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The False Claims Act Year in Review—Part II

By John Pachter, Edmund Amorosi, Todd Garland, Neil Issar, Matthew Liptrot, Samara Taper, Wilson Miller, Jesse Cardinal, Connor Madden and Davis Shugru*

The False Claims Act (FCA) continues to be one of the most commonly used weapons in the federal government's enforcement arsenal to address various forms of fraud. This three-part article highlights key developments from 2024 related to the FCA. The first part, published in the April issue of Pratt's Government Contracting Law Report, *discussed notable settlements, provided an update on legislation and enforcement trends and policies, and examined significant judicial decisions with respect to agency deference, the seal requirement, and the initial hurdles for an FCA plaintiff. This second part reviews significant judicial decisions examining the substantive elements of an FCA claim. The conclusion of this article, to be published in the next issue of this journal, will review significant judicial decisions on reverse false claims, retaliation, recovery/damages/fees, the constitutionality of the qui tam provision, and claims by FCA defendants.*

SIGNIFICANT JUDICIAL DECISIONS

SUBSTANTIVE ELEMENTS OF AN FCA CLAIM

1. Rule 9(b) Particularity

FCA violations require the submission of a false or fraudulent claim to the government. Because the allegations involve fraud, all claims brought under the FCA are subject to the heightened pleading standard of Rule 9(b) of the Federal Rules of Civil Procedure. Rule 9(b) requires a complaint to "state with particularity the circumstances constituting fraud." FED. R. CIV. P. 9(b).

The purpose of the Rule 9(b) particularity requirement is "to alert defendants to the precise mis-conduct with which they are charged," "protect[] defendants against spurious charges of immoral and fraudulent behavior," and "ensure[] that the relator's strong financial incentive to bring an FCA claim . . . does not precipitate the filing of frivolous suits." *Gose v. Native Am. Servs. Corp.*, 109 F.4th 1297, 1317 (11th Cir. 2024) (citing *Hopper v. Solvay Pharms., Inc.*, 588 F.3d 1318, 1324 (11th Cir. 2009)).

Circuit courts have been split for years over how Rule 9(b) applies in practice to FCA claims. Some circuits, including the Sixth, Seventh, Eighth, and Eleventh Circuits, appear to favor—and in some cases have required—detailed

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allegations of a specific false claim that was actually submitted to the government. Most other circuits take a less stringent approach, requiring only particular details of a scheme to submit false claims to the government along with indicia of reliability that false claims were actually submitted.

a. Courts Generally Agree That Rule 9(b) Requires a Relator To Plead the "Who, What, When, Where and How" of the Alleged Fraud

Although the Supreme Court has yet to address the ongoing circuit split as to what exactly is required to satisfy Rule 9(b), most courts generally agree that a relator must plead the "who, what, when, where, and how" of the alleged fraud to survive dismissal at the pleading stage.

For example, in *Gose*, the Eleventh Circuit held the relator's allegations complied with Rule 9(b) because the relator's complaint sufficiently identified who engaged in the alleged fraud, what the alleged fraudulent activity was, details about where the alleged fraud took place, when the defendants' actions became fraudulent, and how the fraudulent activity occurred. 109 F.4th at 1318. Thus, the court found the defendants had enough notice of the specific claims against them and were positioned to prepare a defense. *Id.* at 1319.

b. Recent Fifth Circuit Precedent Clarified That the Rule 9(b) Standard is Context-Specific and Flexible

In the Fifth Circuit, under Rule 9(b), a plaintiff is also generally required to plead the "who, what, when, where, and how" of the alleged fraud. *United States ex rel. Carew v. Senseonics Holdings, Inc.*, No. 20-cv-00657 (W.D. Tex. Mar. 3, 2023) (citing *Williams v. WMX Techs., Inc.*, 112 F.3d 175, 179 (5th Cir. 1997)). But the Fifth Circuit has made clear that this requirement "is not a straitjacket for Rule 9(b)," meaning that the Rule 9(b) standard is "context specific and flexible." *Id.* (citing *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 189–90 (5th Cir. 2009)).

