FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA, *Plaintiff*, and JAMES M. SWOBEN, Qui Tam Relator, *Plaintiff-Appellant*, v. UNITED HEALTHCARE INSURANCE COMPANY, a Connecticut corporation; UNITED HEALTHCARE SERVICES, INC., Minnesota corporation; UHIC; UNITEDHEALTH GROUP; UNITEDHEALTHCARE; UNITEDHEALTH; PACIFICARE HEALTH PLAN ADMINISTRATORS, INC.; UHC OF CALIFORNIA, FKA PacifiCare of California; PACIFICARE LIFE & HEALTH INSURANCE CO.; PACIFICARE HEALTH SYSTEMS; HEALTH NET;	No. 13-56746 D.C. No. 2:09-cv-05013-JFW-JEM OPINION

WELLPOINT; AETNA; HEALTHCARE PARTNERS, LLC; HEALTHCARE PARTNERS MEDICAL GROUP, INC.; HEALTHCARE PARTNERS INDEPENDENT PHYSICIAN ASSOCIATION,
Defendants-Appellees.

Appeal from the United States District Court
for the Central District of California
John F. Walter, District Judge, Presiding

Argued and Submitted December 9, 2015
Pasadena, California

Filed August 10, 2016

Before: Stephen Reinhardt, Raymond C. Fisher
and Jacqueline H. Nguyen, Circuit Judges.

Opinion by Judge Fisher

SUMMARY*

Medicare

The panel vacated the district court's judgment dismissing without leave to amend qui tam relator James Swoben's third amended complaint, which alleged that defendant Medicare Advantage organizations submitted false certifications in violation of the False Claims Act, and remanded with instructions to afford Swoben leave to file a proposed fourth amended complaint.

The Centers for Medicare & Medicaid Services ("CMS") pays Medicare Advantage organizations fixed monthly amounts for each enrollee, and CMS calculates the payment for each enrollee based on various "risk adjustment data" as reflected in submitted diagnoses codes. Medicare regulations require a Medicare Advantage organization to certify that the data it submits are "accurate, complete, and truthful." 42 C.F.R. § 422.504(*l*), (*l*)(2). Swoben alleged that the defendant organizations submitted false certifications by performing biased retrospective medical record reviews designed not to identify erroneously reported diagnosis codes.

The panel held that the district court abused its discretion by denying leave to amend on the ground of futility of amendment. The panel held that the theory alleged here – that the defendants designed their retrospective review procedures to not reveal erroneously reported diagnosis codes – adequately alleged that the defendants' § 422.504(*l*)

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

certifications were false and stated a cognizable legal theory under the False Claims Act. The panel also held that the proposed fourth amended complaint alleged sufficient factual matter to satisfy Fed. R. Civ. P. 8, 9(b) and 12(b)(6).

The panel held that the district court also abused its discretion by denying leave to amend based on undue delay. The panel held that leave to amend was proper in this case where the litigation against the defendants was at an early stage, Swoben did not seek to assert a new legal theory, and this was Swoben's first attempt to cure deficiencies in his pleadings.

COUNSEL

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Charles W. Scarborough and Karen Schoen, Attorneys, Appellate Staff; Eileen M. Decker, United States Attorney; Benjamin C. Mizer, Principal Deputy Assistant Attorney General; Civil Division, United States Department of Justice, Washington, D.C.; for Amicus Curiae United States.

OPINION

FISHER, Circuit Judge:

The Centers for Medicare & Medicaid Services (CMS), administrator of the federal Medicare program, pays Medicare Advantage organizations fixed monthly amounts for each enrollee. CMS calculates the payment for each enrollee based on various "risk adjustment data," such as an enrollee's demographic profile and the enrollee's health status, as reflected in the medical diagnosis codes associated with healthcare the enrollee receives. These diagnosis codes are reported by Medicare Advantage organizations to CMS.

Because Medicare Advantage organizations have a financial incentive to exaggerate an enrollee's health risks by reporting diagnosis codes that may not be supported by the enrollee's medical records, Medicare regulations require a Medicare Advantage organization, as an express condition of receiving payment, to "certify (based on best knowledge, information, and belief) that the [risk adjustment] data it submits . . . are accurate, complete, and truthful." 42 C.F.R. § 422.504(*l*), (*l*)(2).

Qui tam relator James Swoben alleges Medicare Advantage organizations United Healthcare, Aetna, WellPoint and Health Net, and physician group HealthCare Partners, submitted false certifications under this provision, in violation of the False Claims Act, by conducting retrospective reviews of medical records designed to identify and report only under-reported diagnosis codes (diagnosis codes erroneously not submitted to CMS despite adequate support in an enrollee's medical records), not over-reported codes (codes erroneously submitted to CMS absent adequate record support). The district court denied Swoben leave to file a proposed fourth amended complaint, citing futility of amendment and undue delay. We hold the district court abused its discretion.

First, the court erred by concluding amendment would be futile. Swoben's proposed fourth amended complaint asserts a cognizable legal theory. CMS has long made clear that, under § 422.504(*l*), Medicare Advantage organizations have "an obligation to undertake 'due diligence' to ensure the accuracy, completeness, and truthfulness" of the risk adjustment data they submit to CMS and "will be held responsible for making good faith efforts to certify the accuracy, completeness, and truthfulness" of these data.

Medicare+Choice Program, 65 Fed. Reg. 40,170, 40,268 (June 29, 2000). When, as alleged here, Medicare Advantage organizations design retrospective reviews of enrollees' medical records deliberately to avoid identifying erroneously submitted diagnosis codes that might otherwise have been identified with reasonable diligence, they can no longer certify, based on best knowledge, information and belief, the accuracy, completeness and truthfulness of the data submitted to CMS. This is especially true when, as alleged here, they were on notice – based on audits conducted by CMS – that their data likely included a significant number of erroneously reported diagnosis codes. The allegations in Swoben's proposed fourth amended complaint also satisfy Rules 8 and 9(b) of the Federal Rules of Civil Procedure. Although the allegations are not as detailed as they might be, they adequately identify "the who, what, when, where, and how of the misconduct charged," *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010) (quoting *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003)) (internal quotation marks omitted), and afford each defendant notice of its alleged role in a fraudulent scheme.

