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Clinical Integration: A Guide To Working With The Federal Trade Commission To Enhance Care Through Pro-Patient, Pro-Innovation, Pro-Efficiency Provider Networks

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Introduction

Clinical integration of independent healthcare providers has the potential to create significant benefits for practitioners and patients, in terms of both treatment and costs. For instance, where doctors can streamline information-sharing through online networks, and benefit from collectively developed medical protocols, it is not difficult to conclude that the quality of care, likelihood of innovation, and economic efficiency of the delivery of care increase tremendously. However, because clinical integration plans often lead to participating providers collectively negotiating their fees with insurers, these arrangements also have the potential to reduce competition in healthcare markets and drive up prices.

Recognizing both the advantages and inherent risks of clinical integration, the Federal Trade Commission (FTC) has attempted to clarify the circumstances in which providers may implement clinical integration programs while minimizing antitrust risk. As the announcement of a recent FTC workshop on clinical integration pointed out, the agency has an interest in making sure that "legitimate efficiency-enhancing joint venture activities are not discouraged." Understanding this guidance is key to successfully drafting and implementing a clinical integration plan.

We begin with a primer on basic antitrust principles governing the analysis of clinical integration programs and a list of the main sources of authority where these principles are set forth. As part of the review of relevant authority, we also recount a sampling of recent FTC advisory opinions to illustrate how the FTC has approached clinical integration arrangements. Finally, we attempt to distill recent guidance from the FTC into discrete principles for structuring clinical integration arrangements.

The Legal Framework

Governing Antitrust Principles, Authority

The landmark Supreme Court case of *Arizona v. Maricopa County Medical Society*, 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 so-called "Rule of Reason": Does the overall arrangement benefit consumers (in terms of treatment and cost) enough to outweigh the potential harm to competition, and are the aspects of the arrangement that threaten competition necessary to realize 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 collective bargaining is essential to the clinical integration scheme such that the countervailing advantages cannot reasonably be achieved without it. Generally speaking, this necessitates 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.

To understand how a proposed clinical integration arrangement will fare under agency scrutiny, several sources of broadly relevant information are available:

- **United States Department of Justice and Federal Trade Commission, 1996 Statements of Antitrust Enforcement Policy in Health Care, Statement 8.B.1.** This statement by the enforcement agencies indicates that joint contracting plans for nonfinancially integrated networks will pass antitrust muster if: (1) the clinical integration is likely to produce significant efficiencies that benefit consumers; and (2) any price agreements with payors are reasonably necessary to realize those efficiencies.
- **United States Department of Justice and Federal Trade Commission, 2000 Antitrust Guidelines for Collaborations Among Competitors.**This set of

guidelines issued by the enforcement agencies explains in detail the requirements that must be observed by any set of competitors who wish to create a joint venture or other collaboration such as a clinical integration arrangement.

- **United States Department of Justice and Federal Trade Commission "Improving Health Care: A Dose of Competition," 2004.** In this report, the enforcement agencies recount recent hearings and agency activity with respect to several healthcare-related antitrust issues, including clinical integration.
- **"Clinical Integration in Antitrust: Prospects for the Future," Remarks by J. Thomas Rosch, Commissioner, FTC, September 17, 2007**. In this speech, Commissioner Rosch traces the history of the FTC's current approach to clinical integration and summarizes some of its decisions.

Select Case Histories

In addition to these general resources, perhaps the most valuable guidance from the FTC comes in the form of its advisory opinions issued to provider networks with specific clinical integration proposals. Below are summaries of a selection of pertinent FTC advisory opinions, illustrating what is required for conditional approval by the agency and what is likely to prevent approval.

FTC Staff Advisory Opinion to Greater Rochester Independent Practice Association, Inc., September 17, 2007 (GRIPA)

GRIPA is a good example of a clinical integration program that successfully cleared the bar at the FTC in the advisory opinion review process. GRIPA proposed a program of joint contracting with payors 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 payors for the integrated services of more than 500 physicians, with more than 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 (a) presented an easily identifiable set of providers and referring physicians; (b) reinforced the internal referral system; (c) ensured that all physicians were working toward the same financial goals; (d) maximized the effect of the clinical integration program and opportunities for collaboration; and (e) 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: participation by a broad spectrum of specialists and the system of referrals to physicians within the network; a "serious" effort to encourage physician compliance through monitoring and potential expulsion; the high degree of investment by physicians; implementation of benchmarks; and 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 payors not able to reach an agreement with GRIPA would be able to negotiate with individual physicians, although it warned that GRIPA should not 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.

