DSH) adjustment – could provide ACOs with an incentive to avoid referring patients to hospitals that receive IME and DSH patients due to the increased Medicare cost associated with these adjustments.

In response to this concern, CMS considered whether it might be appropriate to remove IME and DSH payments or a portion of these payments from the benchmark and the calculation of actual expenditures for an ACO. As a threshold matter, CMS is precluded from adjusting expenditures for "other factors," and thus CMS is constrained to potentially adjusting the benchmark for these payments. However, CMS has proposed not to remove IME and DSH payments from the per-capita costs included in the benchmark for an ACO for several reasons. First, removing IME and DSH payments from the benchmark would yield an artificially low benchmark and make it more difficult for an ACO to achieve savings under the Shared Savings Program. Second, CMS believes that all relevant Medicare costs should be included in an ACO's benchmark in order to maintain sufficient incentives for ACOs to ensure that their assigned beneficiaries receive care in the most appropriate settings. CMS has solicited comments on this issue, particularly on how including or excluding these payments in the benchmark could affect access to medically necessary services provided at teaching/DSH hospitals.

Technical Adjustments to the Benchmark: Impact of Geographic Payment Adjustments, Bonus Payments and Penalties

Another factor in the Medicare fee-for-service payment systems that could affect an ACO's ability to realize savings is the geographic payment adjustment, which increases and decreases payments under these payment systems to account for the different costs of providing care in different areas of the country. As in the case of IME and DSH adjustments, CMS considered but ultimately elected not to remove these payment adjustments from the calculation of the benchmark and actual expenditures.

Medicare bonus payments are available and penalties may be imposed through value-based purchasing initiatives such as the Physician Quality Reporting System. Incentive payments for similar programs can affect actual expenditures and the benchmark, and thus an ACO's ability to realize savings. CMS has proposed to exclude Medicare expenditures or savings for incentive payments and penalties for value-based purchasing initiatives such as Physician Quality Reporting System, eRx, and the EHR incentives for eligible professionals under the HITECH Act from the computations of both benchmark and actual expenditures during the agreement period. Again, CMS seeks comments on the likely effects of this proposal.

Trending Forward Prior Years' Experience to Obtain the Initial Benchmark

The ACA mandates the use of "the most recent 3 years of per-beneficiary expenditures for parts A and B services" to estimate a benchmark for each ACO. Consequently, the per-capita costs for each year must be trended forward to current year dollars and then averaged to obtain the benchmark for the first agreement period. This benchmark is subsequently updated for each year of the agreement period based on the "projected absolute amount of growth in national per-capita expenditures for parts A and B services" under the fee-for-service program as estimated by CMS.

At present, CMS has proposed to trend the most recent three years of per-beneficiary expenditures using growth rates in per-beneficiary expenditures for Parts A and B services. CMS has solicited comments on whether another trending mechanism – including a flat dollar trend amount – would be more appropriate. CMS also has proposed to use the national growth rate in Medicare Parts A and B expenditures for fee-for-service beneficiaries – as opposed to local growth factors – to trend per-beneficiary expenditures forward. CMS argues that this approach will help to ensure that ACOs in high-spending, high-growth and low-spending, low-growth areas will have appropriate incentives to participate in the Shared Savings Program.

Updating the Benchmark During the Agreement Period

The ACA requires that the benchmark shall be "updated by the projected absolute amount of growth in national per capita expenditures." CMS considered two alternatives to implement this requirement. First, CMS could use a flat dollar amount equivalent to the absolute amount of growth in national fee-for-service expenditures to update the benchmark for the agreement period. Under this approach, ACOs in high-cost, high-growth areas must reduce their rate of growth more to bring their costs more in line with the national average. Second, CMS also considered updating the benchmark by the lower of the national projected absolute amount of growth in national per-capita expenditures or the local/state projected absolute amount of growth in per-capita expenditures. This could provide a more accurate estimate of the updated benchmark based on local conditions. At present, CMS proposes to update the benchmark by the projected absolute amount of growth in national per-capita expenditures because this approach should help to ensure that ACOs in high-spending, high-growth and low-spending, low-growth areas will have appropriate incentives to participate in the Shared Savings Program. CMS has solicited comments on the merits and drawbacks of these approaches.

