Federal Trade Commission

CLINICAL INTEGRATION: THE CHANGING POLICY CLIMATE AND WHAT IT MEANS FOR CARE COORDINATION

Remarks of
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* The views expressed herein are Commissioner Harbour's, and do not necessarily reflect the views of the Commission or any other individual Commissioner.

together to jointly set prices and negotiate with payors. This is precisely the kind of behavior that invites antitrust scrutiny in every other industry. Therefore, when faced with arrangements claiming to involve clinical integration, it makes sense for antitrust enforcers to view these arrangements with a healthy dose of skepticism, and to be vigilant in blocking those that are likely to lead to anticompetitive effects.

The Commission applies a careful legal analysis to purported clinical integration arrangements, on a case-by-case basis. In short, our job is to ensure that cognizable efficiencies are indeed likely to result; that any price-fixing agreements are reasonably related to achieving those efficiencies; and that the arrangement is not likely to create market power.

I intend to cover three main areas during my remarks.

- First, I will sketch out the legal framework that the Commission applies when analyzing current or proposed entities that rely on clinical integration to justify joint pricing.
- Second, I will do my best to put clinical integration into the larger context of health care reform, and to explain why antitrust will not be a barrier to reform efforts.
- And finally, I will talk a little bit about the need for more empirical research on the outcomes of clinical integration, to ensure that promises of efficiencies and quality improvements are being fulfilled.

II. LEGAL FRAMEWORK FOR ANTITRUST ANALYSIS OF PHYSICIAN JOINT PRICING ARRANGEMENTS

To begin, let me briefly review the legal framework for antitrust analysis of physician joint pricing arrangements – especially clinically integrated entities.

A. *Maricopa*: The Antitrust Laws Apply To The Health Care Industry

The analysis begins from the premise I mentioned a moment ago: the antitrust laws apply to the health care industry, including physicians. In its 1982 *Maricopa* decision,[3] the U.S. Supreme Court condemned agreements among competing physicians regarding the fees they would charge health insurers for their services, holding that this constituted *per se* unlawful horizontal price fixing.[4]

The Court has never overruled *Maricopa*.[5] Nor has the Court ever wavered from its position that physicians are capable of unlawful price-fixing under the antitrust laws, and that it is appropriate to use the antitrust laws to stop such conduct.

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[3]Arizona v. Maricopa County Medical Soc'y, 457 U.S. 332 (1982).

[4]*Id.* at 356-57.

[5]*See, e.g.*, North Texas Specialty Physicians v. Fed. Trade Comm'n, 528 F.3d 346, 360 (5th Cir. 2008) [hereinafter *NTSP v. F.T.C.*] (citing *Maricopa* favorably).

[6]In the Matter of North Texas Specialty Physicians, FTC Dkt. No. 9312, Opinion of the Commission (Nov. 2005), *available at* http://www.ftc.gov/os/adjpro/d9312/051201opinion.pdf [hereinafter NTSP Commission Opinion], *aff'd sub nom. NTSP v. F.T.C.*, 528 F.3d 346.

[7]NTSP Commission Opinion at 1.

more flexible "inherently suspect" methodology set forth in its *Polygram Holding* [8] administrative opinion, which had been upheld by the D.C. Circuit earlier that year.[9]

Without going into too many details, the essence of the *Polygram* approach is that it allows for some consideration of defenses, especially efficiency justifications. But when conduct is inherently suspect – when it is the type of restraint that is generally presumed to harm competition, such as horizontal price fixing among competitors – the bar is set fairly high to put forth a plausible procompetitive justification that is worthy of consideration. If this hurdle is not overcome, then the conduct may be summarily condemned, even without a detailed analysis of market facts or competitive effects.

In *NTSP*, both the Administrative Law Judge and the Commission were able to delve deeply into the efficiencies question, based on evidence put forward by a renowned expert whom complaint counsel had retained to analyze and test NTSP's efficiency justifications. The Commission ultimately found, and the Fifth Circuit agreed, that joint pricing by this group of independent competing physicians constituted horizontal price fixing that was not reasonably related to any procompetitive efficiencies. Therefore, said the court, the Commission had properly condemned

[8]In the matter of Polygram Holding, Inc., et al., FTC Dkt. No. 9298, Opinion of the Commission (July 2003), *available at* http://www.ftc.gov/os/2003/07/polygramopinion.pdf, *aff'd sub. nom.* Polygram Holding, Inc., et al. v. Fed. Trade Comm'n, 416 F.3d 29 (D.C. Cir. 2005).

