HEALTH CARE ANTITRUST WITHOUT THE HEALTH CARE GUIDELINES: WHAT WILL THE FUTURE HOLD?

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In a largely unheralded announcement on February 3, 2023, the Department of Justice Antitrust Division ("DOJ") withdrew three major antitrust policy statements applying to the health care industry (the Health Care Guidelines). The announcement has been met with widespread concern about the impact of the withdrawal on the industry, which over the last 30 years has arranged its affairs in the context of this guidance. The stated motivation for the DOJ's withdrawal of the Health Care Guidelines is the significant changes in the health care industry over the period they have been in place. However, rather than engage in any industry consultation concerning the role of the Guidelines and whether to revise or withdraw them, the DOJ jettisoned the Guidelines in their entirety. Antitrust policy in health care needs to be nuanced to account for the complex set of political and regulatory factors applying to the industry, as well as broader challenges in health care and its extension to community health and access. Government health care policies have encouraged a broad range of collaborations, and the Guidelines have provided an important foundation upon which many of those collaborations are built. Before dismantling that scaffold, the agencies should engage in research, consultation, and provide clear and transparent guidance for the industry going forward.

I. INTRODUCTION

In a largely unheralded announcement on February 3, 2023, the Department of Justice Antitrust Division ("DOJ") withdrew three major antitrust policy statements applying to the health care industry (the "Health Care Guidelines").[2] The announcement has been met with widespread concern about the impact of the withdrawal on the industry, which over the last 30 years has arranged its affairs in the context of this guidance.

The stated motivation for the DOJ's withdrawal of the Health Care Guidelines is the significant changes in the health care industry over the period they have been in place. However, the DOJ did not engage in any industry consultation around how the Guidelines operated in practice and the potential impact of their withdrawal. Over the years in which the Guidelines were in place, there have been calls to modernize them to reflect changes in the industry. But rather than take this approach, the DOJ has jettisoned the Guidelines in their entirety, forcing the industry to reconsider longstanding practices in light of general antitrust guidelines, some of which themselves are in a state of flux.[3]

The withdrawal of the Guidelines raises important questions about the future of antitrust enforcement policy in the health care industry. What can companies expect with respect to ongoing benchmarking activities, clinically integrated networks, joint purchasing arrangements, and other practices that are core to many organizations in the health care space and beyond? Will withdrawal of the Guidelines smother procompetitive activities as health care organizations retreat into conservative positions to avoid antitrust risk?

II. OVERVIEW OF THE HEALTH CARE GUIDELINES

A. Health Care Industry Landscape Before the Guidelines

The U.S. health care system has been in a constant state of evolution over the last 50 years. Through the 1970s, Health Maintenance Organizations ("HMOs") emerged and gained legitimacy at a time when health care services were primarily paid for on a fee-for-service basis.[4] The 1980s were characterized by emerging technologies and rising health care costs that caused employers to find ways to combat cost increases and providers to begin exploring ways to provide care more efficiently. At the same time, health insurers began to develop different types of benefit plans (for example, PPOs), driven in part by employers seeking to have employees share more of the ever-increasing health care costs as well as by reluctance among physicians to adhere to gatekeeper models that they perceived as limiting their autonomy.[5] From the mid-1980s and throughout the 1990s, risk-based contracting models emerged, and providers began to seek ways to coordinate care through hospital mergers, Independent Practice Associations, joint ventures, and other collaborative arrangements.

Throughout this evolution, the antitrust enforcement agencies investigated and challenged anticompetitive mergers as well as conduct they viewed as obstructing innovative forms of health care delivery or financing.[6] In the 1990s, the agencies engaged in extensive industry consultation and developed guidelines to bring clarity to their antitrust enforcement goals and policies in the health care industry, and more importantly, their approach regarding applying the antitrust laws to certain activities by health care market participants.

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2 Press Release, U.S. Dep't of Just., Justice Department Withdraws Outdated Enforcement Policy Statements (Feb. 3, 2023), https://www.justice.gov/opa/pr/justice-department-withdraws-outdated-enforcement-policy-statements. While the FTC has not withdrawn the Guidelines, they are widely expected to do so.

