

FTC Issues Advisory Opinion Approving Clinical Integration Program

April 30, 2009

TriState's Proposed Clinical Integration Program

In an April 13, 2009, advisory opinion, the Federal Trade Commission (FTC) Bureau of Competition stated that it has no present intention to recommend that the FTC challenge a clinical integration program (the Program) proposed by TriState Health Partners, Inc., a multi-specialty physician-hospital organization (PHO) based in Hagerstown, Maryland.¹ Under the Program, TriState will jointly contract with payors on behalf of its members. FTC staff concluded that the Program appeared to be a *bona fide* joint venture among TriState's members that has the potential to improve the quality of care and lower health care costs.

TriState has approximately 212 physician members who primarily serve Washington County, Maryland. Physician members include primary care physicians (PCPs), specialists and hospital-based physicians. Washington County Hospital Association, which operates Washington County Hospital, is TriState's hospital member. About 40 of TriState's physician members are employees of Washington County Hospital.

TriState's Program objectives are to:

- Facilitate and assure collaboration among the physician members, thereby improving patients' health
- Engage all TriState stakeholders in a program of comprehensive care management to increase the quality of care rendered to patients and increase the financial benefits to payors
- Allow TriState to offer an integrated set of services not previously available in the market

As part of its Program, TriState intends to engage in several activities:

- Implement a web-based health information technology system
- Develop clinical practice guidelines
- Monitor physician performance targets
- Implement policies and procedures related to the Program's utilization management, case management and disease management activities

Physicians who wish to participate in the Program must be or become TriState members, which entails certain financial obligations. Members will enter into participating provider agreements that will require them to:

- Provide TriState with patient and treatment information necessary to implement its programs
- Refer patients within the TriState network (when medically appropriate)
- Comply with TriState's clinical practice guidelines, rules and regulations
- Assist TriState in completing quality, safety and cost assessments
- Serve on TriState's clinical integration oversight subcommittees
- Cooperate in the development and implementation of the Program
- Use TriState's health information technology system

¹ In re TriState Health Partners, Inc. (April 2009), available at <http://www.ftc.gov/os/closings/staff/090413tristatealetter.pdf>

TriState will monitor each physician's compliance with Program requirements and provide physicians with performance data for benchmarking purposes. TriState has not attempted to quantify the potential or likely overall efficiency benefits of the Program, or how efficiencies will be measured.

Importantly, the Program will be non-exclusive, meaning that payors who do not wish to contract with the Program will be able to contract individually with TriState's member physicians and Washington County Hospital. Moreover, access to the services of Washington County Hospital will not be tied to the TriState program, but will be separately available to payors.

FTC staff reached three central conclusions. First, FTC staff found that the Program has the potential to create substantial integration among its participants, which could create significant efficiencies, including improved quality of care and more cost-effective care. FTC staff also found that TriState's joint contracting on behalf of its members appears to be related to its goal of delivering coordinated care and reasonably necessary to implement the Program and achieve its stated efficiencies. Finally, since TriState intends to operate on a non-exclusive basis, FTC staff found that it is unlikely that the Program will allow TriState or its individual members to increase or exercise market power in their respective markets.

In addition, FTC staff noted that the Program will impose a number of requirements—such as the obligations of the participation agreement—that are likely to discourage providers not fully committed to the Program from seeking to participate in the Program. FTC staff stated that a significant number of TriState physicians also appear to have made, and are likely to continue to make, non-trivial investments of time and effort in the development and ongoing operation of the Program. FTC staff concluded that TriState appears to have included in its program a variety of structural and operational aspects that seem likely to result in significantly increased interaction and cooperation in care delivery by its physician members.

