ARNOLD & PORTER LLP

ADVISORY

April 2011

ACO Alert: Emerging Key Provisions from Federal Agencies' ACO Guidance

On March 31, 2011, the Centers for Medicare & Medicaid Services (CMS), the Department of Health and Human Services (HHS) Office of Inspector General (OIG), the Federal Trade Commission (FTC), the Department of Justice (DOJ), and the Internal Revenue Service (IRS) issued highly anticipated proposed rules and statements addressing the structure and regulation of Accountable Care Organizations (ACOs) that can volunteer to participate in the Medicare Shared Savings Program, established by Section 3022 of the Affordable Care Act. Arnold & Porter LLP's interdisciplinary ACO team of healthcare, tax, antitrust, and corporate attorneys are collaborating on comprehensive analyses of the agencies' proposed rules and will be releasing shortly a series of Advisories and client webinars to provide an in-depth breakdown of the practical implications of the regulations.

These proposals are complex and raise a number of critical issues that will affect providers and suppliers that seek to participate in ACOs, as well as their patients, in a variety of ways. The various agencies have solicited public comments on all areas of these proposals, and stakeholder comments could significantly impact the outcome of the final rules, which will be issued later this year.

For your convenience, we have provided below a brief summary of key points and provisions, as well as links to the proposed regulations and guidance:

1. CMS Proposed Rule: *see*, "Medicare Program: Medicare Shared Savings Program: Accountable Care Organizations," *available at*: http://www.gpo.gov/fdsys/pkg/FR-2011-04-07/pdf/2011-7880.pdf. Comments will be accepted through June 6, 2011. Comments will be accepted through June 6, 2011.

2. CMS and OIG Notice with Comment Period: see, "Medicare Program: *see*, "Medicare Program: Waiver Designs in Connection with Medicare Shared Savings Program and Innovation Center," *available at*: http://www.gpo.gov/fdsys/pkg/FR-2011-04-07/pdf/2011-7884.pdf. Comments will be accepted through June 6, 2011.

3.*See*, Joint FTC and DOJ Antitrust Statement, *available at*: http://www.arnoldporter.com/public_document.cfm?id=17429&key=0J1. Comments will be accepted through May 31, 2011.

4. *See*, IRS Notice 2011-20, *available at*: www.irs.gov/pub/irs-drop/n-11-20.pdf. Comments will be accepted through May 21, 2011.

Contacts

Jeffrey R. Ruggiero
+1 212.715.1089

Alan E. Reider
+1 202.942.6496

Paul M. Rudolf MD
+1 202.942.6426

Asim Varma
+1 202.942.5180

Thomas A. Gustafson PhD
+1 202.942.6570

Highlights of CMS Proposed Rule

Eligibility Requirements

- Eligible ACO participants include physician group practices, networks of individual practices, partnerships or joint ventures of ACO professionals, and hospitals or hospitals employing ACO professionals. ACO professionals include physicians and several other classes of practitioners.
- Hospitals may participate directly, but must be paid under the inpatient prospective payment system (which excludes certain cancer centers and children's hospitals). Critical Access Hospitals are also eligible to participate.
- Federally Qualified Health Centers and Rural Health Centers could not directly participate, but CMS proposes incentives for ACOs that contract with these providers.
- At least 50 percent of an ACO's primary care physicians must qualify as meaningful electronic health record users as defined by the Health Information Technology for Economic and Clinical Health Act and Medicare regulations.

Beneficiary Assignment to ACOs

Beneficiaries would be retrospectively assigned to ACOs on the basis of receiving primary care services from an ACO physician specializing in general practice, family practice, internal medicine, and geriatric medicine. These primary care physicians will be required to be exclusive to a single ACO. Other specialists are free to contract with multiple ACOs. Assignment will not restrict the ability of a beneficiary to seek care from non-ACO providers.

- ACOs will be required to maintain at least 5,000 beneficiaries. CMS assumes that ACOs who achieve the 5,000 threshold will have effectively demonstrated that they have sufficient participating professionals to provide the requisite care to those beneficiaries.
- ACOs that fall below the 5,000 beneficiary threshold in a year will be required to follow a corrective action plan and will be terminated if they do not meet the threshold by the end of the next performance year.
- Beneficiaries will not receive advance notice of their ACO assignment. However, providers participating in ACOs will be required to post signs in their facilities indicating their participation, and make available standardized written information to Medicare beneficiaries whom they serve. Additionally, all Medicare patients treated by participating providers must receive a standardized written notice of the provider's ACO participation and a data use opt-out form.
- CMS expects five million Medicare beneficiaries to receive care from providers participating in an ACO.

