UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
OWENSBORO DIVISION

United States of America **Plaintiff**

v. **No. 4:20-cv-66-BJB**

Kishor N. Vora **Defendant**

OPINION & ORDER

This is the second motion to dismiss filed by the defendant, Dr. Kishor Vora, in this False Claims Act case. The government alleges that a laboratory paid Vora kickbacks so he would order unnecessary and unauthorized tests, including more than one thousand tests that Medicare reimbursed. The Court agrees in part with Vora that the government hasn't adequately pled a critical element of its claim: materiality. The amended complaint doesn't include plausible, non-conclusory allegations that Vora concealed regulatory violations that were material to the government's decision to pay those lab claims. But the Court agrees with the government that it has adequately pled materiality regarding the express—but allegedly false—certifications that Dr. Vora's test orders were medically necessary.

I. Prior Proceedings

The United States accused Dr. Vora of ordering unnecessary lab tests for his Medicare patients between May 2012 and March 2013 because a lab, known as NMTC, was paying him kickbacks. Complaint (DN 1) ¶¶ 3, 15. These payments allegedly violated the Anti-Kickback Statute, which is civilly enforceable under the False Claims Act. 42 U.S.C. § 1320a-7b(g). Vora moved to dismiss those counts, but a previous order (which explains the factual allegations much more fully than this order does) held they survived. *United States v. Vora*, 488 F. Supp. 3d 554, 563 (W.D. Ky. 2020) ("*Vora I*"). The government adequately alleged the kickbacks were at least "one purpose" (if not the only purpose) motivating Dr. Vora to order these tests, which Medicare reimbursed the lab for performing, and which could give rise to liability under the False Claims Act. *Id.* at 562–64.

The government has also alleged that these same claims were fraudulent under the FCA for a separate reason: Vora falsely certified that the medical tests were medically necessary, even though he didn't actually believe they were, and even though he violated Medicare rules in ordering them. Vora certified the claims' eligibility for reimbursement in two ways, according to the government. First, he caused the lab to "expressly" certify their eligibility for payment when the lab signed Medicare claim forms, asserting that the tests were "medically indicated and

necessary for the health of the patient." First Amended Complaint (FAC) (DN 38) ¶ 141; Oral Arg. Tr. (DN 49) at 5:3–20. Second, he caused the lab to "impliedly" certify the claims' truthfulness because the submissions did not disclose noncompliance with underlying regulations. FAC ¶ 90; Tr. at 5:23–6:11. This, the government says, created the false impression that the claims were reimbursable. Both theories can provide a basis for liability under the FCA. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 186 (2016).

A previous order of this Court construed the original complaint to assert only an implied-certification theory, not an express false statement to the government that the tests were necessary. "The *actual* medical necessity of the tests," the Court explained in response to the first motion to dismiss, "is not relevant under the Government's theory of liability." *Vora I*, 488 F. Supp. 3d at 570 (emphasis in original). And that order questioned whether the government had adequately pled that the three alleged regulatory violations at issue were "material" to Medicare's decision to pay the claims. *See id.* at 571.

In response to the Court's order, the government filed an amended complaint that asserted that it wouldn't have paid if it knew about the violations. FAC ¶¶ 90–91, 142–143, 145, 148, 151. But aside from these self-serving and conclusory allegations, discussed below, the amended complaint offered only a single factual allegation in support of the materiality of these violations: the government's post-payment review of some of the claims at issue *in this case*, *id.* ¶ 92; Tr. at 34:16–19, which concluded that the claims shouldn't have been paid and shows, according to the government, that these violations were in fact "material," *id.* ¶ 140, 146.

