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Clinical integration is a health care term that took on new meaning with the publication of the 1996 *Statements of Antitrust Enforcement Policy in Health Care*.[2] A clinical integration network is a joint venture among health care providers—physicians, hospitals, ancillary providers, or any combination thereof—through which they substantially integrate their clinical operations and services in ways likely to achieve significant efficiencies, including higher quality care and reduced, or contained, costs for the delivery of health care services. As the *Health Care Statements* explain, clinical integration "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 [to] create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality."[3]

The reason that clinical integration is a topic on which the Federal Trade Commission ("FTC") and the Department of Justice Antitrust Division ("DOJ") have written[4] and spoken[5]

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[2] FED. TRADE COMM'N & DEPT. OF JUSTICE, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE, (1996) [hereinafter, "*Health Care Statements*"], *available at* http://www.ftc.gov/bc/healthcare/industryguide/policy/index.htm. The tem "clinical integration" only appears in Statement 9, even though both Statements 8 and 9 discuss the concept. *Id.* at 9.A.

[3] *Id.*, Statement 8.B.1.

[4] *Id.*, Statements 8.B.1 and 9.A; FED. TRADE COMM'N & U.S. DEP'T OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION, Ch. 2 (2004) *available at* http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf; Thomas B. Leary, *The Antitrust Implications of "Clinical Integration": An Analysis of FTC Staff's Advisory Opinion to MedSouth*, 47 ST. LOUIS UNIV. L.J. 223 (2003); Letter from Jeffrey W. Brennan, Assistant Director, Bureau of Competition, FTC, to John J. Miles (Feb. 19, 2002) [hereinafter "FTC Staff Advisory Opinion to MedSouth"], *available at* http://www.ftc.gov/bc/adops/medsouth.shtm; Letter from David R. Pender, Acting Assistant Director, Bureau of Competition, FTC, to Clifton E. Johnson & William H. Thompson (Mar. 28, 2006) [hereinafter "FTC Staff Advisory Opinion to Suburban Health Organization"], *available at* http://www.ftc.gov/os/2006/03/SuburbanHealthOrganizationStaffAdvisoryOpinion03282006.pdf; Letter from Markus H. Meier, Assistant Director, Bureau of Competition, FTC, to John J. Miles (June 18, 2007), *available at* http://www.ftc.gov/bc/adops/070618medsouth.pdf; Letter from Markus H. Meier, Assistant Director, Bureau of Competition, FTC, to Christi J. Braun and John J. Miles (Sept. 17, 2007), [hereinafter "FTC Staff Advisory Opinion to GRIPA"], *available at* http://www.ftc.gov/bc/adops/gripa.pdf; Letter from Markus H. Meier, Assistant Director, Bureau of Competition, FTC, to Christi J. Braun (Apr. 13, 2009), *available at* http://www.ftc.gov/os/closings/staff/090413tristateaoletter.pdf [hereinafter "FTC Staff Advisory Opinion to TriState"].

[5] Jon Leibowitz, Chairman, Fed. Trade Comm'n, A Doctor and a Lawyer Walk into a Bar: Moving Beyond Stereotypes, Address before the American Medical Association House of Delegates (June 14, 2010) (*available at* http://www.ftc.gov/speeches/leibowitz/100614amaspeech.pdf); Christine A. Varney, Asst. Att'y Gen., Antitrust Div., Dept. of Justice, Antitrust in Healthcare, Address to the American Bar Association/American Health Lawyers

extensively is that providers who develop and operate clinical integration networks do so with the intent to jointly sell their services to health insurance plans, self-insured employers, and other third-party payers (collectively, "payers"). Concerned about the market power that joint contracting by otherwise independent, competing providers can generate and, thus, the potential harm of higher prices and reduced consumer access to high quality care, the federal antitrust authorities have prosecuted many provider organizations for unreasonably restraining competition through joint contracting.[6] To date, though, neither federal agency has prosecuted, or entered a consent order with, a provider-contracting network that implemented a legitimate program of clinical integration among its participating providers.[7] The reason is their desire to promote, rather than stifle, the development of innovative arrangements through which providers will work collaboratively to improve the quality of care patients receive and to control the spiraling rise of health care costs.[8] And that reason is not surprising, given that controlling costs and improving quality was, and will remain, a major focus of health care reform.

