Proposed Accountable Care Organization Regulation Published

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On March 31, 2011, the Centers for Medicare and Medicaid Services ("CMS") released a notice of public rulemaking for the long awaited proposed regulations to implement the Medicare Shared Savings Program for Accountable Care Organizations (the "Regulation"), created in last year's landmark Health Reform legislation.[1] As with all proposed rulemaking, the Regulation is published in the Federal Register on April 7, 2011, and will be subject to a public notice and comment period prior to issuance of the final rule by CMS. **Comments must be submitted on or before 5 p.m. EST on June 6, 2011**. The following summary is intended as an initial, preliminary review of the Regulation. Please contact a member of the Vorys Health Care Group for further details.

I. Definitions and Eligibility

One of the principal questions raised by the original legislative language creating the Accountable Care Organization ("ACO") program was how CMS would define an ACO and its constituent parts. The Regulation defines an ACO as "a legal entity that is recognized and authorized under applicable State law, as identified by a Taxpayer Identification Number ("TIN"), and comprised of an eligible group . . . of ACO participants that work together to manage and coordinate care for Medicare fee-for-service beneficiaries and have established a mechanism for shared governance that provides all ACO participants with an appropriate proportionate control over the ACO's decision-making process." In addition to this general definition, the Regulation defines the categories of eligible "ACO Participants," limiting them to:

- "ACO Professionals" in group practice arrangements. (In this context an "ACO Professional" is a doctor of medicine or osteopathy legally authorized to practice medicine, or a physician assistant, nurse practitioner or a clinical nurse specialist, as those terms are defined in 42 CFR § 410.74-76.);
- Networks of individual ACO Professionals;
- Partnerships or joint ventures between hospitals and ACO Professionals;
- Providers or suppliers otherwise recognized under the Act that are not hospitals or ACO Professionals; or
- Critical Access Hospitals billing according to the process set forth in 42 CFR §413.70(b)(3).

According to the Regulation, any number of ACO Participants (but at least two or more) may "work together to manage and coordinate care for the Medicare fee-for-service beneficiaries through an ACO that participates in the Shared Savings Program and meets the criteria specified in [Subpart B of the Regulation]." ACOs may also incorporate broader participant categories (i.e., rural health clinics or federally qualified health centers), but these entities cannot be used to define the

[1] Patient Protection and Affordable Care Act ("ACA"), Pub. L. 111-148, 124 Stat. 119, as amended by Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, 124 Stat. 1029 (to be codified in scattered sections of 26 & 42 U.S.C.).

population of beneficiaries assigned to a particular ACO.

II. ACO Beneficiary Assignment and ACO Participation Agreement

According to the Regulation, beneficiaries are assigned to particular ACOs based solely on their individual utilization of physician participants in the ACO. As such, each physician participant, as defined by the TIN reported to CMS, is limited to participation in one ACO, whereas other participants can, theoretically, be a part of multiple ACOs. Concurrent with the issuance of the final rule, CMS will provide a set of materials explaining the ACO assignment process to beneficiaries. Additionally, ACOs will be required to notify beneficiaries seeking services from any ACO participant of the entity's status as an ACO and any implications for the beneficiary.

At the beginning of each calendar year, ACOs can contract with CMS to participate in the Shared Savings Program. ACO applications will need to be submitted by a deadline established by CMS. Each ACO contract is for a minimum of three (3) years, and is proposed to operate on a six-month claims run-out[2] to cover the period from the date services are rendered through final payment from CMS. Shared savings calculations and distributions would be based on claims experience and ACO performance during each calendar year, including the claims run-out period. As part of the contracting process, ACOs can select either a one-sided or two-sided model. In the one-sided model, participating ACOs would share in the benefits of any shared savings without bearing any risk of reduced performance or quality under applicable benchmarks. ACOs would be allowed to operate under the one-sided model for the first two (2) years of the contract and would then operate on the two-sided model for the final year. ACOs may also opt to contract to participate in a two-sided model for the entire contract period. Under this model, ACOs would be required to create a reserve fund, or other financial mechanism, sufficient to repay CMS at least 1% of the ACO's per-capita expenditures for the applicable contract year.