Second, the district court abused its discretion by denying leave to amend based on undue delay. Undue delay by itself is insufficient to justify denying leave to amend, and the record here does not support any additional ground – such as prejudice or bad faith – that would justify the denial. *See Owens v. Kaiser Found. Health Plan, Inc.*, 244 F.3d 708, 712–13 (9th Cir. 2001). On the contrary, leave to amend is proper here given the litigation against these defendants is at an early stage, Swoben does not seek to assert a new legal theory and this is Swoben's first attempt to cure deficiencies in his pleadings.

BACKGROUND

I. The Medicare Advantage Program

Medicare beneficiaries have the option of receiving benefits through private health plans as an alternative to the traditional fee-for-service Medicare program. Under this option, known as Medicare Advantage or Medicare Part C, the government pays Medicare Advantage organizations a capitated (per enrollee) amount to provide medical benefits. The capitated amount is a fixed monthly payment regardless of the volume of services an enrollee uses.

The government adjusts the monthly payments to Medicare Advantage organizations to reflect the health status of their enrollees. *See* 42 U.S.C. § 1395w-23(a)(1)(C)(i), (a)(3); 42 C.F.R. § 422.308(c)(2). This ensures Medicare Advantage "organizations are paid appropriately for their plan enrollees (that is, less for healthier enrollees and more for less healthy enrollees)." Establishment of the Medicare Advantage Program, 70 Fed. Reg. 4588, 4657 (Jan. 28, 2005). The risk adjustment methodology relies on enrollee diagnoses. *See* Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 74 Fed. Reg. 54,634, 54,673 (Oct. 22, 2009). Physicians and other health care providers submit diagnosis codes to the Medicare Advantage organizations, which in turn submit them to CMS. *See id.* at 54,674. These diagnosis codes contribute to an enrollee's risk score, which is used to adjust a base payment rate. *See id.* Each diagnosis code submitted must be supported by a properly documented medical record. *See* 42 U.S.C. §§ 1395*l*(e), 1395y(a)(1)(A); 42 C.F.R. § 422.310(d); Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the

Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29,844, 29,923 (May 23, 2014) ("CMS has required for many years that diagnoses that [Medicare Advantage] organizations submit for payment be supported by medical record documentation.").

"Since there is an incentive for [Medicare Advantage] organizations to potentially over-report diagnoses so that they can increase their payment, [CMS] audits plan-submitted diagnosis data a few years later to ensure they are supported by medical record documentation." Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 1918, 2001 (Jan. 10, 2014). These risk adjustment data validation (RADV) audits review selected medical records to determine whether they support the diagnoses reported by Medicare Advantage organizations. *See id.*[1]

As a further bulwark against fraud, Medicare Advantage organizations must certify the accuracy, completeness and truthfulness of the data they provide to CMS, including risk adjustment data, as a condition to receiving payment:

[1] Initially, when conducting RADV audits, CMS recouped overpayments solely with respect to the sampled beneficiaries. More recently, CMS has implemented a procedure through which the payment error rate calculated for the sampled beneficiaries in the audits is extrapolated to the contract population as a whole. *See* CMS, *Medicare Advantage Risk Adjustment Data Validation Audits Fact Sheet* 1, 3 (updated Dec. 11, 2015), https://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/Downloads/MA_RADV_Audit_Fact_Sheet.pdf; *see also* 74 Fed. Reg. at 54,673–74.

> *As a condition for receiving a monthly payment* under subpart G of this part, the [Medicare Advantage] organization agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, *must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of relevant data that CMS requests*. Such data include specified enrollment information, encounter data and other information that CMS may specify.

42 C.F.R. § 422.504(*l*) (emphasis added).[2] Specifically, a Medicare Advantage organization "must certify (based on best knowledge, information, and belief) that the [risk adjustment] data it submits under § 422.310 are accurate, complete, and truthful." *Id.* § 422.504(*l*)(2).

A Medicare Advantage organization is also required to "[a]dopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements." 42 C.F.R. § 422.503(b)(4)(vi).[3] In addition, although

[2] This regulation has been in force, in substantially the same form, since 2000. *See* 42 C.F.R. § 422.502(*l*) (2000).

[3] This requirement has been on the books, in similar form, since 2005. *See* 42 C.F.R. § 422.503(b)(4)(vi)(F), (G) (2005); 42 C.F.R. § 422.503(b)(4)(vi) (2010).

Medicare Advantage organizations generally submit data to CMS shortly after services are provided, the regulations also allow for data submissions after the payment year. *See* 42 C.F.R. § 422.310(g). CMS uses these data to "recalculate[] the risk factors for affected individuals to determine if adjustments to payments are necessary." *Id.* § 422.310(g)(2)

In light of these provisions, Medicare Advantage organizations may, but are not required to, conduct retrospective reviews of their enrollees' medical records to ensure the accuracy of the diagnosis codes they have provided to CMS. *See* CMS, *2008 Risk Adjustment Data Technical Assistance For Medicare Advantage Organizations Participant Guide* § 7.7.

Certification under § 422.504(*l*) has always required due diligence and good faith. When CMS adopted the "best knowledge, information, and belief" standard in 2000, it explained in the preamble to the regulation that Medicare Advantage organizations "cannot reasonably be expected to know that every piece of data is correct," so "simple mistakes will not result in sanctions." Medicare+Choice Program, 65 Fed. Reg. 40,170, 40,268 (June 29, 2000). But § 422.504(*l*) does not require actual knowledge that the data supplied to CMS are false. Rather, as under the False Claims Act, a certification is false under § 422.504(*l*) when the Medicare Advantage organization has actual knowledge of the falsity of the risk adjustment data *or* demonstrates either "reckless disregard" or "deliberate ignorance" of the truth or falsity of the data. *Id.* Thus, Medicare Advantage organizations "have an obligation to undertake 'due diligence' to ensure the accuracy, completeness, and truthfulness of encounter data submitted to [CMS]" and "will

be held responsible for making good faith efforts to certify the accuracy, completeness, and truthfulness of encounter data submitted." *Id.*

In 2014, CMS considered but ultimately decided not to finalize a proposed rule that would have altogether prohibited Medicare Advantage organizations from performing one-sided retrospective reviews. Under the proposed regulation:

> medical record reviews conducted by [a Medicare Advantage] organization cannot be designed only to identify diagnoses that would trigger additional payments by CMS to the . . . organization; and medical record review methodologies must be designed to identify errors in diagnoses submitted to CMS as risk adjustment data, regardless of whether the data errors would result in positive or negative payment adjustments.

