

Part I

QUALITY

Chapter 1

Clinical Integration: Assessing The Antitrust Issues

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I. INTRODUCTION

§ 1:1 Introduction

In 1996, the federal antitrust agencies announced an

enforcement policy that would allow physician organizations that were “clinically integrated” to engage in joint negotiations over prices with health plans without being condemned as *per se* illegal horizontal price-fixing agreements under the antitrust laws.¹ Instead, the price-related activities of such groups would be subject to rule of reason analysis, which would require the careful assessment of whether the physician members of such organizations had market power and whether their conduct, on balance, would likely have an anticompetitive effect in the markets in which they compete.

Thus, according to the Federal Trade Commission (“FTC”) and the Department of Justice (“DOJ”), sufficiently clinically integrated physician networks for antitrust purposes are treated in the same fashion as financially integrated networks. Agency guidance as to what constitutes financial integration is fairly straightforward. For example, financial integration clearly includes arrangements that involve shared capitation payments, or payments subject to a substantial financial withhold and to meeting group performance goals with respect to cost-containment. In contrast, the *Policy Statements* are much more vague in defining what constitutes “clinical integration.” Moreover, since 1996 the agencies have issued only one advisory opinion—involving the MedSouth physician network in Denver²—addressing the question. While that opinion is illuminating in many respects, it left a number of important questions unanswered.

The dearth of FTC and DOJ guidance on clinical

[Section 1:1]

¹See Federal Trade Comm’n & Dep’t of Justice, *Statements of Antitrust Enforcement Policy in Health Care* (Aug. 1996), reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,153, at <http://www.ftc.gov/reports/hlth3s.htm> [hereinafter *Policy Statements*].

²See Letter from Jeffrey W. Brennan, Ass’t Dir. Health Care Svcs. & Prods., FTC, to John J. Miles, Principal, Ober/Kaler, 2002 WL 463290 (Feb. 19, 2002), at <http://www.ftc.gov/bc/adops/medsouth.htm>.

integration reflects to a large degree their role as antitrust law enforcers—not regulators. For a number of reasons, the agencies' staffs are extremely reluctant to describe the bounds of lawful conduct on a hypothetical basis. First, antitrust analysis is extremely fact specific, and it is very difficult to identify prospectively all of the relevant factors that may come into play in a particular situation. Second, any attempt to describe what constitutes a lawful arrangement runs the risk of being viewed as a “cookie cutter” prescription that must be followed to avoid serious antitrust risk. But following such “recipes” could severely dampen innovative approaches and presumes that the staffs have knowledge of the most efficient ways of structuring health care networks, which they would be the first to admit they do not. Third, attempting to list the “indicia” of clinical integration risks elevating form over substance, with providers seeking to do the minimum they believe is required by the agencies, without focusing on the types of arrangements that actually make sense from quality, cost and practical perspectives. Finally, some agency staff believe that expansive guidelines, without multiple limiting caveats, may come back to haunt them in an enforcement case where the guidelines might be used by respondents in a context that differs dramatically from that originally contemplated.

The net result is that since the revised *Policy Statements* were released in 1996, the federal antitrust agencies have been in a reactive mode in assessing clinical integration and, with the exception of *MedSouth*, there has been very little to which they have publicly reacted.³ This is unfortunate because that lack of guidance has discouraged physicians from exploring clinical integration as a possible means of addressing several issues

³This may change in the near future to the extent that several recent FTC complaints are litigated and these decisions squarely address clinical integration issues. *See, e.g.*, *In re North Texas Specialty Physicians*, No. 9312 (FTC 2003), at <http://www.ftc.gov/os/caselist/d9312.htm>.

that have long plagued the physician community. For, as this chapter will describe, meaningful clinical integration—pursued not simply to justify joint negotiations with health plans, but rather as a means of enabling physicians to achieve efficiency and quality goals that would be difficult to obtain independently—may be a promising way to achieve elusive cost and quality improvements.

This chapter will examine how clinically integrated physician networks⁴ should be assessed under the antitrust laws. In Section II, we begin with a short discussion of some “antitrust basics,” including a review of the guidance from the federal agencies about clinical integration. Section III describes why this may be a particularly propitious time for clinical integration efforts, as they may provide an innovative approach to many of the issues that physicians are confronting currently in their efforts to deliver cost-effective and higher quality medical services. In Section IV, we propose several indicia that antitrust enforcers and the courts should examine to assess whether a physician network is sufficiently clinically integrated to warrant rule of reason treatment. We conclude, in Section V, by addressing several challenging questions posed by clinically integrated arrangements.

II. SOME ANTITRUST BASICS

§ 1:2 In general

Section 1 of the Sherman Act prohibits agreements among two or more parties that unreasonably restrain

⁴The focus here is on clinically integrated networks of physicians. Many of the issues we discuss will also apply to clinical integration involving other health care providers, although there may be differences that relate to how other the providers can work together and the market circumstances they face.

competition.¹ Because the physician organizations discussed here consist of and are controlled by competing, independently practicing physicians, the organizations' activities are deemed to result from an agreement subject to Section 1. Certain types of agreements among actual or potential competitors, such as "naked" horizontal price-fixing or market-allocation agreements, are, on their face, likely to restrain competition and so unlikely to generate significant procompetitive effects, that they are *per se* illegal. Other types of agreements require a more in-depth "rule of reason" analysis that explores the reasonableness and balances the competitive effects of the restraint in the affected geographic and product markets.²

§ 1:3 *Per se* vs. rule of reason distinction

Whether the *per se* rule or the rule of reason applies to determine an agreement's reasonableness depends in large part on the potential of the venture to produce significant efficiencies. The extent of integration among a venture's members has become a proxy for the efficiency-enhancing capability of a venture and, thus, it is the most important variable for determining which

[Section 1:2]

¹"Every contract, combination in the form of trust or otherwise or conspiracy, in restraint of trade or commerce among the several States . . . is hereby declared to be illegal." 15 U.S.C.A. § 1. It is now well accepted that conduct violating Section 1 of the Sherman Act may be found to violate Section 5(a) of the Federal Trade Commission Act, 15 U.S.C.A. § 45(a), which prohibits "unfair methods of competition . . . in or affecting commerce."

²See generally Federal Trade Comm'n & U.S. Dep't of Justice, *Antitrust Guidelines for Collaborations Among Competitors* (2000), reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,161, at <http://www.ftc.gov/bc/guidelin.htm> [hereinafter *Competitor Collaboration Guidelines*]; *Policy Statements* at Statement 8.

antitrust treatment applies.¹ The FTC and DOJ, in their joint *Policy Statements*, have provided guidance on the types of arrangements that they believe tend to foster efficiencies and would, therefore, warrant analysis under the rule of reason. For example, the agencies have stated that financial integration—through substantial risk-sharing arrangements—is a “clear and reliable indicator that a physician network involves sufficient integration [to achieve] significant efficiencies.”²

However, according to the *Policy Statements*, financial integration is only one avenue to rule of reason analysis. Substantial clinical integration is another wholly independent path to that same end,³ and the agencies have indicated an openness to examining other forms of integration that may lead to significant efficiencies.⁴ But rather than provide exhaustive instructions on how to achieve sufficient integration, the agencies have purposefully provided only “broad brush” guidance while acknowledging that innovation should be left to the market and not be constrained by specific directives in the *Policy Statements*. Because both the antitrust enforcement agencies and the physician community have sufficient experience with financially integrated ventures, there is a general understanding regarding what kinds of financially integrated networks would pass legal muster. But this is not the case with physi-

[Section 1:3]

¹See Leary, “The Antitrust Implications of ‘Clinical Integration’: An Analysis of FTC Staff’s Advisory Opinion to MedSouth,” 47 *St. Louis U. L.J.* 223, 233-34 (2003) (“The thing distinguishing a bare cartel that is per se illegal from a legitimate joint venture is the presence of some degree of integration, which can potentially yield efficiencies.”); see also Philip Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 2123(d)(4) (Supp. 2002) (“The requirements for a per se condemnation, then, are a clear restraint accompanied by the absence of efficiency-enhancing integration.”).

²*Policy Statements* at Statement 8 § A.4.

³See *Policy Statements* at Statement 8 §§ B.1, C.1.

⁴See *Policy Statements* at Statement 8 § B.1.

cian networks that rely solely on clinical integration as a means of collaboration. As a result, the line between *per se* and rule of reason treatment for clinically integrated ventures remains somewhat unclear.

§ 1:4 Formal guidance on clinical integration

Until the FTC issued the *MedSouth* advisory opinion in February 2002, the only formal antitrust guidance about sufficient clinical integration was the broad description in Statement 8 of the *Policy Statements*. Despite the guidance from these two sources, tremendous uncertainty about what constitutes sufficient clinical integration remains.

