ON THEIR SILVER ANNIVERSARY, IT'S TIME TO BURNISH THE HEALTHCARE GUIDELINES

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By Peter Mucchetti & Eva Kurban

Twenty-five years have passed since the United States Department of Justice and the Federal Trade Commission last revised their Statements of Antitrust Enforcement Policy in Health Care (the "Healthcare Guidelines"). Given legal developments and advancements in economic analysis, the agencies should now solicit public input on how to revise these guidelines and then issue updated guidelines. In particular, the agencies should add three new statements to address the following issues: (1) what types of steering restrictions are permissible in hospital-payer contracts; (2) how hospitals may structure discounts to payers; and (3) how competitors may collaborate to address healthcare crises, incorporating lessons from the response to the COVID-19 crisis. These and other updates to the Healthcare Guidelines would help foster greater competition, innovation, and consumer welfare in the healthcare sector.

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In 1996, the United States Department of Justice and the Federal Trade Commission issued revised Statements of Antitrust Enforcement Policy in Health Care (the "Healthcare Guidelines").[2] These nine statements address a variety of issues concerning healthcare providers and health insurance companies. But the federal antitrust agencies have not subsequently updated these now 25-year old guidelines. Some of the statements have aged well, providing guidance that is regularly used. Other statements, however, have largely been ignored or effectively been replaced by subsequent guidance.

Updating the Healthcare Guidelines would provide valuable guidance on important healthcare and antitrust issues. We recommend that the FTC and DOJ initiate a process, similar to the one used last year to create the Vertical Merger Guidelines, that includes soliciting public input on what statements should be amended, deleted, or added. As this article discusses, adding new statements to the Healthcare Guidelines may be the most needed update. In particular, the agencies should add three new statements to address the following issues:

1. What types of steering restrictions are permissible in hospital-payer contracts;

2. How hospitals may structure discounts to payers; and

3. How competitors may collaborate to address healthcare crises, incorporating lessons from the response to the COVID-19 crisis.

The creation of new statements on these topics would have particular value because they involve tricky issues where it is often difficult to separate conduct that raises significant competition concerns from conduct that is pro-competitive or competitively neutral. Furthermore, the agencies should create "safety zones" for these new statements, as they did in many of the 1996 statements, that describe conduct that the agencies will not challenge under the antitrust laws absent extraordinary circumstances. In the three areas listed above, the agencies have significant experience, which, along with public comments, should allow the agencies to create antitrust safety zones.

I. THE 1996 HEALTHCARE GUIDELINES AND OTHER AGENCY HEALTHCARE GUIDANCE

The Healthcare Guidelines were originally released in 1993 with six statements. In 1994, the DOJ and FTC added new statements to the guidelines and expanded the antitrust safety zones for several statements. The 1996 Healthcare Guidelines later amplified policy statements concerning physician network joint ventures and multiprovider networks. But since 1996, the antitrust agencies have not further updated the Healthcare Guidelines.

Some statements have been more widely relied upon than others. For example, Statement 6, concerning the exchange of price and cost information among providers, has often been consulted concerning how to structure wage and salary surveys, both in and outside of the healthcare industry.[3] Statement 7, concerning joint purchasing arrangements among healthcare providers, is regularly used as a reference for how to analyze the conduct of group purchasing organizations.[4]

Other statements do not appear to be widely used. In particular, there are almost no court cases, law review articles, or business review letters that cite to Statements 1 through 3 of the Healthcare Guidelines.[5] Furthermore, the Healthcare Guidelines were most often cited in the late 1990s and early 2000s, with relatively few references made after 2010.

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2 Dep't of Justice & Federal Trade Comm'n, *Statements of Antitrust Enforcement Policy in Health Care, available at* https://www.justice.gov/atr/page/file/1197731/download.

3 See, e.g. Response to Greater New York Hospital Association (Jan. 16, 2013) available at https://www.justice.gov/atr/response-greater-new-york-hospital-associations-request-business-review-letter.

4 See, e.g. Response to American Optometric Association and AOAExcel GPO, LLC (Jan. 15, 2020) available at https://www.justice.gov/opa/press-release/file/1235206/download.

5 Statements 1-3 concern (1) hospital mergers; (2) hospital joint ventures involving high technology or other expensive healthcare equipment; and (3) hospital joint ventures involving specialized clinical or other expensive healthcare services.

