No. 13-56746

IN THE 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, et al.,

Defendants-Appellees.

On Appeal from the United States District Court
for the Central District of California

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE IN SUPPORT OF APPELLANT

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases:

Statutes:

False Claims Act:

Social Security Act:

Regulatory Materials:

Legislative Materials:

Other Authorities:

INTRODUCTION AND SUMMARY

A central, distinguishing feature of Medicare Advantage (MA) is the provision of Medicare benefits by private health-insurance organizations in exchange for capitated payments from the government (*i.e.,* fixed monthly payments for each enrollee). The Centers for Medicare & Medicaid Services (CMS) adjusts these payments for various "risk" factors that affect expected healthcare expenditures, to ensure that MA organizations are paid more for those enrollees expected to incur higher healthcare costs and less for healthier enrollees expected to incur lower costs. To make these adjustments, CMS collects "risk adjustment" data, including medical diagnosis codes, from MA organizations.

This payment model creates powerful incentives for MA organizations to exaggerate the expected healthcare costs for their enrollees by "over-reporting" diagnosis codes. To combat these incentives and ensure that the government is not overpaying MA plans, CMS requires that submitted diagnoses be supported by patient medical records. And given the critical importance of accurate data, a fundamental prerequisite to payment under the program is that plans

expressly certify "based on best knowledge, information, and belief" that the information they have provided is "accurate, complete, and truthful," 42 C.F.R. § 422.504(*l*)(2).

In this declined *qui tam* suit under the False Claims Act, relator alleges that defendants conducted retrospective reviews of patient records designed solely to find information that would lead to increased government payments (*i.e.,* to find additional diagnosis codes not previously submitted to CMS but purportedly supported by medical records), and systematically ignored information that would lead to decreased payments (*i.e.*, submitted diagnosis codes not supported by medical records). Relator alleges that defendants thereby submitted "false or fraudulent" claims for payment under 31 U.S.C. § 3729(a)(1)(A), and also knowingly and improperly avoided or decreased an obligation to pay the government under 31 U.S.C. § 3729(a)(1)(G). This Court directed the parties to file supplemental briefs addressing whether the conduct alleged by relator "would cause [an MA organization's] certification to be false for purposes of [42 C.F.R.] § 422.504(*l*) and the False Claims Act."

Because the False Claims Act is the government's primary tool to combat fraud and recover losses due to fraud, proper resolution of this question is important to the United States. Nearly a third of all Medicare beneficiaries are enrolled in Medicare Advantage, and the United States has a strong interest in ensuring that MA organizations provide CMS with "accurate, complete, and truthful" information—and in ensuring that those organizations are held liable under the False Claims Act where they knowingly fail to do so.

To the extent defendants designed chart reviews solely to find and report information that would lead to increased governmental payments (*i.e.*, additional diagnosis codes) and ignored available information that would lead to decreased payments (*i.e.*, unsupported diagnosis codes), defendants' certifications regarding the accuracy, completeness, and truthfulness of the data submitted to CMS were false in at least two ways.

First, CMS has made clear that MA organizations must exercise "due diligence" to ensure the accuracy of submitted data. The certification required under 42 C.F.R. § 422.504(*l*) is thus best understood to carry with it a representation that a plan has acted with

reasonable diligence and implemented measures to find errors. If a plan has not exercised such diligence—especially where it 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).

Second, even apart from the regulatory duty to exercise "due diligence," if an MA organization knows that it has submitted unsupported diagnoses, *see* 31 U.S.C. § 3729(b)(1), its certification that the information it has submitted is "accurate, complete, and truthful" is false or fraudulent under the False Claims Act. A plan cannot escape False Claims Act liability by deliberately ignoring available information suggesting that some of the diagnosis codes it has submitted to CMS may not be supported by medical records.

Finally, regardless of whether an MA organization's certification under § 422.504(*l*) is false, where a plan deliberately designs its chart reviews in a way that prevents the discovery of unsupported diagnosis codes or ignores information suggesting that it may have submitted unsupported diagnoses, it has "knowingly and improperly avoid[ed]" an "obligation" to pay money to the government and is independently liable

under 31 U.S.C. § 3729(a)(1)(G), the "reverse false claims" provision of the False Claims Act. Just as MA organizations cannot shirk their obligation to exercise reasonable diligence to ensure that the information they have submitted is "accurate, complete, and truthful," they cannot purposely avoid taking steps to determine whether they have received payments to which they are not entitled. That is precisely the sort of "ostrich-like" behavior that the False Claims Act was intended to reach. *See United States v. Bourseau*, 531 F.3d 1159, 1168 (9th Cir. 2008).

