

## ACCOUNTABLE CARE ORGANIZATIONS AFTER THE FINAL RULES

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Nearly all of the readers of this article have heard something about Accountable Care Organizations (ACOs) over the past year, and some of you are probably tired of hearing about them. This is not just another article about ACOs. Rather, it provides a basic overview of ACOs, followed by a list of compliance requirements with compliance tips, a "Frequently Asked Questions" section, and concluded with a brief discussion about a structure that we believe is best-suited for the development and operation of ACOs. Such a structure may provide tangible benefits to physicians even if the ACO initiative ultimately fails.

### ***ACO BASICS***

An ACO is a product of the Affordable Care Act ("Act"), which, in part, seeks to reduce health care costs, and increase the quality of health care, by financially incentivizing providers. The Act required the Secretary of the U.S. Department of Health and Human Services ("DHHS") to establish the "Shared Savings Program"<sup>1</sup> ("SSP"), under which an ACO that fulfills the three-part aim of the Act (the "Three-Part Aim") may share-in the savings it achieves for Medicare. The Three-Part Aim is: (i) better care for individuals, (ii) better health for populations, and (iii) lower growth in Medicare Parts A and B expenditures.

In the final rule, the Centers for Medicare and Medicaid Services ("CMS") defines an ACO operationally as a collection of Medicare-enrolled Taxpayer Identification Numbers ("TIN"). This means that an ACO may be composed of eligible individuals (using their Social Security numbers as their TIN) and/or entities (using their Employer Identification Number ("EIN") as their TIN). As discussed below, CMS' focusing on the ACO participants' TIN (not other form of identification, such as the NPI) has implications on the ACO, including an ACO-provider's ability to participate in more than one ACO. An ACO must include a strong foundation of primary care physicians to accommodate its patient population, which must include a minimum of 5,000 assigned beneficiaries. However, an ACO may include multidisciplinary team members, including, without limitation, specialist physicians, non-physician practitioners (e.g., nurses), as well as hospitals and pharmacies.

### ***PARTICIPATION REQUIREMENTS WITH COMPLIANCE TIPS***

In order to participate in the SSP, an ACO must meet the following nine requirements:

1. An ACO must be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service (FFS) beneficiaries assigned to it.

*Compliance Tip: An ACO executive must, in the ACO's application to the DHHS for participation, certify, to the best of his or knowledge, that the ACO participants are willing to become accountable for and report on the quality, cost and overall care of the ACO's assigned beneficiaries.*

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<sup>1</sup> CMS issued its final rule regarding the SSP on October 20, 2011.

2. An ACO must enter into an agreement with the Secretary to participate in the SSP for not less than a three-year period (“Participation Agreement”).

*Compliance Tip: This Agreement must be signed by the ACO’s authorized executive after its approval by the DHHS.*

3. An ACO must include primary care ACO professionals that are sufficient for the number of Medicare FFS beneficiaries assigned to the ACO.

*Compliance Tip: CMS does not prescribe a specific number of primary care professionals that must be part of an ACO. However, because assignment of patients to an ACO will depend on the utilization of primary care services provided by ACO professionals, it is incumbent on the ACO to focus on recruiting a sufficient number of primary care physicians. That being stated, in the Final Rule, CMS created a “step-wise approach” to beneficiary assignment (discussed below), under which beneficiaries who are not seeing any primary care physician may be assigned to an ACO on the basis of primary care services provided by other physicians, including specialists as well as non-physicians (e.g., PAs).*

4. An ACO must provide the Secretary with such information regarding ACO professionals participating in the ACO as the Secretary determines necessary to support the assignment of Medicare FFS beneficiaries to an ACO, the implementation of quality and other reporting requirements, and the determination of payments for shared savings.

*Compliance Tip: An ACO must identify its participants on the application to the DHHS by disclosing their TINS and NPIS, and must update the list periodically.*

5. An ACO must have a formal legal structure that enables the ACO to receive and distribute payments for shared savings to participating providers of services and suppliers, and to repay losses, as applicable.

