LAW360 | Healthcare Authority

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FCA Bar Debates Impact Of Updated Justice Manual

By **Dan McKay**

Law360 (September 29, 2026, 12:39 PM EDT) -- Recent changes to the U.S. Department of Justice's approach to the False Claims Act are set to have an outsize impact on the healthcare industry.

But just what that impact will be in practice as President Donald Trump's administration pursues a high-profile anti-fraud agenda is a subject of disagreement in the FCA bar.

The debate centers on updates to the Justice Manual instructing government attorneys to exercise their authority to dismiss "parasitic" whistleblower suits. The updates also direct prosecutors to avoid pursuing FCA cases rooted in violations of nonbinding guidance rather than federal law or regulations.

While the ramifications are not yet clear, the medical industry is distinctly exposed to whatever consequences emerge, experts say, given the massive amounts of government spending in the sector and the prevalence of complex guidance on sometimes obscure nuances of healthcare law and policy.

The revisions also come in a period of record-breaking qui tam cases and under an administration that has prioritized the pursuit of Medicaid and Medicare fraud, including through data-driven cases.

"I think it's a certainty that there will be a disproportionate impact on healthcare versus other contracted lines," said Paul Werner, an FCA defense attorney and member of Buttaci Leardi & Werner LLC.

Healthcare is "where we see the most False Claims Act enforcement in general. It's certainly where we see the most qui tam False Claims Act enforcement, and it is the industry where this subregulatory guidance tends to be the most relevant," he said.

The anti-fraud law generated a record-breaking haul of $6.9 billion in settlements and judgments last year from contractors accused of improperly billing the government. At $5.7 billion, healthcare fraud made up the bulk of the recovery.

Healthcare is also a frequent target of an emerging FCA trend: qui tam suits pursued by "data miners" who analyze large datasets to spot anomalies and flag potential fraud.

The Justice Manual changes come amid government efforts to exercise some quality control over the rising number of data-mining suits.

The "DOJ is sort of casting a jaundiced eye" at many data-mining suits, said Alexander Owens, a partner at Pietragallo Gordon Alfano Bosick & Raspanti LLP, where he represents whistleblowers and defendants.

"I could see them using this guidance maybe a little bit more liberally in that area," he said.

More broadly, however, FCA attorneys sharply disagree over the practical impact of the policy changes.

Renée Brooker, a former prosecutor who now represents whistleblowers as a partner at Tycko & Zavareei LLP, said the Justice Manual changes don't alter the underlying law. The government has always had authority to dismiss meritless complaints, she said, and whistleblowers are a powerful ally in the DOJ's fight against fraud.

"Nothing about that has changed. The sky is not falling," Brooker told Law360 Healthcare Authority.

Jaime L.M. Jones, a Sidley Austin LLP partner who defends healthcare companies, said she views the revisions as "major shifts" that limit how the DOJ may use guidance in litigation.

They also commit prosecutors to formally reviewing every qui tam complaint for potential dismissal at an early stage as well as through the progress of the case, she said.

FCA relators "should beware," Jones said. "The department is going to scrutinize every one of their complaints, and if it determines that the allegations are meritless or not supported by the relevant regulatory agency, the department may short-circuit the case."

Updated Standards

Earlier this month, DOJ officials described the manual changes as clearer standards that will promote fair, effective enforcement of the FCA.

The anti-fraud law allows whistleblowers, such as insiders or data miners, to sue on the government's behalf and share in the recovery. The DOJ has the option of joining the case, monitoring it while the whistleblower takes the lead or seeking its dismissal.

The changes center on two aspects of FCA prosecutions: the role of agencies' guidance and the DOJ's authority to dismiss whistleblower cases.

"These updates reflect the department's commitment to fair notice, transparent enforcement, and the rule of law," Associate Attorney General Stanley E. Woodward Jr. said in an announcement Sept. 18.

The first revision rolls back changes made by former President Joe Biden's administration that emphasized the value of subregulatory guidance, the documents issued by agencies outlining their thinking on how to comply with federal laws and regulations.

