FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

GERALDINE GODECKE, Relator; ex rel. United States of America, *Plaintiff-Appellant*, v. KINETIC CONCEPTS, INC.; KCI-USA, INC., *Defendants-Appellees.*	No. 18-55246 D.C. No. CV 08-6403 CAS OPINION

Appeal from the United States District Court
for the Central District of California
Christina A. Snyder, District Judge, Presiding

Argued and Submitted April 12, 2019
Pasadena, California

Filed September 6, 2019

Before: A. Wallace Tashima and Jay S. Bybee, Circuit Judges, and M. Douglas Harpool,[*] District Judge.

Opinion by Judge Tashima

---

[*] The Honorable M. Douglas Harpool, United States District Judge for the Western District of Missouri, sitting by designation.

SUMMARY[**]

False Claims Act / Medicare

The panel reversed the district court's dismissal of a relator's qui tam case against Kinetic Concepts, Inc. and KCI USA, Inc. (collectively "KCI"), brought under the federal False Claims Act, alleging that KCI submitted false claims to Medicare.

The panel held that the relator sufficiently alleged that KCI violated the False Claims Act. Specifically, the panel held that the relator adequately alleged a fraudulent scheme to submit false claims and reliable data that led to a strong inference that false claims were actually submitted. The panel further held that the relator sufficiently alleged that KCI acted with the requisite scienter under the False Claims Act. The panel also held that the relator sufficiently alleged that KCI's false claims were material to the government's ultimate Medicare payment decision.

[**] This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

COUNSEL

Kurt Kuhn (argued), Kuhn Hobbes PLLC, Austin, Texas; Patrick J. O'Connell, Law Offices of Patrick J. O'Connell PLLC, Austin, Texas; Mark I. Labaton, Glancy Prongay & Murray LLP, Los Angeles, California; Michael A. Hirst, Hirst Law Group P.C., Davis, California; for Plaintiff-Appellant.

Gregory M. Luce (argued), Skadden Arps Slate Meagher & Flom LLP, Washington, D.C.; Matthew E. Sloan and Kevin J. Minnick, Skadden Arps Slate Meagher & Flom LLP, Los Angeles, California; for Defendants-Appellees.

OPINION

TASHIMA, Circuit Judge:

Relator Geraldine Godecke appeals the district court's dismissal of her qui tam case against Defendants Kinetic Concepts, Inc. and KCI USA, Inc. (collectively, "KCI"), brought under the federal False Claims Act ("FCA"). Godecke alleges that KCI submitted false claims to Medicare. Specifically, Godecke alleges that KCI delivered durable medical equipment to Medicare patients before obtaining a detailed written order from a physician, which was a requirement for Medicare reimbursement. She alleges that if Medicare knew that this delivery requirement had not been satisfied prior to delivery, Medicare's policy would have been to refuse payment on KCI's claims. She alleges that KCI knew that it should not have been able to receive payment, but sought reimbursement regardless of this fact and chose not to alert Medicare to the issue. On this appeal, we must determine whether Godecke sufficiently alleges that (1) KCI

submitted false claims, (2) KCI acted with scienter, and (3) the false claims were material to the government. We hold that she does so. Therefore, we reverse and remand for further proceedings.

BACKGROUND

The facts as presented here are taken from the allegations in the Fourth Amended Complaint ("FAC"). For the purposes of a motion to dismiss, we must take all of the factual allegations in the complaint as true, although we are not bound to accept as true a legal conclusion couched as a factual allegation. *Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009); *Bell Atlantic Corp v. Twombley*, 550 U.S. 544, 555 (2007).[1]

In 2001, Godecke became an employee of MedClaim, Inc., a specialized billing company that was under contract with KCI to submit KCI's claims to Medicare and to provide evidentiary and other support for appeals of claims denied by Medicare. In 2003, KCI purchased MedClaim, and Godecke became an employee of KCI. She was the Director of Medicare Cash and Collections at MedClaim and then KCI from June 1, 2001 to October 1, 2007. Her position required her to work with KCI's information systems related to billing, and also required her to review communications regarding claim payments that were made or denied by Medicare. She was also responsible for the creation of a new department within KCI, informally known as the "back end" of the