Critical Considerations Raised by FTC Advisory Opinions and Guidance

TriState's program is the third clinical integration program proposed by a physician contracting network that FTC staff has approved in an advisory opinion. In 2002, FTC staff approved a clinical integration proposed by MedSouth, Inc., an independent practice association (IPA) located in Denver, Colorado.² Under MedSouth's proposal, primary and specialty care would be coordinated and integrated through a clinical resource management program in which all physician members in the MedSouth network would have to participate, and which would include the sharing of patient information via a web-based clinical data record system, the development and implementation of clinical protocols, and oversight and reporting of physicians' performance relative to established goals. In its MedSouth opinion, FTC staff stated that it would monitor the network's activities. Five years later, FTC staff issued a follow-up letter stating that it found no reason to rescind or modify MedSouth's 2002 advisory opinion.³ MedSouth's membership had declined by 32.5 percent since its inception, which FTC staff believes shows that a clinical integration program requires a "very serious" commitment and effort by physicians to engage in the activities that are necessary to achieve the beneficial objectives of such a program.

In 2007, FTC staff approved a clinical integration proposed by Greater Rochester Independent Practice Association, Inc. (GRIPA), an IPA located in Rochester, New York.⁴ Among other elements of its program, GRIPA sought to design, implement and apply evidence-based practice guidelines and quality benchmarks; monitor individual and collective performance in applying the guidelines and achieving benchmarks; and use a web-based electronic clinical-information system through which member physicians would share clinical information related to their common patients, order prescriptions and lab tests electronically, and access patient information from hospitals and ancillary providers throughout the community. FTC staff concluded that the proposed program would involve substantial integration among GRIPA's physician participants that had the potential to produce significant efficiencies, such as improved quality and the more efficient and appropriate provision of medical services, and that joint contracting was subordinate and reasonably related to GRIPA's planning integration and efficiencies. GRIPA's admission that it anticipated being able to contract at higher rates did not concern FTC staff, which found that GRIPA's higher fees were part of a program that sought to improve the overall quality and reduce the overall cost of care through primary care screening, preventive medicine services and other measures.

² FTC Staff Letter regarding MedSouth, Inc. (February 19, 2002), available at <http://www.ftc.gov/bc/adops/medsouth.shtm>

³ FTC Staff Letter regarding MedSouth, Inc. (June 18, 2007), available at <http://www.ftc.gov/bc/adops/070618medsouth.pdf>

⁴ FTC Staff Letter regarding Greater Rochester Independent Practice Association, Inc. (September 17, 2007), available at <http://www.ftc.gov/bc/adops/gripa.pdf>

FTC staff has also issued one unfavorable advisory opinion to a PHO proposing a clinical integration program. In 2006, FTC staff concluded that the integration and efficiency benefits of a program proposed by Suburban Health Organization (SHO), a super-PHO located in Indianapolis, Indiana, were limited, and that competitive restraints did not appear to be ancillary to those efficiency benefits.⁵ The FTC also failed to see how SHO's program would motivate its participants to act collaboratively.

Comparing some of the key elements of the programs proposed by these IPAs and PHOs highlights several issues that networks intending to clinically integrate for the purpose of collectively negotiating with payors should consider.

INFORMATION TECHNOLOGY AND CLINICAL PROTOCOLS

A key inquiry when assessing the legitimacy of a clinical integration program is the extent to which the program will seek to modify its physician participants' clinical practice behavior. In "Improving Health Care: A Dose of Competition," the FTC and the U.S. Department of Justice (DOJ) stated that two of the four primary *indicia* of clinical integration are the use of common information technology for the exchange of patient data, and the development and adoption of clinical protocols.⁶ All four clinical integration programs that have been the subject of advisory opinions have included the use of web-based information technology and clinical protocols, but to varying degrees.

MedSouth proposed a web-based electronic clinical data record system that would allow MedSouth physicians to share patient health information. Similarly, GRIPA proposed a web-based electronic clinical-information system in which GRIPA physicians would share clinical information related to their common patients and order prescriptions and lab tests electronically, and TriState proposed a web-based health information technology system that would enable the network to identify high-risk and high-cost patients and facilitate the exchange of health information in order to manage care. SHO proposed web-based technology to deliver and track patient information, but proposed to implement the technology over 18 to 24 months.

MedSouth's clinical protocols covered 80 to 90 percent of the prevalent diagnoses in the physician members' practices. As of June 2007, MedSouth had adopted clinical protocols for 60 major diseases. As of January 2007, GRIPA had approved 14 clinical practice guidelines and anticipated developing an additional two to four guidelines per month. As of mid-July 2008, TriState's board of directors had approved 18 clinical practice guidelines, and 30 other clinical practice guidelines were under development. By contrast, SHO's clinical integration program included the joint development of practice protocols and disease-specific treatment parameters, but only for four conditions—asthma, cardiovascular disease, congestive heart failure and diabetes.

