August 30, 2021

DOJ's Agency Guidance Dance: A Tempest in a Teapot for Healthcare Fraud Cases?

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Introduction

On July 1, 2021, Attorney General Merrick B. Garland authored a Memorandum entitled *Issuance and Use of Guidance Documents by the Department of Justice* (Garland Memo).[i] The stated purpose of the Garland Memo is to "revise[] and clarif[y] the principles that should govern the issuance and use of guidance documents by the Department of Justice" (DOJ or Department).[ii] The Garland Memo rescinds two memoranda issued within the Department during the Trump Administration, one by Attorney General Jefferson B. Sessions[iii] (Sessions Memo), and one by Associate Attorney General Rachel Brand[iv] (Brand Memo). The former placed restrictions on the issuance and use of guidance documents by the Department and the latter limited the use of guidance documents from other agencies in Department litigation.

In civil enforcement actions generally, and False Claims Act (FCA) litigation specifically – where over 80 percent of recoveries come from the healthcare industry[v] – the Garland Memo will be seen as a rebuke of the Trump Administration's efforts to curtail or eliminate DOJ's use of subregulatory guidance in prosecuting civil cases, and a vindication of government and whistleblower attorneys who criticized the Trump-era guidance – particularly the Brand Memo – as overbroad and overly restrictive. But a closer analysis of the Garland Memo in light of § 1-20.000 of the Justice Manual (JM), *Limitation on Use of Guidance Documents in Litigation*, which was adopted by DOJ in December 2018,[vi] begs the question of how much the Garland Memo really changes the landscape of the government's use of agency guidance documents in FCA litigation.

The Sessions and Brand Memos

On November 16, 2017, then-Attorney General Sessions issued the Sessions Memo, which placed limitations on DOJ's use of guidance documents. Attorney General Sessions wrote that "the Department has in the past published guidance documents . . . that effectively bind private parties without undergoing the rulemaking process."[i] The Sessions Memo prohibited such practices, stating that "Department components may not issue guidance documents that purport to create rights or obligations binding on persons or entities outside the Executive Branch (including state, local, and tribal governments)."[ii]

On January 25, 2018, then-Associate Attorney General Brand instructed the civil litigation units of the Department and the United States Attorneys that "the principles from the [Sessions Memo] are relevant to more than just the Department's own publication of guidance documents. These principles also should guide Department litigators in determining the legal relevance of other agencies' guidance documents in Affirmative Civil Enforcement ("ACE")."[iii] The Brand Memo went on to state that "Guidance documents cannot create binding requirements that do not already exist by statute or regulation. . . . [T]he Department may not use its enforcement authority to effectively convert agency guidance documents into binding rules . . . [and] Department litigators may not use noncompliance with guidance documents as a basis for proving violations of applicable law in ACE cases."[iv] Associate Attorney General Brand indicated that there could be appropriate uses for guidance documents in ACE litigation, but provided a lone example of documents that "explain or paraphrase legal mandates from existing statutes or regulations," which could be used to demonstrate that a party "had the requisite knowledge of the mandate."[v]

The Brand Memo birthed dozens of articles and blog posts from legal commentators, some hypothesizing as to whether it signaled a more general pullback on ACE and FCA cases by the Department under the Trump Administration. One article even highlighted a specific disagreement between defense counsel and a DOJ trial attorney in correspondence debating the applicability and implications of the Brand Memo for a pending healthcare fraud case.[vi]

The Garland Memo

Elections resulting in a change in the party controlling the Executive Branch usually change the policies of executive agencies, and the Department is no different. For example, on April 16, 2021, Attorney General Garland rescinded the November 7, 2018 Attorney General Memorandum creating new review and approval conditions for settlements and consent decrees with state and local governmental entities; he also rescinded the enacting federal regulations and corresponding JM provisions, §§ 1-21.100-1-21.600.[vii] On July 1, 2021, the Sessions and Brand Memos on

subregulatory guidance met a similar fate.

