

A Closer Look at the Final ACO Rule

October 2011

On October 20th, the federal government released a final rule and other companion releases relating to Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program (MSSP), a key component of the Affordable Care Act enacted in March 2010. The proposed rule, issued in March 2011, generated extensive comment from the healthcare industry. In this bulletin, we provide additional information regarding each of the October 20th releases, and discuss some differences from the proposed rule.

Key Aspects of an ACO Under the CMS and HHS Final Rule

The Centers for Medicare and Medicaid Services (CMS) and the Department of Health and Human Services (HHS) jointly issued a final rule regarding ACOs. The final rule reiterates 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 through "improvements in the coordination and quality of care," the final rule outlines the fundamental characteristics of an ACO. As a result of numerous comments received by CMS, the final rule "made significant modifications to reduce burden and cost for participating in ACOs," including, as described below, the addition of significant flexibility throughout the ACO program.

ACO Participants. In response to many comments objecting to the requirement in the proposed rule that primary care physicians be exclusive to one ACO, the final rule permits a narrow exception to the exclusivity required of primary care physicians in ACOs. Also, as a result of several comments objecting to the exclusion of certain critical access hospitals, federally qualified health centers and rural health centers, the final rule permits these providers, if otherwise qualified, to form ACOs.

ACO Governance. The final rule leaves unchanged the requirement that an ACO must be a legal entity (now permitted to be formed under federal or tribal, as well as state, law) responsible for managing and coordinating care for assigned beneficiaries. The final rule maintains the requirement that an ACO's governing body include a Medicare beneficiary representative. It also provides that an ACO have a governing body that is at least 75% controlled by ACO participants (i.e., providers and suppliers) notwithstanding comments requesting elimination of this requirement. However, as an example of increased flexibility, the final rule permits potential ACOs that would not meet the 75% control requirement to request permission to, instead, "involve ACO participants in innovative ways in ACO governance." CMS did not agree with many comments that requested that the governing board include representatives of all ACO participants. ACOs must have a manager of operations that is a chief executive whose appointment/removal is controlled by the governing body. The final rule continues the requirement that an ACO's clinical management/oversight must be managed by a senior-level medical director, but removed the requirement that this position be full-time.

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Applying as an ACO. During 2012, an ACO may choose to have its initial participation agreement period begin on either April 1 or July 1. Regardless of which date is chosen, the first period will expire on December 31, 2013 and the contract will terminate December 31, 2015.

Changes in the Methodology of Assignment of Medicare Beneficiaries to an ACO.

In the final rule, CMS chose to adopt a “step-wise” approach to beneficiary assignment whereby CMS will identify all patients who received a primary care service from an ACO participating physician, and assign beneficiaries first by identifying primary care physicians who are providing primary care services (internal medicine, family practice, general practice and geriatric medicine), and then identifying specialists who are providing primary care services to beneficiaries who are not seeking services from a primary care physician. The two-step assignment process adopted by the final rule first assigns beneficiaries who have received primary care services from a primary care physician to that physician’s ACO, and then assigns any remaining beneficiaries who have not received any primary care services from a primary care physician but who have received at least one primary care service from any physician (regardless of specialty and including specialist physicians, nurse practitioners, physician’s assistants and clinical nurse specialists) to the ACO from whom such beneficiary received the plurality of his or her primary care services. This is a fundamental change to the proposed rule, which explicitly excluded consideration of primary care services provided by specialists in assigning beneficiaries, and reflects CMS’s decision to allow assignment of beneficiaries based on how they actually seek out and receive primary care services while maintaining a strong emphasis on primary care.

In response to overwhelming support by commenters for prospective assignment, the final rule seeks to strike a balance between retrospective and prospective assignment of beneficiaries by incorporating more of the features and advantages of the prospective approach while preserving the retrospective approach for final assignment of beneficiaries. The model included in the final rule requires CMS to create a prospective list of beneficiaries likely to receive care from the ACO based on primary care utilization during the most recent period for which adequate data is available. This list will be updated periodically and a true-up reconciliation will be performed at the end of each performance year; the shared savings or losses will be determined according to the final, reconciled list of beneficiaries.

Under the model included in the final rule, beneficiaries will be assigned to the ACO where the plurality of primary care services received by each beneficiary is performed, defined in terms of allowed charges. This represents the adoption of the plurality standard of assignment of beneficiaries included in the proposed rule over a majority standard, and rejects any minimum threshold of primary care services performed. The formula for assignment in the final rule differs from the proposed rule, however, by clarifying that, for purposes of determining which ACO provided the plurality of a beneficiary’s primary care services, CMS will take into account allowed charges for each non-ACO provider (as opposed to calculating the total allowed charges in aggregate for all non-ACO providers). This clarification ensures that beneficiaries will be assigned correctly to an ACO, even if they receive a larger percentage in the aggregate of their primary care services from non-ACO providers.

