FTC JOINS DOJ IN WITHDRAWING FROM LONG-STANDING HEALTHCARE ANTITRUST POLICY STATEMENTS

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US Policy and Regulatory Alert

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On 14 July 2023, the Federal Trade Commission (FTC) joined the Department of Justice Antitrust Division (DOJ) in withdrawing from three long-standing antitrust policy statements related to enforcement in the healthcare industry. The policy statements laid out antitrust safety zones for certain collaborations in the healthcare industry. While the statements were never binding on the antitrust agencies, they served as important guidance to healthcare providers and counsel across a range of antitrust issues pertinent to the healthcare industry, including mergers, joint ventures, joint purchasing arrangements, information exchanges, and the formation and operation of financially and clinically integrated networks. The FTC exercises significant enforcement authority over the healthcare industry and its withdrawal from these statements is therefore particularly significant for the healthcare industry, creating increased uncertainty and perhaps signaling increased enforcement activity in the future. The withdrawal is part of an aggressive antitrust enforcement agenda set forth by the Biden Administration, with a focus on the healthcare industry, and signals increased antitrust scrutiny for collaborations and information exchanges within the healthcare industry.

WHAT HAS CHANGED?

The FTC withdrew three policy statements:

1. DOJ and FTC Antitrust Enforcement Policy Statements in the Healthcare Area (1993);
2. Statements of Antitrust Enforcement Policy in Healthcare (1996) (1996 Guidance); and
3. Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations (ACO) Participating in the Medicare Shared Savings Program (2011) (2011 Guidance).

These statements provided guidance in the form of “safety zones,” which described conduct that the antitrust agencies would not challenge under the antitrust laws absent extraordinary circumstances. The safety zones covered a wide variety of collaborations between healthcare providers, including mergers, joint ventures, joint purchasing arrangements, information exchanges, and the formation and operation of financially and clinically integrated networks. The statements also provided guidance on how the agencies would analyze conduct and collaborations that fell outside of the safety zones. Below are a few of the safety zones that the FTC withdrew.

- Statement 1 of the 1996 Guidance stated that the agencies would not challenge “any merger between two general acute-care hospitals where one of the hospitals: (1) has an average of fewer than 100

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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."

- Statement 2 of the 1996 Guidance stated that the agencies would not challenge "any joint venture among hospitals to purchase or otherwise share the ownership cost of, operate, and market the related services of, high-technology or other expensive healthcare equipment if the joint venture includes only the number of hospitals whose participation is needed to support the equipment."
- Statement 3 of the 1996 Guidance stated that the agencies would apply a rule of reason analysis, as opposed to per se treatment, in their review of "hospital joint ventures involving specialized clinical or other expensive healthcare services."
- Statement 4 of the 1996 Guidance provided a safety zone for providers' collective provision of certain types of non-fee-related information (e.g., outcome data).
- Statement 5 of the 1996 Guidance provided a safety zone for providers' collective provision of fee-related information to purchasers of healthcare services.
- Statement 6 of the 1996 Guidance set forth a safety zone for provider participation in written surveys, stating that the agencies would not challenge information exchanges that: (1) were managed by a third party (such as a trade association or healthcare consultant); (2) were for information that was more than three months old; and (3) contained five or more firms contributing data, no single firm's data constituted more than 25% of a statistic, and no single firm's data could be identified. This guidance in particular has been extended to other industries and used to structure information exchanges outside of the healthcare context.
- Statement 7 of the 1996 Guidance created a safety zone for joint purchasing arrangements among healthcare providers where: (1) the purchases account for less than 35% 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% of the total revenues from all products or services sold by each competing participant in the joint purchasing arrangement.
- Statement 8 of the 1996 Guidance provided safety zones for certain physician network joint ventures.
- Statement 9 of the 1996 Guidance established that the antitrust agencies would apply a rule of reason analysis, as opposed to per se treatment, in their review of joint payor negotiations by clinically or financially integrated networks.
- The 2011 Guidance created a presumption that joint negotiations with private payors by ACOs who satisfied certain CMS eligibility criteria would not be considered *per se* antitrust violations.

