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I. INTRODUCTION

The Patient Protection and Affordable Care Act (“PPACA”)² established various mechanisms to make healthcare providers more accountable for both the cost and quality of the services they provide. One of these mechanisms is the establishment of a new class of Medicare provider—the Accountable Care Organization (“ACO”). An ACO is accountable for the quality, cost, and overall care for a defined set of Medicare beneficiaries.

Although popularized by PPACA, the concept of independent providers coming together and being jointly accountable for the cost and quality of care they provide is not new. In 1996, the Department of Justice (“DOJ”) and Federal Trade Commission (“FTC”) in the *Statements of Antitrust Enforcement Policy in Health Care* (“Policy Statements”)³ first recognized the concept of clinical integration as a collaborative activity among competing health care providers that may provide a sufficient basis for analyzing joint pricing negotiations under the rule of reason and not the *per se* standard of illegality.

Following a decline in capitation and other traditional risk-based contracts in the late 90s, some physician-contracting networks pursued clinical integration as a means to continue joint contracting on behalf of their independent, competing members. However, the significant resource investment required for these programs—in electronic health records systems (“EHRS”), for example—and the lack of data to monitor and assess performance goals, coupled with the uncertainty of payor receptivity to these types of programs, limited their widespread adoption. Government incentives for the adoption of EHRS, along with the development of pay-for-performance programs in the commercial insurance marketplace, have reduced these barriers. With the shared-savings program incentive provisions of PPACA, providers who coordinate their care to meet cost and quality objectives now have an additional incentive to jointly pursue these efficiency objectives.

This article explores how the DOJ and FTC (collectively, the “Agencies”) have treated clinically-integrated managed care contracting networks under the antitrust laws, and how the Agencies are likely to apply those concepts to ACOs.

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² Public Law No. 111-148

³ 4 Trade Reg. Rep. (CCH) ¶ 13,153.

II. ANTITRUST IMPLICATIONS OF PROVIDER JOINT CONTRACTING

Several federal antitrust statutes govern competition between competitors, including their formation and operation of joint ventures and other collaborative arrangements.⁴ Independent, competing providers' joint negotiation of fees through an ACO or other clinically-integrated network primarily implicates Section 1 of the Sherman Act, 15 U.S.C. §1, which prohibits contracts, combinations, and conspiracies that unreasonably restrain trade. Traditionally, there have been two methods of analysis under Section 1—the *per se* rule and the rule of reason. Under the *per se* rule, certain conduct, including agreements by horizontal competitors to fix prices and allocate markets, is deemed so egregious and lacking in redeeming value that it is *per se* illegal; it is simply indefensible. Under the rule of reason, conduct is subject to a fact-intensive analysis that takes into account the reason for the restraint and its effects on competition, both pro-competitive and anticompetitive. This results in a balancing of the pro-competitive benefits of the arrangement against its anticompetitive results.

Recently, the FTC has adopted the “inherently suspect analysis” first articulated in *Polygram Holding, Inc.*⁵ (which the D.C. Circuit Court of Appeals affirmed) and applied in *North Texas Specialty Physicians*.⁶ Under this analytic framework, the FTC first asks whether the conduct can be described as “inherently suspect;”⁷ that is, whether there is a “close family resemblance between the suspect practice and another practice that already stands convicted in the court of consumer welfare.”⁸ If the challenged practice is inherently suspect, the burden shifts to the defendant to advance a legitimate justification for the practice that is both cognizable under the antitrust laws and facially plausible.⁹ If the defendant advances a justification for the challenged conduct that is both cognizable and plausible, the plaintiff must then make a more detailed showing that the restraints at issue are likely to harm competition.¹⁰ The degree of proof depends upon the circumstances of the case and is an “enquiry meet for the case.”¹¹ The FTC has interpreted this standard as a “spectrum” or “sliding scale” analysis.¹²

Any agreement among horizontal competitors that affects the prices they charge for goods or services is a price-fixing agreement. Whether a price-fixing agreement will be deemed

⁴ Section 2 of the Sherman Act prohibits monopolization, attempts to monopolize, and conspiracies to monopolize. 15 U.S.C. § 2. More specifically, Section 7 of the Clayton Act prohibits acquisitions of stock or assets if their effect “may be substantially to lessen competition, or to tend to create a monopoly.” 15 U.S.C. § 18 (2000). Clayton Act Section 7 has been construed to apply to the formation of joint ventures between actual or potential competitors. Section 5 of the Federal Trade Commission Act (“FTC Act”) prohibits unfair trade practices, including conduct prohibited under the Sherman Act. 15 U.S.C. § 45. Joint venture analysis under the Clayton Act and the FTC Act is substantially the same as the analysis under the Sherman Act. Section 8 of the Clayton Act prohibits interlocking directors and officers of competing organizations, subject to certain limitations and exemptions. 15 U.S.C. §19.