79 Fed. Reg. at 2000. Although CMS decided not to finalize the proposed rule, *see id.* at 29,926, it reiterated that it has "always expected that [a Medicare Advantage] organization . . . implement, during the routine course of business, appropriate payment evaluation procedures in order to meet the requirement of certifying the data they submit to CMS for purposes of payment," *id.* at 29,923. CMS explained:

> [Medicare Advantage] organizations . . . are responsible for ensuring that payment data they submit to CMS are accurate, truthful, and complete (based on best knowledge, information, and belief), and are expected to have effective and appropriate payment

> evaluation procedures and effective compliance programs as a way to avoid receiving or retaining overpayments. Thus, at a minimum, reasonable diligence would include proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments.

Id. CMS added, "[i]f the requirement to report and return overpayments applied only to situations where the [Medicare Advantage] organization . . . has actual knowledge of the existence of an overpayment, then these entities could easily avoid returning improperly received payments." *Id.* at 29,924.[4] Although these 2014 events postdate the allegations in Swoben's pleadings, which cover the years between 2005 and 2012, they are consistent with the regulatory requirements that have existed since 2000.

II. Procedural History

Swoben filed an initial complaint in this action in 2009. His first amended complaint added claims against United Healthcare. He filed a second amended complaint in 2010.

[4] Also in 2014, CMS adopted a regulation stating that a Medicare Advantage organization "has identified an overpayment when [it] has determined, or should have determined through the exercise of reasonable diligence, that [it] has received an overpayment," 42 C.F.R. § 422.326(c), and for this purpose an "overpayment" includes a previously submitted medical diagnosis code that is not properly supported by a medical record, *see* 79 Fed. Reg. at 29,921 (stating "a risk adjustment diagnosis that has been submitted for payment but is found to be invalid because it does not have supporting medical record documentation would result in an overpayment").

In 2011, he filed a third amended complaint, adding claims against HealthCare Partners, Aetna, WellPoint and Health Net. In accordance with the False Claims Act, Swoben filed each of these pleadings under seal. *See* 31 U.S.C. § 3730(b)(2).

The gist of Swoben's complaint is that the defendants – Medicare Advantage organizations United Healthcare, Aetna, WellPoint and Health Net, and HealthCare Partners, a physician group providing health care services to the organizations' enrollees in exchange for a percentage of the organizations' capitated payments – performed biased retrospective medical record reviews. According to Swoben, retrospective reviews by Medicare Advantage organizations typically should identify (and report to CMS) two types of errors in the risk adjustment data previously submitted: (1) diagnosis codes supported by an enrollee's medical records but not previously submitted to CMS (under-reporting errors); and (2) diagnosis codes previously submitted to CMS but not supported by the enrollee's medical records (over-reporting errors). Identifying and reporting the first type of error is favorable to the Medicare Advantage organization; identifying and reporting the second type of error is unfavorable. Swoben alleges the defendants conducted one-sided retrospective reviews designed to identify (and report to CMS) solely the first type of error. He alleges these reviews were designed to exaggerate enrollees' health risks and cause CMS to make inflated capitated payments to the defendants. These actions, Swoben alleges, rendered the defendants' periodic certifications under § 422.504(*l*) false, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1).

Specifically, Swoben alleges the defendants' retrospective reviews were biased in three respects. First, he alleges each of the defendants retained coding companies or purchased specialized software to perform retrospective reviews of the medical charts of tens of thousands of their patients with severe illnesses but "concealed from the coders the diagnosis codes that had been previously submitted to the Government." Fourth Am. Compl. ¶¶ 12, 16–17. As a consequence, "the results of the coders' reviews did not identify the diagnosis codes unsupported by proper documentation of the reviewed medical charts that had been previously submitted to the Government." Fourth Am. Compl. ¶¶ 13, 17. Swoben alleges the defendants engaged in these activities beginning in 2005. Fourth Am. Compl. ¶¶ 12, 16.

Second, Swoben alleges United Healthcare instructed its medical providers, including Healthcare Partners, to review the medical charts of selected patients to determine whether those charts supported specific diagnoses that had not previously been reported to CMS. Fourth Am. Compl. ¶ 14. The medical providers reported the additional diagnosis codes supported by the records "but made no attempt to determine or report those previously reported diagnosis codes that were unsupported by properly documented medical charts that were reviewed." Fourth Am. Compl. ¶ 14. Swoben alleges United Healthcare and Healthcare Partners engaged in this activity from approximately 2005 to 2007. Fourth Am. Compl. ¶ 14.

Third, Swoben alleges the defendants used a template to report the results of their retrospective reviews to CMS that allowed coders to enter any additional diagnosis codes identified by the reviews but "did not permit the entry of

information indicating what previously submitted [diagnosis] codes should be withdrawn." Fourth Am. Compl. ¶ 23. Swoben alleges the defendants used the faulty template from approximately 2006 to 2012. Fourth Am. Compl. ¶ 24. He further alleges the defendants were involved in the development of the template and were aware of its shortcomings. Fourth Am. Compl. ¶¶ 22, 27.

Swoben also alleges CMS conducted annual RADV audits of sample medical charts for United Healthcare, Aetna, WellPoint and Health Net. Fourth Am. Compl. ¶ 25. He alleges that each of these Medicare Advantage organizations "had RADV audit error rates well in excess of 20%, reflecting that more than 20% of [their] diagnosis codes submitted to CMS were not supported by properly documented medical charts." Fourth Am. Compl. ¶ 25.[5] Swoben alleges the over-reporting error rate found in these audits of representative medical records placed the defendants on notice that the risk adjustment data they more broadly submitted to CMS also contained significant over-reporting errors. Fourth Am. Compl. ¶ 25.

Swoben alleges the defendants' practices rendered their § 422.504(*l*) certifications false and fraudulent. He alleges they submitted false claims by attesting to the accuracy of their risk adjustment data even though they knowingly designed and performed retrospective reviews to conceal and not withdraw previously submitted diagnosis codes that were unsupported by retrospectively reviewed medical records. Fourth Am. Compl. ¶ 27. He alleges, moreover, that the

[5] Swoben alleges the RADV audits showed a high percentage of over-reporting errors. His allegations do not address whether the RADV audits also identified under-reporting errors.

defendants knew their certifications were false because they (1) helped develop the reporting template and knew the template would not capture over-reporting errors identified by retrospective reviews; (2) had RADV audit over-reporting error rates in excess of 20 percent, placing them on notice that "a similar percentage of medical charts that were retrospectively reviewed should have resulted in [diagnosis] codes being withdrawn as unsupported by the medical charts"; and (3) designed their retrospective reviews to avoid identifying or reporting unsupported diagnosis codes that should have been withdrawn. Fourth Am. Compl. ¶ 27.

