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Provider Networks and Joint Ventures: Avoiding Antitrust Scrutiny Through Clinical Integration

By P. Gavin Eastgate

Health care providers who combine significant resources and share bottom line financial risk are not considered competitors and may legally negotiate fees with payers as a group. By contrast, collaborations and joint ventures among competing health care providers, like other agreements among independent firms, are subject to antitrust scrutiny because of their potential for suppressing competition and fixing prices. Joint ventures may also produce significant benefits to consumers that the venturing parties could not produce independently. The threshold question then becomes—without risk-sharing, what level of integration is required of competing providers in order to be considered a legitimate joint venture and not a price-fixing cartel?

Prior to 1996, there were only two clearly recognized ways for competing providers who wished to jointly negotiate with payers to avoid antitrust price-fixing concerns. First, the parties could employ a "messenger model" in which the individual or entity representing the providers simply shuttled back and forth between the providers and the payer with the fee proposals of each. Second, the parties could integrate financially. If competing providers invested significant resources in a joint venture and shared bottom-line financial risk, they would be permitted to jointly negotiate

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Reed Smith is pleased to announce that, beginning with this edition, *Health Law Monitor* will be available via a "blog" on the Internet. This new website, which will feature content from a variety of publications from Reed Smith's Life Sciences Health Industry ("LSHI") Group, is designed to make our informative newsletters more accessible by providing a more efficient, timely and environmentally friendly method of distribution. Since we will no longer be distributing this publication in hard copy format after the next edition, if you currently receive *Health Law Monitor* in hard copy, we invite you to send your email address to Erin Evans at *eevans@reedsmith.com* or to subscribe through the active blog site: *http://www.lifescienceslegalupdate.com/*. However, if you currently receive this publication via email, no further action will be required.

Stark II, Phase III Final Rule

By Heather M. Zimmerman

This article is dedicated to our friend, colleague, and fellow "Starkie," Kevin Barry, who after more than 20 years with Reed Smith, has entered the realm of public service by joining the HHS Office of Counsel to the Inspector General.

In December 2007, the Centers for Medicare & Medicaid Services' "Phase III" Stark Law regulations became effective. Phase III does not establish any new exceptions to the Stark Law. It does, however, make a number of important changes and clarifications to the existing regulations. A few of the more significant provisions are highlighted below.

> "In December 2007, the Centers for Medicare & Medicaid Services' "Phase III" Stark Law regulations became effective."

"Stand in the Shoes"

Prior to Phase III, a physician had an indirect compensation relationship with a DHS ("Designated Health Services") entity if between the physician and the DHS entity there was an unbroken chain of at least one other individual or entity that had a financial relationship with the DHS entity. For example, a physician had an indirect compensation relationship with a hospital if the physician was an owner in a group practice and the group had an agreement with the hospital to be compensated for call coverage. The physician could refer patients to the hospital for DHS as long as the call coverage arrangement met the requirements of the "indirect compensation" exception.

Under the new "stand in the shoes" provision, a physician is now deemed to have a direct compensation relationship with a DHS entity if the only intervening entity between the physician and the DHS entity is his or her physician organization. A "physician organization" is defined as a physician (including a professional corporation of which the physician is the sole owner), a physician practice, or a group practice. As a result, the physician in the above example would have a direct compensation relationship with the hospital, so the call coverage arrangement would need to meet the more stringent requirements of the "personal services" exception rather than the "indirect compensation" exception.

Direct Contract and On-Site Requirement for Independent Contractors

CMS modified the definition of a "physician in the group practice" to specifically require that any independent contractor physician furnishing patient care services for a group practice must have a direct contractual relationship group practice. It will no longer be sufficient, for example, for the president of a radiology practice to sign one contract with a group practice on behalf of all radiologists who will perform services for the group. In addition, CMS reiterated that independent contractors must perform patient care services "in the group practice's facilities" in order to qualify as a "physician in the group practice."