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Many of the statements appear to be collecting dust in part because a wide variety of other guidance from the federal antitrust agencies has been provided since August 1996, including the following:

- the 2000 Antitrust Guidelines for Collaborations Among Competitors;
- the 2004 report Improving Health Care: A Dose of Competition;
- the 2010 Horizontal Merger Guidelines;
- the 2011 Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program;
- the 2020 Vertical Merger Guidelines;
- filings relating to the approximately 35 DOJ and 220 FTC healthcare enforcement actions since August 1996; and
- approximately 30 DOJ business review letters and 50 FTC advisory opinions relating to healthcare issued since August 1996.

These additional sources for guidance have supplanted some of the Healthcare Guidelines. For example, Statement 1, which concerns hospital mergers, has essentially been replaced by the 2010 Horizontal Merger Guidelines. Updating the Healthcare Guidelines would provide the federal antitrust agencies with the opportunity to withdraw outdated statements and synthesize antitrust guidance from subsequent materials into a modern set of guidelines.

One of the salient innovations in the Healthcare Guidelines was the inclusion in most statements of antitrust safety zones describing conduct that the agencies would not challenge absent extraordinary circumstances. For example, Statement 7 creates an antitrust safety zone for group purchasing organizations that fall below certain market-share thresholds. Businesses, including non-healthcare businesses, have consulted many of the Healthcare Guidelines safety zones to understand how the federal antitrust agencies would analyze business conduct and to determine how to structure their operations to minimize antitrust concerns.

II. THE VALUE IN HOLDING HEALTHCARE HEARINGS AND PROVIDING UPDATED GUIDANCE

Hearings conducted by the DOJ and FTC concerning how to update the Healthcare Guidelines would be beneficial in at least two ways. First, the process would enable companies and other participants in the healthcare industry to identify for the federal antitrust agencies the areas that are most in need of updated antitrust guidance. Second, the hearings would allow for input from businesses, academics, government agencies, and others on difficult issues that are facing the antitrust healthcare community. Discussions should focus on the difficult questions because unsettled areas are precisely where guidance is most valuable.

At least three areas are ripe for new statements: (1) steering restrictions in hospital-payer contracts; (2) the structure of hospital discounts to payers; and (3) lessons from the COVID-19 crisis on how competitors may collaborate to address healthcare crises.

These three issues have common characteristics. First, they are not addressed in the current Healthcare Guidelines. Second, antitrust agencies have developed significant experience, and competition analysis has significantly advanced, in these areas since 1996. Third, despite these advancements, thorny antitrust questions still exist in these areas, as discussed below.

In the absence of DOJ and FTC providing guidance through healthcare statements on these and other topics, antitrust practitioners will continue to review case and other enforcement developments to navigate complex antitrust issues. But developments through enforcement actions can be fragmented, haphazard, and uncertain because they vary depending on the investigations, settlements, and litigation that the antitrust agencies can and do pursue. Issuing new statements, in contrast, provides an avenue for comprehensive consideration of issues, systematically analyzing conduct that can benefit or harm consumers, and providing more holistic guidance.

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III. STEERING RESTRICTIONS

The antitrust community's understanding of the potential for harm concerning hospital steering restrictions has advanced significantly since 1996. Steering is a method used by insurers to offer consumers options to reduce their healthcare expenses, including designing health benefit plans that give patients financial incentives to choose more cost-effective hospitals and physicians. Two principal cases have laid out the antitrust concerns that can arise from a dominant hospital's use of restrictions that prevent steering: *Atrium Health* and *Sutter Health*.[6]

In *Atrium*, the DOJ and the State of North Carolina alleged that Atrium, the largest hospital system in the Charlotte area, used its market power to restrict health insurers from encouraging consumers to choose healthcare providers that offered better overall value. The litigation was resolved in 2019 when the court entered a consent decree that enjoined Atrium from using certain steering restrictions.

In *Sutter*, the California Attorney General joined a lawsuit filed by private plaintiffs in California state court, challenging Sutter's use of anti-steering provisions and other allegedly anticompetitive contracting practices. On the eve of trial, in October 2019, the parties reached a settlement agreement. In addition to a $575 million monetary settlement, the settlement includes wide-ranging injunctive relief through behavioral remedies.