3 For example, since January 2022 the DOJ and FTC have been engaging in a consultation around new merger guidelines which, at time of writing, have not been released.

4 This was due in large part to the Health Maintenance Organization Act of 1973, which provided funding to encourage the development of HMOs, overrode state laws that prohibited the development of HMOs, and required large employers to offer HMO products as an option to their employees. See U.S. Dep't of Just. & Fed. Trade Comm'n, Improving Health Care: A Dose of Competition 11 (2004), https://www.ftc.gov/sites/default/files/documents/reports/improving-health-care-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf.

5 See Ellen M. Morrison & Harold S. Luft, *Health Maintenance Organizations in the 1980s and Beyond*, 12 Health Care Fin. Rev. 81 (1990), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4193099/pdf/hcfr-12-1-81.pdf. Employers also began to develop self-insured health plans in an effort to control their spending on health care.

6 The DOJ sued the Utah Society for Healthcare Human Resource Administration for conspiring to exchange nonpublic prospective and current wage information about registered nurses and settled via a consent order. See Judgment, *United States v. Utah Soc'y for Healthcare Hum. Res. Admin.*, No. 94-C-282G (D. Utah Sept. 9 1994), https://www.justice.gov/atr/case-document/file/628496/download. The FTC sued the Michigan State Medical Society alleging it sought to "[f]ix, stabilize, or otherwise tamper with the fees which physicians in Michigan receive for their services." See *In re Mich. State Med. Soc'y*, 101 F.T.C. 191 (1983), https://www.ftc.gov/sites/default/files/documents/commission_decision_volumes/volume-101/ftc_volume_decision_101_january_-_june_1983pages_191-315.pdf.

B. The Health Care Guidelines

Between September 1993 and August 1996, the Department of Justice and Federal Trade Commission issued several policy statements related to antitrust enforcement in health care markets. These statements addressed antitrust enforcement policy in a variety of hospital and health insurer transactions and conduct, and provided "antitrust safety zones" under which the Agencies would not, absent extraordinary circumstances, pursue antitrust enforcement against health market participants. In essence, the statements gave market participants some comfort around certain categories of conduct when such conduct occurred in circumstances that did not raise concerns about market power and/or occurred in a way that was designed to minimize the risk of anticompetitive effects.

The 1993 policy statements[7] provided guidance to hospitals and health care providers on: hospital mergers; hospital joint ventures; physicians' provision of information to purchasers of health care services; hospital participation in exchanges of price and cost information; health care providers' joint purchasing arrangements; and physician network joint ventures. As health care markets continued to evolve, the 1993 policy statements were revised and supplemented first in 1994, and then by the 1996 Health Care Statements.[8] The 1996 policy statements consolidated earlier guidance and made notable updates to the statements regarding network joint ventures and multiprovider networks.

After a long hiatus in health care guideline-making, shortly after the passage of the Affordable Care Act,[9] in 2011 the FTC and DOJ issued the Affordable Care Organization ("ACO") Policy Statement,[10] which applied to collaborations among independent providers and provider groups participating in the Medicare Shared Savings Program, and provided an antitrust safety zone for such ACOs that also operate in the commercial market.

C. Summary of the Health Care Guidelines

The 1996 Health Care Statements set forth safety zones in the following areas where, absent extraordinary circumstances, the federal antitrust agencies would not pursue antitrust enforcement:

