Client Advisory

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Health Care

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CMS Issues Final ACO Regulations

After receiving more than 1,300 public comments on its Proposed Rule for Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program, CMS published its Final ACO Rule in the Federal Register on November 2. In addition, the FTC and DOJ filed their Final Statement of ACO Antitrust Enforcement Policy and CMS issued an Interim Final Rule with a 60-day comment period describing five separate fraud and abuse waivers applied to Stark, the Anti-Kickback Statute and the Civil Monetary Penalty laws. Finally, the IRS also issued Fact Sheet 2011-11 confirming Notice 2011-20 from April 18, 2011, on its expectations regarding ACOs participating in the Shared Savings Program.

As stated by CMS in the Final ACO Rule, the overall intent of CMS, the IRS, FTC and DOJ in modifying their respective rules and statements (collectively, the Final Rules) was to incorporate greater flexibility in terms of eligibility requirements, ACO governance and legal structure, the antitrust review process, and the timing for shared savings evaluations and repayment of losses. These standards also have reduced and simplified the quality performance standards, increased financial incentives to participate in an ACO, eliminated the downside risk and first-dollar sharing in the Track 1 shared savings model, increased the sharing caps and removed the 25% withhold requirement on shared savings.

While initial industry reaction has been positive and the barriers to ACO certification and the risk of participation have been reduced, time will tell as to whether the changes will motivate health care providers to submit applications by the revised due dates of April 1, 2012, or July 1, 2012, pushed back from January 1. A likely outcome will be that many providers will evaluate the Final Rule closely and continue with their various clinical integration, merger, and acquisition strategies, but wait for the U.S. Supreme Court's decision on the constitutional challenges to the Affordable Care Act as well as to see how the Final Rule impacts those ACOs that seek certification in 2012.

The purpose of this Advisory is to provide a high-level summary of the Final Rules, followed by a more detailed analysis of each. We also have offered our comments and recommendations where appropriate.

EXECUTIVE SUMMARY

Eligibility

- ACOs can and will take many different forms and encompass different provider groups, including:
  - ACO professionals (defined as ACO providers/suppliers that are either physicians legally authorized to practice medicine, or practitioners as defined in the Affordable Care Act, including physician assistants, nurse practitioners and clinical nurse specialists) in group practice arrangements;
  - Networks of individual practices of ACO professionals;
  - Partnerships or joint venture arrangements between hospitals (defined as acute care hospitals paid under the hospital inpatient prospective payment system) and ACO professionals;
  - Hospitals employing ACO professionals;
  - Providers or suppliers otherwise recognized under the Act that are not ACO professionals;
  - Critical access hospitals billing under Method II;

- Rural health centers; and
- Federally qualified health centers.
- Other ACO participants not identified above are eligible to participate through an ACO formed by one or more of the ACO participants identified above.

Legal Structure

- An ACO's structure must be one recognized and authorized to conduct business under state law (e.g., corporation, partnership, LLC, foundation) with adequate legal authority through a governing body to implement and enforce all required ACO functions.
- An ACO must be able to receive and distribute shared savings.
- An ACO can be an existing legal entity and the governing body can be the same if it otherwise meets all other requirements.
- An ACO must have a tax identification number.
- An ACO need not be enrolled in Medicare Program, but each ACO participant must be so enrolled.
- An ACO formed by two or more otherwise independent ACO participants must be a legal entity separate from any of its ACO participants.

Shared Governance

- An ACO's governing body must have a board of directors that has adequate legal, management and executive authority to implement and enforce all requirements under the Affordable Care Act (the Act) and Final Rule, including the promotion of evidence-based medicine and patient engagement, reporting on quality and cost measures, and the coordination of care.
- The governing body must be composed of ACO participants or their designated representatives, each of whom owes a fiduciary duty to the ACO.
- The governing body must include at least one Medicare beneficiary representative who is served by the ACO.
- At least 75% control of an ACO's board of directors must be held by ACO participants.
- An ACO must have a conflict of interest policy consistent with industry standards.
- ACO participants must have meaningful participation with respect to the composition and control of the ACO's governing body.

Management

- An ACO must be managed by an executive, officer, manager or general partner under the control of the ACO's governing body.
- Clinical management must be through a senior-level medical director who is present on a regular basis and is a board-certified physician licensed in the state in which the ACO operates.

Sufficient Number of ACO Professionals and Beneficiaries

- An ACO must have a sufficient number of primary care ACO professionals to treat at least 5,000 Medicare patients assigned to it and must maintain an assigned beneficiary population of at least 5,000 such patients.

Quality Assurance and Process Improvement

- Internal performance standards for quality of care and services, cost-effectiveness and other standards must be adopted and implemented.
- ACO participants must be held accountable for meeting performance standards.
- ACO participants must make a meaningful commitment either through financial investment or meaningful investment of time and effort.
- An ACO must have data collection and evaluation infrastructure, such as information technology.
- An ACO must provide to CMS a description and example of an individualized care plan.

Compliance Plan

- An ACO must have a compliance plan that meets specific requirements which are standard within the health care industry, including a compliance official who is not the in-house general counsel.