Vora again moved to dismiss the claims—this time because, in Vora's view, the amended complaint failed to allege the materiality of the Medicare regulations he allegedly violated. *See* Partial Motion to Dismiss (DN 43). He initially read the amended complaint (like Judge McKinley had read the original complaint) to assert only an implied-certification theory. *Id.* at 3. But the government's opposition brief pointed to allegations of express *and* implied certifications that it contended the amended complaint contained. Brief in Opposition (DN 44) at 16 (citing FAC ¶ 142). So Vora's reply brief (DN 45 at 5) broadened his attack on the amended complaint: whether its theory was viewed as express or implied or both, the government hadn't adequately alleged that the purported certifications were material to the government's decision to pay these claims back in 2012 and 2013.

At oral argument each side clarified its position on important questions.

The government clarified its position on the relationship between materiality and regulatory violations. Although its pleadings might be read more broadly, the government didn't maintain that *any* reimbursement request that violated a Medicare regulation or guideline *automatically* violated the False Claims Act, subjecting erroneous billers to the prospect of treble damages and civil penalties. Tr.

at 12:11–13:14. Such an argument would stand in some tension with the Sixth Circuit's ruling that the FCA "is not a vehicle to police technical compliance with complex federal regulations." *United States ex rel. Williams v. Renal Care Grp.*, 696 F.3d 518, 532 (6th Cir. 2012); *see also Escobar*, 579 U.S. at 196 (FCA doesn't police "insignificant regulatory or contractual violations" with treble-damages fraud liability).

Instead, the government agreed that a violation of healthcare regulations or guidelines, standing alone, does not necessarily violate the FCA. That requires an attempt to defraud the government, not just a billing error. In this context an actionable false claim, in the government's view, requires a violation that the provider knowingly masks by falsely certifying compliance, despite also knowing that the government would not pay the claim if it knew the truth. Tr. at 12:14–22; *see also Escobar*, 579 U.S. at 181 ("What matters is … whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision.").

Vora, for his part, conceded that the statutory "reasonable and necessary" requirement is material. Reply at 1; Tr. at 29:5–25. But he maintained that the particular regulatory violations identified in the amended complaint were not material, even though the government purported to deem any claims not in compliance with these regulations as not "reasonable and necessary." Tr. at 29:5–30:14.

II. False Claims Act

The False Claims Act applies to "any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the U.S. government. 31 U.S.C. § 3729(a)(1)(A). A successful claim requires that "(1) the defendant made"—or, in this case, caused to be made, *see* § 3729(a)(1)(B)—"a false statement or created a false record; (2) with scienter; (3) that was material to the Government's decision to make the payment sought in the defendant's claim; and (4) that the defendant submitted to the U.S. government causing it to pay the claim." *United States ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822, 830 (6th Cir. 2018) (citing 31 U.S.C. § 3729(a)(1)(A)–(B)).

The only element at issue now is materiality. As defined by Congress, that means the violations would have "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). And as described by the Supreme Court, the FCA's materiality requirement is "rigorous" and "demanding." *Escobar*, 579 U.S. at 192–93. At argument, Vora made clear that his pending motion to dismiss doesn't implicate the scienter element, though he disputes that the government can establish it. *See* Tr. at 53: 9–17; *see also id.* at 53:1–8 (government agreeing scienter not raised by this motion). But his second

motion to dismiss, at issue here, addresses the issue of materiality only. *See* MTD at 4.

III. Implied-Certification Claims

Reviewing the amended complaint, either in isolation or alongside the original, reveals the government hasn't sufficiently pled materiality with respect to its implied-certification theory. Its allegations are largely conclusory, and therefore count for nothing under *Iqbal* and *Twombly*. The court must accept as true all factual assertions, but needn't accept "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). To say nothing of Rule 9's heightened standard requiring plaintiffs to plead fraud with "particularity." Fed. R. Civ. P. 9(b). Stripped of its legal conclusions, the amended complaint's single factual assertion, even accepting it as true, is inadequate to indicate that the Medicare rules were in fact material to the government's payment decisions.

A. Specific regulatory violations. The amended complaint alleges that Vora violated three Centers for Medicare & Medicaid Services requirements. What converts those violations to false claims, according to the government, is that Vora implicitly certified that he had *not* violated any regulations when he caused the lab to submit these claims without mentioning any noncompliance.

