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Client Alert

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Accountable Care Organizations – The Feds Offer Proposals/Seek Public Comments on Medicare Shared Savings Program

Overview: Healthcare providers and policymakers have long been intrigued by the notion of shifting from the current volume of services reimbursement system to one based on patient outcomes, measurable quality controls and aligned financial incentives for collaborating providers. Many providers have taken initial steps to move in that direction. Efforts to date have been hampered by scarce guidance on knotty questions like:

- How to incentivize providers to transition from "silo" rewards and responsibilities to enhanced cooperation and coordination;
- How to afford the organizational, infrastructure and operational initiatives required to implement a shared approach to managing costs, measuring quality, and rewarding success;
- How to navigate safely through self-referral prohibitions, antikickback restrictions, civil money penalty risks, antitrust constraints, tax exemption challenges and unrelated business income tax risks.

The New York Times quips that until now ACOs "were like unicorns, creatures that flourished in the imagination but proved persistently elusive in the natural world."

A single section of the March 2010 Affordable Care Act (ACA) caused renewed hope for more clarity in this area. On March 31, 2011, a coordinated federal agency response to this legislation has shed new light, and sought public comment, on how these issues might be resolved in connection with the Medicare program, set to "go live" on January 1, 2012. Although proposals are limited at this point to Medicare, the agencies recognize that whatever final rules result will have a profound effect on other public and private reimbursement arrangements seeking to implement shared savings programs among collaborating providers.

Statutory Background: Section 3022 of the ACA amends Title XVIII of the Social Security Act by adding a new §1899, http://www.ssa.gov/OP_Home/ssact/title18/1899.htm. This provision directs the DHHS Secretary (Secretary) to establish a Medicare Shared Savings Program (MSSP). The MSSP is to:

- promote accountability for care of Medicare beneficiaries;
- improve the coordination of Medicare fee-for-service items and services; and
- encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery.

Under new §1899, groups of health care service providers and suppliers that meet criteria specified by the Secretary are eligible to participate as ACOs under the MSSP. Examples of groups of service providers and suppliers that may form an ACO include (i) physicians and other health care practitioners (ACO professionals) in a group practice, (ii) a network of individual practices, (iii) a partnership or joint venture arrangement between hospitals and ACO professionals, and (iv) a hospital employing ACO professionals.

Under new §1899, an ACO desiring eligibility for the MSSP must:

- Be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it;

- Enter into an agreement with the Secretary to participate in the MSSP for not less than a 3-year period;
- Have a formal legal structure that allows it to receive and distribute MSSP payments to participating providers of services and suppliers;
- Include primary care ACO professionals sufficient for the number of Medicare fee-for-service beneficiaries assigned to the ACO. At a minimum, the ACO must have at least 5,000 beneficiaries assigned to it;
- Provide the Secretary with such information regarding its ACO professionals as the Secretary determines necessary to support the assignment of Medicare fee-for-service beneficiaries, the implementation of quality and the other reporting requirements, and the determination of MSSP payments;
- Have in place a leadership and management structure that includes clinical and administrative systems;
- Define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of health information technology, telehealth, remote patient monitoring, and other such enabling technologies; and
- Demonstrate to the Secretary that it meets patient-centeredness criteria specified by the Secretary, such as the use of patient and caregiver assessments or the use of individualized care plans.

Also under new §1899, the Secretary must establish quality performance standards to assess the quality of care furnished by ACOs and monitor ACOs for avoidance of at-risk patients. If the Secretary determines that an ACO has taken steps to avoid at-risk patients to reduce the likelihood of increasing costs to the ACO, the Secretary may impose appropriate sanctions, including termination from the MSSP.

ACOs participating in the MSSP will manage and coordinate care for their assigned Medicare fee-for-service beneficiaries. Health care service providers and suppliers participating in an ACO will continue to receive Medicare fee-for-service payments in the same manner as such payments would otherwise be made. In addition, an ACO that meets quality performance standards established by HHS and demonstrates that it has achieved savings against an appropriate benchmark of expected average per capita Medicare fee-for-service expenditures will be eligible to receive payments for Medicare shared savings (MSSP payments).