The Garland Memo rescinds the Sessions and Brand Memos, and directs "the Department to initiate the process to revise the JM to be consistent with this Memorandum. . . ."[viii] Attorney General Garland begins by acknowledging that "guidance documents 'do not have the force and effect of law,'"[ix] but notes that they still serve valuable functions, such as (1) notifying the public as to how an agency understands and is likely to apply binding statutes and legislative rules;[x] (2) explaining the agency's programs; (3) collecting applicable legal requirements in a single place; and (4) making statutes and regulations clearer and more accessible to the general public.[xi]

Attorney General Garland then lays out revised principles for the Department's use of guidance documents. With regard to ACE cases and FCA prosecutions, the Garland Memo again acknowledges that "an agency guidance document by itself 'never forms the basis for an enforcement action' because such documents cannot 'impose any legally binding requirements on private parties.'"[xii] But the Garland Memo goes on to state that:

Department attorneys handling an enforcement action (or any other litigation) may rely on relevant guidance documents in any appropriate and lawful circumstances, including when a guidance document may be entitled to deference or otherwise carry persuasive weight with respect to the meaning of the applicable legal requirements. To the extent guidance documents are relevant to claims or defenses in litigation, Department attorneys are free to cite or rely on such documents as appropriate.[xiii]

In isolation, the Garland Memo appears to be a step back from the Department's more conservative approach to the use of agency guidance documents in ACE and FCA cases announced in the Brand Memo. Such a policy shift could signal that more aggressive fraud enforcement actions from the Department are on the horizon. But to truly understand whether the Garland Memo offers a meaningful, substantive change in DOJ policy, one must compare it to the Department's operative written policy on the use of agency guidance documents. That is not the Brand Memo, it is JM § 1-20.000.

JM § 1-20.000 *et seq.*

Considering the intricacies and complexities of modern FCA practice, particularly in the healthcare space, both the two-page Brand Memo and the three-page Garland Memo are short on specifics regarding how their approaches to subregulatory guidance should be implemented. The

Brand Memo states that "Department litigators may not use noncompliance with guidance documents as a basis for proving violations of applicable law in ACE cases,"[xiv] but leaves the door open a crack for at least some use of guidance documents.[xv] The Garland Memo is more affirmative in its dictate that "Department attorneys handling an enforcement action (or any other litigation) may rely on relevant guidance documents in any appropriate and lawful circumstances," but provides limited guidance on where lines should be drawn.[xvi] Absent more specifics, the true import of either memorandum is in the eye of the beholder.

Interestingly, the Department did attempt to clarify its approach to using agency guidance in affirmative civil cases after the Brand Memo. In December 2018, DOJ adopted JM § 1-20.000, entitled *Limitation on Use of Guidance Documents in Litigation*. Its provisions provide significant detail on how the Department interpreted the dictates of the Brand Memo in affirmative civil cases, including healthcare fraud enforcement. Indeed, the last sentence of the JM provisions states that it "fully implements, clarifies, and *supersedes* prior Department memoranda on this topic."[xvii]

Although the Garland Memo fully rescinds the Sessions and Brand Memos, it does not rescind JM § 1-20.000 in the same way that Attorney General Garland's April 16, 2021 Memorandum rescinded JM §§ 1-21.100-1-21.600. Instead, the Garland Memo directs the Department to "initiate the process to revise the JM to be consistent with this Memorandum."[xviii]

Despite JM § 1-20.000 superseding prior memoranda, Attorney General Garland took the step of formally rescinding the Brand Memo. This is not surprising given that some commentators continued to reference the Brand Memo after DOJ enacted § 1-20.000, often without reference to the JM. Some seemed unaware that the Brand Memo had been superseded, or did not see any importance in the adoption of the JM provisions.[xix] But the fact that the Garland Memo spares JM § 1-20.000 intimates that the Department still sees value in its contents. In divining where the Department may be heading on this issue, § 1-20.000 merits significant attention.