III. Legal Structure and Governance

The Regulation provides a fair amount of flexibility in how ACOs legally can be structured. Under the Regulation, an ACO may be organized as a corporation, partnership, limited liability company, foundation or any other entity permitted under applicable state law, provided that the entity must:

- Maintain its own, independent TIN;
- Be capable of receiving and distributing shared savings among its constituent ACO participants;
- Be capable of repaying any shared losses (for those ACOs operating under a two-sided model);
- Be capable of reporting on and ensuring that each of the ACO participants complies with program requirements; and
- Be capable of performing any other function required by the Regulation.

Within this relatively flexible framework, however, the Regulation provides for very specific governance and management requirements for any participating ACO. Each ACO must be structured to ensure that the ACO executes the required functions, including, but not limited to, defining processes to promote evidence-based medicine and patient engagement,

[2] The "run-out" period will encompass claims for services provided during the calendar year, but not reimbursed or paid until the following year.

and reporting on quality and cost measures while defining and coordinating an appropriate continuum of care for each beneficiary. In addition, the governing body of the ACO must:

- Be comprised of 75% or more ACO participants;
- Include at least one Medicare beneficiary representative served by the ACO who does not have a conflict of interest;
- Have broad authority to oversee the administrative, clinical and fiduciary operations of the ACO; and
- Be separate and unique to the ACO (in cases where the ACO comprises multiple, otherwise independent entities).
- **Note:** If the ACO is comprised of a single, financially and clinically integrated entity, and if 75% of the governing body of the integrated entity is comprised of representatives of the entity, the parent entity governing body may serve as the ACO governing body, provided it satisfies the other requirements of the Regulation, signally the inclusion of an ACO Medicare beneficiary member.

In addition to the governance requirements, the Regulation provides additional discussion of the requirements for management of the ACO. Specifically, the ACO must submit with its application evidence that:

- The operations of the ACO are managed by an executive/officer whose appointment is under the control of the ACO governing body;
- The clinical operations of the ACO are overseen and managed by a medical director who is a board-certified physician licensed in the state where the ACO operates and is physically present in that state;
- The ACO participants have a meaningful commitment to the ACO clinical integration (in this case, "meaningful commitment" may mean financial or human investment in the ACO), such that the potential loss or recoupment of the investment is "likely to motivate" each such participant;
- The operations of the ACO include a physician-directed quality assurance and improvement program; and
- The ACO has an infrastructure, such as information technology, enabling it to collect and report data required for the Shared Savings Program.

During the three-year agreement, an ACO may not add ACO participants; however, the ACO may remove ACO participants (TINs) or add/subtract ACO providers/suppliers (NPIs). ACOs are required by the Regulation to provide CMS with at least thirty (30) days notice prior to any significant changes, such as a deviation from the approved application due to a change in the legal structure or reorganization of the ACO. CMS will then review the ACO's notification and determine if the ACO can continue to operate under the new structure or if it will be required to submit a new application and/or undergo an antitrust review due to the inclusion of additional providers/suppliers.

IV. Shared Savings Distributions: Qualifications and Process

The Regulation references sixty-five (65) outcome, process and patient experience measures that will be used to measure overall performance and improved health in ACO Medicare beneficiary populations. CMS has classified these measures into five (5) "domains:"

1. Patient/caregiver experience
2. Care coordination

3. Patient safety

4. Preventative health

5. At-risk population/frail elderly health

CMS designates quality standards for each measure, including a performance benchmark. An ACO must meet all relevant/required measures for each domain in order to qualify for shared savings distributions. Eligibility for shared savings also requires that each ACO meet the minimum savings rate ("MSR"). Separate from the MSR, CMS will apply two additional tests to determine eligibility for shared savings. First, CMS will set and compare an expenditure benchmark for the expenses that would have been incurred in the absence of an applicable ACO. Second, CMS will compare this benchmark with actual spending for the ACO beneficiaries. CMS will then calculate the MSR.

Once the MSR is calculated, ACOs can demonstrate eligibility for shared savings by comparing their savings rate in relation to the overall MSR determined for the applicable year. ACOs in the one-sided model could be eligible to receive up to 50% of the total savings above the MSR. ACOs in the two-sided model may be eligible to receive up to 60% of the total savings above the MSR. The Regulation also includes a cap on the total amounts of savings that can be paid to any individual ACO. For one-sided model ACOs, the cap is set at 7.5% of the ACO's "benchmark" for the first two years of the agreement, and for two-sided model ACOs, the cap is set at 10% of the ACO's "benchmark." In order to determine the appropriate "benchmark," the Regulation proposes and seeks comment on two separate approaches.