Minimum Savings Rate (MSR) and Sharing Rate

The ACA provides that an ACO will be eligible to receive payment for shared savings "only if the estimated average per-capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark . . . ." Furthermore, the ACA mandates that HHS shall "determine the appropriate percent… to account for normal variation in expenditures under this title, based upon the number of Medicare fee-for-service beneficiaries assigned to an ACO."

Based on these statutory requirements, CMS was required to specify a MSR to account for normal variations in expenditures, based upon the number of Medicare fee-for-service beneficiaries assigned to the ACO. CMS attempted to set the MSR in such a way that the ACO's performance and shared savings are a result of its interventions, not normal variation. For example, a higher MSR would provide CMS with greater confidence that the shared savings amounts reflect legitimate quality and efficiency gains, thereby providing greater protection to the Medicare Trust Funds. However, a higher MSR also establishes a larger barrier to achieving savings, which could discourage potentially successful ACOs, including physician-organized ACOs and smaller ACOs in rural areas, from participating in the Shared Savings Program. A lower MSR, on the other hand, would encourage more potential ACOs to participate in the program, but would also provide less assurance that any realized savings are actually the result of quality and efficiency improvements attributable to the ACO.

For the one-sided model, CMS has proposed a sliding scale MSR based on the number of assigned beneficiaries in each ACO. For example, an ACO with 5,000 beneficiaries must achieve an MSR of 3.6 – 3.9 percent, while an ACO with 50,000 beneficiaries must achieve an MSR of only 2.0 – 2.2 percent. An ACO that exceeds its MSR would be eligible to share up to 50 percent of the savings in the one-sided model. CMS set the MSRs to provide confidence that an ACO with a given number of beneficiaries that are assumed to be of average national baseline per-capita expenditure and expenditure growth rate would be unlikely to achieve a shared savings payment by random chance alone. CMS has invited comments on the most appropriate method to establish the MSR for an ACO in the one-sided model.

Significantly, an ACO that opts into the one-sided risk model cannot determine the applicable MSR – and thus the savings target required to receive shared savings – prior to contracting with CMS because the MSR is dependent on the number of beneficiaries assigned to the ACO. However, CMS assigns beneficiaries to an ACO at the end of each performance year if the beneficiary has received a plurality of his or her primary care services from primary care physicians who are ACO participants. Thus, ACOs under the one-sided risk model face considerable uncertainty about required targets and potential shared savings when making the initial enrollment decision.

Unlike the one-sided model, the calculation of MSR in the two-sided model is not based on the number of beneficiaries enrolled in the ACO. Whereas the minimum savings rate under the one-sided model varies with the number of beneficiaries assigned to the ACO, it is fixed at 2 percent under the two-sided model. Consequently, to qualify for shared savings under the two-sided model, an ACO's average per-capita Medicare expenditures for the performance year must be below its benchmark costs for the year by at least 2 percent. Similarly, an ACO would share losses with Medicare if its average per-capita Medicare expenditures are at least 2 percent above its benchmark costs. The shared loss rate is determined based on the inverse of the ACO's final sharing rate, which essentially serves as a cushion for ACOs that meet quality targets and include RHCs or FQHCs in the ACO but fail to meet cost benchmarks. The loss recoupment limit for an ACO's liability for shared losses may not exceed 5 percent of its benchmark in year one, 7.5 percent in year two, and 10 percent in year three. Since ACOs under the two-sided model share in both losses and saving – and thus more is at risk – the participants in the two-sided model are eligible to share more of the savings than in the one-sided model. Specifically, the participants are eligible to share 60 percent of the savings.

Net Sharing Rate

CMS considered several formulas to determine how savings would be shared with qualifying ACOs under the one-sided model. First, CMS considered permitting the ACO to share on first dollar savings once the MSR was

exceeded, which would maximize the reward that an ACO could realize. Due to normal variations in expenditures, however, CMS expressed the concern that sharing on first dollar could result in sharing unearned savings rather than savings achieved by the ACO for redesigned care processes. Second, CMS considered an alternative that would require ACOs to exceed the MSR and then share with the ACO only those savings in excess of the MSR. CMS observes that such a requirement would encourage ACOs to strive to generate greater levels of savings.