FTC Staff Advisory Opinion to MedSouth, Inc., February 19, 2002, and Follow-Up Letter, June 18, 2007 (MedSouth)

The case of MedSouth also is instructive as an example of a clinical integration program that passed muster with the FTC. MedSouth intended to establish nonexclusive joint contracting and a web-based data system permitting physicians to access and share clinical information about their patients. It would: (1) require its physicians to comply with the protocols; (2) monitor such compliance; (3) compare physician performance to network benchmarks; (4) develop corrective action programs for deficient performance; and (5) expel members who could not or would not comply with the program standards. Network members would contract with payors on a fee-for-service basis for the integrated package of services under the plan, but the physicians would not be prohibited from participating in other physician contracting organizations or from contracting with payors independently.

In its 2002 advisory opinion letter, the FTC concluded that the joint contracting component of MedSouth's plan appeared reasonably necessary for the integration of MedSouth's members based on two main observations. First, the success of the program depended on full participation by all the physician members, which could not be guaranteed if the physicians were required to contract with payors individually. Second, the joint contracting permitted the network to allocate returns to individual physician participants in order to provide incentives for the physicians to invest the necessary time and effort in the program.

In 2007, the FTC revisited the MedSouth network to see how it had performed in practice and whether, as implemented, it presented any anticompetitive issues. The FTC did not recommend challenging the MedSouth arrangement, but did express some concerns. First, the number of doctors participating in the network had significantly declined, which reduced market power concerns but also imperiled the benefits of a comprehensive network of doctors in all specialties. Second, important safeguards needed to be put in place to ensure the doctors could not share competitively sensitive information. Third, the FTC emphasized the importance of the mechanism for expelling noncompliant physicians and monitoring compliance. Fourth, the FTC found it important that patients and payors recognized MedSouth's integrated services as a product distinct from, and more valuable than, individual physician services, and that they were willing to pay for it.

FTC Staff Advisory Opinion to Suburban Health Organization, Inc., March 28, 2006 (SHO)

SHO is an excellent example of a program that did not receive the FTC's stamp of approval in the advisory opinion letter review process. SHO requested FTC guidance regarding a partial integration among several hospitals and their primary care physicians. SHO's joint contracting program involved negotiating rates of primary care physician services with payors and was the exclusive means by which payors could get access to those services. Its proposed clinical integration program consisted of: (1) "medical management activities," including patient monitoring and the adoption of practice guidelines and medical protocols with respect to asthma, cardiovascular disease, congestive heart failure, diabetes, and the provision of preventive healthcare services; (2) "quality management programs" to measure compliance with guidelines and protocols and their effectiveness and to identify opportunities for improvement using centralized, web-based technology; (3) "practice support," which involves distribution of educational materials to physicians and staff and credentialing programs; and (4) "a physician incentive plan," intended to encourage physician compliance through a bonus of five percent of their compensation in exchange for meeting quality management targets.

The FTC was critical of several facets of the clinical integration program. First, it found that SHO did not explain why it was necessary for multiple hospitals to be involved in the integration or why a single hospital could not reap the same benefits by implementing the programs independently. Second, it found that SHO relied too heavily on the individual hospitals to track, reward, and discipline doctors according to the quality management data collected through the centralized tracking system. Third, the FTC found a shortcoming in the program because SHO had no mechanism to discipline hospitals for not requiring, or monitoring, physician participation and compliance. Fourth, the FTC found very little evidence of "interdependence," the keystone of any clinical integration program.

The FTC also criticized the narrow focus of the clinical integration program, finding that it covered too few diseases and medical diagnoses, and that the inclusion of only primary care physicians, without specialists, limited the benefits of the program in terms of treatment. It found "implausible" SHO's claim that the program would track the effectiveness of referrals to nonparticipating specialists. Ultimately, the narrow focus of the clinical integration led the FTC to doubt that the joint contacting program was necessary to achieve the claimed efficiencies of the clinical integration program: "[I]t is not evident, and SHO provides no explanation, why agreement on the entire schedule of fees to be charged for all medical services performed by the employed primary care physicians in SHO is necessary to implement a program that only addresses treatment of a very limited subset of medical conditions treated by those physicians."

