model, Fairview Health Services in Minnesota, and Blue Cross Blue Shield of Massachusetts (BCBSMA) are examples of ongoing programs in the private sector. The Alternative Quality Contract (ACQ) offered to providers by BCBSMA is the most comprehensive model to date and it covers all conditions a member may present with across the continuum of care. An estimated 20 percent of the provider network has signed on to the ACQ. [6]

Pertinent Issues for the Orthopaedic Surgeon: What should I know?

For the surgeon anticipating future participation in a bundled payment model there are numerous questions, issues, and concerns. These will vary from general issues to specifics that depend on the particular market and the services being bundled.

Questions that need to be considered include:

- What data are needed to support the bundled payment?
- What capabilities are needed for your organization to administer a bundled payment?
- Which providers and services should be included in the bundled payment?
- To which procedures or conditions should bundled payments be applied?
- How can provider cost accountability be determined?
- How should the bundled payment amount be calculated?
- What should be the timeframe included in the bundled payment?
- How should the bundled payment be risk-adjusted?
- Will bundled payments work in your specific market?
- Will bundled payments affect your ability to provide high quality care for your patient population?
- What are potential unintended consequences of bundled payments for your patients?

Given the nascent stage of the market movement toward bundled payments, there are clearly more questions than answers. Orthopaedic providers are encouraged to actively survey their local healthcare markets and seek to engage their major payers in this particular effort to control costs if this effort materializes.

The Bundled Payment in an ACO Framework

At this stage in their deployment, the role of bundled payments in the ACO payment model is unclear. As emphasized above, in a typical bundled payment model the savings (and the losses) generated accrue to the providers. The ACO model is based upon the concept of shared savings between the provider and the payer. It is unclear how this potential conceptual conflict will be addressed, but given the flexibility of the ACO models one would expect to see some bundling. It is also expected that fee-for-service, versions of capitation, and bundled payments will all be part of transitional or perhaps permanent ACO payment methodology. The ultimate goal in the ACO, however, would be a single comprehensive payment for the management of a defined population divided between all providers.

References


4. Ibid.


6. Ibid


Chapter 6

Legal Considerations in Establishing an ACO

When designing an ACO under the ACA, organizers must successfully navigate critical legal and regulatory landmines. This brief survey focuses in particular on the following five key issues.

A. Organizational Dynamics Fundamentally, an ACO must agree to be responsible for the quality, cost, and overall care of a defined population of Medicare fee-for-service beneficiaries for a period of at least three years. To qualify under ACA, an ACO must be organized as a formal legal entity so that it can receive and distribute payments for shared cost savings. To manage the risk associated with its clinical and administrative responsibilities, an ACO must have a proper governance infrastructure, including well-defined management and administrative systems. Congress enumerated five different ACO models in the ACA, an explicit acknowledgement that one size does not fit all insofar as healthcare markets are concerned. These alternative models are:

1. ACO professionals in group practice arrangements
2. Networks of individual practices of ACO professionals
3. Partnerships or joint venture arrangements between hospitals and ACO professionals
4. Hospitals employing ACO professionals
5. Such other groups of providers of services and suppliers as the HHS Secretary determines appropriate

In general, the first three models above will most likely provide physicians with the ability to assume leadership positions in ACO development and operations. The first model, more commonly referred to as the group practice model, contemplates the organization of a large, multispeciality medical group through the consolidation of multiple primary care and single specialty practices. The physicians — ACO professionals — would own and govern the group practice while performing professional services as employees. The group practice model will likely achieve the highest degree of clinical and economic integration of the alternate models. The group practice model will likely also require ACO professionals to make substantial capital investments.

The second model, the so-called network model, involves the formation of a large multi-specialty physician network (i.e., an independent practice association) through the affiliation of multiple primary care and specialty medical practices. The network model can achieve clinical and economic integration, but not to the same extent as the group practice model. On the other hand, the network model will not require the same level of capital investment by ACO professionals as the group practice model. And, the network model permits ACO professionals to maintain their existing practice paradigms and, correspondingly, to retain the lion’s share of their professional autonomy.