Coordinated Regulatory Guidance: On March 31, 2011, several federal agencies simultaneously announced coordinated guidance for ACOs under the MSSP:

1. **The Centers for Medicare & Medicaid Services (CMS)** issued a proposed rule for the MSSP, to achieve what CMS defines as its "three part aim" – better care for individuals; better health for populations; and lower growth of expenditures. www.ofr.gov/inspection.aspx. Under this proposed rule:

    a. Providers wishing to participate in the MSSP must either form or join an ACO, which then must submit an application to CMS for approval. Upon CMS approval, the ACO is accepted into the MSSP under a three-year agreement. There is no proposal that the ACO itself be enrolled in the Medicare program.

    b. For CMS approval, the ACO must establish shared governance among the ACO participants, including proportionate board representation for all service providers, as well as representation from community stakeholders, suppliers, and Medicare beneficiaries. Non-ACO participants may invest and may gain board representation, but ACO participants must control at least 75% of the governing body.

c. For CMS approval, the ACO must demonstrate both clinical management and oversight by a board certified physician and clinical integration through "meaningful" financial or human capital commitments from ACO participants and suppliers.

d. ACOs will be required to have infrastructure allowing them to monitor and report claims review and financial and quality data. In addition, ACOs will be required to provide site visits, patient surveys, and periodic reports in the areas of patient/caregiver care experiences; care coordination; patient safety; preventive health; and at-risk population health.

e. ACOs must demonstrate processes to develop evidenced-based medicine, to encourage patient participation, to report quality and cost measures, and to promote coordination of care, all within an overall system of patient-centeredness. CMS has proposed 65 separate quality reporting categories, broken down among five (5) separate domains: Patient/Caregiver Experience; Care Coordination; Patient Safety; Preventive Health; and At-Risk Population/Frail Elderly Health.

f. ACO participants will receive reimbursement under the regular Medicare payment systems. Subject to threshold, ceiling and withhold requirements set by CMS, the ACO may also receive MSSP payments to the extent it meets quality performance measures and exceeds benchmarks developed by CMS. ACOs must choose between one of two risk-sharing tracks, each with a different percentage of savings available for the ACO:

   i. One-Sided Risk Track (50% of shared savings to the ACO) -- Savings are shared for the first two years of the contract, but in the third year savings and losses are shared.

   ii. Two-Sided Risk Track (60% of shared savings to the ACO) -- Savings and losses are shared for all three contract years.

g. Once losses are shared, poor performing ACOs may be subject to varying penalties up to between 7.5 – 10% of what CMS would have expected to pay on assigned beneficiaries.

h. While acknowledging uncertain assumptions at this point, CMS currently estimates:

   i. Aggregate median savings to the Medicare program in 2012-2014 at $510 million, assuming a median number of 112 ACOs participate.

   ii. Aggregate median estimated bonuses of $800 million during 2012 – 2014 (calculates to an average of $7.14 million each).

   iii. Aggregate median penalties to poorly performing ACOs of $40 million.

   iv. Start-up and first year operating expenses for a participating ACO at $1.76 million each.

i. Public comments are widely solicited on most aspects of the proposed rule. CMS emphasizes that the final rule may be markedly different than the proposed rule.

2. **CMS and the DHHS Office of Inspector General (OIG)** jointly issued a notice and request for comments dealing with fraud and abuse waivers. www.ofr.gov/inspection.aspx Under this notice, waivers are proposed to the Stark self-referral regulations, to the Antikickback Statute, and to the Civil Money Penalty provisions prohibiting hospital payments to physicians to reduce or limit services. Although these proposed waivers only apply to the distribution of MSSP payments, CMS and OIG have requested comments on areas where waivers are not currently proposed, such as the arrangements for establishing an ACO.

