

BRACH EICHLER Health Law UPDATE



APRIL 2011

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ACCOUNTABLE CARE ORGANIZATION OVERVIEW

Proposed ACO Regulations



Centers for Medicare & Medicaid Services (CMS) has released proposed regulations governing Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program (MSSP) enacted as part of the Patient Protection and Affordable Care Act (PPACA). An ACO is defined as “a legal entity 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.” ACO participants include doctors, physician assistants, nurse practitioners and clinical nurse specialists. ACO participants are eligible separately or in combination to form ACOs that may participate in the MSSP. The MSSP will begin operating on January 1, 2012.

Each ACO participant is required to commit to a three-year agreement with CMS in order to participate in the MSSP. In order to participate, the ACO would have to submit an application to CMS, which includes information on how the ACO plans to deliver high-quality care at lower costs to the beneficiaries it serves. Each ACO would have to agree to accept responsibility for 5,000 beneficiaries. Each ACO would also be responsible for routine self-assessment, monitoring and reporting of the care it delivers. Under the proposed rule, there are a number of circumstances under which CMS may terminate the ACO’s agreement, including avoidance of at-risk beneficiaries and failure to meet certain quality performance standards.

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The proposed rule requires providers participating in an ACO to notify the beneficiary that he or she is participating in an ACO, and then the beneficiary may choose to receive services from the provider or seek services from another provider who is not participating in an ACO. The rules would also require providers to notify beneficiaries that a beneficiary's claims data may be shared with the ACO so that it will be easier to coordinate the beneficiary's care. However, the beneficiary would have the ability to opt-out of the data sharing arrangements.

There are two proposed models for ACOs. The first would allow an organization to share in savings only for the first two years and share in savings and losses in the third year. The second would allow an ACO to share in savings and losses for all three years, which would leverage more risk with more potential benefit. CMS would be required to develop a benchmark for savings to be achieved by each ACO if the ACO is to receive shared savings, or be held liable for losses. In addition, an ACO would be accountable for meeting or exceeding established quality performance standards to be eligible to receive any shared savings.

The proposed regulations were published in the April 7, 2011 Federal Register. Comments may be submitted, no later than 5 p.m. on June 6, 2011, in one of four ways: (1) electronically, by following the "submit a comment" instructions at <http://www.regulations.gov>; (2) by regular mail, to Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1345-P, P.O. Box 8013, Baltimore, MD 21244-8013; (3) by express or overnight mail, to Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1345-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850; or (4) by hand or courier, in Washington, D.C., to Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, S.W., Washington, D.C. 20201 (or use CMS drop slots in the main lobby); and

in Baltimore, MD, to Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850 (with advance call).

CMS and OIG Propose Waivers of Stark, Anti-Kickback and CMP Provisions for ACOs

CMS and the Office of Inspector General (OIG) are soliciting public comments regarding proposed waivers of the application of the federal Physician Self Referral Law (the Stark Law), the federal anti-kickback statute, and certain civil monetary penalties (CMP) law provisions to specified financial arrangements involving ACOs under the MSSP. The agencies propose to waive these laws in certain instances so that the laws do not unduly impede the development of beneficial ACOs, while also ensuring that ACO arrangements are not misused for fraudulent or abusive purposes that harm patients or federal health care programs. Section 1899(f) of the Social Security Act, as added by PPACA, authorizes waivers of these and certain other laws as necessary to carry out the MSSP, and CMS and the OIG propose to do so under certain circumstances in light of stakeholders' concerns that the restrictions these laws place on certain financial arrangements between physicians, hospitals, and other individuals and entities may impede development of some of the integrated-care models envisioned by the MSSP. CMS and the OIG expect to issue waivers applicable to ACOs participating in the MSSP concurrently with CMS's publication of final regulations for ACOs and the MSSP. Comments to the proposed waivers are due on or before June 6, 2011 and should be submitted as stated above for the CMS proposed ACO regulations, except that when submitting comments by regular, express or overnight mail, the "Attention" line should read "Attention: CMS-1345-NC2."

