

January 2014 North Carolina Accountable Care Organization Update



This Bulletin provides an update on the development of Accountable Care Organizations (ACOs) in North Carolina through the 2013 year end.

ACOs are networks of providers that jointly develop and implement clinical processes and technologies to improve clinical outcomes and efficiency for a defined patient population. ACOs enter into contracts with payors under which providers participating in the ACO share in any cost savings to the payor resulting from the increased care coordination, and some ACOs may also share in payor losses. To participate in a federal ACO program with the Centers for Medicare and Medicaid Services (CMS), an ACO must be organized as a legal entity with its own taxpayer identification number, but that ACO might be a joint venture among existing network entities, such as IPAs, PHOs and other ACOs. The ACO does not have to enroll as a provider under the Medicare program.

ACO Payment Arrangements

While ACOs might engage in a variety of payment arrangements with private payors, ACOs are intended under current CMS regulations to enter into payment arrangements in which the ACO's performance is measured along clinical and quality metrics and the ACO is incentivized to perform well because it receives a portion of the savings that the government realizes from better clinical integration and care. ACOs differ from IPAs, PHOs and PPOs because ACOs (a) must be clinically integrated, (b) in their current form, generally do not contract on a capitated or other risk-basis, and (c) beneficiaries have freedom to pick their providers and are "assigned" to ACOs based solely on the decisions the beneficiaries make and solely for purposes of attributing the savings to one ACO versus another.

CMS currently has two active ACO programs: (1) the Medicare Shared Savings Program (MSSP) and (2) the Advance Payment ACO Model. CMS' Pioneer ACO program has been closed to new applicants because that program was intended to encourage early adopters of the ACO model.

Under the MSSP, there are two types of agreements which CMS refers to as

"tracks." Under Track 1, which is also called the "one-sided model," the ACO has the potential to earn shared savings if the ACO achieves savings and meets set quality metrics, but the ACO is not subject to the risk of losses. Under Track 2, which is also called the "two-sided model," the ACO shares in both savings and losses. Each track requires a three-year agreement, but the ACO participant can terminate the agreement on 60 days' notice.

The key business terms among participants and providers in the ACO will be the method of sharing in shared savings and, if applicable, shared losses. The MSSP regulations do not prescribe or restrict how this allocation is made within the ACO, but the methodology is reviewed as part of the application process.

The Advanced Payment ACO program is available only for physician-based and rural provider ACOs that were accepted into the Shared Savings Program in April 2012 or July 2012. Participants receive up-front payments to fund the start-up, which are repaid through their share of future savings. To date, there are only 35 ACOs in this program, and only one North Carolina ACO (Coastal Carolina Quality Care, Inc.) has been accepted into the Advanced Payment ACO program.

ACO Formation and Contracting in North Carolina

Most public information about ACO formation in North Carolina concerns those ACOs that have contracted with CMS.

CMS has approved the North Carolina entities listed below to participate in federal ACO programs. All of these ACOs are participating in the MSSP, except Coastal Carolina Quality Care, Inc., an eastern North Carolina-based entity that is participating in the Advanced Payment ACO program.

- Accountable Care Coalition of Caldwell County, LLC, formed by Caldwell Memorial Hospital and Collaborative Health Systems
- Accountable Care Coalition of Eastern North Carolina, LLC, formed by Atlantic Integrated Health Network and Collaborative Health Systems
- AnewCare Collaborative, LLC, a Johnson City, Tennessee-based limited liability company that is affiliated with Mountain States Medical Group and the Crestpoint Health Insurance Company
- Bayview Physician Services, P.C. (d/b/a Bayview Physicians Group), a Norfolk, Virginia-based physician group serving patients in northeastern North Carolina
- Carolinas ACO, LLC, formed and managed by a physician
- CaroMont Medical Group, a Gastonia-based regional health system
- Central Virginia Accountable Care Collaborative, LLC, a Virginia entity