At first blush, the general premise of the JM provisions seems similar to that of both the Garland and Brand Memos. The JM states that "Criminal 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."[xx] But the JM departs from, or at least expounds upon, the Brand Memo, by affirmatively stating that "The Department may continue to rely on agency guidance documents

for purposes, including evidentiary purposes that are otherwise lawful and consistent with the Federal Rules of Evidence, that do not treat such documents as creating by themselves binding requirements that do not already exist by statute or regulation."[xxi]

Perhaps more importantly, the JM sets forth "specific, but not exhaustive, illustrations of appropriate uses of guidance documents."[xxii] The legitimate uses of agency guidance documents listed in § 1.20-200 include, but are not limited to:

· *Establishing Scienter, Notice, Knowledge, and Mens Rea*. For example, Department attorneys can use a party's knowledge of a guidance document to establish that the party knew about the applicable, binding law, or that the party tried to craft a false claim to appear consistent with applicable law or guidance;[xxiii]

·*Establishing Professional, Industry, or Government Standards*. The JM explicitly cites examples from healthcare fraud scenarios, including (1) a physician prescribing opioids "in excess of the CDC Guideline for Prescribing Opioids for Chronic Pain" as acceptable evidence that the "opioids [were] dispensed without any 'legitimate medical purpose' and outside 'the usual course of [] professional practice,' . . . in violation of the Controlled Substances Act;" and (2) the use of guidance documents as "relevant evidence of violations of requirements that procedures billed to Medicare or Medicaid be medically 'reasonable and necessary;'"[xxiv] and

· *Establishing a Party's Compliance with Guidance*. For example, in the healthcare space, the Department can use guidance documents to establish falsity, materiality, and scienter, "when a provider falsely certifies compliance with a guidance document, and the certification is material to an agency's payment decision."[xxv]

To the extent that the Brand Memo's broadly worded prohibition on the use of agency guidance in affirmative civil cases was ambiguous, the JM provisions provided detailed examples of what the Department considers – or considered at the time of their adoption – to be acceptable uses of these documents. Many would argue that the JM provisions themselves were a retreat from some of the broader language in the Brand Memo due to their expanded, more detailed list of situations in which the Department's use of agency guidance documents would be appropriate.

The Garland Memo's Potential Impact

It will be interesting to see the revisions, if any, the Department makes to § 1.20-000 of the JM pursuant to the Garland Memo's mandate, and whether they are accompanied by any noticeable shifts in policy from the Department of Health and Human Services. The General Principles articulated in § 1.20-100 seem consistent with those of the Garland Memo as it relates to the use of agency guidance documents in civil enforcement actions. The JM provides specific examples of appropriate uses of agency guidance documents, particularly in healthcare fraud cases, that appear in line with the Garland Memo's general statement that "To the extent guidance documents are relevant to claims or defenses in litigation, Department attorneys are free to cite or rely on such documents as appropriate."[xxvi] Indeed, § 1.20-000's statement that it supersedes prior memoranda on agency guidance indicates that the Department already had abrogated any broader language contained in the Brand Memo by December 2018.

Although a revised § 1.20-000 seems unlikely to loosen any of the limitations on the use of agency guidance documents already adopted by the Garland Memo, it is conceivable that it will expand the list of examples of their acceptable use. This is particularly true should divisions within the Department seize this opportunity to address arguments parties have made invoking the Brand Memo as an obstacle to pending DOJ civil investigations. On the other hand, it is also possible that any revisions will be minor, and will travel largely under the radar. In that case, the Garland Memo will be more of a philosophical reassessment than a substantive alteration of established DOJ policy. This scenario would further formalize what has been written Department policy since December 2018, and arguably returns the Department to where it was before the Brand Memo was ever written.