'Exclusive Use' of a Shared Facility

One model used by physicians to provide DHS to their patients in a shared facility (*e.g.*, an imaging suite, clinical laboratory, physical therapy office) is a "shared expense" model under which the physicians use the facility on an "as-needed" basis. A public commenter questioned whether a "shared expense" model that permits simultaneous use of the DHS facility complies with the "same building" requirements of the "in-office ancillary services" exception. CMS responded that a physician utilizing a

shared facility must have "exclusive use" of the facility at the time the DHS is furnished to that physician's patient and noted that, as a practical matter, "this likely necessitates a block lease arrangement." CMS further commented that "per use" fee arrangements are unlikely to satisfy the supervision requirement of the in-office ancillary services exception and may also implicate the federal anti-kickback statute. These statements are significant in that they could cause parties currently engaged in "as-needed" or "per-use" lease arrangements to restructure or dissolve their arrangements.

Elimination of Hourly Payment Safe Harbor

CMS made a significant change to the definition of "fair market value" that affects personal service arrangements involving compensation on an hourly basis. Specifically, CMS deleted the existing safe harbor that deemed hourly payment to a physician for personal services to be consistent with fair market value if the hourly rate was consistent with the average of certain community emergency room hourly rates, or was set at the 50th percentile level in specified national physician compensation surveys. Reasons cited for the withdrawal of the safe harbor included:

- Inconsistent availability of survey data
- Expense of obtaining survey data
- Difficulty in obtaining emergency room physicians' rates at competitor hospitals

Physician Recruitment Exception

The "physician recruitment" exception allows a hospital to furnish remuneration to a physician to induce the physician to relocate to the geographic area served by the hospital and become a member of the hospital's medical staff. Phase III makes several substantive changes to this exception.

The Phase II rule created a controversial requirement prohibiting an existing medical practice from imposing "additional practice restrictions" (*e.g.*, a non-compete provision) on a physician if that medical practice received money from the hospital to recruit the physician. Phase III revised this requirement to now permit a medical practice to impose restrictions as long as they do not "unreasonably restrict the recruited physician's ability to practice medicine in the geographic area served by the hospital." CMS indicated that several types of restrictive covenants may now be permissible, including:

- Post-employment non-competition agreements
- Restrictions on moonlighting
- Prohibitions on soliciting patients and/or employees
- Requiring that the recruited physician treat Medicaid and indigent patients
- Requiring the recruited physician to repay losses that are absorbed by the medical practice in excess of any hospital recruitment payments

Under Phase II, the "geographic area" served by the hospital was defined as the lowest number of contiguous postal zip codes from which the hospital draws at least 75 percent of its inpatients. In response to public comments suggesting that this definition was too narrow, CMS expanded the definition in certain instances. For a hospital for which no combination of contiguous zip codes represents at least 75 percent of the hospital's inpatients, the hospital's geographic service area can now encompass all of the contiguous zip codes from which the hospital's inpatients are drawn. For a hospital located in a rural area, the geographic area is that composed of the lowest number of contiguous zip codes from which the hospital draws at least 90 percent of its inpatients. If the rural hospital draws fewer than 90 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, the hospital may include noncontiguous zip codes—beginning with the noncontiguous zip code in which the highest percentage of the hospital's inpatients reside—and then continuing to add noncontiguous zip codes in decreasing order of percentage of inpatients.

Finally, CMS expanded the types of physicians who can qualify for recruitment by expanding the relocation requirement to include physicians who were employed during the preceding two years on a full-time basis by a federal or state bureau of prisons or similar entity to serve exclusively a prison population, the Department of Defense or Department of Veterans Affairs to serve active or veteran military personnel and their families, or facilities of the Indian Health Service to serve patients who receive medical care exclusively through the Indian Health Service.

Non-Monetary Compensation Exception

The "non-monetary compensation" exception protects non-monetary compensation (such as gifts, meals, entertainment, etc.) provided to referring

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physicians up to $300 per year (adjusted annually for inflation according to the CPI-U) in specified circumstances. Phase III expanded the exception in two ways to protect certain non-monetary compensation in excess of the $300 limit ($329 in CY 2007 accounting for inflation).