- Coastal Carolina Quality Care, Inc., a North Carolina corporation owned by physicians who are members of Coastal Carolina Health Care, P.A.
- Cornerstone Health Care, PA, a central North Carolina-based multispecialty physician group
- Duke Connected Care, LLC, owned by Duke Integrated Network, Inc.
- Meridian Holdings, Inc., a multistate corporation that includes providers serving patients in and around Charlotte
- Physicians Healthcare Collaborative LLC, formed by Wilmington Health, an eastern North Carolina multispecialty group practice
- Triad Healthcare Network, LLC, formed by Moses H. Cone Memorial Hospital, Inc.
- WakeMed Key Community Care, LLC, formed by Key Physicians and WakeMed Health & Hospitals

Some of these federally contracted ACOs have also entered into ACO-type reimbursement agreements with private payors. While information on agreements between ACOs and private payors is not necessarily publicly available, the following federally contracted North Carolina ACOs have publicly announced ACO arrangements with private payors:

- AnewCare Collaborative, LLC, which is affiliated with Crestpoint Health Insurance Company
- Cornerstone Health Care, PA, which, in conjunction with Wake Forest Baptist Medical Center, has entered into accountable payment agreements with UnitedHealthcare and Cigna
- Physicians Healthcare Collaborative LLC, which, in conjunction with New Hanover Regional Medical Center, has entered into an accountable payment agreement with BlueCross BlueShield of North Carolina

- WakeMed Key Community Care, LLC, which has entered into accountable payment agreements with BlueCross BlueShield of North Carolina and Cigna

Several other North Carolina-based providers, while not participating in federal ACO programs, have also begun to enter into innovative agreements with private payors. Under these agreements, the parties operate under a model that requires or provides incentives for a new degree of clinical integration that is similar to ACO-type activity.

- Boice-Willis Clinic, PA, a multispecialty group practice in northeast North Carolina, which has entered into an accountable payment agreement with Cigna
- Cape Fear Valley Health System, an eastern North Carolina regional health system, which has entered into an accountable payment agreement with BlueCross BlueShield of North Carolina
- Carolinas Healthcare System, a Charlotte-based health system, which has entered into an accountable payment agreement with Aetna
- Novant Health, which has entered into an accountable payment agreement with Cigna

According to records of the North Carolina Secretary of State, several entities have been organized in North Carolina with possible plans to operate as ACOs, including the following:

- Accountable Care Coalition of Charlotte, LLC, a manager-managed LLC formed by Collaborative Health Systems
- Accountable Care Organization of Union County, LLC
- Pinehurst Accountable Care Network, Inc., formed by Pinehurst Surgical Group and Pinehurst Medical Clinic

- Sandhills Accountable Care Alliance, LLC
- UNCHCS Accountable Care I, LLC, a manager-managed LLC formed by UNC Hospitals
- UNCHCS Accountable Care II, LLC, a manager-managed LLC formed by UNC Hospitals
- UNCHCS Accountable Care III, LLC, a manager-managed LLC formed by UNC Hospitals

Core Issues for ACO Formation

An ACO may contract with both public and private payors. Even if an ACO initially plans to contract only with private payors, the ACO may choose to organize in a manner to comply with the federal regulations and thereby provide flexibility for possible future contracting with public payors and address the antitrust compliance risk of ACO contracting procedures.

Choice of Entity and Corporate

Structure. Federal regulations do not dictate the type of legal entity for ACO formation, but they do require that the ACO be a legal entity with a federal taxpayer identification number (TIN). There are many considerations in selecting the choice of entity and related affiliates of an ACO. Most North Carolina ACOs have been organized as limited liability companies (LLCs) due to the flexibility of that LLCs can offer. Further, there are a host of other issues entities must consider in organizing and structuring an ACO (e.g., whether the ACO is to be wholly owned by a tax-exempt entity, whether it is to be jointly owned by multiple providers, whether a separate affiliate is to provide management services to the ACO, etc.).