In other words, "even if [a relator's complaint] cannot allege the details of an actually submitted false claim," the complaint can still sometimes survive by "alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id.*

In contrast, allegations that only create mere speculation are not enough. For example, in *Carew*, the district court held that the relator's complaint failed to provide sufficient details of an alleged fraudulent scheme. *Id.* at *4. Even though it was possible that the alleged payments at issue were illegal kickbacks, the relator failed to plead strong or reliable indications that the payments were in fact illegal. *Id.* at *6. The court found that relator's complaint was "too speculative" and failed to allege, as required, "particular details of a scheme to

submit false claims paired with reliable indicia that lead to a strong inference that false claims were actually submitted." *Id.* The Fifth Circuit affirmed the district court's holding without further analysis. *United States ex rel. Carew v. Senseonics Holdings, Inc.*, No. 23-50307 (5th Cir. Feb. 28, 2024) (per curiam).

c. The Second Circuit Continues to Recognize an Exception When Billing Information is Peculiarly Within the Opposing Party's Knowledge

The U.S. Court of Appeals for the Second Circuit has similarly said that Rule 9(b) requires a party alleging fraud to:

> (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *United States ex rel. Askari v. PharMerica Corp.*, No. 23-909 (2d Cir. Mar. 15, 2024) (quoting *United States ex rel. Chorches for Bankr. Estate of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 81 (2d Cir. 2017)).

But the Second Circuit also allows a plaintiff to plead "on information and belief" if it can (1) show billing information is "peculiarly within the opposing party's knowledge," and (2) "mak[e] plausible allegations creating a strong inference that specific false claims were submitted to the government." *United States ex rel. Pilat v. Amedisys, Inc.*, No. 23-566 (2d Cir. Jan. 17, 2024) (citing Chorches, 865 F.3d at 86).

In *Pilat*, the relators were former employees of a home health and hospice care company. *Id.* They alleged that the defendant "falsely certified unqualified patients for home health care, provided unnecessary and improper treatment, falsified time records, and manipulated patient records." *Id.* In support, the relators identified multiple specific instances in which clinicians were instructed to either incorrectly document patient information or recommend an unnecessary course of treatment. *Id.*

The court held that the relator's allegations raised a strong inference that false claims were indeed submitted to the government. *Id.* But the court also held that the relators had not established relevant billing information was "peculiarly within" the defendant's knowledge since they admitted to being able to review some of the forms that showed falsified billing information. *See id.* As such, the Second Circuit affirmed dismissal for failure to satisfy Rule 9(b), but held the relators should be granted leave to amend to address the billing information issue.

2. Scienter

FCA liability requires that a defendant acted "knowingly." *See* 31 U.S.C. § 3729(a)(1). The FCA "is not intended to punish honest mistakes or incorrect

claims submitted through mere negligence." *United States ex rel. Skibo v. Greer Labs., Inc.*, 841 F. App'x 527, 531 (4th Cir. 2021) (citation omitted); *see also United States ex rel. Jacobs v. Walgreen Co.*, No. 21-20463 (5th Cir. Mar. 2, 2022) (allegations of fraud that do not amount to "anything more than innocent mistake or negligence" are insufficient).

The terms "knowing" and "knowingly" are defined by the FCA to "mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A); *see also United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 750 (2023) ("In short, either actual knowledge, deliberate indifference, or recklessness will suffice.").

In its 2023 *SuperValu* decision, the U.S. Supreme Court held that in FCA cases involving ambiguous legal requirements, the scienter element turns on a defendant's subjective beliefs, not what an objectively reasonable person may have believed—rejecting a standard previously followed by many circuit courts. *See* 598 U.S. at 749.

In the aftermath of *SuperValu,* numerous lower courts were forced to reevaluate prior decisions involving scienter. *See e.g., United States ex rel. Sheldon v. Allergan Sales, LLC*, 143 S. Ct. 2686 (2023) (remanding "for further consideration in light of [*SuperValu*]"); *Olhausen v. Arriva Med., LLC*, 143 S. Ct. 2686 (2023) (same); *United States ex rel. Heath v. Wisconsin Bell, Inc.*, 92 F.4th 654, 663 (7th Cir. 2024) (reversing lower court and applying *SuperValu* scienter standard to find genuine issue of material fact existed as to recklessness), *cert. granted*, 144 S. Ct. 2657 (2024); *United States ex rel. Miller v. Reckitt Benckiser Grp. PLC*, No. 1:15-cv-00017 (W.D. Va. Oct. 17, 2023) (staying the case, requiring briefs addressing the impact of *SuperValu*, and thereafter finding the relator had sufficiently alleged scienter).