First, the exception now provides that the value of an annual "medical staff appreciation event" will no longer be counted towards the $300 limit. To qualify for the exemption, the medical staff appreciation event must be held locally and be open to all medical practitioners in the entity's formal medical

In the Spotlight: Fraud and Abuse

This issue of the *Health Law Monitor* contains two articles on fraud and abuse topics. Allegations of fraud and abuse can instantly threaten your health care concern and destroy the good will you've taken years to build. Reed Smith's Health Care team helps structure operations to prevent violations and perceived violations, and aggressively defends client interests if and when charges are brought.

We advise on federal and state anti-kickback laws; physician self-referral restrictions, including the "Stark Law's" prohibitions and exceptions; restrictions on beneficiary inducements; the False Claims Act; and other civil and criminal laws.

Our team conducts legal audits of existing contracts and operations, and develops tailored, comprehensive compliance programs. We provide counsel regarding regulatory and legislative developments such as existing and proposed "safe harbor" regulations, the Office of Inspector General's Special Fraud Alerts, and the Medicare Prescription Drug, Improvement and Modernization Act.

Firm lawyers structure contractual arrangements between health care entities, including joint ventures, discount and bundling arrangements, employer/employee relationships, and integrated delivery systems. We advise on relationships with physicians, vendors, distributors, GPOs, and managers. We conduct due diligence reviews, and advise on new financial offerings and prospectuses.

We minimize risk by consulting with and obtaining guidance from the Office of Inspector General ("OIG"), the Centers for Medicare & Medicaid Services ("CMS"), and the U.S. Department of Justice.

When disputes arise, Reed Smith has the firepower to provide a strong defense. The firm has built a leading regulatory litigation practice, and our attorneys have defended clients subject to civil and criminal investigations; actions brought by the OIG and Department of Justice; and whistleblower matters, at both the state and federal level.

Representative Matters

- Negotiated for a leading health care provider a global settlement agreement with the U.S. Department of Justice – Civil Division, the Office of Inspector General of the Department of Health and Human Services, and the Centers for Medicare & Medicaid Services to resolve issues associated with various Medicare billing practices. The settlement agreement included a cash payment, and resolved additional qui tam lawsuits filed by "whistle-

staff. Any "gifts or gratuities" provided will continue to be subject to the non-monetary compensation limit.

Second, non-monetary compensation given in excess of the limit will not violate the exception so long as its value is no greater than 50 percent of the limit, and the physician repays the excess, either before the end of the calendar year in which the physician received it or 180 days from the date the physician received it (whichever is earlier). The parties may use this exception for excess compensation only once every three years.

For a more detailed description of the changes discussed above, as well as the entire Phase III rule, please see our October 4, 2007 memorandum "CMS Stark II (Phase III) Final Rule" available on the Reed Smith website at *http://www.reedsmith.com/_db/_documents/Health_Care_Client_Memo_Stark_II.pdf*.

blowers" under the False Claims Act. The settlement also included an agreement by CMS to withdraw all pending administrative appeals and related federal court cases, and the administrative closure of all Medicare cost reports.

