Client Advisory

Katten
Katten Muchin Rosenman LLP

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.

PROVISIONS OF THE FINAL RULE

I. Eligibility and Governance

A. Eligible Entities

- The following ACO participants (providers and suppliers as defined in the Affordable Care Act and identified by a taxpayer identification number (TIN)) are eligible, separately or in combination, to form ACOs that may participate in the Shared Savings Program:

- 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.
- ACO applicants must provide the TINs of the ACO and ACO participants and the national provider identifiers (NPIs) associated with the ACO's providers/suppliers. Such information must be maintained, updated and annually reported to CMS.
- Each ACO participant's TIN upon which the beneficiary assignment is dependent must be exclusive to one Shared Savings Program ACO for purposes of the beneficiary assignment. Each ACO participant's TIN upon which the beneficiary assignment is not dependent is not required to be exclusive.

B. Legal Structure

- An ACO must be formed as a legal entity that is recognized and authorized under applicable state, federal or tribal law.
- An ACO must certify that it is recognized as a legal entity in the state in which it was established and that it is authorized to conduct business in each state in which it operates.
- The legal entity must be constituted such that it can receive and distribute shared savings, repay shared losses owed to CMS, and establish, report and ensure provider compliance with health care quality criteria, including quality performance standards.
- An ACO must have a TIN. The ACO need not be enrolled in the Medicare program, but each ACO participant must be so enrolled.
- There is no requirement that existing legal entities, appropriately recognized under state law, must form a new entity to participate in the Shared Savings Program. If an existing legal entity meets the eligibility requirements to be an ACO, it may so qualify.
- An ACO formed by two or more otherwise independent ACO participants must be a legal entity separate from any of its ACO participants.

C. Shared Governance

- An ACO must establish and maintain a governing body with adequate 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 coordinate care.
- The governing body must have responsibility for oversight and strategic direction of the ACO, and be able to hold ACO management accountable for the ACO's activities.
- The governing body must have a transparent governing process.
- The governing body members owe a fiduciary duty to the ACO and must act consistent with that fiduciary duty.
- The governing body must be separate and unique to the ACO in cases where the ACO comprises multiple, otherwise independent ACO participants.
- If the ACO is an existing entity, the ACO governing body may be the same as the governing body of that existing entity, provided it satisfies other applicable requirements.

- The governing body must provide for meaningful participation in composition and control of the governing body by the ACO participants or their designated representatives.
- The governing body must include a Medicare beneficiary representative(s) served by the ACO who (along with immediate family members) do not have a conflict of interest with the ACO.
- At least 75% control of the ACO's governing body must be held by ACO participants.
- In cases where composition of the ACO's governing body fails to meet the requirements of meaningful participation by ACO participants (the Medicare beneficiary representation, and at least 75% control by ACO participants), the ACO must describe why it seeks to differ from these requirements and to show how the ACO will provide meaningful representation and participation by ACO participants and Medicare beneficiary.
- The ACO governing body must have a conflict of interest policy that requires each member to disclose relevant financial interests, provides a procedure to determine whether a conflict exists and a process to address any conflicts, and addresses remedial actions for members who fail to comply with the policy.

D. Leadership and Management

- An ACO's operations must be managed by an executive, officer, manager or general partner whose appointment and removal are under the control of the ACO's governing body, and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency processes and outcomes.
- Clinical management and oversight must be managed by a senior-level medical director who is physically present on a regular basis at any clinic, office or other location participating in the ACO, and who is a board-certified physician licensed in the state in which the ACO operates.
- Each ACO participant and each ACO provider/supplier must demonstrate a meaningful commitment to the mission of the ACO, which may include a sufficient financial or human investment in the ongoing operations of the ACO or agreement to comply with and implement the ACO's processes and to be held accountable for meeting the ACO's performance standards.
- CMS retains the right to give consideration to an innovative ACO with a management structure that differs from the above requirements, other than the meaningful commitment requirement.

E. Sufficient Number of ACO Professionals and Beneficiaries

- For eligibility purposes, an ACO must have and will be determined to have a sufficient number of primary care ACO professionals to serve the number of Medicare beneficiaries assigned to it if the number of beneficiaries historically assigned to the ACO participants in each of the three years before the start of the agreement period exceeds the 5,000-beneficiary threshold.
- If an ACO's assigned population falls below 5,000 during the course of the agreement period, CMS will issue a warning and place the ACO on a corrective action plan. The ACO will remain eligible for shared savings for the performance year for which the warning was issued.
- If the ACO fails to have more than 5,000 beneficiaries by completion of the next performance year, the ACO's participation agreement will be terminated and the ACO will not be eligible to share in savings for that year.

F. Required Processes and Patient-Centeredness Criteria

- Generally, an ACO must:
  - Promote evidence-based medicine and beneficiary engagement, internally report on quality and cost metrics, and coordinate care;
  - Adopt a focus on patient centeredness that is prompted by the governing body and integrated into practice by leadership and management;
  - Have defined processes to fulfill these requirements; and
  - Have a qualified health care professional responsible for the ACO's quality assurance and improvement program.

- The ACO's quality assurance and improvement program must define, establish, implement and periodically update the following processes to:
  - Promote evidence-based medicine that covers diagnoses with significant potential to achieve quality improvement based on individual beneficiaries;
  - Promote patient engagement by complying with patient survey and beneficiary representative requirements and a process for evaluating the health care needs of its diverse patient population through a plan;
  - Develop an infrastructure for its ACO participants and ACO providers/suppliers to internally report on quality and cost metrics that enables the ACO to monitor and evaluate performance and use these results to improve care; and
  - Coordinate care across and among primary care physicians, specialists, and acute and post-acute providers and suppliers throughout a beneficiary's episode and transition of care.
- In its application, an ACO must submit a description and an example of an individualized care plan and explain how the program is used to promote improved outcomes for at least its high risk and multiple chronic condition patients.
- Applications also must describe target populations that would benefit from these care plans, which must take into account available community resources.
- The plan must describe how an ACO intends to partner with community stakeholders to improve the health of its population.
- As part of its requirement to provide patient engagement, the ACO must also communicate clinical knowledge/evidence-based medicine to its beneficiaries in an understandable way; must take into account the unique needs, preferences, values and priorities of the beneficiaries; and must develop written standards for beneficiary access and communication and a process for accessing their medical records.

G. Participation in Other Shared Savings Initiatives

- CMS will deny an ACO's application if any ACO participants are participating in another Medicare Shared Savings Program.

H. Application for Participation in the Shared Savings Program

- A prospective ACO must submit and complete an application in the form and manner required by CMS that addresses the following major areas:
  - Accountability for beneficiaries
  - Disclosure of prior participation in the Shared Savings Program
  - Satisfaction of program eligibility requirements
  - Distribution of shared savings
  - Selection of track and option for interim payment calculation
  - Assurance of ability to repay losses for which the ACO may be liable
- CMS will provide written notice to each ACO applicant of its determination to approve or deny the ACO's application.
- If the application is denied, the CMS notice will indicate the reasons why the ACO is not qualified and inform the ACO of its right to request reconsideration.

I. Agreement with CMS

- An ACO must enter into an agreement with CMS for a period of not less than three years.
- Term of agreement:
  - For 2012: Start date for agreement will be April 1, 2012 (term of three years and nine months), or July 1, 2012 (term of three years and six months).
  - For 2013 and subsequent years: Start date of January 1 of that year and a term of three years.
- Performance year:
  - The 12-month period beginning January 1 of each year.

- For start dates April 1, 2012, and July 1, 2012, the performance year is 21 months and 18 months, respectively.