[1] Godecke began this action in 2008 when she filed the original complaint under seal. This case has been up to the Ninth Circuit before on the issue of subject matter jurisdiction. *See U.S. ex rel. Hartpence v. Kinetic Concepts*, Inc., 792 F.3d 1121 (9th Cir. 2015).

billing department, that dealt specifically with the appeal process for KCI's claims that had been denied by the Medicare billing and payment system. She and her staff evaluated whether KCI should appeal those denials and provided supporting information for challenging those denials in administrative hearings.

KCI manufactures a piece of durable medical equipment known as a Vacuum Assisted Closure device ("VAC"), which is used to perform negative pressure wound therapy ("NPWT"). The VAC was added to the list of Medicare covered devices starting on October 1, 2000, and, at that time, no other NPWT pump was approved for Medicare reimbursement. Pursuant to Medicare Part B, the VAC device is rented on a monthly basis, and the supplies needed for VAC treatment, such as dressings and a canister, are purchased. In 2006, the total monthly cost for a VAC for a Medicare patient was about $2,224 for the first 3 months and $1,794 for each subsequent month; Medicare pays 80% of this cost and the patient is liable for the remaining 20%. Between 2001 and 2011, KCI's Medicare Part B revenue totalled $1.325 billion.

Medicare administers the rules for use of the VAC and similar NPWT devices through private claims processing contractors known as Durable Medical Equipment Medicare Administrative Contractors ("DME MACs"). These DME MACs have issued Local Coverage Determinations ("LCDs") that govern reimbursement rules for VACs. DME MACs are also authorized to make payments on behalf of the government to Medicare claimants. Because Medicare is required to pay claims submitted within just a few weeks of receipt of the claim, the Medicare program has historically paid claims quickly without verifying the accuracy of the

claims before payment. Medicare accepts claims as submitted by providers as being a true representation that the claim either qualifies for reimbursement or does not qualify and automatically pays those claims represented as qualifying. Medicare must then seek reimbursement or recoupment if it later determines that the claim should not have been paid. This payment system has become known as "pay and chase," and relies on the honesty of providers and the accuracy of the claims they submit.

Under the LCD, KCI must receive, prior to delivery of the VAC to a patient, a detailed written order from a physician, also known as a written order prior to delivery ("WOPD"), referred to as a "prior written order" by KCI. If KCI does not receive a WOPD prior to delivery of the VAC, then KCI is not entitled to payment from Medicare. This requirement to obtain a WOPD before delivering the VAC has been in the Medicare Program Integrity Manual since KCI first started billing Medicare in 2000. Importantly, if KCI does not receive a detailed written order prior to delivery, payment will not be made for the device *even if* KCI was able subsequently to obtain a written order after delivery.

When KCI submitted claims to Medicare, it used certain billing code modifiers on the claims to indicate whether all of the reimbursement requirements had been met. The KX billing code modifier specifically represents to Medicare that all requirements for payment have been satisfied. By adding the KX modifier to a claim, KCI attested that the specific required documentation is on file before submitting the claim to the DME MAC. As early as 1999, the Office of Inspector General of the U.S. Department of Health and Human Services warned that misuse of the KX modifier could result

in false claims.[2] In contrast, there is a separate billing code modifier that must be used in order to represent to Medicare that not all requirements for payment have been satisfied. In 2003, the billing code modifier "EY" was adopted for use when a NPWT item was delivered before a signed written order had been received by the supplier. KCI is allowed to submit claims for costs that are presumptively non-reimbursable, but must do so openly by using the proper Medicare billing code modifier, describing the claims accurately while challenging the presumption and seeking reimbursement.