· *Small hospital mergers*: "any merger between two general acute-care hospitals where one of the hospitals (1) has an average of fewer than 100 licensed beds over the three most recent years, and (2) has an average daily inpatient census of fewer than 40 patients over the three most recent years…"[11]
· *Hospital joint* ventures to purchase, operate, and market high-technology or other expensive medical equipment where the participants count not individually bear the cost;[12] and to jointly recruit and train specialized personnel for clinical care.[13]
· *Providers' collective provision of non-fee information to purchasers of health care* services providing a safe harbor for a "medical society's collection of outcome data from its members about a particular procedure that they believe should be covered by a purchaser and the provision of such information to the purchaser" and "providers' development of suggested practice parameters--standards for patient management developed to assist providers in clinical decision-making--that also may provide useful information to patients, providers, and purchasers."[14]
· *Provider collective provision of fee-related information*. Providers can collectively provide purchasers of health care services with information about current or historical fees or other aspects of reimbursement where (1) the collection is managed by a third-party (e.g. a purchaser, government agency, health care consultant, academic institution, or trade association); (2) the information shared among competing providers provided data is more than 3 months old; and (3) there are at least five providers reporting data upon which each disseminated statistic is based, no individual provider's data represents more than 25 percent on a weighted basis of that statistic, and

7 U.S. Dep't of Just. & Fed. Trade Comm'n, Antitrust Enforcement Policy Statements Issued for the Health Care Industry (1993), https://www.justice.gov/atr/page/file/1197731/download.

8 U.S. Dep't of Just. & Fed. Trade Comm'n, Statements of Antitrust Enforcement Policy in Health Care (1996), https://www.justice.gov/atr/page/file/1197731/download [hereinafter Health Care Statements].

9 Patient Protection and Affordable Care Act, Pub. L. No. 111-48, 124 Stat. 119 (2010).

10 U.S. Dep't of Just. & Fed. Trade Comm'n, Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (2011), https://www.justice.gov/sites/default/files/atr/legacy/2011/10/20/276458.pdf [hereinafter 2011 ACO Policy Statement].

11 Health Care Statements, supra note 8, at 8 (Statement 1).This safety zone did not apply to hospitals less than five years old. *Id.* at 9.

12 *Id.* at 13 (Statement 2).

13 *Id.* at 31 (Statement 3).

14 *Id.* at 40 (Statement 4).

any information disseminated is sufficiently aggregated such that it would not allow recipients to identify the prices charged by any particular provider.[15] A similar safety zone applies to provider participation in surveys of prices for health care services or surveys of salaries, wages, or benefits of personnel.[16]

· *Joint purchasing arrangements* among health care providers where: (1) the purchases account for less than 35 percent of the total sales of the purchased product or service in the relevant market; and (2) the cost of the products and services purchased jointly accounts for less than 20 percent of the total revenues from all products or services sold by each competing participant in the joint purchasing arrangement.[17]

· *Certain physician network joint ventures:*

- "[A]n 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."[18]
- "[A] non-exclusive physician network joint venture whose physician participants share substantial financial risk and constitute 30 percent or less of the physicians in each physician specialty with active hospital staff privileges who practice in the relevant geographic market."[19]

The 2011 ACO Policy Statement established a safety-zone for ACOs meeting CMS eligibility criteria, presuming that an ACO is unlikely to raise significant competitive concerns if the combined share of services in a professional services agreement ("PSA") for the ACO is 30 percent or less of each common service in a PSA.[20] Hospitals and ambulatory surgery centers must be non-exclusive to the ACO to fall within the safety zone, regardless of share.[21] Even for ACOs not falling within the safety zone, the statement provides that the Agencies will not challenge as per se illegal a Medicare Shared Savings Program ACO that jointly negotiates with private insurers to serve patients in commercial markets if the agreement is reasonably necessary to accomplish the procompetitive benefits of the integration.[22] Finally, the ACO Statement highlights conduct that could raise competitive concerns and recommends safeguards to protect against conduct that may facilitate collusion between ACO participants in the sale of competing services outside the ACO.[23]

III. PURPOSE AND IMPACT OF THE HEALTH CARE GUIDELINES

Collectively, the Health Care Guidelines were designed to facilitate procompetitive interactions and activities in the health care industry. In announcing the 1993 Health Care Statements, the FTC and DOJ noted they were "designed to provide information to the health care community in a time of tremendous change, and to resolve, as completely as possible, any antitrust uncertainty that might deter beneficial mergers or joint ventures that promise to reduce health care costs."[24] The guidance in the 2011 ACO Statement was intended to "help health care providers form procompetitive ACOs that benefit both Medicare beneficiaries and patients with private health insurance, while protecting health care consumers from higher prices and lower quality."[25]

Did the Guidelines accomplish their goals? In many respects, yes. Over the past 30 years, the Health Care Guidelines have provided a basis for structuring collaborations and conduct across the health care industry. Health care providers turned to the Health Care Guidelines to

15 *Id.* at 43 (Statement 5).