Required Processes and Patient-Centeredness Criteria

- An ACO must meet patient-centeredness criteria specified by CMS, including evidence-based medicine, patient engagement, coordination of care across the ACO continuum, and processes to report on quality and cost metrics.

Assignment of Medicare Beneficiaries to ACOs

- Medicare fee-for-service beneficiaries are assigned to an ACO based on their utilization of primary care services by a primary care physician who is an ACO provider/supplier during the performance year for which savings are determined.
- Beneficiary assignment does not in any way diminish or restrict the rights of beneficiaries to exercise free choice in determining where to receive health care services, including a provider who is not a participant in the assigned ACO.

Distribution of Savings

- ACOs will be required to provide in their application a description of the criteria to be employed for distribution of shared savings among ACO participants and how such savings will be used to align with the aims of better care for individuals, better health for patient populations, and lower growth of expenditures.

Three-Year Agreement with CMS

- ACOs will be required to enter into a three-year agreement with CMS with revised start dates of April 1, 2012, or July 1, 2012, and then January 1 for every start year thereafter.
- Performance year varies with start date (21 months for 4/1/12 start date and 18 months for 7/1/12 start date).

CMS Monitoring, Termination, Audits and Record Retention

- CMS will monitor the compliance of ACOs with all requirements, conduct investigations as may be necessary and collect information relevant to assessing financial and quality performance, and may terminate an ACO or otherwise impose some form of corrective action plan as determined by CMS.

Quality and Other Reporting Requirements

- The Final Rule identifies 33 quality measures, which is a reduction from the proposed 65. The required benchmarks for each measure have not yet been identified by CMS.
- Measures are divided into four domains:
  - Patient/caregiver experience (7 measures)
  - Care coordination/patient safety (6 measures)
  - Preventative health (9 measures)
  - At-risk population
    - Diabetes (5 measures)
    - Hypertension (1 measure)
    - Ischemic vascular disease (2 measures)
    - Heart failure (1 measure)
    - Coronary artery disease (2 measures)

  Click here to view CMS's Measures for Use in Establishing Quality Performance Standards for That ACOs Must Meet for Shared Savings.

- Where an ACO fails to meet minimum attainment levels for one or more domains, fails to report all required measures or provides inaccurate or incomplete recording, the ACO agreement may be terminated under certain conditions.

- An ACO must submit quality measures data to CMS in order to monitor and determine whether it has achieved minimal compliance with required benchmarks.
- The level of compliance with these benchmarks will affect the percentage of savings that the ACO will be entitled to receive and distribute to its participants.

Shared Savings Determination

- As was the case with the Proposed Rule, the Final Rule allows ACOs to choose between two tracks:
  - Track 1: a "one-sided" shared savings only model for organizations that have less experience in at-risk arrangements; or
  - Track 2: a "two-sided" shared savings and losses model.
- Under the Proposed Rule, an ACO could participate for a maximum of two years under the one-sided model before it would be required to transition into the two-sided model. The Final Rule makes Track 1 a shared savings only model for all three years of the ACO's first agreement period. (This is intended to benefit ACOs new to risk-based arrangements, such as small, rural, safety-net and physician-only ACOs, by providing additional time under the one-sided model before being required to accept risk.)
- After the initial agreement period, all ACOs will operate under the at-risk Track 2 model.
- The Final Rule also allows continued participation by ACOs that experience a net loss during the first agreement period. However, in order to participate in a subsequent agreement period, such ACOs must identify in their application the causes for the net loss and identify safeguards that are in place to enable the ACO to achieve savings in its next agreement period. CMS intends to monitor this aspect of the program, and may revise its policy in future rulemaking.
- To be eligible for shared savings, ACOs must, in addition to meeting all contractual requirements of the ACO agreement and all quality performance standards, realize savings compared to an expenditure benchmark that exceeds a minimum savings rate (MSR).
- A sliding scale, based on the size of the ACO's assigned population, is used to establish the MSR for ACOs participating under the one-sided model (the sliding scale is set forth in Regulation § 425.604).
- A flat 2% MSR applies to all ACOs participating under the two-sided model.
- ACOs under the one-sided model can earn up to 50% of total savings based on quality performance and ACOs under the two-sided model can earn up to 60% of total savings based on quality performance.
- The Final Rule revises the CMS proposal to allow for sharing on first-dollar savings for ACOs under the one-sided model once savings meet or exceed the MSR, and finalizes the proposal similarly allowing sharing on a first-dollar savings for ACOs under the two-sided model once savings meet or exceed the MSR.
- The Final Rule raises the performance payment limit from 7.5% to 10% of an ACO's updated benchmark for ACOs under the one-sided model, and from 10% to 15% of an ACO's updated benchmark for ACOs that elect the two-sided model.
  - The amount of shared losses for which an eligible ACO is liable may not exceed the following percentages of its updated benchmark:
    - 5% in the first performance year of participation in a two-sided model under the Shared Savings Program;
    - 7.5% in the second performance year; and
    - 10% in the third performance year.
  - The Final Rule revises the proposal to eliminate the 25% withhold and the related proposal for ACOs to forfeit the 25% withhold in the event of early termination from the program.

