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Health Law Alert

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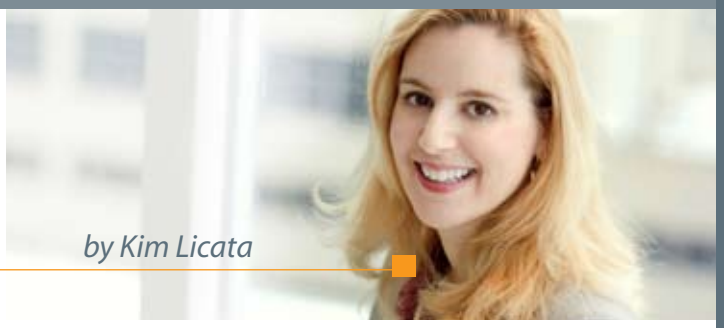
Accountable Care Organizations (ACOs): Where Are We Now?



by Kim Licata

Overview

The three federal agencies — Centers for Medicare and Medicaid Services (CMS), the Federal Trade Commission (FTC), and the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) — most likely to become entangled in legal disputes over accountable care organizations (ACOs) hosted a workshop on ACOs on October 5, 2010. Representing these agencies were CMS Administrator Don Berwick, M.D., FTC Chair Jon Liebowitz, and HHS Inspector General Dan Levinson. The three key regulators vowed to work together to promote ACOs and the integration of care made possible by ACOs as ACOs are described in the 2010 health reform law, the Patient Protection and Affordable Care Act (PPACA). They each professed concern over the inhibiting effect that inconsistent enforcement could have on innovative providers who test new models of care. Each regulator must manage and consider means to overcome the unique legal and regulatory hurdles created by their own laws and regulations. This article summarizes some key points from this workshop.

Because interest in this topic was "phenomenal" according to Administrator Berwick, the agencies plan to have similar workshops in other venues to collect more information. The focus of these workshops is how to manage the integration of care in the U.S., which requires that the OIG, CMS, and FTC work together to align all regulations and perspectives. Integrated care is essential, they say, to assist patient and their caregivers in efficiently and proactively managing chronic illness. The open question remains, how will the various agencies resolve conflicts in their regulatory regimes to permit ACOs to prosper and flourish?

CMS

In his opening remarks, Administrator Berwick identified the "Triple Aim of CMS" in health reform, that is,

- Better care,
- Better health, and
- Lower per capita cost.

CMS recognizes that agency coordination is necessary and will decrease misinformation. All agree that an integrated experience is needed for ACOs and innovation to thrive.

Administrator Berwick gave an example of the type of care integration he felt was critical to achieving health care reform and improvement in the United States. His experience at Harvard Community Health Plan with its coordinated care team in a multispecialty practice demonstrated that practitioners of all levels and types could expedite patient care and provide high quality care when provider interests are aligned and health care is patient-centered. His example was of a child receiving a new allergy medicine rapidly because of the parent's communication to a nurse, a nurse's communication to an attending physician, and a pharmacy's quick response to a prescription. This led to a seamless delivery of care.

CMS's view of ACOs is that they must be patient-centered care delivery systems. This would include: (i) shared decision-making on diagnostic testing; ACO memory about patients to avoid repetition of story, increased teamwork, effective handoffs between providers; (ii) decreased waste and focus on added value of each interaction of care; (iii) prevention and anticipation of problems to reduce hospitalizations and keep patients at home where they want to be; (iv) proactive with outreach and reminders to patients; and (v) ACOs being data rich to track outcomes and use registries. Finally, ACOs will be innovative and nurture cooperation while decreasing lingering corrupt practices.

The FTC

In his opening remarks, Chair Liebowitz stated that the promise of ACO is legal collaboration between providers, something from which all providers and all patients will benefit. Government regulation must benefit innovation, not hinder, the collaboration. Like CMS, the FTC recognizes that the agencies must coordinate their enforcement efforts as to the Stark self-referral law, the anti-kickback statute, civil monetary

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penalties law, and antitrust laws. In the past, each of these laws and regulations curtailed innovative in Gainsharing and other shared savings arrangements. Specifically, the FTC is focused on both creating safe harbors for collaboration and an expedited review process for those outside safe harbor. FTC in this workshop sought input on how to proceed.