In 2012, the United States intervened in the action as to Swoben's claims against certain defendants not relevant here. In January 2013, the United States declined to intervene as to the defendants who are parties to this appeal (collectively, "the defendants"). The district court ordered the complaints unsealed and served on the defendants. In June 2013, after the district court issued an initial scheduling and case management order, the newly served defendants moved to dismiss Swoben's claims, arguing his third amended complaint failed to satisfy Rules 8, 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure.

In his opposition to the defendants' motions, Swoben did not defend the third amended complaint. Instead, he advised the court he would voluntarily dismiss his claims under state law and would seek leave to amend his complaint with respect to his claims under the False Claims Act. The district court ordered Swoben to file a declaration describing "in detail the proposed Fourth Amended Complaint and why such an amendment would not be futile or denied due to evidence of a lack of diligence or undue delay." As directed, Swoben

filed a declaration of counsel setting out the additional allegations he would include in a fourth amended complaint.

In a July 2013 order, the district court dismissed the third amended complaint with prejudice, concluding Swoben failed to allege a claim under the False Claims Act with particularity as required by Rule 9(b). The court denied leave to amend, citing both futility of amendment and undue delay. The court entered final judgment, and Swoben timely appealed. He does not challenge dismissal of the third amended complaint but contends the district court abused its discretion by denying leave to amend.

After hearing oral argument, we asked the parties to submit supplemental briefing to address when conducting retrospective medical record reviews designed to identify only diagnoses that would trigger additional payments by CMS, not errors that would result in negative payment adjustments, would cause a certification to be false for purposes of § 422.504(*l*) and the False Claims Act. The parties filed briefs addressing this question, and the Department of Justice, representing the United States as amicus curiae, filed a brief supporting Swoben.

STANDARD OF REVIEW

We review the denial of leave to amend for an abuse of discretion, *see United States ex rel. Lee v. Corinthian Colls.*, 655 F.3d 984, 995 (9th Cir. 2011), but we review the question of futility of amendment de novo, *see Carvalho v. Equifax Info. Servs., LLC*, 629 F.3d 876, 893 (9th Cir. 2010).

DISCUSSION

The district court denied leave to amend on two independent grounds – futility of amendment and undue delay. We address these in turn.

I. Amendment Would Not Be Futile

The district court denied leave to amend in part on the ground that amendment would have been futile. Accordingly, we address whether Swoben's proposed fourth amended complaint would have been adequate to survive a motion to dismiss.

A. The Proposed Fourth Amended Complaint Adequately States a Cognizable Legal Theory

The parties dispute whether Swoben's proposed fourth amended complaint alleges a cognizable legal theory.

1. The False Claims Act imposes liability in part on "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A), or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," *id.* § 3729(a)(1)(B).[6] "In an archetypal *qui tam* False Claims action, such as where a private company overcharges under a government contract,

[6] In addition to these False Claims Act provisions, the United States, as amicus curiae, argues the defendants' conduct violates § 3729(a)(1)(G), known as the "reverse false claims" provision. Swoben, however, did not rely on that provision in his opening and reply briefs. We therefore do not address it here.

the claim for payment is itself literally false or fraudulent." *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1170 (9th Cir. 2006). As relevant here, however, "a claim under the False Claims Act can be false where a party merely falsely certifies compliance with a statute or regulation as a condition to government payment." *Id.* at 1171. Under a false certification theory, "it is the false *certification* of compliance which creates liability when certification is a prerequisite to obtaining a government benefit." *Id.* (alteration omitted) (quoting *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996)). The essential elements of a false certification claim are: "(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." *Id.* at 1174.[7] Proof of damage to the government is not required. *See Bly-Magee v. California*, 236 F.3d 1014, 1017 (9th Cir. 2001); *United States ex rel. Hagood v. Sonoma Cty. Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991); Claire M. Sylvia, *The False Claims Act: Fraud Against the Government* §§ 4:2, 4:3 (2015).

The defendants challenge Swoben's theory that the manner in which they designed and conducted their retrospective reviews rendered their certifications under § 422.504(*l*) false. They contend:

> During the time period alleged in the complaint, no statute, regulation, or guidance

[7] The defendants' briefing challenges only the first and second of these elements here. Accordingly, for purposes of our analysis, we assume Swoben's proposed fourth amended complaint satisfies the third and fourth elements.

> from CMS indicated that a certification could only be "accurate, complete, and truthful" if [a Medicare Advantage] plan validated for itself that the millions of diagnosis codes submitted to it by third-party providers were supported by the underlying medical charts – i.e., that the plan was required to attest to the accuracy of someone else's work. Nor did any authority indicate that a plan was obliged to undertake affirmative steps to unearth potentially unsupported codes before it could certify the third-party risk adjustment data based on its "best knowledge, information, and belief."

Joint Suppl. Br. 1. These arguments are unpersuasive for two distinct reasons.

First, the defendants mischaracterize Swoben's theory of the case. Swoben does not allege the defendants' certifications are false merely because they passively forwarded to CMS unsupported diagnosis codes they received from their medical providers. That type of conduct would not necessarily result in false § 422.504(*l*) certifications. As CMS made clear in the 2000 preamble, Medicare Advantage organizations "cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that [CMS and the Department of Justice] believe is reasonable to enforce." 65 Fed. Reg. at 40,268. "[S]imple mistakes will not result in sanctions." *Id.* Instead, Swoben alleges the defendants took affirmative steps to generate and report skewed data. Even in the face of "RADV audit error rates well in excess of 20%" (Fourth Am. Compl. ¶ 25), they "conceived, planned and conducted the retrospective reviews

by not causing the previously submitted diagnosis codes that were unsupported by the retrospective reviews to be corrected and withdrawn from the Government," doing so "with the knowledge and intent that the retrospective reviews would only increase, and not decrease, the number of diagnoses, and thus their respective risk scores in order to increase capitated payments paid by the Government" (Fourth Am. Compl. ¶ 19). The defendants' attempts to portray themselves as the passive victims of their providers' errors wholly misstates Swoben's theory of the case, which focuses on the defendants' own conduct in allegedly conceiving, directing and conducting retrospective reviews designed to identify only favorable reporting errors.