- Application of an ACO's CMS Participation Agreement
  - An ACO executive who has legal authority to bind the ACO must certify as to the accuracy, completeness and truthfulness of the application.
  - An ACO must provide a copy of its CMS participation agreement to all ACO participants, ACO providers/suppliers and individuals/entities involved in ACO governance.
  - All contracts/arrangements between or among the ACO, ACO participants, ACO providers/suppliers and others performing functions/services related to ACO activities must require compliance with the requirements and conditions of the CMS participation agreement and the Shared Savings Program and agree to be accountable for the quality, cost and overall care of its beneficiaries.

J. Legal Changes to Program Requirements During the Agreement Term

- ACOs will be subject to all statutory changes. ACOs also will be subject to all regulatory changes, except:
  - Eligibility requirements concerning the structure and governance of ACOs;
  - Calculation of sharing rate; and
  - Beneficiary assignment.
- Where there are changes in law or regulations, an ACO will be required to submit to CMS for review and approval a supplement to its original application detailing how the ACO will modify its processes to address these changes.
- If an ACO cannot effectuate the changes needed to conform to the regulatory modifications, it will be placed on a corrective action plan and, if it fails to effectuate necessary modifications, will be terminated from the program.

K. Managing Changes to the ACO During Agreement Period

- During the term of the participation agreement, an ACO may add or remove ACO participants or ACO providers/suppliers. ACOs must notify CMS within 30 days of such an addition or removal and CMS, in its discretion, may adjust the ACO's benchmark, risk scores and preliminary prospective assignment.
- ACOs must notify CMS within 30 days of any significant change, which is defined to occur when an ACO no longer meets the eligibility or program requirements.
- Upon receipt of an ACO's notice of significant change, CMS may make a determination that includes any of the following:
  - The ACO may continue to operate under the new structure;
  - The ACO structure is so different from the initially approved ACO that it must terminate its agreement and submit a new application;
  - The ACO no longer meets the program's eligibility criteria and its participation agreement must be terminated; or
  - CMS and the ACO may mutually decide to terminate the agreement.

L. ACO Termination and Reapplication

- If CMS determines that termination of an ACO is warranted, it may take one of the following pre-termination steps:
  - Provide a warning notice to the ACO;
  - Request a corrective action plan from the ACO; or
  - Place the ACO on a special monitoring plan.
- CMS may terminate an ACO's participation agreement when the ACO, its ACO participants, ACO providers/suppliers or other individuals or entities performing functions related to the ACO's activities fail to comply with any of the program requirements.
- If an ACO decides to terminate the CMS participation agreement, it must provide at least 60 days advance written notice to CMS and its ACO participants of its decision and the effective date of its termination. The ACO will not share in any savings for the performance year during which it notifies CMS of its termination decision.

- An ACO terminated from the program may participate again only after the date on which the term of the original participation agreement would have expired if the ACO had not been terminated, and the ACO must demonstrate that it has corrected the deficiencies that caused its termination from the program.

M. Audits and Record Retention

- An ACO must agree, and must require its ACO participants, ACO providers/suppliers and entities performing services or functions on behalf of the ACO to agree that CMS, DHHS, the Comptroller General, the federal government or their designees have the right to audit, inspect and evaluate any books, contracts, records, documents and other evidence pertaining to the ACO's activities under the Shared Savings Program.
- These same ACO parties must maintain such 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, whichever is later, unless there is a special reason to maintain such records for a longer period of time or unless there has been a termination, dispute or allegation of fraud or similar fault against the ACO parties, in which case the records must be retained for an additional 6 years from the date of any resulting final resolution of such termination, dispute or allegation.
- Regardless of any arrangements between or among the ACO parties, the ACO bears ultimate responsibility for fully complying with all the terms and conditions of its agreement with CMS, including this record retention requirement.

N. Program Requirements and Beneficiary Protections

- An ACO must comply with program requirements including those related to the following:
  - Adoption of a compliance plan
  - Data submission and certification
  - Public reporting and transparency
  - Marketing
- Each ACO must publicly report the following information:
  - Name and location
  - Primary contact
  - Organizational information including identification of ACO participants, identification of participants in joint ventures between ACO professionals and hospitals, identification of members of its governing body, identification of committees and committee leaderships, shared savings and losses information
  - Results of patient experience survey and claims-based measures
- ACO participants must provide notification to beneficiaries of participation in the Shared Savings Program.
- ACOs, ACO participants, ACO providers/suppliers and other individuals or entities performing functions or services related to ACO activities are prohibited from:
  - Making inducements to beneficiaries for receiving items or services from such parties or remaining in an ACO or with such parties; and
  - Conditioning the participation of ACO participants, ACO providers/suppliers or other individuals or entities performing ACO functions or services on referrals of federal health care program business that such parties know or should know is being provided to beneficiaries who are not assigned to the ACO.

O. Marketing

- Marketing materials must be submitted to CMS prior to use and will be deemed approved if not rejected within five days of submission.
- An ACO must use CMS template language, if available; materials cannot be used in a discriminatory manner; and an ACO may not engage in improper beneficiary inducements or provide information that is materially inaccurate or misleading.

P. Compliance Plan

- An ACO must have a compliance plan that satisfies specified requirements which are standard for the health care industry, including a designated compliance official who is not the in-house legal counsel.

Q. CMS Monitoring During Agreement

- CMS will monitor and assess the performance of ACOs, ACO participants and ACO providers/suppliers and will use a range of methods, including analysis of financial and quality measurement data reported by the ACO, annual and quarterly reports, analysis of beneficiary and provider complaints, and audits.
- CMS also will monitor an ACO's avoidance of at-risk beneficiaries and its compliance with quality performance standards.

R. 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 physician who is an ACO provider/supplier during the performance year for which shared savings are determined.
- Medicare will assign beneficiaries in a preliminary manner at the beginning of a performance year based on most recent available data; assignment will be updated quarterly based on the most recent 12 months of data, and final assignment is determined after the end of each performance year, based on data from the performance year.
- CMS will employ the following assignment methodology:
  - For each ACO, identification of all patients who had at least one primary care experience with a physician who is an ACO provider/supplier of that ACO;
  - Identification of all primary care services rendered by primary care physicians during either of the following: the most recent 12 months (for purposes of preliminary perspective assignment and quarterly assignment updated), or the performance year (for purposes of final assignment); and
  - The beneficiary is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by all primary care physicians who are ACO providers/suppliers are greater than the allowed charges for primary care services furnished by primary care physicians who are ACO providers/suppliers in any other ACO and not affiliated with any ACO and identified by a Medicare-enrolled TIN.
- Such beneficiary assignment in no way diminishes or restricts the rights of beneficiaries assigned to an ACO to exercise free choice in determining where to receive health care services.

S. Distribution of Savings

- Any shared savings payments will be made directly to an ACO as identified by its TIN.
- 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 providers/suppliers, and how any shared savings will be used to align with the aims of better care for individuals, better health for populations and lower growth in expenditures.
- There is no specification as to how shared savings must be distributed.

Comments and Recommendations

- The Final Rule generally provides for greater flexibility in ACO eligibility and governance than was the case with the Proposed Rule. The universe of eligible entities has been expanded to include rural health centers and federally qualified health centers.
- There is no longer a requirement that each ACO participant have a representative on the ACO's governing body, although the ACO will be required to provide meaningful participation for ACO participants in the composition and control of that body.
- The requirement that at least 75% control of the ACO's governing body must be held by ACO participants has been retained.

- The ACO's governing body now is required to have an explicit conflict of interest policy.
- The Final Rule provides for additional flexibility in that an ACO may add as well as remove ACO participants during the term of the ACO's agreement with CMS.
- The Final Rule requires ACO participants and providers to have a meaningful commitment to the ACO's clinical integration program, including through a meaningful financial or human investment (time and effort) in the ACO.
- CMS retains the right to consider an innovative ACO management structure not meeting the specified requirements.
- The initial start date has been moved back from January 1, 2012, until April 1, 2012, or July 1, 2012, and then to January 1 for each year thereafter.
- Providers interested in participating in or forming an ACO need to consider the type of legal entity that best suits their needs and to establish the required governance and management structure consistent with state law and the Final Rule.

