

## HHS Issues Final ACO Regulations

On Oct. 20, 2011, the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) released the final regulations (Final Rule) pertaining to Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program (SSP). In conjunction with the release of the Final Rule, other Federal agencies also released guidance or regulations related to the SSP. In addition, HHS also announced a new program called the Advance Payment Program, which is designed to provide financial incentives for physician groups and other types of providers to participate in the SSP.

### Upcoming Webinar

Please click here to join a panel discussion with Drinker Biddle's ACO Task Force at 1 p.m. EDT/Noon CDT on Nov. 3, 2011, to discuss the implications of the final ACO regulations and what they mean for your organization.

In general, the Final Rule provides greater flexibility and increased financial incentives for entities wishing to participate as ACOs in the SSP. In particular, CMS has provided more flexibility, not only in terms of the types of entities eligible to participate as ACOs, but also in terms of ACO operations and governance.

An outline of the three most significant aspects of the Final Rule is provided below, followed by a summation of the Final Rule's key provisions on ACO structure and operations, a summary of Federal agency guidance and supplemental regulations, and an overview of the agency announcement on the Advance Payment Program.

### Top 3 Major Highlights of the Final Rule

- > ACO Option for No Downside Risk. One of the most significant changes in the Final Rule is that providers can participate in an ACO and the SSP without any risk of losing money. The Final Rule outlines two different tracks a provider group can opt to take: the first (Track 1) assumes no downside risk, and the second (Track 2) allows provider groups with resources to assume downside risk and in return receive an increased share of the savings they are able to achieve. By allowing providers to enter into an ACO arrangement with no downside risk, and providing provider groups under the Advance Payment Program with financial support, HHS is hoping to incentivize smaller, risk averse physician groups to consider participation in the SSP.
- > Reduced Quality Measures an ACO Must Meet. Another significant change intended to reduce the administrative hurdles associated with participation in

the SSP, is the reduction in the number of quality measures that ACOs must meet in order to qualify for bonuses through shared savings – from 65 in the Proposed Rule, to 33 in the Final Rule. CMS had received many negative comments concerning the number and complexity of the original quality measures, which many viewed as a significant impediment to participation in the SSP.

- > **Assignment of Medicare Beneficiaries to an ACO.** The last of the three most significant changes in the Final Rule, viewed by the industry as fundamental to the success of the SSP, is that an ACO will be told in advance which Medicare beneficiaries will likely be assigned to their ACO. The Proposed Rule received much criticism for outlining a retrospective assignment model where ACO providers had no way of knowing which beneficiaries were to be in an ACO until the end of the performance year. The concern was that a retrospective methodology would impair ACO providers' ability to effectively coordinate care with other providers and to develop appropriate treatment protocols for members of the ACO population, in particular, members with chronic diseases. CMS will now use a hybrid prospective/retrospective model, providing ACOs with preliminary beneficiary assignment data that will be updated quarterly. Final ACO assignment will be determined retrospectively based on the plurality of primary care services received by beneficiaries in an ACO.

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## Other Significant Changes in the Final Rule

### Structure and Operations of ACOs

#### *Who is Eligible to Participate?*

- > Federally Qualified Health Centers (FQHCs) and Rural Health Centers (RHCs) may now form their own ACOs. Previously, FQHCs and RHCs could only participate as members of an ACO. Under the Proposed Rule, additional bonus incentives would have been made available for those ACOs that incorporated FQHCs/RHCs into their ACO structure. Now that these entities can form ACOs directly, the Final Rule does not allow for these bonus incentives.
- > Any physician specialty can now function as an ACO beneficiary's primary care provider, if two requirements are met: 1) the beneficiary did not receive any primary care services from a primary care physician, and 2) the beneficiary did receive at least one primary care service from a specialist. Under the Proposed Rule, only primary care physicians (family practitioners, internists, geriatricians and general practitioners) would have been allowed to function as a primary care provider.