*Compliance Tip: An ACO must be a legal entity (e.g., an LLC) to participate in the SSP. The legal entity must be recognized under state law and authorized by such state to conduct its business. CMS does not require an ACO to be licensed as an ACO under state law, but states may impose a licensure or similar requirement on ACOs (e.g., in New Jersey, the Department of Banking and Insurance could require ACOs to become licensed as Third Party Administrators (TPAs) or Organized Delivery Systems (ODSs), though this has not yet been determined). An ACO formed between two or more otherwise independent ACO participants (such as a hospital and two physician group practices) must establish a new entity and obtain a TIN. Existing legal entities, which are eligible to be ACOs (e.g., a group medical practice, discussed below), are permitted to continue to use their existing legal structure as long as they meet other eligibility and governance requirements. However, if such legal entities will add ACO participants that will remain independent legal entities (such as a joint venture with another group practice), the ACO must create a new legal entity. The key is to establish and maintain common governance among all ACO participants. An ACO must indicate, on its application, how it plans to use the shared saving to meet the goals of the program; CMS does not dictate to an ACO how to distribute its shared savings among its participants.*

6. An ACO must have in place a leadership and management structure that includes clinical and administrative systems.

*Compliance Tip: An ACO must have a governing body (e.g., a management committee) with authority to execute the functions of the ACO, which governing body must also be responsible for oversight and strategic direction of the ACO, and which is accountable for the ACO's activities. The governing body will have a fiduciary duty to the ACO. The governing body must provide for meaningful participation in the composition and control of the ACO's governing body for ACO participants. Though there is no requirement that the ACO participants be proportionately represented on the governing body, at least 75% of control of the governing body must be held by ACO participants; 25% or less may be held by non-Medicare enrolled entities, such as management companies or health plans. A FFS beneficiary must be part of the ACO's governing body, but the ACO may avoid this requirement by proposing innovative ways to involve beneficiaries in governance, subject to the DHHS' discretion. An ACO's operations must be managed by an executive, officer, manager or general partner. An ACO must also have a medical director.*

7. An ACO must have at least 5,000 such beneficiaries assigned to it during the term of the Participation Agreement.

*Compliance Tip: As mentioned above, Medicare FFS beneficiaries will be assigned to an ACO on the basis of utilization of primary care services provided by the ACO professionals that are physicians. Failure to meet this requirement may result in the ACO's being terminated from the SSP. In order to maintain the threshold number of Medicare FFS beneficiaries, it is important that the ACO have a strong foundation of primary care physicians. Where the ACO is not able to meet or exceed the aforementioned thresholds due to some patients' obtaining primary care services through specialists, the ACO may be able to recruit sufficient specialists to cure the deficiency because of CMS' step-wise approach to patient assignment.*

8. An ACO must define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.

*Compliance Tip: An ACO must develop and furnish to the DHHS, in its application, documentation describing its plan to execute the functions described above. Such a plan must describe how the ACO intends to require ACO participants and ACO providers/suppliers to comply with and implement the processes developed by the ACO, including remedial processes and penalties. To meet the requirement to promote evidence-based medicine, the ACO must develop and periodically update clinical processes and guidelines. As part of its requirement to promote patient-engagement, an ACO must, in its application, describe how it intends to address all of the following areas: (a) evaluating the health needs of the ACO's assigned population, (ii) communicating clinical knowledge/evidence-based medicine to beneficiaries, (iii) beneficiary engagement and shared decision-making, and (iv) written standards for beneficiary access and communication, and a process in place to access their medical records. An ACO may internally report on quality and cost measures through such processes as it may develop. Finally, an ACO must define its care coordination processes across and among primary care physicians, specialists, and acute and post-acute provided. An ACO must disclose, in its application, how it will partner with community stakeholders. Beneficiary notices must comply with CMS' "Marketing Materials and Activities" requirements.*

9. An ACO must demonstrate to the Secretary that it meets patient-centeredness criteria specified by the Secretary, such as the use of patient and caregiver assessments or the use of individualized care plans.

*Compliance Tip: ACO participants must post signs in their facilities indicating their associated ACO providers'/suppliers' participation in the SSP, and make available standardized written notices developed by CMS to Medicare FFS benefit whom they serve. An ACO may, if it chooses, provide its prospective Medicare FFS beneficiaries with advance notice of the ACO's participation in the SSP, as long as those beneficiaries had previously*

*received services from ACO providers/suppliers and as long as they are likely to return. In a scenario where an ACO does not renew its Participation Agreement or an ACO is terminated, the ACO will not be required to notify beneficiaries that the ACO, its ACO participants and its ACO providers/suppliers will no longer be participating in the SSP.*

## **FREQUENTLY ASKED QUESTIONS**

*Question:* Is formation of or participation with an ACO mandatory?

