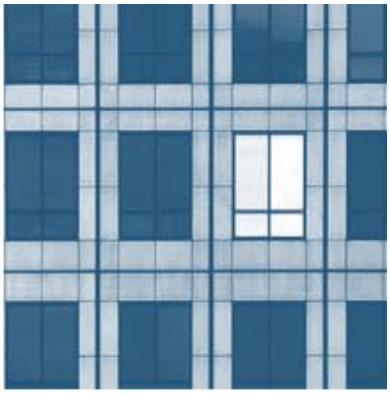
McDermott Will & Emery

On the Subject



Health Industry Advisory

October 6, 2010

The FTC, CMS and OIG hosted a public workshop on October 5, 2010, featuring panel discussions on antitrust issues and an announcement from the FTC that it will develop antitrust safe harbors for accountable care organizations (ACOs), as well as an expedited review process for ACOs that do not qualify for those safe harbors.

FTC to Develop Safe Harbors and Expedited Review Process for ACOs

Introduction

During a workshop held by the U.S. Federal Trade Commission (FTC), the Centers for Medicare & Medicaid Services (CMS) and the Office of the Inspector General (OIG) on October 5, 2010, FTC Chairman Jon Leibowitz announced the FTC will develop antitrust safe harbors for accountable care organizations (ACOs) and an expedited review process for ACOs that do not qualify for those safe harbors.

For many providers with ACOs in development who have been looking for more definitive antitrust guidance, the announcement may be a welcome relief. That being said, providers should know that fundamental antitrust principles will continue to apply to the formation and operation of ACOs—namely, that ACOs formed and operated to improve quality and reduce health care costs that do not create undue market concentration are pro-competitive and ACOs formed by independent, competing providers solely to raise prices are not.

This newsletter summarizes the morning sessions of the workshop concerning antitrust issues. A future newsletter will address other regulatory issues discussed during the afternoon sessions of the workshop.

Background

Section 3022 of the Patient Protection and Affordable Care Act (PPACA), Public Law No. 111-148, directs the secretary of the U.S. Department of Health and Human Services (HHS) to establish, no later than January 1, 2012, a shared savings program that promotes accountability for a patient population, coordinates services under Parts A and B of Medicare, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Under the shared savings program, ACOs that meet quality performance standards established by the HHS secretary are eligible to receive shared savings payments. Among other requirements, an ACO must be accountable for the quality, cost and overall care of the Medicare fee-for-service beneficiaries assigned to it.

Although popularized by PPACA, the concept of independent providers coming together and being jointly accountable for the cost and quality of care they provide is not new. In 1996 the U.S. Department of Justice (DOJ) and FTC in the Statements of Antitrust Enforcement Policy in Health Care (Policy Statements), which can be found at http://www.ftc.gov/bc/healthcare/industryguide/policy/index.htm, first recognized the concept of clinical integration as a collaborative activity among competing health care providers that may provide a sufficient basis for analyzing joint-pricing negotiations under the rule of reason and not the per se standard of illegality. Since the passage of PPACA, many providers have wondered how the DOJ and FTC would apply the standards they developed for clinically integrated managed care contracting networks—through the Policy Statements, advisory opinions and other, subsequent guidance—to the formation and operation of ACOs.

Government Officials' Remarks

CMS Administrator Don Berwick, MD, stated the government wants to help integrated care thrive. He also noted the government needs to be a proper steward of the antitrust laws. Said differently, the government wants providers to cooperate and achieve synergies without colluding.

Leibowitz stated the promise of ACOs—improved quality and reduced costs—offers a real opportunity for health reform and explained that the government's job is to ensure that regulations encourage ACO development while also protecting consumers. He then announced the FTC wants to explore the development of safe harbors so providers can know when they can collaborate. Further, the FTC will explore an expedited review process for ACOs that fall outside the safe harbors. Leibowitz acknowledged the difficulty of establishing safe harbors—that is, categories of conduct that, absent extraordinary circumstances, the DOJ and FTC will not challenge—that displace traditional facts and circumstances analysis under the antitrust laws. He then appealed to the provider community, stating that in order to develop effective safe harbors, the FTC needs input from providers. Specifically, the FTC is interested in the types of activities providers may engage in through ACOs and how providers envision ACOs operating in the marketplace.

FTC Panel Discussions

The FTC conducted two moderated panel discussions. Provider and payor representatives, as well as policy experts, participated in the sessions.

Sufficient Integration and the Rule of Reason

The first panel addressed the issue of when ACO participants should be deemed sufficiently integrated through the ACO such that their collective price negotiations should be analyzed under the rule of reason and not the per se standard of illegality. The panel considered whether the FTC should establish a safe harbor for ACOs that satisfy CMS' criteria for ACO participation in the Medicare program. Under the proposal, the FTC would view any ACO qualified by CMS to be sufficiently clinically integrated for rule of reason treatment. The panel also considered how CMS should elaborate on PPACA requirements for ACOs—namely, that an ACO be accountable for the quality, cost and overall care of the Medicare fee-for-service beneficiaries assigned to it—to ensure that ACO participants are sufficiently integrated within the meaning of the antitrust laws.

Panelists discussed possible criteria. Many provider representatives emphasized the importance of providers' ability to share data and the ability of the organization to capture and analyze data. A representative from a clinically integrated independent practice association emphasized the importance of electronic tools to improve cost and care coordination. These tools allow providers to evaluate their performance against their peers. Another representative from a clinically integrated physician-hospital organization expressed the view that the importance of the adoption and implementation of electronic health records systems (EHRS) has been overemphasized, and that his organization has been clinically integrated despite its participants not having universally adopted EHRS. Among other initiatives, his organization created disease registries to manage patient populations. Later, it required participants to adopt high-speed internet technology, then e-prescribing. As a result of federal stimulus money, the provider participants in his organization are now adopting EHRS.

