# Key FCA Developments From 2020 And What To Expect Next

By **George Breen, Erica Bahnsen, and Daniel C. Fundakowski** (February 5, 2021)

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While the U.S. Department of Justice's recoveries decreased substantially, fiscal year 2020 saw the largest total number of new False Claims Act matters brought in a single year. The DOJ initiated new FCA matters at its highest rate since 1994, and the number of DOJ-initiated cases against health care entities more than doubled from fiscal year 2019 to fiscal year 2020, the highest level ever reported.[1]

Qui tam relators filed 672 new cases in fiscal year 2020, an increase over fiscal year 2019 and the fifth highest number of cases in reported history, filing, on average, almost 13 new cases per week, 68% of which were related to the health care and life sciences industries.

More than $2.2 billion was recovered from settlements and judgments in fiscal year 2020, the lowest level since 2008, and almost $1 billion less than fiscal year 2019. Notably, over 80% of recoveries, amounting to almost $1.9 billion, came from the health care and life sciences industries.

Health care-related recoveries focused on cases pursued against drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories and physicians.

The most significant recoveries again came from the pharmaceutical industry and involved allegations of improper patient copay amounts and illegal kickbacks. These recoveries include those related to the opioid crisis, which continues to be a point of emphasis for DOJ enforcement actions.

**The circuit split on the FCA's required falsity standard for clinical judgments may be resolved by the high court.**

While the FCA requires that claims be false or fraudulent, the statute does not define those terms, and a circuit split emerged in 2020 on the appropriate standard for proving falsity in the context of clinical judgments.

On Sept. 9, 2019, the U.S. Court of Appeals for the Eleventh Circuit issued a key decision in U.S. v. AseraCare Inc. concerning the FCA's standard for proving falsity.[2]

The government alleged that AseraCare improperly billed Medicare for hospice benefits provided to individuals who were not properly certified as terminally ill. In adopting an objective falsehood standard, the Eleventh Circuit held that a "mere difference of reasonable opinion between physicians, without more," is insufficient to create a triable issue of fact regarding the FCA's falsity element.

Months after the Eleventh Circuit's AseraCare decision, the U.S. Court of Appeals for the Third Circuit, in U.S. v. Care Alternatives, expressly rejected the objective falsehood requirement.[3] In this factually similar Medicare hospice benefit case, the Third Circuit held that "a difference of medical opinion is enough evidence to create a triable dispute of fact regarding FCA falsity."[4]

The U.S. Court of Appeals for the Ninth Circuit later weighed in on FCA falsity in U.S. v. Gardens Regional Hospital and Medical Center Inc., where it considered whether an objective falsehood is required at the pleading stage to avoid dismissal.[5]

The relator alleged that the hospital falsely certified that patients' inpatient hospitalizations were medically necessary. In reversing the district court's decision that "subjective medical opinions ... cannot be proven to be objectively false," the Ninth Circuit held that the broad language of the FCA "does not distinguish between 'objective' and 'subjective' falsity or carve out an exception for clinical judgments and opinions."[6]

The practical effects of the circuit split and the differing standards are likely to become more apparent in 2021 as courts continue to apply them. Care Alternatives filed a certiorari petition on Sept. 16, 2020, so it remains possible that the U.S. Supreme Court could resolve the circuit split this year.[7]

**Courts continue to grapple with materiality following Escobar.**

The FCA requires that a false record or statement be material to the government's payment decision before liability can attach.

In accordance with the Supreme Court's 2016 decision in Universal Health Services Inc. v. Escobar, the touchstone of materiality is whether the government would have paid the claim in question if it had known of the defendant's noncompliance with an applicable law or regulation.[8] Throughout 2020, courts across the country continued to grapple with the FCA's materiality framework.

In U.S. v. Lawrence Memorial Hospital, the relator alleged that the hospital fabricated patient arrival times associated with certain Centers for Medicare & Medicaid Services pay-for-reporting and pay-for-performance programs.[9]

A key issue in the case was from whose perspective materiality should be judged; the relator argued that materiality should be judged based on the likely impact of the noncompliance on a reasonable person (an objective standard).

