CHAPTER 25

ANTITRUST CONCERNS IN THE FORMATION AND OPERATION OF PROVIDER NETWORKS

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SCOPE

In this chapter, the author provides an overview of the antitrust and other regulatory issues under state and federal law that may impact the formation and operation of networks of physicians such as IPAs and PHOs. State and federal antitrust laws are discussed, as well as state and federal laws prohibiting physician self-referrals and prohibiting kickbacks for referrals. Several recent cases of antitrust enforcement initiated by the FTC against physician groups are discussed, as are the DOJ/FTC *Statements of Antitrust Enforcement in Health Care.*

SYNOPSIS

§25.01 Introduction

Any discussion of the formation and operation of a network of physicians, or any group of health care providers for that fact, must include an analysis of the antitrust and other related regulatory issues which may affect the new arrangement. Ignoring these issues poses an unhealthy risk to the new group. There is more of a risk that the matter will be raised by unhappy competitors who will file complaints with federal or state regulatory agencies or file a suit for violating anti-trust laws, than the risk that a federal agency will take action on its own.

Any time two or more competing groups make a new business arrangement, or any time physicians with several offices in different locations decide to join together or participate in collective efforts, anti-trust becomes a concern. Any time an Individual Providers Association (IPA) is concerned, or any type of collective negotiations with hospitals, managed care companies or insurers is considered, anti-trust issues should be considered.

[1] Conflicting Factors Involved

Health care antitrust has become more hazardous to the health of innovative providers and to competition in the $1 trillion health care field. There are several conflicting factors at work here.

First, the private revolution in health care continues at accelerating speed, approaching that of the expansion we have seen in the fields of computers and credit card fields. This unprecedented private innovation and leapfrogging of technical advances in the medical field are driven by the twin forces of (1) the historic switch to selective contracting plans (including most managed care and integrated delivery systems), and (2) the unprecedented level of legal freedom and flexibility provided to over 100 million people covered by ERISA health plans.[1]

Second, in the past, some federal antitrust officials seem torn between enlightened guidance, and a mechanical and formalistic view of antitrust law. Specifically, some officials are only approving the totally impractical "pure" messenger model for provider networks of various types, and are actively investigating a number of Physician Hospital Organizations ("PHOs") on the same issue.

It appears that the U.S. Supreme Court case of *Arizona v. Maricopa County Medical Society*,[2] is being applied far beyond its legal, factual and policy underpinnings, while the rest of 100 years of antitrust law and current health care market facts and realities are effectively being ignored. Hopefully, this development is temporary. As the U.S. Supreme Court reiterated, long after *Maricopa*, "actual market realities," not "formalistic distinctions," are controlling in antitrust law.[3]

Third, the continuing litigious trend in our society can also be seen in actions taken by competitors and even disgruntled former employees (and independent contractors), especially those well-off enough to spend money on anti-trust litigation. These actions can take the form of complaints made to state or federal regulators

(including the U.S. Department of Justice (DOJ), the U.S. Federal Trade Commission (FTC), the Florida Department of Agriculture and Consumer Affairs (for unfair and deceptive trade practices), the Florida Attorney General, and criminal or civil investigations commenced as a result. This may also take the form of litigation, although actually being brought for other reasons, that includes allegations of violations of the federal or state anti-trust laws, allegations of violations of the federal or state unfair and deceptive trade practices acts, and allegations of conspiracy and civil RICO.

Competitors and former employees (including independent contractors) often overlook the fact that the anti-trust laws were enacted to address injuries to competition itself (to society as a whole) and not injuries to any individual competitor or person. Unfortunately, this lesson may only be learned by a plaintiff bringing such a suit after many years of costly litigation. Even more unfortunately, such litigation itself may cause the FTC, DOJ or State Attorney General to begin an investigation of the matter.

[2] Application of FTC and DOJ Joint Guidelines

When this author wrote an article several years ago on this issue,[4] health care organizations had been following the Antitrust Guidelines that had been issued by the FTC and the DOJ in 1994. These joint Guidelines had been issued in September 1994 and were called "Statements of Enforcement and Analytical Principles Relating to Health Care Antitrust" and are often referred to as the "Guidelines" or "Antitrust Guidelines." The 1994 Guidelines actually updated and expanded the joint statements of Antitrust Enforcement Policy in the Health Care Area that had been issued earlier, on September 15, 1993.

The 1994 Guidelines provided eight categories of "safe harbors" or "safety zone" type of health care transactions or arrangements, as well as providing analytical principles for "rule of reason" review of transactions not within the safe harbors.

[3] "Safety Zones" for Health Care Arrangements

One safe harbor was hospital mergers; however, to qualify, one of the hospitals had to have had fewer than 100 licensed beds, an average daily census of under 40 for the three most recent years and the hospital had to be at least five years old.

Another safe harbor related to hospital joint ventures, which related to high-tech or other expensive equipment. The qualifying characteristic was that the hospital could not ordinarily afford the equipment individually and the provision of the service would not create a monopoly in the market. Joint purchasing agreements among health care providers also could qualify as a safe harbor if "(1) purchases accounted for less than 35% of total sales of the product in the relevant market, and (2) costs of products jointly purchased accounted for less than 20% of revenues for services sold by participants."[5]

The eight categories were not finite but were given explanatory rules of reason, which could disqualify a particular transaction.

Next in 1996 the FTC and the DOJ addressed issues relating to physician's network joint ventures and multi-provider networks. On August 28, 1996 the FTC and the DOJ issued revised Guidelines clarifying the September 1994 statements relating to physician networks and multi-provider networks.

The general philosophy of the FTC and the DOJ concerning physician joint ventures seems to be that they are pro-competitive, that their formation and operation increases competition among health care providers, and that they operate to generally benefit the public. Physician network joint ventures are defined by the Policy Enforcement Statement as "physician-controlled venture in which otherwise competing physicians jointly agree on prices or other competitively significant terms, and through which the members jointly market their services."[6]

When analyzing physician network joint ventures, one significant factor is "exclusivity." The term exclusivity relates to the network and whether "the network's physician participants are restricted in their ability to individually contract or affiliate with other network joint ventures or health plans."[7] The 1996 guidelines set forth proof of non-exclusivity which included "(1) the existence of viable competing networks or managed care plans; (2) actual participation by network physicians in other networks or managed care plans; and/or (3) network physicians earning substantial revenues through contacts with other networks or managed care plans."[8]

In comparison, a non-exclusive physician would be free to affiliate with other networks and would be available to contract individual health plans. Some issues to examine when determining exclusivity would relate to whether "(1) viable competing networks or plans with adequate provider participation currently exist in the market, (2) providers in the network actually participate in other network . . . or there is other evidence of their willingness and incentive to do so, and (3) providers in the network earn substantial revenue outside the network...."[9]

The next safety zone requirement deals with "risk-sharing." The Guidelines discussed the importance of physician members within a network to "share substantial financial risk" because such aspects are reliable gauges that a network is sufficiently integrated to achieve pro-competitive efficiencies. The Policy Enforcement Statements provides examples to demonstrate arrangements that typify risk sharing. The examples include "(1) agreements by the venture to provide services to health insurance plan at a . . . per subscriber rate; (2) agreement by the venture to provide designated services or classes of services to a payor for a predetermined percentage of premium or revenue from the payor; (3) use by the venture of significant financial incentives for its physicians participants, as a group, to achieve specified cost-containment goals...."[10]

Additionally the FTC and the DOJ expanded their definition of multi-provider networks. Multi-provider networks are organized generally to include ventures among providers of different kinds to market their services collectively. Some examples of single type providers may include, physicians, hospitals, or hospices. An example of a single provider specialty would include maybe orthodontists. The typical multiple provider group though would likely include, physician-hospital organizations. As discussed above, the physician network joint venture is just one form included in multi-provider networks.

The 1994 and 1996 Guidelines helped define safe harbors and gave explanatory terms to better analyze whether a physician group or multi-provider fell into the acceptable parameters of the FTC and the DOJ. These guidelines encourage competitive strategy with in the health care industry, while preventing restraint on trade, which only damages the public in the end.

In the interim as well as the long term, a century of fundamental antitrust law applied to current health care market realities is the best remedy for the present antitrust paradox facing innovators in the health care field.

§25.02 Fundamentals of Antitrust and Health Care

[1] The Private Revolution in Health Care

A private revolution is now underway in health care. The driving force of this revolution is the private sector.

As of 1995, nearly two-thirds of the U.S. population, 160 million people, had employment-based health coverage, with about 100 million self-insured.[11] Medicare, by comparison, in 1995 covered only 30 million people.

