THE RECORDER

134RD YEAR NO. 201 www.therecorder.com TUESDAY, FEBRUARY 1, 2011

Health Care Reform May Prompt Antitrust Violations

David Garcia, Sheppard, Mullin, Richter & Hampton partner

Helen Cho Eckert, Sheppard, Mullin, Richter & Hampton associate

The 2010 Patient Protection and Affordable Care Act calls for the implementation of a new health care delivery model — an "accountable care organization" — intended to promote better care at lower cost through health care provider accountability, investment in infrastructure, redesigned care processes and coordination among different types of providers. ACOs, in the form contemplated by the statute, will inevitably raise significant antitrust concerns at the formation stage as they contemplate collaborative arrangements among actual or potential competitors.

The ability of ACOs (especially networks including both hospitals and doctors) to jointly contract on behalf of their participants, and the ability of such networks to mandate various sorts of exclusivity are two hot button antitrust issues that will have to be dealt with as industry participants attempt to position themselves for a health care landscape in which ACOs are expected to play a significant role, first with Medicare recipients and eventually with privately insured patients. While the health care industry awaits interagency enabling regulations, which hopefully will provide some guidance on these two issues, among many others, for now we are left with applying basic antitrust principles developed for prior forms of multiprovider health care networks. A cautionary note is thus required because the principles applied essentially rely on health care policy statements by the Department of Justice and Federal Trade Commission dating back to the mid-1990s, and a series of nonprecedential actions by the two agencies to specific factual situations in the form of Business Review letters, advisory opinions and consent decrees.

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 functions as ACOs.

Helen Cho Eckert is an associate in the antitrust practice group in the Los Angeles/downtown office of Sheppard, Mullin.

BRIEF OVERVIEW OF THE ACO MODEL

As contemplated by the PPACA, ACOs are, in essence, organizations of independent providers willing to coordinate care and ultimately be accountable for the quality, cost and overall care of a defined patient population. ACOs are centered around the concept of enhanced coordination of patient care in order to improve both the quality and cost of care. Under §3022 of PPACA, the following organizations of providers may form ACOs to coordinate the care of a defined population of Medicare beneficiaries: (1) a group practice of physicians; (2) networks of group practices, such as independent practice associations; (3) joint ventures or partnerships of hospitals and independent providers, such as physician-hospital organizations; (4) fully-integrated organizations of hospitals and their employed physicians; and (5) such other groups of providers as the Secretary of Health and Human Services deems appropriate.

ABILITY OF ACOS TO JOINTLY CONTRACT

Historically, the most sensitive antitrust issue for all types of health care collaborations has been the ability to jointly contract on behalf of their participants with Medicare and other payors, and ACOs will inevitably have to confront the same concern. Jointly setting fees charged by competing providers, without more, would be condemned as per se illegal under the antitrust laws. However, it is now generally accepted in the health care context that, where competitors are sufficiently integrated in a partnership, joint venture or other collaborative network that has the potential to achieve pro-competitive, efficiency-enhancing benefits, the legality of such joint contracting should instead be analyzed under the more lenient "rule of reason" standard, in which the ultimate determination of legality would require a weighing of the ACO's pro-competitive benefits with its anti-competitive potential.

There are currently two generally recognized pathways to achieve the kind of integration necessary to justify rule of reason analysis: (1) clinical integration; and/or (2) financial integration through risk sharing. (It should also be noted that, at least with respect to California, certain state regulations will affect the extent to which networks of hospitals and physician groups can contract for combined services — no matter how much integration the network achieves — unless the network takes a particular legal form, but the effect of such state laws on the broader antitrust implications of ACOs is beyond the scope of this article.)

First, the essential components of "clinical integration" are the creation of interdependence and joint responsibility — a vested interest in the care provided — among providers in a single network. Such interdependence ensures that providers' financial and other incentives are closely aligned to best meet common efficiency-enhancing goals, thereby improving the overall quality and cost of care. While interested parties will surely desire more concrete guidance, the existing antitrust enforcement agency guidance, which should likely remain relevant, includes the following clinical integration characteristics: (1) establishing mechanisms to monitor and control utilization of health care services that are designed to control costs and assure quality of care; (2) selectively choosing network physicians who are likely to further those efficiency objectives; (3) identifying inefficient network physicians; and (4) significant investment in infrastructure and capability, including, for example, a health information technology system, to realize claimed efficiencies.

While the regulatory details of the ACO structure will not be fully known for some time, ACOs, by definition, appear to naturally encompass traditional notions of clinical integration. Both the ACO model and clinical integration focus on a health care delivery model dedicated to interdependence, quality and efficiency, which is able to impose and enforce compliance with clinical practice guidelines and performance goals.

