

## Additional Information About Accountable Care Organizations

April 2011

On March 31st, the federal government outlined proposed actions relating to Accountable Care Organizations (ACOs), a key component of the healthcare reform legislation (the Affordable Care Act, or ACA) enacted in March 2010. In this bulletin, we provide some additional information regarding each of the March 31st releases.

### Key Aspects of an ACO Under the CMS and HHS Proposed Rules

The Centers for Medicare and Medicaid Services (CMS) and the Department of Health and Human Services (HHS) jointly issued proposed rules regarding ACOs. The proposed rules note that the government hopes to accomplish three main goals through ACOs: better care for individuals, better health for populations and lower growth in healthcare expenditures.

To accomplish these goals, the proposed rules outline certain key characteristics of an ACO, including the scope and length of an ACO's contract with CMS, the required governance of an ACO, assignment of Medicare beneficiaries to an ACO, the payment models under which an ACO can share in cost savings, and the quality and other reporting requirements expected of an ACO.

**ACO Agreements with CMS.** An ACO must enter into a three-year agreement with CMS that is either: (1) a one-sided model (no risk of losses) for two years, then a two-sided model (ACO may receive payment or may be responsible for loss) for the third year, or (2) a two-sided model for all three years. Regardless of the initial model chosen, after the first three-year agreement period, the ACO must participate in a two-sided model.

**ACO Governance.** An ACO must be a legal entity responsible for managing and coordinating care for assigned beneficiaries; have a governing body that is at least 75% controlled by ACO participants (i.e., providers and suppliers); and have a manager of operations that is a chief executive whose appointment/removal is controlled by the governing body. An ACO's clinical management/oversight must be managed by a full-time, senior-level medical director who is physically present on a regular basis in an established ACO location and who is a board-certified physician. ACO participants must have meaningful commitment to the clinical integration program (such as financial or human investment).

**Assignment of Medicare Beneficiaries to an ACO.** A Medicare beneficiary will be assigned to an ACO if the beneficiary's primary care physician is a participant in the ACO and the Medicare beneficiary receives a sufficient level of the requisite primary care services from the participating physician to appropriately designate the ACO as exercising basic responsibility for that beneficiary's care. Only primary care services provided by primary care physicians are considered in determining whether a beneficiary's physician is a participant in an ACO and consequently whether the beneficiary should be assigned

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to the ACO. Primary care services provided by specialists are not considered. Once a Medicare beneficiary is assigned to an ACO, the ACO will be held accountable for the quality, costs and overall care of the beneficiary. The assignment of a beneficiary does not limit the beneficiary's freedom of choice. Tax identification numbers will be used to associate healthcare professionals and providers with an ACO. Primary care physicians within the respective tax identification number on which beneficiary assignment is based will be exclusive to one ACO. The ACO's participating physicians and providers and suppliers must post signs and provide information to beneficiaries about the providers' participation in the ACO and about the beneficiaries' right to opt out of having their data shared among the ACO participants.

Beneficiary assignment to an ACO will occur at the end of each performance year, or retrospectively; however, an ACO will be provided with certain information concerning the expected assigned population and other information derived from the assignment algorithm used to generate the three year benchmark for the ACO.

**ACO Payment Models and Shared Savings.** An ACO is paid under both a traditional fee for service method and a share of the amount saved by the Medicare program as a result of the ACO's efficient provision of medical services. In order to receive the shared savings payments, an ACO must meet both the quality and savings requirements in the rules. Savings otherwise payable to an ACO are subject to a 25% withhold by CMS to ensure repayment of potential future losses. The amount withheld is paid out at the end of the three-year agreement period or forfeited if the ACO terminates the agreement prior to the end of the agreement period. An ACO also must establish (annually) a means whereby it could repay losses to CMS of at least 1% of the ACO's per capita expenditures from the most recent year. Any ACO that terminates its agreement with CMS would be required to provide CMS with 60 days notice of termination, and would also be required to notify all ACO participants, providers, suppliers, and beneficiaries.

CMS will establish an expenditure benchmark for each ACO by creating an estimate using per capita expenditures of Medicare beneficiaries who would have been assigned to the ACO in any of the prior three years, which estimate is adjusted for overall growth and beneficiary characteristics.

An ACO is eligible to receive a shared savings payment of 50% (under the one-sided model) and 60% (under the two-sided model) if the ACO exceeds its minimum savings rate and meets the required quality standards. The proposed rules provide for additional percentages of the shared savings if the ACO includes a rural health clinic or federally qualified health center. However, under the two-sided model, there are also detailed rules regarding the ACO's shared losses calculations, caps, and offsets of shared losses against the ACO's shared savings.