Two of the requirements—for "treatment" and "use"—are set forth in 42 C.F.R. § 410.32.[1]

1. **Treatment.** "[D]iagnostic tests," it asserts, "must be ordered by the physician who is *treating* the beneficiary." *Id.* (emphasis added). The government says Vora violated this requirement by having staff use pre-signed forms to order tests for any patient who met pre-identified risk factors. FAC ¶¶ 98–102.

[1] 42 C.F.R. § 410.32 provides:

> Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.
>
> (a) Ordering diagnostic tests. Except as otherwise provided in this section, all diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary (see § 411.15(k)(1) of this chapter).

2. **Use.** "[T]he physician who furnishes a consultation," moreover, must "*us[e]* the results in the management of the beneficiary's specific medical problem." 42 C.F.R. § 410.32 (emphasis added). Vora, the government maintains, failed to use the test results in treatment: he would sometimes order them despite knowing they would arrive too late to be useful, never mention the results to patients, or fail to record the results in patient records. *See* FAC ¶¶ 114–136.

The third requirement is found in Chapter 32, § 250, of the Medicare Claims Processing Manual.[2]

3. **Warfarin-responsiveness.** The government also says many of Vora's orders violated requirements for ordering warfarin-responsiveness tests. Medicare only covers these, according to the Manual, "if beneficiaries have not been previously tested," "have received fewer than five days of warfarin" during treatment, and are receiving the tests "in the context of a prospective, randomized, controlled clinical study." *Id.* The government alleges that Vora violated these requirements by ordering tests that were not part of a "prospective, randomized, controlled clinical study" and ordering tests when a patient had received more than five days of warfarin. FAC ¶¶ 138–39.

The government has failed to allege facts indicating that it treated violations of these three provisions as "material" to its payment decision, not to mention that Vora knew they were material to that decision, *see Escobar*, 579 U.S. at 181. The Supreme Court has made clear that materiality requires more than the government's ex post determination to treat a provider's representation or regulatory violation as decisive to the government's payment decision:

> The standard for materiality that we have outlined is a familiar and rigorous one. And False Claims Act plaintiffs must also plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and

[2] Section 250.1 ("Coverage Requirements") of the Medicare Claims Processing Manual provides that:

> Effective August 3, 2009, pharmacogenomic testing to predict warfarin responsiveness is covered only when provided to Medicare beneficiaries who are candidates for anticoagulation therapy with warfarin; i.e., have not been previously tested for CYP2C9 or VKORC1 alleles; and have received fewer than five days of warfarin in the anticoagulation regimen for which the testing is ordered; and only then in the context of a prospective, randomized, controlled clinical study when that study meets certain criteria as outlined in Pub 100-03, section 90.1, of the NCD Manual.

> 9(b) by, for instance, pleading facts to support allegations of materiality.

Id. at 195 n.6. In other words, the Justice Department's decision to file an FCA lawsuit that describes a regulation as "material" cannot itself prove that CMS would've declined to pay such claims. *Id.* at 191 ("materiality cannot rest on a single fact or occurrence as always determinative") (quotation omitted). Otherwise the Supreme Court wouldn't have had any need to examine "the effect on the likely or actual behavior of the recipient of the alleged misrepresentations" under the three "holistic" and non-"exclusive" factors emphasized in *Escobar*:

> (1) "the Government's decision to expressly identify a provision as a condition of payment";
>
> (2) whether "the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement" or if, with actual knowledge of the non-compliance, it consistently pays such claims and there is no indication that its practice will change; and
>
> (3) whether the "noncompliance is minor or insubstantial" or if it goes "to the very essence of the bargain."

Prather, 892 F.3d at 831 (quoting *Escobar*, 579 U.S. at 193 n. 5; *id.* at 194–95).

