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UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

CENTRAL DIVISION

UNITED STATES OF AMERICA AND STATE OF CALIFORNIA *ex rel.* EMILY ROE, Plaintiffs, v. STANFORD HEALTHCARE BILLING OFFICE, *et al.*, Defendants.	No. CV 17-08726-DSF-AFMx STATEMENT OF INTEREST OF THE UNITED STATES REGARDING DEFENDANTS' MOTION TO DISMISS Date: July 13, 2020 Time: 1:30 p.m. Ctrm.: 7D (350 W. 1st Street)

I. INTRODUCTION

The United States, the real party in interest in this action, files this Statement of Interest ("SOI") pursuant to 28 U.S.C. § 517[1] for the purpose of responding to certain arguments made by the Defendants in their "Memorandum of Points and Authorities in Support of Motion to Dismiss Second Amended Complaint" (Dkt. 63-1 (the "Motion")). The Motion seeks the dismissal of Relator's Second Amended Complaint ("SAC"), which she filed pursuant to the *qui tam* provisions of the False Claims Act ("FCA"), 31 U.S.C. § 3730.

While the United States has declined to intervene in this FCA case, it remains the real party in interest, entitled to the majority of any damages and penalties that may be recovered on its behalf. 31 U.S.C. § 3730(d). Moreover, the FCA is the primary tool in the United States' ongoing effort to combat fraud affecting the public fisc. *See*, *e.g.*, *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 745 (9th Cir. 1993). Thus, the United States has a substantial interest concerning the legal contentions advanced in connection with Defendants' Motion, as the Court's rulings with respect to such contentions may impact both this case in particular and the development of FCA law more generally.

The United States files this SOI for the limited purpose of clarifying what is required to allege falsity under the FCA; the import of Medicare billing guidance in FCA cases; the effect of an agreement by Defendants to follow Medicare rules; and the effect of the government's continued payment of claims that Defendants submitted. The United States is not taking a position on any arguments or issues raised in connection with the Motion other than what is addressed in this SOI. In addition, the United States takes no position on the overall merits of Defendants' Motion or the sufficiency of the allegations in Relator's Second Amended Complaint. .

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[1] 28 U.S.C. § 517 authorizes the Attorney General "to attend to the interests of the United States in a suit pending in a court of the United States, or in a court of a State, or to attend to any other interest of the United States."

II. FALSITY AND SCIENTER ARE SEPARATE ELEMENTS OF AN FCA VIOLATION.

Defendants assert that under *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166 (9th Cir. 2006), "[t]o allege falsity under the FCA, a relator must allege 'a palpably false statement, known to be a lie when it is made.'" Motion at p. 13:21-22 (*quoting Hendow*, 461 F.3d at 1172). This assertion is based on Defendants' confusion of the FCA's requirement of falsity with its separate requirement of scienter. *United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89, 96 (3d Cir. 2020) ("separate" elements of scienter and falsity should not be "conflate[ed]."); *United States ex rel. Ormsby v. Sutter Health*, ___ F.Supp.3d ___, No. 1-cv-01052-LB, 2020 WL 1590521 at *48 n.465 (N.D. Cal. March 3, 2020) (FCA "separately imposes a scienter requirement . . . ."). The Ninth Circuit has repeatedly held that a claim can be false under the FCA when a party fails to comply with applicable statutory or regulatory requirements. *See, e.g., Hendow*, 461 F.3d at 1171 (a claim under the FCA "can be false where a party merely falsely certifies compliance with a statute or regulation as a condition to government payment"); *United States ex rel. Winter v. Gardens Reg'l Hosp. & Med. Center, Inc.*, 953 F.3d 1108, 1118 (9th Cir. 2020) (holding that a claim that "fails to comply with . . . regulatory requirements" is false)(citation omitted). The Ninth Circuit has also made clear that "after alleging a false statement, a plaintiff must still establish scienter." *Id.* Thus, contrary to Defendants' assertion, the FCA's falsity requirement is separate and distinct from its scienter requirement. A plaintiff is required to allege each element, and is not required to allege knowledge or intent in order to properly plead falsity.