1995 Health Insurance Coverage

160 million	All employee health plans (includes Medicare Supplements)
30 million	Medicare (primarily over age 65)
10 million	Medicare Supplement from employers
20 million	Medicaid
15 million	Private individual coverage
50 million	HMOs (includes employee coverage)
100 million	Self-insured plans

[2] A Brief History of Government Antitrust and Health Care

[A] "Ancient History" (1939-1952)

In 1939, the "ancient" era of antitrust enforcement in the health care field began harshly. Thurmond Arnold, chief of President Roosevelt's Antitrust Division,

indicted the American Medical Association for alleged antitrust violations involving an HMO in Washington, D.C.

In 1943, the U.S. Supreme Court affirmed the AMA's criminal conviction under the federal antitrust laws.[12]

In 1952, the "ancient" era of antitrust enforcement came to an end with a loss by the government. The Justice Department lost its civil case against the Oregon State Medical Society in the Supreme Court.[13]

The government's loss in 1952 may explain the next era, one of almost complete antitrust silence with regard to health care activities. For more than twenty years, government antitrust enforcement in the health care field was essentially nonexistent.

[B] Silent History (1952-1975)

For the nearly quarter of a century between 1952 and 1975, health care, as a practical matter, was simply ignored by federal and state antitrust enforcement officials.[14]

Not surprisingly, many in the health care field came to think the antitrust laws did not apply to health care or to the "learned professions."

[C] Modern History (1975-Present)

The modem era of health care antitrust enforcement began in 1975, in two unusual ways.

First, in a case involving lawyers, not health care, the U.S. Supreme Court *unanimously* rejected the idea that there was a "learned professions" exemption from the antitrust laws.[15]

In December 1975, the Federal Trade Commission began its modern health care antitrust enforcement efforts challenging the American Medical Association's ethical restrictions relating to free choice, contract practice and advertising.[16]

In the twenty-seven years since 1975, more antitrust cases have been filed in the health care field than in the preceding ninety-one year history of the Sherman Act. As a result, antitrust has become a critical legal consideration for hospitals and others in the health care field.

Antitrust is even more important in today's environment, where private action is taking place faster and more pervasively than state or federal government action.

[D] Florida's Antitrust Laws

Florida has had a long common law tradition of discouraging contracts and activities that impede competition in any way. Contracts which limited production or control, or which fixed prices in certain commodities markets were held to be ille-

gal under Florida law.[17] This is now reflected in several different sections of Florida Statutes including those, which were enacted to directly address antitrust concerns.

Florida first adopted a general law to prohibit combinations or trusts that restricted trade or commerce in 1915.[18] This statute has been reenacted as the Florida Antitrust Act of 1980.[19] The stated purpose of the Florida Antitrust Act is to "complement the body of federal law prohibiting restraints of trade or commerce in order to foster effective competition."[20] The Act itself states that it should be "liberally construed to accomplish its beneficial purpose."[21]

[3] Overview of State and Federal Antitrust Law

[A] Purpose

The basic purpose of both state and federal antitrust law is the same to encourage competitive private markets: "[C]ompetition is our fundamental national economic policy, offering as it does the only alternative to the cartelization or governmental regimentation of large portions of the economy,"[22] as the U.S. Supreme Court stated in a 1963 case. Florida antitrust laws complement the federal laws in order to better foster competition in Florida.[23]

[B] Concept

A basic concept underlying the antitrust laws is the critical distinction between protecting *competition* versus protecting *competitors*; i.e., individual businesses and institutions: "The antitrust laws protect *competition*, not *competitors*."[24]

[C] Two Basic Provisions

Although there are numerous specific statutes and terms that make up state and federal antitrust law, there are basically two types of provisions and prohibitions:

1. Multiple-firm conduct that prevents competition. e.g., conspiracies in restraint of trade under §1 of Sherman Act or §542.18, Florida Statutes (1995).
2. Single-firm conduct that prevents competition. e.g., monopolization under §2 of Sherman Act or §542.19, Florida Statutes (1995).

[D] Enforcement

One or more of the following may enforce the antitrust laws:

1. U.S. Department of Justice, Antitrust Division,
2. Federal Trade Commission (FTC),

3. State Attorneys General and Local Prosecutors, or
4. Private Parties.

(1) Department of Justice Antitrust Division

The Antitrust Division is responsible for enforcement of the Sherman Act (under which it can bring criminal or civil actions and recover damages suffered by the federal government) and the Clayton Act (under which it can obtain civil injunctions and recover damages suffered by the federal government).

Criminal violations of the Sherman Act are felonies punishable by imprisonment for up to three years, and fines up to the largest of three numbers. For individuals, the larger of $350,000; twice the pecuniary gain the individual derived, or twice the pecuniary loss of the victims. For corporations, the larger of $10 million, twice the pecuniary gain the individual derived, or twice the pecuniary loss of the victims.[25] Antitrust Division enforcement actions, either civil or criminal, are brought in federal district courts.

Under the similar sections of the Florida Antitrust Act, criminal violations of §542.18 or §542.19 are felonies punishable by imprisonment for up to three years, and fines up to $100,000 for an individual or $1,000,000 for corporations.[26] The Attorney General or his designee may commence the prosecution.

(2) FTC

The FTC is responsible for enforcement of the FTC Act and, with the Justice Department's Antitrust Division, of the Clayton Act, as well as numerous other specific statutes dealing primarily with product labeling, consumer credit, and consumer warranties. The FTC is composed of five commissioners (not more than three of the same political party) appointed by the President for seven-year terms. The President designates one of the five to be the chair. Because the FTC Act has two different aspects (antitrust and consumer protection), the agency's investigative and enforcement responsibilities are divided between two bureaus: the Bureau of Consumer Protection and the Bureau of Competition. The chairman appoints directors to head each bureau. A third unit, the Bureau of Economics, provides economic expertise to the commission and the staff and reports on various economic and business matters.

FTC enforcement proceedings initially are brought in an administrative setting. A trial is held before an administrative law judge with a right of appeal by either the FTC staff or the party sued (the respondent) to the full Commission. (As used here, FTC means the entire agency, while Commission refers to the five appointed members acting as a judicial body.) Commission

decisions adverse to the respondent can be appealed to a federal court of appeals; those adverse to the FTC staff (i.e., complaint counsel) cannot be appealed.

If the Commission determines a practice to be unlawful, it enters a cease-and-desist order that not only may require that the practice be stopped but also may call for affirmative action by the violator. A violation of a cease-and-desist order is punishable by a civil penalty of $10,000 for each day of the violation. The Commission also has authority to promulgate rules defining acts or practices that either are unfair or deceptive or are unfair methods of competition. Depending on the manner in which the rule was promulgated, a knowing violation may subject a party to civil penalties.[27]

In lieu of a cease-and-desist order, the respondent and the Commission frequently enter into a consent agreement. Although a consent agreement is for settlement purposes only and is not an admission by the respondent that it has violated the law, when issued on a final basis it carries the force of law with respect to future actions. In addition, violation of an order may result in a civil penalty of up to $10,000 per instance.

(3) State Attorneys General and Local Prosecutors

States have their own-antitrust laws, which generally are similar to the federal antitrust laws. In Florida, state attorneys general, local prosecutors, and private parties can enforce them.[28] Significantly, they usually include criminal as well as civil penalties. Florida's is no exception.[29]

"Health care," according to Laurel Price, a leading state antitrust official, "has been a focal point of state antitrust enforcement." For example, the United States Department of Justice deferred jurisdiction to Pennsylvania's Attorney General in a case where a health care alliance sought to coordinate health care delivery of three of the four hospitals in Lycoming County, Pennsylvania.[30] In order to settle charges brought by the Pennsylvania Attorney General, the alliance agreed to pass onto consumers $31.5 million of anticipated cost savings in the form of free or reduced-cost health care services over a five-year period.

Similarly, the Florida Attorney General's Office and the DOJ Antitrust Division jointly challenged the merger of the two largest hospitals in north Pinellas County.[31] On June 17, 1994, the parties filed a consent decree which would bar the merger but which would permit the hospitals to form a joint venture partnership to provide specified health care services.

(4) Private Parties

Private parties may bring suit in federal court either to recover three times the damages suffered or to enjoin a violation of the antitrust laws.[32] Florida's Antitrust Act provides for a similar recovery.[33] In addition, a successful treble damages plaintiff may recover its costs and reasonable attorney fees. Recoveries in private treble damages actions sometimes involve millions of dollars. Many such suits are brought as class actions under Rule 23 of the Federal Rules of Civil Procedure. In a class action, the plaintiff represents not only itself but also all others who are similarly situated.

