

What is Clinical Integration and Why Is It So Important?

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Physicians typically, and traditionally, practice in small groups. According to the AMA Physician Practice Information Survey (2007-2008), 78 percent of office based physicians in the U.S. are in practices in sizes of nine physicians and under, with a majority of those physicians being in either solo practice or in practices of between 2 and 4 physicians. Under the antitrust laws separate groups of physicians that practice in the same or related specialty and are in the same geographic market are considered “competitors”. Therefore, if individuals and different physician groups come together and engage in certain concerted activities, such as collective negotiation of fees with individual payors, such action would be considered an illegal conspiracy among competitors and could be held to be a per se violation of the antitrust laws.

WHAT ARE THE STANDARDS FOR ANTITRUST REVIEW?

There are, generally, two standards to determine whether concerted action is “unreasonable” and a violation of the antitrust laws. The most common conduct is examined under the “Rule of Reason”. Under the Rule of Reason analysis, the plaintiff has the burden of establishing that a particular activity unreasonably restrains trade. The defendant does not have the initial burden of demonstrating that the challenged practice is reasonable. The Rule of Reason requires a weighing of all relevant circumstances of a case in order to determine whether a challenged practice constitutes an unreasonable restraint on competition in the relevant market. The Rule of Reason requires a balancing test. This requires a thorough examination of the industry or profession under review and a balancing of the challenged activity’s positive and negative effects on competition.

The “Per Se Rule” is an exception to the general Rule of Reason. The Per Se rule involves a limited analysis as to whether the alleged conduct occurred and, if it’s is found that the conduct occurred, whether the conduct that occurred falls within the category of conduct that has been condemned under the antitrust laws as per se illegal. If the conduct under review is subject to the Per Se rule, it is presumed to be illegal without the need for any elaborate examination as to the precise harm that it may have caused, or any justification for its use. There is no balancing test, and the defendant has no opportunity to argue that the activity had pro-competitive effects.

Specific practices that have been condemned by the courts as “per se illegal” include price fixing, horizontal allocation of customers, certain types of tying agreements and certain group boycotts. Thus, if physicians in distinctly separate medical practices (and therefore considered to be “competitors”) come together in order to collectively negotiate with individual payors, or to collectively agree to not deal with an individual

payor unless terms demanded by the physicians are met, such concerted activity could be found to be a per se violation of the antitrust laws.

Obviously, it is far preferable to have one's conduct examined under the Rule of Reason than the Per Se Rule. Under the Rule of Reason, not only does the plaintiff have the burden of showing that the conduct is unreasonable, but the defendant has the opportunity to demonstrate that, on balance, the conduct promoted competition.

The Department of Justice and Federal Trade Commission Statements
of Antitrust Policy in Health Care – August 1996

The FTC and the DOT have jointly issued policy statements to provide guidance to the health care profession. The Statements issued in 1996 provided revisions to guidelines that were issued in 1994. In the 1994 Statements, the agencies only discussed financial integration as a means through which physicians could come together to structure a collaborative physician joint venture or network through which physicians could negotiate prices without running afoul of the antitrust laws. The 1996 statements included a discussion of a new concept – Clinical Integration.

DO ANTITRUST SAFETY ZONES EXIST?

Statement 8 of the FTC and DOJ statements provides a “safety zone” for certain types of physician networks that share substantial financial risk. A “safety zone” describes conduct that neither the FTC nor the DOJ will challenge under the antitrust laws absent “extraordinary circumstances”.

The Statements establish somewhat different safety zones depending upon whether a network is “exclusive” or “non-exclusive”. In an exclusive network, the network's physician participants are restricted in their ability to, or do not in practice, individually contract or affiliate with other physician network joint ventures or health plans. In a non-exclusive venture, the physician participants in fact do, or are available to, affiliate with other physician networks or contract individually with health plans. The FTC and DOJ state that a truly non-exclusive network poses fewer antitrust risks than an exclusive network because payors can contract independently with network physicians and are not forced to solely contract with the network. As a result the Statements provide more latitude for non-exclusive networks.

Non-exclusive – A financially integrated physician network that is non-exclusive may receive safety zone treatment if it includes no more than 30 percent of the physicians in each specialty in the relevant geographic market.

Exclusive – A financially integrated physician network that is exclusive may receive safety zone treatment if it includes no more than 20 percent of the physicians in each specialty in the relevant geographic market.

Whether the physician network is exclusive or non-exclusive, in order to obtain safety zone treatment, the network must involve substantial financial risk sharing. The Statements provide that safety zones are limited to networks that involve substantial financial risk sharing not because such risk sharing is a desired end in itself, but because “it normally is a clear and reliable indicator that a physician network involves sufficient integration by its physician participants to achieve significant efficiencies”. According to the Statements, “Risk sharing provides incentives for the physicians to cooperate in controlling costs and improving quality by managing the provisions of services by network physicians”.

