

Feds' Antitrust Efforts May Ease ACO Formation

BY M. ALEXANDER OTTO

FROM A FEDERAL TRADE COMMISSION WORKSHOP

Many 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 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.

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," Mr. 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 those same 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 peo-

ple 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 that "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 proved 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. ■

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National Institutes of Health Lead New Clinical Trials Push

BY MARK S. LESNEY

FROM THE ANNUAL MEETING OF THE AMERICAN SOCIETY OF HUMAN GENETICS

WASHINGTON – Breakthroughs in human genetics, combined with funding from the Affordable Care Act, have poised the National Institutes of Health to make real progress in the areas of orphan human diseases, according to NIH Director Francis S. Collins.

Speaking with enthusiasm to those he addressed as his "peeps" at the meeting, Dr. Collins shared his excitement at the state of human genetics in the postgenomic world, in large part driven by technology that has significantly lowered the cost of DNA sequencing, in turn speeding genetic research tremendously.

This, combined with new ACA funding, has enabled the NIH to fund and pursue translational research, moving laboratory results toward and into clinical trials, something that is a new way of thinking for the agency, Dr. Collins said.

Rather than relying on pharmaceutical and biotechnology companies to take charge of the translational research, Dr. Collins encouraged academic researchers to consider partnering with NIH, at least for those orphan disease conditions in which the federal government would not be seen as being in competition with private enterprise.



"There is a serious crisis underway in the way in which this pipeline for drug discovery has been floundering. ... Pharma has been investing a larger and larger amount of money (between \$40 and \$50 billion dollars a year) and yet in spite of that, [Food and Drug Administration] approvals of new molecular entities – that is, genuinely new drug therapeutics, not 'me-toos' – have been dropping steadily over the last 15 years," he said.

The reasons are complex, he added, but a big part of the problem involves coming up with appropriate targets and targeting compounds. He said this is an area in which the NIH is and can be very much involved.

Despite annual investments of up to \$50 billion by the drug industry, FDA approvals of new entities have dropped steadily.

DR. COLLINS

become more druglike and to match current ADME (absorption, distribution, metabolism, and excretion) criteria.

With NIH assistance, more than 150 lead compounds have reached this stage in the last 4-5 years; more than half are "poised to go to the next step" of preclinical trials in animals, or the "Valley of Death," Dr. Collins said, "because this is where projects often go to die."

The NIH can now assist in this high-risk area through the Therapeutics for Rare and Neglected Diseases

(TRND) program in its Office of Rare Diseases Research. The TRND was funded at \$24 million in fiscal year 2009. The agency also is positioned to assist researchers in early phase human trials of orphan diseases through its 240-bed clinical center, Dr. Collins said.

"And we have 50 and soon we will have 60 clinical and translational science awards scattered all across the country which will also be set up to conduct these sorts of trials for new molecular entities," he added.

This new direction in research funding has involved unprecedented cooperation with the FDA, he said, with an NIH-FDA leadership council formed to ensure that new drug candidates are most safely and efficiently moved into the clinical trials framework in ways that would best enable FDA analysis and validation, particularly for rare diseases.

Dr. Collins was particularly excited about five instances in which NIH is using this new model of helping "de-risk" the drug development process for orphan or neglected diseases through TRND. These include four rare diseases (Niemann-Pick disease type C, hereditary inclusion body myopathy, sickle cell disease, and chronic lymphocytic leukemia) and one neglected disease (schistosomiasis).

If and when these compounds and those for other rare diseases become ready for marketing and production, NIH would then work with private companies to achieve licensing agreement to enable their manufacture and sale, according to Dr. Collins.

Dr. Collins reported having no financial conflicts of interest with regard to his presentation. ■