Godecke alleges that KCI delivered many VACs without the required WOPD. Due to time constraints and business pressures, KCI management would authorize "exceptions" to KCI's standard operating procedures, which were based on Medicare's requirements. These exceptions would allow KCI employees to release the VAC and supplies for delivery to the patient before receiving the written order. The exception granted by management would make the claim appear to be billable under KCI's internal procedures, even though Medicare's WOPD requirements had not been satisfied. KCI was not required to disclose the actual date on which it received the written order, and there was a 30-day window after a patient's treatment started before KCI had to bill Medicare. During this 30-day window, KCI could get a detailed written order from a physician for the VAC. In such cases, of course, the order was not technically a WOPD because it was not written *prior to delivery*. Based on

[2] The KX billing code replaced the ZX billing code in 2002. The only difference between the codes is that ZX was a temporary designation and KX is a permanent designation. For the sake of simplicity, we use "KX" throughout this opinion.

reviews of reports and conversations with customer service representatives and KCI management, Godecke learned that KCI management granted these exceptions and allowed customer service representatives to deliver VACs to patients before all the WOPD requirements had been satisfied. She also knew that KCI management understood the Medicare requirements and the rules for reimbursement, and she also helped KCI management set up tracking systems specifically for following up on orders for VACs that had been delivered but did not satisfy the WOPD requirements.

Godecke next alleges that KCI knowingly used the wrong billing code modifiers to conceal from Medicare that these VACs were delivered before receiving a WOPD. KCI would routinely submit claims for payment when KCI either did not have any WOPD in its possession or had some form of a WOPD, but the order was defective. KCI would bill Medicare using the KX modifier as long as it was able to obtain a detailed written order before the 30-day window to submit bills had closed. KCI would submit these claims without including the EY modifier, even though it was required to do so. Because of the 30-day window and the fact that KCI was not required to submit the actual date the WOPD was received, KCI's alleged scheme avoided detection by Medicare, unless Medicare chose to audit a claim and knew exactly what to look for and where to look.

Godecke provides fifteen representative examples of false claims that were submitted for reimbursement without the EY code. These claims are identified by Rental Order Entry ("ROE") numbers, a unique identifying number assigned to each VAC delivery request. Godecke used an internal KCI report to identify ROEs for a group of VACs delivered without a WOPD (or with an incomplete WOPD). By cross-

referencing this group with another internal report, Godecke was able to identify the ROEs in this group for which KCI management granted an exception in order to approve the delivery and billing of these VACs without a WOPD. Then, Godecke generated a report through KCI's billing and appeals databases to confirm that these ROEs had been either paid or appealed. Therefore, because claims with the EY modifier would not be paid and could not be appealed, these ROEs not only were delivered despite noncompliance, but also were billed by KCI without the required EY modifier.

After gathering evidence and customized reports, Godecke brought her concerns about the billing non-compliance issues to the attention of KCI's management. Godecke presented her findings at a meeting with her boss Rich Brinkley, KCI Senior Vice President Steve Hartpence, and with Godecke's former supervisor Deb Smith on the phone. Smith disputed Godecke's interpretation of the Medicare rules, but Hartpence requested that Godecke continue her research on the issue. Within hours of the meeting, Hartpence was fired and escorted out of KCI's building. About a month later, Brinkley was also fired, and he called Godecke to say that she was going to be fired "because senior management told him she was going to be a whistleblower." Godecke was fired a few weeks later on October 1, 2007.[3]

[3] The district court stayed Godecke's retaliation claim and KCI's breach of contract and conversion counterclaims pending the outcome of this appeal.

JURISDICTION AND STANDARD OF REVIEW

We have jurisdiction pursuant to 28 U.S.C. § 1291. We review the dismissal of claims under the FCA de novo. *U.S. ex rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166, 1170 (9th Cir. 2006). We assume that the facts as alleged are true and examine only whether the relator's allegations support a cause of action under the FCA, under the theories presented. *Id.* A Rule 12(b)(6) dismissal "can be based on the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1990). A complaint must plead "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' " *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). A claim under the FCA must not only be plausible, Fed. R. Civ. P. 8(a), but pled with particularity under Rule 9(b), *U.S. ex rel. Cafasso v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1054–55 (9th Cir. 2011). Rule 9(b) requires that the circumstances alleged to constitute fraud be specific enough to give the defendant notice of the particular misconduct so that it can defend against the charge. *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1124 (9th Cir. 2009). The party must allege the "who, what, when, where, and how" of the misconduct. *Id*.

