Antitrust Advisory: FTC Emphasizes Human Capital Investment over Financial Investment in Recent Clinical Integration Advisory Opinion

4/17/2009

One important issue for health care provider joint ventures is determining when the venture is sufficiently clinically integrated so that, if the venture jointly contracts with providers, its activities will be tested under the more forgiving antitrust rule of reason rather than being condemned as *per se* illegal. The Federal Trade Commission ("FTC" or "Commission") has given limited guidance in the past on this issue,[1] and industry participants have pressed the Commission for additional guidance. On April 14, 2009, the FTC released an advisory opinion regarding a clinical integration proposal from TriState Health Partners, Inc. ("TriState") which provides some additional nuggets of guidance, but demonstrates that the Commission has not strayed far from its three previous clinical integration advisory opinions. Importantly, the TriState advisory opinion also signals the Commission's willingness to allow clinical integration programs to proceed that consist of minimal financial investment, but require significant investment of human capital.

TriState's Proposed Program

TriState proposed developing a program through a multi-provider network joint venture that would clinically integrate its members. Under the program, which importantly was non-exclusive, TriState's members would provide medical, hospital, and other health care services to persons covered under health benefits programs offered by self-insured employers and other payers in TriState's service area. The proposed program includes the following:

- A web-based health information technology system to identify high-risk and high-cost patients and to facilitate the exchange of patients' treatment and medical management information in order to "more aggressively manage" TriState's patients care than could be done on an individual provider basis;
- Clinical practice guidelines and a program to monitor member physicians' adherence to those guidelines;
- Changes in policies and procedures, including the clinical practice guidelines, designed to improve clinical efficiency;
- Policies and procedures related to the clinical integration program's utilization management, case management, and disease management activities; and
- Physician performance measurement (*e.g.,* report cards, peer counseling, educational efforts, discipline and expulsion from the program for physicians who fail to conform to program parameters).

The proposed program contemplates that referrals of patients under the contract should remain within the TriState network. The proposed program consists of two classes of membership: physicians and a hospital association (the sole member of the class).

Rule of Reason Analysis of Clinical Integration Programs

Without an adequate pro-competitive justification for joint negotiation of terms, including price terms, between groups of physicians and payers, such coordinated activity may be condemned as *per se* illegal price fixing under the antitrust laws. But in its earlier advisory opinions, the FTC found that rule of reason analysis (which considers pro-competitive justifications) is appropriate for such activity when the joint negotiation of price is:

1. reasonably related to an efficiency-enhancing integration of the participants' economic activity; and
2. reasonably necessary to achieve the pro-competitive benefits of the integration.

Evidence of clinical integration, according to the FTC's early clinical advisory opinions, includes:

1. an organized process to control costs and improve quality of medical services;
2. selective choosing of network physicians who are likely to further the efficiency objectives; and
3. significant monetary investment and significant investment of human capital.

The Commission relied on these same standards to evaluate the TriState clinical integration proposal.

Process to Control Costs And Improve Quality of Medical Services

According to the Commission, TriState included several "structural and operational aspects that seem likely to result in significantly increased interaction and cooperation among its physician members in the treatment of patients covered under the program," including:

1. establishing a mostly closed panel of providers who will practice consistently with evidence-based medicine standards and clinical guidelines developed or tailored by program participants;
2. maintaining continuity and coordination of care through a within-network referral policy;
3. requiring use of health information technology, such as electronic health records;
4. establishing mechanisms to collect and evaluate treatment and performance data;
5. requiring broad participation of member physicians in several parts of the proposed program's development, implementation, and ongoing operation; and
6. establishing procedures and mechanisms to provide feedback on individual and group performance (including potential expulsion from the program for chronically poor performance).

The Commission recognized that the possibility of patient "leakage" to non-TriState providers could undercut some of the goals of the contemplated integrated care. The FTC also realized that the within-network referral policy would lead to less competition. It reached no conclusions about these tensions, other than indicating that these questions did not lead the Commission to reject the TriState proposal. Although TriState did not provide a significant amount of detail regarding how it will measure success or failure of the proposed program over time "on a more macro level, such as in terms of cost or utilization of services by covered populations, or improvements in health status or outcomes," the Commission noted that it would likely be a business necessity for TriState to provide performance outcome data over time in order to convince employers and other payers of the benefits of contracting with TriState. Accordingly the FTC was "reasonably confident" that TriState could implement, and would have the incentive to implement, mechanisms to measure and evaluate member physician performance.

The FTC also analyzed the effect of the hospital association member (which operates an affiliate hospital) on the program's overall ability to achieve the proposed efficiencies, and determined that the hospital association's effect was unclear. While the hospital has significant resources that would help the program operate more effectively, the hospital association is the largest employer in TriState's primary service area, and so its employee benefits program is the potential source of the largest number of covered lives for the proposed program. Ultimately, the FTC stated that "it is difficult to conclude one way or the other as to whether [the hospital association's] and its affiliates' involvement in TriState's operation is likely to enhance, undermine, or have no net effect on the ability and likelihood of TriState's achieving significant efficiencies as a result of the proposed program."