II. Quality Performance Standards and Reporting Requirements

A. Measures to Assess Quality of Care Furnished by an ACO

- Measures will be adjusted over time based on industry developments, results from quality reports and other factors.
- For patient/caregiver experience measures, a standardized survey will be developed for the ACO as a whole to be funded by CMS.
- In 2014, an ACO must select and pay for an approved CMS certified survey vendor to administer the survey and report results using standardized procedures.
- All 33 measures must be completely and accurately reported in each performance year.
- Actual pay for performance standards will be phased in for years two and three.
- CMS retains the right to audit and validate reported quality data and can request medical records.
- An audit consists of three phases of medical record review. If at the end of the third record review there is a discrepancy of 10% or greater between the quality reported and the medical record, the ACO will not be given credit for meeting quality targets for any measures where this mismatch exists.
- Failure to report accurately, completely and in a timely manner or to correct in a timely manner can result in termination or some form of monitoring or corrective action plan.
- The minimum attainment level for each performance benchmark established by CMS will be the 30th percentile. Zero points will be assigned to any scores below this percentile.
- Performance equal to or greater than this 30th percentile will be given points on a sliding scale.
- Performance at or above the 90th percentile of the performance benchmark will be given the maximum points available for the measure.
- Some measures will be designated as "all or nothing"—all must be met or no points will be received.
- Within each of four domains, an ACO must score the minimum CMS attainment level in 70% of the measures in the domain.
- If an ACO achieves the minimum attainment level for at least one measure in each domain and also satisfies the requirements for realizing shared savings, the ACO may receive the proportion of those shared savings for which it qualifies.
- If an ACO fails to achieve the minimum attainment level on all measures in a domain, it will not be eligible to share in any savings generated.

B. Incorporating Reporting Requirements Related to the Physician Quality Reporting System (PQRS)

- The Final Rule incorporates reporting requirements and incentive payments under the Shared Savings Program in a more streamlined fashion.

- If an ACO, on behalf of its eligible professionals (EPs), satisfactorily reports ACO Group Practice Reporting Option (GPRO) measures, the EPs' ACO participant TIN will receive the PQRS incentive even if the ACO does not meet the quality performance standards and lower growth in costs requirements to share in savings under the Shared Savings Program.
- ACO participant TINs that wish to qualify for PQRS would need to participate as a group practice in the PQRS under the Shared Savings Program and may not separately participate in or earn a PQRS incentive under the traditional PQRS, outside of the Shared Savings Program.
- If ACO providers/suppliers who are EPs within an ACO qualify for a PQRS incentive payment, each ACO participant TIN, on behalf of its ACO supplier/provider participants who are EPs, will receive an incentive based on allowed charges under the Medicare Physician Fee Schedule for that TIN.
- Individual ACO providers/suppliers who are EPs in an ACO participant TIN may not seek to qualify for an individual PQRS incentive under the traditional PQRS.
- The PQRS incentive under the Shared Savings Program is equal to 0.5% of the HHS Secretary's estimate of the ACO's EPs' total Medicare Part B Physician Fee Schedule allowed charges for covered professional services furnished during the applicable calendar year reporting period for years 2012 through 2014.

C. Electronic Health Records Technology

- As in the Proposed Rule, a robust EHR infrastructure is encouraged.
- In the Final Rule, EHR participation is no longer a condition of participation but remains a quality measure.
- CMS did not adopt its proposal to require that 50% of PCPs in ACOs be meaningful users by the start of the second performance year in order for the ACO to be eligible to continue to participate in the Shared Savings Program.
- The quality measure regarding EHR adoption will be based on a sliding scale.
- Highlighting the importance of EHRs, the EHR quality measure will be scored with twice the weight of other quality measures.

Comments and Recommendations

- Compliance with these quality performance standards will be mandated in order to remain eligible for the Shared Savings Program and will affect the percentage of savings that can be shared among ACO participants.
- Compliance may also have a direct or indirect impact on provider responsibilities under accreditation standards, the doctrine of corporate negligence and related civil liability theories, and DOJ/OIG expectations on board responsibility for delivering quality health care services, the violation of which could trigger False Claims Act exposure.
- ACOs and participating providers therefore need to incorporate these quality metrics and standards—minimally at the ACO entity level, but possibly at the local provider level as well (e.g., participating hospitals, physician groups, ASCs).
- ACOs must develop standards that track the 33 measures, and ensure that they are communicated to providers and then monitored for compliance.
- Providers need to receive periodic reports regarding their individual and comparative performance.
- ACOs must develop remedial action plans that are designed to assist providers in meeting standards but also include the ability to suspend or terminate participation, at least at the ACO entity level, and possibly at the local provider level.
- Performance results should be taken into consideration at the time of appointment, reappointment and contract renewal, and some internal administrative process/fair hearing for participants who are excluded should be provided.
- It is important that an ACO evaluate its processes and procedures, reports, analyses, etc. so as to maximize available confidentiality and immunity practices under state and federal law (e.g., participation in a Patient Safety Organization under Patient Safety and Quality Improvement Act of 2005).

III. Savings and Losses

A. Overview of Shared Savings and Losses Methodology

- CMS had to make a number of determinations about the specific design of the shared savings methodology:
  - First, CMS had to establish an expenditure benchmark. This involves:
    - Determining the patient population for whom the benchmark is calculated;
    - Determining adjustments for beneficiary characteristics such as demographic factors or health status;
    - Determining whether other adjustments to the three-year benchmark are warranted; and
    - Trending the three-year benchmark forward to the start of the agreement period and subsequently updating the benchmark for each performance year during the term of the agreement with the ACO.
  - Second, CMS had to compare the benchmark to the assigned beneficiary per capita Medicare expenditures in each performance year during the term of the agreement in order to determine the amount of any savings.
  - Third, CMS had to establish the appropriate MSR to account for normal variation in expenditures based upon the number of Medicare Fee-For-Service (FFS) beneficiaries assigned to an ACO, and determine the shared savings rate for ACOs that have realized savings against the benchmark and meeting or exceeding the MSR.
  - Fourth, CMS had to determine the required sharing cap on the total amount of shared savings that may be paid to an ACO.
  - Finally, CMS had to establish, for the two-sided model, a methodology for determining shared losses where an ACO realizes a loss as opposed to a savings against its benchmark in a performance year. CMS proposed adopting a similar structure of minimum loss rate (MLR), shared loss limits and loss sharing rate.

B. Details of the Final Rule

- **Setting the ACO's Expenditure Benchmark**
  - As proposed, the ACO's initial benchmark is based on the Parts A and B FFS expenditures of beneficiaries who *would have been assigned* to the ACO in any of the three years prior to the start of an ACO's agreement period using the ACO participants identified at the start of the agreement period. CMS thus declined to adopt a second option that it considered, under which the benchmark would be based upon the Part A and B FFS expenditures of beneficiaries *actually assigned* to the ACO in each of the three years with relevant expenditures being those actually incurred during the last three years.
  - CMS explained that it selected Option 1 because it establishes a statistically stable benchmarking methodology based on an ACO's average population, by which CMS can assess improvements the ACO makes in quality and efficiency of care delivery. A recognized drawback, however, is that it incents ACOs to seek or avoid specific beneficiaries during the agreement period so that their average expenditures would likely be less than for their historical beneficiaries included in the benchmark. CMS noted that it favored a methodology based on an ACO's actual assigned population but lacked experience with this model, and may later reconsider its approach.
  - Benchmark expenditures for all ACOs will be calculated by categorizing beneficiaries in the following cost categories, in the order in which they appear: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.
  - The Final Rule takes into account payments made from the Medicare Trust Fund for Parts A and B services (including geographic payment adjustments and HVBP payments), for assigned Medicare FFS beneficiaries, and including individual beneficiary identifiable payments made under a demonstration, pilot or time-limited program, when computing average per capita Medicare expenditures under the ACO.
  - Not included are expenditures under Parts C and D, hospital outlier payments, Graduate Medical Education expenditures, PQRS, eRX and EHR incentive payments.