Second, the defendants' contention that, during the relevant time period between 2005 and 2012, there was no "authority [to] indicate that a [Medicare Advantage] plan was obliged to undertake affirmative steps to unearth potentially unsupported codes before it could certify the third-party risk adjustment data based on its 'best knowledge, information, and belief'" is unpersuasive. When it adopted the "best knowledge, information, and belief" standard in 2000, CMS made clear this was the same standard as the one establishing liability under the False Claims Act – i.e., that it encompasses not only actual knowledge of falsity but also reckless disregard and deliberate ignorance. *See* 65 Fed. Reg. at 40,268; *see also* 31 U.S.C. § 3729(b)(1)(A) (False Claims Act). As we have explained in describing this standard under the False Claims Act:

> In defining knowingly, Congress attempted "to reach what has become known as 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." S. Rep. No. 99-345, at 21 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5286. 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.* at 20; *see also id.* at 7 (discussing the importance of individual responsibility because the government has limited resources to police fraud). "While the Committee intends that at least some inquiry be made, the inquiry need only be 'reasonable and prudent under the circumstances.'" *Id.* at 21.

United States v. Bourseau, 531 F.3d 1159, 1168 (9th Cir. 2008); *see also Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 2000 (2016) (holding "half-truths – representations that state the truth only so far as it goes, while omitting critical qualifying information – can be actionable misrepresentations" under the False Claims Act).

Thus, as CMS made clear, Medicare Advantage organizations have always had "an obligation to take steps to ensure the accuracy, completeness, and truthfulness of the encounter data" and "an obligation to undertake 'due diligence' to ensure the accuracy, completeness, and truthfulness of encounter data submitted to [CMS]." 65 Fed. Reg. at 40,268. CMS made perfectly clear that Medicare Advantage organizations would be "held responsible for making good faith efforts to certify the accuracy, completeness, and truthfulness of encounter data submitted."

Id. Indeed, CMS expressly rejected the argument that Medicare Advantage organizations "should not be required to certify the accuracy of the encounter data they receive from third parties." *Id.* The defendants' contention that they were under no obligation to take affirmative steps to address errors also ignores § 422.503, which since 2005 has required Medicare Advantage organizations to have effective compliance programs in place, including "[p]rocedures for internal monitoring and auditing" and for "ensuring prompt response to detected offenses." 42 C.F.R. § 422.503(b)(4)(vi), (vi)(F), (vi)(G) (2005).

In light of these authorities, we hold that when, as alleged here, Medicare Advantage organizations design retrospective reviews of enrollees' medical records deliberately to avoid identifying erroneously submitted diagnosis codes that might otherwise have been identified with reasonable diligence, they can no longer certify, based on best knowledge, information and belief, the accuracy, completeness and truthfulness of the data submitted to CMS. This is especially true, when, as alleged here, they were on notice that their data included a significant number of erroneously reported diagnosis codes. We do not see how a Medicare Advantage contractor who has engaged in such conduct can in good faith certify that it believes the resulting risk adjustment data reported to CMS are accurate, complete and truthful. As the government argues in its amicus brief, when a Medicare Advantage plan "has implemented record-review procedures specifically designed *not* to reveal unsupported diagnosis codes – the plan's certification under § 422.504(*l*) is 'false or fraudulent' under 31 U.S.C. § 3729(a)(1)(A) & (B)." Br. United States as Amicus Curiae 4.

By holding that one-sided retrospective reviews *can* result in false certifications under § 422.504(*l*), we do not suggest that they necessarily always do. The "best knowledge, information, and belief" standard under § 422.504(*l*) prohibits only a "reckless disregard" or "deliberate ignorance" of the truth or falsity of the risk adjustment data submitted to CMS. We do not in this opinion attempt to define the parameters of these requirements. We hold only that the theory alleged here – that the defendants designed their retrospective review procedures to not reveal unsupported diagnosis codes, allegedly for no other reason than to avoid reporting that information to the government – states a cognizable legal theory under the False Claims Act. That the defendants allegedly did so in spite of RADV audit errors rates of 20 percent or more only strengthens Swoben's claims.

We also do not intend to suggest that the practice of concealing previously submitted diagnosis codes from coders conducting retrospective reviews is necessarily a suspect practice. On the contrary, blind coding may help ensure the integrity of a retrospective review: if reviewers are told in advance which codes were submitted to CMS, they may have an especially strong incentive to find support for those codes in the records under review.

But blind coding cannot be squared with the good faith required by § 422.504(*l*) when it is employed as a means of avoiding or concealing over-reporting errors. If Medicare Advantage organizations acquire the codes identified by retrospective coders, compare them to the codes previously submitted to CMS, identifying both under- and over-reporting errors, but withhold information about the over-reporting errors from CMS, this would result in a false certification. The same is true when a Medicare Advantage organization

undertakes comprehensive blind coding but then runs a unidirectional comparison with the previously submitted codes to reveal only under-reporting errors. As the government explains, the use of blind coding cannot excuse failing to "check whether diagnosis codes previously submitted to CMS were included on the list of diagnoses found by the reviewers to be supported by the medical records." Br. United States as Amicus Curiae 15. In the first example, in which a Medicare Advantage organization withholds known over-reporting errors from CMS, the organization has actual knowledge that the data are false. In the second example, where the organization turns a blind eye to the over-reporting errors, it exhibits reckless disregard and deliberate ignorance toward the truth or falsity of the data submitted to CMS. Both examples show a lack of diligence and an absence of good faith. On the other hand, if through reasonable diligence the comparison between the codes identified by the retrospective reviewers and the codes previously submitted to CMS is capable of identifying only under-reporting errors, we assume this would not result in false certifications under current CMS regulations. The due diligence standard requires only reasonable efforts.

In sum, Swoben has alleged a cognizable legal theory.

2. The defendants' arguments to the contrary are not persuasive.

The defendants argue their certifications cannot have been false because they did not *know* of any specific unsupported diagnosis codes in the data they submitted to CMS. Joint Suppl. Br. 4. As explained, however, neither the "best knowledge, information, and belief" standard under § 422.504(*l*) nor the scienter element of the False Claims Act

requires actual knowledge of falsity. Under the False Claims Act,

> the terms "knowing" and "knowingly" – (A) mean that a person, with respect to information – (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud.