MONETARY AND NON-MONETARY INVESTMENT

Another important issue is the extent of physician investment of time and/or money in program development. In both the TriState and GRIPA proposals, the physician members were to invest significant time and effort in developing elements of their respective clinical integration programs. By contrast, SHO physician members were not required to invest any money or significant time in SHO's proposed clinical integration program.⁷

COLLECTIVE MOTIVATION

Financial incentives may be a means to collectively motivate physician participants to seek to achieve network goals. At the time of the FTC staff's 2007 letter to MedSouth, the network had a major payor contract containing a pay-for-performance provision entitling it to a financial bonus if, as a whole, it met or exceeded specified performance targets. By contrast, if SHO physicians met certain quality performance targets, they would have been eligible to receive up to 5 percent of their compensation, but half of the bonus would have been based on individual, not collective, performance.

⁵ FTC Staff Letter regarding Suburban Health Organization, Inc. (March 28, 2006), available at <http://www.ftc.gov/os/2006/03/SuburbanHealthOrganizationStaffAdvisoryOpinion03282006.pdf>

⁶ Page 37 of Chapter 2 of "Improving Health Care: A Dose of Competition," A Report by the FTC and DOJ (July 2004), available at <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf>

⁷ SHO estimated that it would have made an initial investment of \$75,000 to \$100,000 and spent \$300,000 on annual operating costs of the program.

NETWORK COMPOSITION

The composition of a network may indicate whether the physician participants are likely to coordinate care in a meaningful manner. MedSouth, GRIPA and TriState's networks all include both PCPs and specialists. As of the date of MedSouth's 2007 follow-up letter, MedSouth's network included 75 PCPs and 205 specialists. As of the date of GRIPA's advisory opinion, GRIPA's network included 230 PCPs and 345 specialists. TriState's network includes approximately 212 PCPs and specialists. By contrast, SHO's network would have been composed of PCPs only, each of whom would have been employed by and practiced exclusively at their respective employer-affiliated hospitals. FTC staff concluded that other than the development of quality management programs, outcomes measurement and professional peer review, little interaction would have occurred between or among SHO's member physicians. The FTC also found that the inclusion of only PCPs in SHO's network appeared to preclude program efficiencies in the provision of services to patients requiring referrals to specialists or other non-participating physicians.

IN-NETWORK REFERRALS

Maximization of in-network referrals may also be important to the ability of a physician contracting network to demonstrate that its members are interdependent. Under both TriState and GRIPA's clinical integration programs, member physicians agree to refer to other member physicians. MedSouth's PCPs also exclusively refer to specialty physician members of MedSouth. Since SHO was composed solely of PCPs, SHO member physicians would not refer to one another.

MONITORING AND ENFORCEMENT

A physician contracting network's ability to enforce program requirements is another important element of a clinical integration program. MedSouth stated it would expel physician members who could not or did not fully participate in MedSouth's clinical integration program or adhere to its standards. GRIPA physician members who do not comply with the network's practice behavior, education and disciplinary requirements are subject to expulsion. TriState will monitor achievement of physician performance targets, and physicians who fail or refuse to conform their practices to the established Program parameters may face discipline or expulsion from the Program. By contrast, SHO's clinical integration program would have relied largely on each individual hospital both to motivate its own employed physician participants and to discipline physicians who failed to comply with clinical integration program requirements and standards. SHO had neither the authority or ability to discipline member physicians, nor any apparent authority to discipline a member hospital for failing to discipline a physician member, other than possible exclusion from SHO.

LIKELY COMPETITIVE EFFECTS

It is noteworthy that no clinical integration program approved by FTC staff in any advisory opinion was proposed by an exclusive network. The MedSouth, GRIPA and TriState provider networks were non-exclusive. SHO, on the other hand, was exclusive. Under TriState's Program, physician members would be required to participate in all contracts that TriState holds with payors, but payors that do not wish to contract with TriState would be free to contract individually with TriState's physician and hospital members. FTC staff stated that non-exclusivity in practice is "of critical importance" to their conclusion that the a clinical integration program is unlikely to result in anticompetitive effects.

