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DOJ withdraws three "outdated" healthcare antitrust policies – implications could be much broader

February 7, 2023 | Client Update | 11-minute read

On February 3, the DOJ's Antitrust Division withdrew three "outdated" policy statements. Those statements described certain antitrust safe harbors that companies in the healthcare space and many other industries had relied on for roughly three decades. The DOJ now intends to analyze companies' conduct on a "case-by-case" basis. Until the DOJ articulates new standards – through enforcement actions or guidelines – parties face the risk that previously "safe" conduct faces unforeseen risks.

The DOJ announcement

On February 3, 2023, the Antitrust Division of the Department of Justice (DOJ) announced "the withdrawal of three outdated antitrust policy statements related to enforcement in healthcare markets."[1] Those three policy statements, issued in 1993, 1996, and 2011, were each jointly issued by the DOJ and the Federal Trade Commission ("FTC") and address various topics in antitrust enforcement, as detailed below. The Federal Trade Commission did not withdraw the guidelines, but it would not be surprising to see a parallel announcement from the FTC in the near future.

The 1993 and 1996 statements described how the agencies would approach nine categories of conduct and established "antitrust safety zones" upon which private parties have relied over the past three decades, not just in the healthcare space, but also across a wide range of other industries. The 2011 policy statements addressed a tenth category: the formation and operation of "Accountable Care Organizations" under the Affordable Care Act.

The healthcare policy statements

- **The 1993 policy statements** were "designed to provide information to the health care community in a time of tremendous change, and to resolve … any antitrust uncertainty that might deter beneficial mergers or joint ventures that promise to reduce health care costs." Accordingly, the 1993 policy statements set forth "antitrust safety zones" to "describe the circumstances under which the Agencies will not challenge conduct under the antitrust laws."[2]
- **The 1996 policy statements** restated the existing safety zones and expanded on prior guidance in order to "amplify the enforcement policy statement on" two subjects: physician network joint ventures and multiprovider networks.[3] In particular, the DOJ and the FTC provided guidance for the following categories, often with illustrative examples. For most categories, the agencies committed not to challenge such conduct if it fell within a specified antitrust safety zone.[4] These included: hospital mergers[5]; hospital joint ventures involving high-technology or other expensive medical equipment[6]; providers' collective provision of fee[7] and non-fee-related[8] information to purchasers of health care services; hospital participation in exchanges of price and cost information[9]; joint purchase arrangements among health care providers[10]; and physician network joint ventures.[11] The agencies

declined to identify antitrust safety zones for two categories of conduct: hospital joint ventures involving specialized clinical or other expensive health care services; and multiprovider networks.[12]

— **The 2011 policy statements** addressed "Accountable Care Organizations" ("ACOs"), which are arrangements promoted by the Affordable Care Act as a way for health care providers "to manage and coordinate care for Medicare fee-for-service beneficiaries."[13] In order "to maximize and foster opportunities for ACO innovation and better health for patients," the 2011 policy statements provided general guidance "to clarify" how the agencies will analyze ACOs under the antitrust laws and established an antitrust safety zone subject to certain conditions and exceptions.[14]

The DOJ's withdrawal

The DOJ's announcement described the 1993, 1996, and 2011 policy statements as "outdated." In particular, the agency noted that "[o]ver the past three decades since this guidance was first released, the healthcare landscape has changed significantly." "As a result," the DOJ concluded, the policy statements had become "overly permissive on certain subjects, such as information sharing, and no longer serve their intended purposes of providing encompassing guidance to the public on relevant healthcare competition issues in today's environment."[15]

The FTC did not join the DOJ announcement, although a parallel statement would not be surprising.[16] This is important because the FTC and the DOJ share healthcare enforcement efforts. The DOJ oversees healthcare enforcement for criminal matters, insurance, Medicare Part D, non-profits, and other areas. The FTC has traditionally broad healthcare enforcement jurisdiction, covering, among other things, drugs (including small molecules and biologics), medical devices, hospitals, provider groups, PBMs, and GPOs. For now, the guidelines continue to apply to FTC enforcement efforts.