§ 1:5 Formal guidance on clinical integration— Statement 8

Statement 8 describes the antitrust agencies' enforcement policy regarding physician network joint ventures. In earlier versions of the *Policy Statements*—those issued in 1993 and 1994—the agencies discussed only financial integration as a means for structuring collaborative physician joint ventures through which physicians could negotiate prices without running afoul of the *per se* rule.¹ While the agencies did not reject the idea that other forms of collaboration might warrant rule of reason treatment, their focus was squarely on financial integration. In light of the agencies' growing experience with physician arrangements, the evolving nature of the U.S. health care market, and the plethora of comments received from the provider community, the agencies issued a revised policy in 1996 to provide a more expansive discussion regarding acceptable forms

[Section 1:5]

¹See Federal Trade Comm'n & U.S. Dep't of Justice, *Antitrust Enforcement Policy Statements in the Health Care Area* (1993), reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,151; Federal Trade Comm'n & U.S. Dep't of Justice *Statements of Enforcement Policy and Analytical Principles Relating to Health Care and Antitrust* (1994), reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13,152.

of integration. This included a more flexible approach to financial integration, as well as a new concept—clinical integration. While a clinically integrated network would not qualify for “antitrust safety zone” treatment (which still requires financial integration), it could justify analysis of the network’s price-related agreements under the rule of reason.

Statement 8 explains that sufficient clinical integration, absent economic risk sharing, “can be evidenced by the network implementing an active and ongoing program to evaluate and modify practice patterns by the network’s physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality.”² Such a program may include:

- (1) establishing mechanisms to monitor and control utilization of health care services that are designed to control costs and assure quality of care;
- (2) selectively choosing network physicians who are likely to further these efficiency objectives; and
- (3) the significant investment of capital, both monetary and human, in the necessary infrastructure and capability to realize the claimed efficiencies.”³

These elements are examples, not requirements. Instead, as reflected in the hypothetical example included in Statement 8, the agencies’ focus is on the substance of integration, and the efficiencies if any, it likely will generate, rather than the form it takes. The agencies will make a case-by-case assessment of whether a clinically integrated network possesses the

²*Policy Statements* at Statement 8 § B.1.

³*Policy Statements* at Statement 8 § B.1.

likelihood of producing significant efficiencies in order to justify joint price-setting.⁴

Since the inclusion of clinical integration in the 1996 version of the *Policy Statements*, the only additional guidance the agencies have provided regarding clinical integration was in 2002 with the issuance by the FTC of the *MedSouth* advisory opinion.

§ 1:6 Formal guidance on clinical integration— MedSouth

According to the Advisory Opinion request, MedSouth is an independent practice association (“IPA”) of over 430 primary care and specialty physicians in 216 practices located primarily in south Denver, Colorado. These physicians include over 100 primary care practitioners and over 330 specialists in 39 specialties and subspecialties. Prior to developing its clinical integration program, MedSouth had been a financially integrated IPA that had capitated contracts with payers. After a number of IPAs in Denver failed, MedSouth terminated its capitated contracts. Its physician members, however, wanted to continue their collaboration through MedSouth.

Using Statement 8 as a guide, MedSouth developed (and proposed to the FTC) an integration model designed to achieve substantial cost and quality efficiencies. The model had three major goals. Specifically, MedSouth would (1) coordinate its members’ delivery of primary and specialty care services; (2) implement a clinical resource management program with clinical information sharing, development and implementation of clinical protocols, and oversight and monitoring of performance against preestablished benchmarks; and (3) offer payers a network of physi-

⁴See *Policy Statements* at Statement 8 § C.1 (discussing arrangement in “Charlestown” as one possible approach to a clinically integrated physician network joint venture that would be unlikely to raise significant antitrust concerns under the rule of reason).

cians who had all agreed to collaborate through MedSouth to improve quality and offer a competitive alternative to other physicians and physician groups—that is, a product integrating physician services and efficiency tools.

To help achieve the program's goals, MedSouth proposed to implement a web-based clinical data record system and to create, adopt, implement, and monitor clinical practice protocols covering up to 80-90 percent of the diagnoses that are prevalent in MedSouth's physicians' practices. Along with the protocols, MedSouth planned to impose corresponding performance goals on its physicians relating to their service quality and utilization. Each physician would be required to purchase the hardware necessary to access the data system, and MedSouth would develop a clinical data system to collect and analyze physician performance data. Failure to satisfy the preestablished performance goals would subject MedSouth physicians to expulsion from the IPA.

MedSouth also proposed to negotiate collectively fee-for-service rates with commercial managed care payers on a non-exclusive basis. Thus, MedSouth physicians would negotiate and contract with payers individually if the payers did not wish to purchase the network's services. Payers contracting through the network would pay physicians directly, and each physician would bill and submit claims directly to the payer. MedSouth stated that it would not begin collective negotiations until all parts of its integration program became operational.

Based on these representations, the FTC staff concluded that the partial integration of MedSouth's physician practices had the potential to produce substantial fiscal, administrative and quality-related efficiencies. For example, MedSouth's clinical resource management program, including its computer and data system elements, would likely facilitate and increase communication and cooperation among MedSouth physicians regarding treatment and practice patterns, and would

increase interdependence and accountability among the physicians through their development and implementation of practice protocols. This type of collaboration, according to the staff, had the potential for enabling the physicians to achieve improved clinical and economic outcomes that would be difficult for the physicians to attain independently.

The FTC staff also concluded that the collaboration needed to achieve the various projected efficiencies did “not appear to be possible if contracting for the sale of services is done individually.”¹ Individual contracting would eliminate the assurance of full participation by the physicians in the efficiency-producing collaboration and, without such assurance, the proposed efficiencies would likely go unrealized. Therefore, the FTC concluded that the joint negotiations appeared to be reasonably necessary to the success of MedSouth’s integration program.

The FTC staff cautioned that it could not provide an analysis of all the possible competitive effects arising from MedSouth’s program because the program had not been implemented. However, the staff attempted to highlight several characteristics of the market and the program that could be important in a competitive effects analysis under the rule of reason. For example, MedSouth’s large concentration of physicians in the south Denver area coupled with the rapid population growth of that area, the impending shortage and lack of entry of physicians in the area, and the dearth of feasible alternatives for patients and payers outside of south Denver, suggested that MedSouth might have sufficient market power to negotiate supra-competitive rates. Regardless of its non-exclusivity policy, that power could provide the MedSouth physicians with the

[Section 1:6]

¹See Letter from Jeffrey W. Brennan, Ass’t Dir. Health Care Svcs. & Prods., FTC, to John J. Miles, Principal, Ober/Kaler, 2002 WL 463290, at *8 (Feb. 19, 2002), at <http://www.ftc.gov/bc/adops/medsouth.htm>.

incentive and ability to require plans to negotiate with MedSouth, rather than with MedSouth physicians individually. The FTC suggested that a significant decrease in the number of participating physicians would lessen this risk of anticompetitive harm.

Finally, the staff warned that its opinion was highly dependent on MedSouth's full implementation of its program's various elements (*e.g.*, the electronic record system and evidence-based protocols) and its success in achieving other intangibles, such as physician commitment to the program and effective leadership. Absent fully achieving these goals, the FTC cautioned that MedSouth would be unlikely to achieve many of the efficiencies justifying rule of reason analysis.

§ 1:7 Tremendous uncertainty about clinical integration

Notwithstanding the analysis provided in the *Policy Statements* and the *MedSouth* opinion, there remains tremendous uncertainty regarding the antitrust assessment of clinically integrated physician joint ventures. For instance, some payers and antitrust enforcers question whether networks that claim to be clinically integrated simply wish to obtain cover for efforts to raise their fees through collective negotiations.¹ In addition, neither the *Policy Statements* nor the *MedSouth*

[Section 1:7]

¹*See, e.g.*, Desmarais, Testimony at the Joint FTC/DOJ Hearings on Health Care and Competition Law and Policy, 170-71 (Feb. 27, 2003) (raising concerns of health insurance association regarding whether MedSouth's operations "will function as proposed and not violate antitrust law"), at <http://www.ftc.gov/ogc/healthcarehearings/030227trans.pdf>; Leary, "The Antitrust Implications of 'Clinical Integration': An Analysis of FTC Staff's Advisory Opinion to MedSouth," 47 St. Louis U. L.J. 223, 232 (2003) (discussing test to determine whether proposed clinical integration is a pretext to avoid *per se* condemnation); Panel Testimony at the FTC Health Care and Competition Law and Policy Workshop 183-94 (Sept. 9, 2002) (discussing difficulties of assessing whether increases in price are the result of market power

opinion provide clear answers on how to identify a clinically integrated network; when such integration is sufficient to justify collective price negotiations; and when and how such negotiations can be lawfully undertaken. Before addressing these issues in Sections IV and V, the following section will discuss how clinical integration may provide an alternative approach—different from total integration through physician-practice mergers or financial integration through risk sharing by IPAs—for physicians who wish to find a collaborative means for improving quality and efficiency in the delivery of health care services.