Section 4 of the Clayton Act establishes whether a private plaintiff has standing to sue for treble damages under the antitrust laws.[34] That provision creates a private cause of action for injury resulting from an antitrust violation by providing that "any person who shall be injured in his business or property" by an antitrust violation shall be entitled to recover damages. Section 16 of that Act authorizes private suits for injunctive relief "against threatened loss or damage by violation of the antitrust laws...."[35]

[4] The Basic Antitrust Statutes

[A] Federal Antitrust Laws

The principal antitrust laws at the federal level are Sections 1 and 2 of the Sherman Act, which prohibit, respectively, conspiracies among independent firms that restrain trade and monopolization by single firms,[36] and Section 5 of the Federal Trade Commission Act.[37]

Some of the activities covered by the Sherman Act are also specifically addressed in the Clayton Act. Section 3 of the Clayton Act covers tying and exclusive dealing,38 and Section 7 covers mergers.[39] The Robinson Patman Act, which prohibits some forms of price discrimination, is sometimes referred to as an antitrust law.[40] It has a frequent impact on drug manufacturers.

In addition, most states have some form of antitrust law.[41] Violations of both federal and state antitrust laws usually can be prosecuted criminally as well as civilly. In addition, private parties can sue under both sets of laws and recover treble or other multiple damages.

Some of the key statutes are listed below.

(1) Sherman Act, §1

"Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal."[42]

(2) Sherman Act, §2

"Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony...."

(3) Robinson-Patman Act, §2(a)

"[I]t shall be unlawful for any person engaged in commerce, in the course of such commerce, either directly or indirectly, to discriminate in price between different purchasers of commodities of like grade and quality, where either or any of the purchases involved in such discrimination are in commerce...and where the effect of such discrimination may be substantially to lessen competition or tend to create a monopoly in any line of commerce, or to injure, destroy, or prevent competition with any person who either grants or knowingly receives the benefit of such discrimination, or with customers of either of them...."[43]

(4) Clayton Act, §7

Section 7 of the Clayton Act prohibits the acquisition by any person of the stock or assets of any other person, "where in any line of commerce...in any section of the country, the effect of such acquisition may be substantially to lessen competition...."[44]

(5) Private Civil Actions for Damages

Section 4 of the Clayton Act authorizes any "person...injured in his business or property by reason of anything forbidden in the antitrust laws" to recover treble damages.[45]

(6) Actions for Injunctive Relief

Injunctive relief is provided for by Section 16 to any person "threatened [with] loss or damage by a violation of the antitrust laws...."[46]

[B] The Florida Antitrust Act

The sections of the Florida Antitrust Act, for the most part, mirror the federal antitrust statutes. Each of the key federal statutes mentioned directly above has a comparable section in Chapter 542, Florida Statutes. Similar causes of action are created for individuals and similar enforcement authority is provided to the Florida Attorney General and designees under the Florida Antitrust Act. Florida

courts in interpreting the similarly worded sections of the Florida Statutes extensively rely on federal case law interpreting and enforcing the federal antitrust laws.[47]

Although most of the Florida Antitrust Act closely tracks the federal, there are some differences. A cause of action that might not lie under federal antitrust law because of no impact on interstate commerce will lie under the Florida Antitrust Act. As last amended, the Florida Antitrust Act does provide that some types of contracts, which restrain trade, those traditionally referred to as "non-competition agreements," are valid, with some qualification.[48] Florida Courts have shown a tendency toward not applying antitrust laws as rigorously to relationships between physicians and hospitals.[49] Cases such as *Hackett II* should be reviewed closely for possible use if one is called on to defend a network from allegations of violations of Florida antitrust law.

Any activity or conduct that is exempt from the provisions of the federal antitrust laws or exempt under state common or statutory law is exempt from application of the Florida Antitrust Act.[50] This includes state action immunity.[51]

A practitioner bringing a cause of action arising in Florida sounding in restraint of trade would be well advised to include allegations of violations of both the state and federal antitrust statutes.

[5] Standards of Legality

[A] Rule of Reason

The Supreme Court has held that most restraints of trade must be analyzed in terms of the nature, purpose, and effect of the restraint, and consequently, antitrust analysis is very fact based.[52] In each situation, specific facts of the restraint must be reviewed. This analysis is commonly called the "rule of reason."

[B] Per Se Rule

On the other hand, some types of restraints are so well understood and inimical to competition that they are presumed to be illegal as a matter of law. These are called per se violations. As the Supreme Court stated in 1958 in *Northern Pacific Ry. v. U.S.*, "[t]here are certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are *conclusively presumed to be unreasonable* and therefore illegal without elaborate inquiry as to the precise harm they have caused or the business excuse for their use."[53]

Since the National Society of Professional Engineers[54] case was decided in 1978, the Supreme Court has eroded the traditional dichotomy between the per se rule and the rule of reason. The per se rule flatly prohibits "agreements whose

nature and necessary effect are so plainly anticompetitive that no elaborate study of the industry is needed to establish their illegality."[55]

The rule of reason historically required an often lengthy and complex inquiry into the relative competitive benefits and threats of a particular arrangement. Further, the per se rule often swept too broadly, and the rule of reason often resulted in unwieldy litigation.

The *Broadcast Music, Inc.* or *BMI* case[56] was another indication of the Court's shift away from strict per se treatment of all conduct resembling "price fixing." The case involved price fixing "in the literal sense:"[57] music composers and publishing houses formed two organizations which sold blanket licenses allowing purchasers unlimited use of the organizations' compositions for a stated term.[58]

In *BMI*, the Supreme Court criticized literal definitions of price fixing as "overly simplistic and often overbroad."[59] The behavior by the parties in *BMI*, the Court found, did not fall into a category requiring per se condemnation. In refusing to categorize the price restraints as per se illegal, the Court noted that it had never examined a practice similar to blanket licensing before.[60] Further the licensing, the Court found, was not a "naked restrain[t] of trade with no purpose except stifling of competition," but instead "accompanies the integration of sales, monitoring, and enforcement against unauthorized copyright use."[61] The licenses also were much more efficient than individual fee negotiations for use of each composition.[62] The blanket licenses were "an obvious necessity" to avoid the "virtual impossibility" of conducting thousands of individual negotiations for music use.[63] Because the Court found the blanket licenses to be a different product with unique characteristics from licenses for individual composition use, it found the blanket license agreements did not constitute horizontal price fixing among competitors selling the same product.[64]

Harvard Law School Professor Phillip Areeda, a leading authority on antitrust law, has prepared an extensive analysis of the rule of reason and the per se rule.[65] He concluded that the cases demonstrate that the per se and rule of reason approaches "are less a dichotomy than a continuum." Considering the rules as a dichotomy requiring only that courts classify conduct as per se or rule of reason "may seem easier than analyzing the competitive significance of business practices,"[66] but the dichotomy "is misleading because the per se rule is not so tightly prohibitive and the rule of reason not so hospitable to a claim or defense as is often thought," Areeda wrote.[67] He has found support for his "continuum" approach in the NCAA case, where the Court "made clear that the distinction was more a spectrum than a sharp dichotomy"[68] and "simultaneously used words from both rule-of-reason and per se ideas."[69]

Areeda also explains how the *BMI* case and the *Maricopa* case can be reconciled. According to Professor Areeda, in the Maricopa case, the Court "took pains to make clear that the physicians' price fixing did not appear necessary to any procompetitive end"[70] and "hardly appeared indifferent to the possibility of redeeming virtue."[71] "Had the justices been more impressed by the physicians' defensive arguments, they probably would have spoken more in *BMI* terms."[72]

§25.03 Enforcement Actions Taken Against Physician Hospital Organizations (PHOs) and Other Physician Organizations

[1] The *St. Joseph Physicians* and the *Danbury Health Systems* Consent Agreements

There were two cases investigated and prosecuted as alleged antitrust violations by the Department of Justice (DOJ), which resulted in widely, reported settlements. These should be reviewed, as they are informative as to the problems that may be created by Physician-Hospital Organizations and other groups of physicians. The relevant court documents were filed on both of these cases on September 14, 1995 and a press release from the DOJ announced their details on September 13, 1995.