#### *Governance*

- > There is no longer a requirement that the ACO governing body be proportionally controlled by ACO participants, quelling concerns that every ACO participant needed to be represented. A "community stakeholder" is also no longer required to serve as part of this management group.
- > The ACO governing body must include representation of 75 percent of the

ACO participants and a Medicare beneficiary. However, CMS will permit ACO applicants to waive out of these requirements if the ACO can demonstrate that it will otherwise involve ACO participants “in innovative ways” and provide “meaningful opportunities” for a Medicare beneficiary to participate in ACO governance.

- > A Quality Assurance Program is to be put in place for each ACO to be led by a qualified health care professional. Under the Proposed Rule, there had been a requirement for a physician-led quality assurance committee instead of a program.
- > An ACO does not need to have a full-time medical director as had been proposed in the earlier rule. However, the medical director must be physically present on a regular basis.

#### *Shared Savings and Losses*

- > ACO providers will now be able to share in “first dollar savings” under both Tracks 1 and 2, whereas under the Proposed Rule, ACOs were only entitled to participate in savings in excess of an initial two percent savings margin.
- > CMS will no longer impose a 25 percent withhold of savings to cover an ACO’s share of losses. However, ACOs must still be able to demonstrate the ability to repay losses and identify specific means (e.g. letter of credit, escrow account) for CMS to recoup losses.
- > The caps on an ACO’s share of savings have been increased from 7.5 percent and 10 percent, to 10 percent and 15 percent under Tracks 1 and 2, respectively.

#### *ACO Arrangements*

- > For ACOs electing to begin on April 1, 2012, or July 1, 2012 (so called “early adopters”), CMS has extended the three-year initial agreement; the first performance periods will be 21 months and 18 months, respectively. Given the lengthy first performance year, early adopters may receive an interim savings distribution so long as they report calendar year 2012 quality measures to CMS.
- > CMS will employ a voluntary expedited review process by federal antitrust agencies of an ACO’s arrangements, and will also share ACO applications and claims data with those agencies. ACOs will not be subjected to antitrust mandatory reviews nor will ACO’s be required to provide “no challenge” letters from the Department of Justice, as had been required in the Proposed Rule.
- > ACOs may bring in additional providers to participate in the ACO at any time during the term of their agreement, so long as CMS is notified within 30 days. The Proposed Rule did not allow ACOs to add new provider participants.
- > CMS will not require 50 percent of an ACO’s primary care physicians to be meaningful users of electronic health records (EHR) by the start of the second performance year, as had been required in the Proposed Rule. However, the percentage of ACO primary care physicians who are meaningful users will now be factored into one of the 33 quality measures, and therefore impact the ACO’s share of savings.

### *Assignment of Medicare Beneficiaries to an ACO*

- > Assignment of beneficiaries to a primary care provider within a specific ACO will follow a two-step process: If the beneficiary received at least one primary care service (defined by specific CPT codes under the Final Rule) from a primary care physician, he/she would be assigned to the primary care physician providing the plurality of his/her primary care services. If the beneficiary did not receive any primary care services from a primary care physician, he/she would be assigned to the physician (any specialty type) who, together with any physician assistant or nurse practitioner, provided the plurality of such services to the beneficiary. This initial assignment will be updated quarterly. Final beneficiary assignment to an ACO will be determined at the end of the performance year (retrospectively) based on the same plurality test.

### *Data Sharing Requirements*

- > Though the Final Rule did not change the timing of CMS' provision of aggregate (de-identified) patient data (which will still be provided upon commencement, quarterly and annually), historically assigned beneficiary data (i.e. beneficiary name, date of birth, sex, and HICN) will now be provided quarterly, as well as at contract commencement.
- > ACO providers may contact the Medicare beneficiaries that appear on a list of individuals being prospectively assigned to a given ACO for the purpose of notifying the patient of the provider's participation in an ACO, and to request whether or not the patient wishes to "opt-out" of data sharing with respect to identifiable data. If the patient does not opt-out within 30 days, the provider may request the patient's data from CMS. The provider must again offer the patient the opportunity to opt-out of ACO data sharing at the patient's next office visit. As under the Proposed Rule, even if the patient opts-out of data-sharing, the health care costs attributable to that beneficiary will still be counted toward the ACO's shared savings (or loss).