III. THE TIME MAY BE RIPE FOR CLINICAL INTEGRATION

§ 1:8 In general

Observers have noted for decades that despite unparalleled achievements in many areas, health care services in the United States are costly and uneven in quality. The United States spends about 14 percent or \$1.4 trillion per year of its gross domestic product on health care.¹ Although health care spending is increasing globally, other industrialized nations spend significantly less of their GDP—about 8.5 percent—on health

or a reflection of a better product), at <http://www.ftc.gov/ogc/healthcare/20909trans.pdf>; see also *In re California Pacific Medical Group, Inc.*, No. 9306 (FTC 2003).

[Section 1:8]

¹See Heffler et al., “Health care spending projections for 2002-2012,” *Health Affairs*, W3-54 (Feb. 7, 2003), Web Exclusive, at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.54v1.pdf>; Ginsburg and Nichols, “The Health Care Cost-Coverage Conundrum: The Care We Want vs. The Care We Can Afford,” *HSC Annual Essay 2002-03*, 1 (Fall 2003), at http://www.rwjf.org/research/files/HSC%20Annual%20Essay%20__FINAL.pdf.

care.² Despite these expenditures in the United States, the quality of health care services here could be substantially improved, as evidenced by the Institute of Medicine (“IOM”) report released in 2000, which estimated that between 44,000 and 98,000 preventable deaths occur each year in the United States from medical error.³ But notwithstanding their desire to achieve better clinical and fiscal outcomes, health care providers have been slow to employ tools, such as evidence-based medicine protocols and information technologies, that hold the promise of improving quality, enhancing efficiencies, and reducing medical errors and costs.

The slow implementation of these types of mechanisms can be ascribed, in part, to a long-standing physician culture that tends to value autonomy and independence over the benefits resulting from larger organizations, such as fully integrated multi-specialty group practices.⁴ These organizations often provide capital, administrative expertise and a collaborative infrastructure for achieving economies of scale in both “production” and contracting that physicians have difficulty achieving independently. Despite these potential benefits, 2000-2001 survey data reveal that the vast majority (82%) of physicians in private practice continue to work in groups with nine or fewer physicians (47% work by themselves or in a pair and 35% work in practices of between three and nine physicians).⁵ Although single-specialty groups of between five and 20 physicians have grown to some extent, less than 10 percent

²See Health at a Glance—OECD Indicators 2003 Briefing Note (United States of America) (Oct. 16, 2003), at <http://www.oecd.org/dataoecd/20/48/16502658.pdf>.

³See Institute of Medicine, “To Err is Human: Building a Safer Health System,” ed. L. Kohn, J. Corrigan, and M. Donaldson (Washington, D.C., National Academy Press, 2000).

⁴Berenson, “Beyond Competition,” 16 Health Affairs 171, 174-75 (Mar./Apr. 1997).

⁵See Casalino et al., “Benefits and Barriers to Large Medical Group Practice in the United States,” reprinted in 163 Arch. Intern. Med. 1958, 1960, tbl. 2 (AMA Sept. 2003).

of physicians work in single or multi-specialty practices of 10 or more, and that percentage decreases substantially as the size of the group increases.⁶

In addition, the decline in risk-contracting arrangements offered by health maintenance organizations (“HMOs”) has removed a powerful incentive to integrate for those physicians who would be willing to join larger, efficiency-producing organizations, such as risk-sharing IPAs. IPAs can provide the administrative benefits and other efficiencies of large pre-paid multi-specialty groups—such as the Mayo Clinic and Permanente Medical Group—to physicians who desire to remain independent. Of course, because they share financial risk, physicians in IPAs also can negotiate collectively with health plans on risk-based HMO contracts without running afoul of the *per se* rule.

However, beginning in the late 1990s, HMOs began to experience a strong consumer backlash against tightly managed care. Since that time, consumers have increasingly disfavored restrictions on access based on limited provider networks and gatekeepers. As consumers retreat to other more loosely structured forms of managed care offered through preferred provider organizations (“PPOs”), health plans and providers have moved away from capitation and other risk-based arrangements.⁷

With the exodus of patients from HMOs, the decline of risk contracting and poor management (in some cases), many IPAs have failed in various parts of the

⁶See Casalino et al., “Benefits and Barriers to Large Medical Group Practice in the United States,” reprinted in 163 *Arch. Intern. Med.* 1958, 1960, tbl. 2 (AMA Sept. 2003).

⁷See Lesser et al., “The End of an Era: What Became of the ‘Managed Care Revolution’ in 2001?,” 38:1 *Health Services Research* 337, 344-45 (Feb. 2003), at <http://www.hschange.com/CONTENT/524/>; Strunk and Reschovsky, “Kinder and Gentler: Physicians and Managed Care, 1997-2001,” HSC Tracking Report No. 5, 1-2 (Nov. 2002).

country.⁸ Moreover, unless the IPAs are clinically integrated, they risk antitrust exposure if they engage in collective negotiations in PPO and other non-risk contracts. As explored below, clinical integration could be a promising alternative to risk sharing and group affiliation for physicians who desire to maintain their independence but wish to obtain the resources and infrastructure for containing cost, improving quality and achieving other efficiencies.

§ 1:9 Potential benefits of clinically integrated physician practices

The potential benefits of combining independent physician practices into clinically integrated networks—if pursued creatively and conscientiously—are numerous. Such networks could support increased use of evidence-based medicine and information technologies, provide the opportunity for greater transaction efficiencies with health plans, and promote increased teamwork and clinical education.

§ 1:10 Potential benefits of clinically integrated physician practices—Increased use of evidence-based medicine

Clinical guidelines and care management programs furnish health care practitioners with reliable and effective treatment information based on medical literature and scientific review (*i.e.*, evidence-based medicine). But while many evidence-based guidelines and programs are publicly available, to be successful initiatives, they need to be physician-driven. Physicians, however, often lack sufficient time to research these

⁸See Casalino, Testimony at the Joint FTC/DOJ Hearings on Health Care and Competition Law and Policy 7 (Sept. 25, 2003) (“The reason that the number of IPAs is declining is really due to the changes in managed care from the expectation, if not the reality, of what I would call tight managed care with a lot of risk contracting to loose managed care.”), at <http://www.ftc.gov/ogc/healthcarehearings/030925ftctrans.pdf>.

sources or focus on how they and their staff should implement them in a useful manner. Physicians also generally lack or are unwilling to devote the resources necessary to hire qualified managers to oversee and enforce compliance with the guidelines, or the capital to invest in the information systems that collect and analyze critical performance data.¹

Moreover, even if physicians could find enough time and money to overcome these problems, as independent practitioners, they lack access to information from peers against whom their performance could be reliably measured. Because reliable measurements cannot be made when one physician, or a small group, is the only “unit of analysis,”² the reliability of such analysis depends on the agreement by a sufficiently-sized group of physicians to comply with a specific single set of guidelines. Without such an agreement, there would be no external incentive to enforce compliance or push for performance improvements beyond the “low-hanging fruit.” Combining many physician practices into a clinically integrated network that can spread the cost of implementing, monitoring and enforcing clinical processes across all members could provide the infrastructure necessary for physicians to effectively utilize evidence-based medicine protocols to achieve improved outcomes.

§ 1:11 Potential benefits of clinically integrated physician practices—Increased use of information technologies

In addition to evidence-based medicine initiatives, clinically integrated physician groups could increase

[Section 1:10]

¹See Casalino et al., “Benefits and Barriers to Large Medical Group Practice in the United States,” reprinted in 163 Arch. Intern. Med. 1958, 1960-61, 1962 (AMA Sept. 2003).

²See Casalino et al., “Benefits and Barriers to Large Medical Group Practice in the United States,” reprinted in 163 Arch. Intern. Med. 1958, 1962 (AMA Sept. 2003).

the use of information technology to reduce medical errors and achieve other important efficiencies. As information technologies have become pervasive in many sectors of the economy, there is increasing recognition of the value they might add to the practice of medicine.¹ Nevertheless, the physician community lags far behind other sectors in using such technology.²

Electronic medical records, computerized physician ordering systems, personal digital assistants, hand-held computers and electronic prescribing tools, for example, can improve health outcomes by providing clinicians with instant and real-time access to patient information and clinical decision-support software.³ Such technologies have been linked to many efficiencies, including reductions in medical errors associated with drug interactions and misconstrued handwritten and verbal orders.⁴ Electronic and web-based claims submission systems offer major administrative efficiencies by greatly reducing administrative time, paper work errors and turnaround time for accounts receivable.⁵

Although much attention has been focused on increasing the use of these types of technologies in the hospital

[Section 1:11]

¹See Deloitte Research, “Clinical Transformation: Cross-Industry Lessons for Health Care,” 1, 28 (2003), at http://www.dc.com/Insights/research/health/clinical__trans.asp.