DISCUSSION

I. Godecke sufficiently alleged that KCI violated the FCA.

The FCA makes liable anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or "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)(A), (B). A claim under the FCA requires a showing of: "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *U.S. ex rel. Campie v. Gilead Sci., Inc.*, 862 F.3d 890, 899 (9th Cir. 2017), *cert. denied*, 139 S. Ct. 783 (2019).

The district court dismissed the FAC on the ground that it failed to plead a violation of the FCA. Godecke challenges the district court's determination that she failed sufficiently to allege that, either (1) KCI actually submitted any claim without the EY modifier when it was required, or (2) there were "reliable indicia" leading to "a strong inference" that KCI actually submitted claims without an EY modifier. Godecke also challenges the district court's determination that her claims failed to meet the FCA's scienter requirements. KCI, on the other hand, argues that Godecke failed to allege sufficient facts to meet the FCA's materiality requirement. The district court denied KCI's motion to dismiss on materiality grounds in an earlier ruling on the Second Amended Complaint.

A. Godecke adequately alleges a fraudulent scheme to submit false claims and reliable indicia that lead to a strong inference that false claims were actually submitted.

To state an FCA claim, a relator is not required to identify actual examples of submitted false claims; instead, "it is sufficient to allege 'particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.'" *Ebeid ex rel.*

U.S. v. Lungwitz, 616 F.3d 993, 998–99 (9th Cir. 2010) (quoting *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)). A relator is not required to identify representative examples of false claims to support every allegation, although the use of representative examples is one means of meeting the pleading obligation. *Id*. at 998.

Godecke sufficiently alleged particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that the claims were actually submitted. Godecke alleges that she learned about KCI's scheme to submit false claims through her role as KCI's Director of Medicare Cash and Collections. Even though Godecke never personally was directed not to include an EY modifier or directly observed other employees omitting the EY modifier, her complaint alleges particular details of a KCI management scheme to submit claims omitting the EY modifier when it should have been included. Based on knowledge gained from talking with sales representatives, Godecke learned that KCI often delivered VAC devices without receiving a prior written order at the urging of sales executives. She alleges that she "knew from management explanations" that KCI management knew that Medicare would not pay for the VAC devices delivered under these "exceptions" to the rules, and KCI management "set up tracking systems to expedite [the] effort . . . to mask the fact that VACs were delivered without all of the required elements in hand." Godecke has alleged personal knowledge that KCI management was actively and knowingly looking for ways to conceal the fact that certain VAC devices would not be reimbursable.

Godecke's ROEs analysis shows reliable indicia that raise a strong inference that KCI actually submitted false claims.

The district court found that Godecke's analysis did not sufficiently support the theory that KCI actually submitted false claims because Godecke's analysis of ROEs in KCI's appeals database was entirely consistent with an equally plausible interpretation that the ROEs instead represented claims that were submitted with an EY modifier and were consequently denied. But Godecke shows that her system of cross-referencing ROEs in different databases allowed her to rule out that interpretation. In paragraphs 157 through 160 of the FAC, Godecke specifically alleges that she could pinpoint those ROEs for claims without a WOPD where the claim was either paid or appealed, which would have been impossible had the claim included the EY modifier as it should have had.