The revision instructs DOJ attorneys to focus enforcement efforts on violations of actual legal obligations, not guidance.

While directions outlined in guidance can still play a role in case decision-making, according to the manual, they are not the building blocks of an FCA violation itself, absent other factors. A contractor that pledges to abide by guidance documents as part of its federal contract, for example, could face liability for falsely certifying its compliance with the guidance.

A contractor's awareness of guidance documents might also help prove the defendant knew it was violating the law.

The second revision directs government attorneys to evaluate whether to dismiss a complaint at the same time they decide whether to intervene in a case. But even if they don't dismiss the complaint at that point, they may revisit the decision as the case progresses.

"Dismissal will not be warranted in every declined case," the manual states.

"While it is important to be judicious in utilizing [the dismissal authority], such dismissals also provide an important tool to advance the government's interests, preserve limited resources, and avoid adverse precedent," the manual said.

The Stakes for Healthcare

Big or small, the impact of the changes is likely to be felt in healthcare primarily because of the large share of FCA qui tam cases targeting medical providers or others in the sector, experts said.

About 460 new qui tam complaints filed last year made claims against companies billing the U.S. Department of Health and Human Services, compared with just over 40 whistleblower complaints involving U.S. Department of Defense contractors.

"Obviously, [the policy update] is not just limited to healthcare, but that is often where you're going to see it," Owens of Pietragallo said.

Werner of Buttaci Leardi called the changes "as close to a healthcare-specific set of guidance as you can imagine without them explicitly stating so."

Even so, the Trump administration's aggressive approach to healthcare fraud suggests medical defendants shouldn't count on fewer prosecutions and more dismissals, experts said.

Augustine Ripa, a partner at Whistleblower Law Collaborative LLC and former senior counsel for healthcare fraud at the DOJ, said the department's FCA approach already demonstrated an understanding that subregulatory guidance documents alone don't create binding legal obligations.

And the DOJ and HHS, he said, have signaled a willingness to take on complex healthcare cases.

"They're as committed to fighting healthcare fraud as I've ever seen. I don't see any letting up on the gas pedal when it comes to fighting healthcare fraud," said Ripa, who left the DOJ in August.

Brenna Jenny, a deputy assistant U.S. attorney general, said last year that an interagency working group's enforcement priorities included drug pricing, Medicare Advantage and network adequacy requirements for health plans.

Debate Over Impact

Jones, global co-leader of Sidley's healthcare practice, is among the FCA experts who expects the revisions to have significant consequences.

Defendants already have been asking the DOJ more often to review qui tams, she said, and the agency isn't afraid to exercise its dismissal authority.

"Requests for dismissal historically have received only cursory attention, and I take DOJ at its word now that this will no longer be the case," Jones said.

The guidance language also breaks with the DOJ's approach to guidance before Trump returned to office last year.

"This DOJ has erased a prior willingness to suggest that subregulatory agency guidance deserves deference and narrowly limited how the department may use guidance in litigation," Jones said.

Taken together, the Justice Manual changes "will have a significant effect on the enforcement landscape," she said.

Brooker of Tycko & Zavareei said she doesn't foresee much of a practical impact. Prosecutorial discretion, she said, is nothing new.

Just as defense lawyers may seek DOJ dismissal at every stage of a case, the relators bar "will be doing the same on the flip side," explaining to government counsel what's at stake, the merits of the case and the potential recovery, she said.

"The government is not going to deprive itself of the successes of the private plaintiffs bar to recover sizable monies on behalf of the government," Brooker said. "And this administration has been vocal about the abuses in the Medicaid program as well as many other programs."

Erica Blachman Hitchings, a partner at Whistleblower Law Collaborative and former FCA attorney for the DOJ, expressed a similar view.

"When we look back, I doubt it will be a sea change," she said.

Owens said the updated Justice Manual may give the defense some new "sound bites" to cite when lobbying prosecutors for dismissal. But the practical impact will depend on the underlying case, he said.

The DOJ "doesn't change the Justice Manual for no reason, so there is some signal here," Owens said. "Is it going to change the whole enforcement landscape? I don't think so."

--Editing by Aaron Pelc.

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