31 U.S.C. § 3729(b)(1). Section 422.504(*l*) adopts precisely the same standard. *See* 65 Fed. Reg. at 40,268. And this standard reaches "what has become known as 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." *Bourseau*, 531 F.3d at 1168 (quoting S. Rep. No. 99-345, at 21) (internal quotation marks omitted). Although the False Claims Act's scienter requirement is "rigorous," *Universal Health Servs.*, 136 S. Ct. at 2002, Swoben's allegations satisfy it here.

The defendants also suggest they could not have conducted their retrospective reviews in bad faith because retrospective reviews of a *portion* of an enrollee's medical records are not a plausible means of identifying over-reporting errors. They point out that "CMS regulations deem a diagnosis code proper if it is supported by a single medical record by a single provider." Joint Answering Br. 36. "Accordingly, the absence of documentation for a diagnosis code in a single retrospective review of a single provider's charts does not establish that the submission of that code to CMS was improper: the code may simply be located in charts

not encompassed by the retrospective review." *Id.* We are not persuaded. First, if the retrospective reviews were designed in bad faith, then it is no defense that the reviews, as designed, could not readily identify over-reporting errors. Second, the record at this early stage does not tell us how easy or difficult it would have been for the defendants to identify over-reporting errors, and Swoben alleges only that the defendants intentionally prevented coders from doing so. Whether the defendants had a good-faith reason to design the reviews as they did is not a matter to decide at this stage of the proceedings, particularly where the defendants' factual assertions are less than obvious. For instance, because CMS requires medical diagnosis codes to be supported by a medical record, it may be that each diagnosis code reported to CMS is linked to a *specifically identified* supporting medical record. In that event, if a reviewer finds a previously reported diagnosis code is not supported by the very medical record used to document the diagnosis code in the first place, then the diagnosis code was reported in error, even if it is possible that some other, unidentified record might support the same diagnosis.[8] As the government points out, "[e]ven if it turns out that the diagnosis is supported by other medical records, the failure of [the] plan to investigate to make that determination – after it has been put on notice that the diagnosis may not be supported – makes its broad certification regarding the accuracy, completeness, and

[8] In other words, if a Medicare Advantage organization relied on medical record X to justify submitting a particular diagnosis code to CMS initially, and the retrospective reviewer concludes X does not support that diagnosis, then the code should be withdrawn. If it turns out the code can be substantiated by a different medical record, then the code can be left in place or resubmitted. But the Medicare Advantage organization cannot simply ignore the reporting error because it speculates that some other medical record might support the same diagnosis code.

truthfulness of submitted data false." Br. United States as Amicus Curiae 17.

The defendants also argue the statements by CMS in 2000 regarding due diligence and good faith should not be given weight because, at the time, risk adjustment was based primarily on demographic factors rather than patient encounter data. Joint Resp. to Amicus Br. 9–10 & n.3. We disagree. First, the statements by CMS are authoritative not because of what they say about encounter data or diagnosis codes but because they provided clear guidance to Medicare Advantage organizations (then known as Medicare+Choice organizations) regarding their obligations under § 422.504(*l*) (then codified at § 422.502(*l*)), including their obligations under the "best knowledge, information, and belief" standard. Second, the defendants' representations to the contrary notwithstanding, it is quite clear that the risk adjustment methodology in place in 2000 focused on patient encounter data, just as it does today. *See* 65 Fed. Reg. 40,246–51. The defendants point out that at the time CMS collected encounter data only for inpatient care. Joint Resp. to Amicus Br. at 9 n.3. But, as CMS made clear at the time, it was already "developing a more comprehensive risk-adjustment methodology that uses diagnosis data from physician services and hospital outpatient department encounters" as well. 65 Fed. Reg. at 40,247–48. Thus, when CMS emphasized the importance of due diligence and good faith in reporting patient encounter data in 2000, it clearly had within its contemplation the regime that was then in development and which was in place at the time the allegedly false claims were submitted in this case. Third, even if the defendants were correct that the focus of the risk adjustment methodology in 2000 was on demographic factors rather than encounter data,

there is no question that CMS' statements about due diligence and good faith were focused on the latter:

> M+C organizations have an obligation to take steps to ensure the accuracy, completeness, and truthfulness of the *encounter data*. We acknowledge that *encounter data* come into M+C organizations in great volume and from a number of sources, presenting significant verification challenges for the organizations. However, we believe that M+C organizations have an obligation to undertake "due diligence" to ensure the accuracy, completeness, and truthfulness of *encounter data* submitted to [CMS]. Therefore, they will be held to a "best knowledge, information, and belief" standard. Therefore, M+C organizations will be held responsible for making good faith efforts to certify the accuracy, completeness, and truthfulness of *encounter data* submitted.

Id. at 40,268 (emphasis added).[9]

[9] The statements CMS made in the preamble to the certification regulation merit deference. *See, e.g.*, *Christopher v. SmithKline Beecham Corp.*, 132 S. Ct. 2156, 2163 (2012); *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 158 n.13 (1982) ("[W]e look to the preamble . . . for the administrative construction of the regulation, to which 'deference is . . . clearly in order.'" (third alteration in original) (quoting *Udall v. Tallman*, 380 U.S. 1, 16 (1965))). CMS' statements regarding the meaning of the "best knowledge, information, and belief" standard are entitled to deference because they represent the agency's interpretation of its own regulation. The interpretation is also entitled to deference because it represents the agency's considered judgment after notice and comment,

The defendants also contend their certifications could not have been knowingly false because their conduct between 2005 and 2012 represented at least an objectively reasonable interpretation of their obligations under § 422.504(*l*). Joint Suppl. Br. 12. *See Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 70 n.20 (2007) ("Where, as here, the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a knowing or reckless violator."); *Hagood*, 929 F.2d at 1421 ("To take advantage of a disputed legal question . . . is to be neither deliberately ignorant nor recklessly disregardful."). We again disagree. CMS' clear statements in the 2000 preamble – "[Medicare Advantage] organizations have an obligation to undertake 'due diligence' to ensure the accuracy, completeness, and truthfulness of encounter data submitted to [CMS and] will be held responsible for making good faith efforts to certify the accuracy, completeness, and truthfulness of encounter data submitted," 65 Fed. Reg. at 40,268 – resolved any ambiguity about the meaning of § 422.504(*l*). *See Fid. Fed. Sav. &*