ACO Issues for Tax-Exempt Entities.

Tax-exempt entities that participate in ACOs will want to understand the potential tax consequences of having an ownership interest in an ACO. ACOs are often organized as LLCs that are classified as partnerships for tax purposes. If classified as a partnership, the LLC's items of income and loss flow through to its members and are reported on their income tax returns. The activities of an LLC treated as a partnership for tax purposes are considered to be the activities of a nonprofit organization that is an owner of the LLC when evaluating whether the nonprofit is operated exclusively for exempt purposes within the meaning of IRC Section 501(c)(3). Similarly, the activities of such an LLC are attributed to its nonprofit partners in determining whether they are engaged in an unrelated trade or business that may produce unrelated business taxable income.

In Notice 2011-20, the IRS solicited comments as to whether existing guidance governing tax-exempt organizations is sufficient for those planning to participate in the MSSP through an ACO. The IRS also made the following statements in the Notice:

- The IRS expects it will not consider a tax-exempt organization's participation in the MSSP through an ACO to result in inurement or impermissible private benefit to private party ACO participants where certain basic requirements are met.
- The IRS expects that, absent inurement or impermissible private benefit, any MSSP payments received by tax-exempt organizations from an ACO will derive from activities that are substantially related to the performance of a charitable purpose of lessening the burdens of government as long as the ACO meets all of the eligibility requirements established by CMS for participation in the MSSP.

Thus, in such circumstances, an exempt organization's share of MSSP payments should not be subject to unrelated business income tax.

- The IRS understands that some exempt organizations might participate in ACOs conducting activities unrelated to the MSSP, including entering into and operating under shared savings agreements with other types of health insurance payors. The IRS anticipates that many non-MSSP activities are unlikely to lessen the burdens of government but may in certain circumstances be substantially related to or advance an exempt purpose.

The Notice does not address whether an exempt organization's participation in non-MSSP activities through an ACO will be consistent with the organization's tax-exemption or will not result in unrelated business income tax. The IRS, however, requested comments regarding those issues.

Choice of Owners. A threshold decision in ACO formation is to define the scope of the owners of the ACO. Capital formation may influence the extent to which physicians, as compared to hospitals and health systems, are owners in the ACO. To some extent, the financial benefits of ACO operations and performance can be shared with participating providers even if they are not owners through the allocation of shared savings payments. For a hospital or health system, a structure without physician ownership allows ACO start-up costs to be paid by the hospital/health system without the requirement for any pro rata contribution by physicians. On the other hand, physician ownership can be key to achieving the real aims and operational success of an ACO or other clinically integrated network. Indeed, federal regulations require all participants to demonstrate a "meaningful commitment" to the ACO, and these regulations identify financial investment as

one example of meaningful commitment. A hybrid model, in which the institutional investors provide the bulk of initial capital and receive equity interests with priority over the equity interests of those who do not provide as much capital, may also be considered. Another option is for the ACO to be owned by the larger institution with better access to capital, with management and administrative services provided by a management service organization that includes physician ownership.

To the extent that ownership of the ACO is offered to a large number of physicians or other providers, the ACO will need to comply with securities laws applicable to private and public offerings. At some point, the number of security holders can become so large that the ACO becomes subject to public company filing requirements.

Governance.

Federally contracted ACOs must satisfy detailed governance requirements.

The ACO must have an identifiable governing body, unique to the ACO, which is responsible for overseeing the ACO's activities and charting its strategic direction. Absent CMS' approval to an exception to this general rule, ACO participants must have 75% control of the governing body, and the governing body must include a Medicare beneficiary representative. ACOs also are required to have an administrative officer that manages the ACO's operations and activities, and a board certified medical director who oversees the ACO's clinical programs and initiatives. Typically, ACOs

will establish additional provider-led committees to identify opportunities to reduce costs or improve quality, create clinical guidelines, and oversee adherence to those guidelines. ACOs are required to have a conflict-of-interest policy, and must have a compliance plan with a compliance officer who is different from the person serving as legal counsel to the ACO.