A trade association representative encouraged the FTC to set the criteria at a high level in recognition that there are various care integration models. Another panelist added that the FTC criteria cannot be too specific, otherwise competition could be stifled. These comments recognize that one of the purposes of the antitrust laws is to foster innovation such as new care delivery models. One of the challenges for the FTC as they consider a possible safe harbor will be how to answer the industry's call for clear standards while also allowing for flexibility in model design.

Market Power, Over-Inclusiveness and Exclusivity

The second panel discussion addressed issues of market power, over-inclusiveness and exclusivity. The participants considered whether the FTC should adopt an antitrust safety zone pertaining to market share for ACOs. Statement 8 of the Policy Statements contains an antitrust safety zone that applies solely to physician networks. Under the safety zone, the DOJ and FTC will not challenge, absent extraordinary circumstances, an exclusive physician network joint venture whose physician participants share substantial financial risk and constitute 20 percent or less of the physicians in each physician specialty who practice in the relevant geographic market, or a non-exclusive physician network whose physician participants share substantial financial risk and constitute 30 percent or less of the physicians in each physician specialty who practice in the relevant geographic market. The DOJ and FTC did not extend the antitrust safety zone for physician networks to multiprovider networks, which the DOJ and FTC analyze under Statement 9 of the Policy Statements.

The panel first addressed the issue of how large an ACO needs to be in order to deliver care effectively. Many panelists believed that ACOs need sufficient scale in order to achieve program objectives and properly measure performance. ACOs also need scale in order to spread out the cost of infrastructure investments, staff and other resources. Scale also enables an ACO to spread risk effectively. The payors on the panel addressed the extent to which they are experiencing market power issues with providers and, not surprisingly, stated that they have experienced price

increases in markets where certain providers are dominant. One of the challenges for the FTC as they consider a possible safe harbor will be how to balance the need for scale to achieve program objectives against market power concerns.

Panel participants also discussed the issue of exclusivity. Under an exclusive ACO, provider participants negotiate with payors only through the ACO and they may not join other ACOs. A professor expressed the concern that the advisory opinions on clinically-integrated networks the FTC has issued to date unfairly emphasize non-exclusivity. He doubted whether a high-functioning ACO can have provider participants whose loyalty is split among competing organizations. Several representatives stated that exclusivity is necessary to achieve the benefits of clinical integration, at least with respect to primary care physicians. As with other concerns the FTC must balance, it will be challenged to develop ACO guidance that recognizes both the benefits and foreclosure implications of exclusivity.

For more information, please contact your regular McDermott lawyer, or:

Ashley M. Fischer: +1 312 984-7766 amfischer@mwe.com

For more information about McDermott Will & Emery visit: www.mwe.com

McDermott Will & Emery

Office Locations

Boston
28 State Street
Boston, MA 02109
USA
Tel: +1 617 535 4000
Fax: +1 617 535 3800

Brussels
Rue Père Eudore Devroye 245
1150 Brussels
Belgium
Tel: +32 2 230 50 59
Fax: +32 2 230 57 13

Chicago
227 West Monroe Street
Chicago, IL 60606
USA
Tel: +1 312 372 2000
Fax: +1 312 984 7700

Düsseldorf
Stadttor 1
40219 Düsseldorf
Germany
Tel: +49 211 30211 0
Fax: +49 211 30211 555

Houston
1000 Louisiana Street, Suite 3900
Houston, TX 77002
USA
Tel: +1 713 653 1700
Fax: +1 713 739 7592

London
7 Bishopsgate
London EC2N 3AR
United Kingdom
Tel: +44 20 7577 6900
Fax: +44 20 7577 6950

Los Angeles
2049 Century Park East, 38th Floor
Los Angeles, CA 90067
USA
Tel: +1 310 277 4110
Fax: +1 310 277 4730

Miami
201 South Biscayne Blvd.
Miami, FL 33131
USA
Tel: +1 305 358 3500
Fax: +1 305 347 6500

Milan
Via A. Albricci, 9
20122 Milan
Italy
Tel: +39 02 89096073
Fax: +39 02 72095111

Munich
Nymphenburger Str. 3
80335 Munich
Germany
Tel: +49 89 12712 0
Fax: +49 89 12712 111

New York
340 Madison Avenue
New York, NY 10173
USA
Tel: +1 212 547 5400
Fax: +1 212 547 5444

Orange County
18191 Von Karman Avenue, Suite 500
Irvine, CA 92612
USA
Tel: +1 949 851 0633
Fax: +1 949 851 9348

Rome
Via Parigi, 11
00185 Rome
Italy
Tel: +39 06 4620241
Fax: +39 0648906285

San Diego
11682 El Camino Real, Ste. 400
San Diego, CA 92130
USA
Tel: +1 858 720 3300
Fax: +1 858 720 7800

Shanghai
MWE China Law Offices
Strategic alliance with
McDermott Will & Emery
28th Floor Jin Mao Building
88 Century Boulevard
Shanghai Pudong New Area
P.R.China 200121
Tel: +86 21 6105 0500
Fax: +86 21 6105 0501

Silicon Valley
275 Middlefield Road, Suite 100
Menlo Park, CA 94025
USA
Tel: +1 650 815 7400
Fax: +1 650 815 7401

Washington, D.C.
600 Thirteenth Street, N.W.
Washington, D.C. 20005
USA
Tel: +1 202 756 8000
Fax: +1 202 756 8087