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The Latest FTC Clinical Integration Advisory

Law360, New York (June 18, 2009) -- The rise of clinical integration of independent health care providers is one of the most closely watched phenomena in the health care antitrust area.

As the new administration articulates its position on how to balance the care and cost benefits of clinical integration with the potential for harm to competition from the often-accompanying joint contracting, this confluence of health care policy and antitrust law only promises to get more interesting.

President Obama's stated goal of improving care and lowering costs through measures that have long been part of the clinical integration model — such as storing medical information electronically for sharing among practitioners — may result in these kinds of collective arrangements flourishing during his administration.

On the other hand, it is clear that this administration intends to more aggressively enforce the antitrust laws, and potentially anti-competitive practices in the health care industry have been singled out for extra scrutiny.

In some respects, the area of clinical integration will be the crucible in which antitrust regulators will attempt to harmonize these policy initiatives.

The Federal Trade Commission, the federal agency principally charged with regulating health care under the antitrust laws, has consistently expressed its interest in making sure that "legitimate efficiency-enhancing joint venture activities are not discouraged."

A significant means of communicating how organizations should attempt to achieve efficiencies through joint efforts without threatening competition is through advisory opinions, issued at the request of organizations seeking conditional approval of a proposed program.

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Without conditional approval, physician networks remain open to challenge from the FTC, as reflected by recent litigation and prelitigation settlements.[1]

Understanding the guidance imparted through these advisory opinions is key to successfully drafting and implementing a clinical integration plan, particularly in light of the Supreme Court's recent decision not to review the first federal appellate clinical integration decision, which resulted from a hard-fought litigation between the FTC and a physician network.[2]

In its first advisory opinion under its new chairman, the FTC examined the proposed clinical integration program of Maryland's TriState Health Partners Inc., issued April 13, 2009, adding useful information to the body of FTC guidance on clinical integration.[3]

This article begins with a brief primer on antitrust principles governing the analysis of clinical integration programs. Its main purpose is to summarize the conventional wisdom concerning clinical integration as reflected in the 2007 FTC advisory opinion concerning the Greater Rochester Independent Practice Association Inc., and then to discuss what new information can be gleaned from the recent TriState Health advisory opinion.

Antitrust Principles at Play in Analyzing Clinical Integration Programs

The landmark Supreme Court case of Arizona v. Maricopa County Medical Society et al., 457 U.S. 332 (1982), established the general principle that, absent exceptional circumstances, the antitrust laws condemn as per se illegal any agreement among independent physicians as to the fees they will charge health plans for their services.

Specifically, the court found that to avoid per se illegality, these arrangements must be "analogous to partnerships or other joint arrangements in which persons who would otherwise be competitors pool their capital and share risks of loss as well as the opportunities for profit." Id. at 356.

However, since the Maricopa decision, the antitrust enforcement agencies have indicated that nonfinancially integrated provider networks engaging in collective bargaining may avoid antitrust problems if there is sufficient integration of the clinical aspects of the network.

The FTC's analysis of any clinical integration plan with collective bargaining therefore proceeds from the most basic antitrust questions under the "Rule of Reason:"

Does the overall arrangement benefit consumers (in terms of care and cost) enough to outweigh the potential harm to competition, and are the aspects of the arrangement that threaten competition necessary to capture the benefits?

With respect to collective bargaining, which in and of itself rarely benefits consumers and may be characterized as illegal price-fixing, the challenge is to demonstrate that

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collective bargaining is essential to the clinical integration scheme such that the countervailing advantages cannot reasonably be achieved without it.

Generally speaking, this requires the creation of a contracting structure that facilitates and requires a high degree of interdependence and cooperation among participating providers who share material financial risk.

In other words, the FTC must find that the collective bargaining aspect of the arrangement is a “necessary evil” required to achieve significant clinical benefits.

FTC Staff Advisory Opinion to GRIPA, Sept. 17, 2007

In 2007, the FTC issued an advisory opinion conditionally approving the GRIPA clinical integration program.

This opinion, which builds on prior advisory opinions,[4] has in some respects come to be perceived as setting forth the “gold standard” of a well-developed clinical integration program capable of clearing the FTC’s antitrust bar.