Two sections of the new health care reform law, the Patient Protection and Affordable Care Act ("PPACA"), describe new payment mechanisms under Medicaid and Medicare for provider organizations referred to as accountable care organizations ("ACOs").[9] The statute allows an ACO to take a number of forms, including a fully integrated physician multi-specialty group practice, a hospital system and its employed physicians, a network of individual practices, or a joint venture between hospitals and providers. To avoid *per se* condemnation for naked horizontal price-fixing agreements when contracting with payers, the latter two categories of ACOs must integrate the delivery of their providers' individual services through the ACO.

Association Antitrust in Healthcare Conference (May 24, 2010) (*available at* http://www.justice.gov/atr/public/speeches/258898.htm); Pamela Jones Harbour, Commissioner, FTC, *Clinical Integration: The Changing Policy Climate and What It Means for Care Coordination*, Remarks at the Annual Membership Meeting of the American Hospital Association (Apr. 27, 2009), *available at* http://www.ftc.gov/speeches/harbour/090427ahaclinicalintegration.pdf; J. Thomas Rosch, Commissioner, FTC, *Clinical Integration in Antitrust: Prospects for the Future*, Remarks before the AHLA, ABA Antitrust Section and ABA Health Law Section, 2007 Antitrust in Health Care Conference (Sept. 17, 2007), *available at* http://www.ftc.gov/speeches/rosch/070917clinic.pdf; Susan A. Creighton, Director, Bureau of Competition, FTC, *Diagnosing Physician-Hospital Organizations*, Remarks before the AHLA Program on Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions (Jan. 22, 2004); Thomas B. Leary, Commissioner, FTC, *Antitrust in Healthcare*, Remarks before the ABA Antitrust Law Section and AHLA Forum on Antitrust and Healthcare (May 15, 2003).

[6] *See, e.g.,* FED. TRADE COMM'N, OVERVIEW OF FTC ANTITRUST ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS (June, 2010), *available at* http://www.ftc.gov/bc/0610hcupdate.pdf.

[7] The only case in which the FTC has challenged the contracting activities of a group purporting to be clinically integrated was the FTC's case against California Pacific Medical Group, Inc., d/b/a Brown & Toland. In July 2003, the FTC issued a complaint against Brown & Toland for allegedly contracting on the collective behalf of unintegrated providers. *In re* California Pacific Medical Group, Inc., 137 F.T.C. 411, 412-23 (2003). Six months into the administrative litigation process, the parties entered a consent agreement, under which Brown & Toland was required to give the FTC 60 days notice prior to contacting a payer to on behalf of any clinically integrated joint arrangement in which it participated. *Id.* at 424-35. Within a month of the settlement becoming final, Brown & Toland gave the FTC the required notice. In April 2005, the FTC staff issued a letter to Brown & Toland explaining that the staff had reviewed Brown & Toland's proposed clinical integration program and would not recommend a challenge. Letter from Daniel P. Ducore, Assistant Director, Bureau of Competition, FTC, to Richard A. Feinstein (Apr. 5, 2005), *available at* http://www.ftc.gov/os/adjpro/d9306/050405cpbresponsetbtnotice.pdf.

[8] Leibowitz, *supra* note 5 (stating, "But, when we see a bona fide joint venture that is intended – and has the potential – to improve care and lower its cost, we won't stand in the way."); Varney, *supra* note 5.

[9] Patient Protection and Affordable Care Act of 2010, §§ 2706 and 3022, Pub. L. No. 111-148.

Because the new payment methodologies do not necessarily contemplate the sharing of substantial financial risk, it is likely that many networks of physician practices and physician-hospital joint ventures will implement programs of clinical integration.

A comparison of the descriptions of the Medicare program for ACOs and clinical integration reveals remarkable similarities. PPACA requires that the Secretary of the Department of Health & Human Services (HHS) establish a program that:

> promotes accountability for a patient population and coordinates items and services under Parts A and B [i.e., Medicare insurance for hospital, skilled nursing facility and physician services], and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery.[10]

The *Health Care Statements* explain that a program of clinical integration 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.[11]

Thus, clinical integration has become a topic of great interest to many outside of the antitrust field, and compliance with the antitrust laws has become a significant focus of providers seeking to develop ACOs.