Legal Structure and Governance

- ACOs would be required to have a governance structure that provides proportional control by participants over ACO operations. While the ACO itself need not be enrolled in Medicare, it must be able to receive shared savings for distribution to ACO participants who would be expected to be enrolled to treat Medicare patients. Medicare enrolled participants/entities would be required to have at least 75 percent control of each ACO governing body.
- ACOs would be required to include at least one Medicare beneficiary treated by the ACO on the organization's governing body. In addition, ACOs will be required to partner with community stakeholders, either by including such stakeholders on their boards or other governing bodies, or through advisory boards.
- CMS expects the structure of each ACO to require sufficient integration of otherwise competing providers to demonstrate that the ACO is likely to achieve savings.
- ACO participants would be expected to be committed to the ACO for the three-year contract of the ACO, but with a "remedial process" for participants that don't satisfy performance standards.
- The proposed rule includes other governance requirements, including the establishment of various committees and requirements for physician leadership.

ACO Agreement Requirements

- ACOs will be required to enter into an agreement with CMS for a three-year term. Participants will have the

right to terminate the agreement upon 60-day notice, but ACOs that terminate before the end of the three-year term will forfeit 25 percent of any shared savings achieved (payments will be subject to a 25 percent withhold to offset potential future losses). ACOs that terminate and wish to re-apply for participation must document safeguards to prevent recurrence of the termination events, and ACOs that terminate with incurred losses relative to their benchmark will not be able to re-apply.

- Participating ACOs must be prepared to accept changes in the requirements imposed by CMS during the contract term, except in the requirements for eligibility, calculation of the sharing rate, and beneficiary assignment.
- CMS proposed 16 grounds for termination of the Agreement. ACOs would have the right to appeal termination on certain specified grounds.

Measuring ACO Performance on Cost and Quality

Cost Performance

- **Risk Model:** CMS proposes that all ACOs in the Shared Savings Program should not only be able to share in savings but also be at risk for losses. ACOs would have the option of electing from one of two tracks for their initial, three-year agreement period. An ACO could elect a two-sided risk model (under which the ACO would be accountable for losses, but also would be eligible for a larger share of achieved savings than under the one-sided model). Alternatively, an ACO could elect a one-sided model for the first two years of the agreement period, but it would be required to automatically transition to the two-sided model for the third year (and for subsequent agreement periods).
- **Shared Savings and Losses:** CMS proposes to establish a "benchmark" level of savings for each ACO, reflecting the patients assigned to it. Shared savings and losses must exceed some percentage around the ACO's benchmark in order to demonstrate confidence that the savings or losses are not simply the result of random variation. Therefore, CMS proposes a "minimum savings rate" of between 2-4 percent, based on the size of the ACO.
- CMS proposes to share savings up to a "maximum sharing rate." In order to incentivize the two-sided approach, CMS proposes a maximum sharing rate of 60 percent for ACOs in the two-sided model, compared with 50 percent for the one-sided model. The total amount payable would be capped at a percentage of the ACO's benchmark for the performance year (7.5 percent for the one-sided model, and 10 percent for the two-sided model).
- In the two-sided model, ACOs would be required to accept downside risk of losses once a "minimum loss rate" of two percent is exceeded. CMS proposes a cap on the amount of losses to be shared, beginning at five percent in the first year and moving to 7.5 percent in the second year and 10 percent in the third year. Losses in excess of the cap would not be shared.

Quality Performance

- **65 Quality Measures:** Achieving and maintaining good quality care would be critical for earning incentive payments under the Shared Savings Program. CMS proposes 65 quality measures, across five domains: patient/caregiver experience of care, care coordination, patient safety, preventive health, and at-risk population/frail elderly health. The aggregated domain scores would determine the ACOs eligibility for sharing in the savings generated by the ACO. CMS seeks to align measures across Medicare and Medicaid's public reporting and payment systems, in an effort ultimately to achieve a core set of measures appropriate to each provider category that reflect the level of care and the most important areas of service and measures for that provider.
- **Quality Requirements:** CMS proposes that each ACO submit quality data on all 65 measures for each year of the three-year agreement period. Reporting during the first year would determine the performance standard

for the next two years. Each ACO would be scored on overall achievement and on improvement. ACOs that do not meet the quality performance thresholds for all proposed quality measures would not be eligible for shared savings under the proposal, regardless of how much per capita costs were reduced.