The third model, or joint venture model, contemplates the formation of a joint venture between the group practice and/or network organization, on the one hand, and a hospital or health system, on the other hand. By its very name, the joint venture model is a partnership between ACO professionals and an institutional provider(s), with operating control shared between or among the “partners.” The joint venture model may provide the vehicle for ACO professionals to tap the resources of the institutional providers to finance the delivery of healthcare products that ACO professionals could not otherwise fund on their own. The joint venture model would achieve the level of clinical and economic integration commensurate with its healthcare products. In the latter regard, the joint venture model would provide ACO professionals and institutional providers with the most flexibility to develop new and/or expand existing bundled service programs.

As the above makes clear, capitalization is a critical issue. ACO promoters will need to raise funds to finance both start-up and ongoing clinical operations, most likely through capital contributions by participating ACO professionals. Depending on the size of their investment, ACO professionals/equity stakeholders may require reasonable assurances regarding the recovery of their investments upon dissociation, and the financial means by which an ACO would fund its redemption obligation. The ACO “buy-sell” issues are typically addressed by contract, along with the provisions relating to dissociation generally. Importantly, financial integrity and related solvency standards may restrict the ability of an ACO to redeem the ownership interests of dissociating providers. In short, issues concerning ACO ingress and egress are complicated and, if not properly considered, could be traps for the unwary.

Additionally, nonprofit, tax-exempt hospitals are subject to certain additional requirements and restrictions. Most notably, tax-exempt hospitals which participate in ACO joint ventures must be certain that the integrated delivery systems serve community purposes and do not generate impermissible “private benefits” to others.

The statutory definition of an ACO is necessarily general. Congress has ordered HHS to provide guidance on the formation and operation of an ACO. HHS has not yet issued ACO-related regulations, leaving a vacuum in the healthcare market about key organizational dynamics. For example, what types of healthcare providers can form an ACO? What governance requirements must an ACO adopt and implement? What capitalization and other specific financial standards will demonstrate the ability of an ACO to manage patient outcomes and medical costs efficiently and effectively? [1]

B. State Law Preemption Many states prohibit hospitals and health insurance companies, among other lay entities, from entering into arrangements or series of arrangements with physicians or groups of physicians through which those lay entities improperly influence or affect the professional judgment of such physicians. Hospitals are unable to employ physicians in states with the “corporate practice of medicine” prohibition. Many states have also adopted sophisticated statutory frameworks to regulate payment for and delivery of healthcare services by or through networks of risk-bearing and/or risk-sharing arrangements. Consumer protection is at the heart of these statutory paradigms.

Will HHS promulgate regulations that interpret the statutory models of ACO organization as preempting conflicting state laws? Specifically, will state medical boards retain the authority to regulate their licensiates generally and ACO-related activities specifically? Will state insurance commissioners and/or managed care directors retain the authority to regulate ACO risk-bearing and/or risk-sharing activities in order that traditional Medicare beneficiaries have the same or substantially similar consumer safeguards and protections as the enrollees of Medicare Advantage organizations?

For physicians in most states, hospital affiliation, including medical staff membership and the ability to
exercise clinical privileges, constitutes a fundamental economic right that cannot be abrogated without cause and, typically, where there is no nexus to patient care or safety. Furthermore, even where good cause may exist, the hospital cannot take final adverse action without providing the affected physician with written notice of the charges and a forum to challenge the allegations that meets the standards of procedural due process.

In some states, these same legal principles that protect physicians vis-à-vis their hospital affiliations have been extended to protect physicians and their memberships on provider panels of payers, including preferred provider organizations and independent practice associations, that control substantial volumes of patients in the communities. If so, then must an ACO accept all qualified physicians on its provider panel? Can an ACO limit membership on its provider panel, even if that decision results in certain otherwise qualified physicians being denied access to patients and, correspondingly, the ability to exercise their vested and fundamental economic rights? Will applicable state law or, if necessary, HHS regulations exempt ACO from such legal scrutiny?