⁵ See *Polygram Holding, Inc.*, 5 Trade Reg. Rep. (CCH) ¶15,453 (FTC 2003), available at <http://www.ftc.gov/os/2003/07/polygramopinion.pdf>, *aff'd*, *Polygram Holding, Inc. v. FTC*, 416 F.3d 29 (D.C. Cir. 2005) (*Polygram*).

⁶ See *North Texas Specialty Physicians*, 2005-2 Trade Cas. (CCH) ¶75,032 (FTC 2005), available at <http://ftc.gov/os/adjpro/d9312/051201opinion.pdf>, *aff'd*, *North Texas Specialty Physicians v. FTC*, 528 F.3d 346 (5th Cir. 2008) (*NTSP*).

⁷ *Polygram*, 416 F.3d at 35-36.

⁸ *Polygram*, 416 F.3d at 37.

⁹ *NTSP*, 528 F.3d at 362; *Polygram*, 416 F.3d at 35-36.

¹⁰ *Id.*

¹¹ *NTSP*, 528 F.3d at 361; *Polygram*, 416 F.3d at 35.

¹² *Polygram*, 416 F.3d at 35.

per se unlawful depends upon whether it is a “naked” price-fixing agreement or an “ancillary” price-fixing agreement. A naked price-fixing agreement is a restraint on prices or output that competitors agree to impose with no purpose other than to suppress competition, and is *per se* illegal under Section 1. By contrast, horizontal agreements on price or output that are ancillary to a legitimate integration of capital and risk by competitors are subject to rule-of-reason analysis. This means that antitrust analysis of joint pricing activities turns on the nature of the competitors’ relationship with one another.

Single-signature contracting with payors by competing physicians is a form of horizontal price-fixing since competing physicians agree on the prices they will charge for professional services. In the absence of any claim of financial or clinical integration establishing a legitimate joint venture, when competing physicians agree or negotiate jointly with respect to prices, a *per se* violation may be found. Where, however, competitors integrate through a legitimate joint venture, price-fixing agreements, if they are reasonably necessary to accomplish the pro-competitive benefits of the venture, are analyzed under the rule of reason and are often lawful.

III. DEVELOPMENT OF CLINICALLY-INTEGRATED MANAGED CARE CONTRACTING NETWORKS

A joint venture may achieve significant efficiencies if the competing providers share substantial financial risk for the services they provide through the venture. The Policy Statements offer four examples of substantial financial risk sharing:

- an agreement by the venture (on behalf of its participants) to contract with payors on a capitated basis;
- an agreement by the venture to provide designated services or classes of services to a payor for a predetermined percentage of premium or revenue from the payor;
- the use by the venture of significant financial incentives for the competing providers, as a group, to achieve specified cost-containment goals, such as (i) withholding from all provider participants a substantial amount of the compensation due to them, with distribution of that amount to the participants based on group performance in meeting the cost containment goals of the network as a whole, or (ii) establishing overall cost or utilization targets for the network as a whole, with the providers being subject to subsequent substantial financial rewards or penalties based on the group’s performance in meeting the targets; and
- an agreement by the venture to provide a complex or extended course of treatment that requires the substantial coordination of care by different types of providers offering a complementary mix of services, for a fixed, pre-determined payment (e.g., a case rate), where the costs of that course of treatment for any individual patient can vary greatly due to the individual patient’s condition, the choice, complexity, or length of treatment, or other factors.

The Policy Statements also recognize that clinical integration may achieve pro-competitive benefits. The Policy Statements suggest that to be clinically integrated, the network must have an active and ongoing program that evaluates and modifies practice patterns by the network’s physician participants and creates a high degree of interdependence and cooperation among the physicians to control costs and ensure quality. The program should include: (i) mechanisms to monitor and control utilization; (ii) careful selection of network physicians who

are likely to further these efficiency objectives; and (iii) the significant investment of capital in the necessary infrastructure and capability to realize the claimed efficiencies.