Furthermore, the FAC includes detailed allegations from Theresa Duffy, a former colleague of Godecke, who personally reviewed KCI's claims denied by Medicare to determine whether KCI should appeal the denials. Starting in 2002, "Duffy complained to Godecke about the inadequate documentary support for submitted claims," and Duffy and Godecke "discussed that numerous claims lacked required documentation." Less than two weeks before Godecke filed the FAC (in 2017), Duffy confirmed to Godecke "that KCI's claims submitted to Medicare that Duffy had personally reviewed lacked appropriate documentation, including claims which required an EY modifier because KCI did not have a valid WOPD before delivery of a VAC." In 2017, Duffy also confirmed to Godecke that she "personally saw that claims for first cycle treatment had routinely been billed to Medicare, and paid by Medicare, even though the VAC had been delivered before KCI had obtained a valid WOPD."[4] Duffy also stated that she "did not recall ever seeing an EY

[4] First cycle treatment refers to the first month of VAC therapy.

modifier placed on any first cycle claims, even when Medicare required that an EY modifier be included." Duffy also confirmed that when she "reported to KCI management, including Deb Smith, that she had not found any WOPD for claims submitted, Smith directed Duffy not to appeal the claim . . . because Smith was worried that Medicare would notice the lack of a WOPD."

Duffy's allegations provided the necessary reliable indicia that give a strong inference that KCI actually submitted false claims to Medicare, and the district court incorrectly disregarded the information provided by Duffy. The district court recognized that, "[w]hile it is certainly suspect that Plaintiff is on her Fourth Amended Complaint, and Plaintiff now, for the first time, alleges facts pertaining to conversations that occurred starting in 2002, the Court must accept Plaintiff's allegations as true when deciding a motion to dismiss." In spite of that acknowledgement, however, the district court did not accept the allegations as true, stating that the "allegations regarding [Godecke's] conversations with Duffy are not particularly reliable, given that Duffy was allegedly recounting what she recalled from fifteen years prior." The district court ultimately held that "Plaintiff's allegations regarding her 2002 conversations with Duffy and Duffy's recollections that Plaintiff 'confirmed' in 2017 do not provide the necessary "reliable indicia" that KCI actually submitted false claims to Medicare."

The district court imposed too high of a hurdle to test the sufficiency of these allegations. The only unreliable aspect of Duffy's allegations is the fact that Duffy's recollection is based on events that happened fifteen years prior. Although it is true that a fifteen year old memory is less reliable than a more recent one, Duffy's memories clearly allege a false

claim: she "personally saw that claims for first cycle treatment had routinely been billed to Medicare, and paid by Medicare, even though the VAC had been delivered before KCI had obtained a valid WOPD." Duffy's recollections can be more closely examined in a deposition, and it is possible that they would not hold up under cross-examination. But a motion to dismiss is too early a stage to render a judgment on the reliability of Duffy's recollections when the only indication that they might be less than reliable is the length of time that has elapsed since she witnessed the events at issue.

Godecke alleges details of a scheme to submit claims that were fraudulent because they lacked the EY modifier when it should have been included. And Duffy's recollections and Godecke's cross-referencing of ROEs are enough reliable indicia to lead to a strong inference that KCI actually submitted false claims to Medicare.

B. Godecke sufficiently alleges that KCI acted with the requisite scienter under the FCA.

Liability under the FCA is established only when the defendant "knowingly" presents a false or fraudulent claim for payment. 31 U.S.C. § 3729(a)(1)(A). "Knowingly" is defined as having: (1) actual knowledge of the information; (2) deliberate ignorance of the truth or falsity of the information; or (3) reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b)(1)(A). The FCA's "knowingly" requirement "require[s] no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1)(B). Instead of pleading specific intent to defraud, it is sufficient to plead that the defendant knowingly filed false claims, or that the defendant submitted false claims with reckless disregard or deliberate ignorance as to the truth or falsity of its

representations. *United States v. Bourseau*, 531 F.3d 1159, 1167 (9th Cir. 2008). The deliberate ignorance standard can cover "the ostrich type situation where an individual has buried his head in the sand and failed to make simple inquiries which would alert him that false claims are being submitted." *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1174 (9th Cir. 2016) (internal quotation marks omitted). "Congress adopted the concept that individuals and contractors receiving public funds have some duty to make a limited inquiry so as to be reasonably certain they are entitled to the money they seek." *Id.* (internal quotation marks omitted).