- The Final Rule finalizes the proposals to: (a) truncate an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile of national Medicare FFS expenditures as determined for each benchmark and performance year; (b) weight the third year of the benchmark at 60%, the second year at 30% and the first year at 10%; and (c) reset the benchmark at the start of each agreement period.

- **Adjusting the Benchmark and Actual Expenditures**
  - CMS explained that in the absence of risk adjustment, some ACOs may realize savings merely because they are treating a patient mix with better health status than the patient population reflected in their benchmark. CMS noted that its goal is to measure improvements in care delivery of an ACO and to make adjustments to reflect the health status of assigned patients and changes in the ACO's organizational structure that could affect the case mix of assigned patients rather than changes arising from the way ACO providers code diagnoses.
  - CMS considered several options for risk adjusting the initial benchmark: a method that considered only patient demographic factors without diagnostic information; one that incorporated diagnostic information in addition to demographic factors (i.e., the CMS-HCC prospective risk adjustment model used in the Medicare Advantage program); and one that includes adjustments for age, sex, Medicaid enrollment status and originally disabled status, but would not take into account the health status of assigned beneficiaries.
  - The Final Rule finalizes CMS's proposal to risk adjust historical benchmark expenditures using the CMS-HCC model. CMS explained that the CMS-HCC model more accurately predicts health care expenditures than a demographic-only model, as it accounts for variation in case complexity and severity. CMS also noted that incorporating diagnosis data in the model would encourage ACOs to code more fully or intensely for purposes of population management and quality reporting, which might optimize their risk scores to achieve shared savings. CMS will monitor and evaluate completeness and accuracy of coding through an audit process.
  - The Final Rule modifies CMS's proposal to make additional risk adjustments to performance year assigned beneficiaries instead of capping growth in risk adjustments during the term of the agreement at zero percent.
    - For newly assigned beneficiaries, there will be annual updates to an ACO's CMS-HCC prospective risk scores, to take into account changes in severity and case mix for this population.
    - For the continuously assigned population, if there is no decline in CMS-HCC prospective risk scores, CMS will use demographic factors to adjust for severity and case mix relative to the historical benchmark. However, if this population shows a decline in its CMS-HCC prospective risk scores, CMS will lower the risk score for this population.
  - The Final Rule also reflects CMS's agreement with a commenter's suggestion on the need for benchmark expenditures to be adjusted relative to the risk profile of the performance year assigned beneficiaries. Thus, an ACO's updated benchmark will be restated in the appropriate performance year risk relative to the risk profile of the performance year assigned beneficiaries.
  - Benchmark adjustments also will be made for each of the following categories of beneficiaries to reflect differences in disease severity across subpopulations: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.
  - CMS will use a three-month run-out of claims data and a completion factor to calculate performance year expenditures.
  - ACO expenditures will be calculated for each of the following categories of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.
  - All Parts A and B expenditures, with the exception of indirect medical education (IME) and disproportionate share hospital (DSH) adjustments, are included in the calculation of the benchmark and performance year expenditures. IME and DSH payments will be excluded from ACO benchmark and performance year expenditures (the Proposed Rule included such payments). CMS explained:

- Excluding IME and DSH adjustments will help ensure participation of hospitals receiving IME and DSH payments, and removes a disincentive for ACOs to refer patients to teaching hospitals.
- Thus, excluding such payments helps ensure that beneficiaries be referred to the most appropriate place of service.

- **Trending Forward Prior Year's Experience to Obtain the Initial Benchmark**
  - The Final Rule provides that in establishing an ACO's benchmark, CMS will trend forward the most recent three years of per-beneficiary expenditures using growth rates in per-beneficiary expenditures for Parts A and B services; that is, trend BY1 and BY2 forward, based on a growth rate, to BY3 dollars.
  - The Final Rule also provides that in trending forward the benchmark, calculations will be made for separate cost categories for ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.
  - CMS uses a national growth rate in Medicare Parts A and B expenditures for FFS beneficiaries for trending forward the recent three years of per-beneficiary expenditures for Parts A and B services in order to estimate the benchmark for each ACO.
  - CMS also finalizes the proposal to update the benchmark by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program using data from CMS's Office of the Actuary (in updating the benchmark, separate calculations will be made for ESRD, disabled, aged/dual eligible and aged/non-dual eligible beneficiaries).
- **Determining Shared Savings**
  - The Final Rule eliminates the proposal to provide an incentive (a sliding scale-based increase in the shared savings rate) for ACOs to include federally qualified health centers (FQHCs) and/or rural health centers (RHCs) as participants.
  - The Final Rule does not contain additional financial incentives, beyond those established for quality performance, for the care of dual eligible beneficiaries or other factors related to the composition of the ACO or its activities; nor does the Final Rule include a preference for ACOs participating in similar arrangements with other payers.
- **Calculating Sharing in Losses**
  - The Final Rule provides that the shared losses methodology will mirror the shared savings methodology, comprised of: a formula for calculating shared losses based on the final sharing rate, use of an MLR to protect against losses resulting from random variation, and a loss sharing limit to provide a ceiling on the amount of losses an ACO would be required to repay.
  - The Final Rule provides that the shared loss rate for an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark will be determined based on the inverse of its final sharing rate based on quality performance (that is, 1 minus the shared savings rate).
  - However, the Final Rule modifies the original proposal to provide that an ACO's shared loss rate will be subject to a cap of 60%, consistent with the maximum rate for sharing savings.
- **Limits on Shared Losses**
  - As noted, the Final Rule eliminates the proposed requirement for ACOs under the one-sided model to accept risk in their third performance year; thus, CMS is not finalizing proposed limits on shared losses for ACOs transitioning from the one-sided model to the two-sided model.
- **ACO Repayment of Shared Losses**
  - The Final Rule allows ACOs flexibility to specify their preferred method for repaying potential losses, and how that would apply to ACO participants and ACO providers.
  - During the application process and annually, each ACO under the two-sided model must demonstrate that it has established a repayment mechanism.

- One-sided ACOs requesting interim payment must make a similar demonstration at time of application.
- CMS will determine the adequacy of an ACO's repayment mechanism each year under the two-sided model.
- The repayment mechanism must be sufficient to ensure repayment of potential losses equal to at least 1% of total per capita Medicare Parts A and B FFS expenditures for assigned beneficiaries based either on expenditures for the most recent performance year or expenditures used to establish the benchmark.
- If an ACO's repayment mechanism does not enable CMS to recoup the losses for a performance year, CMS will not carry forward unpaid losses into subsequent performance years and agreement periods.
- If an ACO incurs shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

- **Determining First Year Performance for ACOs Beginning April 1, 2012, or July 1, 2012**
  - ACOs with start dates of April 1, 2012, or July 1, 2012, may opt for an interim payment calculation to determine shared savings and losses at the end of their first 12 months of program participation.
  - Generally, the same methodology for determining shared savings and losses applies to this interim payment calculation.
  - Reconciliation for the first performance year will occur after the completion of the ACO's first performance year (21 months for April starters and 18 months for July starters).
  - ACOs must indicate in their application whether they are requesting an interim payment calculation. ACOs opting for interim payment during the first performance year must demonstrate that they have an adequate repayment mechanism in place, consistent with requirements for two-sided model ACOs.
  - ACOs that generate shared losses under interim payment calculation must repay such losses within 90 days of notification.
  - Any monies determined to be owed by an ACO after first year reconciliation (whether additional shared losses or overpayment of shared savings) must be repaid to CMS within 90 days of notification.

