DOJ WITHDRAWS LONG-STANDING HEALTHCARE ANTITRUST POLICY STATEMENTS

Date: 15 February 2023

US Antitrust, Competition, and Trade Regulation Alert

By: Lauren Norris Donahue

On 3 February 2023, the US Department of Justice Antitrust Division (Division) announced its withdrawal of three long-standing antitrust policy statements related to enforcement in the healthcare industry. The policy statements were issued jointly with the Federal Trade Commission (FTC), which has not yet announced a similar withdrawal but it is anticipated to follow suit. 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. In describing its rationale for the withdrawal of the guidance documents, Principal Deputy Assistant Attorney General Doha Mekki of the Division explained, "we believe the healthcare industry has evolved considerably since the statements were issued and that they no longer serve their intended purposes to provide encompassing guidance to the public on relevant healthcare competition issues." 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 Division withdrew three policy statements:

1. Department of Justice and FTC Antitrust Enforcement Policy Statements in the Health Care Area (1993);
2. Statements of Antitrust Enforcement Policy in Health Care (1996) (1996 Guidance); and
3. Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations 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 Division 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 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."

©2005-2026 K&L Gates LLP. All Rights Reserved.

- 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 Accountable Care Organizations 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 Division of rule of reason treatment for certain types of conduct that the Division may otherwise have viewed as *per se* illegal. The distinction is significant because the Division *criminally* prosecutes *per se* illegal conduct while conduct subject to the rule of reason analysis has historically been subject only to *civil* enforcement.

©2005-2026 K&L Gates LLP. All Rights Reserved.

WHY DID THE DIVISION WITHDRAW THE POLICY STATEMENTS?

The Division justified its policy shift by noting that “the healthcare landscape has changed significantly” over the past three decades, thus rendering these guidance documents as “out of date” and “overly permissive” on certain subjects—including information sharing and certain mergers. Principal DAAG Mekki pointed to increased vertical and adjacent consolidation in the healthcare industry, an increase in multi-sided markets, and advanced data analytics and artificial intelligence as a few examples of the ways in which the Division believes the healthcare industry has changed and explained that the Division was “no longer confident that the documents fully reflect market realities, the risk of serious competitive harm, or the full scope of liability under the antitrust laws.”

Principal DAAG Mekki emphasized the Division's particular concern regarding the safety zones around the exchange of competitively sensitive information, stating, “the Division is concerned that the factors do not consider the realities of a transformed industry and, therefore, understate the antitrust risks of competitors sharing competitively-sensitive information.”

The withdrawal of these statements is consistent with the Biden administration's aggressive approach to antitrust enforcement, particularly in the healthcare industry.

WHAT ARE THE IMPLICATIONS FOR THE WITHDRAWAL?

Rejecting a “one-size-fits-all” approach to assessing the conduct of healthcare companies, the Division intends to proceed now with a “case-by-case enforcement approach.” Principal DAAG Mekki stated that the Division currently has no plans to replace them and that, instead, “recent enforcement actions and competition advocacy provide guidance to the public about our enforcement priorities.” This withdrawal marks another step in the Division's increased effort to “vigorously enforce” the antitrust laws in the healthcare industry and requires healthcare companies and their antitrust counsel to regularly monitor the Division's enforcement actions and competition advocacy for guidance on how the Division may regulate the industry.

The full impact of the withdrawal of these statements remains to be seen. However, healthcare providers should expect increased antitrust scrutiny of information exchanges and collaborations and should carefully consider the potential anticompetitive effects of either. Healthcare companies should also exercise caution when relying on FTC or DOJ guidance that pre-dates the Biden administration, particularly when contemplating future exchanges or collaborations.

KEY CONTACTS



LAUREN NORRIS DONAHUE
PARTNER

CHICAGO
+1.312.807.4218
LAUREN.DONAHUE@KLGATES.COM

©2005-2026 K&L Gates LLP. All Rights Reserved.

This publication/newsletter is for informational purposes and does not contain or convey legal advice. The information herein should not be used or relied upon in regard to any particular facts or circumstances without first consulting a lawyer. Any views expressed herein are those of the author(s) and not necessarily those of the law firm's clients.

©2005-2026 K&L Gates LLP. All Rights Reserved.