- **Benchmark Calculation Methodology 1**: the benchmark is based on fee-for-service expenditures for Part A and B beneficiaries for the three-year period prior to ACO operations in the population that could have been assigned to the ACO.
- **Benchmark Calculation Methodology 2**: the benchmark is based on fee-for-service expenditures for Part A and B beneficiaries for the three-year period prior to ACO operations in the population that are actually assigned to the ACO.

At this juncture, CMS is proposing to use Benchmark Calculation Methodology 1.

For purposes of the Shared Savings Program, the Regulation will require each ACO to publicly report a variety of information regarding its ACO in a standardized format to be specified by CMS. Required information will include organizational information such as the identities of the ACO's participating providers and suppliers; quality performance standard scores; and shared savings or losses, including the amount of any shared savings performance payment received by the ACO.

V. Data Sharing with ACOs

The Regulation permits CMS to share data with ACOs about their assigned beneficiaries in order to improve quality of care and care coordination. Specifically, pursuant to the Regulation, CMS will provide aggregate data reports at the start of the agreement period based on beneficiaries' historical utilization of health care, and then will provide quarterly aggregate data reports based on the most recent twelve (12) months of data for beneficiaries. The aggregate data reports will include some limited beneficiary identification information such as name, date of birth and Health Insurance Claim Number ("HICN"). An ACO will be required to enter into a Data Use Agreement with CMS prior to receiving any beneficiary information. The ACO must also inform beneficiaries

that they may be requesting personal health information about the beneficiary for purposes of its care coordination and quality improvement work as part of the ACO, and it must give the beneficiary the opportunity to opt-out of having his or her claims information shared with the ACO.

VI. Monitoring and Auditing ACO Performance

The Regulation gives CMS fairly broad authority to generally monitor and assess the performance of ACOs and their participating providers and suppliers. CMS plans to use a range of methods to conduct these assessments, which may include reviewing financial and quality-assessment analyses, conducting site visits, analyzing beneficiary and provider complaints and performing audits. CMS also has broad authority to monitor other, more specific requirements under the Regulation. These include:

- Potential avoidance of at-risk beneficiaries, such as patients with high-cost diagnoses or chronic conditions and patients with high-utilization rates;
- Compliance with quality performance standards;
- Continued fulfillment of eligibility requirements;
- Implementation of appropriate beneficiary notification and opt-out provisions; and
- Conformity with CMS's pre-approval requirements for marketing materials and activities.

Failure to adhere to the requirements set forth for each of these categories could lead to one of the pre-termination actions set forth below, and ultimately, if the ACO does not become compliant, to termination from the Shared Savings Program.

To facilitate the auditing process, the ACO and all of its participating providers, suppliers, and contracted entities[3] must agree to grant the Department of Health and Human Services Comptroller General, the Office of Inspector General, and their designees access to audit all books, records and other related documents that pertain to the ACO's compliance with regulatory requirements, its quality of service and cost reporting, and, for ACOs utilizing the two-sided model, ability to bear the risk of potential losses. All entities must retain these types of documents for at least ten (10) years from the final date of the agreement period or from the date of completion of any audit, whichever is later. In some circumstances, the entities may be required to retain the records for longer periods, and in all cases, CMS can inspect the ACO or a related entity's records at any time if CMS determines there is a reasonable possibility of fraud by any of the involved parties.

VII. Pre-Termination Actions

CMS has considerable discretion to take action against ACOs where, based on its monitoring activities, CMS concludes that the ACO is not adequately performing. CMS outlines three (3) main potential pre-termination actions:

- Submitting a warning notice specifying a certain activity that violates ACO requirements;
- Requesting that the ACO provide a corrective action plan ("CAP"); and
- Placing the ACO on a special monitoring plan.

[3] The definition of contracted entities is quite broad, and includes "any party that enters into an arrangement with an ACO to provide services (including administrative management or clinical services) to the ACO or health care services to the beneficiaries assigned to the ACO. It also includes any party that enters into an arrangement with an entity that is in an arrangement with the ACO down to the level of the ultimate provider of services."

