ALERT MEMORANDUM

DOJ Revises Justice Manual Sections on False Claims Act Enforcement

September 24, 2026

On Friday, September 18, 2026, the U.S. Department of Justice (DOJ) announced revisions to two Justice Manual sections governing False Claims Act (FCA) enforcement. The revisions narrow DOJ's enforcement approach in two respects. First, DOJ revised Justice Manual § 1-19.000 to reinstate and expand a 2017 policy that limited the use of sub-regulatory guidance documents in enforcement actions, reinforcing the principle that guidance cannot impose legal obligations beyond those established by statute or regulation. Second, DOJ revised Justice Manual § 4-4.111 to mandate that Department attorneys assess "in each case" whether to seek dismissal of *qui tam* actions when the government declines to intervene; allow Department attorneys to revisit that assessment as litigation progresses; and encourage Department attorneys to consider curbing meritless *qui tam* actions (without limitation to those that are facially frivolous or legally defective) when making that assessment.

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The Guidance Document Revisions (JM § 1-19.000)

The revised Justice Manual § 1-19.000 reinstates and expands a 2017 DOJ policy providing that sub-regulatory guidance documents cannot impose new legal obligations on persons outside the Executive Branch unless authorized by statute or regulation.[1] Under the revised policy, DOJ components may not issue guidance that creates binding rights, obligations, or compliance standards on outside parties.[2]

The revisions adopt a new, more detailed definition of "guidance document": "any agency statement of general applicability and future effect that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statute or regulation, other than a substantive action by an agency that promulgates or is expected to promulgate a regulation."[3] The revised definition also carves out four categories of documents that do not qualify as "guidance documents": (1) adjudicatory decisions that do not bind anyone beyond the parties; (2) documents informing the public of the agency's enforcement priorities or prosecutorial discretion; (3) internal directives, training materials, litigation positions, or legal advice provided by the Department; and (4) documents shared with state, local, and tribal law enforcement agencies in order to assist their cooperation with DOJ.[4]

The core enforcement principle, stated in § 1-19.200, is that criminal and civil enforcement actions must be based on violations of applicable statutes and regulations, not on mere noncompliance with guidance.[5] DOJ may not bring enforcement actions based solely on a party's failure to follow guidance documents.[6]

Importantly, the revisions do not eliminate the use of guidance documents altogether. Rather, they specify limited purposes for which guidance may still be used in enforcement proceedings:

Scienter and Notice. DOJ may rely on a party's awareness of a guidance document as evidence of the requisite scienter, notice, or knowledge of the law.[7] However, three limiting principles apply: (1) awareness of guidance does not give the guidance the force of law; (2) guidance does not establish the applicable *mens rea* standard; and (3) a party's awareness of an interpretation of the legal requirements in a statute or regulation that is set forth in guidance documents is not treated as an admission that the interpretation is correct.[8]

Professional or Industry Standards and Duties, Customs, or Practices for Government Agencies. DOJ may use guidance as probative evidence of satisfaction or failure to satisfy professional or industry standards.[9] This rationale applies particularly in the healthcare industry, where guidance documents such as CMS's Medicare Benefit Policy Manual or Local Coverage Determinations may serve as evidence of relevant standards of care.[10] However, such usage does not give these documents the force of law or create a presumption that a guidance document correctly states the relevant standard.[11] Similarly, in government fraud and insider trading cases where the government must establish the existence of a duty or a breach of that duty, DOJ may rely on agency guidance documents as evidence of the duty's existence.[12]

Scientific and Technical Processes. DOJ may use guidance reflecting generally accepted scientific or technical processes to show that a certain action or a witness's opinion is consistent or inconsistent with those processes.[13]

Compliance-Based Claims. Where a party's compliance or failure to comply with guidance is itself

[1] Press Release, U.S. Dep't of Justice, "DOJ Revises Justice Manual to Strengthen False Claims Act Enforcement" (Sept. 18, 2026).
[2] Justice Manual § 1-19.100.
[3] *Id.*
[4] *Id.*
[5] Justice Manual § 1-19.200.
[6] *Id.*
[7] Justice Manual § 1-19.220.
[8] *Id.*
[9] Justice Manual § 1-19.230.
[10] *Id.*
[11] *Id.*
[12] *Id.*
[13] Justice Manual § 1-19.240.

at issue—for example, where a party has falsely certified compliance with a guidance standard—DOJ may cite the guidance to support the enforcement action.[14]

Legal and Factual Context. DOJ may use guidance to provide relevant legal or factual context in filings.[15]

The *Qui Tam* Dismissal Policy Revisions (JM § 4-4.111)

The revised Justice Manual § 4-4.111 provides more opportunities for DOJ to seek dismissal of *qui tam* actions under 31 U.S.C. § 3730(c)(2)(A). The policy directs that, when DOJ declines to intervene in a *qui tam* action, Department attorneys must assess whether seeking dismissal would serve the government's interests.[16] In cases where dismissal is not initially warranted, DOJ should revisit that assessment as litigation progresses.[17]

The revised policy identifies seven non-exhaustive factors for evaluating whether to seek dismissal:[18]

— Curbing meritless *qui tam* actions;

— Preventing parasitic or opportunistic *qui tam* actions that duplicate a pre-existing government investigation;

— Preventing interference with an agency's policies or the administration of its programs;

— Controlling litigation brought on behalf of the United States to protect DOJ's litigation prerogatives;

— Safeguarding classified information and national security interests;

— Preserving government resources where continued litigation costs are likely to exceed the expected recovery; and

— Addressing egregious procedural errors that could frustrate the government's efforts to conduct a proper investigation.

Key Takeaways

— Companies facing FCA exposure should take note that DOJ's revised guidance document policy narrows the bases for enforcement actions. Obligations arising solely from sub-regulatory guidance—rather than from statute, regulation, or contract—are now less likely to support an FCA claim. Companies may wish to reassess their compliance programs in light of this distinction between binding legal obligations and non-binding guidance.

— The permissible uses of guidance documents remain substantial. While guidance can no longer independently support an FCA theory of liability, DOJ retains considerable latitude to use guidance as evidence of scienter, industry standards, and factual context. Companies should not assume that their awareness of applicable guidance is irrelevant to an enforcement proceeding.

— The *qui tam* dismissal policy signals DOJ's intent to exercise greater gatekeeping over relator-driven litigation. Companies that are defendants in declined *qui tam* cases should consider proactively bringing to DOJ's attention meritless aspects of pending *qui tam* suits.

— The emphasis on preserving government resources and curbing meritless suits may create opportunities for defendants to engage with DOJ regarding dismissal, particularly where the action duplicates a prior government investigation, threatens to interfere with agency programs, or imposes litigation costs disproportionate to any potential recovery.

— These developments should be read alongside DOJ's broader enforcement reorganization. Together, they suggest an administration focused on consolidating enforcement authority, prioritizing high-impact cases, and ensuring that FCA enforcement targets clearly established legal obligations.

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[14] Justice Manual § 1-19.250.
[15] Justice Manual § 1-19.260.
[16] Justice Manual § 4-4.111.
[17] *Id.*
[18] *Id.*