- Helped several major metropolitan hospital systems respond to a malpractice insurance crisis and preserve the availability of affordable insurance for independent physicians practicing at their facilities. Firm lawyers structured novel arrangements addressing anti-kickback and Stark Law concerns.
- Counseled one of the largest global pharmaceutical companies concerning Medicare fraud and abuse issues; Medicare coverage, coding and payment; and reimbursement.
- Advised a well-known web-based company on avoiding fraud and abuse risk in the operation of its online service, which includes patient referrals.
- Obtained favorable OIG advisory opinions in a number of matters involving drug and device companies.
- Negotiated Corporate Integrity Agreements, which have minimized administrative burdens, on behalf of both providers and manufacturer clients.
- Advised an international vaccine manufacturer on a wide range of fraud and abuse and compliance issues, principally under the federal health care anti-kickback law. This included providing advice on pricing, discounting, bundling, and marketing practices, as well as revising sales contracts.
- On behalf of a health care company, analyzed and assessed the risk of fraud and abuse of various arrangements, including disease management programs, arrangements with PBMs and HMOs, and nominal pricing.
- Served as special counsel to two leading long-term care providers in connection with ongoing regulatory compliance matters.
- Assisted a major pharmaceutical and device manufacturer in getting False Claims Act claims dismissed in Puerto Rico.
- Represented a leading pharmacy benefits manager in a qui tam case challenging manufacturer discounting relationships.
- Conducted an internal review for a publicly owned hospital company related to Department of Justice ("DOJ") subpoenas investigating hospital, physician groups, and medical device manufacturers for potential civil false claims liability for an institutional device exemption ("IDE"). We managed large document production, coordinated joint defense issues with counsel for other parties and experts, and led development of a "white paper" presentation to DOJ on analysis of alleged claims, which led to the investigation being discontinued.

Health Law 101: Health Care Fraud and Abuse

By Rahul Narula and Jamie Schreiber

National estimates project that billions of dollars are lost every year to health care fraud and abuse. Generally, health care fraud is an act of misrepresentation, deception, or deceit for the purpose of receiving greater reimbursement from federal health care programs such as Medicare and Medicaid. Health care abuse is conduct that goes against and is inconsistent with acceptable business and/or medical practices, also resulting in greater reimbursement. To limit health care fraud and abuse, the federal government relies heavily on two statutes: the anti-kickback law, and the physician self-referral law, also known as the Stark Law.

> "To limit health care fraud and abuse, the federal government relies heavily on two statutes: the anti-kickback law, and the physician self-referral law, also known as the Stark Law."

What is the Anti-Kickback Statute?

In 1972, Congress passed the Anti-Kickback Statute, which made it illegal for anyone involved in the health care industry to knowingly and willfully receive or pay anything of value to influence the referral of federal health care program business, including Medicare and Medicaid. The impetus for the Anti-Kickback Statute was to protect patients and federal health care programs from fraud and abuse by limiting the influence of money on health care decisions. However, the reach of the Anti-Kickback Statute is broad, and the health care industry began to express concern that the law actually prohibits harmless, and potentially even beneficial, arrangements. Congress responded to these concerns in 1987, when it authorized the Department of Health and Human Services, through the Office of Inspector General ("OIG"), to issue regulations setting out exceptions for various business arrangements that, while potentially prohibited by the anti-kickback law, would not be prosecuted. There are now more than 20 such exceptions, called safe harbors. The OIG also addresses specific business arrangements through the issuance of advisory opinions.

The Statute

The anti-kickback law, at 42 U.S.C. § 1320a-7b(b), establishes criminal penalties for anyone who "knowingly and willfully" solicits or receives or offers or pays "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind" in return for a referral, purchase, lease, order, or arranging for or recommending the purchase, lease, or order of any good, facility, service, or item for which payment may be made in whole or in part under a federal health care program.

There are two key elements of the Anti-Kickback Statute. The first element is the "knowingly and willfully" requirement; for prosecutors to obtain a conviction for an anti-kickback violation, they must prove criminal intent, which is often difficult to do. The second element is the inducement factor. The OIG, following the direction of several circuit courts, has interpreted the Anti-Kickback Statute to cover any arrangement where one purpose of the remuneration is to induce referrals, even if there are other legitimate purposes of the remuneration (*e.g.*, for professional services rendered).

Penalties associated with the Anti-Kickback Statute include a fine of no more than $25,000, imprisonment, or both. In addition, violators are subject to exclusion from participation in federal health care programs, such as Medicare and Medicaid, whether or not there has been a criminal conviction, as well as the imposition of civil monetary penalties.