Second, it has been generally accepted, since at least the 1996 Health Care Statements, that the sharing of substantial financial risk is normally a reliable indicator of sufficient integration and so justifies rule of reason analysis. Financial risk sharing naturally provides powerful incentives for participants to cooperate in controlling costs and improving quality by better managing the provision of services. Moreover, because the participants share the risk, it is generally reasonable and necessary for them to also collectively agree on the fees to be charged for their services. Risk sharing to date has involved, for example, joint contracting with respect to payment for services at capitated or all-inclusive case rates, or use of financial incentives (including rewards and/or penalties) based on the network's performance in meeting cost-containment goals.

It is important to note that no particular ACO structure will automatically confer the requisite level of financial risk sharing. There is a common misconception that a formal joint venture, by its very structure, necessarily implicates risk sharing. In reality, however, whether an ACO is organized as a formal joint venture entity or some other type of contractual joint venture arrangement, genuine risk sharing (such as an agreement to forgo the traditional fee-for-service arrangement for capitated or all-inclusive rates) will still need to be implemented in order for joint contracting to be analyzed pursuant to the rule of reason under a risk sharing theory.

There is some indication in the PPACA that ACOs may be expected to involve a certain amount of economic integration akin to risk sharing. A central concept in §3022 is that of "shared savings" in which an ACO that meets quality and cost standards, in addition to being paid for its services under the Medicare program, will be awarded a portion of the savings it achieves for its Medicare beneficiaries. Moreover, §10307 allows for flexible payment models, including partial capitation, where appropriate.

ABILITY OF ACOS TO MANDATE EXCLUSIVITY

ACOs will likely also have to analyze the extent to which a health care network can legally require some sort of exclusivity from its participating physicians and/or hospitals. As PPACA calls for ACOs to simultaneously improve quality while reducing cost, prospective ACO participants, especially in affiliations of hospitals and physician groups, may very well regard some level of exclusivity as "reasonably necessary" to the formation of ACOs which can achieve these goals. Without the ability to mandate exclusivity, it may prove difficult to ensure the critical mass of patients, and/or other sufficient economic incentives, to justify the significant investment of monetary and human capital necessary to form an effective ACO. A significant antitrust issue therefore emerges, because antitrust enforcement agencies thus far appear to disfavor exclusivity (although the small body of applicable agency actions is hardly definitive).

Antitrust agencies have thus far taken the position that where integrated networks are nonexclusive, the network offers a new, additional product that payors may choose if they find the product beneficial, while still retaining the option to contract directly with providers. Thus, there is no net elimination of competition (rather, a net gain) as compared to the competitive landscape before formation of the network. Notably, of the only four FTC advisory opinions to date analyzing the legality of clinical integration proposals, the only proposal to be rejected by the FTC contemplated, among other things, that a "super physician-hospital organization" comprised of eight member hospitals and their employed physicians would be the exclusive means by which these otherwise competing hospitals could contract with large regional and national managed care plans. The FTC also has determined, on at least one occasion, that nonexclusivity was of "critical" importance in its ultimate conclusion that another clinical integration proposal did not constitute an unreasonable restraint on competition, demonstrating that clinical integration as a justification for joint contracting necessarily intersects with the issue of exclusivity. Finally, the 1996 Health Care Statements afford greater latitude to nonexclusive networks to contract jointly, delineating a "safety zone" free of antitrust exposure for a nonexclusive, physician-only network which shares substantial financial risk and constitutes less than 30 percent of the physicians in a relevant market, as opposed to a safety zone for an exclusive network of only 20 percent.

That said, the DOJ and FTC have made clear that exclusive arrangements are not necessarily anti-competitive. Ultimately, determinations of the legality of exclusivity will necessarily involve an analysis of market power in the relevant geographic health care market in which the ACO will operate. This requires a case-by-case inquiry requiring examination of the market share of the network providers in that relevant market, the terms of the exclusive arrangement (such as its duration and providers' ability and likely incentives to withdraw from the network), the number of providers that need to be included for the network and potentially competing networks to compete effectively, and the justification for the exclusivity.

Any ACO considering exclusivity must

thus do so very carefully. As a practical matter, exclusivity may pose a greater challenge to an ACO than joint contracting, particularly if any of the affiliated providers or the completed affiliation possesses market power. Uncertainty as to whether ACOs may mandate exclusivity without fear of antitrust challenge is exacerbated by the lack of definitive, precedential authority on the subject. Moreover, exclusivity can take on various forms which in turn impact the antitrust analysis: Exclusivity in an ACO which includes multiple horizontal competitors generally raises more antitrust concerns than exclusivity within a vertically integrated network.

Only time will tell if the new legislative mandate for ACOs will spur more concrete guidance from these agencies, and perhaps eventually the courts, as to what exactly is required for health care provider networks interested in engaging in joint contracting and/or mandating exclusivity to withstand antitrust challenge. Until then, guidance in this area of law remains an uncertain exercise in applying certain basic antitrust principles and a body of fact-specific consents and informal guidance. Interested parties will consequently have to proceed carefully in structuring ACOs to avoid antitrust risk.