[9]*Polygram*, 416 F.3d 29.

would be made possible by the joint venture. Of course, the arrangement as a whole is still subject to a full rule of reason analysis to determine overall competitive effects.[12]

Most of the advisory opinions the Commission staff has issued in recent years regarding c

[12]The foregoing abbreviated summary of the legal analysis assumes that there is no market power issue – i.e., that combining the group of physicians is unlikely to create market power. Of course, the competitive effects analysis would proceed differently if the arrangement involved a large enough number of physicians (e.g., from a given geographic area, practice specialty, etc.), posing a risk that market power might be created by the arrangement.

[13]Organizing for America, *Barack Obama and Joe Biden's Plan to Lower Health Care Costs and Ensure Affordable, Accessible Health Coverage For All* [hereinafter *Obama Health Care Plan*], *at* http://www.barackobama.com/pdf/issues/HealthCareFullPlan.pdf.

[14]Office of Mgmt. & Budget, *A New Era of Responsibility: Renewing America's Promise* (F

I was able to discern a few themes that are relevant to any discussion of clinical integration.

1. The Importance of Competition

First and foremost, the Obama Administration has emphasized that competition is, and will continue to be, an important element of the American health care system. The Administration supports a combination of government mandates and market-based approaches, but has made clear that competition is central to the Administration's reform proposals.[15] For those of us in the antitrust community – and especially those of us who think the Fifth Circuit got it right in *NTSP* – this is welcome news. As best as I can tell, the Administration does not intend for health care reform to supplant or conflict with either the antitrust laws or competition policy.

2. Improving Quality and Efficiency

Next, the Administration's plan strongly emphasizes improving the quality of health care delivery. Quality can be defined in different ways. Expanded access to care, broader insurance coverage, and implementation of better patient safety measures all would be expected to improve health care outcomes.

But as I read the plan, a critical component of the Administration's philosophy is that *more* health care does not always mean *better* health care. For example, the plan emphasizes preventive care and disease management, which presumably will reduce the need for aggressive and

[15]For example, the Administration proposes the creation of a National Health Insurance Exchange. This has been described as a government-organized marketplace, where consumers will be able to compare health plans, gather information about their options, and exercise informed choices. In the end, however, consumers will pick their own plans and their own doctors. The President also has suggested that any government-sponsored insurance plan should compete with private insurers in that same marketplace. *See Obama Health Care Plan*, *supra* note 13.

[16]*See* American Academy of Family Physicians, American Academy of Pediatrics, American College of Physicians, & American Osteopathic Association, *Joint Principles of the Patient-Centered Medical Home* (March 2007), *available at* http://www.medicalhomeinfo.org/Joint%20Statement.pdf

3. A Note About HIT

I mentioned HIT a moment ago, and I'd like to say just a few more words about that topic, because it is something that will be of particular interest to the FTC in the coming years.

The stimulus package included a number of provisions, and $19 billion in financial incentives, to encourage investments in HIT.[17] I think it would be fair to say that the Administration views HIT development and deployment as central to its vision of health care reform.

When used to its fullest potential, a robust HIT system can serve as a hub for effective coordination-of-care efforts, which can lead to improvements in quality, access, and cost – all three of the dimensions of the "iron triangle" of health care delivery. For example, the effective use of HIT may reduce medical errors and duplicative testing, increase transparency of information regarding the comparative quality of different provide arding the comparative quality

[17] American Recovery and Reinvestment Act of 2009, H.R. 1, 111th Cong. (2009); *see especially id.* at Title XIII ("Health Information Technology").

minutes ago – as a hub for coordination-of-care efforts – its implementation will be completely consistent with procompetitive clinical integration.

It is important to realize, however, that HIT adoption *alone* does not constitute lawful and effective clinical integration. HIT is a tool, not an end in itself. Far more important is the quality of the coordination facilitated by HIT. Is it being used to reduce fragmentation and foster interdependence among providers? Does it contribute toward aligning provider incentives so that they are all working toward common goals? Does its use actually lead to better health care outcomes and improved efficiency? These are key questions, the answers to which will inform a determination of whether HIT has helped providers achieve clinical integration.