For each performance year, CMS will notify each ACO of the ACO's shared savings or shared loss amounts. Each ACO must then submit a written request to CMS for its shared savings payment, or acknowledge its shared losses, along with a certification of the ACO's compliance with the Medicare Program and ACO participation requirements. An ACO will have 30 days from the receipt of the CMS notification to make any required shared loss payment to CMS.

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**Quality and Other Reporting Requirements.** Each ACO must have a physician-directed quality assurance and process improvement committee that oversees an ongoing action-oriented quality assurance and improvement program. An ACO will be considered to have met the quality performance standard if it has reported quality measures and met the applicable performance criteria for each of the three performance years. The quality performance standards for the first year are set forth in the proposed rule. Quality measures for the remaining two years will be proposed in future rulemaking. Sixty-five measures organized under five domains to be used in the calculation of the ACO quality performance standard are contained in the proposed rules. The five domains are patient/caregiver experiences; care coordination; patient safety; preventive health; and at-risk population/frail elderly health.

An ACO that does not meet the quality performance thresholds for all of the proposed measures will not be eligible for shared savings, regardless of how much per capita costs were reduced, and the ACO will be issued a warning from CMS. If the ACO continues to underperform on the quality performance standards in the following year, CMS will terminate the ACO's agreement.

As part of its quality measurement and quality requirements, CMS' proposed rules place emphasis on the use of electronic health records (EHR) and a new Group Practice Reporting Option (GPRO) tool. CMS proposes requiring that at least 50% of an ACO's primary care physicians are determined to be "meaningful EHR users" by the start of the second performance year in order to continue participation in the shared savings program. In subsequent years, CMS anticipates proposing greater alignment between the shared savings program and EHR Incentive Program through future rulemaking.

Under the proposed rules, CMS will use quality performance standards to arrive at a total performance score for an ACO. Measures would be organized by domain and the performance on each measure would be scored. The scores for the measures would be rolled up into a score by each domain. The percentage of points earned for each domain would be aggregated using a weighting method to arrive at a single percentage that would be applied to determine the quality sharing rate for which an ACO is eligible. The aggregated domain scores will determine an ACO's eligibility for sharing savings. For the first year of the shared savings program, performance scores would be for informational purposes because CMS proposes to set the quality performance standard at the reporting level. CMS proposes setting benchmarks for each measure using Medicare fee-for-service claim data, Medicare Advantage quality performance rates, or, where appropriate, the corresponding percent performance rates that an ACO will be required to demonstrate. For each measure, CMS proposes to set a performance benchmark at a minimum attainment level. The benchmarks would be established using the most currently available data source and most recent available year benchmark data prior to the start of the annual agreement periods.

CMS also seeks comments on whether it should specify a percentage-based EHR requirement for hospitals.

Certain information regarding the operations of an ACO would be subject to public reporting, such as ACO participants; leadership; shared savings performance payments received or shared losses payable to CMS; total proportion of shared savings invested in infrastructure, re-designed care processes and other resources required to support the goals of the ACO program; and quality performance standard scores.

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## How ACOs Will Co-Exist with the Stark Law, Anti-Kickback Law, and Civil Monetary Penalties Law

CMS and the Office of the Inspector General jointly released a notice requesting public comment on proposals for the waiver with respect to an ACO of the application of certain federal laws, with respect to financial relationships for organizations operating as an ACO. In order to qualify for any of the proposed waivers discussed below, the following requirements must be met: (1) an ACO must enter into an agreement with CMS to participate in the shared savings program; and (2) the ACO, ACO participants and ACO provider/suppliers must comply with the terms of the agreement, Section 1899 of the Social Security Act (Act), and its implementing regulations.

**Stark.** With respect to Stark, the proposed waiver applies to distributions of shared savings received by an ACO from CMS under the shared savings program: (1) to or among ACO participants and ACO providers/suppliers during the year in which the shared savings were earned or (2) for activities related to ACO participation and operations in the shared savings program, provided such activities are necessary and directly related to such participation and operations. The proposed waiver is limited to distributions of shared savings and any other financial relationships covered under Stark would still need to satisfy an existing exception.

**Anti-Kickback Statute.** With respect to the anti-kickback statute, its application would be waived under the following situations:

- ✓ Financial arrangements created by the distribution of shared savings both within and outside an ACO, but only if the distribution outside an ACO is necessary for and directly related to an ACO's participation and operations under the shared savings program. Any other financial arrangements outside an ACO would need to fit within a safe harbor.
- ✓ Financial relationships identified that also implicate Stark and fit squarely within one of the exceptions identified in the notice. While generally meeting an exception under Stark does not immunize conduct under the anti-kickback statute and vice versa, a limited exception to the general rule is proposed.