The district court erred in holding that Godecke failed to plead the requisite scienter under the FCA.[5] The district court indicated that Godecke and Duffy's knowledge of the appeals process would only support an inference that KCI found out during the appeals process that it was submitting false claims

[5] The district court misstated the standard for scienter at the conclusion of its scienter analysis, stating that Godecke had not sufficiently alleged that KCI "knowingly submitted false claims with *an intent to deceive the government*." (Emphasis added.) But this incorrect legal standard was only mentioned once, and it is clear from the rest of the district court's analysis that the district court understood that the proper standard only required KCI knowingly to submit false claims. As the district court stated, "[t]he more appropriate inquiry is whether Plaintiff has pleaded facts indicating that KCI knowingly submitted claims without a completed WOPD to Medicare without the requisite EY modifier." Therefore, reversal would not be warranted solely on the ground that the district court misstated once the proper legal standard for scienter. *See Hooper v. Lockheed Martin Corp.*, 688 F.3d 1037, 1049–50 (9th Cir. 2012) (holding that when the district court applies the wrong legal standard by requiring the relator to prove that the defendant acted "with the intent to deceive," reversal may be warranted).

to the government, not that it knew they were false at the time of submission.

But Godecke sufficiently alleges that KCI knowingly submitted claims without the requisite EY modifier when KCI had not gotten a written order prior to delivery. First, Godecke alleges that KCI knowingly delivered VAC devices without receiving a prior written order, as evidenced by the "exceptions" authorized by managers. Although this allegation by itself would not be sufficient to allege that KCI knowingly *submitted* false claims, it is an important building block in the overall allegations sufficiently to plead FCA violations. Building on the allegations that KCI knowingly delivered VAC devices without a WOPD, Godecke sufficiently alleges that KCI knowingly submitted these claims without a WOPD to Medicare without the requisite EY modifier. Godecke alleges that KCI management explained they knew that Medicare would not pay for the VAC devices delivered under the "exceptions" to the rules, and KCI management "set up tracking systems to expedite [the] effort . . . to mask the fact that VACs were delivered without all of the required elements in hand."

Godecke's scienter allegations are bolstered by information from her former co-worker Theresa Duffy. Godecke alleges that Duffy recently confirmed to her "that KCI's claims submitted to Medicare that Duffy had personally reviewed lacked appropriate documentation, including claims which required an EY modifier because KCI did not have a valid WOPD before delivery of a VAC." Duffy also confirmed to Godecke that KCI's billing and management head Deb Smith told her not to appeal denials of certain claims "because Smith was worried that Medicare would notice the lack of a WOPD." Partially through Duffy's

recollection, the FAC alleged that false claims were submitted without the proper WOPD documentation and KCI management deliberately avoided appealing denials of claims that lacked a WOPD. Combined, this is sufficient to allege scienter. The district court explained away Godecke's conversations with Duffy as not alleging the requisite scienter, saying "at most, Duffy 'confirmed' that KCI realized after the fact, during the appeals process, that it had submitted claims to Medicare without a WOPD or the required EY modifier." But at the very least, Duffy's recollections are sufficient to show the "ostrich type situation" of deliberate ignorance on the part of KCI, where KCI "has buried his head in the sand and failed to make simple inquiries which would alert [it] that false claims are being submitted." *See United Healthcare Ins. Co.*, 848 F.3d at 1174.

Furthermore, when Godecke raised concerns about whether KCI was following proper rules for billing Medicare, KCI quickly fired not only Godecke, but also her supervisor, and the senior vice president to whom they both reported. Godecke's supervisor told her that KCI management was afraid she was gathering information on false claims and was going to be a whistleblower. While the circumstances of the firings does not establish on its own that KCI knowingly submitted false claims, KCI's extraordinarily aggressive reaction to these concerns suggest that KCI was at least trying to remain willfully ignorant of the falsity of its VAC claims. When combined with Duffy's recollection and the tracking systems, the firings are added support of the allegation that KCI knowingly submitted false claims.