The ACO application requires submission of the ACO's charter and governing documents, executive job descriptions, committee charters and

other materials, all of which are aimed at allowing CMS to determine whether the applicant has a leadership and management structure that includes clinical and administrative systems to promote evidence-based medicine. These requirements are also based, in part, on addressing antitrust issues by requiring a governance structure that allows a degree of clinical integration

sufficient to justify group contracting at the ACO level.

The governance process during ACO formation is also integral to qualify for applicable waivers under the federal fraud and abuse laws (i.e., the laws and regulations relating to Stark, Anti-Kickback, and Civil Monetary Penalties), which were adopted to allow ACO formation. ACOs must qualify for the waivers so that the ACOs can distribute the shared savings payments among the ACO participants and providers. To qualify, the ACO's governing body must make certain express determinations, and those determinations must be

supported by contemporaneous written documentation. It is important that the governing body take certain action during the organization process of the ACO.

Network Formation. During the start-up phase of an ACO, the ACO engages in broad recruitment efforts to contract with participating providers via provider agreements. The MSSP regulations distinguish between ACO participants and providers. Participants are individual providers or groups of providers that have a Medicare-enrolled TIN and are eligible to bill for Medicare services, which alone or together comprise the ACO. For example, ACO participants might include group practices, acute care hospitals, solo practices, qualified health centers or rural health centers. CMS uses the TINs of ACO participants as a basis for establishing eligibility, assignment of beneficiaries, computation of the ACO's performance benchmark, and quality assessment. ACO providers are individuals or entities that are Medicare-eligible providers that bill for services under the TIN of an ACO participant. MSSP applications must include a list of ACO participants and ACO providers. The ACO application process requires that agreements with participants and providers be signed prior to submission of the application, and these agreements must comply with the MSSP regulations. If accepted into the MSSP, the ACO must then notify CMS within thirty days of changes in the list of participants and providers.

All ACOs will enter into participating provider agreements with primary care and specialist physicians and other providers. In ACOs sponsored by health systems, the health system may be the exclusive hospital provider in the ACO within its geographic area and capabilities. But the reverse is generally not true, i.e., the hospital is not restricted from contracting with other ACOs. In fact, to fall in the antitrust safety zone described

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below, hospitals need to be allowed to contract independently with payors and other ACOs.

A key consideration in network formation of any type is the sufficiency of the network, but for ACOs, this consideration is especially important. The aim of the ACO is to improve the quality of care and clinical outcomes of the beneficiaries assigned to the ACO. The ACO must have authority to influence clinical protocols and to promote evidence-based medicine across a continuum of essential providers in a patient's care. Thus, the choice of quality providers (ideally, with some electronic medical record and data reporting capabilities) can be important.

The federal regulations require that primary care services be provided on an exclusive basis to only one ACO. CMS has responded to several criticisms about this exclusivity requirement, probably because it is so different from the realm of IPA and PHO formation where non-exclusivity is the norm. CMS explains that exclusivity is required for physicians billing under primary physician care codes for purposes of beneficiary assignment. Otherwise, CMS cannot attribute shared savings to one ACO if these services are provided by physicians through multiple ACOs. Exclusivity is determined by TINs, not NPI numbers. The primary care physicians include internal medicine, geriatrics, family practice and general practice, but an ACO also needs to check the HCPCS codes issued by CMS since some specialists may also bill under these codes.

The CMS application process will include a review of the ACO's remedial process for dealing with providers who do not meet performance standards via correction measures and expulsion.

Each ACO participant must demonstrate a "meaningful commitment" via financial contributions or human investment in ACO programs and committees and via an agreement to



follow policies and be subject to corrective measures and expulsion for failure to do so.