Chair Liebowitz also provides success stories on how new models of care were fostered by FTC action. Clearly, the aim of the workshop examples was to dispel the negativity and suspicion many providers have about government enforcement activities. In both the Garfield County case and the Grand Junction, CO case, Chair Liebowitz highlighted restructuring that led to elimination of unlawful pricing practices, collaboration between physicians for cost savings and improved outcomes for patients, and sharing of financial risk.

HHS OIG

In his opening remarks, Inspector General Levinson like his comrades at the FTC and CMS professed the need for working together to foster innovation in business arrangements to implement provisions of PPACA. Levinson stated that fraud and abuse laws and regulations should not stand in the way of improving quality and decreasing costs of health care. The development of ACOs involves the testing of new payment methodologies and models of care, which requires a new look at program integrity. Levinson noted that PPACA provided the Secretary of HHS with authority to waive fraud and abuse laws to achieve the statutory goals. Levinson recognized that new programs are vulnerable to a small subset of bad actors who will game the system to profit. For the OIG, the focus is to use federal laws and regulations to thwart the bad actors, but not stifle innovation.

FTC Panel on Clinical Integration and ACOS

The first panel of the workshop focused on clinical integration and ACOs. Critical to this discussion was the FTC's acknowledgement that ACOs would be treated under the rule of reason. Such an interpretation is important because collaborating as independent providers in an ACO involves some level of price discussions and joint price negotiations with private payers, activities that could have been viewed as anti-competitive and per se illegal. What is important to the FTC is that the providers in an ACO achieve financial and clinical integration with a sharing of the risks of doing well, but also the risks of failing. For the FTC, the necessary level of integration is hard to describe beyond "you know it when you see it."

Many participants in the workshop wanted regulators to give the industry a framework in which to operate. Industry stakeholders gave ideas about minimum requirements for integration from electronic tools and monitoring infrastructure to databases to assist with cost and quality improvement. Some ideas for successful integration can be found in existing FTC policy guidelines and in successfully integrated systems. However, many participants in the workshop sought FTC agreement that requirements for ACOs need to be set at a high level, recognizing the diversity of models, as opposed to micro-level specifications. Participants and regulators alike acknowledged not knowing what model is the "right" model for an ACO, but felt setting some boundaries for a safe harbor will foster innovation and clarity.

Participants noted tension between identifying how high to set the bar as to who get to be an ACO within a safe harbor and how specific to define that bar. The key for the regulators is avoiding sham or incompetent organizations. Participants also stated that the system would not benefit if 100% of ACOs succeeded, meaning too low a threshold was set. Agency coordination in developing consistent guidelines is essential.

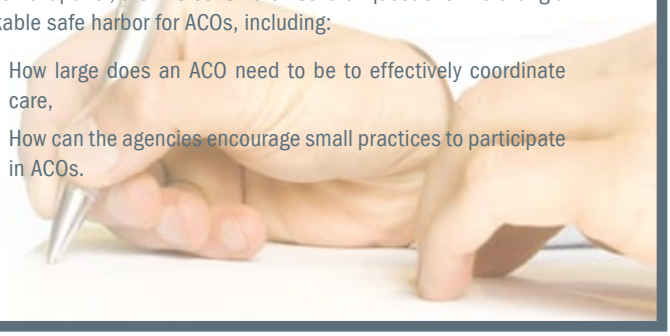
Participants and the regulators felt incentives are a good start to fostering the development of ACOs, but neither anticipates that the shared savings program is the final product. There is some conflict as to how integration and ACOs should be incentivized. Since most savings in health care costs come from hospitalizations, participants feared hospitals will rebel against the lost revenue by acquiring physician practices to get a piece of the shared savings or to stop the reduced hospitalizations. Participants expressed fear that large size ACOs will actually increase prices. Many indicated that having an upside and downside control was important, lest shared savings be like winning the lottery. The regulators can assist by mapping out the relationship for success (and failure) of an ACO.

Another critical issue for the success of ACOs is transparency and uniformity of performance metrics: how providers measure their own performance, as well as how payers and purchasers look at what is an appropriate payment measure. ACOs will need to have valid measures to succeed and many note that health information technology (HIT) and electronic health records (EHR) are important components for transparency and information transfer and flow. Some performance measures can be assessed in the short-term, such as preventable hospital readmissions and disease management. For other complicated diseases and prevention quality measures, it may be years before ACOs are more robust and successful in curbing costs. Regulators will need to set limits on how long it can take an ACO to achieve quality and savings particularly in the context of long term goals that do not have immediate savings.