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industry input and interagency consultation. *See* Establishment of the Medicare+Choice Program, 63 Fed. Reg. 34968, 35017 (June 26, 1998) (interim final rule with comment period); 65 Fed. Reg. at 40,176, 40,268, 40,299 (final rule with comment period). Indeed, the good faith standard about which the defendants now complain appears to have been suggested by the industry. *See* 65 Fed. Reg. at 40,268, 40,299. *Compare* 63 Fed. Reg. at 35103 (interim rule), *with* 65 Fed. Reg. at 40,327–28 (final rule). We also afford deference to CMS' interpretation of the regulation because it is consistent with the standard for liability under the False Claims Act, and therefore presumably carries out congressional intent. *Cf. Wyeth v. Levine*, 555 U.S. 555, 576–80 (2009) (declining to afford deference to statements in an agency's preamble where the agency failed to offer interested parties notice or an opportunity for comment and the preamble was at odds with evidence of Congress' purposes).

Loan Ass'n, 458 U.S. at 158 ("Any ambiguity in [the regulation's] language is dispelled by the preamble accompanying and explaining the regulation."). Consequently, ignoring the good faith and due diligence requirements would not have been objectively reasonable.

The defendants also contend their § 422.504(*l*) certifications could not have been false because they offered only a *qualified* certification of their risk adjustment data, "based on best knowledge, information, and belief." Joint Suppl. Br. 5–6. They rely on *United States v. Ekelman & Associates, Inc.*, 532 F.2d 545, 550 (6th Cir. 1976) ("In certifying the truth of the information in the application 'to the best of its knowledge and belief' Franklin did no more than assert that it had no knowledge of, nor intention to make, misrepresentations."). *Ekelman* is distinguishable on a number of grounds. First, § 422.504(*l*)'s "best knowledge, information, and belief" standard is informed by the 2000 preamble, which makes clear the standard encompasses due diligence, good faith, reckless disregard and deliberate ignorance. *See* 65 Fed. Reg. at 40,268. In this sense, § 422.504(*l*)'s "best knowledge, information, and belief" standard is similar to the "best of the person's knowledge, information, and belief" standard under Federal Rule of Civil Procedure 11, under which an attorney's "signature certifies to the court that the signer has read the document, has conducted a reasonable inquiry into the facts and the law and is satisfied that the document is well grounded in both, and is acting without any improper motive." *Bus. Guides, Inc. v. Chromatic Commc'ns Enters., Inc.*, 498 U.S. 533, 542 (1991). Second, in contrast to *Ekelman*, this is not a case in which it is clear the defendants lacked any "intention to make[] misrepresentations." *Ekelman*, 532 F.2d at 550. Swoben's allegations support the inference that the defendants certified

that they believed the risk adjustment data were complete and accurate even though they did *not* believe that to be the case. Third, *Ekelman* was decided in 1976, a decade before Congress amended the False Claims Act to include a deliberate ignorance standard. *See* False Claims Amendments Act of 1986, Pub. L. No. 99-562, § 2, 100 Stat. 3153 (1986) (codified as amended at 31 U.S.C. § 3729(b)(1)). The deliberate ignorance standard does not allow a contractor to deliberately turn a blind eye to reporting errors and then attest that, to its knowledge, they do not exist.

Finally, notwithstanding the certification and compliance regulations discussed in this opinion, the defendants invoke a separate regulation, 42 C.F.R. § 422.310(d), to argue they reasonably believed they were not required to take any affirmative steps to find unsupported diagnosis codes. Joint Suppl. Br. 6–7. In relevant part, § 422.310(d) states that Medicare Advantage "organizations must submit data that conform to CMS' requirements for data equivalent to Medicare fee-for-service data, when appropriate, and to all relevant national standards." 42 C.F.R. § 422.310(d). According to the defendants, because CMS does not verify diagnosis codes submitted to it by third-party medical providers under the Medicare fee-for-service program, this provision means Medicare Advantage organizations were not required to verify diagnosis codes either. We reject the defendants' contention, again for multiple reasons. First, because nothing in § 422.310(d) speaks to a Medicare Advantage organization's obligations to ensure the accuracy of risk adjustment data, it does not modify a Medicare Advantage organization's obligations under §§ 422.503(b)(4)(vi) and 422.504(*l*). Second, this is not a case about whether Medicare Advantage organizations have to *take* affirmative steps to verify risk adjustment data. The

defendants indisputably took such steps by conducting retrospective reviews. This is a case about whether such organizations, having adopted affirmative verification procedures, have to conduct them in good faith.

In sum, we conclude Swoben's proposed fourth amended complaint adequately pleads a cognizable legal theory.

B. The Proposed Fourth Amended Complaint Alleges Sufficient Factual Matter to Satisfy Rules 8, 9(b) and 12(b)(6)

The parties also dispute whether Swoben's proposed fourth amended complaint satisfies Rule 8 and 9(b).

1. Under Rule 8, we assume the veracity of a complaint's factual allegations and then determine whether they plausibly give rise to an entitlement to relief. *See Corinthian Colls.*, 655 F.3d at 991. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). Under Rule 9(b), a plaintiff "must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). This means the plaintiff must allege "the who, what, when, where, and how of the misconduct charged." *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010) (quoting *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003)). Knowledge, however, may be pled generally. *See Corinthian Colls.*, 655 F.3d at 996.

Swoben's proposed fourth amended complaint satisfies these standards. He alleges that, beginning in approximately

2005, each of the defendants employed coding companies to perform retrospective reviews designed not to reveal over-reporting errors. Fourth Am. Compl. ¶¶ 12–13. He alleges that from approximately 2005 to 2007 United Healthcare and HealthCare Partners used specialized software to identify enrollees for retrospective reviews but, again, the reviews were designed not to reveal over-reporting errors. Fourth Am. Compl. ¶¶ 14–15. He alleges HealthCare Partners used another software product, HCC Manager, to similar effect in approximately June 2008. Fourth Am. Compl. ¶¶ 16–17. He alleges that from approximately 2006 to 2012 each of the defendants used the flawed template to report the results of their retrospective reviews to CMS. Fourth Am. Compl. ¶¶ 23–24. The proposed complaint alleges that each of the defendants (other than HealthCare Partners) had RADV audit error rates exceeding 20 percent during the relevant time period. Fourth Am. Compl. ¶ 25. It alleges that each of the defendants (other than HealthCare Partners) submitted false § 422.504(*l*) certifications periodically, and at least annually, during the relevant time period. Fourth Am. Compl. ¶ 27. We acknowledge that some of these allegations are not as detailed as they might be. But the allegations, each of which is fleshed out to some extent in the proposed pleading, are adequate to satisfy Rule 9(b).

