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The DOJ's Shift Away From "Regulation by Guidance" in False Claims Act Cases

The False Claims Act ("FCA")^[1] authorizes the assessment of civil penalties and treble damages against those who defraud the government by presenting false or inflated claims for payment. Under the FCA, a *qui tam* complaint may be brought by a private plaintiff, referred to as a "relator." The government, through the Department of Justice ("DOJ"), has discretion to step in the place of the relator and pursue the case as an intervener. Private plaintiffs are incentivized to bring FCA lawsuits: they can collect 15-25% of the government's recovery, in addition to attorneys' fees.

In the past, relators and the government relied upon agency guidance documents to try to prove a defendant's noncompliance with conditions for payment. For example, in the wake of the Affordable Care Act, federal agencies such as the Food and Drug Administration and the Centers for Medicare and Medicaid Services issued a number of guidance documents (such as manuals, bulletins, and advisory opinions) to clarify and sometimes expound upon what is required by federal health care laws. A health care provider who failed to comply with a federal agency's interpretation of the conditions for reimbursement could find itself the target of a FCA lawsuit.

But in a move to curtail DOJ's use of "regulation by guidance,"^[2] U.S. Attorney General Jeff Sessions issued a memorandum prohibiting the DOJ from creating binding standards in guidance documents without following the notice-and-comment rulemaking process required by the Administrative Procedures Act. The Sessions Memo, issued in November 2017, makes clear that DOJ guidance documents that are not the result of such formal rulemaking processes cannot create legal obligations on the public, including those who present claims for payment to the U.S. government, such as federal contractors and health care providers.

In January 2018, then-Associate Attorney General Rachel Brand issued a memorandum^[3] expanding upon the Sessions Memo. The Brand Memo, which was issued to attorneys in DOJ's Civil Division, prohibits government attorneys in civil enforcement cases from using their "enforcement authority to effectively convert agency guidance documents into binding rules." The Brand Memo broadly defines a "guidance document" as including not only the DOJ's own guidance documents, but also "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." DOJ litigators "may not use noncompliance with guidance documents as a basis for proving violations of applicable law" in civil enforcement cases. The Brand Memo does allow DOJ to "continue to use agency guidance documents for proper purposes in such cases." For example, DOJ "may use evidence that a party read such a guidance document to help prove that the party had the requisite knowledge of the mandate." But a guidance document cannot "establish[] that the party violated the applicable statute or regulation."

Particularly in the realm of health care law, *qui tam* relators and government lawyers have brought FCA claims premised on alleged violations of health care guidance documents, such as guidance related to billing of Medicare and Medicaid. In 2017, nearly two-thirds of the government's recovery in FCA *qui tam* cases arose from cases involving the health care industry.^[4] Defendants can now argue that the government may not use noncompliance with agency guidance to support a violation of the FCA. Following the Brand Memo, defendants cannot simply be accused of violating a government *policy* to support an FCA lawsuit, and defendants find themselves better positioned to fight back against plaintiffs' overbroad interpretations of what constitutes a "false" claim for payment.

For further information, please contact **Michael W. Magner** or **Avery B. Pardee**.

[1] 31 U.S.C. § 3729 *et seq.*

[2] DOJ, "Attorney General Jeff Sessions Ends the Department's Practice of Regulation by Guidance," Nov. 17, 2017, <https://www.justice.gov/opa/pr/attorney-general-jeff-sessions-ends-department-s-practice-regulation-guidance>.

[3] Associate Attorney General Rachel Brand, "Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases," Jan. 25, 2018, <https://www.justice.gov/file/1028756/download>.

[4] DOJ, "Justice Department Recovers Over \$3.7 Billion from False Claims Act Cases in Fiscal Year 2017," Dec. 21, 2017, <https://www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-false-claims-act-cases-fiscal-year-2017>.