In developing and implementing programs of clinical integration, many provider networks have spent a good deal of time and money developing programs that substantially integrate the services and operations of their providers in ways that will improve the delivery of care and benefit their patients and the payers. Getting past *per se* condemnation, though, is only the first step. As the FTC has explained in its clinical integration staff advisory opinion letters, if payer-contracting by the providers' joint venture is reasonably related to their integration and reasonably necessary to the achievement of significant efficiencies, the agreement on prices among the participating providers is an ancillary restraint, as opposed to a *per se* illegal naked price-fixing agreement, and the arrangement is analyzed under the rule of reason.[12] Analysis of the actual or likely competitive effects of the joint venture is required. That analysis generally focuses on whether the joint venture has the ability to exercise market power—i.e., the ability to increase physician and hospital service prices significantly—and, if so, whether that potentially detrimental effect is offset by benefits to consumers, such as improved quality and access and more efficient delivery of services. When examining the potential market power of clinical integration networks, the FTC has generally begun by identifying the relevant product and geographic markets in which competition will be restricted.

Very generally, services are in the same relevant product market if consumers view them as reasonably interchangeable or, in economics terminology, they exhibit significant "cross-

[10] Social Security Act § 1899(a)(1), 42 U.S.C. § 1395(jjj)(1) (2010) (emphasis added).

[11] Health Care Statements, *supra* note 2, Statement 8.B.1 (emphasis added).

[12] FTC Staff Advisory Opinion to MedSouth, *supra* note 3; FTC Staff Advisory Opinion to Suburban Health Organization, *supra* note 4; FTC Staff Advisory Opinion to GRIPA, *supra* note 4; FTC Staff Advisory Opinion to TriState, *supra* note 4.

elasticity of demand"—i.e., if a price increase of one product results in a more than proportional increase in the quantity demanded of another, indicating that the services are substitutes for one another.[13] Again, very generally, each medical specialty constitutes a separate relevant product market for physician services because payers and patients often do not view the different medical specialists as substitutable, even though there may be overlap among the services they provide. For example, a vascular surgeon and an interventional radiologist may provide similar services, and thus be reasonably interchangeable, but payers generally believe that they need both types of providers on their provider panels or consumers will not buy their insurance products; thus, there is low cross-elasticity of demand between the specialties. The exception is primary care services, which groups together family practice, general practice, and internal medicine (without subspecialties).

Definition of relevant geographic markets for physician services is often complex and very fact specific. In general, it starts with an examination of the location of the providers and includes, for a given set of patients or payers, the geographic areas to which they would turn for services if providers in a given area raised their prices.[14] The market can be defined in part by analyzing patient-origin data and physician referral patterns, but rarely do physicians or their networks have the necessary information systems to collect and analyze such data. Therefore, certain assumptions are often made when identifying the geographic markets for physician services. For example, patients generally receive primary care services close to their home or work. As such, in an urban area the geographic market for primary care services may be no larger than a five-mile radius around each practice. To approximately define specialty care geographic markets, state departments of insurance network access standards may be used (e.g., 30 minutes/10 miles for urban and 30 minutes/30 miles for rural areas), but these provide only a rough estimate. In practice, different medical specialties are likely to have a different geographic markets based on how far patients would be willing to travel—given the cost and difficulty of travel, the immediacy of the medical need, and the complexity of the medical issue—and where patients could go for different services if the network raised prices above competitive levels.

In most industries, the product and geographic market information would then be used to identify the competitors in the relevant market, which permits the calculation of the market share of the joint venture. It is relatively difficult, however, to calculate a clinical integration network's market share unless there is payer utilization data specific to the network and its participating providers. To approximate market shares of physician clinical integration networks, the FTC staff has historically examined participation percentages—the number of physicians, by specialty, participating in the network divided by the number of available physicians of that specialty in the area. This methodology is an imperfect measure of network market power, however, because participation percentages only provide information on the network's share of inputs (i.e., the number of physicians available to provide services), and the methodology assumes that each physician is equally productive which, of course, is not true.