After *SuperValu*, relators must take care to allege and introduce facts regarding a defendant's subjective knowledge. And some defendants who would have prevailed on dispositive motions under an objectively reasonable person scienter standard now may not meet their burden with respect to the subjective knowledge scienter standard.

a. The Ninth Circuit Emphasized That Post-*SuperValu* Relators Must Offer Evidence of Subjective Knowledge of Falsity

In *Evans v. Southern California Intergovernmental Training and Development Center*, No. 22-16715 (9th Cir. May 6, 2024), the Ninth Circuit affirmed summary judgment against a relator who failed to offer facts evidencing the defendant's subjective knowledge that its invoices overstated the cost of its services.

The relator argued that the defendant "was on actual or constructive notice" that its budgeting practices were improper because the defendant's executive director "would have had knowledge of the contents of the contracts . . . because it was her practice to read the contracts in their entirety." Appellant's Opening Brief, *Evans v. S. Cal. Intergovernmental Training & Dev. Ctr.*, No. 22-16715 (9th Cir. Feb. 2, 2023). But the Ninth Circuit held that this was not enough: "[t]hat . . . contracts with [defendant] required actual-cost invoicing does not demonstrate that [defendant] knew actual-cost invoicing was required by the federal government because the inquiry here is focused on what [defendant] *subjectively* thought and believed." *Evans*, *supra*.

b. Seventh Circuit Decision Highlighted How *SuperValu's* Subjective Knowledge Standard May Require Litigation of Fact Disputes

The subjective knowledge standard may require parties to litigate fact disputes that would not have survived summary judgment under the objectively reasonable person standard. The consequence for defendants is exemplified by the Seventh Circuit's decision in *United States ex rel. Heath v. Wisconsin Bell, Inc.*, 92 F.4th 654, 662–63 (7th Cir. 2024), *cert. granted*, 144 S. Ct. 2657 (2024), which applied *SuperValu* to reverse a district court's ruling that the relator had failed to establish scienter.

Heath involved the Schools and Libraries Universal Service Support program (a.k.a. the E-Rate program), which provides federal subsidies for internet access and related services for schools and libraries. Per Federal Communications Commission (FCC) regulations implementing the E-Rate program, telecommunications service providers must follow what is known as the "lowest-corresponding-price" rule and offer schools and libraries the lowest price charged to similarly situated non-residential customers.

The relator alleged that a telecommunications provider submitted overstated bills and false certifications of compliance after failing to implement procedures to evaluate its own compliance with E-Rate program rules for many years. *Id.* at 659, 663. The district court concluded that the defendant's interpretation of the lowest-corresponding-price rule was objectively reasonable and consistent with the rule's language as well as FCC guidance, which in turn, warranted summary judgment against the relator on scienter. *Id.* at 662–63.

But the Seventh Circuit reversed, holding that the defendant's "own conduct at least raises a genuine question as to whether it acted in reckless disregard of the truth or falsity of the claims submitted." *Id.* at 663–64. For instance, the defendant admitted knowing about the lowest-corresponding-price rule, the relator provided evidence that the defendant did not have any methods or processes in place to ensure compliance with the law, and the defendant did not have a system for identifying similarly situated customers. *See id.* at 663.

Accordingly, there was enough evidence to at least create a genuine issue as to whether the defendant acted with reckless disregard of whether the prices it was charging schools and libraries complied with the lowest-corresponding-price rule. *Id.* at 664.

Heath is indicative of courts' greater reluctance to grant summary judgment with respect to scienter after *SuperValu* articulated the subjective knowledge standard. If a relator can plead and supply facts sufficient to suggest that a defendant had subjective knowledge of falsity, then defendant's counsel may be required to engage in a fact-specific analysis that would not have been required in many circuits before *SuperValu*.

c. The Second Circuit Held a Relator Alleging AKS-Premised FCA Claims Must Satisfy the AKS's "Willful" Scienter Standard

The AKS prohibits individuals and entities from *knowingly or willfully* paying another to induce a referral of business that is reimbursable under a federal healthcare program. 42 U.S.C. § 1320a-7b(b). In 2010, Congress amended the AKS to include FCA liability for a claim that includes items and services "*resulting from* a violation of [the AKS]." 42 U.S.C. § 1320a-7b(g) (emphasis added).

