

DOJ Revisits the “Brand Memorandum” and Restores the Use of Agency Guidance Documents to Support False Claims Act Enforcement

SEPTEMBER 2, 2021

Recently, the U.S. Department of Justice (DOJ) issued a memorandum and interim final rule, which effectively revoked elements of the “Brand Memorandum” and reinstated the use of federal guidance documents in False Claims Act (FCA) cases. DOJ’s interim final rule comes on heels of President Biden’s issuance of Executive Order 13992, Revocation of Certain Executive Orders Concerning Federal Regulation, which restored the use of agency guidance documents in FCA enforcement actions.

Guidance documents are typically authored by federal agencies, e.g. the Food & Drug Administration and the Centers for Medicare and Medicaid Services, to assist the regulated industry understand the rules under various federal program. Much to the ire of defendants in regulated industries, such as healthcare, life sciences, and defense, DOJ and relators historically often relied on agency guidance documents in FCA litigation to help establish the falsity of claims and establish that defendants acted knowingly in submission of false claims. DOJ sharply curtailed the “falsity” element of this reliance under the immediate prior Administration.

Prior DOJ Limits the Use of Guidance Documents

Under the previous administration, Attorney General Jefferson B. Sessions III issued a memorandum on November 16, 2017, reversing the DOJ’s practice of using guidance memoranda.¹ The memorandum stated that it had come to his attention that the DOJ “has in the past published guidance documents—or similar instruments of future effect by other names, such as letters to regulated entities—that effectively bind private parties without undergoing the rulemaking process” and that the “Department will no longer engage in this practice.”²

On January 25, 2018, Associate Attorney General Brand issued a follow-up memorandum, the “Brand Memorandum,” limiting the use of agency guidance documents in litigation, stating that “effective immediately for [affirmative civil enforcement] cases, the Department may not use its enforcement authority to effectively convert agency guidance documents into binding rules.”³ Specifically, “this memorandum applies when the Department is enforcing the [FCA], alleging that a party knowingly submitted a false claim for payment by falsely certifying compliance with material statutory or regulatory requirements.”⁴

The DOJ codified the policy statements from the Brand Memorandum into the Justice Manual at Section 1-20.000. [5] The Justice Manual said that “[c]riminal and civil enforcement actions brought by the Department must be based on violations of applicable legal requirements, not mere noncompliance with guidance documents issued by federal agencies, because guidance documents cannot by themselves create binding requirements that do not already exist by statute or regulation.” [6] Therefore, the “Department may not bring actions based solely on allegations of noncompliance with guidance documents.” [7]

However, the DOJ *could* use agency guidance documents to establish knowledge of the law and in some circumstances establish *mens rea*—for example, when “a party has submitted a false claim that is contrary to fact, but was crafted in a way that otherwise appears to be consistent with a guidance document, or where a party’s deliberate indifference to a guidance document is probative of deliberate indifference to the requirements imposed by statute, regulation, or other obligation (e.g., a contract of certification).” [8]

In 2020, the DOJ published two interim final rules, 28 CFR § 50.26 and 28 CFR § 50.27, based on the memoranda from Attorney General Sessions and Attorney General Brand.

Current DOJ Restores Use of Guidance Documents

On July 1, 2021, Attorney General Merrick Garland issued a memorandum “clarif[ying] the principles that should govern the issuance and use of guidance documents by the Department of Justice” and rescinding the November 2017 and January 2018 memoranda. [9] Stating that the “procedures imposed by the November 2017 and January 2018 Memoranda are overly restrictive; the Memoranda and the implementing regulations have discouraged the development of valuable guidance; and the Memoranda and regulations have also generated collateral disputes and otherwise hampered Department attorneys when litigating cases where there is relevant agency guidance.” [10]

On July 16, 2021, the DOJ issued an interim final rule, consistent with Attorney General Garland’s memorandum, that “revokes amendments to its regulations ... which imposed limitations on the issuance and use of guidance documents.” [11] The “Department has concluded that those regulations are unnecessary and unduly burdensome, lack flexibility and nuance and limit the ability of the Department to do its work effectively.” [12] The interim rule stated that the Justice Manual sections regarding agency guidance “will be revised as appropriate at a later date.” [13] While the new rule reaffirms the DOJ’s position that guidance documents do not equate to regulations, it restores the pre-2017 state of affairs for FCA enforcement.

Key Takeaways

- DOJ attorneys handling an enforcement action, or any other litigation, can once again rely on relevant agency guidance documents, and the question will be open whether this change will impact the DOJ’s handling of cases already pending.
- Parties should pay attention to the current agency guidance in their respective field and stay up to date on any new guidance issued because it may be relevant in litigation particularly where whistleblowers will view this DOJ policy change as relaxing the guardrails around which *qui tam* allegations are worthy of intervention or, conversely, meriting a DOJ motion to dismiss despite the whistleblower’s objection.
- Agency guidance documents still do not have the legal authority of statutes or notice-and-comment regulations but can still be particularly relevant to identifying the perimeter of legal compliance with laws and regulations in FCA cases.

If you have any additional questions or need further assistance, please reach out to **Amandeep Sidhu** (Partner, White Collar, Regulatory Defense and Investigations), **T. Reed Stephens** (Partner, White Collar, Regulatory Defense and Investigations), and **Jennie Porter** (Associate, White Collar, Regulatory Defense and Investigations) or your Winston & Strawn relationship attorney.

¹¹ Memorandum from Att’y Gen., *Prohibition on Improper Guidance Documents* (Nov. 16, 2017), available at <https://www.justice.gov/opa/press-release/file/1012271/download>.

¹² *Id.*

¹³ Memorandum from Assoc. Att’y Gen., *Limited Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases* (Jan. 25, 2018), available at <https://www.justice.gov/file/1028756/download>.

¹⁴ *Id.*

¹⁵ Dep’t of Just., *Justice Manual Section 1-20.000 – Limitation on Use of Guidance Documents in Litigation*, (Dec. 2018), available at <https://www.justice.gov/jm/1-20000-limitation-use-guidance-documents-litigation>.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ Memorandum from Att’y Gen., *Issuance and Use of Guidance Documents by the Department of Justice* (July 1, 2021), available at <https://www.justice.gov/opa/page/file/1408606/download>.

¹⁰¹ *Id.*

¹¹¹ Dep’t of Just., 28 CFR pt. 50 (July 16, 2021), available at <https://www.govinfo.gov/content/pkg/FR-2021-07-16/pdf/2021-14480.pdf>.

¹¹² *Id.*

¹¹³ *Id.*

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