²See generally Deloitte Research, “Clinical Transformation: Cross-Industry Lessons for Health Care” (2003), at http://www.dc.com/Insights/research/health/clinical__trans.asp.

³See Deloitte Research and Fulcrum Analytics, “Taking the Pulse: Physicians and Emerging Information Technologies,” 1, 6, 11-12 (2002), at http://www.dc.com/Insights/research/health/ehealth__series.asp.

⁴See Deloitte Research, “Clinical Transformation: Cross-Industry Lessons for Health Care,” 1, 6, 11-12 (2003), at http://www.dc.com/Insights/research/health/clinical__trans.asp.

⁵See Jaklevic, “Making it click,” *Modern Healthcare* (Oct. 27, 2003), at <http://www.modernhealthcare.com/article.cms?articleId=30837>.

setting, industry groups and government agencies are beginning to evaluate whether such tools might also improve performance in physician practices.⁶ Physicians are also exploring information technologies, but many are reticent to adopt these new, and often costly, innovations without hard evidence of the efficiencies they will add to the daily practice of medicine.⁷ Clinically integrated practices could provide the necessary resources and a helpful culture for implementing these types of outcome-enhancing technologies.

§ 1:12 Potential benefits of clinically integrated physician practices—Increased transaction efficiencies

Similar to the role played by IPAs and large group practices, clinically integrated networks could provide an administrative infrastructure to ease the burdens faced by independent physicians in contracting with multiple health plans and implementing numerous health plan contracts. Understanding and evaluating the various types of products offered by different health plans and their associated fee schedules, coverage restrictions, claims and billing standards, utilization management processes, authorization requirements and other terms can be daunting for even the most sophisticated independent practitioners. Additionally, most physicians lack the financial information systems and expertise to assess whether they have been paid according to their contracts. In contrast, clinically integrated networks could reduce the time and cost physicians spend dealing with different payers by employing busi-

⁶See Morrissey, “Adding up quality standards,” *Modern Healthcare* (Oct. 20, 2003), at <http://www.modernhealthcare.com/article.cms?articleId=30780>.

⁷See Deloitte Research, “Clinical Transformation: Cross-Industry Lessons for Health Care,” 1, 14 (2003), at http://www.dc.com/Insights/research/health/clinical_trans.asp; see also Berwick, “Disseminating Innovations in Health Care,” 289 *J. Am. Med. Ass’n* 1969, 1969 (2003).

ness personnel to help evaluate contract offers and oversee streamlined billing, claims and utilization management processes on behalf of all member physicians.

Clinical integration also has the potential to promote other efficiencies for physicians in connection with disease management and pay-for-performance programs. Disease management programs provide education, self-care guidelines and treatment reminders to patients and their physicians as a preventative approach to curbing the exorbitant costs of treating patients with chronic illnesses, such as diabetes, asthma, and heart disease.¹ “Pay-for-Performance” programs offer financial incentives to providers that achieve certain pre-established clinical targets in specified service lines (*e.g.*, pneumonia, hip and knee replacement, or heart failure).² With more and more payers offering or participating in these types of programs, physicians are faced with a multitude of, among other things, inconsistent performance criteria, clinical protocols and formulary compliance standards, each of which applies to only a small portion of the services they furnish. Rather than attempting to manage the plethora of dissimilar requirements associated with these programs and the multiple parties that offer them, many physicians may simply ignore them all. In contrast, a clinically integrated network could

[Section 1:12]

¹See Short et al., “Disease Management: A Leap of Faith to Lower-Cost, Higher-Quality Health Care,” HSC Issue Brief No. 69, 1-2 (Oct. 2003), at <http://www.hschange.com/CONTENT/607/>. See also Ch 3.

²For more information regarding Pay-for-Performance, see, *e.g.*, United States Dep’t of Health and Human Servs., Center for Medicare and Medicaid Servs., CMS Hospital Quality Initiative (HQI), at <http://www.cms.gov/quality/hospital/>; Press Release, Integrated Healthcare Association, “Integrated Healthcare Association Part of National Initiative to Base Health Care Payments on Quality” (Sept. 26, 2002), at <http://www.leapfroggroup.org/RewardingResults/pdf/iha.pdf>; Integrated Healthcare Association, What’s New at IHA, IHA Projects (Pay for Performance), at <http://www.ih.org/wnproj.htm>.

create its own single program or otherwise provide payers with a basis for agreeing to a single set of consistent requirements, which could then be offered to multiple payers. Moreover, the network can use a common set of reporting forms to facilitate data collection and analysis. Such approaches also could provide opportunities for competition on standards and implementation to develop in the marketplace as groups of physicians compete with each other in providing alternative approaches to addressing cost and quality issues.

§ 1:13 Potential benefits of clinically integrated physician practices—Increased opportunities for medical education

Physicians have generally not been receptive to external attempts—particularly by health plans—to provide them with clinical information.¹ Moreover, the realities of independent practice make it difficult for physicians to collaborate with their colleagues outside medical conferences or formal clinical medication education programs. Clinically integrated networks, however, could facilitate interaction among network physicians, facilitating their sharing of ideas and innovations. Physicians may be more receptive to this type of collegial interaction because it is similar, in some respects, to the group learning techniques (*e.g.*, grand rounds) used by the medical profession to train physicians.²

IV. HOW DO WE KNOW A CLINICALLY INTEGRATED NETWORK WHEN WE SEE IT?

§ 1:14 In general

Financial integration is a very useful “marker” for

[Section 1:13]

¹See Berenson, “Beyond Competition,” 16 Health Affairs 171, 176 (Mar./Apr. 1997).

²Gosfield, “Quality and Clinical Culture: The Critical Role of Physicians in Accountable Health Care Organizations” 8 (AMA 1998).

determining whether the rule of reason should apply to network price negotiations because it provides relatively objective criteria that can be relied on by antitrust enforcers, as well as by physician networks and those who advise them. Unfortunately, clinical integration is a much more amorphous concept. This is largely unavoidable because there are a myriad of ways in which providers might come together to create efficiencies. Rigidly defining clinical integration would force the antitrust enforcers to take on a regulatory role that could have the unfortunate effect of discouraging innovative approaches.

On the other hand, without concrete guidance as to what may pass antitrust muster, physicians will be reluctant to venture into the uncharted waters of clinical integration for fear of being accused of *per se* illegal price-fixing if they negotiate prices through the network. As noted above, the *Policy Statements* discuss three factors that may evidence a clinical integration program: (1) mechanisms to monitor and control utilization to control costs and assure quality; (2) selectively choosing network physicians to promote the program's objectives; and (3) significant investment of both monetary and human capital.¹ This section examines these and other factors more closely to shed more light on factors relevant in assessing whether a physician network is clinically integrated for the purpose of antitrust analysis.

A useful starting point is to consider the characteristics of fully integrated and partially integrated arrangements that warrant rule of reason treatment under the antitrust laws. In a fully integrated group practice, where the physicians have merged their independent practices into a single entity, the physicians will have ceded substantial control to that entity. This is similar to the transfer of control to a law firm that occurs when individual lawyers join together to form a law firm partnership. The entity (and, depending on how it is

[Section 1:14]

¹See § 1:5, text accompanying note 3.

structured, the physician members or shareholders of the entity) may be liable for the conduct of each of the physicians. Also, depending on how the entity is structured, competition among the group's physician members will be reduced or eliminated entirely. Again, the law firm analogy is apt. Absent market power, antitrust law presumes that this reduction in "intrafirm" competition should be tolerated, because the entity achieves efficiencies that increase "interfirm" competition.

An IPA, which is only partially integrated, lacks the transfer of control, degree of integration, and shared liability that is typical of a group practice.² The extent to which financial risk is shared varies greatly among IPAs, as it does among group practices. For example, in some group practices (as in some law firms), each member may be paid based largely on the revenues attributable to his or her production, minus that member's share of the group's costs. In contrast, in other practices, net profits are shared among members pursuant to a predetermined formula based on variables such as seniority, reputation, and administrative duties rather than only on individual production.

Generally, IPAs embody less actual and potential financial risk-sharing than group practices. Partly because of this, IPA arrangements typically preserve

²The laws and regulations governing Medicare providers reflect this difference. Specifically, a "group practice" for Medicare purposes requires the integration of two or more physicians into a legally organized entity through which the physicians furnish the majority of their services; the group entity submits claims under one billing number and amounts received are treated as group receipts; and, inter alia, overhead expenses and income are distributed amongst the group members. See 42 U.S.C.A. § 1395nn(h)(4)(A); see also 42 C.F.R. § 1001.952 (providing an exception from the fraud and anti-kickback regulations for qualified investments in group practices that are "unified business[es] with centralized decision-making, pooling of expenses and revenues and a compensation/profit distribution system that is not based on satellite offices operating substantially as if they were separate enterprises or profit centers").

more competition among their physician members. Because of their shared financial risk, IPA members have an incentive to work together to reduce costs and improve quality even though they compete with one another for patients. Thus, there remains substantial “intrafirm” competition, while at the same time the IPA promotes interfirm competition by itself competing with other IPAs or large multispecialty groups.