### *Quality and Other Reporting Requirements*

- > The number of quality measures that ACOs have to meet in order to qualify for shared savings is 33. The Proposed Rule had outlined 65 quality measures.
- > Of the 33 quality measures that must be met, seven are collected through patient survey information, three are calculated via claims data, one is calculated from EHR Incentive Program data and 22 are collected from data included in the Group Practice Reporting Option (GPRO), which is part of the CMS Physician Quality Reporting System. CMS only includes 23 actual scored measures when accounting for the patient experience survey modules (i.e., the all or nothing diabetes composite and the coronary artery disease composite measures are being scored as one measure each).
- > The quality measures are to focus on providing better care to individuals and better health for populations. They are classified for achievement purposes into the following four domains: 1) patient/caregiver experience; 2) care coordination/patient safety; 3) preventative health; and 4) at-risk populations. CMS modified its initial proposed domain structure in the final rule by

combining the care coordination and patient safety domains to better align with other CMS value-based purchasing initiatives and the National Quality Strategy and to emphasize the importance of ambulatory patient safety and care coordination. Each of the four domains will be weighted at 25 percent in calculating an ACO's overall quality performance score for purposes of determining its final shared savings rate.

- > CMS includes only the following disease categories within the at-risk population domain: diabetes, hypertension, ischemic vascular disease, heart failure and coronary artery disease.
- > ACO's must achieve the quality performance standard on at least 70 percent of the measures in each domain, as opposed to 100 percent compliance under the Proposed Rule, in order to be eligible to share in any savings generated.
- > CMS revised its pay-for-reporting versus pay-for-performance phase from the original reporting requirements included in the Proposed Rule. The table below summarizes the number of measures in each category during the initial three-year ACO period.

	Performance Year 1	Performance Year 2	Performance Year 3
Pay for Performance	0	25	32
Pay for Reporting	33	8	1
Total	33	33	33

The only measure that will remain under pay-for-reporting for all three years is the health status survey.

- > For purposes of evaluation, CMS is doubling the weight of the quality measure "Percent of PCPs who Successfully Qualify for EHR Incentive Program Payment." CMS believes that relaxing the requirement in the Proposed Rule to have at least 50 percent of providers in an ACO be meaningful users of EHR will promote provider participation. However, the agency wants to ensure that use of EHR is evaluated as part of the quality measure process to emphasize the importance of health care information technology in ACO development.

## Advanced Payment Model

In a separate notice issued in tandem with the release of the ACO final rule, the CMS Innovation Center announced a new program, the Advanced Payment Model, to support physician-owned and rural practices, including federally qualified health centers (FQHCs) in becoming ACOs. Upon release of the ACO Proposed Rule, many providers had complained that CMS was prioritizing hospital ACO-formation and had provided rules that favored urban locations. One major complaint was the upfront investment costs associated with forming an ACO, which were perceived as cost prohibitive to physician practices and rural providers.

- > The Advanced Payment Model is open only to: ACOs that do not include any inpatient facilities and have less than \$50 million in total annual revenue; and ACOs in which the only inpatient facilities are critical access hospitals and/or

Medicare low-volume rural hospitals and have less than \$80 million in total annual revenue.

- > Advanced payment will be utilized to support an ACO's fixed and variable costs, and it will be made available to those participants who are approved to participate in the Medicare Shared Savings Program, can demonstrate the need for access to capital and promise for eventually generating cost savings on its own.
- > The model will serve as a CMS test demonstration to see whether early payment (prepayment) of shared savings will: 1) increase participation by providers, and 2) increase the speed in which an ACO can generate Medicare savings.
- > Applicants selected to participate in the Advanced Payment Model have the option of receiving:
  1. An upfront, fixed payment for each ACO;
  2. An upfront, variable payment for each ACO based on the number of historically-assigned Medicare beneficiaries; or
  3. A monthly payment of varying amount for each ACO depending on the number of historically-assigned Medicare beneficiaries.
- > The size of the payment made to a selected ACO will be based on the size of the group. The ACO will have to pay back the funds from any savings it is able to earn after its second year, and those that do not succeed in generating savings or that terminate participation early must repay the advanced payment.
- > A total of \$170 million for the Advanced Payment Model is being made available. Payments will be made available only to those ACOs that enter into the Medicare Shared Savings Program in 2012, and payments will end in June 2014.

