# BREAKING NEWS: CMS ISSUES ITS FINAL RULE FOR ACCOUNTABLE CARE ORGANIZATIONS

*This installment of Hall Render's Health Law Broadcast series on health care reform is designed to provide you with the insight, analysis and practical suggestions with respect to the various reform initiatives that will affect your organization.*

"WE HAVE MADE SIGNIFICANT MODIFICATIONS TO REDUCE THE BURDEN AND COST FOR PARTICIPATING ACOs"1

## BACKGROUND

**Introduction**. On October 20, 2011, the Centers for Medicare and Medicaid Services ("CMS") issued its final rule (the "Final Rule") implementing Section 3022 of the Affordable Care Act ("Affordable Care Act"), which provides the framework for Accountable Care Organizations ("ACOs"). The Final Rule purports to provide hospitals, physicians and other practitioners additional flexibility, at less financial risk, than the proposed rule ("Proposed Rule") published April 7, 2011. CMS received approximately 1,320 public comments to the Proposed Rule, and this Final Rule reflects changes made in response to such comments.

In developing the Medicare Shared Savings Program ("Program"), CMS worked closely with other federal government agencies to ensure a coordinated approach in the implementation of the Program. Accordingly, along with the Final Rule, several other agencies issued related documents, including (i) a joint CMS and Office of the Inspector General ("OIG") interim final rule with comment period entitled Medicare Program; *Final Waivers in Connection with the Shared Savings Program*; (ii) an Internal Revenue Service ("IRS") fact sheet; and (iii) a *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Shared Savings Program* issued by the Federal Trade Commission and Department of Justice (collectively, the "Antitrust Agencies").

What follows is a detailed summary with select commentary and Proposed Rule comparisons from the Final Rule. Further, detailed analysis will follow this Broadcast.

## OVERVIEW AND INTENT OF THE MEDICARE SHARED SAVINGS PROGRAM.

In the Final Rule, CMS took steps to reduce the burden and cost for ACO Participants and provide additional options for entities desiring to participate in an ACO. Notably, the Final Rule included the following changes from the Proposed Rule: (1) greater flexibility in eligibility to participate in the Program; (2) multiple start dates in 2012; (3) establishment of a longer agreement period for those starting in 2012; (4) greater flexibility in the governance and legal structure of an ACO; (5) simpler and more streamlined quality performance standards; (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 shared savings withhold; (10) greater flexibility in timing for the evaluation of sharing savings; (11) greater flexibility in antitrust review; (12) greater flexibility in timing for repayment of losses; and (13) additional options for participation of FQHCs and RHCs.

## PROVISIONS OF THE FINAL RULE

### DEFINITIONS.

The Final Rule provides more detailed definitions of an ACO, ACO Participant and ACO Provider/Supplier. Most notable in this section is the addition of a definition for an ACO Professional and a list of entities and individuals who qualify as an ACO Provider/Supplier.

ACO. CMS added that the ACO be authorized under applicable State, Federal or Tribal law, as opposed to simply State law as in the proposed rule.

*ACO Participant*. CMS merely clarified this definition without substantive revisions. It states that an ACO Participant means an individual or group of ACO Provider(s)/Supplier(s) that is identified by a Medicare-enrolled Tax Payer Identification Number ("TIN"), that alone or together with one or more other ACO Participants comprise(s) an ACO and that is included on the list of ACO Participants that is required under §425.204(c)(5).

*ACO Professional*. ACO Professional means an ACO Provider/Supplier who is either of the following:

1. a physician legally authorized to practice medicine and surgery by the State in which he or she performs such function or action; or
2. a practitioner who is one of the following:
   - a physician assistant ("PA") (as defined at §410.74(a)(2));
   - a nurse practitioner ("NP")(as defined at §410.75(b)); or
   - a clinical nurse specialist (as defined at §410.76(b)).

*ACO Provider/Supplier*. ACO Provider/Supplier means an individual or entity that:

1. is a provider (as defined at §400.202) or a supplier (as defined at §400.202);
2. is enrolled in Medicare;
3. bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a Medicare billing number assigned to the TIN of an ACO Participant in accordance with applicable Medicare regulations; and
4. is included on the list of ACO Providers/Suppliers that is required under §425.204(c)(5).

**ELIGIBILITY AND GOVERNANCE.**

Agreement Requirement. CMS maintained the requirement that Program agreements entered into between CMS and the ACO will be for a period of not less than three years, although some agreement periods may be longer than three years.

*Sufficient Number of Primary Care Providers and Beneficiaries*. CMS maintained the limit set by Congress, at 5,000 beneficiary lives, as the minimum threshold needed to qualify as an ACO.

Identification and Required Reporting on Participating ACO Professionals. CMS clarified their position regarding the need for exclusivity of an ACO Professional to a specific TIN. CMS reiterated that some ACO participants, specifically those that bill for the primary care services on which it 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. Exclusivity of the assignment-based participant TIN ensures unique beneficiary assignment to a single ACO. However, exclusivity of an ACO Participant TIN to one ACO is not necessarily the same as exclusivity of individual practitioners (ACO Providers/Suppliers) to one ACO.

