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ACO Workshop: The Feds commit to making Accountable Care Organizations work with safe harbors, waivers

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Don Berwick kicked off the day-long Accountable Care Organization (ACO) Workshop and Listening Session, co-hosted by the FTC, CMS and the OIG, with a short, stirring speech that touched on his Triple Aim for health care: better care for individuals, better health for populations and reduced per-capita costs. He committed the government to interpreting applicable statutes "wisely, so as not to impede the development of ACOs." That sums up the reason this workshop was so eagerly anticipated. Health care providers are extremely eager to become ACOs - though the term has yet to be fully defined - yet are extremely concerned about the potential to have specific ACO arrangements identified as illegal by the FTC, the OIG or CMS because the arrangements violate antitrust law, Stark, anti-kickback or anti-fraud and abuse laws, or may be subject to civil monetary penalties. The health reform legislation authorized these agencies to develop waiver programs and safe harbors in order to implement the ACO concept, and proposed rules doing so will have to be issued this fall in order to have these systems up and running next year, as called for by the law. Berwick's commitment to make this as pain-free as possible was echoed by FTC Chairman Jon Leibowitz and HHS Inspector General Dan Levinson. Check out the live-tweeting transcript of the day's events. (Audio of the day's proceedings should be posted in the near future.)

So, this leaves just a few questions:

- What is an ACO and why are they given special status under the law?
- Why are waivers or safe harbors needed if ACOs are authorized by the Federal health reform law?
- What waivers or safe harbors are likely to be proposed in the next month or so?
- Will these waivers and safe harbors protect ACO activity where the payor is a commercial payor, rather than a federal health care program payor?

What is an ACO and why are they given special status under the law?

The health reform law, now known by its acronym PPACA or ACA (Patient Protection and Affordable Care Act, or simply Affordable Care Act), authorizes (among many other demo and pilot programs) the establishment of a shared savings program known as the ACO program, in Section 3022 (codified as Title XVIII, Section 1899). See CMS Shared Savings (ACO) FAQ for details. At its core, the law requires that an ACO must:

1) Have a formal legal structure to receive and distribute shared savings
2) Have a sufficient number of primary care professionals for the number of assigned beneficiaries (to be 5,000 at a minimum)
3) Agree to participate in the program for not less than a 3-year period
4) Have sufficient information regarding participating ACO health care professionals as the Secretary determines necessary to support beneficiary assignment and for the determination of payments for shared savings.
5) Have a leadership and management structure that includes clinical and administrative systems
6) Have defined processes to (a) promote evidenced-based medicine, (b) report the necessary data to evaluate quality and cost measures (this could incorporate requirements of other programs, such as the Physician Quality Reporting Initiative (PQRI), Electronic Prescribing (eRx), and Electronic Health Records (EHR), and (c) coordinate care
7) Demonstrate it meets patient-centeredness criteria, as determined by the Secretary.

The ACO provision in the ACA has garnered a disproportionate amount of attention, likely because of the opportunity for

shared savings and the opportunity for hospitals to more closely ally their affiliated physicians. However, the point was made time and again at the workshop that the goal of the program is to improve patient care and the patient experience -- without that guidepost at the core, the exercise won't work.

Aside from large IDS's seeking to use the ACO program as a means to protect and potentially grow market share and margin (after all, "no margin, no mission"), why would hospitals want to get involved? Hospital reimbursement is on the line here: about 70% of costs -- and potential savings -- are on the hospital side of the equation, and much of the control over those costs lies with physicians. If they are not already employed physicians, the sharing of savings means the hospital will be sharing with the physicians, and not vice versa. Despite this apparent disincentive, past experience has shown that strong physician-led initiatives can bring hospitals into the fold. Two examples: the Medicare Physician Group Practice Demonstration Project (an ACO precursor) and the Grand Junction, Colorado experience: a physician-led arrangement initially targeted by the FTC as a price-fixing scheme, eventually resolved through a settlement agreement, and now seen as a national model of collaboration, aligned incentives, cost-effectiveness, and quality improvement.

Why are waivers or safe harbors needed if ACOs are authorized by the Federal health reform law?

