

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Room 352-G
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Office of Media Affairs

MEDICARE FACT SHEET

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Federal agencies address legal issues regarding Accountable Care Organizations

On March 31, 2011, the Centers for Medicare & Medicaid Services (CMS), an agency within the Department of Health and Human Services (HHS), proposed new rules under the Affordable Care Act to help doctors, hospitals, and other health care providers better coordinate care for Medicare patients through Accountable Care Organizations (ACOs). ACOs create incentives for health care providers to work together to treat an individual patient across care settings – including doctor’s offices, hospitals, and long-term care facilities. The Medicare Shared Savings Program will reward ACOs that lower growth in health care costs while meeting performance standards on quality of care and putting patients first. Patient and provider participation in an ACO is purely voluntary.

Accountable Care Organizations require health care providers to work closely and share information – and share in the savings achieved through providing more efficient care. To do so, providers may need to address certain legal or tax issues. This fact sheet describes the proposals to ensure that ACOs provide high quality care, while not violating Federal law. There will be a 60 day public comment period on both the proposed rules and these proposals. CMS encourages all interested members of the public, including providers, suppliers, and Medicare beneficiaries to submit comments so that CMS can consider them as it develops final regulations on the program.

The HHS Centers for Medicare & Medicaid Services (CMS) has worked closely with agencies across the Federal government to ensure a coordinated and aligned inter- and intra-agency effort to address these legal and tax implications. In particular, CMS, the HHS Office of Inspector General (OIG), the Federal Trade Commission (FTC), the Antitrust Division of the Department of Justice (DOJ), and the Internal Revenue Service (IRS) have released three documents in conjunction with the proposed ACO rules on which they seek comment:

1. A joint CMS and OIG Notice and Solicitation of Public Comments on Waivers in Connection with Sections 1899 and 1115A of the Social Security Act.

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2. An IRS notice, Notice 2011-20, requesting comments regarding the need for guidance on participation by tax-exempt organizations in the Medicare Shared Savings Program through ACOs.
3. A joint FTC and DOJ Proposed Statement of Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (Antitrust Policy Statement).

Notice and Solicitation of Public Comments on Waivers in Connection with Sections 1899 and 1115A of the Social Security Act:

Sections 1899 and 1115A give the Secretary of Health and Human Services authority to waive certain fraud and abuse laws as necessary to achieve the goals of each section, respectively. In conjunction with the issuance by CMS of the proposed rule that would establish ACOs, CMS and the Health and Human Services Office of Inspector General (OIG) issued a joint notice with comment period outlining proposals for waivers of certain federal laws - the physician self-referral law, the anti-kickback statute, and the civil monetary penalty law - for the Shared Savings Program. CMS and OIG have also solicited comments on further waiver design considerations for the Shared Savings Program and Innovation Center.

The Laws Addressed in the Notice: The joint CMS and OIG notice and solicitation of public comments addresses the application of the following federal laws to ACOs participating in the Shared Savings Program:

- The Physician Self-Referral Law (Section 1877(a) of the Social Security Act (the “Act”)), which prohibits physicians from making referrals for Medicare “designated health services,” including hospital services, to entities with which they or their immediate family members have a financial relationship, unless an exception applies.
- The Federal anti-kickback statute (Section 1128B(b) of the Act), which provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward the referral of business reimbursable under any Federal health care program, as defined in section 1128B of the Act.
- The civil monetary penalties law (Section 1128A(b)(1) and (2) of the Act) that prohibits a hospital from making a payment, directly or indirectly, to induce a physician to reduce or limit services to Medicare and Medicaid beneficiaries under the physician’s direct care (the CMP).

What Waivers are CMS and the OIG Proposing? The agencies have outlined proposals to waive the laws listed above in three circumstances (as further detailed in the notice and solicitation of public comments):

- The distribution of Program's shared savings payments received by an ACO to or among qualified ACO participants and ACO providers/suppliers described in the notice with comment period.
- An ACO's distribution of Program's shared savings payments to other individuals or entities for activities necessary for and directly related to the ACO's participation in the Shared Savings Program.
- For the anti-kickback statute and CMP *only*, certain financial relationships that are necessary for and directly related to the ACO's participation in the Shared Savings Program *and* fully comply with an exception to the physician self-referral law.

These waivers would cover shared savings earned during the agreement period with CMS and, as applicable, financial relationships existing during the agreement period. The notice and solicitation of public comment explains the conditions that would apply to the waivers in more detail.

Solicitation of Comments: CMS and OIG solicit public comments on a list of topics regarding other waiver design considerations. For example, the notice solicits comment on exercising the waiver authority to address start-up costs, continuing operating expenses, non-shared savings relationships between ACO members or outside entities, and special considerations relating to two-sided risk. CMS and OIG ask specific questions about each of these topics and others in hopes of eliciting detailed information from the public.

The notice also solicits comments on the best way to exercise the separate waiver authority under Section 1115A of the Act, which applies to the Innovation Center.

For more information on this document, please contact:

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Notice Addressing Federal Tax Issues Affecting Tax-Exempt Organizations:

With the issuance of the Medicare Shared Savings Program's proposed rule, the IRS anticipates that tax-exempt organizations (such as hospitals and other health care organizations) will be participating in the Program through ACOs. Accordingly, the IRS has issued a notice, Notice 2011-20, soliciting comments as to whether its existing guidance is sufficient for those tax-exempt organizations planning to participate in the Program through ACOs and, if not, what additional guidance is needed.

