THE RECORDER

134RD YEAR NO. 42 www.therecorder.com THURSDAY, NOVEMBER 10, 2011

No Mandatory Antitrust Review for ACOs

David Garcia and Helen Eckert
The Recorder, November 10, 2011

The Department of Justice and Federal Trade Commission recently issued their final "Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program" pursuant to the 2010 Patient Protection and Affordable Care Act. The final statement was issued in conjunction with the Department of Health and Human Services' Centers for Medicare and Medicaid Services' final regulations implementing the shared savings program as part of a coordinated interagency effort to facilitate health care provider participation in the shared savings program, so as to achieve the cost savings and improvement in quality of care Congress intended. Both the final statement and CMS' final regulations aim to further encourage and incentivize formation of Accountable Care Organizations and participation in the shared savings program. As such, the final statement includes significant, material changes from the proposed statement of antitrust enforcement policy with respect to ACOs issued earlier this year. (See the April 15 article on the proposed statement.)

ACOs are, in essence, collaborations of independent health care providers and/or provider groups (including physician practice groups, hospitals, physician-hospital organizations and any other provider groups that CMS deems appropriate) centered around the concept of enhanced coordination of care to improve both the quality and cost of care. ACOs are to be accountable for the overall care of a defined population of Medicare beneficiaries, and upon meeting certain performance standards set by CMS, are awarded some portion of savings realized (in addition to traditional fee-for-service payments).

As explained in the final statement, the agencies recognize that health care providers are more likely to create ACOs that serve both Medicare beneficiaries and privately insured patients, and thus present an opportunity for health care providers to achieve for many other consumers the benefits Congress intended for Medicare beneficiaries through the shared savings program. To further this goal, the final statement aims to clarify antitrust enforcement policy regarding ACOs, including whether ACOs that meet CMS' eligibility criteria may nevertheless be subject to antitrust scrutiny.

The agencies explain that while they continue to refrain from delineating specific requirements of clinical integration, they do recognize that CMS' eligibility criteria — including a management structure that comprises clinical and administrative processes, and processes to promote evidence-based medicine and patient engagement — are broadly consistent with the agencies' prior statements regarding clinical integration. The agencies also make clear that joint negotiations with private payers will be deemed reasonably necessary to an ACO's purpose of improving health care, and ACOs utilizing the same structure and processes used in the shared savings program to serve privately insured patients will accordingly be afforded rule of reason treatment.

As for the significant changes from the proposed statement, first and most significant, the final statement eliminates the mandatory antitrust review that had previously been a prerequisite for entry into the shared savings program. Mandatory antitrust review had initially been contemplated for all ACOs whose share for any common service that two or more independent ACO participants provided to patients in the same PSA exceeded 50 percent. The Final Statement does away with this mandatory review in favor of a voluntary, expedited (90 day) antitrust review process for any "newly formed ACOs" that may desire further antitrust guidance. The new voluntary process will examine "whether the ACO will likely harm competition by raising the ACO's ability or incentive profitably to raise prices above competitive levels or reduce output, quality, service, or innovation below what likely would prevail in the absence of the ACO." The reviewing agency may also consider other factors appropriate in the rule of reason analysis as explained in the 1996 Statements of Antitrust Enforcement Policy in Health Care and the 2000 Antitrust Guidelines for Collaborations Among Competitors.

An FTC/DOJ ACO Working Group will be established to collaborate and discuss issues arising out of the ACO reviews to ensure efficient, cooperative and expeditious reviews. The policy statement also reaffirms the agencies' commitment to protecting competition in the health care markets, explaining the agencies' intent to monitor data and other information from CMS to assess the competitive effects of ACOs and guide future enforcement policies.

Second, the final statement — with the exception of the voluntary expedited antitrust review discussed above — applies to all collaborations among otherwise independent providers and provider groups that are eligible and intend, or have been approved, to participate in the shared savings program. The applicabil-

---

David Garcia is a partner in Sheppard, Mullin, Richter & Hampton's Los Angeles/Century City office. His practice focuses on antitrust litigation and counseling, including recent counseling to health care clients on antitrust issues arising from business combinations designed to function as ACOs. Helen Eckert is an associate in the antitrust practice group in the Los Angeles/downtown office of Sheppard, Mullin.

ity of the final statement is not limited to only those collaborations formed after March 23, 2010 (the date on which PPACA was enacted), as was contemplated by the proposed statement.

The final statement is otherwise largely consistent with the guidelines set forth in the proposed statement. Notably, the antitrust "safety zone" for ACOs, whose independent participants provide a "common service" and have a combined share of 30 percent or less of each such common service in each participant's PSA, remains the same in the final statement, wherever two or more ACO participants provide that service to patients from that PSA. The "rural exception" and the "dominant provider limitations" from the proposed statement also remain intact.

The final statement also includes a list of specific types of conduct which, under certain circumstances, may raise competitive concerns and should be avoided. It makes clear that all ACO participants should avoid improper exchanges of price or other competitively sensitive information among competing participants, which may facilitate collusion in the provision of services outside the ACO. The agencies also identified the following four types of conduct which ACOs with high PSA shares (or other indicia of market power) should avoid:

1. Discouraging private payers from directing or incentivizing patients to choose certain providers.

2. Tying sales of the ACO's services to the private payer's purchase of other services from providers outside the ACO, and vice versa.

3. Contracting with ACO participants on an exclusive basis.

4. Restricting a private payer's ability to make available cost, quality, efficiency and performance information to aid enrollees in evaluating and selecting providers in the health plan if it is similar to that used in the shared savings program.

Whether the final statement will in fact further encourage and incentivize ACO formation by, among other things, replacing mandatory antitrust review with a voluntary one, remains to be seen and will undoubtedly by the subject of further study and debate. Furthermore, whether independent providers interested in collaborations by way of clinical integration will have to, at a minimum, meet CMS' eligibility criteria in order to avoid antitrust scrutiny also remains to be seen.

SHEPPARD MULLIN

SHEPPARD MULLIN RICHTER & HAMPTON LLP