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False Claims Act Spotlight (1 of 3): Sub-Regulatory Guidance Subjugated No More in FCA Enforcement Actions

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The False Claims Act ("FCA") is a punitive civil statute that acts as the federal government's primary tool for combatting fraud in government health care programs, such as Medicare, Medicaid, and Tricare. In fiscal year 2020 alone, the Department of Justice ("DOJ") obtained more than $2.2 billion in FCA settlements and judgments (not including potential recoveries from pending cases or ongoing negotiations); the largest of these many recoveries came in the health care and pharmaceutical sectors, with several recoveries totaling over $100 million each.

Given the frequency of FCA application in the health care context, and despite this vast body of law and commentary spanning more than a century and a half since the FCA's inception, novel applications and interpretations of the law still arise, especially as the health care industry evolves and new modes of payment and care delivery come to the fore. In 2021, the FCA has once again been the focal point of government attention, with a DOJ memorandum, proposed federal legislation, and recent federal court decisions adding new context and authority to guide future applications of the law.

This post is the first of three covering recent FCA updates, and in it we discuss the re-emergence of federal guidance as a tool in the belt of the DOJ in enforcing the FCA.

FCA in Brief

Among other provisions, the FCA prohibits and penalizes with treble damages any individual or entity that "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or that makes, or causes to be made, false records or statements material to a false claim. 31 U.S.C. 3729 et seq. It is similarly illegal under the FCA to knowingly either retain payments from the federal government that are not properly due to the recipient or to withhold payments owed to the federal government, and for conspiring to do any of the foregoing. Id. Claims under the FCA can be brought by the government or via individual "relators" with independent knowledge of violations via *qui tam* suits, with relators that prevail in such suits eligible to receive up to 30 percent of the recovery award.

Brand New Restrictions Under Trump

In July 2021, Attorney General Merrick Garland rescinded two memoranda (those issued by former Associate Attorney General Brand and former Attorney General Sessions) by issuing his own memorandum (the "Garland Memo") aimed at restoring the utility of sub-regulatory guidance to aid the DOJ in fulfilling its prosecutorial duties vis-a-vis the FCA. Under the Trump Administration, the Brand and Sessions memos and their progeny (DOJ Manual Section 1-20.000) restricted how DOJ attorneys could use executive branch agency sub-regulatory guidance, such as Medicare Manuals, advisory opinions, and guidance documents, in the process of building FCA cases. The Brand Memo, issued in January 2018, which cited the November 2017 Sessions Memo's prohibition on DOJ's use of its own sub-regulatory guidance in bringing enforcement actions, largely barred DOJ enforcement actions premised on violations of requirements set forth in other agencies' sub-regulatory guidance.

The Brand memo postulated that because sub-regulatory guidance "cannot create binding requirements that do not already exist by statute or regulation," DOJ attorneys cannot use sub-regulatory guidance "to coerce regulated parties into taking any action or refraining from taking any action beyond what is required by terms of the applicable statute or lawful regulation." Put bluntly, the Brand Memo instructed that the DOJ "may not use noncompliance with guidance documents as a basis for proving violations of applicable law in [affirmative civil enforcement] cases." A year after the Brand Memo, the DOJ Manual implemented the Memo's core provisions but somewhat relaxed the Memo's rigid prohibitions by prescribing five areas in which sub-regulator guidance could be used to establish: (1) scienter, notice, knowledge, and mens rea; (2) professional or industry standards or practices and duties, customs, or practices for government agencies; (3) scientific or technical processes; (4) party's compliance with guidance; and (5) legal or factual context. Notably, use of guidance as binding legal obligations or programmatic requirements were not included in this permissive list.

Thus, the practical legal effect of the Brand Memo was that, during the period in which it was operative, federal health care program policy communicated and implemented through guidance without going through notice-and-comment rulemaking procedures would be deemed as "voluntary standards" with which industry actors *may* comply. However, non-compliance with standards set by such guidance would not necessarily result in an FCA violation or prompt an enforcement action, although guidance and knowledge thereof could still be used as evidence to prove elements of an FCA offense.

New Administration, New Memo

Ironically, the Brand Memo constraining the use of sub-regulatory guidance was issued via…guidance, making it relatively simple to jettison at the change of presidential administration. In January 2021, President Biden issued Executive Order 13992, "Revocation of Certain Executive Orders Concerning Federal Regulation," which instructed agencies to remove rules and policies that restricted executive branch agencies' authority and aimed to equip such agencies with flexibility for "robust regulatory action to address national priorities." Accordingly, the Garland Memo and the following DOJ interim final rule implementing EO 13992, claiming that the Brand Memo and its progeny were "overly restrictive," tactfully loosened the shackles placed by the Trump Administration on the DOJ's use of sub-regulatory guidance.