Conclusion

The Garland Memo reaffirms that agency guidance documents are not legally binding and cannot, in and of themselves, form the basis for FCA violations. It also clarifies that the Department can use such documents as evidence establishing knowledge and intent, governing legal or industry standards, or other elements of a fraud case. Healthcare entities and their counsel should carefully review any agency guidance documents relevant to a pending government investigation and consider how the Department may plan to use such materials given the situations discussed in JM § 1.20-200. Considering these examples will help parties determine whether the Department may be using subregulatory guidance appropriately, or overstepping its own stated boundaries.

Footnotes

1 Memorandum from Attorney General Merrick B. Garland to Heads of All Department Components (July 1, 2021), *available at* https://www.justice.gov/opa/page/file/1408606/download.

2 *Id.* at 1.

3 Memorandum from Attorney General Jefferson B. Sessions to All Components (Nov. 16, 2017), *available at* https://www.justice.gov/opa/press-release/file/1012271/download.

4 Memorandum from Associate Attorney General Rachel Brand to Heads of Civil Litigating Components and United States Attorneys (Jan. 25, 2018), *available at* https://www.justice.gov/file/1028756/download.

5 Press Release, Department of Justice, Justice Department Recovers Over $2.2 Billion from False Claims Act Cases in Fiscal Year 2020 (Jan. 14, 2021), *available at* https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020.

6 The JM "contains publicly available [DOJ] policies and procedures." JM § 1-1.100. It is prepared and maintained by DOJ leadership and revised periodically as coordinated by the Executive Office of United States Attorneys (EOUSA). *See* JM § 1-1.200. The JM was previously known as the United States Attorneys' Manual, and was renamed in 2018 after a comprehensive revision. The Department adopted a new provision of the JM, § 1-20.000, in December 2018 shortly after it released the majority of the other comprehensive revisions.

7 Sessions Memo at 1.

8 *Id.* at 1-2. Although the Sessions Memo merits brief mention as the foundation for DOJ's overall limitations on the use of guidance documents, the majority of this article focuses on the Brand Memo as the source of this more restrictive policy, as the Brand Memo specifically addressed the use of agency guidance documents in litigation that is discussed here.

9 Brand Memo at 1.

10 *Id.* at 2.

11 *Id.* at 2.

12 *New DOJ Memo Will Make Waves in Fraud Cases*, Law360 (Jan. 29, 2018), https://www.law360.com/articles/1006854/new-doj-memo-will-make-waves-in-fraud-cases.

13 Memorandum from Attorney General Merrick B. Garland to Heads of Civil Litigating Components and United States Attorneys (Apr. 16, 2021), *available at* https://www.justice.gov/ag/page/file/1387481/download.

14 Garland Memo at 2.

15 *Id.* at 1 (quoting *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 97 (2015) (quoting *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 99 (1995))).

16 *Id.* (quoting *Kisor v. Wilkie*, 139 S. Ct. 2400, 2420 (2019) (plurality opinion) (quoting *Perez*, 575 U.S. at 97)).

17 *Id.*

18 *Id.* at 2 (quoting *Kisor*, 139 S. Ct. at 2420 (plurality opinion)) (internal quotation marks omitted).

19 *Id.* at 2-3 (internal citations omitted).

20 Brand Memo at 2.

21 *See generally* Chris Sabis, *The Brand Memo is Dead*, Sherrard Roe Voigt & Harbison, PLC (Feb. 21, 2020), *available at* https://srvhlaw.com/government-compliance-investigation/the-brand-memo-is-dead/.

22 Garland Memo at 2.

23 JM § 1-20.000 (emphasis added).

24 Garland Memo at 2.

25 *See* Sabis, *supra* n. 21.

26 JM § 1.20-100.

27 *Id.*

28 JM § 1.20-200.

29 *See* JM § 1.20-201.

30 *See* JM § 1.20-202 (internal citation omitted).

31 *See* JM § 1.20-204 (internal citation omitted).

32 Garland Memo at 3.

About the Author

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