Comments and Recommendations

- Academic medical centers and hospitals receiving DSH payments may be more favorably inclined to participate in an ACO in light of CMS's decision to exclude, in the Final Rule, IME and DSH payments from ACO benchmark and performance year expenditures. Excluding IME and DSH payments removes a disincentive for ACOs to refer patients to teaching/DSH hospitals and will help ensure that beneficiaries are referred to the most appropriate place of service for their care.
- Physician practices and other small, rural or safety net providers may benefit from the revised three-year Track 1 shared savings only, one-sided model adopted in the Final Rule, which includes, among other benefits, the first-dollar sharing feature. As adopted, Track 1 will allow such providers, many without previous ACO experience, to participate in ACOs without risk and to transition to a risk-based ACO model after three years.
- Interested parties may wish to consider pursuing alternative payment models in the Shared Savings Program through the CMS Innovation Center.
- CMS has noted that it supports the Innovation Center's testing of alternative benchmarking approaches through the Pioneer Model ACO initiative, and looks forward to applying lessons learned through the Pioneer experience to developing a robust benchmarking methodology for possible use within the Shared Savings Program. Interested parties may wish to monitor CMS's plan to revisit use of a benchmarking methodology based on an ACO's assigned population in future rulemaking.
- In deciding to risk adjust an ACO's historical benchmark expenditures using the CMS-HCC model, CMS noted that it is necessary to guard against changes that result from more specific or comprehensive coding as opposed to improvements in the coordination and quality of health care. ACO participants should be aware that CMS intends to use an audit process to assure the appropriateness of ACO coding practices and to adjust ACO risk scores. ACOs may wish to consider including coding monitoring in their compliance programs.

IV. Data Sharing with ACOs

As in the Proposed Rule, CMS will share both aggregate data and beneficiary identifiable data with ACOs.

A. Aggregate Data Reports

- The aggregate data reports will be shared at the start of the agreement period based on the beneficiaries' claims data used to calculate the benchmark, and then quarterly.
- The aggregate data will typically include de-identified, aggregated metrics on the assigned beneficiary population and certain utilization data and expenditure data.

B. Initial Identifiable Data Points Used to Generate the Aggregate Report

- At an ACO's request, CMS will also provide information (including name, date of birth, HICN and sex) regarding preliminarily prospectively assigned beneficiaries whose data was used to generate the aggregate data reports.
- This information would be provided for population-based activities relating to improving health or reducing growth in health care costs, process development, case management and care coordination.
  - **Certification.** In its data request, an ACO must certify as to (1) its status as a HIPAA covered entity or business associate, and (2) that the request reflects the minimum necessary data for the ACO to conduct health care operations within the first two paragraphs of the definition of health care operations at 45 CFR 164.501.
  - **No Opt-Out.** The beneficiary's right to decline data sharing does not apply to CMS's sharing of the initial identifiable data points.

C. Beneficiary-Identifiable Data

- Beneficiary-identifiable data may be shared with an ACO on the condition that the ACO, its ACO participants, ACO providers/suppliers and other individuals or entities performing functions or services related to the ACO's activities comply with all applicable confidentiality/privacy laws, including HIPAA, and execute and comply with the data use agreement.
- An ACO may not limit or restrict appropriate sharing of medical record data with providers and suppliers, both within and outside the ACO in accordance with applicable law.
- An ACO must submit a formal data request (this can be done monthly). Permissible purposes are for evaluating the performance of its ACO participants or its ACO providers/suppliers, conducting quality assessment and improvement activities, and conducting population-based activities relating to improved health.
- An ACO must make certifications similar to those required to receive the initial identifiable data points, and must also certify that it will use data only for activities related to coordination of care and to improving the quality and efficiency of care that apply uniformly to all Medicare beneficiaries with primary care services at the ACO.
- Data cannot be used to reduce, limit or restrict care for specific beneficiaries.
- An ACO may only request beneficiary-identifiable information if (1) the beneficiary's name appears in the preliminary prospective assignment list or the beneficiary has received primary care services from an ACO participant upon whom assignment is based during the agreement period, and (2) the beneficiary has been notified in writing about the proposed use and has not opted out.
- ACOs must limit identifiable data requests to the minimum necessary. The rule clarifies that the minimum necessary Part A and Part B elements may include (but are not necessarily limited to) TIN, NPI and POS codes, in addition to the data elements noted in the Proposed Rule.
- The beneficiary opt-out process must be meaningful, and CMS has refined the process to allow for contacting preliminarily assigned beneficiaries who have not had an office visit. Specifically:
  - An ACO may contact preliminarily prospectively assigned beneficiaries in writing to request data sharing. The ACO must provide a form explaining the opt-out process and provide 30 days for these beneficiaries to opt out.

- For beneficiaries that have a primary care service office visit with an ACO participant, the ACO must provide written notice explaining the opt-out process. This form must be provided to each beneficiary as part of the beneficiary's first primary care service visit during the agreement period.

- An ACO that misuses or discloses data in violation of applicable law or the terms of a data use agreement will no longer be eligible to receive data under the data sharing provisions, may be terminated from the Shared Savings Program, and may face other penalties and sanctions under other applicable laws.

Comments and Recommendations

- Overall, the data sharing provisions are more flexible and practical than those originally proposed. The data furnished by CMS, while useful, will have certain limitations, such as a to lack of "real time" data. As a result, it is important that ACOs independently develop and refine their capability for internal analysis of data to improve quality as well as improving coordination of care by better communication between ACO participants and non-participant providers.
- It will be critical that ACOs have the infrastructure, policies and procedures and training necessary to ensure compliance with the data sharing provisions of the regulations and any data use agreements. Particular areas of focus should include ensuring compliance with the beneficiary's right to decline data sharing, the minimum necessary standards, and permissible purposes for which beneficiary identifiable information may be used and requested (including ensuring that it is not used to stint on care or avoid at-risk beneficiaries). ACOs also need to ensure that they have appropriate agreements with business associates.

V. Overlap with Other CMS Shared Savings Initiatives

A. Background

In order to prevent duplicative shared savings, the Final Rule expressly prohibits Medicare provider and supplier participants in other enumerated Shared Savings Programs from participating in the Medicare Shared Savings Program. The primary purpose of the prohibition "is to prevent a provider or supplier from being rewarded twice for achieving savings in the cost of care provided to the same beneficiary." However, in order to ensure that beneficiaries receive the highest quality of care possible, the prohibition will be tracked based on Medicare-enrolled TIN. Consequently, providers and suppliers will be allowed to submit claims under multiple TINs participating in different Shared Savings Programs as long as the patient population is unique to each program.

B. Enumerated Programs Expressly Excluded Under the Final Rule

- Independence at Home Medical Practice Pilot Program (Section 1866E of the Affordable Care Act)
- A model tested or expanded under Section 1115A of the Act that involves shared savings
- Any other Medicare initiative that involves shared savings
  - CMS will review and reject ACO applications if the ACO participants are participating in another Medicare initiative that involves shared savings payments.
  - A physician group practice (PGP) demonstration site applying for participation in the ACO Shared Savings Program will be required to complete a condensed application form.
- Although not expressly excluded under the Proposed Rule, CMS has determined that the following existing Shared Savings Programs overlap with the ACO Shared Savings Program and are therefore precluded from participating in the ACO Shared Savings Program:
  - Independence at Home Medical Practice Demonstration Program, as established by Section 3024 of the Affordable Care Act
  - Medicare Health Care Quality Demonstration programs, as established by Section 646 of the Medicare Modernization Act

- Medical home demonstrations with a shared savings element (currently only the multi-payor advanced primary care demonstration)
- PGP transition demonstration

C. Programs Under Which Duplicative Share Savings Are Prohibited

Although ACOs are allowed to dually participate in both the Medicare Shared Savings Program and other state Shared Savings Programs involving dually eligible beneficiaries, ACOs may not receive shared savings payments from both. Under the Final Rule, while dual participation is allowed, duplication of payment is not.