FTC and DOJ Propose Statement of Antitrust Enforcement Regarding ACOs

In conjunction with CMS's release of proposed regulations governing the operation of ACOs, the Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice (DOJ) released a joint notice of a proposed antitrust enforcement policy regarding the application of the antitrust enforcement laws to health care provider collaborations seeking to participate as ACOs under the MSSP. While such collaborations may generate opportunities for substantial cost savings, forming ACOs also raises concerns about competition.

The proposed joint statement is intended to ensure that providers have the antitrust guidance they need to form pro-competitive ACOs. It describes: (1) the ACOs to which it will apply; (2) when the FTC and DOJ will apply rule of reason antitrust analyses to those ACOs; (3) an antitrust safety zone for certain ACOs; (4) the CMS-mandated antitrust review process for certain other ACOs; and (5) options for ACOs to gain additional antitrust clarity if they fall outside the safety zone but below the CMS-mandated antitrust threshold.

The FTC and DOJ will evaluate applicants that meet CMS eligibility criteria for the MSSP based on the ACO's share of services in each participant's Primary Service Area (PSA). High PSA shares may reduce the ability of competing ACOs to form, and could allow an ACO to raise prices charged to commercial health plans above competitive levels. Depending on an ACO's range of PSA shares, CMS may mandate, or an ACO may choose to seek, an expedited antitrust review.

If antitrust review is required, the agencies will apply a rule of reason analysis to determine whether the collaboration is likely to have substantial anti-competitive effects and, if so, whether the collaboration's potential pro-competitive efficiencies are likely to outweigh those effects. The greater the likely anti-competitive effects, the greater the likely efficiencies must be to pass muster under the antitrust laws. The DOJ and FTC currently apply the rule of reason

analysis when analyzing the anti-competitive effects of physician network joint ventures and multiprovider networks according to their Statements of Antitrust Enforcement Policy in Health Care issued in 1996.

Public comments regarding the proposed antitrust policy may be submitted on or before May 31, 2011. Comments should state "Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program, Matter V100017" both in the text and on the envelope, and should be sent (1) electronically, at <http://www.ftcpublic.commentworks.com/ftc/acoenforcementpolicy>, or (2) in paper form, to Federal Trade Commission, Office of the Secretary, Room H-113 (Annex W), 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580 (with courier or overnight service recommended).

IRS Seeks Comments Regarding the Need for Guidance on Tax-Exempt Organizations Participating in ACOs

On March 31, 2011, the IRS posted a notice requesting comments as to whether its existing guidance is sufficient for those tax-exempt organizations planning to participate in the MSSP through ACOs and, if not, what additional guidance is needed. The IRS is also soliciting comments concerning whether guidance is needed regarding the tax implications for tax-exempt organizations participating in activities unrelated to the MSSP, including shared savings arrangements with commercial health insurance payors, through an ACO.

The IRS notice identifies certain circumstances in which it expects that a tax-exempt organization's participation in the MSSP through an ACO generally would not result in prohibited inurement or impermissible private benefit to the private party ACO participants. In addition, the IRS expects that MSSP payments received by a tax-exempt organization from an ACO that complies with all MSSP requirements generally would not result in unrelated business taxable income.

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All comments are due to the IRS on or before May 31, 2011, and may be sent (1) electronically, at **notice.comments@irsounsel.treas.gov**, with “Notice 2011-20” in the subject line; (2) by mail, to Internal Revenue Service, SE:T:EO:RA:G (Notice 2011-20), P.O. Box 7604, Ben Franklin Station, Washington, D.C. 20044; or (3) by hand delivery to SE:T:EO:RA:G (Notice 2011-20), Courier’s Desk, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington, D.C. 20224.

We will continue to keep you updated on ACO developments. Should you need assistance in submitting comments or have questions about the information contained in this publication, feel free to contact us.

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