Exclusivity of the assignment-based participant TIN 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 CMS's preference to use TINs to identify ACO Participants over NPIs; adopting NPIs in place of TINs would result in the much stricter exclusivity rules for individual practitioners than the use of TINs to identify ACOs.

Lastly, CMS expanded the exclusivity policy to the TINs under which the services of specialists, PAs and NPs are included in the assignment process. These TINs would have to be exclusive to one ACO for purposes of the Shared Savings Program.

*Eligible Entities*. CMS maintained that the following entities, or combinations thereof, are eligible entities to form an ACO:

- 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;
- CAHs that bill under Method II (as described in §413.70(b)(3));

- RHCs; and
- FQHCs.

Other ACO Participants that are not identified in the above list are eligible to participate through an ACO formed by one or more of the ACO Participants identified above.

CMS clarified that there is no requirement that an ACO include a hospital and that the Program has not established any "hospital-oriented" requirements.

**LEGAL STRUCTURE AND GOVERNANCE.**

- *Legal Entity*. The Final Rule maintains that an ACO must be a legal entity. CMS clarified that an ACO formed among two or more otherwise independent ACO Participants (such as between a hospital and two physician group practices) will be required to establish a separate legal entity and to obtain a TIN.
- *Distribution of Shared Savings*. This requirement was unchanged as adopted by CMS in the Final Rule.
- *Governance.* An ACO must maintain an identifiable governing body with authority to execute the functions of the ACO, 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.
- *Composition of the Governing Body*. In response to a myriad of comments to this portion of the Proposed Rule, CMS revised the governing body requirements in the Final Rule so as to provide ACOs greater flexibility in the composition of their governing bodies. The Final Rule does not contain the following requirements: (a) that each Medicare-enrolled ACO Participant TIN, or its representative, be on the ACO's governing body; (b) that each ACO Participant have proportionate control of the ACO governing body; and (c) representation of particular categories of providers and suppliers or other stakeholders. The Final Rule does require that the ACO governing body meet the following requirements:

1. 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;
2. the ACO governing body must include a Medicare beneficiary representative served by the ACO who does not have a conflict of interest with the ACO and who has no immediate family member with a conflict of interest with the ACO;
3. at least 75% control of the ACO's governing body must be held by ACO Participants;
4. the governing body members may serve in a similar or complementary manner for an ACO Participant; and
5. in cases in which the composition of the ACO's governing body does not meet the requirements of paragraphs (2) and (3) above, the ACO must describe why it seeks to differ from the requirements and how the ACO will involve ACO Participants in innovative ways in ACO governance or provide meaningful representation in ACO governance by Medicare beneficiaries.

***LEADERSHIP AND MANAGEMENT STRUCTURE.***

CMS, in response to comments regarding the requirement for a full-time medical director, reiterated its belief that physician leadership of clinical management and oversight is important to an ACO's ability to achieve the three-part aim. However, in an effort to respond to the financial burden a full-time medical director would place on some small or rural ACOs, the Final Rule eliminated the full-time requirement. The Final Rule requires that the ACO have a senior-level medical director who is a board-certified physician, is licensed in one of the States in which the ACO operates, is one of the ACO's physicians, and who is physically present on a regular basis in an established ACO location.

***PROCESSES TO PROMOTE EVIDENCE-BASED MEDICINE, PATIENT ENGAGEMENT, REPORTING, COORDINATION OF CARE AND DEMONSTRATING PATIENT-CENTEREDNESS.***

The Final Rule maintains that in order to be eligible to participate in the 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.

***OVERLAP WITH OTHER CMS SHARED SAVINGS INITIATIVES.***

- *Duplication in Participation in Medicare Shared Savings Programs*. 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.

- *Overlap with the Center for Medicare & Medicaid Innovation (Innovation Center) Shared Savings Models.* Pioneer ACO Model participants are excluded from participation in the Shared Savings Program.

**ESTABLISHING THE AGREEMENT WITH THE SECRETARY.**

*Options for Start Date of the Performance Year*. CMS is on target with the legislative mandate to establish the Program no later than January 1, 2012 and will start accepting applications from prospective ACOs shortly after January 1, 2012.

Due to the amount of public comment requesting a delayed start date, CMS will provide for two application periods for the first year of the Shared Savings Program whereby CMS will accept applications for an April 1, 2012 or July 1, 2012 start date.

ACO starts April 1, 2012: First performance year is 21 months, ending on December 31, 2013. Agreement period is 3 performance years, ending on December 31, 2015.

ACO starts July 1, 2012: First performance year is 18 months, ending on December 31, 2013. Agreement period is 3 performance years, ending on December 31, 2015.

