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Navigating the Changing Landscape: The FTC's Withdrawal of Health Care Enforcement Policy Statements

Darío Martínez Jove · Tuesday, August 22nd, 2023

On July 14, 2023, the Federal Trade Commission, announced the withdrawal of two antitrust policy statements related to enforcement in healthcare markets: *Statements of Antitrust Enforcement Policy in Health Care*, published in August 1996, and *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program* from October 2011. This decision follows a similar action taken by the Department of Justice (DOJ) in February 2023.

The FTC determined that both statements no longer reflect the changes in the healthcare sector that have occurred in recent years. By removing them, the FTC believes that the Commission's extensive record of enforcement actions, policy statements, and competition advocacy in healthcare provides more up-to-date guidance to the public.

Prior to this decision, there were also voices advocating for the need for new statements, as the old ones were considered outdated. According to Principal Deputy Assistant Attorney General Doha Mekki, a wave of consolidation in the healthcare industry has brought together industry participants who once served distinct or adjacent functions. For instance, large health insurance companies now own providers, pharmacy benefit managers (PBMs), health data analytics companies, and acute care clinics. In many cases, these combinations and other entanglements may have changed the underlying incentive structures in the industry.

One of the key reasons for removing these statements is the exchange of competitively sensitive information. The Agencies are concerned that the factors considered in the old statements do not reflect the realities of a transformed industry and may understate the antitrust risks of competitors sharing competitively sensitive information.

As a result of the removal, the FTC will now evaluate healthcare sector cases on a case-by-case basis, and certain protections offered by the statements no longer exist. The FTC and the DOJ intend to apply more pressure to address various conducts, including collusive agreements and anticompetitive behaviours in the US healthcare sector.

The changes implied a departure from previous circumstances. The removal of the Antitrust Safety Zone, as outlined in the Statements, indicates that certain behaviours that previously did not raise concerns could now be classified as anti-competitive. This suggests a more aggressive stance by the Agencies against anti-competitive behaviour.

Although the statements lacked binding force on the Agencies, they held significant value as guidance for healthcare providers and counsel. Frequently, they served as the foundation for providers to structure their collaborations and interactions with other healthcare providers. To understand the consequences, it is necessary to examine the withdrawn statements, their origin, and their intentions.

The Statements: Origin and intentions

Statements of Antitrust Enforcement Policy in Health Care

In 1993, the Department of Justice and the Federal Trade Commission introduced the Statements of Antitrust Enforcement Policy in Health Care, comprising six policy statements to regulate areas like hospital mergers, medical equipment joint ventures, physician collaborations, and more, aiming to balance cost reduction with consumer protection. These policies were expanded in 1994 to encompass specialized clinical services and analytical principles for healthcare provider networks. Over time, the policies evolved to focus on physician network joint ventures and multi-provider networks, ensuring competitive and quality healthcare while incorporating discussions on integration and financial risk-sharing among physicians. The aim of these revisions was to maintain a competitive healthcare market with effective options for consumers, preserving existing safety zones for physician network joint ventures and identifying additional qualifying financial risk-sharing arrangements.

Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program

The Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations (ACOs) in the Medicare Shared Savings Program originates from the Affordable Care Act of 2010, designed to enhance healthcare quality and affordability. This policy supports the formation of ACOs, which are groups of healthcare providers collaborating to manage care for Medicare beneficiaries. The policy, created by the Federal Trade Commission and the Antitrust Division of the Department of Justice, ensures that ACO collaborations adhere to antitrust regulations, focusing on maintaining competition and safeguarding patients. It offers guidance for ACOs operating in both Medicare and commercial markets, outlining an Antitrust Safety Zone and additional guidelines. The policy doesn’t cover mergers or fully integrated entities, which are assessed separately.

Various elements were common to both statements: the Antitrust Safety Zone – an antitrust safe harbour which protected certain conducts from the acting of the Agencies in order to promote certain behaviours -, the Rule of Reason, and a legal presumption of illegal agreements.

These last elements are common to US antitrust legislation and case law. The Rule of Reason is, in fact, a very important rule applied by the US courts since the 19th century, which comprehends an analysis of the circumstances of each case, where the behaviours are only considered illegal when their effect is to unreasonably restrain trade.

Per se illegal agreements vs. the Rule of reason

Antitrust law treats naked agreements among competitors that fix prices or allocate markets as *per se* illegal, as stated in Section 1 of the Sherman Act. This logic is also followed by Article 101 TFEU. However, the US Antitrust legislation approaches such agreements differently. If these agreements are reasonably necessary to achieve pro-competitive benefits through integration, they are analysed under the rule of reason. This analysis is done on a case-by-case basis to determine the arrangement's true nature and likely competitive effects. On the contrary, in the EU, Article 101(3) TFEU specifies certain requirements to consider the pro-competitive effects of the conduct.

Various factors may indicate an anti-competitive nature in a network. Firstly, the presence of statements revealing an intention to undermine competition can be concerning. Additionally, a history of engaging in anti-competitive behaviour or collusion within the market, such as obstructing the development of managed care, can further substantiate these concerns. The network's structure itself can also be telling, for example, if it lacks any plausible business or efficiency justification. Moreover, the absence of mechanisms that could generate significant efficiencies or enhance competition within the network is another factor to consider. Furthermore, the presence of anticompetitive collateral agreements can contribute to the perception of an anti-competitive stance. Lastly, if the network's operation is not equipped with mechanisms to prevent anti-competitive spillover effects outside its boundaries, it can add to suspicions of anticompetitive intent. By evaluating these factors, one can gain insights into whether a network's practices might be negatively impacting competition in the market.

