

# THE NATIONAL LAW REVIEW

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## DOJ Updates its Justice Manual to Include Section Limiting Use of Guidance Documents in Litigation

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Nearly one year ago, on January 25, 2018, the Department of Justice's (DOJ) Regulatory Reform Task Force issued a memorandum entitled "[Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases.](#)" Many refer to this memorandum as the "Brand Memo" because it was authored by Associate Attorney General Rachel Brand. The Brand Memo implemented the [prohibition previously issued by U.S. Attorney General Jeff Sessions in November 2017](#) against, in part, DOJ using guidance documents issued by other agencies "to create binding standards by which [DOJ] will determine compliance with existing statutory or regulatory requirements" (the "Sessions Memo").

The Brand Memo explicitly prohibits DOJ from using its enforcement authority to "effectively convert agency guidance documents into binding rules" and from using "noncompliance with guidance documents as a basis for proving violations of applicable law...." By its own terms, the Brand Memo explicitly applied, in part, to all future False Claims Act (FCA) cases brought by DOJ, as well as those pending as of the date of the Brand Memo (to the extent practicable).

Many in the FCA defense bar - including those of us who have handled cases and investigations where the conduct at issue allegedly implicated an Advisory Opinion issued by the Office of Inspector General for the Department of Health and Human Services, CMS Transmittal, or other agency guidance documents - were excited by this development and intrigued to see whether and how DOJ would put it into practice. We finally have some insight into DOJ's views on this issue. Effective December 2018, DOJ added Title 1-20.000 to its Justice Manual (the Manual): "[Limitation on Use of Guidance Documents in Litigation.](#)" We have summarized the relevant language of this Title below.

Title 1-20.000 starts with an introduction, which reiterates the Brand Memo teaching that "[c]riminal and civil enforcement actions brought by [DOJ] 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." Accordingly, the Manual instructs that DOJ "should not treat a party's noncompliance with a guidance document as itself a violation of applicable statutes or regulations[,but instead] establish a violation by reference to statutes and regulations."

Likewise, the Manual instructs against "bring[ing] actions based solely on allegations of noncompliance with guidance documents." However, DOJ 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."

The Manual provides a number of examples of appropriate use of guidance documents by DOJ, many of which may



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not ultimately reflect a drastic change in DOJ's current practices:

## **1. Scier, Notice, Knowledge, and Mens Rea**

Where a guidance document describes a relevant statute or regulation, DOJ may use "awareness of the guidance document (or its contents) as evidence that the party had the requisite scier, notice, or knowledge of the law." In some circumstances, DOJ may also use a guidance document (or its contents) to establish *mens rea* (e.g., where a party's deliberate indifference to a guidance document is probative of deliberate indifference to certain statutory or regulatory requirements).

Notably, however, DOJ **may not** treat awareness of a legal interpretation set forth in a guidance document as an admission that the guidance document correctly interprets the binding legal requirements in a statute or regulation.

## **2. Professional or Industry Standards or Practices and Duties, Customs, or Practices for Government Agencies**

DOJ is also permitted to use a guidance document as "probative evidence that a party has satisfied, or failed to satisfy, professional or industry standards or practices relating to applicable statutory or regulatory requirements." This category of guidance documents may be particularly relevant in FCA cases premised on lack of medical necessity, where DOJ (or a relator) argues that a provider's failure to provide services in compliance with a particular National or Local Coverage Determination renders those services medically unnecessary and thus any claims submitted to federal health care programs for those services false for purposes of a FCA claim ([see our previous blog post](#) discussing the use of agency guidance documents in these cases).

As an example of a case in which it would be appropriate to rely on agency guidance documents, DOJ explains, "if a primary care physician writes prescriptions in excess of the CDC Guideline for Prescribing Opioids for Chronic Pain, which contain medical recommendations for primary care physicians, that fact may be offered as evidence that the prescriptions were made and opioids dispensed without any 'legitimate medical purpose' and outside 'the usual course of [ ] professional practice'" in violation of the Controlled Substances Act.

The Manual observes that this same "rationale applies more broadly in the healthcare arena, where guidance documents, like other statements of professional standards such as CMS's Medicare Benefit Policy Manual or Local Coverage Determinations, are relevant evidence of violations of the principal requirement that procedures billed to Medicare or Medicaid be medically 'reasonable and necessary.'" The Manual also explains that such usage of these guidance documents does not give them the force of law "but rather aids in demonstrating that the standards in the relevant statutory and regulatory requirements have been or have not been satisfied."

## **3. Scientific or Technical Processes**

DOJ may cite and use a guidance document reflecting scientific or technical processes that are generally accepted in a particular field to support a claim that a certain action is, or that a factual or expert witness is rendering an opinion that is, consistent or inconsistent with those processes.

## **4. Party's Compliance with Guidance**

DOJ may also cite a guidance document where a party's compliance or noncompliance with the guidance is itself relevant to the claims at issue. "For example, when a provider falsely certifies compliance with a guidance document, and the certification is material to an agency's payment decision, the false certification to obtain a payment may be offered to establish the elements of falsity, materiality, and scier." In this situation, according to the Manual, "the deceit of the false certification is probative, not the binding or nonbinding nature of the guidance." In addition, "when a government contract or provider agreement requires compliance with some agency guidance document, it is the contract—not the agency guidance itself—that makes the agency guidance pertinent and, in these cases, violations of that guidance undertaken with the requisite mental state may expose individuals to liability."

## **5. Legal or Factual Context**

Finally, the Manual permits DOJ to use agency guidance documents to provide relevant legal or factual context in briefs and other filings. For example, DOJ may cite an agency guidance document or manual in the background section of a brief to explain how an agency processes payments.

Because the Manual puts into writing guidance that was issued nearly a year ago in the Brand Memo, it remains to be seen whether the Manual will result in any actual change to DOJ's use of agency guidance documents. Like

many in the FCA defense bar, we will be watching this issue closely. We will also be watching to see if the Manual has any discernible impact on how DOJ conducts its ongoing investigations, selects the FCA filings in which it elects to intervene or decline, or selects the FCA filings it moves to affirmatively dismiss.

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