In affirming the district court's opinion that the alleged false claims were not material, the U.S. Court of Appeals for the Tenth Circuit held that the proper focus in determining materiality is on the actual reaction of the recipient of the false claim, not on a reasonable person.

Applying that standard, the Tenth Circuit held that CMS' inaction and continued payment of claims, even after CMS was made aware of the alleged noncompliance six years earlier, suggests immateriality.[10] The Supreme Court denied the relator's certiorari petition on Oct. 5, 2020.

In U.S. v. Salus Rehabilitation LLC, the Eleventh Circuit reinstated an $85 million jury verdict — over $255 million after trebling and penalties — on Medicare claims that the district court initially set aside after a month-long jury trial where the judge found that the relator "failed to introduce evidence of materiality and scienter at trial."[11]

The case involved allegations that the nursing home operators artificially inflated Medicare patients' resource utilization group scores by upcoding and ramping to yield increased Medicare payments.[12]

The Eleventh Circuit dismissed the district court's conclusion that the relator's allegations amounted to a handful of paperwork defects, and found that the upcoding and ramping allegations were a "simple and direct theory of fraud" with "plain and obvious materiality [that] went to the heart of the SNFs' ability to obtain reimbursement from Medicare."[13]

Given the Supreme Court's apparent reluctance to take up materiality again in the near term — every certiorari petition on materiality since Escobar has been denied — district courts will continue to be where the key decisions as to how FCA materiality, and the scope of what can be enforced with the FCA, will be made.

**Agencies and courts continue contemplating ramifications of the "substantive legal requirement" concept following the Supreme Court's Allina decision.**

On June 3, 2019, the Supreme Court in Azar v. Allina Health Services held that any Medicare issuance that establishes or changes a substantive legal standard governing Medicare eligibility, benefits or payments for services must go through notice-and-comment rulemaking to be valid.[14]

Since that decision, district courts and agencies have acknowledged Allina's broad impact on FCA litigation, albeit reaching different conclusions on the actual effects as applied in specific instances.

For example, in Agendia Inc. v. Azar and Polansky v. Executive Health Resources Inc., the U.S. District Courts for the Central District of California and the Eastern District of Pennsylvania have thrown out cases on summary judgment where the guidance at issue constituted a substantial legal standard that was not promulgated through notice-and-comment rulemaking. Both decisions are on appeal.[15]

The U.S. District Court for the Northern District of Mississippi, in denying the defendants' motion to dismiss in U.S. v. Mitias Orthopaedics, noted that while it had some skepticism about whether FCA actions would necessarily be subject to Allina, it expressly did "not rule out the possibility that it will eventually agree with [defendants'] interpretation of Allina in this case."[16]

On Dec. 7, 2020, the U.S. Department of Health and Human Services issued its good guidance practices final rule, which limits HHS' ability to issue and rely upon subregulatory guidance documents in enforcement actions, investigations, and audits, including actions relating to coverage and reimbursement for items and services under Medicare and other federal health care programs, and establishes a petition process to challenge guidance.[17]

The effect was swift: On Jan. 8, 2021, HHS released its first formal response to a petition submitted pursuant to the good guidance practices final rule's petition process.[18] HHS agreed to withdraw certain guidance documents that DaVita Inc. challenged as unlawful, as CMS determined that "they impose binding new obligations that are not reflected in duly enacted statutes or regulations lawfully promulgated under them."[19]

Given recent judicial and agency action, there may be new avenues both to challenge and, potentially seek early resolution of FCA cases or investigations premised on allegations of noncompliance with subregulatory guidance not lawfully promulgated. We expect to see additional challenges play out in 2021.

**Courts continue scrutinizing the DOJ's discretion to dismiss qui tam claims**

**following the Granston memorandum.**

Section 3730(c)(2)(A) of the FCA gives DOJ the express authority to seek dismissal of an FCA case, even over the relator's objection, if the relator is provided notice and an opportunity for a hearing.