The Statutory Exceptions and Safe Harbors

Because of the breadth of the Anti-Kickback Statute and the limitations it places on the ability to conduct business transactions, Congress also created eight statutory exceptions that allow for some discounting and risk-sharing agreements. For example, the Anti-Kickback Statute does not apply to any amount paid by an employer to an employee for the provision of covered items or services (such as a hospital's payment of a salary to a physician-employee), nor does it apply to a manufacturer's sale of drugs at a discount. In addition, the statute does not apply to various regulatory safe harbors adopted by the OIG. The safe harbors cover a variety of conduct, including certain personal service arrangements, discount arrangements, and payments for bona fide services. A list of the safe harbors can be found on the OIG's website. It is worth noting that noncompliance with a statutory exception or safe harbor does not necessarily mean that an arrangement is illegal.

OIG Advisory Opinions

Occasionally the OIG issues formal and informal guidance to provide further information about the types of conduct that the OIG considers to be permissible or in violation of the Anti-Kickback Statute. Such guidance includes Fraud Alerts, Compliance Guidance, and Advisory Opinions. An Advisory Opinion is a legal opinion issued by the OIG to one or more requesting parties about the legality of a proposed or existing business arrangement; it is binding on the OIG and the requesting party, but is only an indication of the OIG's method of analysis and probable conclusions for other transactions.

When Does an Arrangement Violate the Anti-Kickback Statute?

Determining whether an arrangement violates the Anti-Kickback Statute is a multi-step process that is very fact-specific. In general, one must first determine whether the arrangement in question involves any remuneration. Second, one must determine whether the remuneration is intended to induce some sort of referral, purchase, or recommendation covered by the anti-kickback law. If so, the third step is to question whether the parties are acting knowingly and willfully; if they are, the fourth step is to determine whether any statutory exception or regulatory safe harbor applies. If not, the arrangement is not necessarily illegal, but it could be suspect.

Health care providers and other industry members should engage in this type of analysis with every business arrangement they undertake to ensure that they are not violating the anti-kickback law.

What is the Physician Self-Referral or "Stark Law"?

The physician self-referral prohibition ("Stark I") was introduced in 1989 by Representative Fortney "Pete" Stark (D-Cal.) with the purpose of prohibiting physicians from referring patients for laboratory services to entities in which the physicians had a financial interest. Congress amended Stark I in 1993, expanding the self-referral limitations from clinical laboratory services to numerous other health services ("Stark II" or "Stark Law"). The rationale behind enactment of the Stark Law stems from the general notion that physicians face an inherent conflict of interest given a physician's position to benefit from certain referrals. According to the Center for Medicare and Medicaid Services ("CMS"), if a physician has a financial incentive to refer, the incentive can adversely affect:

- Utilization by encouraging overutilization of services that would lead to increasing health care costs
- Patient choice by encouraging physicians to steer patients
- Competition by changing the parameters upon which the medical marketplace competes.

The Stark Law and its Key Terms

The Stark Law establishes two general prohibitions: (1) it prohibits a physician from ordering "designated health services" ("DHS") for Medicare patients from entities with which the physician (or an immediate family member) has a "financial relationship," and (2) it prohibits the entity to which a prohibited referral is made from presenting a claim to Medicare or billing any individual, third-party payor or other entity for any service provided pursuant to such a referral.

The term "DHS" includes:

- Clinical laboratory services
- Physical therapy, occupational therapy and speech language pathology services
- Eadiology and certain other imaging services
- Radiation therapy services and supplies
- Durable medical equipment and supplies
- {arenteral and enteral nutrients, equipment, and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies;
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services.

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The term "referral" means, for Medicare Part B services, "the request by a physician for the item or service" and, for all other services, "the request or establishment of a plan of care by a physician that includes the provision of the designated health service," and "entity" refers to the provider that submits a claim to Medicare for the DHS ordered by a physician. A "financial relationship" may include:

- A direct ownership or investment interest;
- An indirect ownership or investment interest;
- A direct compensation arrangement; or
- An indirect compensation arrangement.