In the St. Joseph, Missouri case, DOJ filed a complaint seeking injunctive relief for alleged activities which restrained competition and delayed the development of managed care in Buchanan County, Missouri in violation of §1 of the Sherman Act. The complaint named Health Choice of Northwest Missouri, Inc., Heartland Health System, Inc. and St. Joseph Physicians, Inc. as defendants. The physician component of this physician hospital organization was St. Josephs Physicians, Inc. ("SJPI"). Eighty-five percent (85%) of the 130 physicians in Buchanan County incorporated it in 1986, but they never integrated their separate individual practices or shared risk. It was alleged that from 1986 through 1989, no managed care plan was able to contract with SJPI or one of its physicians. SJPI later joined with the only acute care hospital in a three county area (owned by Heartland), to start a PHO. Heartland and SJPI each owned 50% of the PHO, Health Choice, in 1990. Physicians and practices were never integrated into the PHO and the individual physicians apparently shared no risk in the venture. It is alleged that they collectively negotiated and fixed prices and participated in other illegal activities, which violated the §1 of the Sherman Act.

A stipulated settlement was reached which ended the allegedly illegal conduct and by which the defendants agreed to certain remedial action to prevent a reoccurrence.

In the Danbury, Connecticut case DOJ and the State of Connecticut filed a civil antitrust complaint alleging that HealthCare Partners, Inc., Danbury Area IPA, Inc. and Danbury Health Systems, Inc. agreed and took actions to restrain competition in violation of the Sherman Act, §§1 and 2. It was alleged that this was done to maintain Danbury Health System's (the hospital's) market share in acute care and inpatient care and to help keep managed care out of the market. DOJ alleged that the Hospital was

the only one in the market which provided the services, it possessed a monopoly, it took steps to form an alliance with the physicians on its medical staff in the face of competition from managed care organizations coming into the market and ninety-eight percent (98%) of the doctors on the hospital's staff joined the alliance created. Minimum fee schedules and other vehicles were used to fix prices. A stipulated settlement was reached which ended the allegedly illegal conduct and by which the defendants agreed to certain remedial action to prevent a reoccurrence.

[2] The Louisiana *Women's Hospital* Case

A third case similar to the two discussed immediately above was reported in Louisiana. In *U.S. v. Women's Hospital Foundation*,[73] DOJ and Louisiana Women's Hospital in Baton Rouge, Louisiana, together with its PHO and Physician organization reached and agreement to end alleged price-fixing and other anticompetitive activities involving obstetric and gynecologic care. The hospital was a private hospital which delivered ninety-four percent (94%) of the privately insured newborns in Baton Rouge. It had on its staff approximately 50 OB/GYNs, "nearly every obstetrician and gynecologist in Baton Rouge."

The alleged purpose of the PHO was to establish a minimum fee schedule and serve as a joint bargaining agent on behalf of the hospital and doctors for managed care payers. Participating physicians agreed to only refer patients to other PHO physicians and to Women's Hospital component. DOJ alleged that by creating the alliance, the PHO was able to maintain its monopoly in inpatient obstetric services "by reducing, and practically eliminating, competition among the OB/GYNs in Baton Rouge, and by persuading these doctors not to admit patients to competing facilities...." The alliance appointed a consultant and a committee of non-physicians to set their fees. The result was that the OB/GYNs received fees that were "substantially higher" than when they were acting individually.

Unlike the prior two cases, in the Louisiana *Women's Hosp.* case there did not appear to be any intention to form a managed care plan. DOJ appears to believe that the intent to monopolize the market was clearly demonstrated from the plan's inception. Also, unlike the two prior cases, in this one the consent agreement requires the parties to obtain advance written approval from DOJ before ever attempting to form a managed care plan in the future.[74]

[3] The Denver Physicians Case[75]

The most recent decision regarding these issues was issued on August 20, 2002. The case involved eight Denver area physician practice groups, which specialized in obstetrics and gynecology (OB/GYNs). The group, appropriately named "Professionals in Women's Care" (PIWC) consisted of 80 physicians in the competing Denver area. The

FTC alleged that R. Todd Welter (a non-physician consultant), along with R. T. Welter & Associates, Inc. (RTWA), acting as the physician group's agent, organized eight competing physician practice groups (all specializing in OB/GYN services), into an arrangement for the purpose of engaging in collective contract negotiations with health insurance firms and other third-party payors.

It was alleged that from 1999 until 2001, Welter and the named practiced groups negotiated fees and other competitively significant terms on behalf of the physicians participating in PIWC. However, if the named practiced groups found terms deficient, Welter refused to communicate payor contract offers to the PIWC physicians. What resulted was the demanding and receiving of fees and other terms that where significantly more economically advantageous to the physicians in the group than what the physicians could have achieved by negotiating individually with the payors.

The FTC complaint further alleged "that Welter and the name practice groups enhanced PIWC's bargaining strength by convincing the PIWC physicians to terminate relationships with independent practice associations and practice management groups."[76] What resulted was an exploitation of their strength by demanding higher fees and more favorable price-related terms from the payor.

This anticompetitive conduct caused the FTC to allege that PIWC, by and through Welter, violated section 5 of the FTC Act by facilitating and implementing agreements among the OB/GYNs, by fixing prices and other terms of dealing with health insurance firms and other third-party payors, as well as, refusing to deal with payors except on a collectively determined terms.

The FTC issued a proposed order to Welter, RTWA, and the eight named practice groups. The order was drafted so as to prevent any further collaborative action, while allowing respondents to engage in legally competitive conduct. The order provided that the "respondents would be prohibited from entering into, participating in, or facilitating any agreement: (1) to negotiate on behalf of physicians with any payor or health care provider; (2) to deal, or to refuse to deal, with any payor or health care provider; (3) regarding any term or condition on which physicians deal, or are willing to deal, with any payor; or (4) not to deal individually with any pay, or to deal with any payor only through an arrangement involving the respondents."[77] For more details on this recent case, you may review the Complaint, the Decision and Order, and the Agreement Containing Consent Order to Cease and Desist are attached as a supplement.

What resulted was an order that prohibits Welter for three years from negotiating with any payor on behalf of any current or past participant in PIWC, and from advising any current or past PIWC participant to accept or reject any term, condition, or requirement of dealing with any payor. The order also contains an option for payors to terminate, without penalty, any existing contracts affording physician services,

which was negotiated by Welter. These terms may seem harsh, but demonstrate the FTC's continued monitoring and enforcement efforts at eliminating anticompetitive conduct and restraint of trade involved in the health care industry.

§25.04 Statements of Federal Antitrust Enforcement Policy in the Health Care Area and Review Letters on Proposed Activities

[1] FTC/DOJ Antitrust Enforcement Policy Statements for Healthcare

On September 15, 1993, the Federal Trade Commission and the Department of Justice jointly issued six policy statements containing "safety zones" for provider conduct that the agencies generally will not challenge under the antitrust laws. These statements reflected prosecutorial standards based on the agencies' previous advisory opinions, case law, and experience with respect to the covered activities. The safety zones were updated and expanded on September 27, 1994, when the agencies issued nine statements of enforcement policy and analytical principles.[78] The FTC will not challenge conduct that falls within one of the safety zones set forth in the policy statements. Two of the statements deal specifically with the formation and operation of provider networks.

[A] Physician Network Joint Ventures

Exclusive physician network joint ventures (ventures that restricts the ability of physicians to affiliate with other such ventures or to contract individually with health insurance plans) comprised of no more than 20 percent of the physicians in any specialty in a geographic market who have active hospital staff privileges and who share substantial financial risk. If there are fewer than five of one type of specialist in the market, the venture may include one of them on a non-exclusive basis.

Non-exclusive physician network joint ventures (ventures that do not involve limitations on the ability of participating physicians to affiliate with other ventures or to contract individually with health plans) comprised of no more than thirty percent (30%) of the physicians in each specialty in a geographic market who have active staff privileges and who share substantial financial risk. If there are fewer than four of one type of specialist in the market, the venture may include one of them. This safety zone was expanded in the revised statements to reflect the agencies' experience that truly non-exclusive joint ventures generally raise less risk of foreclosure of competing plans than do exclusive joint ventures. Joint ventures falling outside the safety zone still may pass muster under the antitrust laws under various circumstances. In these cases, the joint ventures will be analyzed by weighing their competitive risks and benefits under the rule of reason.

[B] Multiprovider Networks

Multiprovider networks are ventures among providers to jointly market their services to health benefits plans and others. Because multiprovider networks are relatively new to the health care industry, the agencies do not yet have sufficient experience evaluating them to issue a formal statement of antitrust enforcement policy or to set out a safety zone. The statement explains, however, how the FTC and the DOJ will analyze multiprovider networks.

If such networks involve agreements that allocate markets, fix prices, or similarly restrict competition, the agencies will examine whether the members are sufficiently integrated to allow the agencies to weigh the anticompetitive effects and competitive benefits of the agreements under the rule of reason, rather than being held per se unlawful. If the networks are integrated, the agencies will define the markets where the networks operate and have substantial impact, and then examine the competitive effects of the networks in each of these markets. That examination will take into account any cost savings or other efficiencies that will be attributable to such networks.

