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Less Than Meets the Eye? What DOJ's Justice Manual Revisions on Sub-Regulatory Guidance and Qui Tam Dismissals Mean for Healthcare Providers

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Government agency materials, standing alone, can no longer carry a False Claims Act (FCA) case brought by the Department of Justice (DOJ). That is the practical upshot of one of two significant revisions to the Justice Manual announced on September 18, 2026.

The first revision targets cases brought based on sub-regulatory guidance (agency materials like CMS manuals and FAQs) that can no longer, on their own and without incorporation into a contract, form the basis of an FCA case brought by the DOJ. The second revision directs DOJ attorneys to proactively assess dismissal in every declined qui tam case — and to keep reassessing the question of dismissal as relator-led litigation progresses.

Both revisions matter in practice for providers and healthcare organizations, but their impact is more nuanced and, for the reasons stated below, likely less impactful than the headlines suggest. This article takes a practical look at what these changes actually mean for hospitals, physician groups, and the in-house teams that advise them.

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Sub-Regulatory Guidance and the Contractual Hook

The principle behind the first revision is straightforward: the FCA should be used to enforce binding legal obligations — statutes, regulations, and contracts — not agency guidance that avoided the vetting of a notice-and-comment rulemaking. As Associate Attorney General Stanley E. Woodward, Jr. stated, “The Department of Justice should enforce the law, not make law through enforcement.” The revision builds on memoranda issued in November 2017 and January 2018 (the “Sessions Memorandum” and the “Brand Memorandum” respectively) and is constrained by the contractual structures that pervade healthcare provider agreements. As explained below, its reach may be narrower in practice than it first appears.

A significant number of healthcare FCA cases rely on sub-regulatory materials — CMS manuals, FAQs, OIG advisory opinions, local coverage determinations (LCDs), and coverage policies — to establish the “falsity” element. Under the revised policy, DOJ will not pursue FCA liability based on those materials alone. However, the revision does permit DOJ to continue using guidance documents in more limited ways: as probative evidence of industry standards or practices, as legal or factual background context in filings, and — critically — as evidence of scienter, including a party’s knowledge of or notice regarding a legal requirement.

Critically, the Justice Manual binds DOJ attorneys, not relators or courts, so relators in non-intervened qui tam cases can still pursue guidance-based falsity theories. That raises a fair question: a relator sues in the government’s name and on the government’s claim, so how can a relator’s reach exceed that of the sovereign it represents? The policy itself will not answer that question — the Justice Manual disclaims creating any enforceable rights, and courts apply the FCA, not DOJ policy. For now, the most practical

check remains DOJ's dismissal authority, discussed below.

The revised policy also preserves three categories of binding obligations: statutes, regulations, and ***contractual requirements***. In healthcare, that third category — the contractual hook — is significant, and it limits the revision's practical effect more than may be immediately apparent.

Medicare provider agreements, Medicare Advantage contracts, and managed care contracts routinely incorporate CMS manuals and other sub-regulatory materials by reference. Once that happens, the guidance becomes a *contractual* obligation. The revised Justice Manual itself confirms this at Section 1-19.250, stating that “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.” It further provides that “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” — because “the deceit of the false certification is probative, not the binding or nonbinding nature of the guidance.”

The guidance revision therefore matters most where a theory rests solely on freestanding agency guidance that exists outside any contractual or certification framework. Defense counsel should focus not just on *whether* the relator relies on sub-regulatory guidance, but on *how* that guidance connects to the defendant's obligations.

Dismissal of Declined Qui Tams

The second revision directs DOJ attorneys to assess dismissal under 31 U.S.C. § 3730(c)(2)(A) in every declined qui tam case and to continue reassessing as the litigation progresses. The factors DOJ will weigh

include curbing meritless qui tams, preventing parasitic or duplicative actions, preventing interference with agency programs, controlling litigation brought on behalf of the United States, and preserving government resources. DOJ attorneys may also cite the public disclosure bar, the first-to-file bar, and Rule 9(b), and if the relevant agency does not support the relator's pursuit of the matter, it may recommend dismissal. This dismissal push relates back to 2018's leaked "Granston Memorandum," and, while real, it is likely to be modest in scale.

The legal authority for this position is established, as the Supreme Court confirmed in *United States ex rel. Polansky v. Executive Health Resources, Inc.*, 599 U.S. 419 (2023), that DOJ can dismiss qui tam actions even after initially declining to intervene.