The *Policy Statements* presume that substantial financial risk-sharing provides the physicians in an IPA with significant incentives to achieve efficiencies because the efficiencies inure to the physicians’ financial benefit.³ Accordingly, a close examination of the actual efforts to achieve efficiencies is not necessary. In networks that are only clinically integrated, however, financial incentives are absent, and thus a fact-specific examination is necessary to determine precisely what the physicians are doing together, through their partial integration, to improve their performance.

In conducting this examination, one should look for the same types of structures and efforts that characterize partially-integrated risk-sharing IPAs or fully-integrated practice groups that are engaged in trying to reduce costs and improve quality. We can start with the three factors specifically mentioned by the *Policy Statements*:

(1) **Mechanisms to monitor and control utilization of health care services that are designed to control costs and ensure quality.** The *Policy Statements* and *MedSouth* opinion provide a number of examples of such mechanisms, including the following:

- Establishment of goals relating to quality and appropriate utilization.⁴

³See *Policy Statements* at Statement 8 § A.4.

⁴See Letter from Jeffrey W. Brennan, Ass’t Dir. Health Care Svcs. & Prods., FTC, to John J. Miles, Principal, Ober/Kaler, 2002 WL 463290, at *3 (Feb. 19, 2002), at <http://www.ftc.gov/bc/adops/medsouth.htm>; *Policy Statements* at Statement 8 § B.1.

- Regular evaluation of individual and aggregate performance with respect to the established goals. In *MedSouth*, the network planned to use a computer-based infrastructure to enable this ongoing analysis of performance data.⁵ The opinion also describes how a Medical Director and Clinical Integration Committee would review data on an ongoing basis and meet with physicians to ensure their compliance with established benchmarks and protocols.⁶
- Case management.⁷
- Preauthorization of some services.⁸
- Concurrent and retrospective review of inpatient stays.⁹
- Development of practice standards and protocols, and active review of the care rendered by each doctor in light of these standards and protocols.¹⁰ In *MedSouth*, the network indicated that at least 48 guidelines were under development, and that a total of 100-150 were contemplated that would cover 80-90 percent of the diagnoses that were prevalent in the physicians' practices.¹¹ These protocols would be reviewed periodically to

⁵See Letter from Jeffrey W. Brennan, Ass't Dir. Health Care Svcs. & Prods., FTC, to John J. Miles, Principal, Ober/Kaler, 2002 WL 463290, at *4 (Feb. 19, 2002), at <http://www.ftc.gov/bc/adops/medsouth.htm>.

⁶See Letter from Jeffrey W. Brennan, Ass't Dir. Health Care Svcs. & Prods., FTC, to John J. Miles, Principal, Ober/Kaler, 2002 WL 463290, at *4 (Feb. 19, 2002), at <http://www.ftc.gov/bc/adops/medsouth.htm>.

⁷See *Policy Statements* at Statement 8 § C.1.

⁸See *Policy Statements* at Statement 8 § C.1.

⁹See *Policy Statements* at Statement 8 § C.1.

¹⁰See *Policy Statements* at Statement 8 § C.1.

¹¹See Letter from Jeffrey W. Brennan, Ass't Dir. Health Care Svcs. & Prods., FTC, to John J. Miles, Principal, Ober/Kaler, 2002 WL 463290, at *4 (Feb. 19, 2002), at <http://www.ftc.gov/bc/adops/medsouth.htm>.

ensure that they were current.¹²

- Implementation of a web-based electronic clinical data record system that would allow network physicians to access and share clinical information relating to their patients.¹³

A network need not employ all of these mechanisms to be clinically integrated; nor is this an exhaustive list. There are undoubtedly many other specific ways in which physicians can work together to improve quality and reduce costs.

Such lists are useful in providing examples of mechanisms that may be employed in clinically integrated networks. But there is a danger that an antitrust assessment will take an oversimplified “checklist” approach of simply trying to match the network’s initiatives with those mentioned in the *Policy Statements* or the *MedSouth* opinion. What might make sense and work in south Denver for *MedSouth* may not make sense or work for a network in a different market, composed of a different mix of physicians, facing a different set of challenges. Such a “cookie-cutter” approach also runs a serious risk of elevating form over substance.

(2) **Use of selective participation criteria.** By carefully selecting who can participate, a network can help assure minimum quality and efficiency standards and distinguish itself from its competitors. Networks that apply extremely selective participation criteria tied to quality, cost-control and other efficiency measures present a very compelling case that their joint efforts have significant procompetitive potential. Thus,

¹²See Letter from Jeffrey W. Brennan, Ass’t Dir. Health Care Svcs. & Prods., FTC, to John J. Miles, Principal, Ober/Kaler, 2002 WL 463290, at *4 (Feb. 19, 2002), at <http://www.ftc.gov/bc/adops/medsouth.htm>.

¹³See Letter from Jeffrey W. Brennan, Ass’t Dir. Health Care Svcs. & Prods., FTC, to John J. Miles, Principal, Ober/Kaler, 2002 WL 463290, at *3 (Feb. 19, 2002), at <http://www.ftc.gov/bc/adops/medsouth.htm>.

for example, the *MedSouth* opinion emphasized how physicians who failed to participate fully in the program or adhere to its standards would be subject to network expulsion.¹⁴

On the other hand, although the *Policy Statements* refer to this factor, the absence of rigorous selection criteria, particularly in the early stages of a network, should not necessarily mean that the network lacks clinical integration. When a network starts, it may need to employ relatively permissive selection criteria to ensure a full panel of physicians. Moreover, the network may lack the necessary data to assess physician performance adequately, and substantial time may be needed to gather and analyze the data necessary for making rational and objective participation decisions. Finally, excluding a physician from a network, particularly if it is a successful network, can be a very difficult “political” undertaking. Expelling an existing member for failure to meet the network’s efficiency standards is likely to be even more difficult. Therefore, some networks may have relatively relaxed participation criteria, at least at the beginning, but then implement various enforcement mechanisms to ensure that their members adhere to their standards.

(3) **Significant investment in both human and monetary capital to achieve claimed efficiencies.** As with a fully or partially integrated physician venture, the physicians forming a clinically integrated physician network must devote substantial time, money and commitment to the network for it to achieve meaningful results.¹⁵ The most significant expenditures likely will be for a paid professional staff, including medical and information systems personnel, as well as

¹⁴See Letter from Jeffrey W. Brennan, Ass’t Dir. Health Care Svcs. & Prods., FTC, to John J. Miles, Principal, Ober/Kaler, 2002 WL 463290, at *4 (Feb. 19, 2002), at <http://www.ftc.gov/bc/adops/medsouth.htm>.

¹⁵The commitment of money can also be viewed as a form of financial integration.

for the information system infrastructure, including both hardware and software. Perhaps even more important will be the investment of time and commitment by the physicians. Changing physician practice patterns can be a very difficult task, and will not result from simply adopting a set of clinical guidelines and state-of-the-art information technology. Rather, the network must obtain physician “buy-in” and commitment, which can be achieved only through countless hours of working with physicians so that they understand and take on “ownership” of the network’s goals and programs. This is particularly important in clinically integrated networks because the physicians lack direct financial incentives to increase efficiency.

§ 1:15 Other indicia of clinical integration

In addition to the three aspects of clinical integration specifically mentioned in the *Policy Statements*, other factors should be probative of a network’s clinical integration efforts.

The first is the extent to which the network “brands” itself as a distinct entity with health plans, other providers, employers and the general community. For various reasons, some clinically integrated networks may choose not to invest the time and expense to brand themselves. But if they do, their holding themselves out as a distinct, competing network of providers meeting certain high standards of quality or cost containment reflects a shared commitment to a common undertaking. The act of branding increases the extent to which the performance of each physician in the network implicates and affects other physicians in the network and, therefore, their incentives to work together to improve each other’s practice. One can also look at what investments are made in the brand, how the brand is maintained, and how closely it is linked to the accomplishment of goals that were not achievable before the integration.

Another factor that should evidence clinical integra-

tion is the extent to which the physicians work with and cross-refer primarily or exclusively with other network physicians. This characteristic reflects several important aspects of clinical integration. For example, it could demonstrate the extent to which physicians follow common agreed-upon protocols, take advantage of shared medical record and information systems, identify best practices and those individuals who are most experienced or qualified in certain highly specialized areas, and utilize that knowledge to provide optimum patient care.