C. Antitrust Issues The ACA is shepherding in a revolution in the delivery of inpatient and outpatient medical care. The 1980s, too, saw significant changes in healthcare delivery systems, particularly by physician organizations, along with a flood of antitrust enforcement activity by the Federal Trade Commission (FTC) and Department of Justice (DOJ). Price fixing, group boycott, and product tying became watchwords as healthcare providers attempted to consolidate in order to level the playing field when negotiating with powerful payers. [2]

ACO promoters and their advisors should be aware that federal and state antitrust laws may apply to their arrangements. In the mid 1990s, the FTC issued guidance to providers seeking to consolidate, in the form of safe harbors. Although healthcare reform legislation encourages providers to align more closely in the delivery of patient care, an ACO may be unable to achieve the levels of economic and/or clinical integration necessary to withstand antitrust scrutiny. ACO development yields increases in negotiating leverage of the affiliated professionals, the extent of which will depend on the size of the relevant geographic market. Many experts predict that an ACO will need to service Medicare and commercial patients in order to achieve economic viability. In the absence of a clear safe harbor, an ACO that flexes its newfound negotiating muscle should expect the commercial payers to seek redress to recover the resulting losses and, in so doing, expose the ACO to legal scrutiny under applicable antitrust laws.

The FTC is soliciting public comments as it works to develop policies on ACO competition and reimbursement. Providers can expect updated regulations and guidance as the federal government works out how to address these important issues.

D. Anti-kickback and Stark Laws Federal laws prohibit the acceptance of cash or any item of value in return for the referral of health services that are later billed, in whole or in part, to federal healthcare programs. The cardinal sin that anti-kickback statutes intend to prohibit is the creation of relationships between providers that have as their primary business objective the funding of payments in exchange of patient referrals. [3] The ACO model contemplates the integration of providers in order to create in-network financial incentives regarding the referral of Medicare beneficiaries. The cost savings are shared among ACO providers. Undeniably, the ACO model also has many of the hallmarks of gainsharing arrangements, under which hospitals proposed to share cost savings with referring physicians in order to create financial incentives for them to help re-engineer the delivery system and utilize inpatient services more efficiently.

HHS has struggled with the issue of gainsharing for over a decade, ultimately deciding not to issue any safe harbor for such programs under the federal anti-kickback statute. HHS may change its position on gainsharing when issuing regulatory guidance on ACO development, and additional anti-kickback safe harbors are expected. In all events, ACO promoters and their advisors should consider adopting a conservative approach when structuring and implementing payment and cost-sharing methodologies.

The federal self-referral law, commonly referred to as the Stark law, prohibits a provider from referring federal healthcare program beneficiaries for certain designated health services (eg, inpatient/outpatient hospital services) to entities in which such a provider has, directly or indirectly, a financial interest. The Stark law provides many exceptions to the referral prohibition. In an ACO, each participating provider has the requisite financial interest (ie, the right to receive payment for services furnished to patients and to receive a portion of any shared savings). Accordingly, an ACO provider would be prohibited from referring Medicare beneficiaries to another participating provider for designated health services, unless that financial interest qualifies for an exception to the Stark law. [4] Currently, the Stark law does not provide an exception for gainsharing arrangements. However, it is often possible to structure ACO relationships to meet other Stark law exceptions, such as the personal services arrangement and/or fair market value exceptions.