3. **The U.S. Department of Justice (DOJ) and Federal Trade Commission (FTC)** issued a joint proposed enforcement policy on ACO-related antitrust issues. www.ftc.gov/opp/aco/. Under this proposed policy,

    a. ACOs meeting CMS's eligibility criteria for MSSP participation will be deemed sufficiently integrated so that the per se rule will not apply to the ACO's price negotiations with payers on behalf of the ACO's providers.

    b. ACOs with physician market shares of 30% or less in each physician specialty and in which any hospital participates on a non-exclusive basis will fall within an antitrust safety zone. Under certain conditions, a "rural" ACO can qualify for this safety zone even if some of its physician market shares exceed 30%.

    c. ACOs with physician market shares between 30% and 50% will not likely raise significant antitrust issues if certain specified conduct is avoided. Such ACOs may seek advisory opinions from either DOJ or FTC.

    d. ACOs with physician market shares exceeding 50% must obtain a positive advisory opinion from either FTC or DOJ.

4. Recognizing CMS's intent to encourage MSSP participation by not-for-profit, community based organizations, the **Internal Revenue Service (IRS)** issued a notice and solicitation of comments related to tax-exempt organizations (TEOs) and their potential participation in ACOs with private non-tax-exempt parties. http://www.irs.gov/pub/irs-drop/n-11-20.pdf. Under this notice:

    a. Regarding inurement and private benefit, the IRS concludes that because of CMS's regulation and oversight of the MSSP, a TEO's participation in the MSSP through an ACO will not generally result in inurement or impermissible private benefit to the private party ACO participants, so long as six (6) conditions are met:

        i. The terms of the TEO's participation in the MSSP through the ACO (including its share of MSSP payments or losses and expenses) are set forth in advance in a written agreement negotiated at arm's length;

        ii. CMS has accepted the ACO into, and has not terminated the ACO from, the MSSP;

        iii. The TEO's share of economic benefits derived from the ACO (including its share of MSSP payments) is proportional to the benefits or contributions the TEO organization provides to the ACO;

        iv. If the TEO receives an ownership interest in the ACO, the ownership interest received 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 ownership interests;

        v. The TEO's share of the ACO's losses (including its share of MSSP losses) does not exceed the share of ACO economic benefits to which the TEO is entitled; and

        vi. All contracts and transactions entered into by the TEO with the ACO and the ACO's participants, and by the ACO with the ACO's participants and any other parties, are at fair market value.

    b. Regarding unrelated business income tax (UBIT), the IRS expects that, absent inurement or impermissible private benefit, any MSSP payments received by a TEO from an ACO would derive from activities that are substantially related to the performance of the charitable purpose of lessening the burdens of government. Accordingly, they would not

result in UBIT, as long as the ACO meets all of CMS's eligibility requirements. On the other hand, if the TEO receives non-MSSP payments from an ACO, the UBIT issue may depend on whether the shared savings payments were in connection with a governmental program like Medicaid (where governmental burdens might be lessened) or a private program (where no governmental burdens would be lessened).

c. The IRS seeks public comment regarding what additional guidance, if any, is necessary or appropriate regarding a TEO's participation in non-MSSP activities through an ACO, as that may affect its tax-exempt status and UBIT.

All of these documents will be published in the Federal Register on April 7, 2011, with comment periods ending on May 31, 2011 for the DOJ/FTC and June 6, 2011 for the others. Final rules and related guidance will be issued simultaneously.

Observations for Providers

1. Participation in the MSSP is voluntary, not mandatory.
2. Potential benefit: Additional payment from Medicare in the form of Shared Savings – subject to ACO exceeding CMS established benchmark by more than threshold and limited by aggregate payment limit set up by CMS.
3. Costs and risks:
    a. Start up capital costs for organization, infrastructure, etc to meet CMS eligibility;
    b. Human capital costs in re-negotiating provider relationships, sharing governance and management, demonstrating patient centeredness;
    c. Providing for loss sharing risks as early as year 1 and no later than year 3;
    d. Increased transparency and public reporting; and
    e. Lack of administrative or judicial review for many CMS determinations.
4. Analyze your own situation relative to these proposals, recognizing the reality that final rules may be much different.
5. Consider the value of providing your own relevant comments on one or more aspects of these proposals. Monitor the public comments submitted by others.

Contact Information: If you have any questions concerning the issues discussed in this client alert, please contact Dick Vincent, the principal author of this alert, at (404) 879-2422 or dvincent@wcsr.com, or the Womble attorney with whom you normally work.