The Garland Memo begins by quoting from the who's who of Supreme Court precedent opining on the role of sub-regulatory guidance and limitations thereon, whereas the Brand and Sessions Memos omitted any such citations. After noting that guidance does not "have the force and effect of law" (quoting Perez v. Mortgage Bankers Ass 'n, 575 U.S. 92, 97 (2015)), but conceding that guidance documents provide utility by informing the public of an agency's conception of binding statutes and rules (Kisor v. Wilkie, 139 S. Ct. 2400, 2420 (2019)), the Garland Memo states that the use of guidance promotes "transparency, fairness, and efficiency." Against this backdrop, the Garland Memo proclaims that DOJ attorneys "are free to cite or rely on" guidance documents "[t]o the extent [they] are relevant to claims or defenses in litigation" in "any appropriate and lawful circumstances." Notably, such circumstances include "when a guidance document may be entitled to deference or otherwise carry persuasive weight" regarding the meaning of the legal requirements.

Hello Guidance My Old Friend

The Garland Memo restores to DOJ the flexibility it had prior to the Brand Memo to use sub-regulatory guidance as consistent with applicable law. Attorney General Garland does, however, couch such flexibility within the explicit confines of recent Supreme Court precedent that bounds the role of guidance.

While the return to prior practice is not in itself all that novel, the circumstances under which this return to a pre-Brand era occurs merits recognition. The COVID-19 pandemic has required Congress to pass numerous bills (such as the CARES Act) that aim to combat the debilitating effects of COVID-19 on the United States economy. However, these pieces of legislation have merely created large relief programs without prescribing the requirements or conditions for participation in such programs. Such details have been left to the executive branch agencies responsible for their respective implementation, and agencies have, in turn, promulgated requirements and conditions for participation in such relief programs in the form of sub-regulatory guidance. With hundreds of billions of dollars being hastily granted through relief programs such as the CARES Act Provider Relief Fund, sub-regulatory guidance has recently taken on new importance in program administration. Agencies' ability to promulgate guidance in response to changing conditions during the pandemic has allowed for the flexible operation of such programs. This has been both a blessing and a curse, though. Agencies can react in real time to feedback gathered on program administration by revising guidance documents or issuing new ones, enabling the continuation of necessary broad-spanning relief efforts. Yet, this flexibility has also led to widespread confusion as to which requirements and conditions are operative at any given point in time in the midst of ever-changing guidance documents.

Following the Garland Memo, it is likely that the DOJ will increasingly leverage guidance documents, such as Health and Human Services ("HHS") memoranda, Medicare Manuals and Office of Inspector General advisory opinions, to support FCA enforcement actions in the health care sector. Such practices more closely resemble DOJ's treatment of guidance in years predating the Trump Administration, and are fairly uncontroversial in practice. However, the true test of the Garland Memo's reach will be in the application of its permissive use of guidance to combatting health care fraud related to COVID-19 relief programs.

With a COVID-19 Fraud Task Force now in place to investigate and prosecute such offenses, guidance documents are likely to play an integral role in FCA enforcement actions. The Garland Memo does not mean that failure to comply with these ever-changing and inconsistent requirements and conditions, issued generally "on the fly" by HHS and other regulatory agencies, will necessarily, without more, form the basis for FCA liability. However, it will be up to recipients of COVID relief funds to prove that the guidance did not put them on notice of the requirements attached to receipt or retention of such funds. Recipients of relief funds may come under intense scrutiny for their reckless disregard of guidance that expounded on relief program eligibility conditions, reporting requirements, and circumstances in which relief funds must be returned. Inevitably, enforcement actions in this space will raise questions over which iteration of guidance was effective at any given point in time and whether those under investigation had knowledge or notice of the operative guidance. Of equal importance, though, may be the discretion that DOJ will wield given the chaotic circumstances surrounding COVID and the necessarily rushed nature of the implementation of the relief programs.

Given this new(ish) frontier in FCA enforcement, and tension with the bounds set by Kisor , Perez, and other precedent limiting the agencies' perceived regulatory "lawmaking," the Supreme Court is primed to once again weigh in on the proper role of sub-regulatory guidance. We, and likely most recipients of federal COVID relief funds, will be watching closely.

Upcoming Posts

Stay tuned for parts two and three of this blog series focusing respectively on proposed amendments to the FCA and recent court decisions construing the FCA, to be released in the coming two weeks. The next post will address S.B. 2428, which aims to correct and clarify application of the FCA's materiality requirement in light of the Supreme Court's decision in United Health Services v. United States ex rel. Escobar, 136 S. Ct. 1989 (2016). The third post will address the "objective reasonableness" defense under the FCA endorsed by the 7th Circuit in United States ex rel. Schutte v. SuperValu, Inc., No. 11-cv-3290, 2021 WL 3560894 (7th Cir. Aug. 12, 2021) among other developments in the courts.

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