ARGUMENT

I. The Conduct Alleged Is Sufficient to State a Claim That Defendants Falsely Certified the Accuracy of Data Submitted to Obtain Payments from the Government

A. Defendants' Certifications Are False Because Defendants Failed to Exercise Due Diligence in Ensuring the Accuracy of Submitted Data

1. Unlike the traditional Medicare program, which uses a fee-for-service payment model, Medicare Advantage uses a capitated payment system under which participating plans receive a fixed monthly payment for each enrollee. CMS adjusts these capitated payments to account for various "risk" factors that affect expected healthcare

expenditures, including the relative health of a plan's enrollees compared with that of the average Medicare beneficiary. *See* 42 U.S.C. § 1395w-23(a)(1)(C); 42 C.F.R. § 422.308(c)(1). To make this adjustment, CMS collects data from MA organizations, in particular, diagnosis codes the plans receive from healthcare providers after medical encounters with enrollees. Using past diagnosis codes, CMS calculates a risk score that is used prospectively to calculate monthly payments. *See* 42 C.F.R. § 422.310(g). In general, the more severe the diagnosis, the higher the risk score and thus the greater the risk-adjusted payment made to an MA plan.

Because risk-adjustment data provide the foundation for payment under Medicare Advantage, participating plans must expressly certify that the data they submit, including diagnosis codes, are "accurate, complete, and truthful." 42 C.F.R. § 422.504(*l*)(2). Although CMS has not prescribed precise steps MA organizations must take to verify data, the agency has long made clear that this certification requirement imposes "an obligation to undertake 'due diligence' to ensure the accuracy, completeness, and truthfulness of encounter data submitted." 65 Fed. Reg. 40,170, 40,268 (June 29, 2000). CMS has explained that

the certification is not merely a representation that MA organizations "have not altered the data, and that they have transmitted it to [CMS] as they received it from the provider." *Id*. Rather, MA organizations must make affirmative "good faith efforts to certify the accuracy, completeness, and truthfulness of encounter data submitted." *Id*.[1]

In addition, MA organizations are required to "[a]dopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS'[s] program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse." 42 C.F.R. § 422.503(b)(4)(vi).

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[1] CMS again recognized this affirmative duty to ensure the accuracy of submitted data in 2014, when it promulgated a regulation to implement the Affordable Care Act's overpayment provision, 42 U.S.C. § 1320a-7k(d). The agency explained that it has "always expected" MA organizations to implement "appropriate payment evaluation procedures in order to meet the requirement of certifying the data they submit to CMS for purposes of payment." 79 Fed. Reg. 29,844, 29,923 (May 23, 2014). CMS rejected the suggestion that MA organizations "are not obliged to proactively search for an overpayment without reason to believe that a specific overpayment exists." *Id.* "[A]t a minimum," the agency explained, the "reasonable diligence" referred to in the overpayment regulation includes "proactive compliance activities . . . to monitor for the receipt of overpayments." *Id.* The agency made clear that this "reasonable diligence" standard imposed no new requirement but instead stemmed from the longstanding requirement to certify risk-adjustment data submitted to CMS. *Id.*

Compliance with this threshold requirement for participation in Medicare Advantage is both a condition of participation and a condition of payment for purposes of liability under the False Claims Act. *See United States ex rel. Hendow v. University of Phoenix*, 461 F.3d 1166, 1176 (9th Cir. 2006) (explaining that threshold conditions of participation can also be conditions of payment).

In light of the comprehensive duties MA organizations have to exercise reasonable diligence and implement effective measures to ensure the accuracy of risk-adjustment data submitted to CMS, the certification required by 42 C.F.R. § 422.504(*l*) is best understood to include representations not only that the data are accurate, but also that a plan has made reasonable efforts to uncover and weed out unsupported diagnosis codes. Those representations are false where, as alleged here, defendants not only failed to take affirmative steps to find unsupported diagnosis codes, but deliberately designed their retrospective chart reviews to *prevent* the discovery of unsupported codes and thereby avoid any negative payment adjustments.

The Supreme Court's recent decision in *Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*, 135 S. Ct. 1318

(2015), supports the conclusion that a plan's failure to exercise due diligence to ensure the accuracy of submitted data renders its express certification that the data are "accurate, complete, and truthful" false. In *Omnicare* the Court held that investors could proceed on a securities-fraud claim based on the omission of material facts concerning a statement of opinion. Invoking common-law principles governing the tort of misrepresentation, the Court concluded that it was well-established that even "the expression of an opinion may carry with it an implied assertion, not only that the speaker knows no facts which would preclude such an opinion, but that he does know facts which justify it." *Id.* at 1330 (quoting *Prosser and Keeton on the Law of Torts* § 109, at 760 (5th ed. 1984)).