Clinical integration also might be evidenced by internal arrangements within the network to provide rewards or penalties to physicians based on the extent to which they have met pre-established performance goals. Such financial arrangements would not qualify, on their own, as the sort of financial risk-sharing that warrants rule of reason treatment for joint negotiation of prices because they would be based on individual, not aggregate, network performance. That is, they do not necessarily provide incentives for physicians to work with each other interdependently to help improve the performance of their colleagues. On the other hand, they are potentially powerful mechanisms on the part of the network to achieve its goals. Such forms of financial rewards may provide the financial incentive absent in “pure” clinically integrated networks, increasing the assurance that members will actively participate in the program. Of course, clinically integrated networks also may adopt financial incentive mechanisms that reward group performance, and therefore include elements of financial integration.

Finally, also relevant is the extent to which the network can, in fact, point to specific, measurable achievements in cost control and quality improvement. Obviously, this is impossible during the first stages of the network’s activities, before it has accumulated data and tracked performance. And certainly during this early period, the lack of outcomes data does not mean that a network is not clinically integrated. Thus, for

example, a network may be up and running several years before it is able to track its accomplishments in a statistically meaningful fashion. Nor should it be expected that a clinically integrated network will achieve all its goals. But that a network has instituted reliable ways to assess performance and has achieved demonstrable successes in areas important to health plans, employers and patients is compelling evidence that it is clinically integrated.

§ 1:16 A more “wholistic” approach

The previous discussion highlights some specific factors that should be present in a clinically integrated network. But clinical integration has no simple “cook-book” recipe. In assessing whether a physician network exhibits sufficient clinical integration, rather than simply “checking off” which elements are present, we suggest a more “wholistic” approach that broadly addresses three issues:

- First, to what extent is the clinical integration program focused on achieving improved clinical performance in areas that are important to the physicians’ customers—that is, patients and the government and private health plans and employers who pay for the physicians’ services? The growing number of “Pay-for-Performance” programs now being initiated by health plans can provide very helpful guidance about clinical performance areas important to health care purchasers. Surveys and discussions with health plans can provide additional input.
- Second, it is crucial that the program include ongoing oversight, correction and enforcement mechanisms to ensure performance. This is essential because, unlike financially integrated networks, clinically integrated networks lack the direct financial incentives to drive efficiencies. Thus, there must be other types of oversight or pressure to achieve goals. These could range from peer pressure to individual financial penal-

ties to network expulsion.

- Finally, from an antitrust perspective, an adequate clinical integration program must be a shared undertaking among physicians that enables them to achieve efficiencies together that they would be unlikely to attain independently. The undertaking can be “shared” in many ways. For example, physicians in a clinically integrated network may achieve scale and scope efficiencies that enable them to be more cost-effective and permit them to deliver a broader range of services. They can share their particular areas of expertise with one other. Use of a shared information system and technology can facilitate the coordination of patient care. Through these and other forms of collaboration, the physicians become interdependent on one another and the “whole becomes greater than the sum of the parts.” It is that promise of increased efficiencies through interdependency that justifies examining the venture under the rule of reason instead of condemning it without a further look as *per se* illegal.

V. SOME CHALLENGING QUESTIONS

§ 1:17 In general

Determining whether or not a physician network is clinically integrated is only a threshold question. A number of challenging issues then arise concerning how the network’s conduct should be assessed under the antitrust laws.

§ 1:18 Is the joint negotiation ancillary to the clinical integration?

First, even where a physician network is clinically integrated, the question remains as to whether the joint negotiations by the network are “ancillary” to the network’s integration—*i.e.*, are they reasonably related and necessary to achieve the network’s procompetitive

benefits.¹ In other words, one must ask how the joint negotiations support the clinical integration effort or why the joint negotiations significantly increase the probability of the network's achieving its efficiency goals. In short, why can't the physicians improve their quality, efficiency and performance, but still set their own prices and negotiate independently?

Agreements resulting in restraints on competition (e.g., joint negotiation of prices by competing physicians with payers) are ancillary when they are "reasonably necessary" to a venture's efficiency-enhancing effects.² A "reasonably necessary" restraint need not be "essential" to the achievement of efficiencies.³ The DOJ and FTC,

[Section 1:18]

¹See *Competitor Collaboration Guidelines* §§ 1.2, 3.36(b); *Policy Statements* at Statement 8.

²See *Competitor Collaboration Guidelines* § 3.36(b); see also *Northwest Wholesale Stationers, Inc. v. Pacific Stationery and Printing Co.*, 472 U.S. 284, 296 n.7, 105 S. Ct. 2613, 86 L. Ed. 2d 202 (1985) (the restraint should be "substantially related to the efficiency-enhancing or procompetitive purposes"); *Broadcast Music, Inc. v. Columbia Broadcasting System, Inc.*, 441 U.S. 1, 19-20, 99 S. Ct. 1551, 60 L. Ed. 2d 1 (1979) (the analysis of ancillarity should "focus on whether . . . the practice facially appears to be one that would always or almost always tend to restrict competition and decrease output"); *SCFC ILC, Inc. v. Visa USA, Inc.*, 36 F.3d 958, 970 (10th Cir. 1994) (restraints that are "reasonably related" to the venture's operations and makes them "more effective in accomplishing its purposes" should be assessed under the rule of reason); *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 224 (D.C. Cir. 1986) ("the restraint imposed must be related to the efficiency sought to be achieved"); *Polk Bros., Inc. v. Forest City Enterprises, Inc.*, 776 F.2d 185, 189 (7th Cir. 1985) ("If the restraint . . . may promote the success of . . . more extensive cooperation, then the court must scrutinize things carefully under the rule of reason."); *General Leaseways, Inc. v. National Truck Leasing Ass'n*, 744 F.2d 588, 595 (7th Cir. 1984) (there must be an "organic connection between the restraint and the cooperative needs of the enterprise that would allow us to call the restraint . . . ancillary").

³See *Competitor Collaboration Guidelines* § 3.36(b). *But see* *New York ex rel. Spitzer v. Saint Francis Hosp.*, 94 F. Supp. 2d

however, will conclude that the relevant agreement is not “reasonably necessary” if the participants could have achieved similar efficiencies by practical, significantly less restrictive means.⁴ Identifying practical alternatives requires consideration of the business realities faced by a joint venture’s members. Business realities also help determine the “reasonable necessity” of a restraint. For example, a restraint may be reasonably necessary to dissuade opportunistic conduct, such as free-riding by individual venture participants, or it may be necessary to discourage one participant from appropriating an undue share of the fruits of the collaboration or to align participant incentives to encourage cooperation in achieving the efficiency goals of the venture.⁵

There are several reasons why joint pricing may be ancillary in a clinically integrated network. First, as the *MedSouth* opinion recognized, for a clinical integration program to be effective, a network must be able to count on the active participation of all of the group’s members.⁶ This cannot be guaranteed without collective negotiations that would assure that, if an agreement is reached with a payer, all the network’s physicians would participate. Thus, there may be a need for an agreement that if the payer’s contracts satisfy certain price and non-price criteria, all of the network physicians will participate.

Second, as discussed above, the network may wish to allocate revenues achieved from contracts through various reward and penalty mechanisms to provide incen-

399, 415 (S.D. N.Y. 2000) (restraints that would otherwise be unlawful under antitrust laws should be “necessary” to make the services or products of a joint venture available).

⁴See *Competitor Collaboration Guidelines* § 3.36(b).

⁵See *Competitor Collaboration Guidelines* § 3.36(b).

⁶See Letter from Jeffrey W. Brennan, Ass’t Dir. Health Care Svcs. & Prods., FTC, to John J. Miles, Principal, Ober/Kaler, 2002 WL 463290, at *8 (Feb. 19, 2002), at <http://www.ftc.gov/bc/adops/medsouth.htm>.

tives for physicians to meet the network's goals. As the *MedSouth* opinion acknowledged, to implement such a program may require joint contracting.⁷

Joint negotiations also may be necessary to guard against the possibility of “free-riding” by certain physician members. The concern is that unless the network can negotiate and contract on behalf of all of its members, some physicians could free-ride on the contributions of their colleagues and the accomplishments of the network so that they can offer more efficient, higher quality services, and then contract independently to provide these services at a lower price by undercutting other network members. If this can occur, physicians may be reluctant to fully commit themselves to the program at the outset, thereby limiting the potential of the network.

Another rationale for collective negotiations is to assure the active and ongoing participation of the physician members. Clinical integration programs require substantial commitments in both time and money by network physicians. Without the joint negotiation that can help them recover these costs, many of these physicians might be unwilling to participate in the clinical program. Therefore, such price agreements can be viewed as reasonably necessary for the success of the collaboration.

Finally, and perhaps most importantly, by implementing a clinical integration program, the network can sell a “new product”—that is, an integrated package consisting of more than merely the individual physician services, but, rather, an integrated package of those services tied to the network's clinical program. This claim is strengthened to the extent the network markets the physician services furnished through the clinical integration program as a new product to health plans,

⁷See Letter from Jeffrey W. Brennan, Ass't Dir. Health Care Svcs. & Prods., FTC, to John J. Miles, Principal, Ober/Kaler, 2002 WL 463290, at *8 (Feb. 19, 2002), at <http://www.ftc.gov/bc/adops/medsouth.htm>.

employers and consumers. And because it is offering a new product, the network's physicians necessarily must agree on the price for which its integrated product will be sold.