Comments and Recommendations

- Providers should calculate from which Shared Savings Program they will receive the most reimbursement or other benefits before deciding whether to participate in the Medicare Shared Savings Program.
- The Center for Medicare and Medicaid Innovation is seeking input on how it can best test different payment models that provide financial and technical assistance to groups of providers and suppliers that may wish to develop into ACOs.
- With minor clarifications and the elimination of a provision regarding antitrust review that became inapplicable in light of revised antitrust review procedures, the Final Rule adopts the reconsideration review process as set forth in the Proposed Rule.

FTC/DOJ FINAL STATEMENT OF ANTITRUST ENFORCEMENT POLICY

A. Background

The FTC and DOJ's Final Statement addresses a concern expressed by physicians, hospitals and other health care providers regarding how the FTC and DOJ would evaluate the impact of ACOs participating in the Shared Savings Program and their expected interaction and negotiation with commercial payors in light of existing enforcement standards as reflected in the Statements of Antitrust Enforcement Policy in Health Care (1996), the revised Horizontal Merger Guidelines (2010), other related antitrust guidelines and the relevant advisory opinions issued by the FTC (collectively, the Antitrust Standards). In particular, providers were seeking additional flexibility so as to promote and support collaborations among otherwise competing providers, as well as additional clarity on whether ACOs would be presumed to be "clinically integrated" in light of the requirements for certification set forth under the Affordable Care Act. In response to numerous comments and criticisms voiced by individual commentators and trade associations, a number of significant changes ultimately were made. These are summarized below.

B. Summary of Final Statement

- The Final Statement applies to "all collaborations among otherwise independent providers and provider groups that are eligible and intend, or have been approved to participate in the Medicare Shared Savings Program." The Proposed Rule had only applied to collaborations formed after March 23, 2010.
- "Collaboration" is defined as a "set of agreements, other than merger agreements, among otherwise independent entities jointly to engage in economic activity, and the resulting economic activity."
- In light of the degree of clinical integration that must be achieved in order for an ACO to be certified by CMS, in addition to other requirements such as the establishment of a formal legal and governance structure, ACOs that are certified by CMS "are reasonably likely to be bona fide arrangements intended to improve the quality, and reduce the cost, of providing medical and other health care services through their participants' joint efforts."
- The Agencies therefore will apply a "rule of reason" as opposed to the "per se" analysis to a certified ACO in the commercial market if it "uses the same governance and leadership structure and the same clinical and administrative processes as it uses in the Shared Savings Program."

- The rule of reason treatment will apply to an ACO for the duration of its participation in the Shared Savings Program, which will allow the ACO to introduce and the Agencies to consider various community benefits and other factors to offset actual or perceived anti-competitive effects of the ACO's operations and practices.

C. Antitrust Safety Zone for ACOs

- ACOs that fall within the "safety zone" as described below will not be subject to challenge by the Agencies "absent extraordinary circumstances."
- Independent ACO participants that provide the same "common service" 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 PSA for each service is defined as "the lowest number of contiguous postal zip codes from which the ACO participant draws at least 75% of its patients for that service." While this standard does not reasonably reflect the true relevant geographic market, it is used as a "screen for evaluating potential anticompetitive effects."
- There are three major categories of services: physician specialties; major diagnosis categories for inpatient facilities; and CMS outpatient categories for outpatient facilities.
- Each ACO participant will have its own PSA, which must be calculated.
- A hospital will have a separate PSA for its inpatient services, its outpatient services and its physician services provided by physician employees.
- Hospitals or surgery centers participating in an ACO must be nonexclusive to the ACO in order to fall within the safety zone, irrespective of its PSA share.
- An ACO may still enter into exclusive arrangements, but it would not qualify for the safety zone.
- "Nonexclusive" means that the hospital or ASC is allowed to contract individually or affiliate with other ACOs or commercial payors.
- The safety zone applies to physicians and other providers irrespective of whether they are exclusive or nonexclusive to an ACO unless they fall within the rural exception or the dominant participation limitation.
- The safety zone only applies to ACOs participating in the Shared Savings Program. Otherwise, providers must comply with the more restrictive Antitrust Standards.
- Failure to fall within the safety zone does not mean that the ACO arrangement is in violation of the Antitrust Standards and applicable laws.

D. Calculation Methodology for PSA Shares of Common Services

- For physician services, first identify each service provided by at least two independent ACO participants as determined by the CMS Medicare Specialty Code.
  - "Primary care" is defined to include general practice, family practice, internal medicine and geriatric medicine as a single or common service.
- For inpatient facilities, a service is a Medicare Diagnostic Category.
- For outpatient facilities, a service is an outpatient category defined by CMS.
- Next, identify the PSA for each common service, for each participant (e.g., physician group, hospital, surgery center) in the ACO. For each common service and for each participant, the PSA is defined as the lowest number of postal zip codes from which the participant draws at least 75% of its patients for that service.
- Finally, calculate the ACO's PSA share for each common service in each PSA in which at least two ACO participants serve patients for that service.
  - Physician services: Calculate the ACO's shares of Medicare FFS-allowed charges during the most recent calendar year for which data are available.
  - Outpatient services: Calculate the ACO's shares of Medicare FFS payments during the most recent calendar year for which data are available.

- Inpatient services: Calculate the ACO's shares of inpatient discharges using state-level all-payor hospital discharge data, where available.

E. Rural Exception

- Physicians: An ACO may include one physician or physician group practice per specialty for each rural county on a nonexclusive basis even if inclusion causes the ACO's share of any common service to exceed 30% in any ACO participant's PSA for that service.
- To qualify, the practice must be treating patients as a fully integrated group as of October 20, 2011, and the number of FTE physicians does not increase during the agreement period.
- Hospitals: An ACO may include rural hospitals on a nonexclusive basis even if inclusion causes the ACO's share of any common service to exceed 30% in any ACO participant's PSA for that service.
- A rural hospital is defined as a Sole Community Hospital or Critical Access Hospital under CMS regs, or any other acute care hospital that has 50 beds or less and is located at least 35 miles from another hospital.

F. Dominant Provider Limitation

- If an ACO includes a participant with a greater than 50% share in its PSA for any service that no other ACO participant provides to patients in the PSA, the "dominant provider" must be nonexclusive.
  - To remain in the safety zone, the dominant provider cannot require a commercial payor to contract exclusively with the ACO or otherwise restrict the commercial payor's ability to contract or deal with other ACOs or provider networks.

G. Mandatory Review of ACOs Exceeding 50% PSA Share Threshold Is Eliminated in Final Rule

- Under the Proposed Rule, an ACO exceeding the 50% PSA share threshold for any common service involving two or more independent participants could not qualify for the rural exception unless it obtained a letter from the FTC or the DOJ stating that the reviewing Agency has "no present intention to challenge or recommend challenging the ACO under the antitrust laws."
- This requirement was eliminated, although the ACO can seek a voluntary expedited review.
- Under these circumstances, the Agencies will provide an expedited review of any request upon submission of the required documentation under CMS's Final Rule, which must be received by the reviewing Agency at least 90 days before the last day in which CMS will accept ACO applications for the relevant calendar year. (For a list of the documentation requirements, click here.)