In *United States ex rel. Hart v. McKesson Corp.*, the relator sued a pharmaceutical wholesaler alleging that the wholesaler offered its customers business management tools that induced customers to purchase drugs from the wholesaler. 96 F.4th 145, 150 (2d Cir. 2024). The relator argued that this was an illegal kickback in violation of the AKS and the FCA.

The district court dismissed the lawsuit, concluding the relator had failed to allege that the defendant acted with the requisite scienter under the AKS. The Second Circuit affirmed, holding that "[t]o act willfully under the AKS, a defendant must act with a 'bad purpose,' " which means "the defendant must act 'with knowing that his conduct was unlawful,' " even if the defendant is not aware that his conduct is unlawful under the AKS specifically or the defendant did not intend to violate the AKS. *Id.* at 157 (quoting *Bryan v. United States*, 524 U.S. 184, 191–92 (1998)). The court explained that this interpretation of the AKS's willfulness requirement was intended to protect only those "who innocently and inadvertently engage in prohibited conduct." *Id.*

3. Causation

To establish liability under the FCA, the government or relator must demonstrate "causation"—i.e., that a specific false claim or claims "resulted from" the defendant's fraudulent conduct.

The causation requirement has not been applied uniformly across circuits, though most federal courts have required relators to show that the defendant

took an "affirmative act," *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 714 (10th Cir. 2006), with "some degree of participation in the claims process," *United States v. President & Fellows of Harvard Coll.*, 323 F. Supp. 2d 151, 186–87 (D. Mass. 2004). *See also United States ex rel. Polansky v. Exec. Health Res., Inc.*, 196 F. Supp. 3d 477, 513 (E.D. Pa. 2016) ("Numerous courts have held that some level of direct involvement in causing the submission of false claims to the government is necessary for direct liability under the FCA."). Courts continued to grapple with this requirement in 2024.

a. A Circuit Split on the Causation Standard for AKS-Premised FCA Claims Continues

As stated above, the FCA imposes liability for a claim that includes items and services "*resulting from* a violation of [the AKS]." 42 U.S.C. § 1320a-7b(g) (emphasis added). But appellate courts have long struggled to interpret the phrase "resulting from."

The Sixth and Eighth Circuits have adopted an exacting "but-for" causation standard, under which a plaintiff must show "that the defendants would not have included particular 'items or services' [in claims for payment] absent the illegal kickbacks." *See United States ex rel. Martin v. Hathaway,* 63 F.4th 1043, 1052–55 (6th Cir. 2023); *United States ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 835 (8th Cir. 2022).

In contrast, the Third Circuit ruled that "resulting from" did not require "but-for" causation and instead only a "link" is needed—meaning only the demonstration of "some connection between a kickback and a subsequent reimbursement claim is required." *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 96–100 (3d Cir. 2018).

Some circuits have declined to clarify the standard. For example, in 2024, the Seventh Circuit refused to determine whether § 1320a-7b(g) requires a showing of but-for causation or something less since the facts at hand would satisfy even the strictest causal test. *See Stop Illinois Health Care Fraud, LLC v. Sayeed*, 100 F.4th 899, 909 (7th Cir. 2024), *reh'g denied*, No. 22-3295 (May 30, 2024).

And in at least one other circuit, the district courts themselves disagree. In the U.S. Court of Appeals for the First Circuit, different judges for the District of Massachusetts recently reached different conclusions. Compare *Omni Healthcare, Inc. v. MD Spine Sols. LLC*, No. 18-cv-12558 (D. Mass. Jan. 6, 2025) (adopting the but-for causation standard) and *United States v. Regeneron Pharms., Inc.*, No. 20-cv-11217 (D. Mass. Sept. 27, 2023) (same), *perm. app. granted*, No. 23-8036 (1st Cir. Dec. 11, 2023), with *United States ex rel. Witkin v. Medtronic, Inc.*, No. 1:11-cv-10790 (D. Mass. Mar. 31, 2024) (rejecting

but-for causation), and *United States v. Teva Pharms. USA, Inc.*, 682 F. Supp. 3d 142, 148 (D. Mass. 2023) (same). The issue in Massachusetts could be resolved in 2025 because the First Circuit heard oral arguments in the *Regeneron* case.

