



FEDERAL CIVIL ENFORCEMENT

Expert Analysis

Does Violating Medicare Regulatory Guidance Still Create FCA Liability?

The failure to follow federal regulations has been a recurring feature of fraud enforcement actions by the U.S. Department of Justice (DOJ) under the False Claims Act (FCA), which imposes treble damages and onerous penalties on defendants who fraudulently receive federal monies. The imposition of such severe penalties for regulatory non-compliance can be especially onerous given the complexity of the regulatory regimes facing many government contractors.

In January 2018, health care entities and other government contractors saw the promise of some relief when the DOJ Regulatory Reform Task Force issued the “Brand Memo,” a new policy that prohibited DOJ civil attorneys from using noncompliance with regulatory guidance documents—which do not go through the notice-and-comment rulemaking process—to prove violations of law in affirmative civil enforcement actions, including FCA actions. The Brand Memo promised to curtail the frequency of regulatory violations being bootstrapped into punishing FCA cases.

A year and a half later, we can assess how that policy has begun to manifest itself. The early results—in the forms of updates to the DOJ manual



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and recent court decisions—suggest that exceptions to the Brand Memo’s general policy may often swallow the rule in FCA cases. And while the principles outlined in the rule can assist entities seeking to head off a DOJ complaint during the investigative stage of

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a case, they have proven less helpful to defendants once formal litigation is underway.

At the same time, the Supreme Court’s recent decision this month in *Azar v. Allina Health Services* suggests a new line of attack on the aggressive use of regulatory guidance in FCA

cases: challenges not to the appropriateness of looking to guidance documents in a particular action, but to the very validity of the guidance itself.

The DOJ’s Justice Manual Update

In December 2018, the DOJ amended its Justice Manual to reflect the Brand Memo’s guidance, and extended the policy’s prohibitions to criminal as well as civil enforcement cases. The new §1-20.000, “Limitation on Use of Guidance Documents in Litigation,” explains that DOJ attorneys “may not bring actions based solely on allegations of noncompliance with guidance documents.” But §1-20.000 still carves out important exceptions—described as “appropriate uses of guidance documents”—that are significant to FCA cases.

One Justice Manual exception permits the use of guidance documents “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.” The Manual notes that this exception may have a broad application in the health care sector, including where guidance documents may be relevant to show an agency’s views on professional standards—such as what procedures billed to Medicare and Medicaid are “reasonable and necessary,” an issue often at the center of FCA cases.

The Justice Manual also makes an exception where the party’s compliance with agency guidance is itself

relevant to the claims at issue, such as an FCA action alleging that a party falsely certified compliance with a guidance document, which certification is alleged to have been material to payment. This too may have broad application in FCA cases, where the Government contract at issue may include a catch-all certification requiring compliance with agency guidance.

The Brand Memo in FCA Litigation

In the wake of the Brand Memo's issuance, some FCA defendants have attempted to use its policy to challenge litigation. To date, however, the exceptions have again taken center stage.

In *United States ex rel. Polukoff v. St. Mark's Hospital*, 895 F.3d 730 (10th Cir. 2018), an FCA case involving allegations that claims were false because the billed procedures were not "reasonable and necessary," the Tenth Circuit reversed the district court decision dismissing the case for failure to identify any objectively false claims where there was no binding regulation defining the medical necessity of the procedures at issue. The Tenth Circuit held that a certification that a procedure is "reasonable and necessary" is false under the FCA if the procedure is not reasonable and necessary under CMS's non-binding Medicare Program Integrity Manual (MPIM). Although the decision did not expressly refer to the Brand Memo or its exceptions (and defendant's petition for rehearing en banc, including on the basis that the ruling went against the Brand Memo's directive, was denied without opinion), this falls squarely within one of the "appropriate uses" described in the Justice Manual.

Similarly, in *United States v. Adams, et al.*, 371 F. Supp. 3d 1195 (N.D. Ga. 2019), another FCA case involving allegations that claims were false because the treatment provided was not "reasonable and necessary," defendants sought dismissal on the grounds that (among others) reliance on non-binding guidance in the MPIM was prohibited by the Brand Memo.

Again, however, the court rejected this argument, noting that the non-binding guidance at issue was used to determine whether the treatment at issue was "reasonable and necessary"—again, an appropriate use per DOJ's policy.

Adams also raises an additional potential hurdle for defendants seeking to use the Brand Memo as a defense in litigation: It held that the Brand Memo itself could not be used as a basis to dismiss the action, because the memo specifically disclaims that it "is not intended to, does not, and may not be relied upon to, create any rights, substantive or procedural, enforceable at law by any party in any matter civil or criminal." In other words, the memo itself is guidance without the force and effect of law.

Another potential impediment to using the Brand Memo in FCA actions is that, on its face, the memo's prohibition applies only to DOJ-led actions, not to actions brought by relators in which the DOJ declines to intervene. Yet defendants may still have room to argue that the memo's prohibition should also apply to relators, who stand in the shoes of the DOJ. And in any event, defendants may be able to argue that the DOJ should seek to dismiss non-intervened cases that rely on agency guidance (at least where such reliance does not fall within the Justice Manual's "appropriate uses"), under the policy articulated in the DOJ's Granston Memo.

'Allina' and the Future of Guidance Documents

In the midst of these developments of DOJ policy, the Supreme Court's June 3, 2019 decision in *Azar v. Allina Health Services*, 587 U.S. __ (2019), may provide a new path for health care litigants to resist the reliance on agency guidance in FCA cases.

In *Allina*, a hospital group challenged CMS's rule regarding the calculation of hospital reimbursements under Medicare. By issuing the rule through a guidance document instead of a notice-and-comment rulemaking

process, Allina argued that CMS violated §1395hh(a)(2) of the Medicare statute, which provides that "[n]o rule, requirement or other statement of policy ... that establishes or changes a substantive legal standard governing ... payment for [Medicare] services ... shall take effect unless it is promulgated ... by regulation." The Government countered that §1395hh(a)(2) does not apply to "interpretive rules," which are expressly carved out of notice-and-comment rulemaking under a different statute, the Administrative Procedure Act (APA).

In a 7 to 1 decision, the Supreme Court ruled that unlike the APA, §1395hh(a)(2) does not exempt "interpretive rules" from notice-and-comment rulemaking. Thus, because CMS did not abide by the Medicare Act's required notice-and-comment procedure, the Court held that the 2014 reimbursement policy could not be enforced. In reaching its decision, the Court rejected the Government's argument that undertaking a notice-and-comment process for other interpretive rules—like those in the voluminous Medicare Provider Reimbursement Manual, which the court described as roughly 6,000 pages long—would be prohibitively burdensome.

Allina may have opened a door that recent Brand Memo developments seemed to close. How exactly these principles apply to CMS guidance in FCA cases—such as the MPIM and other guidance documents used to evaluate whether procedures are "reasonable and necessary"—remains to be seen. But *Allina*'s rationale offers a potential avenue for FCA defendants to argue that the DOJ's or relators' use of agency guidance documents in a particular case, even if "appropriate" under the Justice Manual exceptions, runs afoul of the Medicare Act's required notice-and-comment process for interpretive rules.