The DOJ also did not announce plans to issue new healthcare policy statements. Instead, the DOJ stated that "[r]ecent enforcement actions and competition advocacy in healthcare provide guidance to the public, and a case-by-case enforcement approach will allow the Division to better evaluate mergers and conduct in healthcare markets that may harm competition."[17]

The DOJ's announcement has implications in healthcare and well beyond

The DOJ's announcement would be notable even if its effects were limited to the healthcare industry. They are not so limited, however. The three policy statements withdrawn by the DOJ have all been in force for over a decade, and in two cases for nearly thirty years.

The statements were designed generally – and in at least one case explicitly – to "resolve … any antitrust uncertainty that might deter beneficial mergers or joint ventures that promise to reduce health care costs."[18] The withdrawal of the policy statements thus re-introduces uncertainty with respect to how the agencies will approach antitrust enforcement within the healthcare industry.

The DOJ's announcement, however, affects industries well beyond healthcare. Indeed, the 1996 policy statements were, by their own terms, a description of how the DOJ and FTC "analyze[d] all types of health care provider networks *under general antitrust principles*."[19] In issuing those statements, the agencies explicitly "emphasize[d] that it is not their intent to treat such networks either more strictly or more leniently than joint ventures in other industries."[20] Consistent with that characterization, for many years the safe harbors created by the policy statements have, as a practical matter, been applied (or often, even consistently, assumed to apply) to industries beyond healthcare. DOJ

Business Review Letters apply the healthcare safety zones outside the healthcare industry.[21] Similarly, the ABA's main antitrust treatise – *Antitrust Law Developments* – and another well-regarded treatise by Professors Areeda and Hovenkamp both suggest general application of the healthcare safe harbors.[22]

Following the withdrawal of these guidelines, few DOJ safe harbors for the analysis of information sharing, benchmarking, and joint purchasing agreements remain. The agencies' *Competitor Collaboration Guidelines* state that the government will not ordinarily challenge a legitimate collaboration between or among competitors where the combined share of the relevant market is less than 20%.[23] The agencies' *Antitrust Guidelines for the Licensing of Intellectual Property* also state that the agencies ordinarily will not challenge a licensing arrangement if (i) the restraint is not facially anticompetitive, and (ii) the licensor's and licensees' combined share of the relevant market is less than 20%.[24] The recent announcement from the DOJ may call into question the extent to which entities can and should continue to rely upon these guidelines.

Until the DOJ articulates new standards (either through guidelines or enforcement actions), businesses in healthcare and many other industries might well continue to conform their benchmarking, information exchange, or joint purchasing activities to the standards set forth in the withdrawn policy statements, particularly if they also face FTC scrutiny. Doing so creates the risk, however, that proceeding without clear standards could result in unforeseen risks.

Key takeaways

The DOJ withdrew policy statements that were designed to "resolve … antitrust uncertainty" in the healthcare industry and describe how the agencies apply "general antitrust principles."[25] The policy statements remain in effect for the FTC. At least for now, the DOJ has indicated any new standards will be expressed not in new policy statements, but by the DOJ's enforcement actions and competition advocacy. This announcement creates uncertainty for businesses – in the healthcare sector and well beyond – that face the potential for DOJ and FTC enforcement actions. We expect that parties may continue generally to follow the standards articulated in the withdrawn guidelines, albeit at higher and potentially unquantifiable risk. We will continue to monitor these developments closely.

If you have any questions regarding the matters covered in this publication, please reach out to any of the lawyers listed below or your usual Davis Polk contact.

