

## 1-20.000 – LIMITATION ON USE OF GUIDANCE DOCUMENTS IN LITIGATION

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### 1-20.100 – GENERAL PRINCIPLES

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. See [JM 1-19.000](#). Thus, the Department should not treat a party's noncompliance with a guidance document as itself a violation of applicable statutes or regulations. The Department must establish a violation by reference to statutes and regulations. The Department may not bring actions based solely on allegations of noncompliance with guidance documents.

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.

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### 1-20.200 – EXAMPLES

The following examples serve as specific, but not exhaustive, illustrations of appropriate uses of guidance documents.

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### 1-20.201 – SCIENTER, NOTICE, KNOWLEDGE, AND MENS REA

Where a guidance document describes a relevant statute or regulation, the Department may use awareness of the guidance document (or its contents) as evidence that the party had the requisite scienter, notice, or knowledge of the law. Additionally, in some circumstances, the Department may use a guidance document (or its contents) to establish *mens rea*, where for example 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 or certification). Such usage does not give guidance documents the force of law. By contrast, the Department may not treat awareness of a legal interpretation in a guidance document as an admission that the guidance document is a correct interpretation of the binding legal requirements in a statute or regulation.

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## 1-20.202 – PROFESSIONAL OR INDUSTRY STANDARDS OR PRACTICES AND DUTIES, CUSTOMS, OR PRACTICES FOR GOVERNMENT AGENCIES

The Department may 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. For instance, 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,” 21 C.F.R. § 1306.04(a), in violation of the Controlled Substances Act. This 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.” *E.g.*, 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C. § 1396 *et seq.*; 42 C.F.R. § 410.50. Such usage does not give these documents 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.

Similarly, in certain types of government fraud and government insider trading cases, the government sometimes must establish the existence of a duty (such as a duty of confidentiality or a duty to disclose with respect to certain information) and/or a breach of that duty. To do so in such cases, it may rely on agency guidance documents as evidence of the existence of that duty. This rationale exists more broadly in cases where the government must prove a duty, custom, or practice with respect to a government agency. Such reliance on guidance documents does not impart to those guidance documents the force of law any more than use of an internal corporate manual to prove a duty, custom, or practice with respect to a private corporation would impart to that manual the force of law.

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## 1-20.203 – SCIENTIFIC OR TECHNICAL PROCESSES

The Department 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.

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## 1-20.204 – PARTY’S COMPLIANCE WITH GUIDANCE

The Department may cite a guidance document where a party’s compliance, or failure to comply, with the agency 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 scienter. In this example the deceit of the false certification is probative, not the binding or nonbinding nature of the guidance. Similarly, when a company falsely represents to investors or auditors that it has complied with all relevant SEC guidance on a particular issue, the false representation properly may be offered to prove securities fraud. Additionally, 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.

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## 1-20.205 – LEGAL OR FACTUAL CONTEXT

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

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This section fully implements, clarifies, and supersedes prior Department memoranda on this topic.

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[Related Enforcement Actions: Chronological List, 1996 >](#)