- **Transparency:** ACOs would be required to report publicly on both their shared savings and, if applicable, on their amount of losses under the two-sided model.

Proposed Waivers of Certain Fraud and Abuse Laws

- **Stark Law, Anti-Kickback, and CMP Gainsharing Waivers:** CMS and OIG released a notice that proposed waivers of the Physician Self-Referral Law (Stark Law), the Civil Monetary Provision Gainsharing Prohibition on payments from a hospital to a physician (CMP Gainsharing Prohibition), and the Federal Anti-Kickback Statute (AKS) that would apply to four scenarios. The Stark Law and the AKS waivers would apply to distribution of the shared savings generated from the Medicare Savings Program by the ACO:
  - within the ACO and among its participants, providers, suppliers, and individuals and entities that were ACO participants, providers, or suppliers during the year in which the shared savings were earned by the ACO; and
  - to individuals/entities outside of the ACO for activities necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program.

The CMP Gainsharing Prohibition waiver would apply to distribution of the shared savings generated from the Medicare Savings Program from a hospital to a physician provided that: (1) the payments are not made knowingly to induce physicians to reduce or limit medically necessary items or services; and (2) the hospital and physicians are ACO participants, providers, or suppliers, or were ACO participants, providers, or suppliers during the year in which the shared savings were earned by the ACO.

In addition, the AKS and CMP Gainsharing Prohibition waiver would apply to certain financial arrangements among the ACO, ACO participants, providers, or suppliers that are necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program that satisfy an exception to the Stark Law.

- **Duration of the Waivers.** The shared savings waivers would apply to distributions earned by the ACO during the term of its agreement with CMS, even if the distributions occur after the expiration of the ACO's agreement with CMS. The AKS and CMP waivers for arrangements that comply with an exception to the Stark Law would apply only during the term of the ACO's agreement with CMS.
- **Application and Timing of the Waivers.** The agencies indicate that the proposed waivers will be applied uniformly to all qualified ACOs, ACO participants, and ACO providers/suppliers participating in the Medicare Shared Savings Program. Waivers are expected to be issued concurrently with CMS's publication of the final rule for the Medicare Shared Savings Program.

OIG and CMS request comments on a number of issues, including: arrangements related to establishing the ACO; financial relationships related to the ongoing operations of the ACO and achieving the ACO's goals; waivers for distributions of shared savings received from private payers; scope, duration, and timing of the proposed waivers; two-sided risk model; and scope of Innovation Center waiver authority granted under the Patient Protection and Affordable Care Act.

Antitrust Laws

- **Market Share Analysis Requirement:** The "Antitrust Agencies" (DOJ and FTC) issued a Proposed Statement that would govern antitrust review of ACOs in the Shared Savings Program. It would require every ACO to undertake a market share analysis to determine whether it must file an application for Antitrust Agency review prior to CMS approval, no matter the intentions of the ACO, with respect to serving non-Medicare patients and negotiating with private payers. The Proposed Statement sets forth the process for computing market shares based on the ACO's combined share

of "Common Services" in each participant's Primary Service Area (PSA). ACOs that seek an antitrust review would be required to submit information sufficient to show its PSA share calculations for Medicare, as well as for each Common Service provided to commercial customers where those shares "differ significantly" from PSA share calculations derived from Medicare data.