Against that backdrop, the government failed to point to factual allegations at argument or in its filings that could meet the *Escobar* materiality standard. The amended complaint did not allege that any of the three requirements were "conditions of payment."[3] It made no representation regarding the consistency of the

[3] The Court previously characterized 42 C.F.R. § 410.32(a) as a condition of payment, and suggested that would satisfy the first *Escobar* factor. *See Vora I*, 488 F. Supp. 3d at 570–71. The order observed, however, that this alone wasn't enough to satisfy the materiality element under *Escobar*, and expressed "reluctan[ce] to decide [the materiality question] now," at least "based on the arguments made thus far by the Defendant." *Id.* at 571. In connection with the initial motion to dismiss, Vora "did not specifically challenge" and the parties "had not … adequately briefed" the materiality of the false statements. *Id.*

The government subsequently amended its pleadings without ever alleging that it in fact treated compliance with § 410.32(a) as a condition of payment. And the amended complaint made no attempt to adopt or support Judge McKinley's characterization, or to otherwise carry this materiality analysis further. The concise section of its opposition brief devoted to the first *Escobar* factor, moreover, entirely omits § 410.32(a) and implied-certification, mentioning only 42 U.S.C. § 1395y and its theory of *express* certification premised on actual medical necessity. Opp. Br. (DN 44) at 20. As noted below in § IV, Vora concedes that compliance with this statutory requirement is material.

government's refusal or non-refusal to pay claims subject to such regulatory violations. And it said nothing about whether these violations were minor, insubstantial, or essential. Although none of these elements is dispositive alone, *Prather*, 892 F.3d at 831, the government's failure to address any of them in response to Judge McKinley's order is notable, to say the least.

Indeed, the government has given the Court no basis to conclude that a physician's use of pre-signed lab order forms, failure to eventually use a test result, or decision to order a test outside CMS's specific warfarin limitations would be material to the payment decision as the Supreme Court required. It remained silent on the critical factual question teed up by Judge McKinley's prior order and Vora's motion for judgment on the pleadings (DN 21).

The government emphasized several allegations at argument that, it contends, bear on materiality. Tr. at 33:24–34:15. But most simply incant this element's legal language without adding any factual support:

> 90. "Medicare would not have paid claims for pharmacogenomics testing, if it knew the claims … violat[ed] the Medicare laws, regulations, and program instructions…."
>
> 91. "Indeed, Medicare has denied claims for pharmacogenomics testing … for failing to comply with these Medicare laws, regulations and program instructions."
>
> 140. Vora "understood he could not cause to be made or us[e] false records or statements material to false or fraudulent claims to Medicare."
>
> 142. "A laboratory's certification of medical necessity for pharmacogenomics testing for a Medicare beneficiary is material to Medicare's decision to pay for the testing."
>
> 143. "Without the certification, Medicare would not pay for the Medicare beneficiary's pharmacogenomics testing."
>
> 147. "A laboratory's certification that a claim for pharmacogenomics testing for a Medicare beneficiary is true, accurate, and complete is material to Medicare's decision to pay for the testing."

The opinion in *Hobbs* also described § 410.32 as "fully provid[ing] the conditions of payment for diagnostic testing." 711 F.3d at 716. But it did so in the context of distinguishing the provision from a condition of *participation* under the pre-*Escobar* materiality regime rejected by the Supreme Court. *See Vora I*, 488 F. Supp. 3d at 570. And again, the amended complaint includes no factual allegations that echo such a characterization.

148. "Without the certification, Medicare would not pay for the Medicare beneficiary's pharmacogenomics testing."

When pressed at argument regarding whether the amended pleadings contained anything besides a restatement of the legal element of materiality, the government responded that "Paragraph 145 is very specific as to what it is that Medicare would not pay for." Tr. at 39:16–20. Legally specific, perhaps, but not factually precise:

145. "Had Medicare known that NMTC's certification of medical necessity for pharmacogenomic testing related to Dr. Vora's referrals was false, then Medicare would not have paid for the tests."

This is just as conclusory as the allegations set forth above.