Since the Policy Statements provide that clinical integration may be sufficient for joint negotiation, but only under certain circumstances, physician networks traditionally have been hesitant to rely on clinical integration alone for joint contracting. In 2002, however, FTC staff issued an advisory opinion approving a clinical integration program proposed by MedSouth, Inc. (“MedSouth”), an IPA located in Denver, Colorado.¹³ MedSouth proposed to coordinate and integrate primary and specialty care through a clinical resource management program in which all physician members in the MedSouth network would have to participate, and which would include the sharing of patient information through a web-based clinical data record system, the development and implementation of clinical protocols, and oversight and reporting of physicians’ performance relative to established goals. In its MedSouth advisory opinion, FTC staff stated that it would monitor the network’s activities. Five years later, FTC staff issued a follow-up letter stating that it found no reason to rescind or modify its 2002 advisory opinion.¹⁴ MedSouth’s membership had declined by 32.5 percent since its inception, which FTC staff believed demonstrated that a clinical integration program requires a “very serious” commitment and effort by physicians to engage in the activities that are necessary to achieve the program’s beneficial objectives.

In 2007, FTC staff approved a clinical integration program proposed by Greater Rochester Independent Practice Association, Inc. (“GRIPA”), an IPA located in Rochester, New York.¹⁵ Among other elements of its program, GRIPA sought to design, implement, and apply evidence-based practice guidelines and quality benchmarks; monitor individual and collective performance in applying the guidelines and achieving benchmarks; and use a web-based electronic clinical-information system through which member physicians would share clinical information related to their common patients, order prescriptions and lab tests electronically, and access patient information from hospitals and ancillary providers throughout the community. FTC staff concluded that the proposed program would involve substantial integration among GRIPA’s physician participants that had the potential to produce significant efficiencies, such as improved quality and the more efficient and appropriate provision of medical services, and that joint contracting was subordinate and reasonably related to GRIPA’s planning integration and efficiencies. GRIPA’s admission that it anticipated being able to contract at higher rates did not concern FTC staff, which found that GRIPA’s higher fees were part of a program that sought to improve the overall quality and reduce the overall cost of care through primary care screening, preventive medicine services, and other measures.

FTC staff has also issued one unfavorable advisory opinion to a physician-hospital organization (“PHO”) proposing a clinical integration program. In 2006, FTC staff concluded that the integration and efficiency benefits of a program proposed by Suburban Health Organization (“SHO”), a super-PHO located in Indianapolis, Indiana, were limited, and that the

¹³ FTC Staff Letter regarding MedSouth, Inc. (February 19, 2002), *available at* <http://www.ftc.gov/bc/adops/medsouth.shtm>

¹⁴ FTC Staff Letter regarding MedSouth, Inc. (June 18, 2007), *available at* <http://www.ftc.gov/bc/adops/070618medsouth.pdf>

¹⁵ FTC Staff Letter regarding Greater Rochester Independent Practice Association, Inc. (September 17, 2007), *available at* <http://www.ftc.gov/bc/adops/gripa.pdf>

competitive restraints did not appear to be ancillary to those efficiency benefits.¹⁶ The FTC also failed to see how SHO's program would motivate its participants to act collaboratively.

Most recently, in an April 13, 2009 advisory opinion, the FTC approved a clinical integration program proposed by TriState Health Partners, Inc. ("TriState"), a multi-specialty PHO based in Hagerstown, Maryland.¹⁷ TriState's clinical integration program includes the following activities: (i) a web-based health information technology system; (ii) clinical practice guidelines; (iii) monitoring of physician performance targets; and (iv) policies and procedures related to the clinical integration program's utilization management, case management and disease management activities.

IV. ACO PROVISIONS OF PPACA

Section 3022 of PPACA directs the Secretary of Health and Human Services ("Secretary") to establish, no later than January 1, 2012, a shared savings program that promotes accountability for a patient population, coordinates services under parts A and B of Medicare, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Under the shared savings program, ACOs that meet quality performance standards established by the Secretary are eligible to receive shared savings payments.

Among other requirements, an ACO must be accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it. Except as otherwise determined by the Secretary, the following groups of providers and suppliers that have established a mechanism for shared governance are eligible to participate as ACOs under the shared savings program: (i) physicians and mid-level practitioners in group practice arrangements; (ii) networks of physicians and mid-level practitioners in group practice arrangements; (iii) partnerships or joint ventures between hospitals and physicians and mid-level practitioners; and (iv) hospitals employing physicians and mid-level practitioners.