It is also noteworthy that the FTC concluded that TriState is unlikely to be able to exercise market power for itself or its participants by implementing the Program. Washington County Hospital is the only hospital in Washington County, TriState's primary service area, and TriState physicians comprise 64 percent of Washington County Hospital's medical staff. FTC staff said that it was not clear whether other physicians practicing in TriState's service area will also be given the opportunity to join TriState and participate in the Program.

The FTC staff, in the TriState advisory opinion, takes a more liberal view of the permissible level of physician membership in a PHO whose hospital member is the only hospital in the market than the DOJ did in 1997 regarding the Santa Fe, New Mexico Managed Care Organization (SFMCO), a PHO located in Santa Fe, New Mexico, that proposed joint contracting on the basis of

financial integration.⁸ Like the hospital member of TriState, SFMCO's hospital member was the only general acute care hospital within its service area. A central element of SFMCO's financially integrated program was that, with limited exceptions, SFMCO would permit no more than 30 percent of the physicians practicing in any one specialty in the city of Santa Fe to be members of SFMCO.

WHETHER JOINT NEGOTIATION IS REASONABLY NECESSARY

In order for participants in a clinically integrated venture to jointly negotiate price and price-related terms, the joint negotiation must be reasonably necessary to achieve the legitimate pro-competitive purposes of the joint venture. In the MedSouth, GRIPA and TriState advisory opinions, FTC staff concluded that it was. MedSouth had argued that joint negotiation was necessary because MedSouth needed to ensure that all of the physician members participated in the clinical integration program. GRIPA argued that the benefits of its program could be achieved only if its member physicians are contractually bound to provide services through the network's participation agreement and payor contracts. TriState argued that full participation by its members in all payor contracts is reasonably necessary for TriState to integrate its members' services with quality improvement measures and medical management programs.

By contrast, FTC staff concluded that joint negotiation did not appear to be reasonably necessary in order to achieve SHO's potential efficiencies. SHO asserted that its clinical integration program created a new and different product from PCP services provided without the educational, monitoring, data collection and other potentially efficiency-enhancing features of SHO's program, which therefore justified joint price negotiation. FTC staff concluded that SHO's program may enhance the attractiveness of physician services but it did not constitute a new product. Also, in response to SHO's claim that joint negotiation was necessary to motivate the physician members to participate in the program, the FTC staff said that since all of the member physicians were employees of the member hospitals, the physicians likely would already be motivated to comply with requirements set by their employers.

Questions Clinically Integrated Provider Networks Must Be Prepared to Address

In "Improving Health Care: A Dose of Competition,"⁹ the FTC and DOJ set forth a series of questions that the FTC and DOJ are likely to ask when analyzing the competitive implications of a physician contracting network that jointly contracts on the basis of clinical integration. These questions focus on the key issues addressed by the FTC staff's advisory opinions, and include the following:

1. What do the physicians plan to do together from a clinical standpoint?
2. How are these activities designed to improve the quality of care, reduce the cost of care or produce other efficiencies?
3. How is the program designed to foster interdependence among the physician participants?
4. How will the physicians be collectively motivated to achieve those goals and efficiencies?
5. How significant will the physicians' investment—monetary and in the form of "human capital"—in the program be?
6. How will performance be monitored and measured?
7. What will be the consequences to an individual physician for non-performance or sub-performance?
8. Why is joint price negotiation reasonably necessary to achieve the intended benefits of the program?
9. What are the likely competitive effects of the physicians' joint negotiation?

Provider contracting networks that want to jointly contract on the basis of clinical integration—while minimizing their risk of violating the antitrust laws—should carefully consider these questions as they develop and implement their clinical integration programs.

⁸ DOJ Business Review letter, In re Santa Fe, New Mexico Managed Care Organization (February 12, 1997), available at <http://www.usdoj.gov/atr/public/busreview/1944.htm>

⁹ See Chapter 2, page 40 of "Improving Health Care: A Dose of Competition," *supra*.

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