b. A Fifth Circuit District Court Applied a Flexible Causation Standard

In line with Fifth Circuit precedent, the Western District of Texas held that the FCA's causation standard is a "flexible" one. *United States ex rel. Hueseman v. Prof'l Compounding Ctrs. of Am., Inc.*, No. 14-cv-00212 (W.D. Tex. May 1, 2024). Specifically, the district court explained that causation requires proximate cause, in which "[a] defendant's conduct may be found to have caused the submission of a claim for . . . reimbursement if the conduct was (1) a substantial factor in inducing providers to submit claims for reimbursement, and (2) if the submission of claims for reimbursement was reasonably foreseeable or anticipated as a natural consequence of defendants' conduct." *Id.* at *5 (quoting *United States ex rel. Ruckh v. Salus Rehab.*, 963 F.3d 1089, 1107 (11th Cir. 2020)).

In other words, in the Fifth Circuit, the FCA's causation standard "demands more than mere passive acquiescence in the presentation of the claim and some sort of affirmative act that causes or assists the presentation of a false claim." *Id.* (quoting *United States ex rel. Aldridge v. Corp. Mgmt., Inc.*, 78 F.4th 727 (5th Cir. 2023) (cleaned up)).

c. The Ninth Circuit Held That the "But For" Causation Standard Applied to FCA Retaliation Claims

To protect whistleblowers, the FCA has an anti-retaliation provision that imposes liability on an employer if an employee is "discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment *because of* lawful acts done by the employee . . . in furtherance of an [FCA] action . . . or other efforts to stop one or more violations of [the FCA]." 31 U.S.C. § 3730(h)(1) (emphasis added).

In 2013, the U.S. Supreme Court held that all Title VII retaliation claims must be proved according to traditional principles of "but-for" causation, which "requires proof that the unlawful retaliation would not have occurred in the absence of the alleged wrongful action or actions of the employer." *Univ. of Tex. Sw. Med. Ctr. v. Nassar*, 570 U.S. 338, 344, 360 (2013).

In 2024, the Ninth Circuit relied on Nassar to rule that the "but-for" causation standard also applies to FCA retaliation claims since the use of "because of" language generally requires "but-for" causation and that language appears in both the FCA and Title VII. *See Mooney v. Fife*, 118 F.4th 1081, 1090 (9th Cir. 2024) (citing *Nassar*, 570 U.S. at 352).

4. Falsity

As the name implies, the FCA only imposes liability for "false claims"—that is, for presenting a false or fraudulent claim or making a false record or statement material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(A)–(B). A defendant may also be liable under the FCA for a "reverse false claim" if it makes or uses a false record or statement for the purpose of avoiding or decreasing an "obligation" owed to the United States. *See* 31 U.S.C. § 3729(a)(1)(G). The terms "false" and "fraudulent" are not defined in the FCA, so the governing standards have been developed through caselaw.

a. The Ninth Circuit Found Falsity Could Be Met Through Allegations of Falling Below the Minimum Standard of Care

In *United States ex rel. Stenson v. Radiology Ltd.*, No. 22-16571 (9th Cir. Apr. 26, 2024), the relator alleged that the defendant had charged the Centers for Medicare and Medicaid Services (CMS) over $6 million for radiology diagnostic readings that did not qualify for reimbursement because they were conducted on non-FDA-approved, non-medical-grade computer displays, and then violated the FCA by falsely certifying compliance with CMS regulations.

CMS coverage laws require that all reimbursed services be "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A). In the Ninth Circuit, "a false certification of medical necessity can give rise to FCA liability." *United States ex rel. Winter v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108, 1118 (9th Cir. 2020). So, even if no federal rule, regulation, or law specifically required radiologists to use FDA-approved devices, the general Medicare statute nonetheless required that all physicians provide services that meet minimum efficacy standards. *Stenson, supra*. As a result, the relator could satisfy the falsity element merely by alleging that the defendant knowingly submitted claims for diagnostic readings that fell below the federally mandated minimum standard of care.

b. A Fifth Circuit District Court Held Off-Label Prescriptions Are Not Inherently Factually False or Misleading

In *United States ex rel. Hearrell v. Allergan, Inc.*, No. 2:21-cv-00204 (E.D. Tex. Apr. 18, 2024), the relator brought a *qui tam* action alleging that the defendant violated the FCA by promoting Botox off-label for pediatric migraines and paying illegal kickbacks to physicians. The defendant countered that off-label prescriptions are not false statements because they do not contain inaccurate information.