III. MEDICARE BILLING GUIDANCE MAY BE RELEVANT FOR ESTABLISHING FCA VIOLATIONS.

Defendants assert that "Medicare billing guidance alone cannot be the basis of an FCA action." Motion at p. 14 n.7 (citing *Azar v. Allina Health Servs.*, 139 S. Ct. 1804,

1808 (2019)). Although Defendants cite *Allina* as support for this assertion, it is important to note that *Allina* was not an FCA case and does not say anything about what is necessary for an FCA action to proceed. The question in an FCA case is whether the defendant knowingly submitted a false claim that was material. Regarding the element of falsity, a claim may be false because (among other possible avenues for establishing falsity) the provider failed to comply with a legally binding obligation, which typically arises from a statute, regulation or contractual relationship. Guidance documents, which themselves may not be binding, may nonetheless serve 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.

For example, in the healthcare context, guidance documents such as Medicare billing guidance can be relevant evidence of violations of a regulation or of the fundamental statutory requirement that procedures billed to Medicare or Medicaid be medically "reasonable and necessary." Such usage does not give these guidance documents the force of law, but rather aids in demonstrating that the standards in the relevant statutory and regulatory requirements have been or have not been satisfied. For example, FCA liability may be based on a defendant's objectively unreasonable interpretation of a regulation in the face of "authoritative agency guidance." *Ormbsy*, *supra*, 2020 WL 1590521 at *42. Further, the government or a relator may cite a guidance document where a defendant's compliance, or failure to comply, with the agency guidance is itself relevant to the claims at issue. For example, when a provider falsely certifies compliance with a guidance document, and the certification is material to an agency's payment decision, the false certification to obtain a payment may be offered to establish the elements of falsity, materiality, and scienter.

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IV. THE COURT SHOULD REJECT DEFENDANTS' ASSERTION REGARDING THE EFFECT OF THE GOVERNMENT'S CONTINUED PAYMENT OF CLAIMS THEY SUBMITTED.

Defendants assert that, assuming the truth of the Relator's allegations regarding the falsity of their claims, nevertheless the claims were not material because the government had "information about th[e] claims" and continued to pay them. Motion at p. 15 n.9. Defendants do not specify what information the government allegedly possessed, but elsewhere in their motion they refer to an earlier FCA complaint against the Defendants that a different relator filed in the Northern District of California. Motion at p. 7-8.

Defendants are conflating the government's knowledge of *allegations* that legal requirements have been violated (which the government may potentially obtain through a *qui tam* complaint or other sources) with government knowledge that violations have actually occurred. In *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), the Supreme Court identified government payments made with "actual knowledge that certain requirements were violated" as a circumstance tending to disprove materiality (but even then not necessarily dispositive).[2] *Id.* at 2003. But it did not suggest that awareness of mere allegations has the same significance. As the First Circuit observed on remand from the Supreme Court's decision in *Escobar*, "mere awareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance." *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 112 (2016); *accord United States ex rel. Rahimi v. Rite Aid Corp.*, No. 11-cv-11940, 2019 WL 1426333 at *8 (E.D. Mich. March 30, 2019).

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[2] For example, in *United States ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890 (9th Cir. 2017), the court rejected an argument that "because the government continued to pay for[the defendant drug company's] medications after it knew of the FDA violations, those violations were not material to its payment decision." *Id.* at 906. The court instead stated that "[r]elators and the United States persuasively argue . . . that to read too much into the FDA's continued approval—and its effect on the government's payment decision—would be a mistake." *Id.*

V. CONCLUSION

For the foregoing reasons, the United States respectfully suggests that the Court should reject Defendants' assertions addressed in this statement of interest. The United States takes no position on other arguments made. In addition, the United States asks that if the Court dismisses Relator's First Amended Complaint because it is inadequately plead, it make such dismissal without prejudice to the United States.

Dated: May 29, 2020

Respectfully submitted,

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