[13] As the Horizontal Merger Guidelines explain, "Market definition focuses solely on demand substitution factors, i.e., on customers' ability and willingness to substitute away from one product to another in response to a price increase or a corresponding non-price change such as a reduction in product quality or service." DEPT. OF JUSTICE & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES 7 (2010), *available at* http://ftc.gov/os/2010/08/100819hmg.pdf.

[14] *Id.*, Section 4.2.1, at 1

As a general rule, courts have indicated that market power may begin to raise concern and require more in-depth examination when market shares reach 30 to 40 percent. In its clinical integration advisory opinions, the FTC staff has used 35 percent as a threshold for judging whether a network's participation percentages could be high enough for the network to have the potential to exercise market power.[15] When a clinical integration network has high participation percentages, it can address potential competitive concerns by having a policy and practice of non-exclusivity—payers who choose not to contract with the clinical integration network will be able to contract directly with the individual providers or contract with them through other networks in which they are members. This was the route chosen by each of the three clinical integration networks that received positive advisory opinions from the FTC staff because each network had high participation percentages in multiple medical specialties.[16]

In the *Health Care Statements*, the FTC and DOJ provided safety zones for exclusive financially integrated joint ventures:

> The Agencies will not challenge, absent extraordinary circumstances, an exclusive physician network joint venture whose physician participants share substantial financial risk and constitute 20 percent or less of the physicians in each physician specialty with active hospital staff privileges who practice in the relevant geographic market. In relevant markets with fewer than five physicians in a particular specialty, an exclusive physician network joint venture otherwise qualifying for the antitrust safety zone may include one physician from that specialty, on a non-exclusive basis, even though the inclusion of that physician results in the venture consisting of more than 20 percent of the physicians in that specialty.[17]

Although there is no safety zone for any clinically integrated joint venture, these same numbers would likely apply. Clinical integration networks, though, should not conclude that exclusivity is impossible simply because they have higher participation percentages than those mentioned in the safety zone. The agencies acknowledge that "a higher percentage of physicians in a relevant market than specified in the safety zones, may be lawful if they are not anticompetitive on balance." The safety zone percentages were set at levels "in which the lack of anticompetitive effects ordinarily will be presumed." Because 35 percent is the threshold mentioned in an FTC staff advisory opinion, clinical integration networks, all else being equal, can likely be exclusive if they have participation percentages at or below 35 percent. Networks in more rural areas, though, are likely to go above the 35 percent threshold, and, therefore, may face risk of prosecution if they adopt and enforce policies of exclusivity. On the other hand, the agencies may be more willing to approve larger participation percentages if larger numbers of physicians are necessary to serve the network's patients.

Non-exclusivity may not be an option for ACOs, though. Assignment of Medicare beneficiaries to ACOs will be "based on [the patients'] utilization of primary care services," meaning that each patient will follow their primary care provider ("PCP"). Each patient can only be assigned to one ACO because the assignment of patients to an ACO determines the ACO's

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[15] FTC Staff Advisory Opinion to GRIPA, *supra* note 4, 24.

[16] FTC Staff Advisory Opinion to MedSouth, *supra* note 4, 8 (explaining, "As long as doctors are, in fact, willing to deal individually on competitive terms with payers who do not want the package product, as you represent will be the case, significant anticompetitive effects appear unlikely."); FTC Staff Advisory Opinion to GRIPA, *supra* note 3, 25; FTC Staff Advisory Opinion to TriState, *supra* note 4, 30.

[17] Health Care Statements, *supra* note 2, Statement 8.A.1.

cost targets and the potential savings in which it, and its participating providers, can share with Medicare. A PCP, therefore, can only be part of one ACO. Thus, it would seem that PPACA mandates that each ACO be exclusive in the sense that its PCPs will not be allowed to contract directly with Medicare (or Medicaid) and will not be able to participate in any other ACO. An ACO with high participation percentages, then, may be able to exercise market power. Price restraints are not a concern under the Shared Savings Program because there will be no ability of an ACO to negotiate with the government payers—the government will set the prices. There are other dimensions of competition, though, that could be restrained. An ACO that is over-inclusive and ties up all available PCPs could preclude other ACOs from forming and competing. Or an ACO could organize a boycott of the government programs. The FTC and the DOJ would not sit idly by in either case.