While that authority has historically been exercised rarely, the DOJ increasingly moved to dismiss cases following release of the Jan. 10, 2018, memorandum authored by Deputy Assistant Attorney General Michael Granston that instructed the DOJ and U.S. Attorney's Office civil litigators to consider dismissal of qui tam actions under Section 3730(c)(2)(A) where it would be in the government's interest to do so, for example, to curb meritless claims, preserve government resources or safeguard classified information.

The DOJ reported that, between Jan. 1, 2018, and Dec. 19, 2019, it sought dismissal of 45 FCA cases.[20] This was roughly the same amount of cases that the DOJ moved to dismiss in the 30 years preceding the Granston memorandum.[21]

However, courts remain divided on what standard to apply when the government exercises that statutory dismissal authority. The DOJ's efforts to dismiss qui tam cases have generally been analyzed under two standards: the U.S. Court of Appeals for the D.C. Circuit's Swift standard and the Ninth Circuit's Sequoia Orange standard.[22]

The Swift standard is the most deferential and provides the government with an unfettered right to dismiss qui tam cases. By contrast, the Sequoia Orange standard applies a rational relation standard that requires the government to show (1) a valid government purpose and (2) a rational relation between dismissal and accomplishment of the purpose before the court can grant the dismissal.

The U.S. Court of Appeals for the Seventh Circuit recently fashioned a new standard for evaluating Section 3730(c)(2)(A) dismissals. In U.S. v. UCB Inc., the DOJ declined to intervene and later sought to dismiss the case after its investigation found the claims lacked sufficient merit to justify the use of government resources. The district court denied the motion to dismiss, holding that the Sequoia Orange standard was not satisfied.[23]

On appeal, the Seventh Circuit declined to adopt Swift or Sequoia Orange, finding the "choice between the competing standards as a false one, based on a misunderstanding of the government's rights and obligations under the False Claims Act."

The Seventh Circuit ultimately held that the FCA requires the DOJ "to intervene as a party before exercising its right to dismiss under § 3730(c)(2)(A)" and therefore construed DOJ's motion to dismiss also as a motion to intervene.

Finding that DOJ had intervened in the action, the Seventh Circuit looked to Federal Rule of Civil Procedure 41(a)(1)(A)(i), which provides that a plaintiff has an absolute right to dismiss an action without prejudice any time "before the opposing party serves either an answer or a motion for summary judgment," and the case was dispensed with on that basis.

While the Seventh Circuit's new standard arguably poses a higher bar than the Swift standard, the court's reasoning indicates that, as a practical matter, the DOJ should have a nearly unfettered right to intervene and dismiss pursuant to Rule 41(a)(1)(A)(i).

Just weeks prior to the Seventh Circuit's decision, the Ninth Circuit, in United States v. Academy Mortgage Corp., refused, on jurisdictional grounds, to invoke the collateral

order doctrine to permit the DOJ to appeal the district court's denial of a motion to dismiss, permitting the case to proceed over the government's objection.[24]

On April 6, 2020, the court denied certiorari on this issue in U.S. v. JPMorgan Chase Bank, where the relator argued that the D.C. Circuit should have required the DOJ to show that the dismissal served a valid governmental purpose, i.e., adopt the Sequoia Orange standard.[25] It remains unclear whether the Supreme Court will weigh in on the circuit split in 2021.

**Other expectations for 2021 include heightened CARES Act enforcement, increased scrutiny on telemedicine and clarifications to physician compensation rules.**

The Coronavirus Aid, Relief and Economic Security Act was signed into law by former President Donald Trump on March 27, 2020, and with $1.8 trillion in direct aid to individuals and businesses, comprises the largest stimulus package in U.S. history.[26]

Under the Trump administration, combating COVID-19-related fraud was a top priority for the DOJ and, while other enforcement priorities remain to be seen, the Biden administration will almost certainly continue to focus on COVID-19 enforcement.[27]

On Jan. 12, 2021, the DOJ announced the first civil settlement to resolve allegations of fraud relating to misuse of Paycheck Protection Program funds, and we expect to see an increase in these resolutions throughout 2021.[28]

