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National Council for Mental Wellbeing Association Executives Meeting

Withdrawal of Federal Health Care Antitrust Policy Statements

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April 18, 2023

WITHDRAWAL OF FEDERAL AGENCY GUIDANCE

- Beginning in 1993, the U.S. Department of Justice (DOJ) and Federal Trade Commission (FTC) jointly issued certain policy statements and guidelines, explaining the factors they consider when analyzing the validity of health care provider arrangements, and in certain, narrow conditions, established “safety zones” in which the agencies would not take enforcement action. These include:
 - [DOJ and FTC Antitrust Enforcement Policy Statements in the Health Care Area \(1993\)](#)
 - [DOJ/FTC Statements of Enforcement Policy in Health Care \(1996\)](#)
 - [FTC/DOJ Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program \(2011\)](#)
- On February 3, 2023, the DOJ [withdrew](#) the above guidance documents, calling the old policy statements “**overly permissive on certain subjects, such as information sharing.**”
- As of today, the FTC has not withdrawn the above policy statements, though many expect them to do so.

1996 STATEMENTS OF ANTITRUST ENFORCEMENT POLICY

- Statement 1 - Mergers Among Hospitals
- Statement 2 - Hospital Joint Ventures Involving High Technology Or Other Expensive Health Care Equipment
- Statement 3 - Hospital Joint Ventures Involving Specialized Clinical or Other Expensive Health Care Services
- **Statement 4 - Providers' Collective Provision Of Non-Fee-Related Information To Purchasers of Health Care Services**
- **Statement 5 - Providers' Collective Provision of Fee-Related Information To Purchasers of Health Care Services**
- **Statement 6 - Provider Participation In Exchanges of Price And Cost Information**
- Statement 7 - Joint Purchasing Arrangements Among Health Care Providers
- Statement 8 - Physician Network Joint Ventures
- **Statement 9 - Multiprovider Networks**

Withdrawn

Statements of Antitrust Enforcement Policy in Health Care



Issued by the
U.S. Department of Justice
and the
Federal Trade Commission



August 1996

PRESIDENT BIDEN'S EXECUTIVE ORDER

- “Robust competition is critical to preserving America’s role as the world’s leading economy. Yet over the last several decades, as industries have consolidated, competition has weakened in too many markets, denying Americans the benefits of an open economy and widening racial, income, and wealth inequality. **Federal Government inaction has contributed to these problems**, with workers, farmers, small businesses, and consumers paying the price.”
- **“Americans are paying too much for prescription drugs and healthcare services — far more than the prices paid in other countries. Hospital consolidation has left many areas, particularly rural communities, with inadequate or more expensive healthcare options.** And too often, patent and other laws have been misused to inhibit or delay — for years and even decades — competition from generic drugs and biosimilars, denying Americans access to lower-cost drugs.”
- The Executive Order affirms the policy of the Biden Administration “to enforce the antitrust laws to combat the excessive concentration of industry, the abuses of market power, and the harmful effects of monopoly and monopsony.”

President Joseph R. Biden, Jr., [“Executive Order on Promoting Competition in the American Economy](#), released July 9, 2021.

DEPT. OF JUSTICE PUBLIC STATEMENTS

- **“Much has changed in the health care industry over the 30 years since these statements were issued. The delivery of health care products and services have changed. In many respects, our understanding of health care economics has evolved for the better.”**
- **“Increasingly health care is a data intensive industry** that relies on the power of machine learning, artificial intelligence, and other advanced tools to develop or deliver products or services. Some markets are increasingly multi-sided. These realities affect how buyers or sellers transact business, which may bear on important dimensions of competition in this industry.”
- **“Moreover, a wave of consolidation in the health care industry** has brought together industry participants who once served distinct or adjacent functions. **As just one example, large health insurance companies now own providers, PBMs, health data analytics companies, and acute care clinics.** If the concept of industry roll up was not in our lexicon then, it is more commonplace now. In many cases, these combinations and other entanglements may have changed the underlying incentive structures in the industry.”
- **“Given these changes and the outdated nature of many statements reflected in those documents, we are 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.”**

[Remarks of Principal Deputy Assistant Attorney General Doha Mekki](#), Antitrust Division, U.S. Dep’t of Justice, February 2, 2023

DEPT. OF JUSTICE PUBLIC STATEMENTS

- “These documents also recognize “safety zones” around **the exchange of competitively-sensitive information**. As I previously discussed, 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**.”
- “At bottom, we believe the health care 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 health care competition issues. **Accordingly, the Division will withdraw these three statements concerning the health care industry. At this time, the Division does not have immediate plans to replace them.**”
- “This withdrawal increases transparency because the guidance provided in these documents no longer reflects the market realities of the modern health care system or the Division’s current enforcement priorities. **Recent enforcement actions and competition advocacy provide guidance to the public about our enforcement priorities. Careful consideration of the facts and an enforcement approach that is consistent with the law as Congress wrote it and as the courts have interpreted it will allow the Division to better evaluate mergers and conduct in health care markets that may harm competition.**”
- “The Division will continue to revisit out-of-date guidance that no longer provides transparency concerning how the Division presently evaluates potentially anticompetitive conduct.”

[Remarks of Principal Deputy Assistant Attorney General Doha Mekki](#), Antitrust Division, U.S. Dep’t of Justice, February 2, 2023

RECENT FEDERAL AGENCY ENFORCEMENT ACTIONS

- The FTC and the DOJ have indicated concerns about **data sharing** in their opposition to recent mergers between Amazon and One Medical, as well as UnitedHealth and Change Healthcare.
 - Although the FTC reportedly had prepared a lawsuit to block the merger between Amazon and One Medical, the FTC did not challenge it in court.
 - The DOJ challenged UnitedHealth Group’s acquisition of Change Healthcare due to concerns that sharing sensitive information and data about prices and their provider networks would further weaken competition among commercial insurers.
 - The DOJ lost in District Court when a court in September 2022 allowed the \$13 billion deal to go.
 - Although the DOJ filed an appeal in November 2022, last month the DOJ dropped its appeal to block the merger.

MANAGING ANTITRUST LEGAL RISKS

- The “rule of reason” standard continues to apply to conduct that does not constitute “naked” per se violations of the antitrust laws.
- The withdrawal of the policy statements by the DOJ does NOT mean that competitor collaborations and joint ventures are now illegal.
- Recommendations:
 - In competitor collaborations, the legal agreements should document the “efficiencies” and procompetitive benefits that result from any agreements on price or restrictions on competition that would otherwise occur.
 - Provider networks that are not sufficiently financially or clinically integrated (and which rely on the “messenger model” to facilitate contracts with payors), should review their compliance program policies, provide additional training to staff on those policies, and ensure that they are operating in compliance with those policies.

MANAGING ANTITRUST LEGAL RISKS

- Highest Risk Activities:
 - Because the DOJ has expressed concern with information-sharing among competitors, any collaboration by providers (including those facilitated by third parties such as networks or state associations) that involve sharing cost or fee-related data should be re-assessed and follow strict compliance policies for the use and disclosure of any shared information.
- New Enforcement Standards
 - Monitor whether the DOJ or FTC articulates new standards – through enforcement actions or otherwise -- that challenge conduct that would have previously been protected in a safety zone or covered under the policy statements.
- Advisory Opinion / Business Review Letters:
 - If unsure whether a particular arrangement would be lawful under the antitrust laws, providers and networks may submit a request for an [advisory opinion](#) or [business review letter](#) to either of the enforcement agencies.

QUESTIONS / COMMENTS



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