*Answer:* No. Participation in the SSP is completely voluntary.

*Question:* Who may form or participate in an ACO?

*Answer:* There is an important distinction between providers who may form an ACO in their own right versus those who may not do so, but, rather, may participate with an ACO. CMS has defined “eligible providers” who may form an ACO in their own right to include, among others: (i) ACO professionals (e.g., M.D.s, D.O.s) in a group practice, (ii) networks of individual practices of ACO professionals, and (iii) partnerships or joint ventures arrangements between hospitals and ACO professionals.

*Question:* What will happen to a provider’s billing processes upon becoming a participant/provider of an ACO?

*Answer:* Providers and suppliers will continue to bill Medicare and receive FFS payments through their TINs. The ACO need not be enrolled in Medicare and will not bill for services provided by its participants or their providers/suppliers.

*Question:* When may an ACO apply for participation in the SSP?

*Answer:* The DHHS will begin accepting applications on January 1, 2012. For an ACO that desires to participate in the SSP in target year 2012, there will be two designated start dates, April 1, 2012 and July 1, 2012. The Participation Agreement of ACOs that begins participation on April 1, 2012 will expire on December 31, 2013, which equates to an initial performance year of 21 months. The Participation Agreement of ACOs that begins participation on July 1, 2012 will expire on December 31, 2013, which equates to an initial performance year of 18 months.

*Question:* What percentage of the ACO’s saving will the ACO be entitled to receive?

*Answer:* If the ACO applies to participate under “Track One”, wherein it operates under the “one-sided model”, the ACO will be entitled to 50% of the shared savings. If the ACO applies to participate under “Track Two”, wherein it operates under the “two-sided model”, the ACO will be entitled to 60% of the shared Savings. Under the one-sided model, the ACO will be entitled to share only in the shared savings during the term of the Participation Agreement; it will not be responsible for losses during the term of the Participation Agreement. Under the two-sided model, the ACO will be responsible to share in both the savings and the losses during the term of the Participation Agreement. The higher sharing ratio attributed to Track Two ACOs is due to their assumption of risk. ACOs may participate in track-one only for one Participation Agreement term

(i.e., three years), after which, they must participate under track-two, if they elect to continue to participate in the SSP.

*Question:* What happens if the ACO does not achieve savings for Medicare, but, instead, incurs a loss?

*Answer:* An ACO, under “Track Two” (described above), must pay the losses to CMS within 90 days after receipt of notification from Medicare.

*Question:* May Medicare FFS beneficiaries treat with providers outside of an ACO once they are assigned to an ACO-participant?

*Answer:* Yes. Unlike HMOs, ACOs do not require patients to stay “in-network.” Accordingly, patients are free to treat with a provider of their choice, even if such provider is not affiliated with an ACO.

*Question:* Would participation with one ACO preclude a physician from participation with other ACOs?

*Answer:* It depends. If the assignment of patients to the ACO is based on the participant’s<sup>2</sup> TIN (the “Assignment-Specific TIN”), then the participant may not participate with other ACOs. However, the individual providers under a certain Assignment-Specific TIN (i.e., an entity group practice) may participate in other ACOs as long as they bill under several different TINs. Similarly, an individual NPI may move from one ACO to another during the Participation Agreement term as long as he or she has not been billing under an individual TIN. However, in the case of ACO-participants who are solo practitioners, such practitioners are required to remain exclusive to one ACO because their billing TIN and individual TIN will be identical. If the assignment of patients to the ACO is not based on the Participant’s TIN, then the Participant is not required to be exclusive to one ACO.

*Question:* May an ACO change its composition during the term of its Participation Agreement?

*Answer:* Yes. ACO-providers/suppliers may be added/subtracted during the term of its Participation Agreement upon 30 days’ notice to CMS.

*Question:* Will CMS provide an ACO with data related to its assigned patient population upon such assignment?