16 *Id.* at 49 (Statement 6).

17 *Id.* at 53 (Statement 7).

18 *Id.* at 64-65.

19 *Id.* at 65.

20 2011 ACO Policy Statement, *supra* note 10, at 7.

21 *Id.* at 8.

22 *Id.* at 4.

23 *Id.* at 10-11.

24 Press Release, U.S. Dep't of Just., Antitrust Enforcement Policy Statements Issued for Health Care Industry (Sept. 15, 1993), https://www.justice.gov/archive/atr/public/press_releases/1993/211661.htm.

25 Press Release, Fed. Trade Comm'n, Federal Trade Commission, Department of Justice Issue Final Statement of Antitrust Policy Enforcement Regarding Accountable Care Organizations (Oct. 20, 2011), https://www.ftc.gov/news-events/news/press-releases/2011/10/federal-trade-commission-department-justice-issue-final-statement-antitrust-policy-enforcement.

determine how to work together with other providers in ways that would steer clear of potential antitrust pitfalls. At a time when many hospitals were seeking productive ways to battle the medical arms race — which many blamed for burgeoning health care costs — the Guidelines allowed providers to explore joint ventures and similar collaborative arrangements without the risk that such arrangements might later need to be abandoned due to antitrust concerns. The guidance on financial and clinical integration, further enhanced by the ACO Statement, encouraged the development of ACOs and other structures that shared risk and coordinated care, which is a significant goal of health policy.

The Health Care Guidelines have been widely relied upon in the health care industry and beyond. For example, they have formed the basis for much of the analysis in other agency guidance on specific instances of clinical integration,[26] and those opinions have been used as benchmarks for a large number of similarly configured networks. The guidance on group purchasing organizations and the antitrust safety zone for such arrangements in Statement 7 of the 1996 Health Care Statements has also been widely consulted in structuring such arrangements in health care and beyond.

Perhaps the most well-known and widely utilized guidance was regarding the exchange of price and other competitively sensitive information in the 1996 Health Care Statements. The information-exchange safe harbor was particularly popular as it provided bright lines for parties to avoid the risk of criminal prosecution for sharing information that risked being viewed as *per se* unlawful. Companies outside of the health care industry, such as trade associations and others that provide benchmarking services, looked to the guidance to establish parameters for information sharing that encouraged and expanded participation, enhancing the utility of benchmarking activities.[27] The agencies encouraged the extension of this guidance beyond the health care arena. For example, when the agencies issued their *Antitrust Guidance for Human Resource Professionals* in 2016, they referenced the information exchange guardrails as a useful tool for HR managers when engaging in information exchanges, such as surveys involving wages and compensation.[28] The agencies also referenced the guidance in informal statements regarding the treatment of information exchanges in other industries.[29]

In some respects, however, the Statements have been overtaken by events and fallen by the wayside. Apart from the ACO Statement, there have been no updates to the original guidance since 1996, and few if any references to the Health Care Guidelines have been made in agency materials since 2013. A host of other antitrust guidelines — for example, the Horizontal Merger Guidelines,[30] and the Antitrust Guidelines for Collaborations Among Competitors[31] — supersede some of the guidance. And other aspects of the Statements — such as the safe harbor for small hospital acquisitions — may be at odds with prevailing enforcement philosophy. Further, new areas of antitrust concern in the health care system — such as steering restrictions in hospital-payer contracts — are not addressed in the Statements at all.[32] In many respects, the federal antitrust agencies' active health care industry enforcement agenda can provide more recent and concrete direction in evaluating transactions and conduct that crosses the lines. And the federal government through CMS and state governments have their own health care agendas and regulatory processes that may displace federal antitrust enforcement policy, such as CMS' price transparency rules[33] and certificates of public advantage.[34]

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26 E.g. Fed. Trade Comm'n, Advisory Opinion on Norman PHO (Feb. 13, 2013), https://www.ftc.gov/sites/default/files/documents/advisory-opinions/norman-physician-hospital-organization/130213normanphoadvltr_0.pdf.