Sutter's use of anti-steering provisions in its contracts with insurers formed a significant part of the foundation of the antitrust claims against it. Sutter's contracts allegedly prohibited or disincentivized insurers from offering incentives to patients to use lower-cost or higher-quality competitors through steering or tiered plan benefit designs. The Sutter settlement recognizes the positive competitive effects that steering can have in providing lower costs and greater choices for consumers and prohibits Sutter from directly or indirectly interfering with many steering or tiering arrangements.[7]

The steering restrictions at issue in *Atrium* and *Sutter* were both evaluated under the rule of reason because some steering restrictions can be pro-competitive or competitively neutral. For this reason, the consent decrees in both cases permitted the defendants to continue to use certain steering restrictions. For example, the *Atrium* decree provides that if Atrium is the most prominently featured provider in a narrow-network plan or hospital-insurer cobranded plan, Atrium may restrict an insurer from steering away from Atrium in that plan. As the DOJ recognized, this type of restriction may help narrow networks and co-branded plans be more effective by allowing insurers to steer patients to a hospital in a narrow network.[8]

Similarly, the proposed *Sutter* decree allows an individual Sutter provider to offer lower prices for networks or products that feature that provider, including co-branded products.[9] The decree also allows Sutter to negotiate and enforce contract terms that provide that an insurer may not unilaterally change the participation status of a Sutter provider in an existing commercial product during the contract term.[10] This provision allows Sutter to restrict one way in which insurers could steer away from a particular Sutter provider.

6 See Final Judgment, *United States v. Charlotte-Mecklenburg Hospital Authority*, No. 3:16-cv-00311-RJC-DCK (W.D.N.C. Apr. 24, 2019), ECF No. 99, available at https://www.justice.gov/atr/case-document/file/1157461/download; Notice of Motion and Motion for Preliminary Approval of Settlement, *UFCW & Employers Benefit Trust v. Sutter Health* and *People of the State of California ex rel. Xavier Becerra v. Sutter Health*, Case No. CGC 14-538451 (Cal. App. Dep't Super. Ct. Feb. 25, 2020), available at https://oag.ca.gov/system/files/attachments/press-docs/2019-12-19%20-%20Notice%20of%20Motion%20and%20Motion%20for%20Preliminary%20Settlement%20Approval%20with%20Exhibits%20-%20REDACTED.pdf.

7 See Notice of Motion and Motion for Preliminary Approval of Settlement at 16, *UFCW & Employers Benefit Trust v. Sutter Health* and *People of the State of California ex rel. Xavier Becerra v. Sutter Health*.

8 Competitive Impact Statement at 14, *United States v. Charlotte-Mecklenburg Hospital Authority*, No. 3:16-cv-00311-RJC-DCK (W.D.N.C. Dec. 04, 2018), ECF No. 89, available at https://www.justice.gov/atr/case-document/file/1117111/download.

9 See [Proposed] Final Judgment and Order Pursuant to Stipulation at 15, *UFCW & Employers Benefit Trust v. Sutter Health* and *People of the State of California ex rel. Xavier Becerra v. Sutter Health*.

10 *Id.* at 14.

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A healthcare statement on steering restrictions: Healthcare systems and insurers today face a difficult analysis when trying to determine what steering restrictions are permissible or problematic because of competition concerns. Holding hearings to study this issue would allow these businesses and other industry participants to discuss their concerns and vet this issue. Additionally, the inclusion of permitted conduct in the *Atrium* and *Sutter* decrees indicates that a healthcare statement on steering restrictions can include an antitrust safety zone for permitted steering restrictions. As in the *Atrium* matter, the proposed safety zone should permit steering restrictions that are reasonably necessary for creating competition based on narrow network or co-branded plans. Along with defining a safety zone, the antitrust agencies should consider articulating additional safeguards that hospitals could implement to make any steering restriction less likely to harm competition, including having the hospital-insurer contract explicitly state that the insurer remains free to create other plans that exclude the hospital.

IV. VOLUME AND LOYALTY DISCOUNTS

Antitrust law recognizes that discounts, including discounts for higher volume, often benefit consumers. Lower prices, after all, is one of the main benefits that competition produces. But economists agree that loyalty discounts or "non-linear pricing" (pricing that does not charge a constant price per unit sold), when used by companies with market power, may foreclose competition and substantially lessen competition.[11] One situation where discounts may be anticompetitive is where the discount results in the price of units sold being below an appropriate measure of cost.