The Final Rule introduces Physician Quality Reporting System ("PQRS") incentive payments. All ACOs will be eligible to receive the PQRS incentive payments for each calendar year in which they fully and completely report the Group Practice Reporting Option ("GPRO") measures, regardless of their start date. This will provide ACOs that join the program in April or July 2012 with some working capital in advance of the completion of the first ACO performance year, regardless of their ability to generate shared savings.

*Timing and Process for Evaluating Shared Savings.* CMS reconsidered its use of a 6-month claims run-out period and adopted, in the Final Rule, a 3-month claims run-out period. CMS rationalized that, although a 6-month claims run-out period would provide a more accurate calculation of the amount of the shared savings payment, a 3-month run-out of claims data, especially in the first year of the agreement, would aid in ensuring success for ACOs by allowing ACOs to offset the initial start-up costs, which would in turn allow the ACOs to remain financially viable.

*New Program Standards Established during the Agreement Period.* The Final Rule modifies the need for an ACO to comply with regulatory changes promulgated during the Agreement period. ACOs will still be obligated to comply with such regulatory changes. However, instead of being placed on a corrective action plan and possibly terminated from the Program for failure to comply, the Final Rule allows an ACO the choice of whether to terminate its agreement without penalty when there are regulatory changes to the Program that impact the ability of the ACO to continue to participate.

*Managing Significant Changes to the ACO During the Agreement Period.* CMS modified the Proposed Rule in this Final Rule so that ACO Participants and ACO Providers/Suppliers may be added and subtracted over the course of the agreement period.

**COORDINATING THE SHARED SAVINGS PROGRAM APPLICATION WITH ANTITRUST AGENCIES.**

- *Antitrust Policy Statement*. The Proposed Rule required that certain ACOs be subject to mandatory review by the Antitrust Agencies before CMS would approve their participation in the Shared Savings Program. Certain ACOs were required to submit a letter from the reviewing Antitrust Agency that the Agency had no present intent to challenge or recommend challenging the proposed ACO. The Final Rule does not include such a mandatory review. Instead, CMS will rely on three prongs to maintain competition among ACOs:

  a. a voluntary review initiated by the newly formed ACO;

  b. CMS will provide the Antitrust Agencies with aggregate claims data regarding allowable charges and fee-for-service payments, which will assist the Antitrust Agencies in calculating Primary Service Area shares for ACOs participating in the Shared Savings Program, and CMS will provide the Antitrust Agencies with a copy of the ACO's application; and

  c. reliance on existing enforcement processes for evaluating concerns raised about an ACO's formation or conduct and filing antitrust

complaints when appropriate.

**ASSIGNMENT OF MEDICARE FEE-FOR-SERVICE BENEFICIARIES.**

The proposed regulations provided that, while an ACO Professional may include a number of different provider types, the Program must consider only a beneficiary's utilization of primary care services by ACO Professionals who are physicians. CMS outlined four elements for considering beneficiary assignment to an ACO in its Proposed Rule:

- an operational definition of an ACO;
- a definition of primary care of services;
- a determination concerning whether to assign beneficiaries respectively or retrospectively during a given year; and
- a determination concerning the proportion of primary care services necessary to assign them to an ACO.

CMS again reinforced its previous comment that "assignment" of Medicare beneficiaries is more of an "alignment" of beneficiaries and that all Medicare beneficiaries may exercise free choice in their selection of providers.

Definition of Primary Care Services. CMS finalized its proposal in defining "primary care services" as the set of services identified by the following HCPCS codes: 99201 through 99215, 99304 through 99340, 99341 through 99350, G0404, G0438 and G0439. CMS also crosswalks these codes to corresponding FQHC and RHC revenue center codes for the assignment process. In addition to the type of services, "primary care services" can also be defined based on the type of provider rendering the service. CMS has decided in the Final Rule to use what is referred to as a "step-wise" approach for its basic assignment methodology. In Step 1 of this approach, beneficiaries are first assigned to an ACO based on whether they received at least one primary care service from a physician who is an ACO Provider during the most recent measuring period, and if the allowed charges of the ACO participating physician are greater than the allowed charges for primary care services provided by non-ACO participating physicians (identified by TIN). Under Step 2, beneficiaries who have not received any primary care services from a primary care physician (as defined in the Proposed Rule) may be assigned to an ACO if the beneficiary has received at least one primary care service from any physician in the ACO, regardless of specialty, during the most recent measuring period. If these conditions are met, the beneficiary will be assigned to the ACO if the allowed charges for primary care services furnished to the beneficiary by ACO Professionals who are ACO Providers/Suppliers (including nurse practitioners, physician assistants and clinical nurse specialists) are greater than the allowed charges for primary care services provided by non-ACO participating ACO Professionals. Finally, following extensive comment, CMS is permitting primary care services furnished in FQHCs and RHCs to be considered for purposes of beneficiary assignment, which also means that FQHCs and RHCs may independently form ACOs.