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## Tax and Antitrust Regulatory Guidance

### *Tax Guidance*

The Internal Revenue Service (IRS) issued a Fact Sheet confirming that the notice released last spring (Notice 2011-20) continues to reflect the IRS's views regarding participation by tax-exempt organizations in ACOs. The IRS emphasizes that the tax implications of an exempt organization's participation in an ACO depend on (i) the legal structure of the ACO as either a corporation, partnership or LLC, (ii) whether the ACO's activities further exempt purposes (i.e., lessening the burdens of government, relieving the poor and distressed or the underprivileged), and (iii) whether participation in the ACO represents a substantial part of the exempt organization's total activities.

The IRS issued a Q&A format to elaborate on a number of considerations set forth in Notice 2011-20, addressing many of the questions that have arisen since the release of the IRS guidance in tandem with the Proposed Rule from last spring. The following provides an overview of the Fact Sheet.

- > When considering joint ventures treated as partnerships, the IRS generally expects the exempt organization to retain sufficient control to ensure that its participation in the venture furthers exempt purposes. However, in the case of an ACO participating in the SSP, the IRS will not expect the exempt organization to be in a control position, instead relying on CMS's oversight and regulation to ensure that the exempt organization's participation furthers exempt purposes (specifically, the charitable purpose of lessening the burdens of government).
- > The IRS has not yet reached a definitive conclusion on whether participation in ACOs engaged in activities outside the SSP can be considered to further exempt purposes. The IRS advises exempt organizations to consult existing tax law standards for joint ventures to evaluate whether participation furthers exempt purposes.
- > Addressing the unrelated business income tax (UBIT) implications of participating in non-SSP ACOs treated as a partnership for tax purposes, the IRS acknowledges that the traditional UBIT rules apply to income associated with an ACO (i.e., considering whether the ACO is engaged in trade or business activities that are regularly carried on and are not substantially related to exempt purposes). The IRS confirms that exempt organizations may have several different types of income arising from an ACO, some of which (e.g., dividends and interest) may fall within existing modifications under the Code and thus avoid UBIT.
- > In a considerable step forward from Notice 2011-20, the IRS acknowledges that an ACO itself conceivably may qualify for tax-exempt status under Code Section 501(c)(3). Such status may be available for ACOs that participate solely in the SSP and/or non-SSP activities that further charitable purposes, provided that all other requirements for exemption are also met.
- > In Notice 2011-20, the IRS had identified five factors relevant to demonstrating that an exempt organization's participation in an ACO does not result in prohibited inurement or substantial private benefit. The IRS now emphasizes that it is not necessary for all five factors to be met, and no one factor is determinative. And, with respect to the factor providing that economic benefits derived from the ACO must be proportional to the exempt organization's contributions to the ACO, the IRS clarifies that this standard should be applied in the totality to all types of contributions made to the ACO (whether as cash, property or services), and all types of benefits derived from the ACO (including, but not limited to, shared savings payments). The IRS also specifies that the written agreement governing the ACO need not state the exempt organization's precise share or entitlement, but rather can include a methodology for the allocation of shared savings payments to participating providers.
- > Wrapping up a lingering loose end associated with how the ACO standards may interface with prior IRS guidance regarding exempt organizations that provide subsidized electronic health record arrangements to physicians, the IRS confirmed that hospitals participating in ACOs will continue to be subject to the same standards that were previously articulated in a 2007 IRS internal memorandum.