Although an ACO could, theoretically, be exclusive as to the government payers and non-exclusive as to private payers, this may not be a viable option. One reason is that PPACA gives ACOs an incentive to put together a single network of providers who participate through the ACO with government and private payers. Under PPACA, the HHS Secretary "may give preference to ACOs who are participating in similar arrangements with other payers."[18]

How similar the arrangements must be is an open question. It seems highly likely, though, that "similar arrangements" will be interpreted to mean an arrangement that involves shared savings between a private payer and the same network of providers. An ACO won't be able to meet this requirement, absent a policy of exclusivity. Even if "similar arrangements" under the statute is not interpreted to mean "similar exclusive arrangements," clinical integration networks that are ACOs may need to be the exclusive contracting agents of their PCPs with private payers. If a network puts in the infrastructure and develops the processes to ensure its participating physicians change their practice patterns and provide more efficient, higher quality care to 30 to 50 percent of their patients (i.e., those covered by Medicare and Medicaid), then any payer who does not contract with the ACO will be able to free ride on those same benefits. That is, those payers' patients would receive the benefit of higher quality care, but the payer could avoid paying for the ACO's investments by contracting directly with individual providers. If an ACO is exclusive and prohibits its participants from selling their services outside of the ACO, then it could prevent the free-riding by private payers.[19] The FTC staff has acknowledged that exclusivity may "be a necessary and appropriate mechanism (*i.e.*, an ancillary restraint) for avoiding free riding in that particular joint venture."[20]

Assuming that exclusivity is an ancillary restraint, the antitrust analysis will be the same analysis explained above for the joint setting of price by a clinically integrated network. There is no antitrust exemption in PPACA for ACOs, so the FTC and the DOJ will have the ability to prosecute ACOs for antitrust violations related to the Medicare and Medicaid programs and contracts with private payers. The FTC co-sponsored a workshop on October 5, 2010 to learn about industry concerns relating to ACOs, and the topic of exclusivity as a policy and practice of ACOs was raised. It is unclear, though, whether the FTC will provide any written guidance on the topic as a result of the workshop. The FTC and the DOJ are, however, talking, and working,

[18] Patient Protection and Affordable Care Act of 2010, § 10307, Pub. L. No. 111-148.

[19] This requirement, though, must be agreed to by the physicians, and getting their agreement may be difficult. Physicians may not be willing to take a chance of losing patients, due to out-of-network participation status, if payers are not willing to contract with an ACO.

[20] FTC Staff Advisory Opinion to Suburban Health Organization, *supra* note 4, n. 48.

with HHS on the development of the regulations that will govern the development and operation of ACOs, and those regulations, which are due in December 2010, may provide some guidance.

Until then, providers seeking to form ACOs will have only the clinical integration guidance from the agencies on which to rely. If the participation percentages are likely to be greater than 30-40 percent, then the ACO should take some precautionary measures. First, it should be able to readily explain why high participation percentages are necessary. In particular, it should be able to explain why all of the providers in specialties where participation percentages are high are essential to the viability of the network or the program of clinical integration. Second, the ACO should work to ensure that the pro-competitive efficiencies of the joint venture outweigh the potential anticompetitive effects. The ACO's clinical quality improvement activities should be designed to achieve measurable improvements that benefit patients and payers. To do this, the ACO should target patients with chronic conditions whose health status can be improved through preventive care and regular health status monitoring. In addition, the ACO should work on preventing avoidable emergency department and in-patient hospital admissions, readmissions, and duplicative laboratory and diagnostic-imaging tests. The avoidance of these unnecessary costs is the easiest way to attain measurable savings. Payers are unlikely to complain to the agencies if they are happy with, and receive good value from, the network with which they are contracting. And the antitrust agencies are unlikely to challenge a clinical integration network that is able to generate significant efficiencies that benefit consumers and about which payers do not complain.