CMS provides the most detail on its proposed CAPs, and plans to use them for relatively minor violations that pose no immediate risk of harm to beneficiaries or level of care. Upon the ACO's receipt of notice of a violation, it would be required to submit a CAP to CMS by the indicated deadline. The ACO's CAP would have to address the actions the ACO plans to take to address the compliance violation, and CMS would monitor the ACO's subsequent performance. While under a CAP, an ACO cannot receive shared savings payments, even for performance periods that are outside the CAP period, and later cannot be eligible to earn any shared savings attributable to the CAP period. Aside from this general description of the CAP process, however, the Regulation provides little substantive guidance as to the contents and detail of any required CAP. CMS seeks comment on other procedures, short of termination, that might be appropriate for a noncompliant ACO.

VIII. Termination

The Regulation creates multiple grounds for termination of non-compliant ACOs. These include:

- Avoidance of at-risk beneficiaries;
- Failure to meet quality performance standards;
- Failure to completely or accurately report required information or make timely corrections as needed;
- Failure to maintain continued compliance with eligibility requirements;
- Inability to effect required regulatory changes;
- Noncompliance with beneficiary notification requirements;
- Material noncompliance or a pattern of noncompliance with reporting requirements;
- Failure to submit or adhere to a CAP when required;
- Violation of Stark, Anti-Kickback, antitrust or other applicable laws and regulations;
- Submission of false, incomplete or inaccurate information;
- Use of unapproved marketing materials or beneficiary communications;
- Failure to maintain the requisite beneficiary population;
- Failure to allow beneficiaries to opt out of sharing claims information;
- Restricting or limiting internally compiled beneficiary information;
- Violation of HIPAA or other applicable privacy restrictions; and
- Failure to demonstrate an ability to repay potential losses or to maintain adequate resources to be able to do so.

An ACO may also voluntarily terminate its agreement, but must notify CMS at least sixty (60) days prior to doing so. An ACO that is terminated either voluntarily or involuntarily before the end of the three-year agreement period forfeits its mandatory 25% withholding of shared savings. Once terminated, an ACO must wait until after the end of the original three-year agreement period to reapply, and must demonstrate that it has corrected any earlier deficiencies. In addition, reentry into the Shared Savings Program can only be under the two-sided model.

IX. Reconsideration and Review of Agency Decisions

Most ACO-related decisions follow a typical agency appeals process. The proposed process requires a written request for review that is received within fifteen (15) days of the initial adverse

decision. The reconsideration official can then conduct a review, either orally or on the record. This decision can be reviewed again by an independent CMS official, who will make the final agency determination.

The Regulation, however, sets out a few instances where no reconsideration or other administrative or judicial review will be provided. These include:

- Specification of quality and performance standards;
- An ACO's quality-of-care assessment;
- The assignment of Medicare beneficiaries;
- The eligibility for and amount of shared savings;
- A termination determination for failure to meet quality performance standards;
- Regulations surrounding the permissible percentages of shared savings and shared losses; and
- An adverse antitrust determination.

For these agency decisions, the initial agency determination will be final.

X. Coordination with Other Agencies and Programs

a. The Proposed Rule on Waiver Provisions

CMS, in conjunction with the Office of Inspector General, released a proposed rule ("Rule") that solicits comment on possible waivers of the Stark Law, federal Anti-Kickback Statute and certain civil monetary penalty ("CMP") provisions.

The Rule proposes to waive application of the Stark Law only to distributions of shared savings received by an ACO through the Shared Savings Program. This waiver would apply under two circumstances: 1) to distributions of shared savings to ACO participants, providers and suppliers; and 2) to distributions of shared savings for activities that are necessary for or directly related to the ACO's operations or participation in the Shared Savings Program.

The proposed rule similarly seeks to waive application of the federal Anti-Kickback Statute for distributions of shared savings received by an ACO that go either to ACO participants, providers and suppliers, or that are necessary for or directly related to the ACO's operations or participation in the Program. Additionally, CMS and OIG proposed Anti-Kickback and CMP waivers that would apply to financial relationships between ACOs and their participants, providers and suppliers that might otherwise implicate Stark but are fully compliant with a Stark exception. In other words, these waivers would apply to financial relationships outside of shared savings distributions, so long as those relationships fit squarely within an established Stark exception.

Finally, the proposed rule would waive application of CMP provisions for hospital payments to physicians that induce a reduction or limitation of services, so long as the distributions under an ACO agreement are not knowingly made to induce the physician to reduce or limit medically necessary items or services.