GRIPA proposed a program of joint contracting with payers on behalf of independent and hospital-affiliated primary care physicians and specialists, “intertwined” with collaborative clinical improvement programs designed to enhance patient care and create efficiencies.

This “new product” replaced a joint contracting program based on risk-sharing arrangements. GRIPA’s proposed product involved negotiating with payers for the integrated services of over 500 physicians, with over 40 specialty areas represented among them.

GRIPA highlighted the main aspects of the new product’s clinical integration component:

1) creation of a network of primary care physicians and specialists to provide “seamless” care, with GRIPA physicians agreeing to refer patients to one another;

2) promotion of physician collaboration through protocols, benchmarks, and performance and compliance monitoring;

3) a Web-based information sharing system;

4) expansion of care management to several additional diseases and diagnoses; and

5) forecasting of savings attributable to avoidance of unnecessary costs.

GRIPA offered several justifications for the joint contracting portion of its program, including that it:

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1) presented an easily identifiable set of providers and referring physicians;

2) reinforced the internal referral system;

3) ensured that all physicians were working toward the same financial goals;

4) maximized the effect of the clinical integration program and opportunities for collaboration; and

5) reduced administrative burdens.

In its advisory opinion letter indicating approval of the program, the FTC emphasized the importance of the following aspects of the clinical integration program:

1) participation by a broad spectrum of specialists and the system of referrals to physicians within the network;

2) a “serious” effort to encourage physician compliance through monitoring and potential expulsion;

3) the high degree of investment of time and money by physicians;

4) implementation of benchmarks; and

5) the necessity of integration to achieve these efficiencies.

Ultimately the FTC agreed that GRIPA’s proposed joint contracting through agreed-upon prices for services was reasonably necessary to achieving the efficiencies and benefits.

It found that a joint contracting program was not likely to discourage competition where it was “nonexclusive,” meaning that payers not able to reach an agreement with GRIPA would be able to negotiate with individual physicians, although it warned that GRIPA should in no way facilitate agreements on price by physicians for services delivered outside the network such that there would be a “spillover” effect on these prices.

Although GRIPA admitted it intended to charge higher prices for some services, the FTC found that the enhanced quality of services could justify the increases.

TriState Health Inc. Advisory Opinion, April 13, 2009

In the main, the TriState Health program features all of the elements of the GRIPA program detailed supra, with the differences being of degree rather than kind.

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In addition to these points of commonality, however, TriState Health presented some issues unique to a market in which the member physicians represented a true majority of the physicians in the service area.

TriState Health's proposed program involves integration of 200-plus primary care and specialist physicians in western Maryland, along with Washington County Hospital and its physicians.[5]

In a relatively rural service area, the network would comprise what the FTC characterized this as "very substantial majority"[6] of physicians practicing in the service area and the only hospital.

Moreover, the FTC also expressed concern about the "over-inclusive" nature of the program, which ran the risk of "comprising significantly more total physicians or physicians in particular medical specialties than is necessary for it to provide services effectively to its likely customers."[7]

While the FTC indicated that the program members may possess market power under all of these circumstances (particularly as to hospital services), because the joint contracting aspect of the program allowed members to contract with payers outside the program, the program's ability to exercise or grow market power was minimal.[8]

As in GRIPA, this nonexclusivity feature was deemed "critical" to the determination that the program was unlikely to hurt competition, with the FTC going so far as to warn that the advisory opinion would be "rescinded" and enforcement action recommended should the agency later learn that members were not operating on a nonexclusive basis, that payers were not able to contract for services required by their programs outside TriState, or that TriState was undermining competition from remaining nonmember providers.[9]

In contrast to GRIPA, where members comprised no higher than 35 percent of physicians in internal medicine and other major practice areas, TriState members comprise between 50 and 100 percent of many practice areas.

However even with that level of potential market power, by promising to aspire to "de jure and de facto" nonexclusivity with respect to members' ability to contract with payers, TriState Health was able to gain FTC conditional approval.[10]

The FTC noted that if in practice payers are not able to "attract sufficient individual TriState member physicians to contract outside of TriState," there would be cause for "further investigation and clarification."[11]

The TriState Health opinion therefore underscores the particular importance of the nonexclusivity aspect of a clinical integration program.