27 "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 health care industry." Peter Mucchetti & Eva Kurban, *On Their Silver Anniversary, It's Time to Burnish the Healthcare Guidelines*, CPI Antitrust Chronicle (May 11, 2021), https://www.competitionpolicyinternational.com/on-their-silver-anniversary-its-time-to-burnish-the-healthcare-guidelines/.

28 See U.S. Dep't of Just., Antitrust Div., & Fed. Trade Comm'n, Antitrust Guidance for Human Resource Professionals 1, 4-5 (Oct. 2016), https://www.justice.gov/atr/file/903511/download (issuing the guidance in an effort to "alert human resource (HR) professionals and others involved in hiring and compensation decisions to potential violations of the antitrust laws" and to encourage HR professionals to "implement safeguards to prevent inappropriate discussions or agreements with other firms seeking to hire the same employees").

29 See U.S. Dep't of Just., Antitrust Div., *Participating in Information Sharing and Trade Associations* (Nov. 12, 2020), https://www.justice.gov/atr/antitrust-issues-and-your-small-business/participating-information-sharing-and-trade-associations (listing various sources of useful guidance, including an FTC resource issued in December 2014 titled: "Information Exchange: Be Reasonable," which cites the information sharing safe harbor in Statement 6).

30 U.S. Dep't of Just. & Fed. Trade Comm'n, Horizontal Merger Guidelines (Aug. 19, 2020), https://www.justice.gov/sites/default/files/atr/legacy/2010/08/19/hmg-2010.pdf.

31 Fed. Trade Comm'n & U.S. Dep't of Just.: Antitrust Guidelines on Collaborations Among Competitors (Apr. 2000), https://www.justice.gov/atr/page/file/1098461/download.

32 See e.g. Mucchetti & Kurban, *supra* note 27.

33 See https://www.cms.gov/hospital-price-transparency.

34 See e.g. Lisl Dunlop, *Certificates of Public Advantage: Bypassing the FTC in Healthcare Mergers?*, 27 Competition (Cal. Lawyers Ass'n), No. 1, 2017-18, https://calawyers.org/publications/antitrust-unfair-competition-law/competition-winter-2017-18-vol-27-no-1-certificates-of-public-advantage-bypassing-the-ftc-in-health care-mergers/.

IV. HEALTH CARE GUIDELINES: REVISION OR ELIMINATION?

Most would agree that the world has changed significantly since the Health Care Guidelines were issued. Changes in the competitive landscape — such as the growth of value-based care and population health management, price transparency rules, and increasing vertical integration in the health care industry — have transformed the health care industry. Health care antitrust also has evolved significantly: our understanding of health market economics has developed, generalized antitrust policy statements have proliferated, and there are new theories of anticompetitive harm. Moreover, federal health care policies have been overhauled.

But there is not agreement about how to address this state of affairs: should we revisit, revise, and supplement the existing guidance, or repeal the guidance in its entirety and go back to first principles? And, given the age, complexity, and scope of the Guidelines, should a debate about these topics be more extensive and transparent?

According to the DOJ, the Guidelines were outmoded and no longer necessary, and their withdrawal "best serves the interests of health care competition" and "the interest of transparency with respect to the Antitrust Division's enforcement policy in health care markets."[35] In lieu of a replacement policy, the DOJ stated that a "case-by-case enforcement approach will allow the Division to better evaluate mergers and conduct in health care markets that may harm competition." The DOJ's view that health care should be addressed case-by-case according to general antitrust principles is consistent with the policy position expressed by both agencies in the past that industry-specific guidance is unwarranted because health care is no different from other industries.