Prospective v. Retrospective Beneficiary Assignment. CMS has revised its earlier proposal of retrospective assignment of beneficiaries to provide for a preliminary assignment on a prospective basis using the most recent data available. Assignments will be updated quarterly based on the most recent 12 months of data with final assignment being determined after the end of each performance year.

*Majority v. Plurality* Rule for Beneficiary Assignment. CMS finalized is proposal to assign beneficiaries based "on their utilization of primary care services" using a plurality of allowed charges. The only change relates to how plurality is measured using the "step-wise" approach.

Quality and Other Reporting Requirements.

*Measures to Assess the Quality of Care Furnished by an ACO*. CMS has reduced the initial 65 measure set to a total of 33 measures among 4 domains with a focus on prevention and management of chronic diseases (23 if including patient experience survey modules and coronary artery disease measures that are each scored as 1 measure). Of these 33 measures, 7 are collected by patient survey, 3 by claims, 1 from EHR Incentive Program data and 22 by CMS' GPRO data collection and survey tool. Another change by CMS is to phase in selected measures from year 1 to year 2 for purposes of transitioning from pay for reporting to pay for performance with all but 1 of the measures being pay for performance in year 3. All ACOs beginning in 2012 will be required to conduct a CAHPS survey of ACO assigned beneficiaries.

*Quality Performance Standards*. In recognizing that it may be difficult for ACOs to achieve defined quality performance standards for all quality measures, the Final Rule provides that ACOs need only achieve the prescribed quality performance standard on 70% of the measures in each of the four domains. Failure to achieve this 70% minimum will trigger a corrective action plan and subsequent re-evaluation. A failure to maintain 70% performance will result in termination in the Program. Each domain (patient/caregiver experience, care

coordination/patient safety, preventative health and at-risk population) will be weighted equally for assessing an overall performance score.

*Other Reporting Requirements Related to PQRS and Electronic Health Record Technology*. CMS is finalizing its proposal to incorporate PQRS reporting requirements and incentive payments into the Program. Only ACOs with "eligible professionals" (as defined by PQRS) that are a group practice are eligible for PQRS incentive payments. CMS has also removed the requirement that 50% of primary care physicians in ACOs be meaningful users by year 2. EHR participation, though, does remain a quality measure and to signify the importance of EHR adoption, CMS has weighted the EHR quality measure higher than other measures.

**SHARED SAVINGS AND LOSSES.**

*Authority for and Selection of Shared Savings/Losses Model*. CMS has affirmed its 2 Tracks approach for Program participation but has notably dropped the proposal that Track 1 transition to shared risk in year 3. All Track 1 ACOs will remain under a shared savings only model for the duration of their agreement. Track 2 ACOs will remain under a Two-Sided or risk sharing model for all three years of their agreement, but all ACOs must participate in the Two-Sided model in any subsequent agreements following their initial agreement periods. ACOs that experience a net loss during their initial agreement period may continue in the Program provided they identify the cause of the net loss and outline safeguards to avoid its reoccurrence.

Overview of Shared Savings and Losses Determination. CMS had initially proposed a hybrid approach that combined the elements of a pure shared savings model and a risk-based option. CMS noted the hybrid approach as benefiting organizations with less experience with risk models (physician organizations and smaller ACOs) by having a perhaps easier way to access the Shared Savings Program without the downside associated with sharing and losses. As modified, ACOs initially have a choice between two models:

- One-Sided Model - This option allows for ACOs to reconcile the shared savings on an annual basis using a pure shared savings approach for the duration of the three year agreement period. CMS removed the requirement that One-Sided models accept risk in the third year of their agreement; or
- Two-Sided Model - ACOs with more experience at managing populations and who are ready to share in the losses with a greater upside in savings, may elect to enter a risk-based model for the entire three years of its agreement. ACOs choosing this model are eligible for higher sharing rates. Only those ACOs that voluntarily choose to participate as a Two-Sided model are subject to a loss repayment requirement.

*Establishing, Adjusting and Updating the Benchmark*. CMS finalized its proposed methodology to establish an ACO's initial benchmark based on Parts A and B fee-for-service expenditures during the most recent three years prior to commencement of the ACO's participation agreement. CMS has also finalized its proposal to risk adjust an ACO's historical benchmark expenditures using its CMS-HHS model (hierarchical condition categories) to produce a health-based measure of future medical need. A number of additional benchmark risk adjustments and monitoring activities have been included in the Final Rule. As a nod to numerous comments, CMS has decided to exclude IME and DSH payments from ACO benchmark and performance year expenditures for purpose of determining cost performance. With the exception of IME and DSH payments, CMS for the most part finalized its proposal for all technical updates and adjustments to the benchmark (e.g., geographic, trending, national growth rate, etc.).

*Minimum Savings Rate*. Section 3022 of the Affordable Care Act provides that ACOs would be eligible for shared savings payments "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." CMS has finalized its proposal for establishing this Minimum Savings Rate ("MSR") for One-Sided models through use of a sliding scale that takes into consideration the number of assigned Medicare beneficiaries (ranging from 2% for large ACOs to 3.9% for smaller ACOs). For Two-Sided models, CMS has finalized its proposal to use a flat 2% MSR.