Penalties and Sanctions

Unlike the Anti-Kickback Statute, the Stark Law is a "strict liability" statute; therefore the government does not have to generally prove the intent of the parties to find a Stark Law violation. Violations of the Stark Law are subject to various penalties, including:

- Denial of payment for the DHS provided;
- Refund of monies received by physicians and facilities for amounts collected on a timely basis;
- Payment of civil penalties of up to $15,000 for each service that a person "knows or should know" was provided in violation of the Stark Law, and three times the amount of improper payment the entity received from the Medicare Program;
- Exclusion from the Medicare program and/or state health care programs including Medicaid; and
- Payment of civil penalties for attempting to circumvent the Stark Law of up to $100,000 for each circumvention scheme.

Regulations and Exceptions

In an attempt to find a balance between monitoring fraud and allowing physicians to provide efficient care, Congress authorized CMS to promulgate regulatory interpretations of the Stark Law that include several exceptions that insulate certain conduct that would normally be suspect. To date, CMS has issued three regulations for Stark II.

Stark Law exceptions fall into three general categories:

- General exceptions that apply to both ownership/investment interests and to compensation arrangements;
- Exceptions that apply only to ownership or investment interests; and
- Exceptions that apply only to compensation arrangements.

For example, the "Physicians' Services Exception" applies to both ownership and compensation arrangements by protecting any referrals a physician makes for physician services that are DHS, if those services are furnished:

- Personally by another physician in the same group practice as the referring physician; or
- Under the supervision of another physician in the same group practice.

Because the Stark Law is a strict liability statute, it is important for a physician to understand whether an arrangement implicates the Stark Law and, if so, whether it can be structured under a valid exception.

How Does One Analyze an Arrangement under the Stark Law?

A three-step analysis is useful in evaluating transactions and arrangements to

determine compliance with the Stark law:

(1) Has there been a referral by a physician to an entity for the furnishing by the entity of a designated health service?

(2) Is there a financial relationship between the physician (or an immediate family member) and the entity in the form of either: a direct or indirect ownership or investment interest; or a direct or indirect compensation arrangement?

(3) If the answer to both questions is yes, does the financial relationship fully satisfy one of the exceptions?

Conclusion

Given the increasing aggressiveness of the federal government in the area of health care fraud, it is important for health care providers, suppliers, and manufacturers to be more cautious of both the anti-kickback law and the Stark Law, and their relevant exceptions.

Provider Networks and Joint Ventures: Avoiding Antitrust Scrutiny…

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fees and other payment terms with payers if the benefits to consumers flowing from the joint venture (increased quality of care and reduced costs) outweighed the joint pricing risk (higher prices) resulting from a decrease in competition. Without substantial financial integration, however, jointly negotiating fees with payers could be found to constitute per se illegal price fixing in violation of Section 1 of the Sherman Act.

In 1996, the Justice Department and the Federal Trade Commission issued revised *Statements of Health Care Antitrust Enforcement Policy*, which provided new examples of financial integration and announced that "clinically integrated" joint ventures may pass antitrust scrutiny even without substantial financial integration. The concept of clinical integration in the 1996 *Statements* requires an "active and ongoing program to evaluate and modify practice patterns" of the physician participants that creates "a high degree of interdependence and cooperation" between the physicians to "control costs and ensure quality." To avoid antitrust scrutiny, the parties must demonstrate that joint pricing is reasonably necessary to the achievement of cost efficiencies and quality improvements generated through clinical interdependence and cooperation.

In the decade following the 1996 *Statements*, the lack of guidance as to what constitutes sufficient clinical integration, and the expense involved in adopting new programs and systems to control costs and ensure quality, have largely dissuaded providers from taking advantage of this clinical integration "safety zone." In an effort to provide additional guidance regarding clinical integration, over the past few years, the Federal Trade Commission ("FTC") Staff has issued several advisory opinion letters, and one of the Commissioners has presented prepared remarks at an antitrust healthcare conference. This article will review the recent guidance letters issued by the FTC Staff and the remarks of Commissioner J. Thomas Rosch, and briefly examine what they mean for competing providers seeking to integrate clinically but not financially.