E. Civil Monetary Penalties Law The Civil Monetary Penalties Law (CMP) gives HHS the power to levy substantial monetary penalties for various forms of improper conduct. Among other matters, CMP prohibits the payment or offer of any other form of inducement to reduce or limit the items or services provided to fee-
for-service federal healthcare program beneficiaries. ACO payment models are intended to improve efficiency and, as a result, generate cost savings in which the participating providers share. ACO providers can certainly achieve operational efficiency, ie, cost savings, by reducing the volume or the scope of services, especially when such reduction deviates from the historic clinical practices of such providers. To withstand CMP scrutiny, ACO providers should be prepared to demonstrate that limitations or reductions in items or services yielded no adverse affect on the quality of care or patient outcomes.

Importantly, participating providers can mitigate potential CMP liability by meeting an ACO core value — namely, the implementation of patient-centered protocols, consistent with evidence-based medicine, along with incentives for improving patient outcomes. In short, CMP presents another regulatory concern. In recognition of the consequences of CMP liability, ACO promoters and their advisors should be mindful to avoid the adoption of clinical protocols that are intended to control cost and improve efficiency, without implementing safeguards to improve patient outcomes, particularly when the treatment protocols deviate from historic practices of the participating providers.

There remains a paucity of regulatory guidance available on these critical issues, although federal agencies are charged with addressing them in the near future. If and/or when approached by promoters to participate in ACO’s, physicians and other healthcare providers should consult their healthcare counsel about the legal and regulatory issues that arise from the proposed ACO model. Indeed, the devil is in the detail.

References
1. 42 USC §1320a-7(a)
3. 42 USC §1395nn.
4. 42 USC §1320a-7(a).

Chapter 7
On-going Challenges to the ACO Model

There are multiple challenges to the ACO coordinated care model. The deep fragmentation of our current delivery system has created mistrust issues among stakeholders. There is also the question of how any potential shared savings will be divided among providers. The ACO model requires a paradigm shift in referral and follow-up discipline, which may create antitrust issues. The CMS and the FTC, in a recent open workshop to discuss FTC regulatory approval and oversight as it pertains to the development and implementation of ACOs, acknowledged that ACO formation is challenged and inhibited by existing antitrust safe harbor laws. The maximum percentages of market share dictated in current antitrust laws are an impediment to the development of ACOs, because it is to the benefit of the ACO and patients if providers agree to exclusively provide services to only a single ACO. In fact, the stakeholder interviews supported this concern. PCPs will need to be exclusively tied to a single ACO as they represent the core of the business model.

Another issue is the extent to which the Secretary of HHS is granted liberal use of power to waive the application of the Stark law, anti-kickback statutes, and civil monetary penalty laws. The Stark law prohibits self-referrals. In other words, physicians are not permitted to refer to a designated health service or provider if the referring physician or any member of their immediate family has a financial stake in the referred provider’s entity. The CMS, FTC, and Administration are currently working on language for an exemption to the Stark law for the ACO model as it pertains to incentives and savings sharing. This should not discourage a practice from investigating opportunities around forming an ACO. Lawmakers and regulatory agencies are finalizing the rules for formation and operation of ACOs. It will be important for orthopaedic specialists to get proper legal counsel to navigate the legal framework and protect themselves from civil or criminal liabilities.

Information technology infrastructure is another challenging area. Many providers, including hospitals, lack the ability to track services, costs, and care protocols. The federal government is driving adoption of health IT, and promoting and supporting the growth of health information exchange efforts. ACOs will require a level of patient health management that pushes the capability envelope of most current Electronic Health Record (EHR) systems. Supplemental technologies, such as systems for tracking, monitoring, and creating actionable reports on care gaps will be required to integrate existing EHR systems. Supplemental information technologies will include, but may not be limited to, electronic registries, multiple outreach and communications methods, software or systems capable of grouping patients by health conditions or status coupled with assessment programs that will then be able to automatically deliver educational materials and health notices directly to patients. HHS is funding several grant programs for the development and implementation of statewide exchanges that may assist some providers in meeting IT challenges. There are working examples of these types of state-wide exchanges, such as the Indiana Health Information Exchange (www.ihie.com).