Safe Harbors and Encouraging Competition Among ACOS

In the next panel, the FTC considered several questions in crafting a workable safe harbor for ACOs, including:

- How large does an ACO need to be to effectively coordinate care,
- How can the agencies encourage small practices to participate in ACOs.



In terms of size, participants want the focus to be on size of the pool of patients versus of the ACO. Some participants feel scale creates value and increases bargaining power, as well as economies of scale and sufficient data to measure outcomes. Others note that pricing can be affected by large hospital, large practice, large health plan, etc. For them, domination affects cost and thus, it will be a problem if ACOs further this market dominance. Accountability is voiced as a key to minimize any negative impact on competition.

Participants urged a change in payment methodology as essential to a successful change in the U.S. health care system. Dysfunction in the health care system, they say, is driven by payment for quantity of services. Change requires an alignment of incentives that support efficiency and quality care because many activities that truly help care and its coordination do not have CPT codes. Therefore, there is no incentive for providers to do these coordinating activities.

Many participants expressed concerns about recent increased consolidation in health care through mergers and joint ventures. The reasons for consolidation may differ by market, but most have seen significant consolidation in recent times. Naturally, participants expressed concern over whether smaller groups will be forced to consolidate to take advantage of the ACO program, a trend that would reduce their independence and flexibility. Many expressed concerns over any system that creates a dominate powerhouse in terms of a hospital or specialists, which can have unintended consequences. Increased market power is not all about drawbacks, as one benefit of ACOs is the spillover effect in conversations with payers and employers shifting focus to how providers and payers can demonstrate value and improve care while reducing cost.

More specifically, the FTC must define the safe harbor(s) and define the geographic area of competition. Many factors will shape a safe harbor, including type of provider, rural versus metropolitan area, supply and demand, and relative size of provider (and service area). Several participants noted that it is hard to adjust patterns of behavior, but patterns of care are trackable and can be used as a basis for reform efforts. To make ACOs pro-competitive, participants urged transparency requirements, making geography less important.

Exclusivity is a touchy issue for ACOs. Some think that exclusivity promotes loyalty; for others, exclusivity stifles choice of best provider and adversely affects market power. To some extent, whether a particular provider will or should be exclusive to an ACO will depend on whether the provider is in primary care or is a specialist. For PCPs, it seems likely that exclusivity will be required. PCPs are the main focus on cost containment, trending, and resource management. A conflict may occur with a PCP being in multiple ACOs. This conflict is not as present for specialists, who may or may not be exclusive. Regardless of where one comes down on exclusivity, all in the ACO must remain accountable for the care received.

The conclusion for the panel is that the industry needs permission to experiment and clear guidance on enforcement expectations from the FTC, CMS, and the OIG.

HHS Challenges

The third and final panel discussed challenges to ACOs from the fraud and abuse laws and regulations enforced by HHS. The existing fraud and abuse laws are designed to prevent overutilization and increased cost because of a provider's financial interest in providing more services. All of these laws, to some extent, constrain financial relationships between parties, such as those participating in an ACO. Because of these concerns, PPACA empowers the Secretary of HHS with broad waiver authority under Section 3021 (hospital innovation zones) and Section 3022 (Medicare Shared Savings program). In addition, both CMS and the OIG have the authority to make new regulatory exceptions and/or safe harbors as needed to effectuate the statutory goals and changed circumstances.

In terms of existing guidance, both CMS and the OIG have issued proposed and final rules on safe harbors and exceptions that may apply to ACOs. Additionally, CMS proposed, but has not yet finalized, a Stark exception for risk and shared savings, and many feel that finalizing this exception should this be revisited. In addition, proposed regulations regarding ACOs are expected to be issued by CMS "shortly" according to the regulators at the workshop.