CMS ultimately adopted a third option in the proposed rule: requiring all ACOs to exceed the MSR to be eligible for shared savings, but only sharing savings in excess of a certain threshold. ACOs meeting certain criteria – such as an ACO in which all participants are physicians or 75 percent of the ACO's beneficiaries reside outside an MSA – could be exempted from this provision and allowed to share in first-dollar savings. Unless exempted, ACOs that exceed the MSR under the proposed rule would be eligible to share in net savings above a 2-percent threshold, calculated as 2 percent of its benchmark. In addition, ACOs that include an RHC or FQHC within the structure of the ACO would also be eligible for an increase of 2.5 percentage points in their shared savings rate in the first two years of their agreements with CMS under the one-sided model. Due to the increased risk-sharing under the two-sided model, an ACO's shared savings rate may be increased by up to 5.0 percentage points if the ACO includes an RHC or FQHC.

Performance Payment Limits

The ACA requires HHS to "establish limits on the total amount of shared savings that may be paid to an ACO…." For purposes of the Shared Savings Program, CMS considered an option to vary the performance payment limit by the readiness of the ACO to take on greater responsibility and risk. Specifically, CMS considered limits of 5, 10, and 15 percent to provide an incentive for ACOs to develop quality and efficiency improvements that could result in greater shared savings. However, CMS expressed reservations about opportunities to earn greater savings because it might provide an incentive for some ACOs to reduce utilization inappropriately to achieve greater savings, thereby harming beneficiaries. Consequently, CMS proposed a shared savings limit of 7.5 percent of an ACO's benchmark for the first two years of the agreement under the one-sided model. In order to encourage ACOs to assume risk and participate in the two-sided model, CMS proposed a payment limit at 10 percent of an ACO's benchmark for those ACOs that either elect the two-sided model for all three years or are transitioned from the one-sided model during the third year of their agreement with CMS. CMS is soliciting comments on these proposed payment limits and on whether a higher limit – for example, 10 percent for all ACOs – would be more appropriate.

Appeals of Agency Determinations

The ACA severely limits the ability of ACOs and ACO participants to obtain review of determinations made by the relevant government agencies involved in the process. Specifically, the statute prohibits administrative or judicial review of the following actions:

- the specification of criteria for meeting quality performance standards
- the assessment of the quality of care furnished by an ACO and establishment of performance standards
- the assignment of Medicare fee-for-service beneficiaries to an ACO
- the determination of whether an ACO is eligible for shared savings and the amount of such shared savings, including determination of the estimated average per-capita Medicare expenditures under the ACO and the average benchmark for the ACO
- the percent of shared savings specified by the Secretary of Health and Human Services and any limit on the total amount of shared savings established by the Secretary
- the termination of an ACO for failure to meet quality performance standards

The proposed CMS rule allows review of the following remaining agency determinations: (1) denial of an ACO application and (2) termination of an existing ACO agreement for reasons other than failure to meet quality performance standards. The appeal process proposed limits review to two levels of reconsideration by CMS officials. No reconsideration would be permitted, however, for applicants rejected on the basis that their application was not timely submitted. CMS considers there to be no valid application in that situation. This leaves no forum for review of whether the application was indeed untimely filed or not.

Requests for reconsideration must be in writing and received by CMS within 15 days of the adverse initial determination. The review may be held orally (in person, by telephone or other electronic means) or on the record (review of submitted documentation), with the burden of proof on the ACO or ACO applicant. CMS will only consider documentation previously submitted by the ACO.

Upon reconsideration, CMS will issue a recommended decision. An ACO or ACO applicant that disagrees with the recommended decision may request a record review by an “independent CMS official” not involved in the initial determination or reconsideration review process. That official’s determination will be the final agency determination, and will be final and binding. If the final determination made is to deny an ACO’s application, the application will be considered to have been denied based on the effective date of the original notice of denial.

An ACO whose Shared Savings Program application is denied or terminated due to a determination by a reviewing antitrust agency may not contest the merits of the antitrust agency’s determination through the reconsideration review process proposed in the rule.

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