MedSouth, Inc.

In 2002, MedSouth sought an advisory opinion regarding its proposed joint venture, which included contracting with payers on behalf of all of MedSouth's physician members on terms agreed upon by the physicians, including the prices to be charged and paid for services. By letter dated Feb. 9, 2002, FTC Staff concluded that the proposed program had the "potential to increase the quality and reduce the cost of medical care that the physicians provide to patients," and that the "joint contracting appears to be sufficiently related to, and reasonably necessary for, the achievement of the potential benefits to be regarded as ancillary to the operation of the joint venture." As a result, the proposed venture was permitted to move forward, but the FTC Staff warned that it would closely monitor the competitive effects of the venture.

In June 2007, the FTC Staff issued a follow-up opinion, reaffirming the staff's decision not to challenge the MedSouth joint venture. The opinion initially notes that achieving clinical integration of the level required to avoid antitrust scrutiny is "not simple, easy or costless." The Staff emphasizes that clinical integration may necessitate selectively restricting participation in the network, both initially and as the venture continues, including even dismissing persistently uncooperative members. It may also require significant investment in the venture by the physician participants, either in terms of money or time, in order to assure that all participants are committed to working together to

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achieve the quality and cost efficiencies. The opinion further notes that clinical integration must involve some or all of the following aspects or characteristics:

- Development or adoption of appropriate performance standards and goals, referral guidelines or requirements, or other performance criteria and measures for the participants, both individually and as a group
- Establishment of mechanisms, including information systems that permit collection and analysis of relevant data to monitor and evaluate both individual and group performance relative to the established standards, goals and measures
- Provision for appropriate educational, behavior modification, and remedial action, where warranted, to improve both individual and group performance

The usefulness of these tools is measured through cost reduction and improved quality or efficiency in the provision of medical care. For a program to be successful, there must also be an appreciation by employers, patients, and payers of the benefits of clinical integration programs and a willingness by these parties to contract for what the programs offer. Lastly, a key factor in the FTC's decision to permit the program to move forward concerned the non-exclusivity of the physician network. Payers wishing to contract with MedSouth physicians outside of the programs are able to do so.

"A key factor in the FTC's decision to permit the program to move forward concerned the non-exclusivity of the physician network."

The FTC Staff recognized in its 2002 letter that the MedSouth program appeared to have the potential to achieve significant efficiencies in the provision of medical care by MedSouth's physician participants. After a review of the information provided by MedSouth in response to the FTC's request, there was no evidence that the MedSouth arrangement was having any anticompetitive effect in the market for physician services in the Denver area. Accordingly, the Staff saw no need to modify or correct its prior conclusions. The MedSouth program is achieving sufficient efficiencies to permit its continued operation.

Remarks of FTC Commissioner J. Thomas Rosch

The MedSouth opinion letter was followed in September 2007 by a somewhat conflicting viewpoint from current FTC Commissioner J. Thomas Rosch.* Commissioner Rosch provided a brief review of clinical integration as introduced in the 1996 *Statements*, and he commented on the recent opinion letters issued by the FTC Staff. Commissioner Rosch contrasted the 2007 MedSouth opinion letter with the Staff's 2006 letter to Suburban Health Organization. He emphasized several lessons to take away from these opinions:

- Even if there is clinical integration likely to create efficiencies, the analysis must still consider whether the competitive restraint (joint pricing) is reasonably necessary to create the integration and achieve the efficiencies.
- Where multiple groups are involved, there must be an explanation of why it is not reasonably practicable for each group to achieve the efficiencies on its own. In Suburban Health Organization's case, it did not show why the individual hospital members on their own could not develop educational materials, adopt practice protocols, monitor compliance, and encourage participation.
- There must be a detailed explanation of how the participating members

will work together to achieve the program's goals.