- **Safety Zone:** Qualifying ACOs need not seek prior antitrust review and the Antitrust Agencies will not challenge ACOs that fall within the safety zone, absent extraordinary circumstances. To qualify for the safety zone, an ACO would have to meet the following criteria:
  - *All* of the ACO's Common Service PSA shares must be 30 percent or below;
  - *All* hospitals or ambulatory surgery centers (ASCs) participating in the ACO must be non-exclusive to the ACO;
  - Any "Dominant Provider" must be non-exclusive to the ACO. A Dominant Provider is an ACO participant providing a service no other ACO participant provides and with a market share greater than 50 percent in its PSA for that service; and
  - An ACO with a Dominant Provider cannot contractually restrict a commercial payer's ability to contract or deal with other ACOs or provider networks.
- **Mandatory Filing Review:** Every ACO that includes two or more participants who, combined, have a 50 percent share or more in *any* Common Service within a PSA would be *required* to obtain a letter from the FTC or DOJ stating it has no present intent to challenge the ACO *before* CMS review. The Antitrust Agencies promise expedited review of such ACOs.
- **Gray Area:** ACOs that do not fall in the safety zone and that are not subject to mandatory review may nonetheless seek expedited review. The Antitrust Agencies also identified five anti-competitive practices an ACO can avoid to reduce the likelihood of an antitrust investigation, including:
  - Using contractual terms that have the effect of discouraging commercial payers from directing or incentivizing patients to choose certain providers, such as "anti-steering," "guaranteed inclusion," "product participation," "price parity," and most favored nations clauses or similar;
  - Conditioning (either explicitly or through pricing) the ACO's services on a commercial payer's purchase of other services from providers outside the ACO and vice versa;
  - Making any of the ACO's participants (including hospitals, ASCs, and specialists) except for primary care physicians exclusive to the ACO;
  - Restricting a commercial payer's ability to make available to enrollees information similar to the Shared Success performance measures; and
  - Sharing competitively sensitive data such as pricing outside the ACO among the ACO's provider participants.

Tax Implications for Tax-Exempt Organizations

- **Tax-Exempt Organizations:** The IRS expects that a section 501(c)(3) organization's participation in ACO activities would not result in inurement or impermissible private benefit to the organization's insiders (e.g., hospital staff), where the following precautions are observed: (1) the terms of the tax-exempt organization's ACO participation are set forth in an arm's-length contract; (2) CMS has accepted the ACO into the Shared Savings Program, and this status had not been terminated; (3) the tax-exempt organization receives benefits from the ACO that are proportionate to the contributions it has made to the ACO; (4) its share of losses do not exceed the share of economic benefits it receives; and (5) all contracts and transactions by and between the tax-exempt organization and the ACO are at fair market value.
- **Joint Ventures and Partnerships with Non-Exempt Organizations:** As the IRS anticipates that ACO participation in shared savings arrangements with commercial insurers would not necessarily further the charitable interests of section 501(c)(3) participants,

the Notice also requests input on: (1) how a tax-exempt organization's participation in activities not part of the Shared Savings Program would further its exempt purposes; and (2) where a tax-exempt organization is a partner (or LLC member) of an ACO, how the ACO's activities will be attributed to the tax-exempt organization.

Regulatory Impact

Provider participation in an ACO is voluntary. CMS anticipates that 75 to 100 ACOs will be active in the first three years. CMS estimates Medicare savings of approximately US$510 million in the first three years of the program (2012-2014), although this prediction is quite sensitive to the final rule and the actual level of program participation.

Again, stakeholders have the opportunity to provide critical input on the proposed ACO rule and the associated notices, which could impact the policies that are ultimately finalized later this year.

Arnold & Porter's ACO team will continue to analyze the proposals and will issue a detailed Advisory in the coming days. In the meantime, if you have any questions about any of the topics covered above, please contact your Arnold & Porter attorney or any of the following attorneys:

Kirk Ogrosky
+1 202.942.5330
Kirk.Ogrosky@aporter.com

Alan E. Reider
+1 202.942.6496
Alan.Reider@aporter.com

Jeffrey R. Ruggiero
+1 212.715.1089
Jeffrey.Ruggiero@aporter.com

Paul M. Rudolf MD
+1 202.942.6426
Paul.Rudolf@aporter.com

Asim Varma
+1 202.942.5180
Asim.Varma@aporter.com

Thomas A. Gustafson PhD
+1 202.942.6570
Tom.Gustafson@aporter.com

Rosemary Maxwell
+1 202.942.6040
Rosemary.Maxwell@aporter.com

Chandra N. Branham
+1 202.942.5659
Chandra.Branham@aporter.com

Theodore Lotchin
+1 202.942.5250
Ted.Lotchin@aporter.com

Nicole Liffrig Molife
+1 202.942.6611
Nicole.Liffrig@aporter.com

Ryan Z. Watts
+1 202.942.6609
Ryan.Watts@aporter.com

Bridget M. Weiss
+1 202.942.5839
Bridget.Weiss@aporter.com