[2] Business Review Letters

Individuals or entities having concerns that proposed activities might bring an antitrust enforcement action from DOJ may request a review of the proposed activity. In response, DOJ will prepare a written response analyzing the activity and advising whether or not it has the intention of challenging the proposed activities under the antitrust laws. These are letters issued pursuant to the procedures found in Federal Regulations.79 In the jointly issued FTC/DOJ policy statement discussed immediately above, DOJ and the FTC expressed a commitment to the timely review and issuance of business review letters for the health care industry.

[3] New Federal Antitrust Guidelines

The Federal Trade Commission and the Department of Justice jointly issued new federal antitrust guidelines that deal exclusively with provider networks. These were released in September of 1996. The most important changes addressed:

[A] Risk-Sharing

The new guidelines emphasize a substantial expansion of what constitutes "risk-sharing" to include:

1. Bonus only arrangements, without downside risk;
2. Global or "bundled" fees, e.g., for all services by all providers for a CABG; and

3. Provider networks as "joint selling agencies" using their own employees to do the negotiating, with fee information kept confidential to them, thus avoiding the need for using expensive and often impractical outside consultants.

This broadening of "risk-sharing" opens a tremendous area of new opportunity for provider networks, since capitation and withheld fees are not the only way to get to the rule of reason analysis.

It also means that provider networks do not need to be licensed under state law, since no "insurance" risk sharing is involved. Ironically, the many state insurance departments that continue to try to regulate "risk-bearing" provider networks will inadvertently have the opposite effect, driving the market and provider networks to these new "non-risk" opportunities.

[B] Non-exclusivity in Fact

The guidelines provide the greatest flexibility, and the lowest antitrust risks, when network providers in fact are free to work with a variety of payers and managed care organizations ("Non-exclusivity in fact").

[C] Caveat, Shams and Buzzwords

There will be more emphasis on aggressive enforcement against provider networks that say they will do good things, but in fact do bad things — typically, networks that act as collective bargaining agents for dictating price and business terms on managed care organizations and payers ("naked" restraints of trade).

Similarly, there is a move away from buzzwords like "integration" and a return to antitrust fundamentals; i.e., there is more emphasis on net competitive effects, the ultimate issue under the antitrust laws.

§25.05 The Messenger Model

Under the FTC/DOJ Guidelines discussed above, there are two acceptable models for organizing a network or managed care organization which will not run afoul of the antitrust laws: the "pure" messenger model and the "modified" messenger model.

[1] "Pure" Messenger Models

The use of a "messenger model" arrangement has been promoted as a method of avoiding the need to economically integrate participating providers to negotiate with managed care organizations. Usually, a third party acts on behalf of the participating providers to obtain and convey information regarding fees and prices. The key com-

ponent for "purity" is that each provider must make a separate independent decision regarding the fees or prices the provider is willing to accept. The purchaser's "office" must be accepted or rejected. Because there is no opportunity for collision among the providers, the antitrust risk of price-fixing allegations (under the holding of the *Maricopa* case) is avoided. In the "pure" model the messenger does nothing but convey the price offer — no negotiation or response other than yes or no is permitted.

Obviously, this has practical limitations on how the "pure" messenger arrangement can accomplish the goals of the network providers. In essence the messenger is little more than a passive agent of the third party payor without the authority to bargain. In short the pure messenger model seldom works because it cannot do the job.

[2] "Modified" Messenger Models

A dangerous variation of the "pure" model involves an "active" messenger who communicates the providers' bargaining position back to the third party payor and who may even share some pricing information with the providers. This mechanism is ill advised even if closely supervised and controlled. The temptation to engage in collusive (illegal) behavior is simply too great. If the messenger is perceived to facilitate price restrictions or otherwise hinders the competitive process through the sharing of information among the providers then all the network members run a serious risk of antitrust exposure.

The messenger model could soon follow "clinics without walls" as a failed mechanism to achieve indirectly what cannot be done directly. However, there is opportunity for those who seek the solution in the application of traditional antitrust principles — as opposed to trying to finesse technicalities.

[3] Criticism of Both Models

There are some inherent problems, which have been identified by health care providers in the models, which have been approved by the DOJ and FTC. Time and space does not permit a discussion of these here. However, one association's comments and criticisms recently provided to the FTC are attached as Appendix F for those who may be interested.

§25.06 Dangers and Opportunities for Physicians

[1] Beyond the "Model T"

"Managed care" is now still at a "Model T" stage. However, like the "Model T," it has unleashed a private revolution. The "Model T," after all, was revolutionary in its day for consumers and horseless carriage companies — and horse and buggy manufacturers. For the first time in the history of American health insurance, large doses of provider

cost, price, quality and service competition are being applied through HMOs and network plans virtually everywhere. Cost reimbursement and Usual Customary and Reasonable ("UCR") fees for providers have largely gone the way of the buggy whip. In basic antitrust terms, there has been de facto deregulation of the health care field, particularly in the last ten years.

Thus, for those who believe private markets responsive to consumers (patients) are superior to government command-and-control regulation, this is the best of times. For people of this worldview, the superiority of private markets over government regulation is not a shock — it is to be expected.[80] At bottom, they have a revolutionary view: let the patient — not government — decide.

For regulatory advocates, however, who believe that private markets and health care are an oxymoron, and that massive doses of state and federal regulation are "best" for patients,[81] this is the worst of times. Today, they are either in denial, baffled by the stunning speed and success of private innovation in health care, or both. Indeed, like those who believed the world was flat, many are confident that private market innovation will soon fall off the ends of the earth.

Health care is now poised to move beyond the "Model T" stage of managed care to the next generation, what could be called the "Patient Choice" generation of private reform. There are many complex issues, particularly for the 100 million people covered by network plans and the hospitals, doctors and other providers that serve them. One could, for example, make total cost, not unit price, the key to cost performance in health care. Yet most doctors[82] and many hospitals are separate and often small businesses that have never collaborated among themselves or together to manage total cost and quality (unlike the typical large businesses and corporations that are familiar with the antitrust laws).[83] Even when health care providers and others want to collaborate, there is a babble of incompatible computer systems in doctors' offices, hospitals, employee health plans and carriers, as well as the antitrust risks (discussed herein), that add to the complexity. Finally, there are incentive system complexities: How do you reward cost and quality performance among thousands of independent businesses and solve the classic health care paradox of rewarding excellence without rewarding either under-service or over-service?[84]

[2] Enlightened Enforcement Creates New Opportunities

Unfortunately, there is good news and bad news regarding federal antitrust policy and health care today. The good news is that federal policy is providing enlightened guidance85 to the HMO and capitated form of managed care. The bad news is that, as happened with joint ventures several years ago, "uncertainties in enforcement policy have almost certainly blocked, delayed, or raised the cost of legitimate undertakings,"[86]

especially for the most prevalent form of managed care, network plans that cover on the order of 100 million people.

Contrary to the conventional wisdom, as noted earlier, HMOs played a much smaller role in this historic change to managed care. PPOs and other non-HMO "managed care" plans went from zero to about 100 million people, while HMO penetration increased about 25 million people to about 50 million enrollees in 1994. Moreover, the HMOs' role nationally is actually less, since nearly half of all HMO enrollees are in just five states.

Current federal antitrust policy is focused on capitation, risk-sharing and *Maricopa*, with the result that an unnecessarily mechanistic and unrealistic antitrust approach is being applied to the most prevalent form of managed care network plans. For example, "pure" messenger models recently have been prescribed as a federal antitrust cure for provider network "price-fixing." The commonly used "modified" messenger model has not been so fortunate, hence it might be called the "impure" messenger model. In the real world, both models are totally impractical, very expensive, unnecessary and actually anticompetitive. As discussed above, the nature of competition in health care has changed profoundly since *Maricopa*; current antitrust analysis does not adequately take this change into account, and current antitrust policy unnecessarily impairs new forms of collaboration as well as the ability of small businesses, including most physicians, to compete and potentially benefit patients and the public.

Practically speaking, public and private antitrust plaintiffs that resort to the temptation of mechanistic antitrust, where anticompetitive effects are presumed rather than proven, generally lose.[87]

The 1980s were basically a decade when employers and their benefit consultants tried to "fix" indemnity plans by imposing co-insurance and deductibles. For various reasons, these "fixes" didn't work. By the end of the decade, a new approach was desperately needed because employee plan costs returned to double-digit inflation.