We also expect increased government scrutiny on telemedicine. As part of the ongoing efforts to provide safe medical care during the COVID-19 pandemic, HHS issued an amended declaration under the 2005 Public Readiness and Emergency Preparedness Act to expand its COVID-19 emergency countermeasures to allow clinicians to engage in certain limited telemedicine activities in states other than those in which they are licensed.[29]

While telemedicine enforcement actions to date have focused largely on criminal kickback schemes, providers practicing pursuant to HHS' amended declaration should be aware of enhanced scrutiny and potential liability in 2021.

On Nov. 20, 2020, HHS released complementary rules to modernize and clarify the regulations that interpret the Physician Self-Referral Law, also known as the Stark Law, and the federal Anti-Kickback Statute as part of its Regulatory Sprint to Coordinated Care.[30] The rules reflect an attempt to create exceptions and safe harbors that refine the Stark Law's strict-liability-based civil penalties and the Anti-Kickback Statute's criminal penalties.

The stated goal of these reforms is to prevent certain nonabusive and beneficial arrangements from being subject to enforcement actions. While many components of the rules are, in large part, clarifications of existing rules, they may be used to interpret the provider compensation rules in existing FCA actions.

**Conclusion**

Looking back on 2020, while the DOJ's FCA recovery numbers were the lowest since fiscal year 2008, the key takeaway is that the DOJ set a record for the most new FCA matters ever initiated in a single year — and did so despite a global pandemic, closed courts and conducting investigations remotely.

If the government's heightened enforcement activity relating to prior economic crises and

government stimulus programs is any indication, we can expect a surge in FCA cases and enforcement activity in 2021.

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[1] Department of Justice, Justice Department Recovers Over $2.2 Billion from False Claims Act Cases in Fiscal Year 2020, Jan. 14, 2021, available at https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020.

[2] 938 F.3d 1278 (11th Cir. 2019).

[3] 952 F.3d 89 (3rd Cir. 2020).

[4] Id. at 100.

[5] 953 F.3d 1108 (9th Cir. 2020).

[6] Id. at 1117.

[7] With that certiorari petition being distributed for conference on February 19, 2021, a denial could appear on the Supreme Court's orders list as early as February 22, 2021, or, if not relisted, the petition could be granted as soon as the following week.

[8] 136 S. Ct. 1989 (2016).

[9] 949 F.3d 533 (10th Cir. 2020).

[10] Id. at 542.

[11] 963 F.3d 1089, 1098 (11th Cir. 2020).

[12] As it relates to the Medicare claims, "upcoding" involved allegations of artificially inflating RUG codes and "ramping" involved artificial timing of spikes in patient treatment to coincide with Medicare's regularly scheduled assessment periods to maximize reimbursement going forward. The Eleventh Circuit affirmed the district court's findings on the relator's failure to prove materiality on the Medicaid claims.

[13] Id. at 1105.

[14] 139 S. Ct. 1804 (2019).

[15] Agendia, Inc. v. Azar, 420 F. Supp. 3d 985 (C.D. Cal. 2019) (pending appeal before the Ninth Circuit); Polansky v. Executive Health Resources, Inc., 422 F. Supp. 3d 916 (E.D. Pa. 2019) (pending appeal before the Third Circuit).

[16] 2021 WL 79615, at *11 (N.D. Miss. Jan. 11, 2021).

[17] Department of Health & Human Services, HHS Finalizes Good Guidance Practices Rule and Issues Advisory Opinion Regarding Compliance with Notice-and-Comment Obligations, Dec. 3, 2020, available at https://www.hhs.gov/about/news/2020/12/03/hhs-finalizes-good-guidance-practices-rule-issues-advisory-opinion-regarding-compliance-notice.html.

[18] Department of Health & Human Services, Good Guidance Petition Response 21-01, Jan. 8, 2021, available https://www.hhs.gov/sites/default/files/davita-petition-response-and-exhibit.pdf.