H. ACOs Falling Outside Safety Zone

- If an ACO falls outside of the safety zone, it does not mean that the ACO is illegal, nor that it will be subjected to an Agency investigation.
- ACOs are not required to seek Agency review before seeking certification but can still request an expedited review.
- Providers in this category need to avoid the following types of conduct:
  - Preventing or discouraging commercial payors from directing or incentivizing patients to choose certain providers, including providers that do not participate in the ACO, through "anti-steering," "guaranteed inclusion," "product participation," "price parity" or similar contractual clauses or provisions.
  - Tying sales (either explicitly or implicitly through pricing policies) of the ACO's services to the commercial payor's purchase of other services from providers outside the ACO (and vice versa), including providers affiliated with an ACO participant (e.g., an ACO may not require a purchaser to contract with all the hospitals in the same network as the hospital that belongs to the ACO).
  - With an exception for primary care physicians, contracting with other ACO physician specialists, hospitals, ASCs and other providers on an exclusive basis, thus preventing or discouraging them from contracting outside the ACO, either individually or through other ACOs or provider networks.

- Restricting a commercial payor's ability to make available to its health plan enrollees cost, quality, efficiency and performance information to aid enrollees in evaluating and selecting providers in the health plan, if that information is similar to the cost, quality, efficiency and performance measures used in the Shared Savings Program.
- Sharing among the ACO's provider participants competitively sensitive pricing or other data that they could use to set prices or other terms for services they provide outside the ACO.

I. Expedited Review

- A newly formed ACO that, as of March 23, 2010, had not signed or jointly negotiated a contract with a commercial or private payor, can seek antitrust guidance through a voluntary expedited 90-day review process as long as all documentation required under the Final Statement is provided.

Comments and Recommendations

- ACOs intending to seek CMS certification need to quickly determine which providers are going to participate, whether employed, affiliated, in a joint venture or under contract.
- Market shares in each common service for each participant's PSA need to be determined.
  - Proposed methodology for calculating market shares is more of a proxy determination. If initial calculation puts an ACO outside the safety zone, the ACO can consider a more detailed market analysis for submission to the Agencies for their consideration if concerned about possible antitrust risk.
- Determine whether an ACO falls within the safety zone in each area of common service in all applicable PSAs. If not, the ACO should reevaluate whether to reduce the number of participants, accept the risk of being outside the safety zone or seek an expedited review.
- If an ACO intends to contract with commercial payors, it must maintain the same governance, leadership and other requirements for ACO certification when engaging in negotiations in order to take advantage of the proposed safety zone.
- Depending on the nature of the payor agreement, participating in "at risk" arrangements may be viewed as "financial integration," which also would trigger a rule of reason analysis.
- An ACO must be careful to avoid the high risk activity identified in this Advisory and in the Final Statement in order to mitigate against an Agency investigation, a private challenge or possible loss of ACO certification.

J. Appendix

- There is an Appendix that explains how to calculate the PSA shares for common services and gives examples. Click here to view.

WAIVERS OF FRAUD AND ABUSE LAWS

A. Background

In the Proposed Rule, CMS briefly discusses waivers of the federal fraud and abuse laws (the physician self-referral law (the "Stark Law"), the Anti-Kickback Statute and the Civil Monetary Penalty provision, sections 1877(a), 1128B(b)(1) and (2), and 1128A(b)(1) and (2), respectively) (collectively, the Fraud and Abuse laws). Detailed information regarding these critical waivers was published in a second document—CMS-1345-NC2—entitled "Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center" (the Notice). Despite being classified as a "notice with comment period," CMS and OIG actually proposed three types of waivers for the Shared Savings Program and sought comments on additional waivers and criteria for waivers that might be necessary to form and operate Shared Savings Programs or delivery systems operating under the authority of CMS's Center for Medicare and Medicaid Innovation (the Innovation Center).

Based on CMS's and OIG's consideration of numerous comments regarding the proposed waivers, the interim final rules (IFC) establish five waivers that are intended to provide flexibility to ACOs in a number of situations anticipated before, during and after the formation of the ACO. Moreover, they are self-executing (i.e., no need to file additional notices/materials to CMS or OIG), apply consistently across waived fraud and abuse laws, and apply uniformly to each ACO, ACO participant and ACO provider/supplier participating in the Shared Savings Program. The IFC is effective on the date of its publication in the Federal Register and subject to a comment period of 60 days. In that regard, there may be further changes to the waivers based on the comments CMS may receive during that time.

B. Key Changes

- An ACO arrangement only needs to meet the criteria for one waiver, but it may meet other waivers.
- There is no requirement that there be written and signed agreements, but it is "best practice to do so" according to CMS, since a written or signed agreement would be required for compliance with the Stark Law if a waiver does not apply.
- As currently drafted, the waivers do not require that an arrangement be at fair market value or be commercially reasonable, but CMS will closely monitor for abuse and may incorporate additional restrictions.
- Arrangements need only be "reasonably related" to one of the purposes of the Shared Savings Program rather than a narrower approach of being "directly related," which was CMS's response in simplifying the process and addressing public comments requesting a broader approach.
- An ACO may provide incentives to all new primary care physicians such as covering the EHR proportionate expense or various office service benefits (but cannot pay based on volume of services or require that physicians refer patients to the ACO or ACO participants).
- Waivers are applicable to private payor arrangements, but these must show they are reasonably related to ACO participation in the Shared Savings Program.
- Satisfying the requirements of the Compliance with Stark Law Waiver essentially means that if an ACO arrangement satisfies the Stark law, it need not also comply with the Anti-Kickback Statute or CMP Laws.

C. Pre-Participation Waiver

- The Fraud and Abuse laws are waived with respect to an ACO's start-up arrangement if all of the following are satisfied:
  - The arrangement is undertaken with good faith intent to develop an ACO that will participate in the Shared Savings Program and a complete application has been submitted.
  - The parties to the arrangement include the ACO and at least one ACO participant.
  - No party to the arrangement can be a drug and device manufacturer, distributor, DME supplier or home health supplier.
  - Diligent steps must be taken to develop an ACO that will meet all requirements of the Shared Savings Program rules, including governance, leadership and management requirements.
  - The ACO governing body has determined that the start-up arrangement is reasonably related to the purposes of the Shared Savings Program.
  - The arrangement, the governing body's authorization and the diligent steps to develop the ACO are documented concurrent with such actions. All documentation must be in place for at least 10 years.
  - Public disclosure of the arrangement (other than financial/economic terms) in such manner as required by HHS.
  - If the ACO does not submit an application for the targeted year, it must file a statement on or before the last application due date for the targeted year explaining why it was unable to submit a timely application.
- The waiver period starts on the date of publication of the IFC for a 2012 target date or one year preceding an application due date for subsequent target dates.
- The waiver period ends:
  - On the start date of the ACO participation agreement (if entered into ACO participation agreement).
  - On the denial date (for ACOs that apply for participation but are denied from participation) or six months thereafter for an arrangement that qualified for the waiver before the denial.

- (No newly created arrangements would be protected during the six-month period.)
- On the application due date (if the ACO fails to submit an application).
- On the date the ACO submits reasons for not applying (if the ACO fails to submit an application but provides reasons why it failed to do so, with some ability to extend the time for good reasons for failing to submit an application).

- Pre-application waivers may only be used one time during a single-year period.

D. Participation Waiver

- The Fraud and Abuse laws are waived with respect to an ACO's relationship among the ACO, one or more ACO participants and/or ACO providers/suppliers involving all arrangements, including drug and device manufacturers, distributors, DME and home health suppliers, if all of the following conditions are met:
  - The ACO has entered into or participates in the Shared Services Program.
  - The ACO is in good standing under the Shared Services Program.
  - The ACO meets the requirement addressing governance, leadership and management for ACOs of the Shared Savings Program.
  - The ACO governing body has determined that the arrangement is consistent with the duties under 42 CFR § 425.106(b)(3), and that the arrangement is reasonably related to the purposes of the Shared Savings Program.
  - Both the arrangement and the governing body's authorization are documented concurrent with such actions. All documentation must be in place for at least 10 years and available to HHS upon request.
  - Public disclosure of the arrangement (other than financial/economic terms) in such manner as required by HHS
- The waiver period starts on the start date of participation in the Shared Savings Program.
- The waiver period ends six months after expiration of such participation agreement, including any renewals, or the date of the ACO's voluntary termination.
- The waiver extends to private payor arrangements if activity is reasonably related to the ACO's participation in the Shared Savings Program.