V. APPLICATION OF CLINICAL INTEGRATION CONCEPTS TO ACOS

Since ACOs and clinically-integrated networks share many common elements and are, in essence, collaborative ventures designed to achieve efficiency objectives, the Agencies likely will (and should) view ACOs as collaborative ventures subject to rule of reason analysis. The Agencies likely will evaluate the joint negotiation of payor contracts by competing ACO participants under Statement 9 of the Policy Statements ("Statement 9"), which applies to multi-provider networks. Statement 9 states that the Agencies will evaluate multi-provider networks under the rule of reason if (i) the providers' integration through the network is likely to provide significant efficiencies that benefit consumers, and (ii) any price agreements by the network providers are reasonably necessary to realize those efficiencies. Under the Policy Statements, the provider participants in a network may achieve integration either through substantial financial risk-sharing or clinical integration.

A key inquiry when assessing the legitimacy of a clinical integration program is the extent to which the program will modify its physician participants' clinical practice behavior. In

¹⁶FTC Staff Letter regarding Suburban Health Organization, Inc. (March 28, 2006), *available at* <http://www.ftc.gov/os/2006/03/SuburbanHealthOrganizationStaffAdvisoryOpinion03282006.pdf>

¹⁷ FTC Staff Letter regarding TriState Health Partners, Inc. (April 2009), *available at* <http://www.ftc.gov/os/closings/staff/090413tristatealetter.pdf>

Improving Health Care: A Dose of Competition, the Agencies stated that several of the key *indicia* of clinical integration are: (i) the development and adoption of clinical protocols; (ii) the use of common information technology for the exchange of patient data; and (iii) care review based on the implementation of protocols.¹⁸ Similarly, under the shared savings provisions of PPACA, an ACO will be required to define processes to promote evidence-based medicine and patient engagement; report on quality and cost measures; and coordinate care, such as through the use of telehealth, remote patient monitoring, and other enabling technologies. An ACO will also be required to demonstrate that it meets patient-centeredness criteria specified by the Secretary, such as the use of patient and caregiver assessments or individualized care plans.

While there is no question that the antitrust laws will apply to the formation and operation of ACOs, there are several open issues regarding the manner in which they will be applied in practice. It remains to be seen, for example, whether the FTC will be willing to deem any ACO that meets the participation criteria and requirements the Secretary will establish to be sufficiently integrated to warrant rule of reason treatment, or whether the FTC will still want to evaluate each ACO on a case-by-case basis to determine whether that ACO is sufficiently integrated within the meaning of the antitrust laws to avoid *per se* condemnation.

It also will be interesting to see whether the FTC will extend the “antitrust safety zone” that applies solely to physician networks to multi-provider networks such as ACOs.¹⁹ Further, it would be helpful if the FTC would provide guidance on whether the “percentage of savings” provisions of PPACA—and any other financial incentive provisions that the Secretary adopts under the shared savings program—constitutes “substantial financial integration” within the meaning of the Policy Statements such that the ACO need not also be clinically-integrated for its joint negotiation of fees with private payors to be judged under the rule of reason. Finally, it will be interesting to see how the Agencies will evaluate ACOs in rural or non-metropolitan areas that have to include a majority or most of the physicians in a specialty to be able to treat the requisite number of Medicare beneficiaries.

On October 5, 2010, the FTC, Center of Medicare & Medicaid Services (“CMS”) and Office of Inspector General (“OIG”) held a public workshop on certain legal issues related to ACOs. At the workshop, FTC Chairman Jon Leibowitz announced the FTC will develop antitrust safe harbors for ACOs and an expedited review process for ACOs that do not qualify for those safe harbors. Two sessions of the workshop addressed antitrust issues. The first session addressed circumstances under which collaboration among independent healthcare providers in an ACO should permit ACO providers to engage in joint price negotiations with private payors without running the risk of engaging in *per se* unlawful price fixing. The second session explored ways to encourage the formation of multiple ACOs among otherwise independent providers so that competition among ACOs in any given geographic market will drive improved quality and affordability of health care. Hopefully, the development of ACO safe harbors will provide additional guidance concerning the formation and operation of clinically-integrated ACOs formed in response to healthcare reform.

¹⁸ Page 37 of Chapter 2 of “Improving Health Care: A Dose of Competition,” A Report by the FTC and DOJ (July 2004), available at <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf>

¹⁹ The existing antitrust safety zone applicable to physician networks applies to exclusive networks comprised of 20 percent or less of the physicians in each specialty and to non-exclusive networks comprised of 30 percent or less of the physicians in each specialty.