- If the group already employs a legal and effective "messenger model" and is providing the same programs to improve services as it proposes to offer jointly, that undercuts arguments as to the necessity for joint negotiation of fees.
- Physicians should not underestimate the difficulty in establishing an effective clinical integration program. This includes the time, expense and commitment required to operate the program, as well as attracting payers willing to purchase its offerings.

In addition to noting that successful clinical integration is an extremely onerous and expensive task for provider groups, Commissioner Rosch expressed skepticism that clinical integration alone can generate sufficient procompetitive benefits to outweigh the anticompetitive effects flowing from joint pricing. Without a strong system of rewards and punishment to create the proper incentives for clinical integration, Commissioner Rosch doubts that provider groups can meet the "reasonable necessity" proof required to permit joint pricing. The safest and most realistic form of integration, the Commissioner opines, is *financial* integration.

GRIPA

Finally, in September 2007, the FTC Staff issued another opinion letter on clinical integration, stating that the FTC would not challenge a plan by a Rochester, New York, group, the Greater Rochester Independent Practice Association, Inc. ("GRIPA"), to collectively negotiate with payers. GRIPA requested a staff advisory opinion concerning its proposal to integrate and coordinate the provision of medical services to patients by about 575 physicians in 41 medical specialties through a program of "clinical-improvement services," through which the physicians would work together to improve quality and control costs. GRIPA's proposed program includes the following components:

GRIPA will operate as a non-exclusive network, which means that its individual physician members will be available to negotiate and contract separately with health plans and other customers not wishing to purchase the network services.

Physicians generally will be required to refer patients to physicians within the network, in order to better assure that care is subject to GRIPA's treatment standards at all times, and to better monitor treatment and outcomes. The program includes several components intended to assure that its physicians use "best practices" and "evidence-based" medicine in treating patients.

Patients' treatment and the physicians' individual and aggregate performance will be carefully 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 an extensive 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; and order prescriptions and lab tests.

In addition to agreeing to adhere to all of GRIPA's practice requirements under the program, the physicians, who have a history of working together under GRIPA's HMO risk contracts, will invest significant time and effort in collaboratively developing and overseeing implementation of the program's practice guidelines and protocols. They also 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 adhere to its standards.

The FTC Staff concluded that joint contracting by GRIPA appeared to be subordinate to the program's primary purpose of interdependently improving the quality and efficiency of the member physicians' services, and appeared to be "subordinate to, reasonably related to, and may be reasonably necessary for, or to further, GRIPA's ability to achieve the potential efficiencies" from the program. Staff concluded that it would not recommend a challenge to the program "unless it became apparent that GRIPA in fact was able to exercise market power or otherwise have an anticompetitive effect in a relevant market."

Conclusion

The *MedSouth* and *GRIPA* opinions make clear that, although it may be difficult to achieve, clinical integration provides a means by which providers can jointly negotiate with payers and avoid antitrust scrutiny without financially integrating their operations. However, at least one current FTC Commissioner remains skeptical of clinical integration without financial integration. Prudent planning and commitment to executing a clinical integration program can lead to

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improved quality care and lower health care costs. Where provider joint ventures can demonstrate that joint pricing is reasonably necessary to the achievement of these cost efficiencies and quality improvements, these programs should be viewed as efficiency-enhancing and not as vehicles for price fixing. Reed Smith's Antitrust Health Care attorneys are ready to assist providers in navigating the legal complexities involved in clinical integration.

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* *Clinical Integration in Antitrust: Prospects for the Future*, Remarks of J. Thomas Rosch, FTC Commissioner, American Health Lawyers Association 2007 Antitrust in Healthcare Conference, Sept. 17, 2007, available at: *http://www.ftc.gov/speeches/rosch/070917clinic.pdf*. As with all remarks by FTC Commissioners, the views reflected by Commissioner Rosch are his own and do not necessarily reflect the views of the Commission or other Commissioners.

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