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ACO Payment Models and Shared Savings. Consistent with the general theme of the final rule to provide greater financial incentives for physicians, hospitals and other healthcare providers to participate in the MSSP, CMS made several changes to payment models based on the comments received on the proposed rule.

Shared Savings. Under the final rule, an ACO will be paid under both a traditional fee-for-service method and – if the ACO meets both the quality and savings requirements set forth in the final rule – a share of the amount saved by the Medicare program. Under the proposed rule, savings otherwise payable to an ACO would be subject to withholding by CMS of 25% of the total amount of savings to ensure repayment of potential future losses. In the final rule, however, CMS eliminated this 25% withholding provision.

Revised Two-Model System. The final rule introduces a revised two-model system. The proposed rule required ACOs in the one-sided model to share losses in the third year of the initial agreement period. Under the final rule, however, ACOs participating in the one-sided model will not be exposed to any losses during the initial agreement period. ACOs participating in the two-sided model will remain responsible for shared losses in exchange for greater potential shared savings. ACOs choosing to begin in the one-sided model will be required to shift to the two-sided model after the initial agreement period.

Establishing the Benchmark. Like in the proposed rule, the final rule provides that 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, as adjusted for overall growth and beneficiary characteristics.

Determining Shared Savings. An ACO is only eligible to receive payment for shared savings if its estimated average per capita Medicare expenditure is at least the percentage specified by CMS below the applicable benchmark, the Minimum Savings Rate (MSR). The MSR for ACOs participating under the one-sided model will be established using a sliding scale based on the size of the ACO's assigned beneficiary population. A flat 2% MSR will apply to all ACOs participating under the two-sided model. The proposed rule included a requirement under which ACOs participating under the one-sided model would have to produce savings of at least 2% over the MSR in order to be eligible for any shared savings payments, while ACOs participating under the two-sided model would share first dollar savings once the MSR was exceeded. Under the final rule, however, ACOs participating under either model will be allowed to share in the first dollar of savings once savings exceed the MSR.

Quality Performance Sharing Rate. Assuming satisfaction of the savings criteria, ACOs participating under the one-sided model can earn up to 50% of total savings based on quality performance. ACOs participating under the two-sided model can earn up to 60% of total savings based on quality performance.

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Repayment of Shared Losses. Unchanged from the proposed rule is the requirement that each ACO under the two-sided model (or one-sided model ACOs requesting interim payment) must demonstrate that it has established a repayment mechanism. For each performance year, CMS will notify each ACO of the ACO's shared savings or shared loss amounts (for ACOs participating in the two-sided model). 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. Under the proposed rule, an ACO would have had only 30 days from the receipt of the CMS notification to make any required shared loss payment to CMS. The final rule extends this time period to 90 days from receipt of notification.

Quality Performance Standards and Other Reporting Requirements. Each ACO must have a quality assurance and process improvement program with oversight by a qualified healthcare professional (no longer required to be physician-directed) to promote the required processes. The proposed rule required ACOs to measure and report on 65 quality indicators across five domains. In response to many comments that the measurement targets were overly burdensome, in the final rule, CMS reduced the quality measures from 65 to 33 and eliminated one domain so that there are now only four domains: Patient/caregiver experience; care coordination/patient safety; preventative health; and at-risk population. To satisfy quality performance requirements for a domain, the final rule requires that the ACO must report all measures within a domain and score above the minimum attainment level determined by CMS on 70% of the measures in a domain.

Under the proposed rule, an ACO that did not meet the quality performance thresholds for all of the proposed measures would not be eligible for shared savings, regardless of how much per capita costs were reduced. Under the final rule, however, an ACO that achieves the minimum attainment level for at least one measure in each of the four domains, and also satisfies the requirements for realizing shared savings under the final rule, would be eligible to receive the portion of those shared savings for which it qualifies.

As part of its quality measurement and quality requirements, CMS's proposed rule placed emphasis on the use of electronic health records (EHR) and a new Group Practice Reporting Option tool. The proposed rule required that at least 50% of an ACO's primary care physicians be determined to be "meaningful EHR users" by the start of the second performance year in order to continue participation in the MSSP. In the final rule, CMS is no longer requiring a minimum level of EHR meaningful use as a condition of participation. EHR use is still retained as a quality measurement, however, and will be weighted higher than other measures for quality-scoring purposes.

Additional Program Requirements. Because of concerns that cost saving incentives may cause negative consequences, including avoidance of at-risk patients, "stinting" on care, fraud and abuse, overutilization, deliberate delay in the submission of claims and other detrimental activities on the part of providers, the final rule seeks to ensure that beneficiaries receive high quality and appropriate care without putting beneficiaries and/or the Medicare Trust Fund at risk. As such, a central theme of the MSSP is transparency.