Under the rule of reason, a determination about the lawfulness of a network's activity can sometimes be made without an extensive inquiry due to the aforementioned factors, where the Agencies may quickly conclude that the conduct is unlikely to be anti-competitive.

The Rule of reason is mentioned in the introduction and throughout the text of both Statements, being a key to determining if a conduct has anticompetitive behaviour or not. For reaching this conclusion, usually, the Agencies applied a four-step analysis, consisting of defining the market and evaluating the conducts and their effects.

In the Statements of 1996, there are examples which specify certain situations and the likelihood of anti-competitive behaviour, one the section regarding Hospital High-Technology Joint Ventures.

The Antitrust Safety Zone

The Antitrust Safety Zone was an important part of the statements. In the introduction of the *Statements of Antitrust Enforcement Policy in Health Care*, it is stated that the safety zones are not a limit of joint conduct that is permissible under the antitrust laws. The inclusion of certain conduct within the Antitrust Safety Zones does not imply that conduct falling outside the safety zones would be challenged, as the safety zones are designed to require consideration of only a few factors that are relatively easy to apply, stating arrangements that were unlikely to raise substantial competitive concerns.

The Statements outline the analysis the Agencies will use to review conduct that falls *outside* the safety zones. For this purpose, examples were included in the Statements of 1996.

We can see the Antitrust Safety Zone in the scope of mergers and joint ventures that the Agencies would not challenge, specifically the ones involving hospitals with few beds or a low flow of patients, or joint ventures related to the acquisition or sharing of high-tech or expensive medical equipment.

For the Antitrust Safety Zone to be applied, certain requirements and conditions were to be met. For example, in the case of provider participation in written surveys of (a) prices for healthcare services, or (b) wages, salaries, or benefits of healthcare personnel, there were specific conditions that had to be satisfied in order to apply it (page 50 of the *Statements of Antitrust Enforcement Policy in Health Care*).

In situations where businesses were uncertain about the legality of their conduct prevailed, they could request a business review or advisory opinion from the Agencies, which typically lasted for 90 days.

However, there were cases where the Antitrust Safety Zone was not applied, particularly in hospital joint ventures involving specialized clinical or other expensive healthcare services. The Agencies believed that they needed to acquire more expertise in evaluating the cost, demand, and potential benefits of such joint ventures before they could establish a meaningful safety zone. In this case, the absence of a safety zone for such collaborative activities did not imply that they created any greater antitrust risk than other types of collaborative activities.

Outside the Antitrust Safety Zone, the Agencies applied the rule of reason, which involves a four-step analysis. However, this four-step analysis was not applied in all situations where the behaviour fell outside the Antitrust Safety Zone. In such cases, the Agencies would assess them on a case-by-case basis, analysing whether the anticompetitive effects outweighed any procompetitive justifications. In specific fields, the Statements analysed certain safeguards to mitigate or eliminate anticompetitive risks. For example, the section regarding Joint Purchasing Arrangements That Fall Outside The Antitrust Safety Zone in the Statements of Antitrust Enforcement Policy in Health Care listed certain safeguards to mitigate risks, while the section regarding ACOs Outside the Safety Zone from the Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program listed conducts to avoid.

If businesses still had doubts regarding their conduct, the 90-day mechanism would be actioned to help them assess their compliance with antitrust legislation.

The changes

The recent announcement marks the end of the safety zones in the healthcare industry, which were criticised as outdated and overly permissive on certain issues, like information sharing. The Antitrust Division now encourages the healthcare sector to rely on recent enforcement actions and competition advocacy for guidance.

Information exchanges have been particularly relevant in recent enforcement actions, including those facilitated by third parties, due to their potential role in facilitating conducts like price-fixing. This move is part of a broader effort by the DOJ and FTC to reshape antitrust enforcement in the healthcare sector, reflecting concerns about consolidation and monopoly issues across the industry. Vigilance is deemed necessary in addressing these challenges.

However, some opinions stated that key healthcare antitrust issues enjoy a *de facto* exemption from the traditional antitrust doctrine. Even though the Supreme Court usually treats antitrust defendants the same, there is an argument worth making that the application of the law to the facts in healthcare cases is inevitably different given the pervasive distortions caused by third party payors. Section 6 of the FTC Act provides another investigative tool while Section 6(b) empowers the Commission to require an entity to file "*annual or special . . . reports or answers in writing to specific questions" to provide information about the entity's "organization, business, conduct, practices, management, and relation to other corporations, partnerships, and individuals"*.

Due to their powers, the Agencies are taking a broader approach to antitrust enforcement and have been critical of healthcare industry consolidation. The focus on labour markets and information sharing practices may lead to increased scrutiny, affecting compensation benchmarking activities. Entities involved in healthcare collaborations, under this new legal framework, should review their arrangements and assess their procompetitive rationale and impact on competition.

Commentators have put forward that the withdrawal reflects Biden Administration's aggressive stance on antitrust enforcement and creates uncertainty for healthcare collaborations that previously fell within safety zones, while the viability of other safety zones policies is also called into question.

Both Agencies emphasise the need for continued focus on competition in the evolving healthcare markets. We will see how the changes impact the market and how other legislation is affected, as the Principal DAAG Mekki stated that the Division currently has no plans to replace the Statements and that, instead, "*recent enforcement actions and competition advocacy provide guidance to the public about our enforcement priorities*".

The withdrawal marks another step in the Agencies' increased efforts to "*vigorously enforce*" the antitrust laws in the healthcare industry and will require healthcare companies to regularly monitor the enforcement actions and competition advocacy for guidance on how the Agencies may regulate the industry.

This entry was posted on Tuesday, August 22nd, 2023 at 9:00 am and is filed under Competition enforcement, Enforcement, United States of America
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