[19] On December 3, 2020, the HHS Office of the General Counsel issued Advisory Opinion 20-05 to clarify how HHS will comply with Allina. While caveated as not binding on "HHS or the federal courts," the opinion states that "to the extent that guidance documents set forth Medicare policies or rules that are not closely tied to statutory or regulatory standards, the government generally cannot use violations of that guidance to inform the basis for any enforcement action, because under Allina, it was not validly issued."[19]

[20] See Department of Justice, Letter from DOJ Office of the Assistant Attorney General to Senator Chuck Grassley, Dec. 19, 2019, available at https://www.grassley.senate.gov/sites/default/files/2019-12-19%20DOJ%20to%20CEG%20%28FCA%20dismissals%29.pdf; see also Department of Justice, Remarks of Deputy Assistant Attorney General Michael D. Granston at the ABA Civil False Claims Act and Qui Tam Enforcement Institute, Dec. 2, 2020, available at https://www.justice.gov/opa/speech/remarks-deputy-assistant-attorney-general-michael-d-granston-aba-civil-false-claims-act (noting how DOJ "has filed motions to dismiss in approximately 50 qui tam actions" since DOJ's September 2018 update to the Justice Manual with the dismissal guidance outlined in the Granston memorandum).

[21] See Department of Justice, Principal Deputy Assistant Attorney General Ethan P. Davis Remarks on the False Claims Act at the U.S. Chamber of Commerce's Institute for Legal Reform, June 26, 2020, available at https://www.justice.gov/civil/speech/principal-deputy-assistant-attorney-general-ethan-p-davis-delivers-remarks-false-claims.

[22] Swift v. United States, 318 F.3d 250 (D.C. Cir. 2003); U.S. ex rel. Sequoia Orange Co. v Baird-Neece Packing Corp., 151 F.3d 1139 (9th Cir. 1998).

[23] 970 F.3d 835 (7th Cir. 2020).

[24] 968 F.3d 996 (9th Cir. 2020).

[25] 2019 WL 4566462 (D.C. Cir. Aug. 22, 2019), cert. denied 140 S.Ct. 2660 (Apr. 6, 2020).

[26] The CARES Act, Pub. L. No. 116-136 (2020).

[27] See, e.g., Press Release, Department of Justice, Combating CARES Act Fraud: Ensuring Economic Relief for Americans Through Law Enforcement Efforts, July 8, 2020, available

at https://www.justice.gov/usao-edtx/pr/combating-cares-act-fraud-ensuring-economic-relief-americans-through-law-enforcement; Press Release, Department of Justice, Acting Assistant Attorney General Brian Rabbitt Delivers Remarks at the PPP Criminal Fraud Enforcement Action Press Conference, Sept. 10, 2020, available at https://www.justice.gov/opa/speech/acting-assistant-attorney-general-brian-rabbitt-delivers-remarks-ppp-criminal-fraud.

[28] Press Release, Department of Justice, Eastern District of California Obtains Nation's First Civil Settlement for Fraud on Cares Act Paycheck Protection Program, Jan. 13, 2021, available at https://www.justice.gov/usao-edca/pr/eastern-district-california-obtains-nation-s-first-civil-settlement-fraud-cares-act.

[29] Department of Health & Human Services, Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19 and Republication of the Declaration, available at https://www.phe.gov/Preparedness/legal/prepact/Pages/4-PREP-Act.aspx; Department of Health & Human Services, HHS Amends PREP Act Declaration, Including to Expand Access to COVID-19 Countermeasures Via Telehealth, available at https://www.hhs.gov/about/news/2020/12/03/hhs-amends-prep-act-declaration-including-expand-access-covid-19-countermeasures-telehealth.html.

[30] Centers for Medicare & Medicaid Services, "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations," 85 FR 77492 (Dec. 2, 2020), available at https://www.federalregister.gov/documents/2020/12/02/2020-26140/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations; Office of Inspector General, "Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements," 85 FR 77684 (Dec. 2, 2020), available at https://www.federalregister.gov/documents/2020/12/02/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the.