Tax Issues Addressed in the Notice: A tax-exempt organization must ensure that its participation in the Shared Savings Program through an ACO will not result in its net earnings inuring to the benefit of "insiders" with respect to the organization or in its being operated for the benefit of private parties, such as other participants in the ACO. Whether prohibited inurement or impermissible private benefit has occurred is determined on a case-by-case basis, based on all the facts and circumstances. The notice describes the proposed CMS regulation and oversight of the Shared Savings Program and identifies certain circumstances in which, in light of the CMS regulation and oversight, the IRS expects that a tax-exempt organization's participation in the Shared Savings Program through an ACO generally would not result in prohibited inurement or impermissible private benefit to the private party ACO participants.

In addition, because Congress created the Shared Savings Program to lessen the government's burden associated with providing Medicare benefits, the IRS expects that Program payments received by a tax-exempt organization from an ACO that complies with all Program requirements generally would not result in unrelated business taxable income.

Solicitation of Comments: The IRS is soliciting comments regarding whether additional guidance is needed to facilitate participation by tax-exempt organizations in the Shared Savings Program through ACOs. 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 Program, including shared savings arrangements with commercial health insurance payers, through an ACO. In particular, comments should describe the activities a tax-exempt organization might expect to participate in through an ACO, identify how such non-Program activities might further exempt purposes and explain what criteria, requirements, and safeguards would ensure the furtherance of these exempt purposes.

For more information on this document, please contact:

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Proposed Antitrust Policy Statement Regarding ACO Participation in the Medicare Shared Savings Program:

The DOJ and FTC have worked together to facilitate the creation of ACOs by giving providers the clear and practical guidance they need to form innovative, integrated health care delivery systems without running afoul of the antitrust laws. Accordingly, DOJ and FTC have issued a joint Proposed Statement of Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (“Antitrust Policy Statement”).

Antitrust Agency Review of ACOs: The proposed Antitrust Policy Statement applies to collaborations, not including mergers, among otherwise independent providers formed after March 23, 2010, that seek to participate, or have otherwise been approved to participate, in the Medicare Shared Savings Program. DOJ and FTC will provide rule of reason treatment to an ACO if, in the commercial market, the ACO uses the same governance and leadership structure and the same clinical and administrative processes as it uses to qualify for and participate in the Program.

Safety Zone: The Antitrust Policy Statement describes a Safety Zone for certain ACOs that participate in the Shared Savings Program. ACOs that fall within the Safety Zone are highly unlikely to raise significant competitive concerns and the Antitrust Agencies will not challenge ACOs that fall within the Safety Zone, absent extraordinary circumstances. To fall within the Safety Zone, independent ACO participants that provide a common service must have a combined share of 30 percent or less for each common service in each participant’s Primary Service Area (“PSA”), wherever two or more ACO participants provide that service to patients from that PSA.

Mandatory Antitrust Review: An ACO applicant that has a share above 50 percent for any common service that two or more independent ACO participants provide to patients in the same PSA is required to obtain a letter from one of the Antitrust Agencies advising that the reviewing Agency has no present intent to challenge or recommend challenging the ACO.

- If DOJ or FTC advises it is likely to challenge or recommend challenging an ACO if it proceeds, the ACO as proposed will be ineligible to participate in the Shared Savings Program.
- DOJ and FTC have committed to provide a 90-day expedited review of ACOs that exceed the 50 percent PSA share threshold. The reviewing Agency, therefore, must receive all of the required documents and information at least 90 days before the last day on which CMS has stated that it will accept applications to participate in the Shared Savings Program for the relevant calendar year.

Additional Antitrust Guidance: ACOs that are outside the Safety Zone and below the 50 percent mandatory review threshold that do not impede the functioning of a competitive market and that engage in pro-competitive activities will not raise competitive concerns and may participate in the Shared Savings Program without Antitrust Agency review.

- An ACO that desires further antitrust certainty can seek an expedited review from one of the Antitrust Agencies, similar to the mandatory review for ACOs above the 50 percent threshold. The reviewing Agency will complete the review within 90 days of receiving all of the necessary documents and information and will inform the ACO of the outcome of the review.
- In addition, the Antitrust Policy Statement identifies five types of conduct that an ACO can avoid to reduce significantly the likelihood of antitrust concern.

For more information about this document, contact:

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The proposed rule and joint CMS/OIG notice are posted at:

www.ofr.gov/inspection.aspx?AspxAutoDetectCookieSupport=1#special

They will appear in the **XX**, 2011 issue of the *Federal Register*.

Comments on the proposed rule will be accepted until **XX**, 2011. CMS will respond to all comments in a final rule to be issued later this year. Comments on the joint CMS/OIG notice will be accepted until **XX**, 2011.

The Proposed Antitrust Policy Statement is posted at: www.ftc.gov/opp/aco/. Comments on the Proposed Antitrust Policy Statement will be accepted until **XX**, 2011.

The IRS Notice 2011-20 will be posted at: www.irs.gov/pub/irs-drop/n-11-20.pdf.

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