Statement 8 provides examples of types of arrangements through which participants in a network can share substantial financial risk:

1. agreement by the venture to provide services to a health plan at a capitated rate;
2. agreement by the venture to provide designated services or classes of services to a health plan for a predetermined percentage of premium or revenue from the plan;
3. use of the venture of significant financial incentive for its physician participants, as a group, to achieve specified cost-containment goals.

Two examples are:

- a. withholding from all participants in the network a substantial amount of the compensation due to them, with distribution of that amount to the physician participants based on group performance in meeting cost-containment goals of the network as a whole;
 - b. establishing overall cost or utilization targets for the network as a whole, with the network’s physician participants subject to subsequent financial rewards or penalties based on group performance in meeting targets:
and
4. Agreement by the venture to provide a complex or extended course of treatment that requires the substantial coordination of care by physicians in different specialties offering a complementary mix of services, for a fixed, predetermined payment, where the costs of that course of treatment for any individual patient can vary greatly due to the individual patient’s condition, the choice, complexity or length of treatment, or other factors.

The FTC and DOJ have emphasized that the arrangements above are merely examples. New types of risk sharing arrangements may develop. A physician network

may seek an advisory opinion if the physician network is uncertain whether a proposed arrangement would be found by the FTC and DOJ to constitute substantial financial risk sharing.

WHAT IS CLINICAL INTEGRATION?

Statement 8 reiterates that “naked price agreements” among competitors is illegal per se. However, the Statement 8 provides that a physician network that does not involve the sharing of substantial financial risk may nevertheless involve sufficient clinical integration and, accordingly, will merit evaluation under the Rule of Reason. According to Statement 8:

“Physician network joint ventures that do not involve the sharing of substantial financial risk may also involve sufficient integration to demonstrate that the venture is likely to produce significant efficiencies. Such integration can be evidenced by the network implementing an active and ongoing program to evaluate and modify practice patterns by the network participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality. This program may include: (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 these efficiency objectives; (3) the significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies.”

Statement 8 does not define “clinical integration” but gives examples of clinical integration. The FTC and DOJ emphasize that physician networks may consider and develop other arrangements that can evidence sufficient integration as to warrant Rule of Reason treatment. However, Statement 8 emphasizes that the FTC and DOJ will focus on substance, rather than form, in assessing a network’s likelihood of producing significant efficiencies.

WHAT ARE THE INDICIA OF CLINICAL INTEGRATION?

The FTC and DOJ provide further guidance regarding clinical integration in a jointly issued report Improving Health Care: A Dose of Competition (Jul 2004) see:

www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf

The report states that commentators and industry experts have identified four indicia of clinical integration. The four indicia are:

1. Use of common information technology to ensure exchange of all relevant patient data;
2. the development and adoption of clinical protocols;
3. Review of care based upon implementation of clinical protocols; and
4. Mechanisms to ensure adherence to protocols.

Other indicia mentioned in the report include physician credentialing, case management, preauthorization of medical care, and review of associated hospital stays.

The agencies stated that some commentators have asked the agencies to provide more definitive guidelines as to what constitutes clinical integration because without more specific guidelines, there is uncertainty regarding what types of clinical integration arrangements are required in order to warrant Rule of Reason treatment. The FTC and DOJ emphasized however that the agencies would not suggest particular structures that would achieve clinical integration because this would risk innovation and development of new clinical integration arrangements within the medical profession.

Nevertheless, the FTC and DOJ stated that in order to provide guidance, the agencies will outline some of the kinds of questions the agencies will ask when analyzing a physician network joint venture that claims to be clinically integrated:

1. What do the physicians plan to do together from a clinical standpoint?
 - What specific activities will be undertaken?
 - How does this differ from what each physician already does individually?
 - What ends are these collective activities designed to achieve?
2. How do the physicians expect actually to accomplish these goals?
 - What infrastructure and investment is needed?
 - What specific mechanisms will be put in place to make the program work?
 - What specific measures will there be to determine whether the programs is in fact working?
3. What basis is there to think that the individual physicians will actually attempt to accomplish these goals?
 - How are individual incentives being changed and re-aligned?
 - What specific mechanisms will be used to change and re-align the individual incentives?
4. What results can reasonably be expected from undertaking these goals?
 - Is there evidence to support these expectations, in terms of empirical support from the literature or actual experience?
 - To what extent is the potential for success related to the group's size and range of specialists?
5. How does joint contracting with payors contribute to accomplish the programs clinical goals?
 - Is the joint pricing reasonably necessary to accomplish these goals?
 - In what way?

6. To accomplish the group's goals is it necessary (or desirable) for physicians to affiliate exclusively with one IPA or can they effectively participate in multiple entities and continue to contract outside the group?

The FTC and DOJ emphasized that a joint venture must demonstrate that joint price negotiations are reasonably necessary to achieve substantial efficiencies arising from clinical integration.

