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DOJ Enforcement Memorandum Signals Policy Shift in Deference to Agency Guidance Documents for Civil Health Care Enforcement Matters

On January 25, 2018, the U.S. Associate Attorney General issued a [memorandum](#) directing civil litigators in the U.S. Department of Justice (“DOJ”) to limit their use of governmental agency guidance documents in affirmative civil enforcement (“ACE”) matters. Specifically, the memorandum directs DOJ litigators not to use guidance documents issued by governmental agencies for purposes of determining the merit of ACE matters, or as a basis for proving violations of applicable law in those matters. This alert describes key considerations with respect to the memorandum, and summarizes the issues that will need to be monitored over time in order to understand the memorandum’s ultimate impact on civil health care enforcement matters.

DOJ Guidance Policy

The memorandum is issued in the context of the Trump Administration’s deregulatory activities and the DOJ’s corresponding efforts to review and revise its policy positions in key areas. On November 16, 2017, the Attorney General issued a [policy memorandum](#) (“Guidance Policy”) prohibiting DOJ components from issuing guidance documents that effectively bind the public without undergoing the notice-and-comment rulemaking process. The Guidance Policy also prohibited the DOJ from using its guidance documents “to coerce regulated parties into taking any action or refraining from taking any action beyond what is required by the terms of the applicable statute or lawful regulation.” The U.S. Associate Attorney General introduces the January 25 memorandum by noting that the principles from the Guidance Policy should guide DOJ litigators in determining the legal relevance of *other agencies’* guidance documents in ACE matters.

New Limitations on Deference to Guidance Documents

The memorandum defines the term “guidance document” to mean “any agency statement of general applicability and future effect...that is designed to advise parties outside the federal Executive Branch about legal rights and obligations.” Historically, guidance documents issued by governmental agencies often have served as key sources of legal authority in organizations’ interpretation of law and regulation and in enforcement actions, given their obvious significance as an agency’s interpretation of its own regulations and of related law.

The memorandum states that the DOJ “may not use its enforcement authority to effectively convert agency guidance documents into binding rules.” Implementing that principle, the memorandum instructs that DOJ litigators “may not use noncompliance with guidance documents as a basis for proving violations of applicable law” in ACE cases. As such, the memorandum limits the legal significance of agency guidance documents in enforcement matters.

The memorandum does not completely foreclose use of agency guidance documents by DOJ in ACE matters—it notes that guidance documents may continue to be used for “proper purposes.” For instance, the memorandum notes that “some guidance documents simply explain or paraphrase legal mandates from existing statutes or regulations, and the [DOJ] may use evidence that a party read such a guidance document to help prove that the party had requisite knowledge of the mandate.”

The policy position articulated in the memorandum reaffirms what is, on the surface, a noncontroversial and fundamental legal principle—executive branch agencies may not enact law, but instead are tasked with administering statutes issued through the legislative process and promulgating regulations under those statutes in accordance with

appropriate notice-and-comment rulemaking processes. Guidance documents issued by federal agencies under such laws and regulations do not create independent legal obligations, but instead serve to clarify the issuing agency's interpretation of the applicable statutes and regulations. Notwithstanding the foregoing, in practice, agency guidance documents often do serve as important sources of legal authority in enforcement matters. Both DOJ litigators and *qui tam* relators routinely rely upon agency guidance documents as an integral component of arguments crafted to prove that a particular defendant violated the law.

Analysis of Implications on Health Care Guidance Documents

In the health care context—where much federal enforcement is through civil litigation managed by DOJ under the False Claims Act—guidance documents historically have played a role of particular importance. Given the complexity of the laws and regulations governing federal health care programs, the U.S. Department of Health and Human Services (“HHS”) along with its agencies, including the Centers for Medicare & Medicaid Services (“CMS”) and its contractors, and the HHS Office of Inspector General (“HHS-OIG”), have issued countless volumes of sub-regulatory guidance documents in the form of preamble commentary, manuals, special fraud alerts, advisory opinions, national and local coverage determination policies, and similar materials. DOJ litigators, *qui tam* relators and defendants alike historically have relied upon such guidance documents in developing their respective understandings of, and legal positions regarding, the laws and regulations governing the federal health care programs, both for litigation and ongoing compliance purposes.

The memorandum serves to limit substantially the sources of authorities that DOJ may use in ACE matters. This may be significant for health care companies, life sciences companies, and other industry stakeholders facing DOJ civil enforcement actions in areas layered with complex and voluminous sub-regulatory guidance. In addition, the memorandum may serve to discourage DOJ litigators from pursuing ACE matters that turn on factors cited in guidance documents if those factors are not apparent from the underlying laws and regulations. Similarly, the memorandum may provide defendants and their attorneys a stronger footing to persuade DOJ litigators that certain claims, whether originally raised by a *qui tam* relator or otherwise, are meritless and should not be pursued.

Assessment of Impact

The precise effect that the memorandum will have on health care enforcement actions is difficult to assess given its limitations in scope. The memorandum does not address the distinction between the permissible use of agency guidance to “explain or paraphrase legal mandates from existing statutes or regulations” and the impermissible use of guidance to demonstrate a “binding rule.” As the difference between these two types of usages is not always straightforward, differences of opinion are sure to arise.

Further, the memorandum applies only to the civil division of DOJ. As such, at least as a formal matter, the policy articulated in the memorandum does not extend to the criminal division of DOJ. Similarly, although DOJ often works closely with CMS, HHS-OIG, and other agencies in pursuing ACE matters, the memorandum does not apply to administrative actions brought by or before those agencies. It also does not bind *qui tam* relators litigating non-intervened actions that they have brought under the False Claims Act. The policy change therefore, on its face, applies only to some, not all, enforcement actions that actors in the industry may face.

Contact

We will continue to monitor developments relating to the DOJ's treatment of agency guidance documents and its impact on health care companies, life sciences companies, and other industry stakeholders. Please contact your usual Ropes & Gray attorney with any questions.