When the January 2018 Granston Memorandum directed DOJ attorneys to consider dismissals, approximately 600–700 new qui tam complaints were being filed annually. Before the Granston Memo, DOJ moved to dismiss only one to two qui tam cases per year. In the two years following the Granston Memorandum, the DOJ moved to dismiss at least 50 qui tam actions. While the previous administration averaged six dismissals per year, the pace has accelerated to 25 dismissals in 2025 under the current administration (an uptick that was called out in an April 2026 letter from Senator Charles E. Grassley).

Two textual changes suggest the current revision may carry more force. First, the prior Justice Manual offered dismissal as something DOJ attorneys *should* consider, while the new version says attorneys "will" assess whether dismissal is warranted, converting discretion into a mandatory evaluation. Second, the old policy targeted qui tams that lacked merit on their face, while the new version drops that qualifier, opening the door to dismissal of cases whose weaknesses emerge only after factual development.

Still, even at the accelerated pace, 25 dismissals against 1,297 filings in Fiscal Year 2025 is less than 2%, and hardly cause for complacency given that FCA recoveries hit a record \$6.8 billion in the same fiscal year.

Implications for Materiality

Materiality under *Universal Health Services, Inc. v. United States ex rel. Escobar*, 579 U.S. 176 (2016), is a “demanding” standard. It turns on the paying agency’s conduct, not DOJ’s enforcement policy. The strongest evidence is whether the relevant government agency continued paying despite knowing of the alleged noncompliance. Defendants may cite DOJ’s position as corroboration that guidance-only deviations are not the kind of violations the government treats as payment-critical, but it is a supporting point, not a standalone defense. And where a provider agreement or certification incorporates the guidance, the Justice Manual would support (rather than undercut) a false certification theory.

The Scier Element

After *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739 (2023), scier turns on what the defendant *subjectively* knew or believed. Agency guidance that put a provider on notice of a regulatory expectation remains relevant to that inquiry, but a published manual standing alone — without evidence that the defendant read it, understood it, or believed its claims violated it — will not suffice.

This distinction matters for the growing wave of data-mined qui tams. As we discussed in our [recent article on AI-assisted data mining and the FCA](#), data-miner relators typically lack access to internal evidence of what the defendant actually knew. That gap makes data-mined qui tam actions particularly vulnerable on the scier element.

Practical Steps for Healthcare Providers and In-House Counsel

For hospital systems, physician groups, post-acute providers, and their in-house legal and compliance teams, these developments call for action on several fronts:

- **Audit provider agreements for the contractual hook.** Determine whether the sub-regulatory guidance at issue in any pending matter has been incorporated into a provider agreement, managed care contract, or compliance certification. If it has, the obligation is contractual and the guidance revision does not help.
- **Recalibrate compliance programs.** Distinguish between guidance that creates a binding obligation through a contractual or regulatory pathway and guidance that is purely advisory. Document the analysis, as the documentation itself becomes evidence of good-faith compliance.
- **Revisit materiality arguments.** Pair DOJ's position on freestanding guidance with evidence of the paying agency's own conduct, such as continued payment despite knowledge of the alleged noncompliance, under *Escobar*.
- **Calibrate defenses to new legal and DOJ-policy changes.** The changing FCA landscape — from the origination of data-centered cases to changes in law and DOJ policy — has materially altered the viability of certain defenses. But it has, at the same time, birthed new opportunities. Focus on the ability of a relator to allege scienter and the complaint's focus, if any, on sub-regulatory guidance. And where the relevant agency guidance does not support the relator's theory, raise that with the U.S. Attorney's Office or DOJ's Fraud Section throughout the defense of the case.
- **Monitor the Article II and political landscape.** The Take Care and Vesting Clause arguments remain live after *Zafirov's* remand, and ongoing congressional interest in FCA enforcement adds further uncertainty. As we discussed in our

earlier coverage of the *Zafirov* decision, the broader Article II fight is far from over.

Conclusion

These revisions create real opportunities for healthcare FCA defendants, but their value depends on understanding where they help and where the contractual and certification structures and realities of healthcare agreements limit their reach.

Akerman's healthcare team will continue to monitor these developments and their impact on healthcare FCA enforcement.

This information is intended to inform firm clients and friends about legal developments, including recent decisions of various courts and administrative bodies. Nothing in this Practice Update should be construed as legal advice or a legal opinion, and readers should not act upon the information contained in this Practice Update without seeking the advice of legal counsel. Prior results do not guarantee a similar outcome.