2. Again, the defendants' arguments to the contrary are not persuasive.

The defendants argue Swoben's pleadings are insufficient because they "do not describe *any* specific instances of falsity, let alone any such instances *with particularity* by identifying the time, place, and manner of the alleged falsity, the person making the false representation, or what they obtained thereby." Joint Answering Br. 35; *see also id.* at

40–41. Under our case law, however, the plaintiff need not "identify representative examples of false claims to support every allegation." *Ebeid*, 616 F.3d at 998. "[I]t 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.'" *Id.* at 998–99 (quoting *United States ex rel. Grubbs v. Ravikumar Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)). Swoben, therefore, need not identify specific false § 422.504(*l*) certifications.

The defendants also argue Swoben's pleadings "fail[] to identify a single instance where previously submitted codes were inconsistent with those identified during the retrospective reviews, or to explain why any such inconsistencies would necessarily lead to false claims." Joint Answering Br. 35. Under Swoben's theory, however, the false claims are the allegedly false § 422.504(*l*) certifications, not the erroneously reported diagnosis codes. *See Hendow*, 461 F.3d at 1171 (explaining that it "is the false *certification* of compliance which creates liability when certification is a prerequisite to obtaining a government benefit"). Swoben need not identify specific diagnosis codes that should have been withdrawn.

The defendants next fault the proposed fourth amended complaint for using (often, though not exclusively) collective allegations to refer to the defendants rather than differentiating among them. Joint Answering Br. 38. The defendants are correct that "Rule 9(b) does not allow a complaint to merely lump multiple defendants together but requires plaintiffs to differentiate their allegations when suing more than one defendant and inform each defendant separately of the allegations surrounding his alleged participation in the fraud." *Corinthian Colls.*, 655 F.3d at

997–98 (quoting *Swartz v. KPMG LLP*, 476 F.3d 756, 764–65 (9th Cir. 2007)). A plaintiff must "identify the role of each defendant in the alleged fraudulent scheme." *Id.* (quoting *Swartz*, 476 F.3d at 765). There is no flaw in a pleading, however, where, as here, collective allegations are used to describe the actions of multiple defendants who are alleged to have engaged in precisely the same conduct. Under these circumstances, Swoben's allegations, although collective, nonetheless afford each defendant ample notice of its alleged role.

Finally, the defendants argue with respect to the RADV audits that "Swoben fails to provide any of the particular details required by Rule 9(b), . . . which would be necessary for these allegations to have any relevance to the Defendants' knowledge or intent." Joint Answering Br. 42. As noted, however, knowledge need not be pled with particularity. *See* Fed. R. Civ. P. 9(b); *Odom v. Microsoft Corp.*, 486 F.3d 541, 554 (9th Cir. 2007). The defendants' argument therefore falls short.

In sum, we hold the allegations in the proposed fourth amended complaint are adequate to satisfy Rules 8 and 9(b) and hence Rule 12(b)(6). Because the complaint alleges a cognizable legal theory and satisfies Rules 8 and 9(b), we hold that amendment would not be futile. The district court erred by deeming amendment futile, and therefore abused its discretion by denying leave to amend on this ground.

II. The District Court Abused its Discretion By Denying Leave to Amend Based on Undue Delay

The district court alternatively denied leave to amend "based on undue delay" because "Swoben was aware of the

purportedly 'new' allegations he proposes to add to the Fourth Amended Complaint since at least 2005."

We conclude the district court abused its discretion by relying on undue delay. Undue delay by itself is insufficient to justify denying leave to amend, *see Owens v. Kaiser Found. Health Plan, Inc.*, 244 F.3d 708, 712–13 (9th Cir. 2001), and the record here does not support any additional ground – such as prejudice or bad faith, *see Johnson v. Mammoth Recreations, Inc.*, 975 F.2d 604, 607 (9th Cir. 1992) – that would justify the denial of leave to amend in combination with undue delay.

The defendants' argument they would be prejudiced by affording Swoben leave to amend is unpersuasive. They fault Swoben for failing to announce his intention to seek leave to amend during the meet-and-confer conferences preceding the filing of their motions to dismiss. *See* C.D. Cal. R. 7-3. They argue that, if Swoben had announced his intention to seek amendment at that time, they could have avoided the expense of preparing their motions to dismiss. In the absence of bad faith, however, litigation expenses incurred before a motion to amend is filed do not establish prejudice. *See Owens*, 244 F.3d at 712. More broadly, the defendants have not shown prejudice here. The litigation against these defendants is at a very early stage, Swoben does not seek to assert a new legal theory and this is Swoben's first attempt to cure deficiencies in his complaint. The circumstances of this case stand in stark contrast to those in the cases on which the defendants rely. *See AmerisourceBergen Corp. v. Dialysist W., Inc.*, 465 F.3d 946, 953–54 (9th Cir. 2006) (the plaintiff sought leave to amend a reply to a counterclaim to assert a new legal theory, which "would have unfairly imposed potentially high, additional litigation costs . . . that could have

easily been avoided"); *Ascon Props., Inc. v. Mobil Oil Co.*, 866 F.2d 1149, 1160–61 (9th Cir. 1989) (the defendant had filed several motions to dismiss over several years of active litigation, the plaintiff had been given several opportunities to cure the deficiencies in the complaint, the plaintiff had prosecuted the action in a dilatory fashion and the plaintiff sought to amend the complaint to assert a new legal theory).

CONCLUSION

The district court abused its discretion by dismissing Swoben's third amended complaint without leave to amend. Swoben's proposed fourth amended complaint adequately alleges a false certification claim under the False Claims Act, so amendment would not have been futile. The district court also abused its discretion by denying leave to amend on the ground of undue delay. The judgment of the district court is vacated and the case is remanded for further proceedings.

VACATED AND REMANDED. Costs on appeal are awarded to Swoben.