For a more detailed description of the shared savings methodology, see Section III below.

Final Statement of Antitrust Enforcement

- ACOs that are certified by CMS and therefore must meet various clinical integration, legal and governance structural requirements will be viewed by the FTC/DOJ as bona fide arrangements intended to improve quality and reduce costs.

- Consequently, the Agencies will apply a "rule of reason" analysis as opposed to the "per se" analysis to ACOs when negotiating payor contracts in the commercial market, which will allow an ACO to identify community benefits achieved through the ACO to offset any anti-competitive effects of its operations and practices.
- In order to be in the antitrust "safety zone," independent ACO participants that provide the same "common service" (e.g., cardiology, gastroenterology) must have a combined share of 30% or less in each common service in each participant's primary service area (PSA) whenever two or more ACO participants provide that service to patients from that PSA.
- The Agencies will not investigate an ACO that falls within the safety zone, or intervene, barring extraordinary circumstances.
- The PSA for each common service is defined as "the lowest number of postal zip codes from which the ACO participant draws at least 75% of its patients for that service."
- Hospital and surgery center participation in an ACO must be nonexclusive in order to fall within the safety zone.
- The safety zone applies to physicians or other providers irrespective of whether they are exclusive or nonexclusive to the ACO.

For a more detailed description of the calculation methodology for PSA shares, see Section V below. See also our discussion of rural exception and dominant provider limitation and voluntary review of ACOs that exceed the 50% PSA share threshold.

Fraud and Abuse Waivers

CMS and the Office of the Inspector General jointly issued an Interim Final Rule with comment period (IFC) providing waivers from the Stark Law, the Anti-Kickback Statute, and the gainsharing portion of the Civil Monetary Penalty (CMP) laws. While the proposed regulations provided for three types of waivers, the IFC sets forth five waivers that apply across the board to the Stark Law, the Anti-Kickback Statute and the CMP laws. They also are designed to be self-executing and apply uniformly to each ACO, ACO participant and ACO provider/supplier participating in the Shared Savings Plan. Given that this is an interim final rule with comment period, additional comments on waivers and waiver criteria may lead to further changes. The five waivers are as follows:

- Pre-Participation Waiver: Permits potential ACOs and ACO participants to share resources to start ACOs if the arrangement meets certain conditions.
- Participation Waiver: Allows arrangements between the ACO, one or more ACO participants and/or ACO providers/suppliers if the arrangement meets certain conditions.
- Shared Savings Waiver: Allows for distributions under the Shared Savings Program, subject to specified conditions, and for financial relationships among the ACO, ACO participants and ACO providers/suppliers directly related to participation in the Shared Savings Program.
- Compliance with the Stark Law Waiver: Distribution of shared savings received by an ACO from CMS under the Shared Savings Program to or among ACO participants and ACO providers/suppliers, and activities necessary for and directly related to an ACO's participation in the Shared Savings Program are waived from the Anti-Kickback Statute and the gainsharing portion of the CMP laws if such financial relationships fully comply with an applicable Stark Law exception.
- Patient Incentives Waiver: Waives the application of the CMP provisions prohibiting inducement of beneficiaries and the Anti-Kickback Statute for items or services provided by an ACO, ACO participants or ACO providers/suppliers to beneficiaries for free or below fair market value if certain requirements are satisfied.

IRS Notice: Tax-Exempt Hospitals Participating in ACOs

The IRS issued Notice 2011-20 (2011-16 I.R.B. 652 (April 18, 2011)) (the Notice) to address whether Section 501(c)(3) hospitals and other tax-exempt health care entities participating in the Shared Savings Program through an ACO may be affected by current limitations on such entities under the Internal Revenue Code. On October 20, 2011, the IRS issued Fact Sheet 2011-11, which confirms that Notice 2011-20 continues to reflect the IRS's expectations regarding the Shared Savings Program and ACOs.

Generally, as indicated in the Notice, the IRS expects that a tax-exempt hospital's participation in ACO arrangements under the Shared Savings Program will not result in private inurement or benefit if the following factors are present:

- The terms of the tax-exempt hospital's participation in the Shared Savings Program through an ACO are set forth in advance in a written agreement negotiated at arm's length.

- CMS has accepted the ACO into, and has not terminated the ACO from, the Shared Savings Program.
- The tax-exempt hospital's share of the economic benefits derived from the ACO (including its share of Shared Savings Program payments) is proportional to the benefits or contributions that the hospital provides to the ACO.
- The ownership interest received by the tax-exempt hospital, if any, is proportional and equal in value to its capital contributions to the ACO, and all ACO returns of capital, allocations and distributions are made in proportion to such ownership interest.
- The tax-exempt hospital's share of ACO losses (including its share of Shared Savings Program losses) does not exceed the share of ACO economic benefits to which the hospital is entitled.
- All contracts and transactions entered into by the tax-exempt hospital with the ACO and the ACO participants, and by the ACO with the ACO participants and other parties, are at fair market value.

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If you have any questions about the Final ACO Rule or ACO participation, please contact your Katten Muchin Rosenman LLP attorney, or any of the following members of **Katten's Health Care Practice**.

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