Sheila R. Adams James
+1 212 450 3160
sheila.adams@davispolk.com

D. Jarrett Arp
+1 202 962 7150
jarrett.arp@davispolk.com

Arthur J. Burke
+1 212 450 4352
+1 650 752 2005
arthur.burke@davispolk.com

Ronan P. Harty
+1 212 450 4870
ronan.harty@davispolk.com

Nathan Kiratzis
+1 212 450 4157
nathan.kiratzis@davispolk.com

Christopher Lynch
+1 212 450 4034
christopher.lynch@davispolk.com

Mary K. Marks
+1 212 450 4016
mary.marks@davispolk.com

Suzanne Munck af Rosenschold
+1 202 962 7146
suzanne.munck@davispolk.com

Howard Shelanski
+1 202 962 7060
howard.shelanski@davispolk.com

Jesse Solomon
+1 202 962 7138
jesse.solomon@davispolk.com

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[1] Dep't of Justice, Justice Department Withdraws Outdated Enforcement Policy Statements (Feb. 3, 2023), https://www.justice.gov/opa/pr/justice-department-withdraws-outdated-enforcement-policy-statements (hereinafter, "DOJ Press Release").

[2] Dep't of Justice & Fed. Trade Comm'n, Antitrust Enforcement Policy Statements in the Health Care Area at 1 (Sept. 15, 1993), https://www.justice.gov/archive/atr/public/press_releases/1993/211661.htm (hereinafter, "1993 Policy Statements Summary"). The DOJ's press release currently links only to a summary of the 1993 policy statements, which are available in full at Dep't of Justice & Fed. Trade Comm'n, Antitrust Enforcement Policy Statements in the Health Care Area (Sept. 15, 1993), 4 Trade Reg. Rep. (CCH) ¶ 13,151.

[3] Dep't of Justice & Fed. Trade Comm'n, Statements of Antitrust Enforcement Policy in Health Care at 2-3, https://www.justice.gov/atr/page/file/1197731/download (hereinafter, "1996 Policy Statements"). The DOJ announcement did not address the agencies' 1994 healthcare guidelines, which do not appear on the DOJ or FTC websites and which appear to have been withdrawn. *See* Dep't of Justice & Fed. Trade Comm'n, Statements of Enforcement Policy and Analytical Principles Relating to Health Care and Antitrust (Sept. 27, 1994), 1994 WL 642477.

[4] The DOJ and FTC would not challenge conduct within an antitrust safety zone "absent extraordinary circumstances." *See*, *e.g.*, 1996 Policy Statements, *supra* note 3, at 8, 12, 40.

[5] *Id.* at 8-9 (identifying an antitrust safety zone if one of the hospitals was sufficiently small (i.e., over the three most recent years, it had an average of fewer than 100 licensed beds and an average daily inpatient census of fewer than 40 patients) and had operated for at least five years).

[6] *Id.* at 13-14 (identifying an antitrust safety zone if a joint venture involving high-technology or expensive equipment (i) existed "to purchase or otherwise share the

ownership cost of, operate, and market the related services of" new or existing medical equipment, and (ii) only included hospitals "whose participation is needed to support the equipment, absent extraordinary circumstances").

[7] *Id.* at 44-45 (identifying an antitrust safety zone for collectively providing *fee-related* information to purchasers of health care services if the information was (i) collected by a third party, (ii) more than three months old, and (iii) compiled from at least five providers, who each represented no more than 25% of the data, and aggregated so individual prices could not be identified).

[8] *Id.* at 41-42 (identifying an antitrust safety zone for collectively providing *non-fee-related* information to purchasers of health care services if providers (i) gathered "outcome data from … members about a particular procedure that they believe should be covered by a purchaser" and gave such information to the purchaser, or (ii) developed "suggested practice parameters").

[9] *Id.* at 50 (identifying an antitrust safety zone for hospitals sharing "prices for health care services" or "wages, salaries, or benefits of health care personnel" if the information was (i) collected by a third party, (ii) more than three months old, and (iii) compiled from at least five providers, who each represented no more than 25% of the data, and aggregated so individual data could not be identified).

[10] *Id.* at 54-55 (identifying an antitrust safety zone for joint purchasing arrangements if (i) the group's purchases accounted for less than 35% of the total sales of the relevant product or services in the relevant market, and (ii) the cost of the product or service jointly purchased accounted for less than 20% of the total revenues of each competing participant).