The FTC's position on the Guidelines is not clear. Although widely expected to withdraw the Guidelines shortly after the DOJ, at time of writing it has not yet done so. Perhaps even more than DOJ, the FTC has utilized the Guidelines when advising the industry about collaborative practices, with the various advisory opinions on clinically integrated networks forming the backbone of many existing structures. Without that guidance, do we need to reconsider those organizations?

The DOJ's wholesale withdrawal of the Guidelines in a single swoop has drawn concern from many industry participants. The American Hospital Association viewed the withdrawal of all the guidance without consultation as "both unnecessary and reckless."[36] Withdrawing Guidelines that cover such a broad array of conduct and practices without notice or industry engagement, and not specifically addressing how the different aspects of the Guidelines fall short, has left the health care industry in a state of uncertainty and confusion.

Further, the health care industry has operated under the Guidelines for many years, and many structures and practices — particularly around ACOs and clinical and financial integration — are based on the Guidelines. As noted above, FTC policy statements contained in advisory opinions on these topics are grounded in the principles articulated in the Guidelines, as well as other industry-specific materials.[37] The DOJ also has issued business review letters based on the guidance that reference the Guidelines. Enforcement policy relating to the specific examples as well as structures based on those examples will now be called into question.[38]

The DOJ's withdrawal of the guidelines appears to be motivated in no small part by a desire to repeal the information-exchange safe harbor, which has expanded widely beyond the health care context, and which the DOJ believes are "overly permissive." In a recent speech, Principal Deputy Attorney General Doha Mekki described maintaining the safety zones as "like developing specifications for audio cassette tapes and applying them to digital streaming."[39] The DOJ appears to be motivated by industry developments relating to data, particularly machine learning, AI, and other advanced tools, that may undermine the efficacy of the old safeguards to anonymize information and prevent coordination. But while advances in technology and data practices may justify the repeal of safe harbors, those issues deserve to be discussed in an open and broad forum. While ultimately the result may be the same — elimination of the safe harbor — organizations engaged in information exchanges will gain insights into the agencies' concerns and identify acceptable safeguards to address antitrust risk.

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35 See Press Release, *supra* note 2.

36 Press Release, Am. Hosp. Ass'n, DOJ Withdraws Certain Health Care Antitrust Enforcement Guidance (Feb. 3, 2023), https://www.aha.org/news/headline/2023-02-03-doj-withdraws-certain-health-care-antitrust-enforcement-guidance.

37 Such as the joint FTC and DOJ 2004 report, Improving Health Care: A Dose of Competition, *supra* note 4.

38 See e.g. U.S. Dep't of Just., *Response to Greater New York Hospital Association's Request for Business Review Letter* (Jan. 16, 2013), https://www.justice.gov/atr/response-greater-new-york-hospital-associations-request-business-review-letter.

39 Doha Mekki, Principal Deputy Assistant Att'y Gen., Remarks at GCR Live: Law Leaders Global 2023 (Feb. 2, 2023), https://www.justice.gov/opa/speech/principal-deputy-assistant-attorney-general-doha-mekki-antitrust-division-delivers-0.

Will general DOJ and FTC guidelines and enforcement actions provide sufficient coverage? This will likely be inadequate for the health care industry at least. General guidelines fail to account for the specific challenges faced by the health care industry, as well as the impact of federal and state health policy. And while we can always look to examine the rationale behind antitrust enforcement actions for guidance as to how the FTC or DOJ might examine particular conduct, there is still a need for comprehensive guidance that is not couched in the particular facts and circumstances of a particular case.

In the health care industry, the Guidelines have encouraged market participants to act creatively in seeking to address challenges in health care and its extension to community health equity and access. Antitrust policy in health care needs to be nuanced to account for the complex set of political and regulatory factors applying to the industry. To date, government policy has encouraged collaborations, and the Guidelines have provided an important foundation upon which many of those collaborations are built. Before dismantling that scaffold, the agencies should engage in research, consultation, and provide clear and transparent guidance for the industry going forward.

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