C. Antitrust Is Not A Barrier To Health Care Reform

And now, we get to the real reason why I suspect I was invited to speak on this panel.

Start from the premise I just articulated: that clinical integration is, in theory, a strong expression of current health reform principles.

Then, let me a

to consent agreements.[18] *NTSP* was litigated, and resulted in favorable appellate case law that endorses the Commission's analytical framework.[19]

Looking at all of these factors, one might wonder whether antitrust enforcement might impede health care reform. Some people have said directly that antitrust enforcement *is* a barrier

[18]For a summary of recent FTC actions involving physician networks, *see* Federal Trade Commission, Bureau of Competition, Health Care Services and Products Division, *Overview of FTC Antitrust Actions in Health Care Services and Products* (Sept. 2008), at 10 *et seq.* ("Agreements on Price or Price-Related Terms"), *available at* http://www.ftc.gov/bc/0809hcupdate.pdf. *See also* In the Matter of Independent Physicians Associates Medical Group, Inc. d/b/a AllCare IPA, FTC Dkt. No. C-4245 (decision and order entered Feb 2, 2009), *available at* http://www2.ftc.gov/os/caselist/0610258/index.shtm; In the Matter of Boulder Valley Individual Practice Association, FTC File No. 051-0252 (proposed consent agreement accepted Dec. 19, 2008), *available at* http://www2.ftc.gov/os/caselist/0510252/index.shtm.

[19]*See* NTSP Commission Opinion, *supra* note 6, at 11-12, 28-30, 33-34 (discussing clinical integration in evaluating NTSP's claimed efficiencies, and concluding that NTSP had not achieved clinical integration); *accord NTSP v.F.T.C.*, 528 F.3d at 368-69 (rejecting NTSP's "spillover" defense arguments; agreeing with the Commission's conclusion that, even if any efficiencies did exist, NTSP had not explained how such efficiencies were furthered by its anticompetitive activities, i.e., how the restraints were ancillary to any procompetitive integration).

[20]*See, e.g.*, American Hospital Association, *Statement of the American Hospital Association on the Importance of Clinical Integration to the Nation's Hospitals and Their Patients* (May 29, 2008), at 2, *available at*

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guidance is consistent with current reform models. In fact, one might argue that reform efforts are actually moving closer to where the Commission has been all along, in terms of receptivity toward arrangements involving the kind of coordination that aligns provider incentives and generates real efficiencies.

The most current example of FTC guidance is the very recent advisory opinion that Commission staff issued to TriState Health Partners, a physician-hospital organization ("PHO") based in Maryland.[22] Notably, this is the first time a PHO has requested a staff advisory opinion on clinical integration. In a 37-page, single-spaced letter, staff carefully analyzed TriState's description of its proposed program, and concluded that the proposed plan has the potential to lower health care costs and improve the quality of care. As in several earlier advisory opinions, coordination of care is central to the logic of the TriState opinion – including coordination between physicians, as well as between physicians and the hospital. Moreover, the hospital will play an important management and decisionmaking role.

2. The FTC Will Not Endorse Specific Models

The federal antitrust agencies have been criticized for not providing sufficient guidance to providers, who are struggling to craft and implement clinical integration programs whose joint pricing components will pass antitrust muster. The risk, we are told, is that procompetitive arrangements are being deterred by the risk of antitrust enforcement. As a result, there have been

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to Christi J. Braun, Ober, Kaler, Grimes & Shriver (April 13, 2009), *available at* http://www.ftc.gov/os/closings/staff/090413tristateaoletter.pdf (staff advisory opinion concerning TriState Health Partners, Inc.) ([hereinafter TriState Advisory Opinion].

These written forms of guidance are supplemented by frequent speeches delivered by FTC Commissioners and staff, as well as plentiful informal guidance shared by FTC staff.

[22]TriState Advisory Opinion, *supra* note 21.

many calls for "more guidance" – although, reading between the lines, some of those requests may really be calls for "safe harbors," or other bright-line rules, that will offer greater comfort to physicians who choose to engage in joint pricing.