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To advance this goal, CMS has included the following provisions in the final rule, some of which differ from the proposed rule:

- ✓ To ensure that signs and written materials will enhance the beneficiaries' abilities to be more active consumers and partners in the delivery of care, CMS will incorporate the requirements of the Plain Writing Act of 2010.
- ✓ To streamline the marketing materials approval process for ACOs, all written materials and activities are deemed approved following the expiration of the five-day initial review period after the materials are submitted to CMS. CMS, however, reserves the right to retroactively disapprove such materials following the expiration of the five-day initial review period.
- ✓ The definition of marketing materials and activities only includes information about the ACO, its participants or its providers and suppliers.
- ✓ ACOs must publicly report the identity of each member of their governing body and each ACO participant.
- ✓ ACOs must include a compliance program requiring employees, contractors and ACO participants to report suspected fraud and abuse to appropriate law enforcement agencies and CMS added an immediate termination remedy under certain circumstances.
- ✓ While both may have a legal education, the legal counsel to the ACO and the ACO's compliance officer must be different individuals.
- ✓ Compliance plans must be updated periodically to reflect changes in law.
- ✓ ACOs must submit annual certifications of program compliance to CMS (an additional required representation of compliance by participating ACOs).
- ✓ Providers not currently enrolled in Medicare must complete a screening process to be eligible to participate in an ACO.

Final Waivers in Connection with the MSSP

On October 20th, HHS issued an interim final rule with comment period establishing waivers with respect to ACOs (the Final Waivers release). While the Final Waivers release is an interim final rule with comment period, because prior notice and comment procedure are waived, these waivers are final on an interim basis. The waivers additionally apply only to the MSSP and all participating ACOs, as well as ACOs that are also participating in the Advance Payment Initiative, but not to any other Medicare-enrolled providers.

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The Final Waivers release includes the two waivers included in the initial notice issued in March 2011 and three additional waivers in response to comments:

- ✓ An “ACO pre-participation” waiver of the Physician Self-Referral Law, the federal anti-kickback statute and the Gainsharing CMP (limited duration to cover start-up arrangements between providers anticipating establishing an ACO). [NEW]
- ✓ An “ACO participation” waiver of the Physician Self-Referral Law, the federal anti-kickback statute, and the Gainsharing CMP (broad waiver that extends for the term of participation in the MSSP as well as a six-month period after expiration or termination). [NEW]
- ✓ A “shared savings distribution” waiver of the Physician Self-Referral Law, the federal anti-kickback statute and the Gainsharing CMP (applies to distributions of shared savings payments and their uses). [MODIFIED]
- ✓ A “compliance with the Physician Self-Referral Law” waiver of the Gainsharing CMP and the federal anti-kickback statute (applicable to ACO arrangements implicating the Physician Self-Referral Law meeting an existing Stark exemption). [MODIFIED]
- ✓ A “patient incentive” waiver of the Beneficiary Inducements CMP and the federal anti-kickback statute (applicable to medically-related incentives offered to beneficiaries to encourage preventative care and compliance with treatment regimens). [NEW]

Arrangements only need to fit one of the waivers to be protected even if an arrangement meets the criteria of more than one waiver. The Final Waivers apply uniformly to ACOs, ACO participants and ACO providers/suppliers as defined in the MSSP. Additionally, existing exceptions and safe harbors may also be applicable to ACO arrangements. The waivers included in the Final Waivers release only apply to MSSP participants, and do not extend to other laws or regulations. Additional information on requirements to meet these waivers is included in the final rule. The initial notice required that waivers be necessary for and directly related to ACO purposes. In the Final Waivers release, the language was changed to be reasonably related to the purposes of the MSSP. The various waivers also require contemporaneous documentation and an audit trail that is required to be maintained for at least ten years.

FTC/DOJ Policy Guidelines for ACOs

On October 20th, the Federal Trade Commission and the Department of Justice (the Agencies) issued the final version of their joint policy statement relating to enforcement of the antitrust laws with respect to ACOs. The final policy statement incorporates public input and differs from the proposed statement issued in March 2011 in two significant respects:

- ✓ Expanded Coverage – The final policy statement (other than voluntary expedited review provisions) applies to all provider collaborations that are eligible and intend, or have been approved, to participate in the MSSP. The proposed statement applied only to collaborations formed after March 23, 2010.
- ✓ Shift from Mandatory to Voluntary Review – Because the MSSP final rule no longer requires a mandatory antitrust review for collaborations meeting certain market share thresholds, the final policy statement no longer contains provisions relating to mandatory antitrust review.