**Gainsharing Civil Monetary Penalty.** With respect to the gainsharing civil monetary penalty, its application would be waived in two scenarios:

- ✓ Distribution of shared savings received by an ACO from a hospital to a physician, provided that the payments are not made knowingly to induce the physician to reduce or limit medically necessary items or services.
- ✓ Any financial relationship between or among an ACO, ACO participants and ACO providers/suppliers necessary for and directly related to an ACO's participation and operations under the shared savings program that implicates Stark and fully complies with one of the Stark exceptions identified in the notice are protected.

The waiver authority granted under Section 1899 of the Act is specific to the shared savings program and does not address other similar integrated-care delivery models. CMS has stated that it may consider waivers, exceptions or safe harbors for other types of ACOs, integrated-care delivery models, or financial arrangements at a later date.

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CMS recognizes that these proposed waivers do not cover all of the possible financial arrangements involved with setting up and operating an ACO. While some of the arrangements may not need additional protection, others may. Therefore, CMS is also soliciting comments regarding potentially broader waivers and waiver design considerations for financial arrangements that would be necessary to carry out the provisions of the shared savings program. Some of the topics include: arrangements related to establishing the ACO; distribution of shared savings or similar payments received from private payers; use of existing exception and safe harbor for EHR arrangements; the two-sided risk model; and beneficiary inducements, among others.

## FTC Policy Guidelines for ACOs

The Federal Trade Commission and the U.S. Department of Justice (Agencies) issued a proposed statement which describes policy guidelines regarding the application of the antitrust laws to ACOs. These agencies intend to coordinate their competition analysis with CMS' review of ACO applications for participation in the shared savings program.

The proposed statement applies to collaborations among otherwise independent providers and provider groups formed after March 23, 2010 which seek to participate, or have been approved to participate, in the shared savings program. The Agencies will apply a rule of reason analysis (balancing anticompetitive effects against pro-competitive efficiencies) to an ACO if, in the commercial market, the ACO uses the same governance and leadership structure and clinical and administrative processes as used to qualify for and participate in the shared savings program.

The Agencies will evaluate applicants that meet CMS eligibility criteria based on their share of services in each participant's Primary Service Area (PSA). PSA is defined as the lowest number of contiguous postal zip codes from which an ACO participant draws at least 75% of its patients. Depending on an ACO's range of PSA shares, CMS may mandate, or an ACO may choose to seek, an antitrust review. An ACO will submit any request for antitrust review to both the FTC and the DOJ, who will then determine which agency will be the reviewing agency.

The following is a summary of the proposed structure for dealing with the antitrust analysis for the three possible categories of ACOs that meet CMS eligibility criteria:

**Antitrust Safety Zone.** The proposed rules establish the following "Antitrust Safety Zone" in which the Agencies will not challenge an ACO's formation and operations from an antitrust standpoint absent extraordinary circumstances:

- ✓ Independent ACO participants that provide the same service must have a combined share of 30% or less of each common service in each participant's PSA, wherever two or more ACO participants provide that service to patients from such PSA.
- ✓ Any hospital or ambulatory surgery center must be non-exclusive to the ACO (allowed to contract or affiliate with other ACOs or commercial payers), regardless of its PSA.

**Rural Exception.** Even if it results in the ACO's violation of the 30% threshold described above, an ACO may include one physician per specialty from each rural county (as defined by the U.S. Census Bureau) on a non-exclusive basis. An ACO may include Rural Hospitals (meaning Sole Community Hospitals or Critical Access Hospitals, as defined in CMS regulations) on a non-exclusive basis.

**Dominant Provider Limitations.** Any dominant provider (with a greater than 50% share in its PSA of any service that no other ACO participant provides to patients in such PSA) must be non-exclusive to the ACO. An ACO with a dominant provider cannot require a commercial payer to contract exclusively with the ACO or restrict a commercial payer's ability to contract with other ACOs or provider networks.

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***Mandatory Antitrust Agency Review of ACOs Exceeding the 50% PSA Share Threshold.*** The proposed rules require mandatory antitrust review of ACO formation as follows:

- ✓ An ACO that does not qualify for the rural exception cannot participate in the shared savings program if its share exceeds 50% for any common service that two or more ACO participants provide to patients in the same PSA unless, as part of the CMS application process, the ACO includes a letter from either the FTC or the DOJ stating that such agency has no present intention to challenge or recommend a challenge under the antitrust laws.
- ✓ Applicants may obtain an expedited antitrust review by submitting certain required documents and information, including the CMS application and supporting documentation, to the reviewing agency. Such information must be received at least 90 days before the last day on which CMS will accept ACO applications for the relevant calendar year.