And the single non-conclusory allegation regarding the effect of these regulatory violations on the government's payment determination is similarly lacking. The amended complaint asserts that in 2014, the government's retrospective review of claims submitted by the same lab to which Vora referred claims determined that "similarly deficient claims" were medically unnecessary. FAC ¶ 92. But this is largely bootstrapping: many of the claims at issue in that review are the same claims at issue in this very litigation. Whether any of those claims were denied at the time, or only deemed unnecessary in anticipation of litigation, is not clear. The pleadings, moreover, do not clarify whether "similarly deficient" means these claims violated the same provisions at issue here, or other "similar" regulations, or the overarching requirement that all services be "reasonable and necessary," as described below. While materiality doesn't necessarily demand that the government prove prior payment denials for the same violations, *see Prather*, 892 F.3d at 834, the government points to no authority for the proposition that it may rely on only an after-the-fact rejection of the same claim it seeks to litigate. *Contra Escobar*, 579 U.S. at 195 (disagreeing with the Solicitor General's view "that any statutory, regulatory, or contractual violation is material so long as the defendant knows that the Government would be entitled to refuse payment were it aware of the violation").

B. Overarching reasonable-and-necessary requirement. The government also points to a separate and less specific violation that it says Vora failed to disclose. CMS reimburses only services that are medically "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A) (forbidding CMS from paying for any expenses that "are not reasonable and necessary for the diagnosis or treatment of illness or injury"). Congress delegated to the Secretary of Health and Human Services the authority to interpret the phrase "reasonable and necessary." 42 U.S.C. § 1395hh(a)(1). And the Secretary has done so by issuing a host of regulations and other interpretations regarding what Medicare will and won't reimburse. Among those is the testing regulation at issue here: "Tests not ordered by the physician who is treating the beneficiary," the Secretary announced, "are not reasonable and

necessary." § 410.32(a). By tying this provision to the statutory reimbursement requirement, therefore, the regulation purports to deem any service that violates the rule not "reasonable and necessary" by operation of law. Opp. Br. (DN 44) at 3–5; FAC ¶¶ 82–83. By purporting to incorporate the statutory standard into regulatory language, may an agency circumvent the factual materiality analysis described in *Escobar* by choosing to categorize certain regulatory violations as "material" as a matter of law?[4]

Not according to the governing caselaw. "A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment." *Escobar*, 579 U.S. at 193. Rather, courts examine the materiality of a regulatory violation as a mixed question of fact and law. *See United States ex rel. Janssen v. Lawrence Memorial Hosp.*, 949 F.3d 533, 539 (10th Cir. 2020); *United States ex rel. Loughren v. Unum Grp.*, 613 F.3d 300, 308 (1st Cir. 2010). And they do so at the level of the specific regulatory requirement at issue—not by asking whether the agency deemed that requirement material as a general matter.

In *Prather*, for example, the Sixth Circuit responded to alleged violations of a physician-certification timing requirement by assessing whether the government regularly paid or ignored violations of that specific CMS requirement. It did not ask whether the government regularly paid or ignored claims that violated *any* regulatory requirement, or claims that had been deemed unreasonable and unnecessary by the Secretary. *See* 892 F.3d at 831–33. And the court in *Hobbs* determined that 42 C.F.R. § 410.33 is not a condition of payment by analyzing the specific regulation itself—not the "reasonable and necessary" language of 42 U.S.C. § 1395y, the statute that

[4] This incorporation argument, to be clear, would not reach the warfarin requirements. At argument the government distinguished regulations promulgated after notice and comment, such as § 410.32, from less-formal guidelines issued outside the rulemaking process, such as the Medicare Claims Processing Manual. *See* Tr. at 17–18. Even as asserted by the government, the authority to treat services as "not reasonable and necessary" based on a regulatory violation, Tr. 18:18–20, would stretch only to regulations sufficiently formal and binding to carry the "force of law" under contemporary administrative-law doctrine, *see generally United States v. Mead*, 533 U.S. 218, 229 (2001); Thomas W. Merrill & Kathryn T. Watts, *Agency Rules with the Force of Law: The Original Convention*, 116 HARV. L. REV. 467, 470 (2002).