The final policy statement retains many elements of the proposed statement issued. For example, the Agencies will apply a rule of reason analysis (balancing anticompetitive effects against pro-competitive efficiencies) to an ACO if it meets CMS’s eligibility requirements for, and participates in, the MSSP and uses the same governance and leadership structure and clinical and administrative processes it uses in the MSSP to serve patients in commercial markets.

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The final policy statement continues to include an antitrust safety zone, pursuant to which there will be no antitrust challenge absent extraordinary circumstances, for ACOs meeting the following criteria:

- ✓ 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 primary service area, wherever two or more ACO participants provide that service to patients from such primary service area.
- ✓ 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 market share in the primary service area.

The Agencies will offer voluntary expedited 90-day reviews for newly-formed ACOs that are seeking additional antitrust guidance. The final policy statement includes detailed instructions with respect to this review process.

Tax-Exempt Hospitals Participating in ACOs

The Internal Revenue Service (IRS) issued a new Fact Sheet (FS-2011-11), Tax-Exempt Organizations Participating in the Medicare Shared Savings Program through Accountable Care Organizations, that provides additional information for section 501(c)(3) organizations, such as tax-exempt hospitals, that will be participating in the MSSP through an ACO.

The IRS confirmed in the Fact Sheet that its prior statements on ACOs in Notice 2011-20 (Notice) released in March and based on CMS's proposed rule continue to reflect the IRS's expectations regarding the MSSP and ACOs. The IRS reiterated that it will review ACO arrangements on a case-by-case basis, based on all the facts and circumstances. Key items addressed in the Fact Sheet are summarized below:

- ✓ The type of entity selected for the ACO will determine the tax consequences for the ACO and its participants.
- ✓ Tax-exempt hospitals participating in the MSSP through an ACO with for-profit parties or individuals must ensure that they continue to meet the IRS's requirements for tax exemption (including prohibitions on inurement and private benefit).
- ✓ A tax-exempt hospital can further charitable purposes (primarily that of lessening the burdens of government) by participating in an ACO whose sole activity is participating in the MSSP. More importantly, a tax-exempt hospital generally does not need to have control over an ACO treated as a tax partnership that is solely participating in the MSSP to ensure that it furthers charitable purposes. The mere fact that the ACO's sole activity is the MSSP and is subject to CMS regulations and oversight is expected to be sufficient for the IRS to acknowledge that charitable purposes are being met.
- ✓ Certain activities of the ACO that are outside of the MSSP (non-MSSP Activities) may further charitable purposes. The IRS noted, however, that not every activity of an ACO (whether or not a non-MSSP Activity) will further charitable purposes.
- ✓ If an ACO conducts non-MSSP Activities, in some circumstances such activities may or may not jeopardize the exempt status of the hospital. The IRS will apply its general rules applicable to charitable organizations to the particular facts and circumstances of such non-MSSP activities.
- ✓ For those ACOs classified as tax partnerships (multi-member LLCs, limited partnerships, etc.) that will engage in non-MSSP Activities, the tax-exempt hospital will need to review and adhere to the IRS's guidance applicable to joint ventures where "control" factors may be relevant and certain activities will need to be reviewed to determine if they are in furtherance of the charitable purposes of the tax-exempt hospital.

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- ✓ The IRS expects that a tax-exempt hospital's share of MSSP payments through an ACO will not be subject to unrelated business income tax since such payments would be derived from activities substantially related to charitable purposes. If an ACO has non-MSSP Activities, it does not always mean that such activities will generate income that is unrelated business taxable income.
- ✓ Certain ACO entities (such as nonprofit corporations or nonprofit LLCs that have elected to be taxed as corporations) may qualify separately for section 501(c)(3) status.
- ✓ In its earlier Notice, the IRS listed five factors where, if met by the particular ACO arrangement, the IRS expects that it would not consider a tax-exempt hospital's participation in such ACO to result in inurement or private benefit. The IRS clarified in the Fact Sheet that not every factor must be satisfied.
- ✓ Ownership interests in the ACO do not need to be directly proportional to capital contributions and distributions of MSSP payments do not necessarily need to be made in proportion to such ownership interests.
- ✓ For those ACO arrangements involving tax-exempt hospitals where staff physicians may benefit through ACO participation or otherwise, the IRS indicated that the arrangement must meet the general broad based requirements of its EHR guidance (i.e., made available to all staff physicians, same level of benefit or varying benefit based on community healthcare needs, etc.).

Waller Lansden will continue to monitor developments regarding ACOs. For more information regarding ACOs, please contact [David Head](#), [Reggie Hill](#), [Nora Liggett](#), [Kim Harvey Looney](#), [Don Stuart](#), [Beth Vessel](#), [James Bowden](#), [Brent Bowman](#), [Trenton Poynter](#) or any member of [Waller Lansden's Healthcare Department at 800-487-6380](#).

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