[11] *Id.* at 64-66 (identifying an antitrust safety zone for physician network joint ventures if (i) the participating physicians "share[d] substantial financial risk," and (ii) "constitute[d] [X] percent or less of the physicians in each physician specialty with active hospital staff privileges who practice in the relevant geographic market" – where X was 20% for exclusive ventures and 30% for non-exclusive ones).

[12] *Id.* at 32-39 (explaining that hospital joint ventures involving specialized clinical or other expensive health care services were subject to a rule of reason analysis and providing examples); *id.* at 107 (providing the same guidance with respect to multiprovider networks).

[13] Dep't of Justice & Fed. Trade Comm'n, Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program at 2 (Oct. 2, 2011), https://www.justice.gov/sites/default/files/atr/legacy/2011/10/20/276458.pdf (quoting Patient Protection and Affordable Care Act, Pub. L. No. 111-48, § 3022, 124 Stat. 119, 395-99 (2010)).

[14] *Id.* at 6-14.

[15] DOJ Press Release, *supra* note 1.

[16] Notably, Assistant Attorney General Jonathan Kanter can decide, on his own, for the DOJ to withdraw the guidelines. The same action at the FTC would require a majority vote among FTC Commissioners.

[17] DOJ Press Release, *supra* note 1.

[18] 1993 Policy Statements Summary, *supra* note 2, at 1.

[19] 1996 Policy Statements, *supra* note 3, at 3 (emphasis added).

[20] *Id.* at 3.

[21] *See, e.g.*, Response to Request for Business Review Letter from William J. Baer, Assistant Attorney Gen., Dep't of Justice, Antitrust Div., to Garrard R. Beeney (Mar. 26, 2013), https://www.justice.gov/atr/response-intellectual-property-exchange-international-incs-request-business-review-letter (relying on the 1996 Policy Statements, *supra* note 2, to explain how to mitigate concerns about sharing competitively sensitive information among the members of a planned exchange for patent rights, before ultimately declining to provide a business review letter); Business Review Letter from Charles A. James, Assistant Attorney Gen., Dep't of Justice, Antitrust Div., to Alan P. Sherbrooke (Oct. 25, 2001), https://www.justice.gov/atr/response-foss-maritime-company-request-business-review-letter (applying the 1996 Policy Statements, *supra* note 2, with respect to firms that "provide towing and barge services in U.S. waters"); Business Review Letter from John M. Nannes, Acting Assistant Attorney Gen., Dep't of Justice, Antitrust Div., to Daniel R. Barney (Mar. 27, 2001), https://www.justice.gov/atr/response-truckload-carriers-associations-request-business-review-letter (applying the 1996 Policy Statements, *supra* note 2, with respect to the trucking industry).

[22] ABA Section of Antitrust Law, Antitrust Law Developments § 1C-1-c (9th ed. 2022); *id.* § 4C-5 & n.153 (citing the healthcare policy statements as relevant to general antitrust principles for joint purchasing agreements); *id.* § 4E-2 (citing the healthcare policy statements as relevant to general antitrust principles for collateral restraints in a joint venture). *See also* Philip E. Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application ¶ 2135 (5th ed. 2022).

[23] Dep't of Justice & Fed. Trade Comm'n, Antitrust Guidelines for Collaborations Among Competitors § 4.2 (Apr. 2000), https://www.ftc.gov/sites/default/files/documents/public_events/joint-venture-hearings-antitrust-guidelines-collaboration-among-competitors/ftcdojguidelines-2.pdf.

[24] Dep't of Justice & Fed. Trade Comm'n, Antitrust Guidelines for the Licensing of Intellectual Property § 4.3 (Jan. 12, 2017), https://www.justice.gov/atr/IPguidelines/download.

[25] 1993 Policy Statements Summary, *supra* note 2, at 1; 1996 Policy Statements, *supra* note 3, at 3.