Feds' Antitrust Efforts May Ease Formation of ACOs

BY M. ALEXANDER OTTO

FROM A FEDERAL TRADE COMMISSION WORKSHOP

any physicians have wondered how – and even if – they will be able to work together to form accountable care organizations without violating federal antitrust and fraud and abuse laws.

A federal regulatory meeting held earlier this fall offered possible answers to both questions. Federal regulators are considering exemptions to those laws that would allow providers who meet certain requirements to form accountable care organizations (ACOs).

"It is not easy to craft safe harbors that can replace an antitrust review that analyzes the specific facts of each case and market. But we're going to try to do this," said Jon Leibowitz, chairman of the Federal Trade Commission (FTC).

Similarly, Daniel Levinson, inspector general of the U.S. Department of Health and Human Services, noted that the Affordable Care Act gives the HHS secretary the authority to waive some fraud and abuse laws as needed to help ACO programs develop.

"We and our HHS colleagues are looking closely at how the secretary might exercise this authority most effectively," Levinson said, according to the meeting transcript.

The FTC, the HHS Office of Inspector General, and the Centers for Medicare and Medicaid Services conducted the workshop in Baltimore to hear the opinions of panelists and audience members on a variety of ACO issues.

However, much of the questioning focused on how antitrust and fraud and abuse exemptions could be applied to ACOs.

The Affordable Care Act promotes ACO creation to reduce health-care fragmentation, improve outcomes, and cut health spending by, for instance, keeping patients out of hospitals when possible.

The goal is for providers to come together and contract with the CMS to integrate and manage the care of at least 5,000 patients, and to share a portion of the savings their efforts generate for Medicare, so long as quality parameters are met.

Once formed, ACOs could pursue similar types of contracts with commercial insurance companies.

The catch is that encouraging independent providers to jointly negotiate contracts and payment rates with health plans raises concerns about joint price fixing, reduced competition, and other antitrust matters.

Likewise, the shared-savings provision, among others, raises antikickback, self-referral, and other fraud and abuse concerns, according to health care attorney Douglas Hastings, board chair of Epstein Becker & Green, Washington, and a meeting panelist who offered his insights during a later interview.

Regulators are interested in applying to ACOs antitrust protections that already exist for providers who are clinically integrated and jointly accept significant financial risk.

"In those cases, [collaboration is] not viewed as an antitrust matter, since they are behaving as an integrated organization," explained meeting panelist and health policy expert Harold Miller, executive director of the Center for Health Care Quality and Payment Reform, who also offered his insights during a later interview.

Defining the extent of integration required for protection, and the time frame to achieve it, remain key issues for regulators, as does the possible creation of additional antitrust safe harbors related to market share and other matters. Regulators also said that they want to foster multiple ACOs in a given market to increase competition.

Which providers would be covered under fraud and abuse waivers also remains an issue, as well as whether waivers should apply only to shared savings payments or to other financial relationships ACOs create, Troy Barsky, director of the CMS Division of Technical Payment Policy, explained during the meeting.

Overall, the hope is to spur "coordination [and] cooperation among the people and the entities that provide health care," while at the same time ensure "appropriate corporate behaviors," said Dr. Donald Berwick, CMS Administrator.

Proposed ACO regulations are expected from the CMS in late December.

In the meantime, Mr. Miller advised physicians, "If you want to be an ACO, you have to start looking at the data you have – or get access to data from payers, Medicare, and others – to identify opportunities for savings.

"Once you know where they are, figure out what programs to put in place to achieve those savings," he said.

One option among many is to hire a nurse to help chronically ill patients manage their diseases, Mr. Miller said. That's been proven to help reduce emergency department visits and hospitalizations, he added (Arch. Intern. Med. 2003; 163:585-91).

To make such programs cost effective, however, "a small practice will need to think about how to partner with other practices in order to have enough patients who can benefit." he said.

Mr. Miller added that he does not believe recent election results will derail ACO efforts or other aspects of the Affordable Care Act. Despite Republican victories, "I think it would be a near impossibility to pass a repeal by a veto-proof margin. And the ACO stuff is not really controversial – yet," he noted.

The meeting's audio and transcript – as well as public comments on ACO concerns – are available online at www. ftc.gov/opp/workshops/aco/index.shtml

Congress Clarifies 'Creditor' Definition for Red Flags Rule

BY MARY ELLEN SCHNEIDER

ongress passed legislation clarifying its definition of a "creditor" under the Red Flags rule, a move that could help bolster the case that physicians should not have to abide by the new identity theft safeguards.

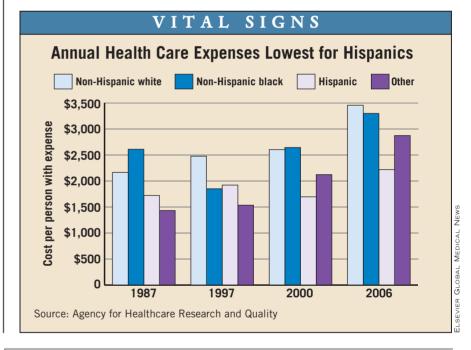
Physicians currently have until Dec. 31 before the Federal Trade Commission is set to begin enforcing the Red Flags rule. The rule was written to implement provisions of the Fair and Accurate Credit Transactions Act, which calls on creditors and financial institutions to address the risk of identity theft.

The rule requires creditors to develop formal identity theft–prevention programs that would allow an organization to identify, detect, and respond to any suspicious practices ("red flags") that could indicate identity theft. However, physician groups have long asserted that they are not creditors and should be exempt from the requirements, which they consider overly burdensome.

Under the new legislation (S. 3987), which was passed this month, Congress clarifies that a creditor is not someone who simply "advances funds on behalf of a person for expenses" related to a service. The American Medical Association and other physician groups are hopeful that the clarification will be enough to convince officials at the Federal Trade Commission to exempt physicians from the Red Flags rule.

"The AMA is pleased that this legislation supports AMA's long-standing argument to the FTC that physicians are not creditors. This bill will help eliminate the current confusion about the rule's application to physicians," AMA President Cecil B. Wilson said in a statement. "We hope that the FTC will now withdraw its assertion that the red flags rule applies to physicians."

The Red Flags rule became effective on Jan. 1, 2008, with an original enforcement deadline of Nov. 1, 2008. However, the FTC has delayed enforcement of the rule several times. ■



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