*Quality Performance Sharing Rate*. CMS finalized its savings rate proposal for both One-Sided and Two-Sided models. As a refresher, CMS proposed that One-Sided models would be eligible for shared savings payments of up to 50% of total savings (above a 2% savings rate) if they exceeded their MSR with a cap of 7.5% of the ACO's benchmark. Two-Sided models would be eligible for shared savings payments of up to 60% of total savings above its MSR. Both One-Sided and Two-Sided models would be eligible for percentage increases if they included an FQHC or RHC. With the modification to include primary care services received from FQHCs and RHCs for determining beneficiary assignment, CMS has removed its proposal to provide an incentive for ACOs to include FQHCs and RHCs.

*Net Sharing Rate*. CMS eliminated its proposal to require a 2% net savings rate and will now share earned savings with ACOs based on first dollar savings for both One-Sided and Two-Sided models.

*Performance Payment Limits.* Also, in response to persuasive comments, CMS is increasing the performance sharing payment limits for One-Sided models to 10% and 15% for Two-Sided models.

*Calculating and Limits on Shared Losses*. CMS made no change to its proposal for determining shared losses, which involves a formula that calculates shared losses based on the ACO's final sharing rate and a Minimum Loss Rate of 2% for Two-Sided models. Two-Sided models will be responsible for shared losses when their average per capita Medicare expenditures for a given performance year exceed their updated benchmark by 2%. The shared loss rate will mirror the modified sharing rate of 60%, but the annual loss percentage limits will be the same (5%, 7.5% and 10% of its updated benchmark in years 1, 2 and 3, respectively).

*Repayment of Shared Losses*. CMS retained its proposal to be codified at 42 CFR §425.204 regarding a shared loss repayment mechanism for Two-Sided models. ACOs also retain the ability to determine the best method for repayment but must still detail this method in their applications. Any repayments are now owed in full within 90 days following notification by CMS. CMS also decided to eliminate the 25% withhold proposal for an ACO's earned shared savings payments. This elimination applies to both One-Sided and Two-Sided models.

*Determining First Year Performance for ACOs Beginning April 1 or July 1, 2012*. With the decision to offer flexible start dates, CMS has developed a methodology for determining savings and losses for ACOs that commence on one of these dates that uses an interim payment approach with a year-end reconciliation.

**ADDITIONAL PROGRAM REQUIREMENTS AND BENEFICIARY PROTECTIONS.**

Background.

CMS believes that one important aspect of patient centeredness is patient engagement and transparency. This section describes certain requirements for ACOs that are intended to protect beneficiaries by ensuring patient engagement and transparency, including requirements related to beneficiary notification and outreach, marketing and public reporting.

*Beneficiary Protections*.

- **Beneficiary Notification**. CMS retained, in the Final Rule, the requirement that ACOs post signs indicating their associated ACO Provider's/Supplier's participation in the Program. However, as a modification from the Proposed Rule, the Final Rule does not require beneficiary notification of the ACO's nonrenewal or termination of its agreement.
- **ACO Marketing Guidelines**. The Final Rule maintains the need to obtain CMS approval of ACO marketing materials. However, the Final Rule allows ACOs to use marketing materials five days after filing them with CMS, provided that the ACO certifies compliance with applicable marketing requirements and CMS does not disapprove of the marketing materials and activities. After the five-day period, the marketing materials will be deemed approved; however, CMS retains the authority to disapprove of the materials at any time.
- **Public Reporting and Transparency**. The Final Rule maintains the public reporting provision requiring ACOs to publicly report the identity of each member of the governing body, not just the ACO Participants.

*Program Monitoring.*

- **General Methods Used to Monitor ACOs**. CMS will conduct audits of ACOs and will rely primarily on claims-based measures and user information provided by beneficiaries and providers to assess an ACO's performance.
- **Monitoring and Penalties for Avoidance of At-Risk Beneficiaries**. CMS is concerned with ACOs avoiding "at-risk" patients in order to reduce the likelihood of increasing costs to the ACO; thus, the Final Rule includes a definition of "At-Risk Beneficiaries" and imposes penalties, including immediate termination of an ACO's agreement, if such avoidance is found.
- **Compliance with Quality Performance Standards**. CMS added to the Final Rule the ability to immediately terminate an ACO's agreement or impose a Corrective Action Plan ("CAP"), in addition to a warning letter, for ACOs who are underperforming on quality performance standards.

*Program Integrity Requirements*. The Final Rule requires ACOs to implement the following Program integrity requirements to protect the

Program from fraud and abuse and to ensure that the Program does not become a vehicle for, or increase the potential for, fraud and abuse in other parts of the Medicare program or in other Federal health care programs.