SHO offered several justifications for joint contracting and uniform pricing, including the claim that the new program, with the advent of the clinical integration component, was a "new product," distinct from the individual services for which payors previously negotiated and, therefore, it merited new, uniform pricing. SHO also argued that without uniform pricing, some hospitals might be tempted to charge higher prices than others while still reaping the benefits of the clinical integration program, resulting in an inequitable sharing of burdens and benefits. SHO further asserted that the contracting and pricing program was needed to motivate physicians to participate in the clinical integration program, and to reward it for the increased liability it would take on because of the implementation of clinical protocols. The FTC found none of the arguments persuasive and noted several alternatives to the horizontal price fixing arrangement that would ensure that SHO members were economically motivated to participate in the clinical integration program. It determined that the SHO program would, in fact, violate the antitrust laws because the joint contracting and pricing aspect was not reasonably necessary to achieve the "limited" benefits and efficiencies of the clinical integration program.

Below is a chart contrasting the key aspects of the GRIPA and SHO clinical integration plans and graphically demonstrating what the FTC may require to approve such an arrangement conditionally.

Aspect of Product	GRIPA [Approved]	SHO [Denied Approval]
Number of diagnoses and diseases covered by clinical integration	Expanded beyond core group to include several diagnoses, but maintains an emphasis on	Only core group of diagnoses. Diagnoses also limited by absence of

	core group.	specialists in network.
Agreement by physicians to refer in network	Yes, among primary care doctors and specialists.	No.
Both specialists and primary care physicians in network	Yes.	No.
Outlay of financial capital by physicians	Yes, in form of very specific start-up technology costs.	No.
Outlay of human resources by physicians	Yes, in form of significant training.	No.
Technology that enables multiple physicians to access patient information	Yes. Description of the information to be input and the hardware used in the physician's office was very specific.	No. There also was no need, as all doctors were primary care physicians.
Reduces paperwork by streamlining recordkeeping and enabling electronic lab orders, prescriptions	Yes.	No.
Mechanism for excluding physicians who do not comply	Yes, because GRIPA had an ongoing relationship with the	No.

with guidelines and standards	physicians who it oversaw.	
Joint contracting is nonexclusive	Yes.	No.
Joint contracting is only for services that also are part of the clinical integration program	Yes.	No.

Conclusions Drawn from FTC Opinions, Decisions

Aspects of Clinical Integration Program

FTC opinions and agency actions, including those noted above, make clear that the agency takes a hard look at the claimed efficiencies of clinical integration and the necessity of joint contracting for those efficiencies. Based on the FTC's statements, it is reasonable to believe that a qualifying clinical integration program must include the following elements:

1. Integration of institutions and practitioners that presents the opportunity for true collaboration and productive sharing of information reflecting actual "interdependence"
2. Participation of both specialists and primary care physicians with a requirement of in-network referrals
3. Treatment of a broad spectrum of diseases and disorders and corresponding clinical protocols
4. Integrated information technology whereby network participants can efficiently exchange information regarding patients and practice experience
5. Integrated information technology whereby utilization and claims information can be gathered, analyzed, and communicated in order to improve treatment quality, rates of utilization, and cost containment
6. Integrated information technology whereby physician compliance and performance, in accordance with collective, physician-authored benchmarks and standards, may be measured
7. A high level of physician investment, both economically and in terms of time for training and utilization of the system, and agreement among physicians to comply with the standards, benchmarks, and protocols put in place by the network
8. Enforceable consequences for noncompliance by physicians and institutions, and systems for improving performance and compliance

This list is not exhaustive, however, and the FTC has indicated that it will "focus on substance, rather than form, in assessing a network's likelihood of producing significant efficiencies." To that end, it will assess the impact of the clinical integration efforts on utilization, cost, and quality. 1996 Health Care Statements, Statement 8.B.1.

Necessity of Joint Contracting to Achieve Clinical Integration

The existence of sufficient clinical integration does not, by itself, guarantee that joint contracting by a physician network will pass muster under the antitrust laws. As evidenced by the FTC's decisions noted above, joint contracting must be reasonably necessary to accomplish the goals of the clinical integration plan, and the FTC will look carefully to see if there are alternative means of achieving efficiencies, other than joint contracting, that do not threaten competition. Based on the FTC's statements, a qualifying joint contracting program appears to require compliance with the following guidelines:

1. It should be nonexclusive and allow for independent contracting where payors and the network cannot come to agreement on terms, as this greatly reduces the chances that the arrangement will present significant antitrust risk
2. It should not involve unnecessary exchange of pricing information among physicians and hospitals
3. Price setting should be only for those services that are part of the clinical integration program

Conclusion

The confluence of the advent of new technology, a national focus on improving the delivery and cost of healthcare, and a desire on the part of antitrust regulators to encourage innovation have presented provider organizations with a unique invitation to develop new products. Following existing regulatory guidance and tracking new developments are key to taking the business of healthcare in exciting new directions.

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