The warfarin provision is not such a provision. It is found in the Medicare Claims Processing Manual, a CMS guidance document. Tr. at 17:13–15; *Medicare Claims Processing Manual Chapter 32 – Billing Requirements for Special Services*, Dept. of Health & Human Servs. (Aug. 25, 2020), https://www.hhs.gov/guidance/document/medicare-claims-processing-manual. While the Manual may serve as evidence that CMS recognizes a professional consensus regarding whether a type of treatment is considered medically necessary, even under the government's view of materiality the Court would not be bound to defer to CMS's judgment set forth in less-formal guidance under *Chevron*. *See Christensen v. Harris County*, 529 U.S. 576, 587 (2000).

§ 410.33 (like § 410.32(a)) purports to interpret. 711 F.3d at 716–17. That decision preceded *Escobar*, which of course requires *more* of FCA plaintiffs than the Sixth Circuit required at the time of *Hobbs*.

Now courts must ask whether "the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the *particular* statutory, regulatory, or contractual requirement." *Escobar*, 579 U.S. at 195 (emphasis added). The government's past actions when confronted with similar claims is relevant to materiality, which no longer rests only on whether a regulatory provision is designated as a "condition of payment." *See Vora I*, 488 F. Supp. 3d at 570 (describing Sixth Circuit practice pre-*Escobar*). So materiality turns on what the government previously did (a factual question), whether payment is conditioned on that requirement's satisfaction (a legal question), and the significance of the requirement to the bargain (a mixed question). *Escobar*, 579 U.S. at 193 & n.5. Otherwise every violation could be treated as material by the executive's regulatory say-so: the simple expedient of deeming any (and perhaps all) regulatory violations to render a service "not reasonable and necessary" under the healthcare laws. "The False Claims Act," the Supreme Court has repeatedly emphasized, "is not an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Id.* at 193 (quotation marks omitted)*; see also id.* at 195 (disagreeing that any violation can be material based only on the Government's entitlement to refuse payment).

This makes sense in light of the important distinction between CMS's decision to pay a claim under the Medicare program, on the one hand, and Congress' decision to treat a claim as fraudulent under the FCA, on the other. The materiality requirement at issue in this case only implicates the latter. This unreasonableness-by-incorporation approach might suffice to support CMS's determinations regarding which claims Medicare will *pay*. *Cf. United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 742 (10th Cir. 2018) ("For a claim to be reimbursable, it must meet the Government's definition of 'reasonable and necessary,' as found in the Medicare Program Integrity Manual."). But whether a regulatory violation renders a request for payment *fraudulent* under the False Claims Act is a separate question. Falsity and materiality are distinct elements.[5] And a false certification of regulatory compliance is not by itself enough to establish materiality, *as a matter of law*, under *Escobar* and precedents interpreting that requirement.

[5] *Escobar* made this separation between falsity and materiality quite clear: "'[I]nstead of adopting a circumscribed view of what it means for a claim to be false or fraudulent,' concerns about fair notice and open-ended liability 'can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements.' Those requirements are rigorous." 579 U.S. at 192 (quoting *United States v. Science Applications Int'l Corp.,* 626 F.3d 1257, 1270 (D.C. Cir. 2010)).

So the government cannot merely match the reasonable-and-necessary language in § 410.32(a) and the statute in order to prove a violation is material. It must allege facts regarding the effect of a violation of that regulation. And as discussed above, those allegations here are lacking. *See* above at § III.A.