### *Antitrust Enforcement*

The Department of Justice (DoJ) and the Federal Trade Commission (FTC) released final policy guidance on ACOs and antitrust issues. The new policy differs from the proposed policy issued earlier this year in tandem with the Proposed Rule in the following ways:

1. The agencies' final policy statement will apply to all approved ACO arrangements — not only collaborations formed after March 23, 2010, as had been proposed earlier this year.
2. The agencies along with CMS will no longer require approved ACO arrangements to be subject to mandatory antitrust reviews, as had been required in the Proposed Rule. The agencies will instead apply a "rule of reason" analysis in looking at any potential antitrust violations. CMS will provide the agencies with data to support the assessment of the competitive effects of all ACOs. CMS encourages ACOs to voluntarily seek a DoJ opinion; however, the burden will not be lessened for any ACO that elects to obtain an antitrust review.

The following are some observances about the final policy guidance:

- > The decision to not require an antitrust review is significant from a policy perspective in that it seems to acknowledge that law enforcement agencies should not have a regulatory role.
- > The agencies preserve an antitrust "safety zone" for specific types of ACOs. There are some exceptions to the safety zones, including rural exceptions. However, these exceptions have been somewhat narrowed. The current rural exception allows an ACO to include one physician or group practice per specialty in a rural area (even if the ACO's resulting share of the common service would exceed 30 percent), provided that the physician or group participates on a non-exclusive basis. The agencies are now saying that, with respect to a group practice: (a) the group practice must be in existence and operating as of the effective date of the final Policy Statement and (b) the number of FTE physicians in the group may not increase during the ACO's SSP agreement period.
- > The agencies seem to acknowledge potential competitive concerns in the market, but only state that ACOs should "refrain from, and implement safeguards against any conduct that may facilitate collusion among ACO participants in the sale of competing services outside of the ACO."
- > The agencies identify additional conduct, including provider consolidation, which could prevent private insurers from obtaining lower prices and better quality services for enrollees when an ACO has market power.

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### **Fraud and Abuse Law Waivers – Interim Final Rule**

CMS and the HHS Office of the Inspector General jointly issued an Interim Final Rule, establishing waivers in connection with the SSP. The Interim Final Rule is effective upon publication in the Federal Register, but comments will be accepted for 60 days upon publication (publication has not occurred as of this writing).

The Interim Final Rule establishes five automatic waivers applicable to one or more of the following: the Physician Self-Referral Law (known as the Stark Law), the Anti-Kickback Statute (AKS), the Civil Monetary Penalties Law (CMP) prohibiting hospital payments to physicians to reduce or limit services (the Gainsharing CMP) and prohibiting inducements to beneficiaries (the Beneficiary Inducement CMP). The waivers apply uniformly to each ACO, each ACO participant and ACO provider/supplier participating in the SSP. An arrangement need fit only in one waiver to be protected. Further, no waiver is necessary if the ACO arrangement fits into an existing exemption, exception or safe harbor of applicable law.

- > *ACO pre-participation waiver:* This waiver waives the Stark Law, the AKS and the Gainsharing CMP, and applies to bona fide start-up, operating and other arrangements that pre-date an ACO's participation agreement. Start up arrangements include items, services, facilities or goods used to create or develop an ACO that are provided by the ACO, ACO participants or ACO providers or suppliers. These may include, but are not limited to: creation and provision of infrastructure; network development and management; care coordination mechanisms; clinical management systems; quality improvement mechanisms; creation of governance and management structures; care utilization management; creation of incentives for performance-based payment systems; hiring of new staff; IT consulting and other professional support; organization and training costs; incentives to attract primary care physicians; and capital investments.

The waiver does not cover arrangements involving drug and device manufacturers or distributors, or durable medical equipment or home health suppliers. This waiver requires:

- Good faith intent to develop an ACO that will participate in the SSP in a target year, and to submit a completed application to participate in the target year.
- Diligent steps to develop an ACO to be effective in the target year, including steps to determine the ACO's governance, leadership and management.
- Bona fide determination that the arrangement is reasonably related to the purposes of the SSP.
- Contemporaneous documentation of the arrangement, its authorization and diligent steps, which must be retained for 10 years and promptly provided to the Secretary upon request.
- Public disclosure of the arrangement in a manner to be determined by the Secretary.
- If the ACO does not submit an application for participation in the target year, notification of the Secretary as to why the ACO was unable to submit the application.