E. Shared Savings Waiver

- The Fraud and Abuse laws are waived with respect to the distribution or use of shared savings earned by the ACO under the Shared Savings Program, if all of the following conditions are met:
  - The ACO has entered into or participates in the Shared Services Program.
  - The ACO is in good standing under the Shared Services Program.
  - The shared savings are earned by the ACO pursuant to the Shared Savings Program.
  - The shared savings are earned by the ACO during the term of its participation agreement (even if actual distribution/use of savings occurs after expiration of program).
  - The shared savings are: (i) distributed to or among the ACO participants, ACO providers/suppliers, or individuals or entities that were its ACO participants or ACO providers/suppliers during the year the shared savings were earned, or (ii) used for activities that are reasonably related to purposes of the Shared Savings Program.
  - With respect to the waiver of the gainsharing portions of the Civil Monetary Penalty provisions, shared savings distributions that are made directly or indirectly from a hospital to a physician must not be made knowingly to induce a physician to reduce or limit medically necessary items or services to patients under the direct care of the physician.
- Comments suggest that "medically necessary" will be interpreted consistent with Medicare program rules and accepted standards of practice.
- Comments also indicate that arrangements to incentivize alternate and appropriate medically necessary care consistent with the purposes of the Shared Savings Program, such as through use of evidence-based protocols, are permitted, but arrangements tied to drugs or devices known to be less effective clinically shall be prohibited.
- Waiver only applies to distribution of shared savings. All other arrangements would need to qualify for one of the other waivers or an existing safe harbor, or must otherwise comply with the law.

- Waiver applies to payments made to referring physicians outside the ACO with shared savings for services reasonably related to the Shared Savings Program or if they were ACO participants at the time the shared savings were earned.

F. Compliance with Stark Law Waiver

- The Fraud and Abuse laws 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, if all of the following conditions are met for each arrangement:
  - The ACO has entered into or participates in the Shared Services Program.
  - The ACO is in good standing under the Shared Services Program.
  - The financial relationship is reasonably related to the purposes of the Shared Services Program.
  - The financial relationship fully complies with an applicable Stark Law exception (under 42 C.F.R. § 411.355 to § 411.357).
- The waiver period starts on the start date of participation in the Shared Savings Program.
- The waiver period ends on the earlier of expiration or termination of the participation agreement, although CMS is considering an extension period.
- The waiver does not apply to non-ACO arrangements.

G. Patient Incentives Waiver

- The fraud and abuse laws are waived with respect the beneficiary inducement portions of the Civil Monetary Penalty provisions and the Anti-Kickback Statute for 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:
  - The ACO has entered into or participates in the Shared Services Program.
  - The ACO is in good standing under the Shared Services Program.
  - There is a reasonable connection between the items or services and medical care of the beneficiary.
  - The items or services are in-kind.
  - The items or services are preventive care items or services or advance one or more of the clinical goals of adherence to a treatment regime, drug regime or follow-up care plan, or management of a chronic disease or condition.
- Waiver only protects in-kind services that relate to medical care and management provided to patient, not financial incentives such as waiving co-pays and deductibles.
- CMS is considering whether the Final Rule will apply only to beneficiaries assigned to ACO or to all beneficiaries.
- ACOs are prohibited from providing gifts or other remuneration to patients as an incentive to receive services or remain in ACO.
- Waiver does not protect the provision of free or below fair market value of goods or services by vendors to beneficiaries or to ACOs, ACO participants or ACO providers/suppliers.
- Waiver period starts on the start date of participation in the Shared Savings Program.
- Waiver period ends on the earlier of expiration or termination of the participation agreement.
- Items legitimately provided can be retained by beneficiary and services initiated during a participating contract period can be continued beyond termination/expiration date.
- The waiver applies to all beneficiaries of the ACO.

Comments and Recommendations

- The waivers apply to the Shared Savings Program and all participating ACOs. They also apply to any ACOs that are participating in the Advance Payment Initiative. However, these waivers do not apply to any other demonstration or pilot programs or any other Medicare-enrolled provider.
- It is possible that additional guidance may be needed to clarify some of the waivers. Hence, if there are questions, comments should be submitted to CMS before the end of the comment period (60 days from the date of publication in the Federal Register on November 2, 2011). For example, the Pre-Participation Waiver provides for an applicant to request an

extension of the waiver if the applicant fails to timely submit an application but also shows that it is likely that the applicant will develop a qualifying ACO by the next application due date. The HHS Secretary has discretionary authority on whether to approve or deny such a request. There is no specific guidance on what factors the HHS Secretary will review in granting an extension. Further, no guidance has yet to be provided on the steps needed to get the extension.

- The Compliance with Stark Law Waiver may not really afford additional protections for financial arrangements that already satisfy the Stark Law because certain Stark Law exceptions already require compliance with the Anti-Kickback Statute and in some cases with the gainsharing portion of the Civil Monetary Penalty Laws. But it does avoid the need for a separate analysis in addition to Stark Law compliance, streamlining the process by which participants can review for compliance.

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.

Comments and Recommendations

- The IRS's approach to a tax-exempt hospital's participation in ACO arrangements is consistent with its approach to any joint venture between a tax-exempt entity and unrelated, non-exempt parties. The same factors apply, including the following:
  - Economic benefits to the tax-exempt hospital are proportionate to its contributions.
  - Ownership interest of the tax-exempt hospital in the ACO is proportionate to the value of its capital contributions, and all distributions and allocations are made in proportion to the ownership interest.
  - Sharing in any profits and losses is proportionate.
  - All transactions and interactions are on a fair market value basis.

Contact Us

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**.

Laura Keidan Martin, Chair	312.902.5487	laura.martin@kattenlaw.com
Michael R. Callahan	312.902.5634	michael.callahan@kattenlaw.com
J. Phillip O'Brien	312.902.5630	phillip.obrien@kattenlaw.com
Joseph V. Willey	212.940.7087	joseph.willey@kattenlaw.com
Steven J. Katz	212.940.6431	steven.katz@kattenlaw.com
Megan Hardiman	312.902.5488	megan.hardiman@kattenlaw.com
Ethan E. Rii	312.902.5522	ethan.rii@kattenlaw.com
Joshua G. Berman	202.625.3533	joshua.berman@kattenlaw.com
James J. Calder	212.940.6460	james.calder@kattenlaw.com
W. Kenneth Davis, Jr.	312.902.5573	ken.davis@kattenlaw.com
Alessandra Denis	212.940.6324	alessandra.denis@kattenlaw.com
Glen Donath	202.625.3535	glen.donath@kattenlaw.com
David A. Florman	212.940.8633	david.florman@kattenlaw.com
D. Louis Glaser	312.902.5210	louis.glaser@kattenlaw.com
Sharon Kantrowitz	212.940.6563	sharon.kantrowitz@kattenlaw.com
Julie S. Marder	312.902.5399	julie.marder@kattenlaw.com
Thomas J. McFadden	312.902.5428	thomas.mcfadden@kattenlaw.com
Peter F. Nadel	212.940.7010	peter.nadel@kattenlaw.com
Steven R. Olson	312.902.5640	steven.olson@kattenlaw.com
Adriane D. Riase	312.902.5220	adriane.riase@kattenlaw.com
Howard R. Rubin	202.625.3534	howard.rubin@kattenlaw.com
Robert T. Smith	202.625.3616	robert.smith1@kattenlaw.com
Jowita J. Walkup	212.940.6706	jowita.walkup@kattenlaw.com

Katten

Katten Muchin Rosenman LLP

www.kattenlaw.com

CHARLOTTE CHICAGO IRVING LONDON LOS ANGELES NEW YORK OAKLAND WASHINGTON, DC