FTC Advisory Opinions - Med South, GRIPA

Recent Advisory opinions issued by the Staff of the FTC may give guidance, or serve as a "road map" regarding the types of clinical integration arrangements the FTC will find to be acceptable, and not challenge.

1. MedSouth Advisory Opinion, February 19, 2002.

MedSouth is a multi-specialty IPA in Denver Colorado. At the time of the Advisory Opinion, MedSouth included approximately 432 physicians in 216 medical practices. Of the physician members, 101 were primary care physicians, and 331 were specialists in 39 specialties and subspecialties.

According to the FTC Staff, MedSouth's clinical integration program consists of two major parts:

First, the physicians will use an electronic clinical data record system that will permit them to access and share with one another certain kinds of clinical information relating to patients.

Second, the organization will adopt and implement clinical practice guidelines and measurable performance goals relating to the quality and appropriate use of services provided by MedSouth physicians. MedSouth will collect and analyze information on individual physician's performance and the performance of the network as a whole relative to benchmarks, and will discipline or terminate physicians who do not fully participate in the program and adhere to its standards.

The FTC staff agreed that MedSouth demonstrated that the collective negotiation was ancillary to the clinical integration and reasonably necessary to accomplish the goals of clinical integration. In order to establish and maintain the on-going collaboration and interdependence among physicians from which the efficiencies flow, the physicians need to be able to rely on the participation of other members in the network and its activities on a continuous basis. The FTC agreed that this did not appear to be possible if contracting for the sale of services is done individually. The price for professional services rendered under health plan contracts needs to be established, and if it is done through individual negotiation and contracting, then no one could count on the full participation on the group's members, according to the FTC.

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

GRIPA is an IPA located in Rochester, N.Y. At the time of Advisory Opinion, GRIPA included 636 physician members, 506 of whom were independently practicing physicians, and 130 of whom were employed by a non profit health care system consisting of two hospitals. In addition GRIPA contacted with an additional 119 physicians to provide certain medical specialty services. Overall, GRIPA included 717 physicians practicing in 41 medical specialties and subspecialties.

The FTC staff concluded that the GRIPA program appeared to “involve substantial integration by its physician participants that has the potential to result in the achievement of significant efficiencies that may benefit consumers”. Accordingly the FTC concluded that it would not recommend that the FTC challenge GRIPA’s clinical integration program. Among clinical integration found in the GRIPA program:

- The program includes components intended to assure that physicians use “best practices” and “evidence-based” medicine in treating patients.
- Patient’s treatment and the physicians’ individual and aggregate performance will be, monitored and measured against benchmarks for improved patient outcomes, and reduced costs and resource use.
- Disease management and case management programs will help patients comply with necessary self-care and behavioral recommendations from their doctors.
- The program will have a Web-based electronic clinical information system allowing physicians to share information regarding their common patients, access patient information from hospitals and ancillary providers throughout the community.
- Physicians will invest significant time and effort in collaboratively developing and overseeing implementation of practice guidelines and protocols.
- Physicians will participate in monitoring and evaluating their peers’ performance and addressing any performance deficiencies, including disciplining and, if necessary, even expelling from the organization physicians who continue to fail to comply with the program’s requirements and standards.

The FTC staff agreed with GRIPA that joint contracting is reasonably necessary in order to facilitate a pre-determined network of physicians, which is necessary to maximize the effective operation of the potentially efficiency enhancing activities.

GRIPA'S Potential Market Effect

The FTC found that GRIPA physicians constitute more than 35% of physicians in Monroe, Wayne, and Ontario counties in 14 of 44 medical specialties or subspecialties. In a few specialties, the percentage is considerably higher than 35%. Notwithstanding, due to the fact that GRIPA operates on a non-exclusive basis, the FTC stated that it would not recommend that the FTC challenge the GRIPA program.

HOW DOES CLINICAL INTEGRATION IMPACT UPON POSSIBLE ACOs?

An ACO consisting of individual physicians and small physician groups will have to negotiate fees with individual payors. If the ACO network chooses not to operate under programs that will involve sharing of substantial financial risk, the ACO will need to develop and implement clinical integration programs in order to avoid per se condemnation under the antitrust laws.

Some have argued that Clinical Integration and ACOs are really two sides of the same coin. If an ACO involves a network of individuals who come together and agree to be held accountable for the quality, cost and overall care of Medicare fee for service beneficiaries, this will require a high degree of cooperation and inter-dependence among the physician network members. The physician members of the ACO will need to have a high degree of cooperation if they are to meet quality performance standards and meet efficiency and savings goals. How will this be accomplished? It is likely that improving care coordination in order to enhance quality and efficiency performance will require the development and implementation of clinical integration programs.

As such revolutionary changes as the development of ACOs unfold in healthcare, physicians seeking to work in a more collaborative fashion must recognize the protections Clinical Integration can afford them through both securing Rule of Reason treatment under the antitrust laws and accomplishing cooperation, inter-dependence and coordination of care amongst ACO physician members.

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