Antitrust. When competing health care providers jointly negotiate with payors, through an ACO or otherwise, they need to avoid violating antitrust laws, which bar competitors from conspiring to set prices or engaging in other anticompetitive conduct. Networks, like IPAs and PHOs, are accustomed to addressing antitrust issues through financial risk-sharing and clinical integration in accordance with the Statements of Antitrust Enforcement Policy in Health Care, jointly adopted by the Department of Justice (DOJ) and Federal Trade Commission (FTC) in 1996.

ACOs present some unique antitrust issues, and the DOJ and FTC have adopted an additional Statement addressing the agencies' antitrust enforcement policy for ACOs (ACO Antitrust Statement). Price fixing is not a concern for federally contracted ACOs since CMS sets Medicare Part A and Part B payment rates, but it is a concern with ACOs that contract with private payors. Recognizing that ACOs' potential to improve quality and reduce costs generally will offset any harm to competition resulting from joint

contracting, the ACO Antitrust Statement includes an antitrust safety zone for ACOs marketed to private payors that qualify for and participate in the MSSP, satisfy certain market share requirements (generally by having 30% or less market share except in rural areas), and whose ambulatory surgical center and hospital members are non-exclusive to the ACO.

ACOs that do not satisfy the safety zone requirements will be subject to scrutiny under the "rule of reason," which assesses whether the procompetitive effects of a restraint on trade are likely to outweigh any associated harms to competition. The ACO Antitrust Statement identifies several types of conduct by ACOs that will receive particularly close scrutiny under the rule of reason, including (1) sharing competitively sensitive information; (2) preventing payors from establishing incentives for their enrollees to choose certain providers; (3) tying sales of ACO services to the purchase of goods and services of providers outside the ACO (and vice versa); (3) exclusive contracting with ACO care providers (with the exception of primary care physicians, who must be exclusive to one ACO); and (5) restricting payors' abilities to make cost, quality and efficiency data available to their enrollees.

Fraud and Abuse. An ACO must consider the applicability of federal fraud and abuse laws, such as the Stark Law, the Anti-Kickback Statute and the Civil Monetary Penalties Law. These laws generally prohibit certain physician self-referrals, compensation in exchange for referrals and providing inducements to beneficiaries of a federal health care program. CMS has recognized that the restrictions that federal fraud and abuse laws place on certain arrangements between hospitals, physicians and other entities may impede the ability of an ACO to participate in the MSSP. For instance, payments of shared savings to employed physicians may not satisfy the requirement of the Stark law employment exception that compensation be based on personally performed and identifiable services if the physician receives shared savings payments for patients who the physician did not see. As a result, CMS has adopted five waivers when applying

federal fraud and abuse laws to ACOs: the Pre-Participation Waiver, the Participation Waiver, the Shared Savings Waiver, the Compliance with Stark Law Waiver, and the Patient Incentive Waiver.

The fraud and abuse waivers apply to certain costs incurred and payments made by an ACO during its preformation stage, during the time period when it is under contract with CMS and during the post-contract stage. The Pre-Participation Waiver permits an ACO participant to fund ACO start-up costs and development without liability under certain federal fraud and abuse laws. The Participation Waiver allows an ACO participant to undertake certain actions during the term of the ACO's participation agreement that might otherwise implicate the federal fraud and abuse laws. The Shared Savings Waiver permits the distribution of shared savings received by the ACO. The Compliance with Stark Law Waiver protects arrangements that meet an

existing exception to the Stark Law from liability under the anti-kickback laws or civil monetary penalties law. Finally, the Patient Incentive Waiver allows an ACO to offer its beneficiaries non-monetary incentives to encourage preventive care and compliance with treatment regimes.

In order to qualify for a waiver, an ACO arrangement must be reasonably related to the purposes of the MSSP. Furthermore, arrangements that fall under an existing exception to federal fraud and abuse laws need not qualify for a waiver. The waivers are self-implementing, meaning an ACO does not need to apply to CMS or any other government body for approval.

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