To the extent some or all of the above rationales apply to a given clinical integration program, the joint price negotiations should be viewed as passing the "ancillarity test." This view is consistent with the *Policy Statements*, which assume that joint price negotiations are reasonably necessary to a genuine clinical integration program.⁸

§ 1:19 When can joint negotiations begin?

Developing and implementing a clinical integration program is an extensive undertaking that can take a substantial amount of time. At what point is it reasonable for the network to begin collective price negotiations?

The network should not engage in joint negotiations until its infrastructure has been assembled and its clinical integration program is established and ongoing. Even the most well-intentioned efforts at clinical integration may run aground, and without such integration the joint negotiations run a serious risk of condemnation as a naked *per se* offense.

On the other hand, if the joint negotiations are reasonably necessary to the success of the clinical integration, delaying it too long runs the risk of dooming the endeavor. Physicians may be unwilling to make extensive time and money commitments without assurances

⁸See *Policy Statements* at Statement 8 § C.1 (a physician network involving substantial clinical integration is unlikely to raise significant competitive concerns under the rule of reason, despite the fact that it jointly negotiated contracts with payers). In this respect, the approach is similar to the analysis of ancillarity in physician networks that involve financial withholds on fee-for-service contracts. Arguably, the physicians would not need to collectively determine the fee-for-service price, but the agencies have never questioned that such negotiations should be viewed as ancillary to the financial integration of the network.

that they will reap some of the rewards of their collaboration in the foreseeable future. Furthermore, in some situations, the clinical integration program may depend on active interaction with payers, including access to data that only health plans can provide. Thus, getting the program off the ground may require collective discussions with health plans about their willingness to work with the physician network on a clinically integrated basis. In such situations, the best approach is to start the education process with payers early, making it absolutely clear that the network is offering its clinically integrated package of services on a non-coercive, non-exclusive basis, so that if the payer does not wish to deal collectively with the physician network it is absolutely free to contract with the network physicians independently.

What share of the clinical services offered by the physicians must be clinically integrated to justify joint negotiations? To address this question, it is necessary to return to the issue of ancillarity, and the extent to which the joint negotiations are reasonably necessary to the clinical integration effort. In some cases, the clinical integration program might be confined to a very narrow set of patients and diagnoses. For example, consider an effort focused only on improving care for patients with diabetes. A clinically integrated program for such care might justify joint negotiations with respect to services furnished for diabetes treatment, but it would be much more difficult to justify collective negotiations for unrelated services. Most clinical integration programs, however, will focus on a broad array of diagnoses and treatments. Some of the initiatives will deal with specific types of chronic or acute conditions, starting out with a relatively small subset of diagnoses that account for a relatively large proportion of patients, and for which evidence-based approaches are available. Other initiatives might involve efforts that span all patients (*e.g.*, electronic medical records or drug formularies). Such a combination of initiatives is likely to affect, to a greater or lesser degree, virtually all

patients. Moreover, in such situations, it likely will be difficult, if not impossible, to try to identify a small subset of services which are not involved in the clinical integration program and for which joint negotiation is not appropriate. In addressing this issue, a useful starting point is to once again consider the type of initiatives that would be undertaken by a risk-bearing physician network. Such a group is likely to focus on the diagnoses and treatments for which collaboration is most likely to provide the greatest return on the effort. This means a program with a range of initiatives, but one that need not have, for example, practice guidelines for every type of condition, as guidelines for more esoteric cases may be unavailable or not warrant the efforts necessary to implement them.

As the above discussion suggests, it would also be unreasonable to require that the clinical integration program have achieved demonstrable efficiency results before any joint negotiations are permitted. The collection and analysis of the data to measure such accomplishments could take a substantial amount of time after the initiation of the program. Such data may be probative about the success and extensiveness of the program, but that does not mean that it must be available *before* joint negotiations may begin. Put differently, outcomes data may help demonstrate the accomplishments of the network, but a network can be operating on a clinically integrated basis before such data can be collected and analyzed. On the other hand, if after an extended period of time the network can point to few or no demonstrable accomplishments, it is vulnerable to the attack that it has indeed little potential for efficiencies.

§ 1:20 Should the network be non-exclusive?

Difficult questions arise as to whether, from an antitrust perspective, it is preferable that a physician network be non-exclusive (that is, its members are available to, and do in fact contract with, health plans

outside of the venture) or exclusive (that is, the physicians are only willing to contract with health plans through the network).

Networks that are truly non-exclusive generally are viewed as posing substantially fewer antitrust risks than those that are exclusive because payers can bypass the network altogether if they wish. If plans like the product offered by the network, they can purchase it; if they do not, they can always contract independently with the physicians. As a result, the *Policy Statements* provide more latitude for non-exclusive networks; for example, financially-integrated physician networks that are non-exclusive receive “safety zone” treatment if they include no more than 30 percent of the physicians in each physician specialty in the relevant geographic market, but must include no more than 20 percent of the physicians if the network is exclusive.¹ Similarly, the *MedSouth* advisory opinion relied heavily on assurances that the physician network would be non-exclusive,² as have numerous other FTC Advisory Opinions and DOJ Business Review Letters.³

On the other hand, even a non-exclusive network can raise antitrust concerns. First, the network poses some risk of anticompetitive “spillover-collusion effects” if adequate precautions are not undertaken to ensure that

[Section 1:20]

¹See *Policy Statements* at Statement 8 § A.

²See Letter from Jeffrey W. Brennan, Ass’t Dir. Health Care Svcs. & Prods., FTC, to John J. Miles, Principal, Ober/Kaler, 2002 WL 463290 (Feb. 19, 2002), at <http://www.ftc.gov/bc/adops/medsouth.htm>.

³See, e.g., Letter from Charles A. James, Ass’t Atty. Gen., Antitrust Div., DOJ, to Patrick R. Gordon, Esq. 2-3 (Aug. 29, 2001), at <http://www.usdoj.gov/atr/public/busreview/8973.htm>; Letter from Joel Klein, Ass’t Atty. Gen., Antitrust Div., DOJ, to Christopher H. Casey, Esq. 5 (Sept. 15, 1998), at <http://www.usdoj.gov/atr/public/busreview/1941.htm>; Letter from Robert F. Leibenluft, Ass’t Dir. Health Care, to David V. Meany, Esq. 7 (May 14, 1997), at <http://www.ftc.gov/bc/adops/yelltone.htm>.

participants do not use the exchange of information in connection with the network's operation to facilitate collusion on their contracting decisions outside of the network.⁴ Second, as a network becomes more successful, it is likely that an increasing share of its participants' contracting will be done through the venture. The result may be that even though there is no agreement among network participants to deal only through the network, an enforcement agency or court may consider the arrangement to be *de facto* exclusive and infer that the physicians have in fact entered into such an agreement.⁵ Finally, non-exclusivity may create a significant disincentive for physicians to commit themselves fully to the network out of fear that their colleagues will "free-ride" off their efforts and compete directly with them. As noted above, this free-riding concern is one basis for finding the joint negotiations ancillary to the network's clinical integration program.⁶ Thus, as FTC Commissioner Leary has noted, "if joint bargaining is necessary, how can the venture tolerate non-exclusivity? Alternatively, if non-exclusivity is

⁴See Letter from Jeffrey W. Brennan, Ass't Dir. Health Care Svcs. & Prods., FTC, to John J. Miles, Principal, Ober/Kaler, 2002 WL 463290, at *10 (Feb. 19, 2002), at <http://www.ftc.gov/bc/adops/medsouth.htm>; Leary, "The Antitrust Implications of 'Clinical Integration': An Analysis of FTC Staff's Advisory Opinion to MedSouth," 47 St. Louis U. L.J. 223, 233 (2003). See generally Balto, "Cooperating to Compete: Antitrust Analysis of Health Care Joint Ventures," 42 St. Louis U. L.J. 191, 234-37 (1998).

⁵The *Policy Statements* emphasize the importance of determining whether a network is *de facto* exclusive even though there is no explicit agreement to be exclusive. In doing so, the agencies will look at, among other things, the extent to which physicians contract with, or obtain substantial revenue through, other networks and arrangements. See *Policy Statements* at Statement 8 § A.3.

⁶See § 1:18, text accompanying note 5.

tolerable, what does this say about the need for joint bargaining?”⁷

Resolving this issue of exclusivity, as with most antitrust analysis, will require a close examination of market circumstances, including how and why the network is structured and operates, and the likely competitive effects. In many respects, an exclusive network may pose a greater promise for efficiencies than does a non-exclusive arrangement, as the physicians will have committed themselves entirely to its success. On the other hand, such a network raises more significant market power concerns if it includes a high percentage of competing physicians in the area. Accordingly, one approach might be to expect clinically integrated networks to be non-exclusive in their early phases. During this period, the network’s new “product” will be developing and the network may have relatively few contracts. Thus, out of necessity, physicians likely will need to contract outside the network. In addition, the venture may start out with a relatively large number of physicians with the expectation that a number of them who are unwilling or unable to meet the network’s requirements will drop out. As the network matures, however, it could require a substantial exclusivity commitment as one aspect of its increased clinical integration. As long as the network’s market share precludes it from having market power, such a requirement may significantly enhance its potential efficiencies.