While the statements were never binding on the agencies, they served as important guidance to healthcare providers and counsel and often formed the basis upon which providers structured collaborations and interactions with other healthcare providers. Of particular importance was the assurance by the DOJ of rule of reason treatment for certain types of conduct that the DOJ may otherwise have viewed as *per se* illegal. The distinction is significant because the DOJ criminally prosecutes per se illegal conduct while conduct subject to the rule of reason analysis has historically been subject only to civil enforcement.

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WHY DID FTC WITHDRAW THE POLICY STATEMENTS?

DOJ made a splash of withdrawing from the policy statements in early February 2023, which we previously analyzed in our alerts, "DOJ Withdraws Long-Standing Health Care Antitrust Policy Statements" and "DOJ Antitrust Division Indicates Increased Scrutiny of Information Sharing and Use of Pricing Algorithms" and discussed in a webinar with Strafford Group, "Healthcare and the End of the Antitrust Safety Zones: Increased Scrutiny of Information Exchanges, Collaborations, Mergers." DOJ's Principal Deputy Assistant Attorney General Doha Mekki gave aspeech announcing DOJ's withdrawal and provided some insight on its rationale for doing so, stating the DOJ's belief that the healthcare industry had changed and the guidance no longer reflected market realities and in particular noting concerns regarding the safety zones around the exchange of competitively sensitive information, which had been extended and adopted by industries beyond healthcare.

FTC's withdrawal from the policy statements was much more subdued, with FTC issuing only a brief statement announcing its withdrawal from the three policy statements. FTC cited to Principal DAAG Mekki's speech and stated:

> The Commission has determined that the withdrawal of the Statements is the best course of action for promoting fair competition. Much of the Statements are outdated, reflecting market realities that are no longer extant. Moreover, the Statements may be overly permissive on certain subjects, such as information sharing. In particular, companies have sometimes used the safety zone for information exchanges in contexts and industries that were never contemplated by the agencies, including to share competitively sensitive wage and benefit information with other employers.

WHAT ARE THE IMPLICATIONS FOR THE WITHDRAWAL?

FTC is unlikely to issue new guidance. It instead stated that it will "rely on general principles of antitrust enforcement and competition policy for all markets, including markets related to the provision of healthcare products and services" and that it will evaluate mergers and conduct in the healthcare market on a case-by-case basis. FTC pointed to its "extensive record of enforcement actions, policy statements, and competition advocacy in healthcare" as the most "up-to-date guidance" for the public.

Notably, FTC included a footnote in its statement confirming its continued commitment to maintaining a working relationship with the Center for Medicare Studies (CMS) regarding CMS' review of ACO applications, as well as discussion of new ACO program ideas and other regulatory reforms involving the Medicare and Medicaid programs that CMS is considering. It remains to be seen how FTC's withdrawal from the 2011 Guidance could impact FTC's future enforcement of ACOs that jointly negotiate with private payors, although this has not been a focus of FTC or DOJ enforcement in recent years.

The agencies' withdrawal from the guidance does not mean that competitor collaborations that previously relied on the safety zones are automatically problematic or subject to antitrust enforcement. Nonetheless, we expect increased enforcement in the healthcare industry, which FTC Chair Lina Khan has repeatedly noted is a top priority for the agency. Accordingly, it is important for entities, particularly those in the healthcare industry, to re-

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evaluate their collaborations and conduct to ensure they do not raise anticompetitive concerns. Entities and their antitrust counsel should consider the following questions, both at a macro and micro level:

4. Is there a legitimate, procompetitive rationale for the collaboration or conduct that will benefit consumers?
5. Does the collaboration or conduct tend to lessen competition? If so, are there measures in place that prevent or limit these anticompetitive effects?
6. Are the legitimate, procompetitive rationales for the collaboration or conduct documented?

The lawyers of K&L Gates' Antitrust, Competition, and Trade Regulation practice regularly counsel clients on antitrust issues in the healthcare industry and are well-positioned to provide guidance and assistance to clients on this development.

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