So far comments have varied on the waiver authority and how to use it. The three agencies have posted comments they have received from industry stakeholders on their websites that relate to ACOs and the waiver authority. In general, there are several options for the exercise of the waiver authority. All agree, however, that some changes to existing laws and regulations through waiver or individual safe harbors or exceptions are necessary if the agencies want ACOs to get off the ground beyond large integrated models. The options are as follows:

- Option 1: Say as little as possible in a broad waiver. This will permit flexibility and experimentation. Option 1 has the advantage of speed and levels the playing field because large nonprofit integrated systems currently have an advantage. It is expensive to consider becoming an ACO in terms of start up costs; it is difficult to invest without assurance of complying with the laws.
- Option 2: Don't start with thought that the fraud and abuse laws are impediments because there are existing entities who are functioning as ACOs; craft specific safe harbors or exceptions to remove

hurdles. The advantage of this approach is that it is one with which regulators are very comfortable. It is neither too broad nor too narrow if the process of developing the safe harbors or exceptions is deliberate. The disadvantage of Option 2 is that it could be time-consuming to get it right.

- Option 3: Say a little more than very little. Speed and flexibility is essential to this whole process. If ACO gets waiver under one program, then the ACO should be ok on all grounds.
- Option 4: Say nothing and do nothing. No waiver and no new safe harbors or exceptions. This is the least desirable approach for providers and regulators alike.

In the discussion, many participants identified problems with existing fraud and abuse laws, which are based on an older healthcare model. Many noted that safe harbors and exceptions are designed in statutory framework that does not favor innovation and experimentation. The end result is that these laws and regulations have the effect of discouraging risk averse players from participating. Others noted that real integration versus sham integration can be measured on the back end and need not be judged at the outset under these laws and regulations.

An additional problem for waiver is the extent of the waiver, which many felt was the most difficult topic for the regulators to address. Where should the regulators draw the line? Participants noted that the waiver would need to protect upfront capitalization to ACO to encourage innovation, as well as remuneration exchanged during the operation of an ACO. Differences are likely to arise by type of provider, small versus large practices, rural versus non-rural, among other considerations. Participants repeatedly focused on the variety of potential models and the need to tread lightly to prevent marketplace disruption and stifling of innovation. Participants urged regulators to make sure that ACOs are accountable to patients.

The fraud and abuse inquiry should be boiled down to two issues:

- Identifying the certain types of relationships that heighten risk of fraud issues, and
- Reducing the regulatory burden so that providers can and will participate.

A hot issue for providers is patient assignment to an ACO and the contact providers in an ACO may have with assigned patients. While participants agreed that ACOs must show patients how they will benefit from being cared for by the ACO, there is the issue of who gets the undesirable patient? Regulators note that to protect patients, every patient must retain the ability to choose providers so that each gets the care that he or she needs and wants. In terms of transparency, participants stated that the PGP demo provided a lot of feedback for ACOs. All PGP performance data was publicly reported and reported to CMS. Participants noted that ACOs must be structured so that the safety net patients do not fall through the cracks.

Participants were also interested in the role of self or government monitoring of ACOs and what role will HIT play in this. Most agreed that self-monitoring is an important and necessary component of ACOs to be "accountable." This means ACOs will need a compliance program in place, preferably one based on a government-circulated "model" to set ACO compliance expectations. Others noted that the downside is that reporting and monitoring is costly as they require significant infrastructure. Participants asked that the regulators consider means of offsetting the costs of this infrastructure. Governmental monitoring is also essential, according to participants. Government needs to keep an eye on ACOs under various laws and build in a feedback loop to ask and answer whether this system is working for participants to prevent failures like managed care in the 1980s and 1990s.

What a safe harbor or exceptions or waiver should say and even how much should be said are open questions. Will specificity chill innovation or create needed structure? Industry stakeholders are split. How can the agencies satisfy the goals of PPACA, while safeguarding program integrity and economic freedom? The solution for many participants was to go back to Congress to establish a different payment system and protect the programs while allowing the new creations to function. The current structure is based on FFS risk and the decision made to pay people by the hour for the work that they do. Existing exceptions won't work – you need to get advisory opinions and that will take too much time for it to matter. Many note arrangements require contortion to fit within the law. The difficulty with heading back to Congress to untangle the mess of the U.S. health care system's reimbursement scheme and the numerous applicable federal laws is that it will take years, if any fix is ever achieved.

Final Thoughts

At the end of the day, the workshop did not answer as many questions, as it provided insight into the approach the agencies will take as to each other in developing the rules of the road for ACOs. We can expect more workshops or forums in the future. Hopefully in these, industry stakeholders will present concrete examples of desired safe harbors, exceptions, and waivers and the regulators will offer real solutions to potential barriers to ACOs.

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