

DOJ Withdraws Decades Old Guidance on Antitrust Enforcement in Health Care

Since the Biden administration's release of the [Executive Order on Promoting Competition in the American Economy](#) in July 2021, federal enforcement agencies have visibly advanced their efforts to step up enforcement actions and continued to push forward new enforcement agenda. In the latest development, the Department of Justice (DOJ) announced on February 3 [the withdrawal](#) of three federal enforcement policy statements, which removes some of the safe harbor protections that were established for healthcare entity activities nearly three decades ago. DOJ's action is a direct response to the executive order's call for federal agencies to strengthen their antitrust guidance and to create and enforce new rules and likely acknowledges that healthcare markets are much more concentrated than when the guidelines were written decades ago. In this post, we take a look at what the policy statements were, why they were withdrawn, and where it leads from here.

What They Were

The three sets of statements were originally jointly released by the DOJ and Federal Trade Commission (FTC) and specifically provides policy guidance for antitrust enforcement in the healthcare industry. While they were not legally binding, they provided guidance for both federal and state enforcement for decades since their release.

1. 1. [Department of Justice and FTC Antitrust Enforcement](#)

Policy Statements in the Health Care Area(released Sept. 15, 1993)

This first set of statements spelled out safe harbors under which healthcare providers could operate and collaborate without violation of antitrust laws. The set of six statements were released to ease concerns and uncertainties for hospitals and providers wanting to engage in mergers, joint ventures, and information exchanges, with the goal of promoting greater efficiencies and lower costs. The six types of transactions that were covered by the “antitrust safety zones” and thus exempt from antitrust challenges were:

- hospital mergers involving a hospital that has less than 100 licensed beds and less than 40 daily patients on average;
- hospital joint ventures involving purchase or operation of high technology or other medical equipment;
- physicians’ collective provision of non-price information to purchasers of healthcare services;
- hospital surveys of price and cost info by third party involving data that is non-identifiable, aggregated from at least five hospitals, and at least three months old;
- healthcare provider joint purchasing arrangements involving purchases that account for less than 35% of the total purchases and costing less than 20% of total revenue of each participant;
- physician network joint ventures involving 20% or less of physicians in each physician specialty in the relevant geographic market, in which members share substantial financial risk.

2. Statements of Antitrust Enforcement Policy in Health Care
(released Aug. 1, 1996)

This second set of statements revised and expanded the first set

of statements released in 1993 to provide additional examples and clarify antitrust guidance to promote healthcare joint ventures and other activities that may be procompetitive and cost-saving, particularly the creation of provider networks. The 1996 guidance was a total of nine statements that included the reissuance of the previously released statements, along with various examples to illustrate “clinical integration” that are deemed procompetitive and integration based upon substantial financial risk. Most notably, the statements specified updated antitrust safety zones that applied to:

- physician network joint ventures that share substantial financial risk and of a particular size in the relevant market for the particular specialty (constituting 20% or less in an exclusive network or 30% or less in a non-exclusive network);
- multiprovider networks such as physician hospital organizations (PHO) involving substantial clinical integration.

3. [Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program](#) (released Oct. 20, 2011)

The last set of guidance involved accountable care organizations (ACOs) and their operation in both the Medicare and commercial markets. The guidance intended to ensure that the ACOs formed were procompetitive and benefit patients in both markets. Specifically, the statements provided a two-step antitrust analysis guidance for Medicare Shared Savings Program ACOs that jointly negotiated with private insurers:

- To qualify for “rule of reason” and avoid “per se” analysis: comply with CMS’s eligibility criteria (determined to be consistent with the clinical integration guidance set forth by the Agencies) and use the same

governance, leadership structures, and clinical/administrative processes to serve patients in both markets;

- To further qualify for the antitrust safety zone: the independent participants of the ACO must have a combined share of 30% or less of each common service in each participant's Primary Service Area (PSA).

Why They Were Withdrawn

Since the release of these statements, drastic changes have occurred in the landscapes of both the health industry and information technology. Consolidation in the healthcare market has proliferated in various forms across the country, including through mergers and acquisitions, joint ventures, joint operating arrangements, and other collaborative transactions. At the same time, the advent and increased sophistication of data and information technology have also enabled greater information sharing and exchange. As a result, Biden's Executive Order had contained specific directives to the DOJ and FTC to "vigorously enforce antitrust laws specific to healthcare" and "review and revise merger review guidelines."

The DOJ certainly heard the call. In the months since the Executive Order, the agency has aggressively challenged mergers and acquisitions, including those involving vertical consolidation. In particular, the DOJ challenge of the UnitedHealth and Change Healthcare merger involved concerns of potential sharing of information and data. Though the trial court shot down DOJ's arguments and approved the merger, the agency has taken the case to the appeals court, even after the transaction has been consummated, signaling its resolve in intensified enforcement efforts.

At the same time, the DOJ has turned to the complementary directive to review its merger review guidelines. In its press release, the DOJ recognized that the existing guidance were outdated and could no longer be used to appropriately assess and capture the existing market realities. Citing the concern that some of the statements may be overly permissive on information sharing, the DOJ notes the withdrawal of the old guidance is the best course of action to promote healthcare competition and transparency.

What it Means and Where it Leads

While the DOJ withdrew the three sets of policy statements, it did not specify when and if new guidelines would be released to replace them. At the same time, the FTC did not officially withdraw the guidance, and the DOJ and FTC's 2000 Guidelines for Collaborations Among Competitors remain in effect. That guidance also covers some of the information sharing and joint purchasing agreements addressed in the three withdrawn policy statements. As such, there is much uncertainty in healthcare antitrust enforcement for the time being. The DOJ noted that it would now take a case-by-case approach to healthcare antitrust enforcement, with recent enforcement actions as general guidance. If that's any indication, healthcare entities paying attention should take extra care in their activities now that a blanket antitrust safety shield may no longer apply. Additionally, given the uncertainties and possibilities during this new transitional phase, it may be prime time for state policymakers to consider comprehensive state enforcement policies and regulations that would be complementary to federal guidance.