Selective Choosing of Network Physicians

TriState's proposed program would be open to all of TriState's current members and contracting members who agree to the program's requirements. The FTC noted that TriState is not initially selective because it does not exclude any providers from eligibility. But because the proposed program will impose several requirements that will likely discourage providers from joining, the FTC stated that those member physicians who do choose to participate in the program will be fully committed to the program's goals and requirements. The Commission found most important the fact that a requirement of participation is that each physician become a full member of TriState and execute a contract obligating the physician to participate and cooperate in all of the efficiency-enhancing aspects of the program.

Monetary and Human Capital Investment

Physician members of the proposed program would only be required to pay a small joining fee (approximately $2,500), to invest in computer and related equipment (approximately $2,600), and to devote time to being trained in the program's operation (approximate cost of about $2,500 in physician billing and office staff time for the average two-physician office). The Commission noted that the combined financial investment, though not trivial, is modest for many physician practices and is "unlikely, by itself, to be sufficiently great to strongly motivate the majority of TriState physicians to work toward the success of the program." But the Commission recognized

that the proposed program's success relies on "significant amounts of time and effort serving on TriState's formal and ad hoc committees, implementing guidelines and protocols in their practices, integrating medical management into their practices, collaborating in the care of their patients, and working together to achieve their quality and cost benchmarks." Because of this substantial human capital investment, in combination with "some degree of financial investment in the program," the Commission stated that there appeared to be a substantial degree of commitment to the proposed program's success.

Need and Justification for Joint Pricing and Collective Contracting

To justify clinical integration, the venture must also show that the joint pricing of services and collective negotiation of contracts with payers are "ancillary" to and reasonably necessary to achieve the proposed program objectives and integrative efficiencies. The Commission found here that a program without joint contracting would likely be "far more difficult, and potentially could compromise TriState's ability to effectively integrate its physician members' provision of care, and to achieve the program's potential efficiencies." The letter embraces Tri-State's arguments that "having a predetermined, identified provider network for all services provided pursuant to contracts with payers for the proposed program appears likely to promote the program's intended integration of its physician members' provision of care, and the efficient operation of the various aspects of the proposed program. It also may help in the effective branding and marketing of the program. Increased physician participation and interaction, in turn, should further TriState's ability to achieve the program's anticipated efficiency benefits."

Competitive Effects

TriState physicians comprise 64% of the hospital's medical staff, and half or more of the physicians in a large number of specialties in TriState's and the hospital's primary service area. There are no other IPAs or PHOs operating in the primary service area. Nonetheless, the Commission concluded that the fact that the proposed program will be non-exclusive, leaving payers free to contract individually with TriState member physicians and the hospital would limit the ability to exercise market power. The Commission cautioned that "the inability of a payer to attract sufficient individual TriState member physicians to contract outside of TriState likely would at least raise serious questions requiring further investigation and clarification. Consequently, non-exclusivity in practice is of critical importance to [the] conclusion that TriState proposed program is unlikely to create or allow it to exercise market power on behalf of its member participants, or to result in anticompetitive market effects."

Finally, the letter cautioned that if the "proposed program ultimately were to fail to achieve significant integrative efficiencies, the anticompetitive effects of the program would likely dominate. A prospective assessment of the program thus does not ensure its legality for all time."

Conclusion

The TriState letter does not create a sea change in the FTC's views on clinical integration, nor is likely to be embraced as the clear guidance affected industries have been seeking. It is a dense, nuanced assessment of a proposed program. The "good news" embedded in the 37-page opinion includes the facts that 1) the Commission was willing to "wave forward" a program that was still being developed and not yet been implemented 2) with no indication that all aspects of the program, such as all practice guidelines and the enforcement mechanism, had to have been completely formulated and in place before contracting took place 3) and without requiring that a heavy financial commitment was required, when the program involves significant investment of human capital in the form of physician member participation in committees, in developing and implementing clinical practice guidelines, in integrating medical management into individual practices, in monitoring quality, in collaborating on patient care, and in working to achieve quality and cost benchmarks.

Endnotes

[1] *Letter from Jeffrey W. Brennan, Assistant Director, Health Care Services & Products, Federal Trade Commission, to John J. Miles, Ober, Kaler, Grimes & Shriver (Feb. 19, 2002), available at http://www.ftc.gov/bc/adops/medsouth.shtm; Letter from Markus H. Meier, Assistant Director, Federal Trade Commission, Health Care Division, to John J. Miles, Ober, Kaler, Grimes & Shriver (June 18, 2007), available at http://www.ftc.gov/bc/adops/070618medsouth.pdf; Letter from Markus H. Meier, Assistant Director, Federal Trade Commission, Health Care Division, to Christi J. Braun, Esq. and John J. Miles, Esq., Ober, Kaler, Grimes & Shriver (Sept. 17, 2007), available at http://www.ftc.gov/bc/adops/gripa.pdf; see also Mintz Levin Client Advisory of June 22, 2007, available at http://www.mintz.com/newsletter/2007/Health-Antitrust-Alert-FTC-MedSouth-06-07/index.htm.*

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