The district court agreed with the defendant, holding that the facts as alleged did not support the inference that the defendant made a false statement or falsely certified compliance with a statute or regulation. *Id.* The relator had not

alleged any facts showing that an off-label prescription is factually false or misleading, and merely pleading an AKS violation did not automatically satisfy the falsity element of an FCA claim. *Id.*

5. Materiality

The FCA imposes liability where a person "knowingly makes, uses, or causes to be made or used, a false record or statement *material* to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B) (emphasis added). The statute defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

The U.S. Supreme Court interprets the materiality requirement to mean that "[a] misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 181 (2016).

The Court explained that the FCA is not "a vehicle for punishing garden variety breaches of contract or regulatory violations" or "minor or insubstantial" noncompliance with government contracts. *Id.* at 194. Evaluating materiality accordingly requires a "rigorous" fact-based inquiry. *Id.* at 195 n.6.

Escobar listed three non-exclusive factors that courts can apply when assessing materiality: (1) whether the government expressly conditions payment on compliance with a particular regulation or provision; (2) whether noncompliance goes to the "essence of the bargain" between the government and recipient; and (3) whether the government has refused to pay in response to similar violations. *Id.* at 193–95. In 2024, the First, Third, Eighth, and Ninth Circuits rendered decisions that clarified their application of the *Escobar* factors.

a. The First Circuit Found Noncompliance With Speed Limit Sign Regulations Not Material to an Agency's Decision to Pay Municipal Claims

In *United States ex rel. Zotos v. Town of Hingham*, 98 F.4th 339, 342–43 (1st Cir. 2024), the relator alleged that a Massachusetts town falsely represented to the Massachusetts Department of Transportation that speed limit signs it installed complied with relevant state and federal regulations, causing the agency to submit false claims to the Federal Highway Administration. The First Circuit applied the three factors from *Escobar* and found the claims were not material. *Id.* at 344.

First, the court noted that the complaint failed to make it clear whether defendants actually certified that they adhered to applicable laws, regulations,

and guidelines when seeking reimbursement but that even if they had, there was no express indication in the reimbursement form that compliance with speed limit sign regulations was necessary for federal funding. *Id.* at 345. The court then turned to the second *Escobar* factor and found the regulatory violations alleged did not go to the "essence of the bargain." *Id*. Instead, they were "at best" the kind where the government could refuse to pay if it were aware. *Id.* Finally, the court found that the third factor favored the defendants because the relator filed numerous prior lawsuits alleging "nearly identical allegations" and the government continued to pay the town despite those suits. *Id.*

b. The Eighth Circuit Held Various Alleged Regulatory Violations by Medicare Advantage Participant Insurance Companies and Brokers Were Not Material

In *United States ex rel. Holt v. Medicare Medicaid Advisors, Inc.*, the Eighth Circuit considered a variety of claims regarding the Medicare Advantage (MA) program. 115 F. 4th 908, 914 (8th Cir. 2024). The relator sued various insurance companies and their broker, alleging three different schemes resulted in insurance carriers submitting false claims. *Id.* at 914–15. The three schemes involved marketing violations, agent certification, and redirecting beneficiary complaints to allegedly improve plan scores in CMS's MA star rating program. *Id.* The court applied the *Escobar* factors and held that none of the alleged schemes involved material false claims. *Id.* at 920–22.

Starting with the alleged marketing violations, the court found none of the *Escobar* factors favored a materiality finding. *Id.* at 920. The relator alleged that the defendant's marketing efforts violated federal regulations, including by cold-calling potential enrollees, conducting door-to-door sales, and enrolling beneficiaries outside of enrollment season. *Id.* at 915.

However, the relator only alleged that carriers made a general certification that they follow MA rules, which was insufficient. *Id.* at 920.