In sum, the allegations of scienter were sufficient, at least under the "deliberate ignorance" standard, based on the FAC's discussion of the tracking systems set up by KCI

management, Godecke's colleague's assertions that she personally reviewed claims that lacked appropriate documentation, KCI management's instructions not to appeal denials for fear that Medicare would notice the lack of a written order prior to delivery, and the quick termination of Godecke, her supervisor, and the senior vice president after they raised concerns about false claims being submitted.

C. Godecke sufficiently alleges that KCI's false claims were material to the government's payment decision.

KCI argues that the FAC fails the FCA's materiality requirement because it does not allege with particularity that the allegedly false submissions would have affected Medicare's ultimate payment decision. In an earlier order, the district court denied KCI's motion to dismiss the Second Amended Complaint on the issue of materiality. "In reviewing decisions of the district court, we may affirm on any ground finding support in the record. If the decision below is correct, it must be affirmed, even if the district court relied on the wrong grounds or wrong reasoning." *Cigna Prop. & Cas. Ins. Co. v. Polaris Pictures Corp.*, 159 F.3d 412, 418 (9th Cir. 1998).

The FCA defines the term "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). Although the requirement is "demanding," the Supreme Court has held that there is not a bright-line test for determining whether the FCA's materiality requirement has been met. *See Universal Health Servs., Inc. v. U S. ex rel. Escobar*, 136 S. Ct. 1989, 2003 (2016). Instead, the Supreme Court has given a list of relevant, but not necessarily

dispositive, factors in determining whether the false claims were material, such as whether the government decided "to expressly identify a provision as a condition of payment." *Id.* "Likewise, proof of materiality can include, but is not necessarily limited to, evidence that 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." *Id*. "Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material." *Id*. "Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material." *Id*. at 2003–04. "Materiality, in addition, cannot be found where noncompliance is minor or insubstantial." *Id*. at 2003.

Filing for Medicare payment for a VAC and related supplies without disclosing that no written order was received prior to delivery is a material false claim. Godecke's allegations, taken together, sufficiently allege materiality to survive a motion to dismiss. According to the FAC, the LCDs explicitly provide that payment would not be made if a VAC was delivered before the written order was received. Although this express identification of a condition of payment "may not be sufficient, without more, to prove materiality, . . . it is certainly probative evidence of materiality." *See U.S. ex rel. Rose v. Stephens Inst.*, 909 F.3d 1012, 1020 (9th Cir. 2018). Godecke further alleges that the prior written order requirement was not just some "paperwork issue" but the result of extensive negotiations KCI had with Medicare representatives in order to prevent fraud and abuse. Although

this is not an allegation based on how Medicare "has treated similar violations," the fact that the requirement was "extensively negotiated" is also probative. *See id*. KCI simply suggests that because the government "*may* reimburse a particular claim in full despite its not meeting the LCD guidelines (including the EY modifier requirement), those guidelines cannot be said to be material to the government's payment determination." (Emphasis added.) But KCI has not shown that Medicare has paid a particular claim in full despite its actual knowledge that there was no prior written order. Nowhere in the record is there evidence that the government actually *has* reimbursed a particular claim in full despite knowing that it did not meet the LCD guidelines related to the EY modifier requirement. Godecke's allegations also do not indicate that noncompliance would be minor or insubstantial. Godecke alleges that Medicare would not pay for the VAC at all if it knew that there was no prior written order. Godecke therefore has sufficiently alleged materiality.

CONCLUSION

For the foregoing reasons, we reverse the district court's dismissal of the FAC.[6]

REVERSED and REMANDED.

[6] Because we hold that the FAC's allegations are sufficient under the FCA, we do not reach Godecke's alternate argument that the district court erred in denying her leave to further amend her complaint.