As against this understanding of binding Supreme Court and Sixth Circuit precedent, the government points to the Ninth Circuit's decision in *Winter ex rel. United States v. Gardens Regional Hospital and Medical Center*, 953 F.3d 1108, 1122 (9th Cir. 2020). But even that out-of-circuit decision wouldn't save the amended pleadings here. The Ninth Circuit held that a relator had sufficiently pled the materiality of a doctor's knowingly false opinion of medical necessity by identifying the applicable Medicare statutes and regulations and alleging "that the government 'would not' have 'paid' Defendants' false claims 'if the true facts were known.'" *Id.* at 1122. Contrary to the government's reading, the panel's opinion did not hold "that failure to satisfy the [relevant regulations] made Defendants' Medicare claims per se false," though it recognized that violations could "support … allegations" of a false medical-necessity representation "because they reflect a medical consensus" about what services are reasonable and necessary. *Id.* at 1121. The *factual* allegations in that case asserted far more than the government does here. And the Ninth Circuit acknowledged that even CMS "consider[s] medical necessity a question of fact," not just a question of legal or regulatory compliance. *Id.* at 1114. Federal Rules of Civil Procedure 8 and 9, of course, require "factual content," not just a "formulaic recitation of the elements," to meet the plausibility standard. *Iqbal*, 556 U.S. at 678–79, 686–87. Because the government's amended complaint lacks such factual allegations of materiality, the Court must grant Vora's motion to dismiss with respect to the implied-certification theory of FCA liability.

IV. Express-Certification Claim

The Court and defense counsel didn't construe the original complaint to include a claim that Vora was responsible for an *express* false statement—that is, an allegation that he didn't actually believe the tests were medically necessary, even as he caused the lab to tell the government they were. *Vora I*, 488 F. Supp. 3d at 570. Whereas implied certification focuses on "misleading omissions," *Escobar*, 579 U.S. at 187, express certification focuses on a statement actually made on the claim form that is factually false.

Now, however, the government contends its amended complaint *does* include such an allegation. And the Court agrees, at least reading the amended complaint charitably, which the Court must do at this stage of the litigation. Vora caused the lab to represent to CMS, on every claim form, that the ordered tests were "medically indicated and necessary for the health of the patient." FAC ¶ 141. Whether Vora actually didn't believe the tests were reasonable and necessary when he caused the lab to certify as much is a separate question, of course, that the government may or may not be able to prove.

The amended complaint alleges that Vora falsely certified to the government, through the claim forms submitted by the lab, that at least some of the tests were medically necessary:

> 102. "By utilizing pre-signed requisition forms and directing staff to test all patients who met certain conditions, Dr. Vora delegated ordering tests from NMTC to his subordinates and *did not order these tests in reaction to a medical need*." (emphasis added).

And yet:

> 141. "Each claim submitted by NMTC for Dr. Vora's orders of pharmacogenomics tests included a statement whereby NMTC certified that the services rendered were 'medically indicated and necessary for the health of the patient.'"

Factual support for this contention, sufficiently specific under *Iqbal* and *Twombly*, is found in several other allegations:

> 99. Vora used "pre-signed" forms to order testing.
>
> 100. Vora directed his staff to order testing for "every one of his patients with a cardiovascular risk factor," instead of individually assessing need.
>
> 108. "During the relevant time period, Dr. Vora ordered pharmacogenomics testing from NMTC with reckless disregard or deliberate ignorance of the medical necessity for the tests."
>
> 109. "Dr. Vora's referrals lacked medical necessity, because he did not use the pharmacogenomics test results in the management of the beneficiary's specific medical problem."
>
> 111. "As early as January 31, 2012" Vora knew that patients were not receiving results from the tests.
>
> 112. "Vora continued to order … tests" despite "knowing that many results would not be returned in time to impact treatment decisions."
>
> 114–118. A specific patient's medical record did not mention testing, did not describe a "medical need" for testing, did not state how the results would impact treatment, and did not establish that the results were ever conveyed to the patient.

See also FAC ¶¶ 121–126 (a second allegation that Dr. Vora ordered tests for a patient despite not using them or believing they'd prove useful).