- **Compliance Plans**. The Final Rule clarifies that legal counsel to the ACO and the compliance officer must be different individuals.
- **Compliance with Program Requirements**. The Final Rule modifies the Proposed Rule in that the Final Rule requires ACOs to submit annual certifications by the time frame CMS will establish through guidance. Such certification, by an individual authorized to legally bind the ACO, may include "to the best of my knowledge or belief" language or language similar to that appearing in other Medicare certifications.
- **Conflicts of Interest**. This requirement was finalized without change.
- **Screening of ACO Applicants**. This requirement was finalized without change.
- **Prohibition on Certain Required Referrals and Cost Shifting**. In order to avoid cost shifting to Medicare or other Federal health care programs for costs associated with beneficiaries not assigned to the ACO, the Final Rule prohibits an ACO from conditioning participation in the ACO on referrals of non-ACO business. The Final Rule modifies the Proposed Rule in that the Final Rule prohibits limiting or restricting referrals of patients to ACO Participants or ACO Providers/Suppliers within the same ACO, with some exceptions.
- **Record Retention**. ACOs must retain their records for a period of 10 years from the final date of the agreement period or from the date of completion of any audit, evaluation or inspection.
- **Beneficiary Inducements**. Although the Final Rule still prohibits providing gifts, cash or other remuneration to beneficiaries as inducements for receiving services or remaining in an ACO, it added a provision allowing an ACO, its ACO Participants or its ACO Providers/Suppliers to provide to beneficiaries items or services for free or below fair-market value, if certain conditions are met. For example, an acceptable condition exists if an item is provided to advance a patient's treatment (e.g., blood pressure monitor to patients with hypertension).

*Terminating an ACO Agreement.*

- **Reasons for Termination of an ACO's Agreement**. An ACO's agreement may be terminated for the following reasons:
  a. non-compliance with the requirements of the Program;
  b. sanctions imposed on an ACO by an accrediting organization, or by State, Federal or Local government agencies;
  c. providers are excluded by the OIG or have their privileges to participate in Medicare revoked; or
  d. an ACO has violated the antitrust laws or the fraud and abuse laws.

ACOs may also voluntarily terminate upon a 60-day notice to CMS and all of its ACO Participants, ACO Providers/Suppliers and other individuals or entities performing functions or services related to ACO activities. 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. CMS deleted the 25% withhold applied to annual earned performance payments; thus, forfeiture of this withhold upon early termination of an ACO's agreement is no longer applicable.

Future Participation of Previously Terminated Program Participants. ACOs that were previously terminated through enforcement action or voluntarily that wish to re-enter the Program may do so at the end of their initial agreement period.

Reconsideration Review Process. ACOs may request an administrative review of certain decisions, such as the denial of an application to participate in the Program or the termination of an existing participation agreement. Such reviews will be conducted by an independent reviewer who was not involved with any previous determination. An ACO must request such a review within 15 days after receipt of the notice of determination.

**ADVANCE PAYMENT MODEL**

With the Final Rule, CMS also released a new initiative referred to as the Advance Payment Model. Eligible ACO Participants will receive advance payments to be recouped from future shared savings. Each participating ACO will receive three types of advance payments:

- An upfront, fixed payment;
- An upfront, variable payment based on the number of historically-assigned beneficiaries; and
- A monthly, variable payment based on the size of the ACO.

Focused on rural and physician-owned ACOs, only two types of ACOs are eligible for the Advance Payment Model:

- ACOs that do not include any inpatient facilities AND have less than $50 million in total annual revenue; or
- ACOs in which the only inpatient facilities are critical access hospitals and/or Medicare low-volume rural hospitals AND have less than $80 million in total annual revenue.

ACOs meeting either of these eligibility criteria must enter the Program in April 2012 or July 2012. Additional information and application instructions regarding the Advance Payment Model are available at: http://innovations.cms.gov/areas-of-focus/seamless-and-coordinated-care-models/advance-payment/

**COORDINATION WITH OTHER AGENCIES**

Three documents were issued contemporaneously with the Final Rule: (i) a joint CMS and OIG interim final rule with comment period entitled Medicare Program; Final Waivers in Connection with the Shared Savings Program; (ii) an IRS fact sheet; and (iii) a Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Shared Savings Program issued by the Antitrust Agencies.

**CMS and OIG Waivers of CMP, Anti-Kickback and Stark Laws**. Certain arrangements between and among ACOs, ACO Participants, Owners, Providers/Suppliers and third parties may implicate the civil monetary penalties ("CMP") laws (relating to both "gainsharing" arrangements and beneficiary inducements), the federal Anti-Kickback Statute and/or the physician self-referral prohibition (referred to as the "Stark Law"). Section 1899(f) of the Act authorized the Secretary to waive certain fraud and abuse laws as necessary to carry out the provisions of the Program. Accordingly, CMS and OIG jointly published an interim final rule ("Interim Final Rule") setting forth waivers of the application of certain CMP law provisions, the Anti-Kickback Statute and the Stark Law. Commentors have 60 days from the date of publication in the Federal Register to comment on the Interim Final Rule.