CMS is soliciting comments regarding possible waivers for other financial arrangements necessary to make ACOs work, including waivers that might be necessary to form ACOs, implement governance requirements, build technological or administrative capacity or permit other financial arrangements necessary for or directly related to operating the ACO or to otherwise achieving the goals of the Shared Savings Program. CMS also seeks comments on whether waivers should be extended to financial arrangements with entities

outside of the ACO or to private payers—and how best to do so while minimizing potential fraud and abuse implications. Finally, CMS seeks comments on whether additional waivers are needed to address ACOs participating in the two-sided risk model, particularly with respect to issues that might arise from the potential for downside risk. A commenter seeking waiver under any of these circumstances must explain how its proposed waiver would be necessary to carry out the Shared Savings Program, and why the identified financial arrangement would not qualify for existing safe harbors or exceptions.

b. FTC and DOJ Antitrust Statement

In addition to the other proposed rules, the Federal Trade Commission ("FTC") and Department of Justice ("DOJ") also issued a joint statement detailing their proposed enforcement policies with respect to ACOs. The statement makes it permissible to evaluate most joint price agreements among competing health care providers in an ACO under the rule of reason standard, which permits certain transactions that might otherwise implicate antitrust regulations if the potential anticompetitive effects of those transactions are outweighed by potential procompetitive efficiencies.

FTC and DOJ set forth a proposed antitrust analysis for potential ACOs that otherwise meet CMS's eligibility criteria. The analysis establishes a so-called "Antitrust Safety Zone" for ACOs in which two or more independent participants that provide a common service have a combined share of 30% or less for each common service in the participant's primary service area ("PSA").[4] On the other hand, the agencies will require antitrust review for proposed ACOs with two or more participants providing over 50% of one or more common services in the relevant market. These ACOs must submit specific information for antitrust review and approval before forming the ACO. The review is expected to take 90 days.

ACOs that fall in the 30% to 50% range will not be required to seek antitrust review prior to formation, but can seek up-front review to reduce the risk of later challenges. In addition, FTC and DOJ set forth five (5) types of conduct that ACOs can avoid, which will significantly reduce any possibility of antitrust investigation.[5]

c. IRS Notice

According to the IRS Notice, the IRS generally does not expect that payments received by tax-exempt organizations that are otherwise in compliance with Shared Savings Program requirements will result in unrelated business taxable income. Even so, the IRS emphasizes that tax-exempt organizations must remain vigilant about ensuring that participation in the program does not result in private inurement to insiders. Because of CMS regulation and oversight, the IRS generally anticipates that it will not consider a tax-exempt organization's participation in the Shared Savings Program through an ACO to result in inurement or impermissible private benefit to the private party as long as the following five (5) general guidelines for structuring ACOs are met:

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[4] The PSA is the "lowest number of contiguous postal zip codes from which the [ACO participant] draws at least 75 percent of its [patients]."

[5] These include: 1) preventing or discouraging commercial payers from directing or incentivizing patients to choose certain providers through use of certain types of clauses; 2) tying sales of ACO services to a commercial payer's purchase of other services from providers outside the ACO; 3) contracting with specialists, hospitals, ASCs or other non-primary care providers exclusively; 4) restricting a commercial payer's ability to make cost, quality, efficiency and performance information available where the information is similar to that used in Shared Savings Program; and 5) sharing competitively sensitive pricing or other data among ACO provider participants.

- The terms of the tax-exempt organization's participation in the ACO (including its share of shared payments or losses and expenses) are set forth in advance in a written, arm's length agreement;
- The ACO is an accepted participant in the Shared Savings Program;
- The organization's share of economic benefits from the ACO is proportional to the benefits or contributions it provides to the ACO, and any ownership interest in the ACO is proportional and equal in value to the organization's capital contributions;
- The organization's share of the ACO's losses does not exceed the share of ACO economic benefits to which the tax-exempt organization is entitled; and
- Any contracts and transactions that the tax-exempt organization enters into with the ACO, its participants or any other related parties are at fair market value.

The IRS Notice also seeks comments on what further guidance, if any, might be needed to facilitate the participation of tax-exempt organizations in ACOs.

d. Other CMS Shared Savings Initiatives

Additionally, the Regulation prohibits providers and suppliers from participating in the Shared Savings Program as an ACO if it participates in other CMS shared savings initiatives, such as the independence at home medical practice pilot program or any other Medicare initiative that involves shared savings.