At the moment, at least, we may just have to agree to disagree about whether more guidance is possible or necessary. By its nature, antitrust analysis is highly fact-specific. The FTC's clinical integration advisory opinions are a prime example. Did I mention that the TriState advisory opinion is 37 single-spaced pages? And the vast majority of those pages are devoted to reviewing the elements of a specific geographic market and a specific proposed arrangement.

History teaches us that when the antitrust agencies issue guidelines, the agencies tend to take a conservative, risk-adverse approach, to leave enough room for case-by-case analysis.[23] Our concern is that any bright-line guidance on clinical integration is likely to stifle the innovation and creativity that are true hallmarks of the ever-evolving American health care system. It is also worth noting that guidelines, once issued, may be difficult to change, even if new infor

[23] *See, e.g.*, Fed. Trade Comm'n & U.S. Dep't of Justice, *Horizontal Merger Guidelines* (rev. April 8, 1997), *available at* http://www.ftc.gov/bc/docs/hmg080617.pdf; U.S. Dep't of Justice & Fed. Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property* (April 6, 1995), available at http://www.ftc.gov/bc/0558.pdf; *Competitor Collaboration Guidelines*, *supra* note 10.

[24] Changes to existing guidelines may be even more difficult to draft and implement when the original guidelines have been issued jointly by two agencies, such as the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice. Even when relationships between these sister agencies are at their most collegial, the agencies' approaches are rarely identical, and coordinated policy development takes time.

[25]FTC Clinical Integration Workshop, *supra* note 20.

[26]For example, during the FTC's May 2008 clinical integration workshop, a speaker from the Agency for Healthcare Research and Quality reviewed the empirical literature on clinical

have been inconsistent, which provides a less-than-stable foundation for further policymaking and legal development.[27]

Let me draw an analogy to another controversial area of antitrust law – vertical minimum price fixing, or resale price maintenance ("RPM"), whereby manufacturers dictate the minimum prices at which retailers can sell their products. The Supreme Court recently reversed *per se* illegality for RPM, which had been in place since 1911. Without a rule of *per se* illegality, the antitrust community has been struggling to develop an appropriate legal framework to analyze this conduct, and we are finding our efforts hampered by a dearth of empirical evidence.

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[27] *See, e.g.*, TriState Advisory Opinion, *supra* note 20, at note 45 (cataloguing recent literature demonstrating that, "[w]hile the potential benefits of a robust [clinical integration] program appear intuitively obvious," clinical integration does not always lead to expected quality of care improvements or other anticipated benefits).

[28] *See, e.g.*, Pamela Jones Harbour, Commissioner, Federal Trade Commission, *Consumer Benefits and Harms from Resale Price Maintenance: Sorting the Beneficial Sheep from the Antitrust Goats?*, Opening Remarks at the Federal Trade Commission Resale Price Maintenance Workshop (Feb. 17, 2009), *available at* http://www.ftc.gov/speeches/harbour/090217rpmwksp.pdf; *Bye Bye Bargains? Retail Price Fixing, the* Leegin *Decision, and Its Impact on Consumer Prices, Hearing Before the Subcomm. on Courts and Competition Policy, H. Comm. on the Judiciary*, 111th Cong., 1st Sess. (April 28, 2008) (statement of Pamela Jones Harbour, Commissioner, Federal Trade Commission), *available at* http://www.ftc.gov/speeches/harbour/090428rpmtesti.pdf.

A DOJ Antitrust Division official has expressed similar thoughts.

If what you are looking for, however, are bright-line rules of antitrust legality, the federal antitrust agencies probably cannot give you much more certainty at this time.

But this should not cause too much discomfort to the medical community. After all, there are no absolute certainties in medicine. Often, it is possible to come up with different interpretations for the same collection of symptoms. And even when a diagnosis is reached, there likely are multiple treatment approaches available, depending on factors very specific to the individual patient. Doctors tend to appreciate autonomy in crafting a recommended course of treatment, relying on their hands-on evaluation of each patient, combined with expertise and good judgment.

The legal approach to clinical integration generally, and physician pricing agreements specifically, requires the same degree of flexibility. This flexibility benefits the health care industry, and consumers, in the long run, in the l