The waivers include two of the waivers originally proposed by CMS and OIG (for shared savings distributions and arrangements that are in compliance with Stark Law), which are being finalized with minor modifications. In addition, CMS and OIG have proposed three new waivers, developed in response to public comment, to address a broader array of ACO activities, including start-up and operating activities, as well as incentives offered to beneficiaries to encourage preventative care and patient compliance. In an effort to ensure the waivers remain current over time and across relevant laws, CMS has proposed not to codify the waivers in the Code of Federal Regulations, but rather to publish them on the OIG and CMS websites.

*ACO Pre-Participation Waiver*. The Stark Law, "gainsharing" CMP and Anti-Kickback Statute are waived with respect to start-up arrangements (i.e., items, services, facilities or goods used to create or develop an ACO that are provided by such ACO, ACO Participants or ACO Providers/Suppliers) that pre-date an ACO's participation agreement, provided all of the following conditions are met:

1. The arrangement is undertaken by the parties with the good faith intent to develop an ACO that will participate in the Program starting in a particular year (the "target year") and to submit a completed application to participate in the Program for that year. The parties to the arrangement may not include drug and device manufacturers, distributors, durable medical equipment ("DME") suppliers or home health suppliers.
2. The parties must be taking diligent steps to develop an ACO that would be eligible for a participation agreement that would become effective during the target year, including taking diligent steps to meet requirements concerning the ACO’s governance, leadership and management.
3. The ACO's governing body has made and duly authorized a bona fide determination, consistent with a duty to the ACO that is equivalent to the duty owed by ACO governing body members, that the arrangement is reasonably related to the purposes of the Program.
4. The arrangement, its authorization by the governing body and the diligent steps to develop the ACO are documented. The documentation of the arrangement must be contemporaneous with the establishment of the arrangement, the documentation of the

authorization must be contemporaneous with the authorization and the documentation of the diligent steps must be contemporaneous with the diligent steps. All such documentation must be retained for at least 10 years following completion of the arrangement (or, in the case of the diligent steps, for at least 10 years following the date the ACO submits its application) and promptly made available to the Secretary upon request.

5. The description of the arrangement is publicly disclosed at a time and in a place and manner established in guidance issued by the Secretary. Such public disclosure shall not include the financial or economic terms of the arrangement.

6. If an ACO does not submit an application for a participation agreement by the last available application due date for the target year, the ACO must submit a statement on or before the last available application due date for the target year, in a form and manner to be determined by the Secretary, describing the reasons it was unable to submit an application.

For arrangements that meet all of the preceding conditions, the pre-participation waiver would start on the date of publication of this Interim Final Rule for target year 2012 or one year preceding an application due date (the "selected application date") for a target year of 2013 or later. Generally, the waiver period will end on the start date of the participation agreement.

Importantly, an ACO may use the pre-participation waiver (including any extensions granted) only one time.

In commentary to the Interim Final Rule, CMS provided a list of examples of appropriate start-up arrangements. Of note, the following are included on such list:

- Hiring of new staff (care coordinators, umbrella organization management, quality leadership, etc.).
- Information Technology, including EHR systems and electronic health information exchanges.
- Consulting and other professional support, including legal services.
- Capital investments, including loans, capital contributions, grants and withholds.

*ACO Participation Waiver*. The Stark Law, "gainsharing" CMP and Anti-Kickback Statute are waived with respect to any arrangement of an ACO, one or more of its ACO Participants or its ACO Providers/Suppliers, or a combination thereof, provided all of the following conditions are met:

1. The ACO has entered into a participation agreement and remains in good standing under its participation agreement.

2. The ACO meets applicable requirements concerning its governance, leadership and management.

3. The ACO's governing body has made and duly authorized a bona fide determination, consistent with the governing body members' duty as set forth in the ACO regulations, that the arrangement is reasonably related to the purposes of the Program.

4. Both the arrangement and its authorization by the governing body are documented. The documentation of the arrangement must be contemporaneous with the establishment of the arrangement, and the documentation of the authorization must be contemporaneous with the authorization. All such documentation must be retained for at least 10 years following completion of the arrangement and promptly made available to the Secretary upon request.

5. The description of the arrangement is publicly disclosed at a time and in a place and manner established in guidance issued by the Secretary. Such public disclosure shall not include the financial or economic terms of the arrangement.

For arrangements that meet all of the preceding conditions, the waiver period will start on the start date of the participation agreement and will end six months following the earlier of the expiration of the participation agreement, including any renewals thereof, or the date on which the ACO has voluntarily terminated the participation agreement. However, if CMS terminates the participation agreement, the waiver period will end on the date of the termination notice.