Other notable points of commonality and divergence are as follows:

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- Number of diagnoses/diseases covered by clinical integration: GRIPA's program included several diagnoses, but maintained an emphasis on a core group. TriState Health stated a goal of having at least 80 percent of the medical conditions comprising at least 80 percent of the cost of care in the community covered by program guidelines.[12]

- Agreement by physicians to refer in-network: GRIPA's program featured a referral requirement except in "unusual circumstances." TriState affirmatively limited the obligation to situations where such a referral is "medically appropriate" and where patient wishes to receive care from referral physician.[13]

- Outlay of capital by physicians: GRIPA participants were required to invest in very specific start-up technology and training costs, totaling approximately $20,000 in costs and lost revenue.

TriState's relatively low $2,500 "joining fee" (which in many instances had been paid by existing members many years ago) and other start-up costs, about $7,600 total, was source of some concern for the FTC, which concluded that this amount of financial investment was unlikely to motivate physicians to help the program succeed.[14]

- Outlay of human resources by physicians: A feature of GRIPA's program was significant training of physicians and staff. In the face of TriState's very low financial outlay requirement, the FTC found that the "nontrivial" amount of time that members would have to devote to devising guidelines, participating on committees, etc. was sufficient to instill a level of commitment to the program.[15]

- Technology that enables multiple physicians to access patient information: GRIPA's program description featured details about the information to be input into the system and the hardware used in physicians' offices.

In TriState Health's program, the Web-based electronic health records updated by members were described as being designed to identify high-risk and high-cost patients and facilitate exchange of information. The software itself was put in place and maintained by a commercial vendor with a long-standing relationship to TriState Health.

The FTC noted a concern that where patients sought care outside of the network, the records would not be complete, which TriState intended to minimize with financial incentives for patients to stay in-network and by gaining access to outside records.[16]

- Mechanism for excluding physicians who do not comply with guidelines and standards: The FTC noted that GRIPA's mechanism for exclusion and discipline was enhanced by the fact that it had an ongoing relationship with the physicians it oversaw.

In TriState Health, a similar system for monitoring compliance was in place, although the stated goal was to increase the mean level of compliance as opposed to excluding outlier noncompliant participants.[17]

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Conclusion

Although the TriState Health advisory opinion does not alter the principles and guidance of the earlier GRIPA advisory opinion, it does underscore the particular importance of nonexclusivity in physician-payer contracting, and in general, of the value of following existing regulatory guidance in taking advantage of the opportunity to take the business of health care in exciting new directions.

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[1] See N. Tex. Specialty Physicians v. Fed. Trade Comm'n, 528 F.3d 346 (5th Cir. 2008); "FTC Settles Price-Fixing Charges Against Two Separate Doctors' Groups," FTC Press Release, Dec. 24, 2008 (describing settlements with physicians groups in Modesto, Calif., and Boulder, Colo.).

[2] See N. Tex. Specialty Physicians v. Fed. Trade Comm'n, No. 08-515 (cert. denied Feb. 23, 2009).

[3] The advisory opinion, available on the FTC's website, is hereinafter referred to as "Advisory Opinion" for purposes of citation.

[4] All FTC clinical integration advisory opinions are available on the FTC's Web site. In addition to GRIPA and TriState Health, another significant advisory opinion indicating that the FTC would not challenge a clinical integration program is the February 2002 advisory opinion concerning the MedSouth Inc. program, revisited in a July 2007 letter.

[5] Advisory Opinion at 2.

[6] Advisory Opinion at 4.

[7] Advisory Opinion at 30.

[8] Advisory Opinion at 2.

[9] Advisory Opinion at 33.

[10] Advisory Opinion at 30.

[11] Advisory Opinion at 31.

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[12] Advisory Opinion at 8 n.22.

[13] Advisory Opinion at 11.

[14] Advisory Opinion at 17-18.

[15] Advisory Opinion at 19.

[16] Advisory Opinion at 8.

[17] Advisory Opinion at 9.

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