These allegations "contes[t]" the "medical need" for these tests, *Hobbs*, 711 F.3d at 715, and contend Vora knowingly or recklessly misrepresented their medical necessity. Vora is wrong that "the Government does not actually challenge the medical necessity of diagnostic tests" and challenges *only* "other purported underlying requirements of 42 CFR 410.32 with which the defendant has impliedly certified compliance." Reply at 2. The amended complaint alleged express false certifications, explaining why the governments stated that its implied-certification theory was "really belt and suspenders." Tr. at 23:14–16. The allegations set forth above, supported by the government's brief and oral argument, bear this out: they state a claim that Vora falsely asserted that the lab tests were necessary.[6]

At argument, Vora conceded that a doctor's actual belief and representation that medical services are "reasonable and necessary" is material to the government's decision to pay. Tr. at 27:11–13 (discussing 42 U.S.C. § 1395y). This is commonsensical: why would CMS pay for a test a doctor considered unnecessary but ordered anyway? Of course the government would decline to pay if it knew the truth. *See United States ex rel. Groat v. Boston Heart Diagnostics Corp.*, 255 F. Supp. 3d 13, 31 (D.D.C. 2017) (false statements regarding medical necessity "have a natural tendency to influence the government's payment"). Presumably that is why "Dr. Vora did not argue that a false certification of compliance with this statute"—which Vora and the lab made on the face of the claims form—"is not material." Reply at 1 (citing 42 U.S.C. § 1395y(a)(1)(A)).

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[6] A previous order, issued in response to Vora's motion to dismiss the original complaint, stated that the "actual medical necessity of the tests is not relevant under the government's theory of liability." *Vora I*, 488 F. Supp. 3d at 570. But the fairest reading of the amended complaint leads to a different conclusion, which the government plainly stated in its briefing and argument in opposition to Vora's second motion to dismiss. *See, e.g.*, Opp. Br. at 16:

> [T]he Complaint alleges that NMTC made an expressly false certification on each claim when it submitted form CMS-1500. Therein, NMTC expressly certified "*that the services shown on [the] form were medically indicated and necessary for the health of the patient.*" FAC Exs. S, T (emphasis added). Thus, each time NMTC submitted a claim for payment to Medicare, the lab expressly certified that the services performed were medically justified. *Id.*; *see also* FAC ¶ 142.

Compliance with various CMS regulations may be relevant to proving an express false certification of medical necessity, but Vora is correct that they are not dispositive, because medical judgment matters too. *See, e.g.*, *United States v. Paulus*, 894 F.3d 267, 275–76 (6th Cir. 2018) ("[O]pinions are not, and have never been, completely insulated from scrutiny."); *United States ex rel. Petratos v. Genentech, Inc.*, 855 F.3d 481, 487 (3d Cir. 2017) ("[T]he 'reasonable and necessary' determination is a process involving the FDA, CMS, *and* individual doctors.").

Instead Vora "argued that the *implied* certifications on which the Government's FCA claim is based in this case are not material." *Id.* (emphasis altered). Focusing only on the express certifications of medical necessity, Vora worried, could cause the government's obligation to allege materiality to "vanish" with respect to the underlying regulatory violations. Tr. at 27:6–10. But as his motion and this order should make clear, implied certifications of regulatory compliance and express certifications of medical necessity are different beasts. Because the government hasn't sufficiently alleged materiality regarding the latter, it cannot hold him liable based solely on regulatory noncompliance; it must show Vora ordered tests he knew or should've known were medically unnecessary. That is a big difference.

Whether the government eventually points to evidence that Dr. Vora did not in fact believe the tests were medically necessary (or recklessly ordered them regardless of their validity under Medicare regulations) is of course a separate question that the defense may raise on summary judgment or at trial. *See, e.g.*, *Hobbs*, 711 F.3d at 715 (allegedly false express certification challenged medical necessity of tests ordered).

ORDER

The Court grants in part and denies in part Vora's partial motion to dismiss (DN 43).

Benjamin Beaton, District Judge
United States District Court

January 7, 2022