*Shared Savings Distribution Waiver*. The Stark Law, "gainsharing" CMP and Anti-Kickback Statute are waived with respect to distributions or use of shared savings earned by an ACO, provided all of the following conditions are met:

1. The ACO has entered into a participation agreement and remains in good standing under its participation agreement;

2. The shared savings are earned by the ACO pursuant to the Program;
3. The shared savings are earned by the ACO during the term of its participation agreement, even if the actual distribution or use of the shared savings occurs after the expiration of that agreement.
4. The shared savings are (i) distributed to or among the ACO's ACO Participants, its ACO Providers/Suppliers or individuals and entities that were its ACO Participants or its ACO Providers/Suppliers during the year in which the shared savings were earned by the ACO; or (ii) used for activities that are reasonably related to the purposes of the Program.
5. With respect to the waiver of the "gainsharing" CMP, payments of shared savings distributions made directly or indirectly from a hospital to a physician are not made knowingly to induce the physician to reduce or limit medically necessary items or services to patients under the direct care of the physician.

Compliance with the Physician Self-Referral Law Waiver. The Stark Law, "gainsharing" CMP and Anti-Kickback Statute are waived with respect to any financial relationship between or among the ACO, its ACO Participants and its ACO Providers/Suppliers that implicates the Stark Law, provided all of the following conditions are met:

1. The ACO has entered into a participation agreement and remains in good standing under its participation agreement.
2. The financial relationship is reasonably related to the purposes of the Program.
3. The financial relationship fully complies with an applicable Stark regulatory exception.

For arrangements that meet all of the preceding conditions, the waiver period will start on the start date of the participation agreement and will end on the earlier of the expiration of the term of the participation agreement, including any renewals thereof, or the date on which the participation agreement has been terminated.

This waiver is designed for use by parties that might elect to use an existing Stark exception to protect its ACO arrangement without a need for further Stark/fraud and abuse analysis under the other waivers.

Waiver for Patient Incentives. The "beneficiary inducement" CMP and the Anti-Kickback Statute are waived with respect to items or services provided by an ACO, its ACO Participants or its ACO Providers/Suppliers to beneficiaries for free or below fair market value if all of the following conditions are met:

1. The ACO has entered into a participation agreement and remains in good standing under its participation agreement.
2. There is a reasonable connection between the items or services and the medical care of the beneficiary.
3. The items or services are in-kind.
4. The items or services (i) are preventive care items or services; or (ii) advance one or more of the following clinical goals:

- Adherence to a treatment regime.
- Adherence to a drug regime.
- Adherence to a follow-up care plan.
- Management of a chronic disease or condition.

For arrangements that meet all of the preceding conditions, this waiver period will start on the start date of the participation agreement and will end on the earlier of the expiration of the term of the participation agreement, including any renewals thereof, or the date on which the participation agreement has been terminated, provided that a beneficiary may keep items received before the participation agreement expired or terminated, and receive the remainder of any service initiated before the participation agreement expired or terminated.

It is of note that this waiver does not protect the provision of free or below fair market value items or services by manufacturers or other vendors to beneficiaries, the ACO, ACO Participants or ACO Providers/Suppliers.

**IRS Guidance Relating to Tax-Exempt Organizations**. The IRS previously issued Notice 2011-20 (April 18, 2011), which summarized how the IRS expects existing guidance to apply to §501(c)(3) tax-exempt organizations participating in the Program through ACOs. A new fact sheet published in connection with the Final Rule confirms that the prior Notice continues to reflect IRS expectations regarding the Program and ACOs and provides additional information for charitable organizations that may wish to participate in the Program.

**Antitrust Policy Statement**. The Antitrust Agencies also issued a final Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (the "Policy Statement"). This Policy Statement differs from the proposed Policy Statement issued earlier this year in two significant respects.

First, the entire Policy Statement, with the exception of the voluntary expedited antitrust review noted below, applies to all collaborations among otherwise independent providers and provider groups that are eligible and intend, or have been approved, to participate in the Program. Previously, the Antitrust Agencies' guidance applied only to those collaborations formed after March 23, 2010, the date of enactment of the Affordable Care Act.

Second, the Final Rule no longer requires a mandatory antitrust review for certain collaborations as a condition of entry into the Program; therefore, the Policy Statement no longer contains provisions relating to mandatory antitrust review. However, as noted above in the Final Rule, the Antitrust Agencies will continue to protect competition in markets served by ACOs that participate in the Program, aided by data and information CMS will compile. Specifically, CMS will provide the Antitrust Agencies with aggregate claims data regarding allowed charges and fee-for-service payments for all ACOs accepted into the Program, along with copies of all applications to the Program after March 23, 2010. The Antitrust Agencies will vigilantly monitor complaints about an ACO's formation or conduct and take appropriate enforcement action.

Notably, upon request, the Antitrust Agencies will provide an expedited 90 day review for newly formed ACOs that wish to obtain additional antitrust guidance.

If you have questions regarding the Final Rule, please contact Brian Betner at bbetner@hallrender.com or 317.977.1466; Erin Drummy at edrummy@hallrender.com or 317.977.1470; or Tina Torossian at ctorossian@hallrender.com or 248.457.7806.

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1 Introductory comment to the Medicare Shared Savings Program Final Rule at p.10 (CMS-1345-F)