§ 1:21 What weight should be given to the views of payers?

A crucial factor in any antitrust inquiry is the views of purchasers. The fact that purchasers have no complaints is probative evidence that the venture’s conduct is not anticompetitive. Moreover, without

⁷Leary, “The Antitrust Implications of ‘Clinical Integration’: An Analysis of FTC Staff’s Advisory Opinion to MedSouth,” 47 St. Louis U. L.J. 223, 233 (2003).

complainants, there are likely to be few witnesses to support an antitrust challenge.

Accordingly, the views of health plans regarding a network's clinical integration activities and contracting are certainly important and, if they are positive (or at least not negative), they should be given significant weight. On the other hand, the absence of endorsements by health plan purchasers, or even a skeptical or negative view from a few payers, should not necessarily condemn the network. Some health plans may prefer a contracting model in which they contract directly with physicians. Some may lack the infrastructure, or desire, to share data or otherwise "partner" with a physician network's efforts to implement a clinical integration program. Finally, as discussed in the next section, it is possible that a clinically integrated network may seek a higher negotiated fee schedule on the grounds that it better controls utilization and offers higher quality services, and it needs to recover some of the costs associated with the clinical integration program that produces these benefits. Some health plans may be pursuing a contracting strategy based solely on price, and they may be very skeptical about, and less interested in, contracting with, networks that do not agree to their prevailing fee schedules.

Thus, while the views of health plans are very important in assessing the potential effects of a clinically integrated venture, as the above discussion suggests, there may be situations where the lack of uniform health plan support should not be dispositive. In such situations, of particular relevance would be the extent to which the health plans must deal with the network—either because the network is exclusive or because it is so large that there are few alternatives outside the network physicians. If health plans have sufficient alternatives, however, and need not purchase physician services through the network, the antitrust concerns are substantially lessened. In such situations, the fact that some plans do not value highly what the clinically integrated network offers and do not wish to contract

with the network may affect the network's ultimate viability, but it should not raise significant antitrust issues.

§ 1:22 What if prices go up?

The ultimate issue in the typical antitrust analysis is the likely effect of the conduct in question on prices. At first blush, one might conclude that if a physician network results in higher fees, the network results in anticompetitive effects.

The analysis, however, may be much more complex because to assess the price effects properly, the network's prices must be compared to those available in a competitive market *for the same services*. To do this, it is essential to consider whether the services offered by the network are the same as those offered by the benchmark peer group to which it is compared. Clinically integrated networks, however, are not necessarily offering the same "product" that the physicians can and do offer individually. Instead, the clinical integration program is designed to enable the physicians to lower costs (which may involve reduced utilization), as well as to provide higher quality services, or to offer a package of physician services and the integration mechanism for achieving efficiencies. Thus, the appropriate analysis may not involve simply comparing the prices per service that would be reflected in a negotiated fee schedule. Indeed, it may be the case that the cost per service may increase through a clinically integrated network in order to compensate physicians for their time and expense in developing and implementing the clinical integration program and the higher value of the network product. Thus, a better comparison would be based on the "quality-adjusted" price of furnishing the total array of medical services needed to provide a certain level of health care to a defined set of health plan enrollees. Such an approach would take into account savings to the health plan due to the reduction in unnecessary procedures, hospital admissions and other

services, as well as the enhanced quality of services furnished through the network.

The challenge, of course, is that it may be very difficult to adjust for utilization and quality differences. Accordingly, clinically integrated networks that seek higher negotiated rates would be well advised from the outset to gather data that can help confirm increases in the overall “value” of the services they provide. Similarly, if such increases are to be the basis for allegations of an anticompetitive price effect, those making such charges should be prepared to address the argument that simple comparisons based on negotiated fee schedules may not be true “apples to apples” tests.

§ 1:23 The relevance of market shares

Under traditional antitrust analysis, as described in Section II, the first step is to determine whether or not a joint venture offers sufficient integration and potential for efficiencies so that an otherwise *per se* unlawful agreement warrants rule of reason treatment. Only then is further inquiry necessary to determine whether the venture will have market power and, thus, likely result in anticompetitive effects.¹

Under this scenario, therefore, the market share of the network should not be relevant to the initial determination of whether the network should be condemned outright as a *per se* price-fixing arrangement. While this is technically true, as a practical matter the antitrust risks posed by a clinically integrated joint venture are related to its share of a properly defined market and whether it can exercise market power. Thus, for example, the agencies have established a safety zone for joint ventures that account for less than 20 percent of each relevant market in which competi-

[Section 1:23]

¹See *Competitor Collaboration Guidelines* at §§ 1.2, 3.3; Leary, “The Antitrust Implications of ‘Clinical Integration’: An Analysis of FTC Staff’s Advisory Opinion to MedSouth,” 47 St. Louis U. L.J. 223, 227-34 (2003).

tion might be affected.² Of course, determining the appropriate product and geographic markets for physician services raises a number of difficult questions beyond the scope of this chapter.³ And, indeed, except in very large metropolitan areas, there may be few physician networks that fall below the 20 percent threshold for every physician specialty.

Nevertheless, a less rigorous analysis may be very helpful in defining the antitrust risks and informing both those who are advising networks, and those who may be investigating them, how much legitimate antitrust concerns are raised by the collaboration. Thus, for example, a network that comprises less than 20-30 percent of physicians in all of the key specialties in the likely geographic market holds little prospect of having an anticompetitive effect. Although this does not give its members a free pass to engage in *per se* illegal conduct, it does suggest that both the intent, and effect, of the collaboration will not be anticompetitive. On the other hand, a network with a substantially larger share does hold a much greater risk of anticompetitive effects. Accordingly, efforts to clinically integrate by networks whose physicians have large market shares are likely to, and should, receive much closer scrutiny to determine whether they hold the promise of substantial efficiencies.

VI. CONCLUSION

§ 1:24 Conclusion

When the *Policy Statements* were last revised in 1996, most physician networks that jointly negotiated with health plans took the form of IPAs that were formed to accept risk and, thus, were financially integrated.

²See *Competitor Collaboration Guidelines* at § 4.

³For more detailed discussion of physician product and geographic markets, see Wiegand et al., "Measuring Physician Services' Markets," 16 *Antitrust Health Care Chronicle* 2 (Fall 2002), at <http://www.abanet.org/antitrust/committees/health/fall02.pdf>.

Indeed, at that time, many health care consultants and policy makers believed that, to be successful, health care providers increasingly would need to be able to contract with health plans on a capitated or other risk-basis. Nevertheless, in response to members of the physician community who believed that the *Policy Statements* mandated risk arrangements before joint negotiations over price could escape *per se* recommendation, the agencies revised the *Policy Statements* in 1996 to recognize clinical integration explicitly. Even though these critics could point to few examples of networks that were clinically, but not financially, integrated, they asserted that it was important to recognize that physicians might collaborate in procompetitive ways that did not involve substantial financial integration.

Few at either the antitrust agencies or in the physician community would have predicted in the early to mid-1990s the movement away from risk contracting arrangements. Because of this evolution, it may be difficult for many physician networks to enter into substantial financial risk-sharing arrangements that warrant joint negotiations with health plans. This does not mean, however, that physicians in separate practices cannot work closely together to improve quality and reduce costs. Indeed, such efforts are more important than ever, particularly given the continued preference most physicians have to work independently or in small practice settings. And because of the change in the revised *Policy Statements*, it is clear that the federal antitrust agencies have recognized that such clinically integrated collaborations may justify rule of reason treatment.

Not surprisingly, however, antitrust enforcers may be concerned that some physicians may claim they are clinically integrated when in fact they have done little to distinguish themselves from naked price-fixing cartels. Moreover, while the federal antitrust agencies have expressly acknowledged clinical integration, some state enforcement agencies may be more skeptical about the approach, and the concept has not been tested in

the courts. But, as this chapter has described, there are a number of specific factors that can be examined to identify clinically integrated networks, and such networks can take various steps to minimize their antitrust risks as they embark on largely uncharted waters. In addition, as the physicians in *MedSouth* did, it is possible to obtain feedback from the federal agencies with respect to clinical integration proposals by submitting a request for an advisory opinion or business review letter.

It is unclear, of course, whether clinical integration will be a successful model for many physicians. Notwithstanding the uncertainties, however, physicians who are willing to undertake the substantial commitments that clinical integration involves should take comfort that there are ways to pursue such efforts without undue antitrust risk.