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New DOJ False Claims Act Guidance Delivers More Questions than Answers for Health Care Industry

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The U.S. Department of Justice (DOJ) kicked off the new year by issuing two internal memoranda that are directly relevant to actions brought under the False Claims Act. The January 2018 memoranda offer valuable insight into how the DOJ intends to prosecute, or opt to dismiss, pending and future civil enforcement actions. These memoranda may have their biggest impact in the health care industry, with its plethora of qui tam matters and heavy reliance on manuals and other sub-regulatory guidance. Each memorandum is discussed more fully in "A New Year, a New, Firmer DOJ: Recently Released Parameters for DOJ in False Claims Act Litigation."

The first such memorandum, issued January 10, 2018, emphasizes the DOJ's "important gatekeeper role" in preserving resources, protecting government interests, and avoiding unfavorable precedent caused by weak cases. While the False Claims Act contains a dismissal provision, 31 U.S.C. § 3730(c)(2)(A), which explicitly gives the DOJ the power to seek to dismiss a case over the objection of a relator (who stands to gain financially if their lawsuit leads the government to recover money), the DOJ historically has been hesitant to exercise that authority. The January 10 memorandum, however, encourages DOJ attorneys to consider not only their power to seek dismissal, but also their responsibility to do so, and outlines seven common, but not exclusive, factors for U.S. attorneys to consider in deciding whether to dismiss a qui tam.

Subsequent to its guidance relating specifically to qui tams, the DOJ issued additional guidance with a slightly broader applicability to the Health Care Industry.

The guidance in a January 25, 2018memorandum limits the use of agency guidance documents in civil enforcement cases, building upon a position statement issued by the DOJ in November 2017. In the November memorandum, the Attorney General announced that the DOJ was prohibited from enforcing as law any agency guidance documents that have the effect of changing the law or creating additional standards. The earlier statement makes clear that agency guidance – which is intended to provide advice illustrating the agency's application or interpretation of the law – *does not* create binding legal obligations or requirements, and cannot be treated as law by the DOJ.

The January 25 memorandum extends the restriction on the DOJ's use of its own guidance to also apply to its use of *other agencies'* guidance, clearly stating that the DOJ "may not use its enforcement authority to effectively convert agency guidance documents into binding rules." Further extrapolating from this policy, the memorandum instructs that the DOJ may no longer rely on a defendant's failure to comply with *guidance documents* as a way to prove that the defendant violated the *statutes or regulations* discussed in those guidance documents.

This position holds several remarkable features and implications:

First, the memorandum explicitly states that the DOJ remains free to use a defendant's acknowledgment of guidance documents to show that the defendant had *knowledge* of the applicable law.

Second, the memorandum does not in any way restrict the use of agency guidance for resolving matters within agency authority. In the health care context, this could include the agency interpretation that shapes claim denials or even exclusion of physicians or hospitals from participation in government programs. Furthermore, the January 25 memorandum was specific to *civil* enforcement actions, suggesting it does not extend to the DOJ's Criminal Division. This suggests that the failure to follow administrative guidance and other informal communications will continue to be used to prove the requisite mens rea in criminal actions.

Third, the memorandum calls into question the continued use of the implied false certification theory as a basis for False Claims Act liability, which was endorsed by the U.S. Supreme Court in June 2016 in *Universal Health Services, Inc. v. United States ex rel. Escobar et al.* Regardless of whether a court may still look to *Escobar* as precedent, the policy raises questions as to what types of guidance the DOJ may rely on in pursuing such a theory to prove False Claims Act liability.

Fourth, specific guidance documents that have routinely been pointed to as authoritative or even binding may no longer carry the same weight they once did. For example, the CMS Medicare Manual contains guidance that has never been the subject of the formal rule-making provisions of the Administrative Procedures Act, as have other forms of informal billing guidance such as local and national coverage determinations. Likewise, the FDA has published useful interpretive guidance, especially in oft-litigated areas like off-label marketing. Other traditional documents, such as advisory opinions and guidance on compliance with the Stark Law and the Anti-Kickback Statute, may no longer have the same strength of argument in a False Claims Act case.

Lastly, the proverbial "flip side" is the fact that the health care industry has routinely relied on this informal advice both to help conduct business and to provide peace of mind that stakeholders could rely on the guidance to explain their interpretation and application of a statute or regulation. The DOJ's recent directive raises the question of whether the DOJ will recognize that good faith reliance on agency guidance may still negate or be a defense to allegations of misconduct, even when the failure to follow the guidance may not in itself be the basis to allege a violation.

For more information on these policies or related questions, please contact Tom Barnard, Marisa Dorough, or a member of Baker Donelson's Government Enforcement and Investigations Group or Health Law Group.