Here, the underlying regulatory scheme expressly requires that an MA organization make reasonable efforts to ensure the accuracy of submitted data. Accordingly, a plan's certification that its data are "accurate, complete, and truthful" necessarily carries with it a representation that the plan has exercised the required due diligence, which must include reasonable efforts to uncover unsupported

diagnoses. If a plan fails to exercise such diligence, its express certification is false for purposes of the False Claims Act.

2. To support their contention that their express certifications under § 422.504(*l*) are not "false or fraudulent" under the False Claims Act, defendants argue (Supp'l Br. 4-8) that they have no obligation to take *any* affirmative steps to ensure the accuracy of the data received from providers in order to make the required certification. Because the certification is based on "best knowledge, information, and belief," defendants contend, MA organizations are certifying only that they are "faithfully submitting" diagnosis codes received from providers, Defs.' Supp'l Br. 1, and that they "did not *know* of any unsupported diagnosis codes," *id.* at 4.

As discussed above, this argument is flatly inconsistent with the "due diligence" requirement CMS adopted when it promulgated the certification requirement in 2000. *See* 65 Fed. Reg. at 40,268 (explaining that MA organizations "have an obligation to undertake 'due diligence' to ensure the accuracy, completeness, and truthfulness of encounter data"). Moreover, this argument is inconsistent with defendants' own practices, which rely on retrospective chart reviews to

supplement their risk-adjustment data with diagnoses that were not reported by providers.

CMS's decision in 2014 not to finalize a proposed requirement that any chart reviews conducted by an MA organization be designed to find not just additional diagnoses to submit to CMS but also unsupported diagnoses that had previously been submitted to CMS—a "look both ways" requirement—does not relieve defendants of the broad obligation to exercise due diligence in ensuring the accuracy of submitted diagnoses. Contrary to defendants' suggestion (Supp'l Br. 11), no negative inference can be drawn from the agency's decision not to specifically mandate a particular type of inquiry to ensure the accuracy of risk-adjustment data. Indeed, as explained above, *supra* note 1, in that same rulemaking, CMS made clear that the certification under § 422.504(*l*) requires plans to exercise reasonable diligence to ensure the accuracy of submitted data. *See* 79 Fed. Reg. at 29,923.

Moreover, the mere inclusion of "best knowledge and belief" language in a certification does not relieve the speaker of all responsibility for the accuracy of the certified statement. If it did, express certifications of this sort would have no meaning or value to the

government as a verification of compliance with essential program requirements.

Defendant's argument that a "best knowledge" certification "does not warrant that plans have undertaken affirmative steps to find unsupported codes," Defs.' Supp'l Br. 6, finds no support in *United States v. Ekelman & Associates*, 532 F.2d 545 (6th Cir. 1976). In that case, the Sixth Circuit held that a representation is not "reckless" unless it is an "unqualified assertion of fact based on the personal knowledge of the party making the assertion when that party has no basis in fact for making it." *Id.* at 549. Stressing that the "certification of truth 'to the best of my knowledge and belief' is a qualified assertion of facts represented," *id.*, the court held that the defendant lending institution lacked "actual knowledge" that the information submitted to secure loan guarantees from the government was false, and therefore was not liable under the common law or the False Claims Act, *id.* at 548-50.

Ekelman was decided before Congress expanded the definition of "knowledge" under the False Claims Act (in 1986) to reach those who "failed to make simple inquiries which would alert [them] that false

claims are being submitted." S. Rep. No. 99-345, at 21 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5286. And CMS has explained that the "best knowledge, information, and belief" standard it adopted in § 422.504(*l*) was meant to be "consistent with" the constructive-knowledge standard of the False Claims Act. 65 Fed. Reg. at 40,268.

Moreover, *Ekelman* involved a regulatory scheme in which the defendant was not expected to make independent efforts to verify the accuracy of information submitted. In contrast, MA plans must implement effective compliance programs and exercise reasonable diligence to ensure the accuracy of data submitted. Thus, whatever force *Ekelman* might have in other contexts, the "best knowledge" certification under § 422.504(*l*) is best understood to convey a meaningful representation that submitted data are accurate.[2] That statement is false if a plan has failed to exercise reasonable diligence to

[2] In any event, even if this Court were to adopt *Ekelman*'s narrow view of a "best knowledge" certification, as we discuss in subsection B, defendants' certifications would still be false because defendants deliberately ignored information suggesting that at least some diagnosis codes were not supported by medical records. *See Ekelman*, 532 F.2d at 550 (limiting analysis to circumstances in which defendant "had no knowledge" of misrepresentations).

ensure the accuracy of submitted data, especially if it has implemented procedures designed *not* to reveal unsupported diagnoses.