*Answer:* Yes. Upon request by the ACO, and upon the ACO’s signing a Data Use Agreement with CMS, CMS will provide the ACO with a list of beneficiary names, dates of birth, sex and HICN. An ACO must enter into a Business Associate Agreement with its participants/providers.

*Question:* How will patients be assigned to the ACO?

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<sup>2</sup> This is limited to ACO participants that bill for primary care services, such as internal medicine, geriatric medicine, family practice and general practice).

*Answer:* As mentioned above, patients will be assigned to an ACO based on their utilization of primary care services provided by a physician. Primary care services are defined to include HCPCS codes: 99201 through 99215, 99304 through 99340, 99341 through 99350, the Welcome to Medicare visit (G0402), and the annual wellness visits (G0438 and G0439). CMS will employ a step-wise approach to assigning patients to an ACO, whereby patients are first assigned to ACOs on the basis of utilization or primary care services provided by primary care physicians. Those beneficiaries who are not seeing any primary care physician may be assigned to an ACO on the basis of primary care services provided by other physicians (specialists) or other suppliers (e.g., NPs, PAs, and CNSs).

*Question:* Under what circumstances may an ACO's Participation Agreement be terminated?

*Answer:* CMS may terminate an ACO's Participation Agreement for non-compliance with the requirements of the SSP, which includes maintaining eligibility. Non-compliance may include avoidance of at-risk beneficiaries or failure to meet quality performance standards. CMS also has at its disposal a variety of sanctions, such as warning letters or corrective action plans (CAPs). Additionally, an ACO may voluntarily terminate its Participation Agreement. In such event, the ACO must provide CMS and all of its ACO participants/providers/suppliers and other individuals or entities performing functions or services related to the ACO with a 60-day notice of its election to terminate the Agreement. An ACO that terminates its Participation Agreement prior to the expiration of the applicable performance year may not share in the savings it achieves during that year.

*Question:* Does the Final Rule preempt any state laws?

*Answer:* No, the Final Rule specifically states that “[w]e are not preempting any State law requirements in this Final Rule.” However, this leaves open the possibility that the Act itself could preempt State laws that conflict with it. ACOs participating under Track 2 should consult with legal counsel as to their state's insurance laws, as Track 2 ACOs are required to share risk, a requirement that may implicate state insurance laws.

*Question:* Will ACO's be subject to federal anti-trust laws or self-referral/anti-kickback/civil monetary penalty laws?

*Answer:* Yes; however, the Federal Trade Commission (FTC) and CMS have respectively created certain waivers related to compliance with anti-trust laws and self-referral/anti-kickback/civil monetary penalty laws. For example, the FTC has created an anti-trust “safety zone” for ACO's that meet the CMS eligibility criteria for and intend, or have been approved, to participate in the SSP and are highly unlikely to raise significant competitive concerns. Additionally, any newly-formed ACO that desires anti-trust guidance regarding its formation and planned operation may seek expedited 90-day review from the anti-trust agencies. CMS has created waivers designed to protect ACOs from exposes under self-referral/anti-kickback/civil monetary penalty laws under certain limited circumstances. Such waivers protect the ACO in the pre-application and participation phases, as well as with respect to the ACOs incentive programs for its beneficiaries.

## **CONCLUSION**

It is difficult to imagine how a loose affiliation of physicians practicing in separate medical groups can possibly meet more than a few of the ACO requirements. Without centralized practice management and corporate governance, and shared billing and EHR software, we believe it will be extremely difficult for an ACO to monitor and enforce performance, or create consistent standards of care among its members. We continue to believe that well-organized, cohesive, large physician groups can most effectively operate ACOs. We believe that group practices have the greatest chance at success (versus their alternatives). Loosely-formed organizations that resemble traditional independent practice associations (IPAs) and physician hospital organizations (PHOs) are unlikely to possess the IT infrastructure, central governance and authority to cause their members to consistently follow the clinical pathways and protocols established by the organization, and create long-term cost savings. The limited success of IPAs and PHOs illustrates the need for ACO participants to have closely-aligned incentives, combined with the ACO's ability to assess and manage the performance of its individual participants.

For years, we have spoken of the advantages of large group practices in order to enhance managed care contracting, generate ancillary revenues and partner with hospitals. Now, there is another reason for physicians practicing in solo or small group practices to consolidate into larger groups: ACOs.