In the early 1990s, employee plans and benefits consultants made a paradigm shift to "managed care," which has been accelerating ever since. Rather than continuing to try to "fix" indemnity plans, they shifted to using private incentives for cost, quality and performance with hospitals and other providers-selective contracting with networks of providers. With the paradigm shift to selective contracting, cost reimbursement, UCR ("Usual Customary and Reasonable") and billed charge pricing, as a practical matter in most cities is dead or dying.

[3] State Enforcement Issues

State insurance departments strongly recommended that capitation and many other risk-sharing arrangements be regulated as the "business of insurance."88 State regula-

tors who take the position that capitation and risk sharing are the "business of insurance" make capitation and risk sharing more risky, less desirable, and thus less likely. Florida's Department of Insurance may adopt this position. It has had draft proposed regulations informally circulating for several years to implement such a position.

§25.07 Other Regulatory Issues to Be Faced

The limits of this presentation do not allow a detailed discussion of all of the other state and federal regulatory concerns that managed care networks must face on a routine basis. However, these are covered adequately elsewhere.[89] The primary ones of which you should be aware are set forth below.

[1] Florida Patient Self-referral Act and Mandatory Disclosures

The Florida Patient Self-Referral Act is found at Section 456.053, Florida Statutes.[90] It is much broader than its federal counterpart (discussed below) in that it applies to all patients, regardless of who is paying for the care. This law prohibits health care providers from referring patients for the provision of any of twelve designated health services to any entity in which he/she (or a family member) is an investor or has an investment interest. The statute provides that any health care provider or other entity that violates it may be subject to a civil penalty and professional disciplinary action or action against its license.[91] The full text of the Act is set out in the Appendix to this book.

Even if a the patient is referred for service which is not one of the ones designated or which is not a prohibited referral, if the health care provider is an investor in the entity to which the patient is referred, he/she must disclose this in writing to the patient.[92] The patient must also be provided the names addresses and telephone numbers of two additional sources of the service.[93] An entity receiving such a referral must make a similar disclosure.[94]

[2] Florida Anti-patient Brokering Act

On April 25, 1996 the Florida Legislature enacted a new law, which was then signed by Governor Lawton Chiles, which made "patient brokering" illegal and punishable as a separate crime.[95] This law became effective on October 1, 1996. It prohibits *any person*, including a health care provider or health care facility from: 1) offering to pay any commission, bonus, rebate, kickback, bribe, directly or indirectly, in cash or in kind, *or to engage in any "split-fee arrangement,"* in any form whatsoever, in order to induce a patient referral or patronage from a health care facility; 2) soliciting or receiving any commission, bonus, etc., in return for referring patients or patronage to a health care provider or facility; or 3) aiding, abetting, advising or otherwise participating in the foregoing conduct. A first violation of this law is punishable as a misdemeanor of the

first degree including up to a $5,000 fine. A second offense is punishable as a felony of the third degree and includes a fine up to $10,000. There are a number of exceptions provided under the new law.

The Anti-Patient Brokering Act states that it does *not* apply to:

1. Discounts, payments, and waivers of payment allowable under 42 U.S.C. § 1320A-7B(B);
2. Payment, compensation, or a financial arrangement within a group practice (as defined in §455.236, Florida Statutes, provided the payment, etc., is not to or from a person who is not in the group practice;
3. Payments to a health care facility or health care provider for consultation services;
4. Commission and fees lawfully paid to insurance agents as provided under the insurance code;
5. Payments by a health insurer for health, mental health or substance abuse care under a health benefit plan;
6. Payments to or by a health care provider, facility or network that has contracted with a health care purchasing group, an insurer or the Medicare or Medicaid program to provide care under a health benefit plan, when the payments are for that care, substance abuse care under a health benefit plan;
7. Insurance advertising gifts that are lawful;
8. Commissions paid to a nurse registry for referring providers of health care to clients of the nurse registry; and
9. Payments by a health care provider or facility to an information service that provides health care information to consumers without charge to enable consumers to select a health care provider or facility provided certain other criteria are met.

The Anti-Patient Brokering Act also closed a loophole by amending the Florida Anti-Kickback Act,[96] by adding a new subsection (3). The new part of the Act states that violations of the Anti-Kickback Act shall also be considered "patient brokering" and punishable under the Anti-Patient Brokering Act.[97] Prior to this, the only potential penalty for violating the Anti-Kickback Act was professional disciplinary action.

This law promises to be the source of much future litigation. Legal counsel advising insurers, health care providers, marketing and advertising agents, health care facilities and pharmaceutical and medical equipment manufacturers would be well advised to review it carefully prior to drafting any future agreements or giving advice on arrangements related to the health care industry.

[3] **Federal Anti-referral Legislation: Stark I and II and the Stark I Regulations**

The *Ethics and Patient Referrals Act*[98] (referred to herein as "Stark I") and its subsequent amendment in 1993 ("Stark II") were introduced by U.S. Congressman Fortney "Pete" Stark. Stark I was originally enacted in December 1989 as part of the Omnibus Budget Reconciliation Act of 1989 (OBRA 1989). Stark I prohibits referrals to clinical laboratories in which the referring physician has a financial interest. It applies to clinical laboratory services provided to Medicare patients. As part of OBRA 1990, certain clarifying amendments were made to Stark I. In 1993, OBRA amended and expanded Stark I to include services provided to Medicaid patients and to extend the Stark prohibitions to certain other "designated health services". This 1993 legislation became known as Stark II. There are eleven "designated health services."

The Health Care Financing Administration (HCFA),[99] a division within the U.S. Department of Health and Human Services (HHS), issued final regulations explaining, clarifying and implementing Stark I on August 14, 1995.100 These final regulations incorporate and apply the Stark II amendments as they relate to clinical laboratories and state that they may be used to interpret the provisions of Stark II.

The Stark legislation, now codified at 42 U.S.C. §1395nn, prohibits certain referrals by physicians to a laboratory or other specified entity, *if the physician has a financial relationship with the laboratory (or other entity).* 42 U.S.C. §1395nn provides:

> **(a) Prohibition of certain referrals**
>
> **(1) In General**
>
> Except as provided in subsection (b) of this section, if a physician ... has a financial relationship with an entity specified, then —
>
> (A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment may otherwise be made under this subchapter [Medicare], and
>
> (B) the entity may not present or cause to be presented a claim under this subchapter, or bill . . . for designated health services furnished pursuant to a referral prohibited under subparagraph (A)....

"Financial relationship" is defined to include an "ownership or investment interest in the entity" or "a compensation arrangement (as further defined in the act) between the physician...and the entity." However, there are 14 exceptions to the definition of a prohibited "financial relationship."

The term "referral" is specifically defined in the implementing Federal Regulations101 as the request by a physician for, or ordering of, any item or service for which payment may be made under Medicare Part B, including (1) a request for consultation with another physician, and any test or procedure

ordered by, or to be performed by, or under the supervision of that physician; or (2) a request by physician that includes the provision of laboratory services or the establishment of a plan of care by a physician that includes the provision of laboratory services. A specific exception states that the term "referral" does not include a request by a pathologist for clinical diagnostic laboratory tests.

[4] Federal Antikickback Law

The federal Antikickback Act[102] provides significant criminal penalties for the payment or receipt (or the offer thereof) of practically anything of value in return for referring or arranging for a patient to receive a service or good paid for by Medicare. The authorized punishment includes up to $25,000 and five years in prison per count. The Florida Anti-Kickback Act, discussed briefly above, is worded similarly, but up until it was amended in 1995, provided no criminal penalties for violation.[103]

[5] Fee-splitting and the Unauthorized Corporate Practice of Medicine

Although Florida does not enforce a doctrine of outlawing the corporate practice of medicine, there are many states which do.[104] To the extent that a network may be providing services in another state, to residents of another state, employing physicians in other states, or merging and contracting with entities in other states, one must be aware of this doctrine and what it encompasses.

Each state defines "the practice of medicine" in state laws similar to Florida's. Most states agree that the practice of medicine involves the diagnosis and treatment of people for disease, pain or suspected illness, injury, deformity or other physical of mental condition. This usually includes the prescribing of medications for this.

The unauthorized corporate practice of medicine doctrine prohibits business organizations that are not formed and owned by physicians from engaging in "the practice of medicine." Statutes which prohibit "fee-splitting" by physicians (or other professionals) may also be used by some states to enforce this doctrine.

The purposes behind such a doctrine include:

1. Only physicians may be licensed to and actually practice medicine.
2. A physician's judgment in the treatment of patients should not be influenced or affected by his/her employer (especially where this is a for-profit corporation).
3. A physician's first and greatest loyalty must be to his/her patient.
4. Commercial exploitation of a physician's services and his/her relationship with a patient must not occur.