The waiver period starts upon publication of the Interim Final Rule or one year preceding an applicable due date for a target year of 2013 or later. The waiver period ends upon: (1) the start date of the ACO participation agreement, (2) the date of the denial notice for an application that is denied, or (3) the earlier of the application due date or notice as to why the ACO was

unable to submit the application when an ACO fails to submit the application by the due date for the target year.

- > *ACO participation waiver*: This waiver waives the Stark Law, the AKS and the Gainsharing CMP and applies to arrangements throughout the term of the ACO participation agreement. This waiver requires:
  - The ACO remain in good standing under a participation agreement.
  - The ACO meet all requirements applicable to governance, leadership and management.
  - Bona fide determination that the arrangement is reasonably related to the purposes of the SSP.
  - Contemporaneous documentation of the arrangement, its authorization and diligent steps, which must be retained for 10 years and promptly provided to the Secretary upon request.
  - Public disclosure of the arrangement in a manner to be determined by the Secretary.

The waiver period starts on the start date of the participation agreement and ends six- months following the expiration of the participation agreement or the date the ACO voluntarily terminates the participation agreement, whichever is earlier. If CMS terminates the participation agreement, the waiver period ends upon the date of the termination notice.

- > *Shared savings distribution waiver*: This waiver waives the Stark Law, the AKS and the Gainsharing CMP and applies to distributions or use of shared savings earned by an ACO. This waiver requires:
  - The ACO remain in good standing under a participation agreement.
  - The shared savings are earned by the ACO pursuant to the SSP and earned during the term of its participation agreement.
  - The shared savings are (1) distributed to or among ACO participants or ACO provider/suppliers during the year in which the shared savings were earned by the ACO, or (2) used for activities reasonably related to the purposes of the SSP.
  - With respect to waiver of the Gainsharing CMP only, payments of distributions made directly or indirectly by a hospital to a physician are not made knowingly to induce the physician to reduce or limit medically necessary items or services to patients under the direct care of the physician. Arrangements that incentivize the provision of alternate and appropriate *medically necessary* care, such as coordinated outpatient care, rather than inpatient services, are protected.
- > *Compliance with Physician Self-Referral Law (Stark Law) waiver*: This waiver is applicable to the AKS and Gainsharing CMP and applies to any financial relationship between or among an ACO, its participants and its provider/ suppliers that implicates the Stark Law. This waiver requires:

- The ACO remains in good standing under a participation agreement.
- The financial relationship is reasonably related to the purposes of the SSP.
- The financial relationship meets the requirements of an existing Stark Law exception.

The waiver period begins on the start date of the participation agreement and ends on the earlier of the expiration of the participation agreement or the date on which the participation agreement is terminated.

> *Patient Incentive Waiver:* This waiver waives the Beneficiary Inducement CMP and the AKS and applies to items or services provided by an ACO, ACO participants or ACO provider/supplies to beneficiaries for free or below fair market value. The waiver does not protect the provision of free or below fair market value items or services by manufacturers or other vendors to beneficiaries, the ACO, ACO participants or ACO providers/suppliers. This waiver requires:

- The ACO to remain in good standing under a participation agreement.
- There is a reasonable connection between the free or below fair market value items or services and the medical care of the beneficiary.
- The items or services are in-kind (i.e., not financial, such as waivers of co-pays or deductibles) and are for: (1) preventative care or (2) advance adherence to a treatment or drug regime or follow-up care plan, or management of a chronic disease or condition.

The waiver period starts on the start date of the participation agreement and ends on the earlier of the expiration or termination of the participation agreement. Beneficiaries may keep items or services received during the term of the participation agreement and continue to receive any services initiated prior to expiration or termination of the participation agreement.

CMS and OIG will closely monitor ACOs entering the SSP in 2012 through June 2013. The agencies plan to narrow the above-described waivers unless the Secretary determines that the waivers have not had the unintended effect of shielding abusive arrangements. Modifications will apply to ACO applicants beyond July 2013 and ACOs that renew their participation agreements.

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