Defendants' reliance on relator's apparent concession that plans that do not conduct chart reviews "have no duty to verify the accuracy of provider diagnosis codes," Defs.' Supp'l Br. 5, is similarly unavailing. Whatever relator may have conceded, CMS has long made clear that it is not enough for plans simply to pass along data received from providers. Instead, plans must exercise "due diligence" to ensure the accuracy of submitted data and must implement effective compliance programs to prevent, detect, and correct errors. At a minimum, plans cannot implement procedures specifically designed *not* to reveal unsupported diagnoses. Otherwise, the express certifications regarding the accuracy, completeness, and truthfulness of submitted data would be worthless.

B. Defendants' Certifications Are Also False Because Defendants Ignored Available Information Suggesting That At Least Some Diagnoses Were Unsupported

Even apart from defendants' false representations concerning their diligence in ensuring the accuracy of submitted data, defendants' certifications that the risk-adjustment data submitted to CMS are

"accurate, complete, and truthful" are false on the independent ground that defendants willfully ignored available information suggesting that at least some of the diagnosis codes submitted were *not* properly supported by patients' medical records. That is just the sort of "ostrich-like" behavior that Congress sought to reach in adding the "deliberate ignorance" and "reckless disregard" prongs to the knowledge standard of the False Claims Act in 1986. *See* 31 U.S.C. § 3729(b)(1); S. Rep. No. 99-345, at 7, 20-21; *see also Bourseau*, 531 F.3d at 1168.

Relator alleges that defendants used coding consultants to retrospectively review patient medical records and compile a list of all supported diagnosis codes, with the goal of finding additional diagnoses to submit to CMS. Defendants, however, did not 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.

To the extent an MA organization "knows" that a submitted diagnosis code is not, or may not be, supported by patient medical records, its certification under § 422.504(*l*) as to the accuracy, completeness, and truthfulness of submitted data is "false" under the

False Claims Act. If a code that had previously been submitted to CMS did not appear on the reviewers' list, then defendants had sufficient information to determine whether the previously submitted code was unsupported—or at least were on notice that further investigation was necessary. That is true even though the reviewers themselves were not provided a list of previously submitted diagnosis codes and even though defendants failed to "look both ways"—that is, to compare the two lists, not only to check whether diagnoses found by the reviewers had been submitted to CMS, but also to check whether submitted diagnoses appeared on the reviewers' list of diagnoses supported by the medical records. That defendants chose not to connect the dots—using information readily available to them—simply confirms that they acted in a deliberately ignorant or reckless manner in falsely certifying the accuracy, completeness, and truthfulness of submitted data. *See* 31 U.S.C. § 3729(b)(1).

In arguing that MA organizations have no legal obligation to conduct chart reviews that "look both ways," defendants contend (Supp'l Br. 10) that a submitted diagnosis may be supported by medical records even if it is not found in a particular chart review, because it may be

supported by other medical records not included in that review.[3] This observation, however, does not advance defendants' argument. At a minimum, the failure of a reviewer to include a previously submitted diagnosis code on its list of supported diagnoses should put the plan on notice that further investigation into the submitted diagnosis is necessary. Even if it turns out that the diagnosis is supported by other medical records, the failure of 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 truthfulness of submitted data false.

[3] Defendants argue that plans could ensure the accuracy of reported data in "myriad ways," but then note only two: (1) plans could attempt to determine whether specific providers "have aberrational patterns of coding," and (2) plans could "separately audit all diagnosis codes submitted during a given year for a sample of their beneficiaries." Defs.' Supp'l Br. 9. Notably, defendants do not assert that they have actually undertaken any of these alternatives, and this Court need not decide whether such measures would constitute reasonable diligence.

II. The Conduct Alleged Is Also Sufficient to State a Claim That Defendants Knowingly and Improperly Avoided an Obligation to Repay Money to the Government

In addition to potentially violating the False Claims Act's prohibitions on false claims, 31 U.S.C. § 3729 (a)(1)(A) & (B), the conduct relator alleges may also give rise to liability under the Act's "reverse false claims" provision, 31 U.S.C. § 3729(a)(1)(G). When an MA organization designs its retrospective chart reviews solely to find information that would lead to increased payments from CMS (*i.e.*, additional diagnosis codes) and ignores available information that would lead to negative payment adjustments, its conduct falls squarely within the reverse-false-claims provision, which "is designed to cover [g]overnment money or property that is knowingly retained by a person even though they have no right to it." S. Rep. No. 111-10, at 13-14 (2009), *reprinted in* 2009 U.S.C.C.A.N. 430, 441.