Therefore, in those states in which the doctrine is enforced, an alternative to the straight physician employee-employer relationship must be used to avoid the state's prohibition. Sometimes this can be done by having the physicians employed by a not for profit foundation and the foundation contracting with the network, facility or corporation. There are a number of other structural arrangements by which the desired results may be achieved.[105]

Methods of avoiding charges of unauthorized practice of medicine allegations:

1. Obtain the advice of experienced health care counsel to form the organizational structure and hiring arrangements of physicians so as to avoid possible allegations.
2. All contracts, job descriptions and other documents should stress that the physician is required to exercise his/her own independent professional judgment at all times.
3. Fully explain in all quality assurance, utilization review, capitation/bonus agreements and related documents that the purpose of the program is not to interfere in the independent medical judgment of the physician.
4. Obtain opinion letter from qualified health care counsel on the arrangement.

A recent Illinois case demonstrated that the doctrine prohibiting the corporate practice of medicine in those states where it is prohibited will be enforced by the courts (even in states where it has not been enforced for decades).[106]

§25.08 Conclusion

A myriad of land mines awaits the unwary practitioner advising managed care networks in today's fast changing political environment. Overly complex laws, confusing regulations (when there are implementing regulations), and court decisions, which interpret these, provide a plethora of confusing, and often seemingly contradictory legal authority. In the field of Health Law, more so than practically any other field, the practitioner must educate him/herself from opinion letters and policy statements, from informal promulgations and settlement agreements, from model acts and draft regulations, from guidelines and agency memoranda. What is set in motion in one session of the legislature is reversed in another. This appears to be especially the case in the areas of antitrust and regulations that affect managed care networks.

Perhaps the most that can be expected is that the health care lawyer will at least be able to spot the land mines, even if he or she alone can't always find the route around them.

§25.09 Supplemental Materials (See Section III)

[1] DOJ and FTC Statements of Antitrust Enforcement Policy in Health Care (Introduction and Statements 8 and 9)

[2] Complaint in the *Denver Physicians Case*, FTC File No. 011-0175

[3] Agreement Containing Consent Order to Cease and Desist in the *Denver Physicians Case*, FTC File No. 011-0175

[4] Decision and Order in the *Denver Physicians Case*, FTC File No. 011-0175

[5] Analysis of Agreement Containing Consent Order to Aid Public Comment, in the *Denver Physicians Case*, FTC File No. 011-0175

§25.10 References

[1] See generally, McAdam, Gallagher and Weller, MANAGED CARE CONTRACTS MANUAL (Aspen 1996).

[2] *Arizona v. Maricopa County Medical Society*, 457 U.S. 332 (1982); referred to herein as *Maricopa*.

[3] *Eastman Kodak Co. v. Image Technical Serv.*, 504 U.S. 451 (1992).

[4] See Richard W. Siehl and George F. Indest III, *Antitrust and Regulatory Issues Impacting the Formation and Operation of Provider Networks*, in NETWORKS IN HEALTH CARE: PHO's, MSO's, ETC. (Florida Bar, 1996).

[5] R. Andrew Rock, *Integration of Providers Antitrust and Structuring Issues*, in 2001 HEALTH LAW CERTIFICATION EXAMINATION REVIEW COURSE 6.6 (Florida Bar, 2001).

[6] David Marx, Jr., Esquire, *Antitrust Issues*, in FUNDAMENTALS OF HEALTH LAW 54 (American Health Lawyers Association, 2001).

[7] Id.

[8] Rock, *supra* note 2, at 6.7.

[9] Marx, *supra* note 3, at 55.

[10] Id. at 56.

[11] See, e.g., Charles Weller, *PPOs and Employers*, in P. Boland, THE NEW HEALTHCARE MARKET: A GUIDE TO PPOS FOR PURCHASERS, PAYORS AND PROVIDERS (1985); Weller, *Rx for the Costly Epidemic of Health Care Legislation*, WALL STREET JOURNAL (May 9, 1988); and Weller and Steinbrink, *Volatile Accrual: What You Need to Know About FAS* 106, MANAGEMENT REVIEW (May 1993).

[12] *American Medical Association v. U.S*, 317 U.S. 519 (1943).

[13] *U.S. v. Oregon State Medical Society*, 343 U.S. 326 (1952). The District Court case below seems to be one of the most unusual judicial opinions ever written. *U.S. v. Oregon State Medical Society*, 95 F. Supp. 103 (1950).

[14] Only one antitrust case involving hospital and medical care was brought by government antitrust officials. *U.S. v. College of American Pathologists*, 1969 CCH Trade Cas. ¶72,825 (N.D. Ill. 1969) (challenged ethical restrictions on pathologists employed by independent clinical laboratories).

[15] *Goldfarb v. Virginia State Bar*, 421 U.S. 773 (1975)

[16] See, e.g., Weller, *Free Choice as a Restraint of Trade in American Health Care Delivery and Insurance*, 69 IOWA L. REV. 1351 (1984).

[17] *McQuaig v. Seaboard Oil Co.*, 118 So. 424 (Fla. 1928); Lee v. Clearwater Growers' Ass'n, 111 So. 722 (Fla. 1927).

[18] Florida Laws 1915, c. 6933, §§ 1 - 11.

[19] §542.15, Fla. Stat. (2002).

[20] §542.16, Fla. Stat. (2002).

[21] Id.

[22] *U.S. v. Philadelphia National Bank*, 374 U.S. 321, 372 (1963).

[23] §542.16, Fla. Stat. (2002).

[24] *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477 (1977).

[25] 15 U.S.C. §1 & 18 U.S.C. §3571.

[26] §542.21(2), Fla. Stat. (2002).

[27] 15 U.S.C. §45(m)(1)(A).

[28] § 542.27, Fla. Stat. (2002).

[29] § 542.21, Fla. Stat. (2002).

[30] *Pennsylvania v. Providence Health System, Inc. & N. Central Penn. Health Sys.*, 4: CV-94-772 (M.D. Pa., filed May 24, 1994) (final judgment entered May 26, 1994).

[31] *U.S. & Fla. v. Morton Plant Health Sys., Inc. & Trustees of Mease Hospital. Inc.*, No. 94-748-CIV-T-23E (M.D. Fla. filed May 5, 1994).

[32] 15 U.S.C. §§15, 26.

[33] §542.22(1), Fla. Stat. (2002).

[34] 15 U.S.C. §15.

[35] 15 U.S.C. §26.

[36] 15 U.S.C. §§1 & 2.

[37] 15 U.S.C. §45.

[38] 15 U.S.C. §14.

[39] 15 U.S.C. §18.

[40] 15 U.S.C. §13.

[41] See 4 CCH Trade Regulation Rep. ¶ 30,000, et seq.

[42] 15 U.S.C. §1.

[43] 15 U.S.C. §13(a).

[44] 15 U.S.C. §18.

[45] 15 U.S.C. §15(a).

[46] 15 U.S.C. §26.

[47] See, e.g., *Greenberg. M.D. v. Mount Sinai Medical Center of Greater Miami, Inc.*, 629 So. 2d 252, 257 (Fla. 3rd DCA 1993); *Hackett. M.D. v. Metropolitan Gen'l Hosp.*, 422 So. 2d 986, 988 (Fla. 2nd DCA 1982) (referred to as *Hackett I*).

[48] §542.335, Fla. Stat. (1996). This section covers covenants not to compete by one selling the goodwill of a business, shareholders, partners and other relationships detailed in the statutes.

[49] *Hackett, M.D. v. Metropolitan Gen'l Hosp.*, 465 So. 2d 1246 (Fla. 2nd DCA 1985) (referred to as *Hackett II*). In this case the Florida Court of Appeal refused to allow the application of the per se test to a physician's suit against a hospital based on denial of staff privileges alleged to violate the Florida Antitrust Act. In a well reasoned analysis, the court stated that the per se rule should never be used in such circumstances and went even further holding that unless the party had "a *dominant* anticompetitive purpose" in its conduct, no unreasonable anticompetitive purpose could be shown. 465 So. 2d 1254, 1257.

[50] §542.20, Fla. Stat. (2002).

[51] *Central Fla. Clinic for Rehabilitation, Inc. v. Citrus County Hosp. Bd.*, 738 F.Supp. 459 (M.D. Fla. 1989).

[52] Charles Weller, *The Antitrust 'Swamp': How Can Healthcare Professionals Avoid It?*, in HEALTHCARE FINANCIAL MANAGEMENT 26 (Oct. 1982); Fennell & Weller, Is *There Still A Per Se Rule for Antitrust Violations in Health Care Cases?*, in ANTITRUST ISSUES IN HEALTH CARE (Am. Bar Assn., 1988).