For example, in *United Regional*, the Justice Department challenged a hospital's use of a discounting mechanism that it alleged resulted in below cost pricing.[12] According to the DOJ, United Regional, the largest hospital in Wichita Falls, Texas, offered insurers contracts with substantially larger discounts if United Regional was the only local hospital in the insurer's network. The DOJ explained that the discounts violated the antitrust laws in part because they failed an appropriate "price-cost" test.[13] The DOJ used this test to compare the entire discount offered in United Regional's contracts to the contestable volume and determined that the resulting price was below any plausible measure of United Regional's incremental costs. This pricing mechanism effectively prevented equally or more efficient hospitals from attracting additional consumers.

A healthcare statement on pricing discounts: Over the past 25 years, antitrust scholarship and case law have progressed significantly in understanding when pricing discounts are potentially harmful or pro-competitive/competitively neutral.[14] Building on these developments, advice from the antitrust agencies concerning pricing programs would be beneficial for several reasons. First, identifying pricing programs most likely to generate antitrust concerns would likely deter businesses from pursuing those types of pricing strategies. Second, creating an antitrust safety zone would encourage healthcare companies to engage in the more conservative pricing programs identified in the safe harbor. For example, the agencies could explain the parameters under which linear discounts are not likely to be challenged. Third, additional guidance would enable companies to better understand at the time that they are offering a discount, rather than years later when the conduct might be challenged, whether the discount likely would be considered to be anticompetitive.

11 See, e.g. Willard K. Tom et al., *Anticompetitive Aspects of Market-Share Discounts and Other Incentives to Exclusive Dealing*, 67 Antitrust L.J. 615, 627 (2000).

12 Competitive Impact Statement, *United States v. United Regional Health Care System*, Civ. No. 7:11-cv-00030 (N.D. Tex. Feb. 25, 2011), ECF No. 4, available at https://www.justice.gov/atr/case-document/file/514151/download.

13 *Id.* at 13-16.

14 See, e.g. *Cascade Health Solutions v. PeaceHealth*, 515 F.3d 883 (9th Cir. 2008).

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V. COMPETITOR COLLABORATIONS DURING A HEALTHCARE CRISIS

The devasting impact of COVID-19 has presented a tremendous challenge to the United States and the world. Early into this crisis, the antitrust agencies, other government actors, and healthcare companies realized that they would need to work together to more effectively address its challenges.[15] In March 2020, the Justice Department and the FTC responded by announcing, that to help enable competitors to provide needed goods and services, the agencies would respond to all COVID-19-related business review and advisory opinion requests within seven days of receiving all necessary information. The DOJ received four healthcare related requests, to which it quickly responded by issuing positive business review letters.[16]

A healthcare statement concerning competitor collaborations to address a healthcare crisis: With the experience of how competitors and government agencies can work together to better address a catastrophic emergency, the DOJ and FTC should draw out what lessons have been learned and create guidance in a new healthcare statement for reacting to future healthcare crises. This statement should define and discuss what conduct is permissible to respond to a national emergency under existing antitrust laws, the National Cooperative Research and Production Act, the Defense Production Act, and the Pandemic and All-Hazards Preparedness Act.

VI. A PROCESS WORTH UNDERTAKING

For many years, the Justice Department's 1984 Non-Horizontal Merger Guidelines Statements were largely ignored because legal and economic developments had made the statements a relic. Last year's Vertical Merger Guidelines surely were a tremendous improvement over the 1984 Statements. Updating the Healthcare Guidelines through critical examination and thoughtful revision would likely create similar significant improvements. As healthcare is fundamental to the well-being of all Americans, the potential for greater competition, innovation, and consumer welfare would make the process well worth the effort.

15 Dep't of Justice & Federal Trade Comm'n, *Joint Antitrust Statement Regarding COVID-19* (Mar. 2020) available at https://www.ftc.gov/system/files/documents/public_statements/1569593/statement_on_coronavirus_ftc-doj-3-24-20.pdf (stating that the spread of COVID-19 "will require unprecedented cooperation between federal, state, and local governments and among private businesses to protect Americans' health and safety").

16 See Response to Baxalta US Inc., Emergent BioSolutions Inc., Grifols Therapeutics LLC, and CSL Plasma Inc., (Jan. 12, 2021); Response to Eli Lilly & Co., AbCellera Biologics, Amgen, AstraZeneca, Genentech, and GSK (Jul. 23, 2020); Response to AmerisourceBergen Corp. (Apr. 20, 2020); Response to McKesson Corp., Owens & Minor, Inc., Cardinal Health, Inc., Medline Indus., Ind., and Henry Schein, Inc. (Apr. 4, 2020); all available at https://www.justice.gov/atr/business-review-letters-and-request-letters.

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