Before 2009, a person was liable for a "reverse" false claim if he "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(7) (2008). The 2009 amendments to the False Claims Act eliminated the

need for a false statement and imposed liability on anyone who "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G). As amended the Act also defines an "obligation" to include "the retention of any overpayment." *Id.* § 3729(b)(3).

The pattern of conduct alleged in this case, which extends from 2005 to 2012, falls comfortably within both the former and current versions of the reverse-false-claims provision. To the extent an MA organization has submitted unsupported diagnoses, the higher risk-adjusted payment associated with those diagnoses exceeds the amount the plan is entitled to. When a plan deliberately ignores information suggesting that it may have submitted unsupported diagnoses, it has "knowingly and improperly avoid[ed] or decrease[d] an obligation to pay or transmit money or property to the Government," 31 U.S.C. § 3729(a)(1)(G).[4]

[4] For conduct occurring before the 2009 amendments, defendants' false certifications would provide the "false record or statement" needed to establish liability under § 3729(a)(7).

The overpayment provision that the Affordable Care Act added to the Social Security Act in 2010, 42 U.S.C. § 1320a-7k(d), confirms that such conduct gives rise to reverse-false-claims liability. Defining an "overpayment" as "any funds that a person receives or retains under [the Medicare and Medicaid statutes] to which the person, after applicable reconciliation, is not entitled," *id.* § 1320a-7k(d)(4), this provision requires that an overpayment be returned within 60 days after it is "identified," *id.* § 1320a-7k(d)(2). It further provides that the continued retention of an overpayment beyond this 60-day deadline is an "obligation" for purposes of the False Claims Act. *Id.* § 1320a-7k(d)(3). CMS's 2014 regulation implementing this provision states that an MA organization "has identified an overpayment when [the entity] 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).[5]

[5] The implementing regulation also defines "applicable reconciliation" to be the final deadline for submitting risk-adjustment data. *See* 42 C.F.R. § 422.326(a). A risk-adjustment payment to which an MA organization is not entitled thus does not become an "overpayment" until the final deadline for submitting diagnosis codes.

An MA organization violates the Affordable Care Act's mandate to return overpayments, and thus the False Claims Act, when it fails to exercise reasonable diligence to uncover unsupported diagnoses or ignores information suggesting that it may have submitted unsupported diagnoses.[6]

In similar circumstances, courts have held that healthcare providers may not avoid reverse-false-claims liability simply by ignoring audits or terminating investigations that would have revealed overpayments received from the government. In *Kane ex rel. United States v. Healthfirst, Inc.*, 120 F. Supp. 3d 370 (S.D.N.Y. 2015), for example, the court denied a motion to dismiss claims brought under § 3729(a)(1)(G) where the defendants were on notice that certain claims submitted to the government might contain erroneous billing codes. Likewise, in *United States ex rel. Keltner v. Lakeshore Medical Clinic, Ltd.*, No. 11-cv-00892, 2013 WL 1307013 (E.D. Wis. Mar. 28, 2013), the court held that the relator stated a claim under § 3729(a)(1)(G) where

[6] Although some of the conduct alleged here predates the enactment of the Affordable Care Act and all of the conduct predates the promulgation of CMS's implementing regulation, these statutory and regulatory overpayment provisions are instructive as to what Congress intended in enacting the reverse-false-claims provision.

the defendant had found high rates of improper "upcoding" by physicians in audits but failed to follow up on non-audited claims.

The reasoning of those cases applies with equal force here. Defendants cannot escape False Claims Act liability by conducting the sort of "one-way reviews" alleged by relator and deliberately ignoring information suggesting that they submitted unsupported diagnoses and therefore received payments to which they were not entitled.

CONCLUSION

For the foregoing reasons, this Court should hold that the conduct alleged by relator is sufficient to state claims that defendants falsely certified the accuracy of data submitted to the government to obtain payment and knowingly and improperly avoided an obligation to repay money to the government.

Respectfully submitted,

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APRIL 2016

CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(a)

I hereby certify that this brief complies with the requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been prepared in 14-point Century Schoolbook, a proportionally spaced font.

I further certify that this brief complies with the 4,200-word limit in this Court's order dated February 16, 2016, because it contains 4,114 words, excluding the parts of the brief exempted under Rule 32(a)(7)(B)(iii), according to the count of Microsoft Word.

/s/ Karen Schoen
Karen Schoen

CERTIFICATE OF SERVICE

I hereby certify that on April 18, 2016, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

The participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

/s/ Karen Schoen
Karen Schoen