***ACOs Below the 50% Mandatory Review Threshold but Outside the Antitrust Safety Zone.*** The proposed rules allow for, but do not require, antitrust review for ACOs that are not in either of the two preceding categories. To gain additional antitrust clarity, such ACOs may, but are not required to, seek an expedited review from the FTC or the DOJ, which will be completed within 90 days of receiving all necessary documents and information. The proposed rules list five types of conduct that an ACO in such category should try to avoid in order to reduce the likelihood of an antitrust investigation.

## **IRS Notice Relating to ACOs**

The Internal Revenue Service (IRS) has issued a notice that preliminarily addresses whether section 501(c)(3) tax-exempt hospitals participating in the shared savings program through an ACO may be impacted by current limitations placed on such hospitals under the Internal Revenue Code. The IRS is soliciting comments as to whether existing IRS guidance is sufficient for those tax-exempt hospitals and other organizations planning to participate in the shared savings program through an ACO and, if not, what additional guidance is needed.

***Participation in an ACO.*** The IRS indicated that a tax-exempt hospital's participation in an ACO may be through a variety of structures, including: (1) membership in a nonprofit corporation, (2) ownership of shares in a corporation, (3) ownership of an interest in a partnership or an LLC and (iv) contractual arrangements with the ACO and/or its other participants. Regardless of structure, the tax-exempt hospital will likely be participating along with private parties, including some that might be considered "insiders" (such as physicians) with respect to the hospital. To avoid any adverse tax consequences (such as loss of section 501(c)(3) status or other sanctions), the IRS advises that tax-exempt hospitals need to ensure that their participation in an ACO is structured so as not to result in private inurement or impermissible private benefit.

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The IRS will review ACO arrangements on a case-by-case basis, based on all the facts and circumstances. However, because of the CMS regulation and oversight of the shared savings program, the IRS generally expects that it will not consider a tax-exempt hospital's participation in an ACO to result in private inurement or private benefit if the following factors are met:

- ✓ The terms of the tax-exempt hospital's participation in the shared savings program through the ACO (including its share of shared savings program payments or losses and expenses) are set forth in advance in a written agreement negotiated at arm's length.
- ✓ CMS has accepted the ACO into, and has not terminated the ACO from, the shared savings program.
- ✓ The tax-exempt hospital's share of economic benefits derived from the ACO (including its share of shared savings program payments) is proportional to the benefits or contributions the hospital provides to the ACO.
- ✓ The ownership interest received by the tax-exempt hospital, if any, is proportional and equal in value to its capital contributions to the ACO. All ACO returns of capital, allocations and distributions are made in proportion to such ownership interest.
- ✓ The tax-exempt hospital's share of the ACO's losses (including its share of shared savings program losses) does not exceed the share of ACO economic benefits to which the hospital is entitled.
- ✓ All contracts and transactions entered into by the tax-exempt hospital 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.

***Unrelated Business Income Tax and Other ACO Activities.*** The IRS also addressed whether the participation of a tax-exempt hospital in an ACO and its portion of the shared savings program payments received would be subject to unrelated business income tax. Unrelated business income could result if the activities generating the shared savings program payments are not substantially related to the performance of the tax-exempt hospital's charitable purposes. The IRS stated that, absent any private inurement or private benefit, and as long as the ACO meets all of the eligibility requirements established by CMS for participation in the shared savings program, it expects that any shared savings program payments received by the tax-exempt hospital from an ACO would derive from activities that are substantially related to the performance of the charitable purpose of lessening the burdens of government.

The IRS indicated that some tax-exempt hospitals might participate in an ACO that is conducting activities unrelated to the shared savings program (such as entering into and operating under shared savings arrangements with other types of health insurance payers). The IRS noted that such unrelated activities are unlikely to lessen the burdens of government. The IRS views any agreement with private health insurers on behalf of unrelated parties as generally not a charitable activity, regardless of whether such an agreement is aimed at achieving cost savings in health care delivery. It conceded, however, that there are certain other activities that may further or be substantially related to an exempt purpose of the tax-exempt hospital. An example provided would be an ACO participating in shared savings arrangements with Medicaid, which may further the charitable purpose of relieving the poor or underprivileged. Since this area may be unclear, the IRS is requesting comments regarding what guidance is needed regarding a tax-exempt hospital's participation in other types of activities through an ACO, particularly as to how exempt purposes would be furthered in the absence of any safeguards.

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## Conclusion

Comments on the proposals described above and other topics have been requested. Waller Lansden will continue to monitor developments regarding ACOs. If you have any questions regarding ACOs, please contact [David Head](#), [Reggie Hill](#), [Nora Liggett](#), [Kim Harvey Looney](#) or any member of Waller Lansden's Healthcare Department at 800-487-6380.

*The opinions expressed in this bulletin are intended for general guidance only. They are not intended as recommendations for specific situations. As always, readers should consult a qualified attorney for specific legal guidance.*

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