[53] *Northern Pacific Ry. v. U.S.*, 356 U.S. 1,4 (1958).

[54] *Nat'l Soc'y of Professional Eng'rs v. U.S.*, 435 U.S. 679 (1978).

[55] Id. at 692.

[56] *Broadcast Music, Inc. v. CBS*, 441 U.S. 1, 8 (1979).

[57] Id. at 8.

[58] Id. at 5.

[59] Id. at 9.

[60] Id. at 10. The Court previously had recognized a need for "considerable experience with certain business relationships" before classifying them as per se illegal. Id. at 9 (quoting *U.S. v. Togo Assocs.*, 405 U.S. 596, 607-08 (1972)).

61 *BMI*, 441 U.S. at 20 (quoting *White Motor Co. v. U.S.*, 372 U.S. 253, 263 (1963)).

62 Id. at 20-22.

63 Id. at 20.

64 Id. at 22.

[65] P. Areeda, VII ANTITRUST LAW, Chap. 15 (1986) and P. Areeda and H. Hovenkamp, ANTITRUST LAW: 1995 SUPPLEMENT 863-88 (1995).

[66] Id., ¶ 1511, at 427.

[67] Id., ¶ 1511, at 428. Areeda suggests that a Rule of Reason analysis sometimes can be conducted very quickly, "in the twinkling of an eye," when a restraint obviously is unreasonable. Id., ¶ 1508, at 403. And courts may make "facial" unreasonableness judgments based on modest information available at the beginning of a lawsuit. Id., ¶ 1508, at 405.

[68] Id., ¶ 1511, at 436.

[69] Id., ¶ 1511, at 430.

[70] Id., ¶ 1510, at 425.

[71] Id., ¶ 1510, at 426.

[72] Id.

[73] *U.S. v. Women's Hosp. Found.*, No. 96-389-B-M2, consent agreement filed Apr. 23, 1996 (M.D. La.), reported at 5 BNA Health L. Rep. 661 (May 2, 1996).

[74] Id.

[75] *Denver-Area Physician Practice Groups and Their Agent Agree to Settle FTC Charges of Fixing Fees*, Federal Trade Commission, Press Release, (August 20, 2002), at ***http://www.ftc.gov/opa/2002/08/piwc.htm.***

[76] Id., at ¶ 8.

[77] Id. at ¶ 10.

[78] The complete text of Policy Statements 8 and 9, and *Statements of Enforcement Principles Relating to Health Care and Antitrust* (September 27, 1994) are attached as a supplement to this Chapter.

[79] 28 C.F.R. §50.6.

[80] "See, e.g., Supreme Court Justice Stephen Breyer's classic writings on the subject, Stephen Breyer, REGULATION AND ITS REFORM (1982) and Stephen Breyer, BREAKING THE VICIOUS CIRCLE (1993), as well as Charles Schultze, THE PUBLIC USE OF PRIVATE INTEREST (1977).

[81] Rationing is perhaps the most extreme example. It involves "Grand Poobahs of Life and Death" deciding who lives and who dies-even though medical science is ever changing and often uncertain, and market forces are now often reducing costs. Rationing is already reality for the poor in some states. For many regulatory types, it is the only "rational" option for the future for all of us. See, e.g., *New Prescription: Rationed Health Care Helps Oregon's Poor but Real Test is Ahead*, WALL STREET JOURNAL, March 22, 1994, at A-1.

[82] Remarkably, about two-thirds of the 570,000 or so practicing physicians are solo practitioners or practice with one other physician. AMA, **Medical Groups in the U.S.**, 43-44 (1993).

[83] Peter Drucker, the "dean" of American management consultants, refers to these joint venture and other alliances of people in today's innovative sectors of the economy as creating a new "Network Society." Peter Drucker, *The Network Society*, WALL STREET JOURNAL, March 29, 1995, at A-14.

[84] Judge Posner recently described these "perverse incentives" in the HMO context: "The HMO's incentive is to keep you healthy if it can but if you get very sick, and are unlikely to recover to a healthy state involving few medical expenses, to let you die as quickly and cheaply as possible." *Blue Cross & Blue Shield United of Wisc. v. Marshfield Clinic*, 1995-2 CCH Trade Cases 171,120, p. 75,374 (7th Cir., Sept. 18, 1995).

[85] As discussed above, the FTC and the Antitrust Division of the U.S. Department of Justice have provided Statements of Enforcement Policy and Analytical Principles Relating to Health Care and Antitrust, and efforts by both agencies providing numerous advisory opinions and business review letters in health care.

[86] Pitofsky, A Framework for Antitrust Analysis of Joint Ventures, 74 GEORGETOWN L. REV. 1605 (1986).

[87] *U.S. v. Baker Hughes. Inc.*, 908 F-2d 981 (D.C. Cir. 1990), is perhaps the most important example, since two sitting Justices of the U.S. Supreme Court (Thomas and Ginsburg) joined in an opinion that handed the government a stunning loss in this merger case. See also, *U.S. v. General Dynamics Corp.*, 415 U.S. 496 (1974); *U.S. v. Morgan*, 118 F. Supp. 621, 688 (S.D.N.Y. 1953), and *U.S. v. Alston*, 974 F.2d 1206 (9th Cir. 1992).

[88] See, e.g., *Overwhelming Opinion of NAIC Group That Provider Networks be Licensed*, in BNA HEALTH LAW REPORTER, Aug. 17, 1995, at 1264; *Georgia: PHO To Change Health Contract Clarifying That It Is Not Insurer*, BNA HEALTH LAW REPORTER, July 6, 1995, at 1042; Maryland Atty. Gen. Op. No. 90-030 (June 19, 1990) (certain provider risk-sharing arrangements ruled to be the business of insurance), and FTC Advisory Opinion Denying Antitrust Clearance For Nevada Orthopaedic IPA, July 11, 1995 (cites Nevada Insurance Department view to the same effect).

[89] For excellent discussions, please see: Stephen H. Siegel, *Anti-Referral Laws*, chap. 1 in Florida Bar, 1996 HEALTH LAW CERTIFICATION EXAMINATION REVIEW COURSE (April 19-20, 1996); R. Andrew Rock, *Integration Issues*, chap. 6 in Florida Bar, id.; Christopher L. Nuland, *Stark I, Stark II and The Florida Patient Self-Referral Act: Making it All Fit*, chap. 1 in Florida Bar, BREAKING THE CIRCLE: FEDERAL AND STATE EFFORTS TO LIMIT SELF-REFERRALS (June 20, 1996); and Stephen H. Siegel, *Group Practices and Other Exceptions and Exclusions to these Restriction*, chap. 3 in Florida Bar, id.

[90] §456.053, Fla. Stat. (2001); previously this section was § 455.236, Fla. Stat. (1995).

[91] §456.053(5)(g), Fla. Stat. (2001).

[92] §§456.052 and 456.053(5)(j), Fla. Stat. (2002).

[93] §456.052(1)(d), Fla. Stat. (2002).

[94] §§456.052 and 456.053(5)(j), Fla. Stat. (2002).

[95] House Bill 283, enacted Apr. 25, 1996, was codified at and incorporated into §§ 817.505 and 455.237(3), Fla. Stat. (1996). The latter statute has been renumbered and reenacted as §456.054(3), Fla. Stat. (2002).

[96] §456.054, Fla. Stat. (2002), previously § 455.237, Fla. Stat. (1995).

[97] §456.054(3), Fla. Stat. (2002), previously § 455.237(3), Fla. Stat. (1995).

[98] *Ethics and Patient Referrals Act*, 42 U.S.C. §1395nn (commonly referred to as Stark

[99] The Health Care Financing Administration changed its name to the Centers for Medicare and Medicaid Services ("CMS") in 2001.

[100] These became effective on September 13, 1995. 60 F.R. 41914.

[101] 42 C.F.R. §411.351.

[102] 42 U.S.C. § 1320a-7B(B).

[103] For a more extensive discussion of this federal law, please see the publications cited at n. 89 above.

[104] Florida does prohibit the corporate practice of dentistry and the corporate practice of optometry. Please see the separate chapter in this book on this issue.

[105] See, McAdams, Gallagher and Weller, HOSPITAL CONTRACTS MANUAL, Chap. 25 (Aspen 1996).

[106] *Richard Berlin. Jr.. M.D. v. Sarah Bush Lincoln Health Center*, No. 4-95-0569 (Ct.App. 4th Div. Ill.).

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