The general idea is to get providers across the continuum of care to band together, work on reducing costs and improving quality, continue to be paid on a fee-for-service basis by CMS, and then retrospectively look at system-wide savings (e.g., avoided readmissions) and share those savings around. Sharing those savings around outside of an integrated delivery system raises a host of potential antitrust, fraud and abuse (anti-kickback), Stark and CMP issues, and the statute authorizes the development of waiver programs and safe harbors in order to make it all work. It's really a square peg-round hole problem, because the policy basis for making illegal this sort of sharing is grounded on fee-for-service, retrospective reimbursement systems. Prospective payment, particularly bundled payments for episodes of care, eliminates the potential for the harm these rules protect against (over-provision of care due to financial incentives), yet they are still on the books. For example, we want physicians to share in the hospital savings experienced as a result of an avoided readmission which would not be eligible for separate reimbursement; this opportunity will incentivize them to work harder to prevent the readmission. Under current rules, however, a payment by the hospital, directly or indirectly, to the physician, tied to that savings, is impermissible.

What waivers or safe harbors are likely to be proposed in the next month or so?

Federal officials at listening sessions are notoriously tight-lipped, so not much was said about what to expect, other than proposed regulations are expected to come out this fall. However, all were keen to emphasize that they want to eliminate the regulatory impediments to ACOs, and welcome further comments from the public.

As a whole, the regulated community is eager to have greater certainty, in the form of new regulated guidance; however, some would prefer to simply be guided by what's out there already: advisory opinions, guidelines, regulations, etc., that lay out safe harbors. For example, the joint DOJ-FTC healthcare antitrust guidelines provide that clinical integration -- even in the absence of full merger or acquisition, or direct employment of physicians by a hospital -- will keep providers out of antitrust hot water even iof they are collaborating in ways otherwise prohibited. At the other end of the spectrum, some folks would prefer to have the federales get broad authority to issue blanket waivers without establishing super-specific criteria.

Establishing criteria for waivers or safe harbors will be somewhat difficult, because the definition of an ACO is a little slippery. The financial arrangement at its core can be simply a shared savings arrangement, but it might also veer into other territory: underwriting patient expenses such as transportation costs or home monitoring device costs, or the payment of a physician group's up-front capital expenses by a hospital in order to kick-start the process (all potentially illegal inducements under current law).

Many of the comments were directed at ensuring that a particular type of arrangement or organization does not escape the feds' notice, so that they can all be written into waiver or safe harbor language.

Will these waivers and safe harbors protect ACO activity where the payor is a commercial payor, rather than a federal health care program payor?

The rules at issue are all Federal health program rules -- except for the FTC antitrust rules, which apply across the board.

A number of forum participants suggested that a rule of reason analysis under the antitrust laws (rather than "per se" analysis) would be needed in order to address market power issues in each unique ACO situation. It seems to me that such an approach would be throwing away the current opportunity to craft a set of guidelines focused not only on ACOs but on other provider arrangements likely to come down the pike under other ACA demo and pilot authority. This opportunity should be seized by the other agencies as well -- not just the FTC.

Final thoughts

Will providers actually come together to form ACOs? The jury is still out. There is certainly a lot of noise being made, but the long-term key from both a policy and business perspective is that the efforts of the provider organizations must be to make themselves more patient-centered. Berwick's emphasis on this point was striking, and he illustrated it with an anecdote from his days of practicing as a pediatrician at Harvard Community Health Plan, where systems were in place to support a patient-clinician partnership at a very high level, suggesting that HCHP was an ACO long ago. In current-day Massachusetts, Blue Cross Blue Shield of MA has rolled out its Alternative Quality Contract to a quarter of its provider network; half of the docs involved are in small practices. While it has taken some years for the AQC program -- another proto-ACO program -- to get off the ground, it is significant because it has allowed for the agglomeration of small practices into a larger whole for purposes of the contract, thus perhaps lighting the way for ACO participation by organizations other than IDS's.

So is this deja vu all over again? Have we stepped back in time a couple of decades to re-experience managed care failures of an earlier era? Certainly, some rpoviders see the ACO structure as a way to increase market share, margin and bargaining power -- and it's a no-downside financial deal. As noted above, it cannot be only that. There are significant costs and potentially difficult negotiations ahead as providers across the continuum work with the regulators to hash out the final status of the ACO landscape, and then deal with integrating themselves into one or more ACOs with a laser focus on patient-centered care. That focus should yield benefits up and down the line: for patients, providers and ultimate payors in both the public and private sectors.

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