Next, the court found that marketing violations do not go to the essence of CMS's agreement with carriers because the regulations merely *permit* CMS to terminate a carrier over "substantial" noncompliance, rather than require it to do so. *Id.* Finally, the court found the third factor neutral because there was no record evidence of how CMS reacts to marketing violations. *Id.*

The court then turned to agent certification. Agents must be certified to sell MA plans, and the relator alleged the defendant broker used uncertified agents to sell MA plans. *Id.* at 915. The court examined but declined to reach a conclusion regarding the first factor and weighed the third factor as neutral due to lack of evidence. *Id.* at 921. The second *Escobar* factor cut against materiality because under the regulatory scheme, CMS would pay the carrier for a policy

sold by an unlicensed agent. *Id.* The government, then, would pay even with knowledge of an agent certification violation. *Id.*

Finally, the court examined the alleged scheme to manipulate the star rating system and found it too was not material. *Id.* The star rating regime is a system CMS uses to rate plans and a plan's rating can affect bonus payments to the carrier. *Id.* at 914. The first two factors suggested the star-rating scheme was not material and the third factor was neutral, so the court found the scheme not material. *Id.* at 921.

c. The Third Circuit Emphasized the Government's Knowledge of the Purported False Statements in Finding Vaccine Misrepresentations Not Material

In *United States ex rel. Krahling v. Merck & Co.*, No. 23-2553 (Aug. 6, 2024), the Third Circuit considered an FCA claim against a vaccine manufacturer. The relator alleged the vaccine company made false representations to the government regarding the potency and effectiveness of vaccines the Centers for Disease Control and Prevention (CDC) purchased for its Vaccines for Children program. *Id.* at *1, *4. The relator filed suit in 2010, and the CDC has continued to purchase the vaccine in annually negotiated contracts since then. *Id.* at *5. Even when a competitor vaccine came to market, the FDA approved the two vaccines as equivalent, and the CDC purchased vaccines from both manufacturers rather than switching entirely to the new vaccine. *Id.*

The Third Circuit also noted that the CDC conducts its own effectiveness trials and purchased the manufacturer's vaccines despite those trials showing the vaccine's real-world effectiveness was lower than the manufacturer's reported effectiveness in clinical trials. *Id.* at *7. Based on those facts, the court concluded any misrepresentations were not material. *Id.* at *9.

d. The Ninth Circuit Reversed a Grant of Summary Judgment That a Radiology Center's Use of Non-Medical Grade Monitors Was Not Material

In *Stenson*, discussed above, the Ninth Circuit considered whether a radiology center's use of non-medical grade computer monitors was material. The court found that the relator sufficiently pleaded materiality when he alleged that using non-medical grade monitors violated the "reasonable and necessary" requirement of Medicare regulations.

Because CMS "routinely declines to reimburse medical providers for services . . . administered below a federally prescribed standard of care," the Ninth Circuit held that using non-medical grade monitors could be material if the monitors were as unsuited to medical use as the relator alleged. Accordingly, the Ninth Circuit reversed the district court's grant of summary judgment on this issue and remanded the case for further proceedings.

6. Submission of a "Claim"

In *Heath*, discussed above, the Seventh Circuit also held that reimbursement requests under the E-Rate program constituted "claims" under the FCA. 92 F.4th at 666. The defendant had argued otherwise because the E-Rate program is funded entirely by contributions of private telecommunications carriers and is administered by a private nonprofit corporation, which meant, according to the defendant, that there are no federal funds involved, and the government is not hurt by fraud in the program. *See id.* at 665. The Fifth Circuit had reached the same conclusion in *United States ex rel. Shupe v. Cisco Systems, Inc.*, 759 F.3d 379 (5th Cir. 2014).

But the Seventh Circuit rejected the argument and *Shupe's* holding, creating a circuit split. The Seventh Circuit held instead that federal funds were involved since the U.S. Treasury collects unpaid debts owed to the E-Rate program and provides criminal restitution payments and civil settlements stemming from the program. 92 F.4th at 667. The court also concluded that the nonprofit corporation administering the program was an agent of the United States in that it was subject to ultimate control by the FCC. *Id.* at 668. Finally, the court held that the federal government's role in establishing and overseeing the E-Rate program was sufficient to say the government "provided" funds to the program. *Id.* at 668–69.

In June 2024, the U.S. Supreme Court granted certiorari to determine whether reimbursement requests submitted to the E-Rate program qualify as "claims" under the FCA. The Court has already heard oral argument and we expect guidance to help answer this question in mid-2025.

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Editor's note: This article will continue in the next issue of *Pratt's Government Contracting Law Report.*

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