United States Court of Appeals
For the Eighth Circuit

No. 12-3206

United States of America, ex rel.

Plaintiff

David Ketroser; Gary Latz; Robert Smith; Jason Kennedy

Plaintiffs - Appellants

v.

Mayo Foundation, et al.

Defendants - Appellees

Appeal from United States District Court
for the District of Minnesota - Minneapolis

Submitted: June 11, 2013
Filed: September 4, 2013

Before LOKEN, BEAM, and BYE, Circuit Judges.

LOKEN, Circuit Judge.

Attorney David Ketroser and three others ("Relators") brought this *qui tam* action under the False Claims Act (FCA) against the Mayo Foundation and several

related entities ("Mayo"), alleging that Mayo billed Medicare for surgical pathology services it did not provide. See 31 U.S.C. § 3729(a)(1)(A) and (B). The government intervened and filed a Complaint in Partial Intervention, alleging that Mayo billed Medicare for "permanent" surgical pathology slides it did not create or examine. See 31 U.S.C. § 3730(b)(2). The parties settled that claim. Relators filed a Second Amended Complaint asserting additional claims. They now appeal the dismissal of their additional claim that Mayo fraudulently billed for services it did not provide whenever it prepared and read a permanent tissue slide but did not prepare a separate written report of that service. The district court[1] concluded that it had subject matter jurisdiction over this claim because there was no prior public disclosure of this false claim, see § 3730(e)(4), but it dismissed the claim under Rule 12(b)(6) because "[t]he billing codes applicable to the claims submitted by Mayo do not explicitly require written reports [and] the regulation that sets forth the Medicare conditions of payment . . . requires a written report for clinical pathology services [but not] surgical pathology services." United States ex rel. Ketroser v. Mayo Found., No. 07-4676, Order, at *5-6 (D. Minn. July 22, 2011). Reviewing these issues *de novo*, we agree and therefore affirm.

I. Background

Medicare compensates qualified healthcare providers on a "fee-for-service" basis in which the provider bills for each discrete medical service. For "surgical pathology services" -- the analysis of tissue samples taken during a surgery -- each tissue slide a pathologist reads is billed as a separate service. Mayo's longstanding practice is to analyze every sample taken during a surgery using two different procedures. First, a "frozen" slide is made from a portion of the sample and immediately diagnosed by a pathologist who communicates with the surgeon while

[1]The Honorable Joan N. Ericksen, United States District Judge for the District of Minnesota.

the patient is still in surgery. Second, a "permanent" slide is made from the remainder of the sample and read after the surgery through a durable, slower process. A published medical study described this dual-slide procedure in 1995. See Jorge A. Ferreiro, Jeffrey L. Myers, & David G. Bostwick, *Accuracy of Frozen Section Diagnosis in Surgical Pathology: Review of a 1-Year Experience with 24,880 Cases at Mayo Clinic Rochester*, 70 Mayo Clinic Proc. 1137, 1137-38 (Dec. 1995).

In August 2001, Medicare audited the records of frozen slides prepared in Mayo's pathology labs and found that many were prepared without the surgeon's specific request.[2] Medicare informed Mayo it would no longer pay for frozen slides unless they were specifically ordered by the treating surgeon. Mayo appealed this ruling, arguing that its practice of routinely preparing frozen slides reduced costs to Medicare by providing immediate diagnoses that reduced the need for subsequent surgeries. The Social Security Administration agreed, concluding that Mayo had documented the "medical necessity" for its frozen slide procedures. In re Mayo Med. Ctr., No. 999-18-0546 at *5 (Social Security Adm. May 27, 2003).

This FCA claim involves a different aspect of Mayo's dual-slide procedure. Mayo submits separate surgical pathology claims for the frozen slide and the permanent slide that are prepared and examined from a patient's tissue sample. Based on initial review of the frozen slide, the Mayo pathologist prepares a written pathology report. The initial report is amended if subsequent review of the permanent slide shows that the initial report was incomplete or inaccurate. In most cases, no amendment is required, so no second report is prepared. Relators argue that Medicare regulations require a written report for every permanent slide for which a healthcare provider bills Medicare. Therefore, Relators argue, Mayo has habitually submitted false claims for Medicare payment of surgical pathology services not provided.

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[2]Mayo's normal practice in this regard is atypical. Most hospitals make only permanent slides unless the surgeon specifically requests a frozen slide.

II. The Public Disclosure Jurisdictional Bar

When Relators filed this action, the FCA included a statutory public disclosure bar that withdrew jurisdiction to afford a relator FCA relief if the existence of the alleged fraud had been publicly disclosed, unless the relator was the "original source" of information demonstrating the fraud. Rockwell Int'l Corp. v. United States, 549 U.S. 457, 467-70 (2007), construing 31 U.S.C. § 3730(e)(4)(A).[3] Relators learned the factual basis for the FCA claim at issue while litigating wrongful death and medical malpractice claims against Mayo on behalf of former patients Dolores Smith and William Kennedy.[4] Comparing Mayo's medical records for these and other patients with the "Explanation of Benefits" the patients received from Medicare, Relators observed that, in most cases where Medicare paid claims for both frozen and permanent slides, only one report was in the patient's medical file.

Mayo moved to dismiss this failure-to-prepare-reports claim on the ground that Mayo's reporting procedures had been widely disclosed in public fora, including the 1995 medical study, the Social Security Administration proceedings, and the Steinlage litigation.

At the motion hearing before the district court, Relators argued that a great deal was publicly disclosed in the medical study and the administrative proceedings, but not the essence of the alleged fraud -- Mayo's practice of not preparing separate reports for permanent slides billed to Medicare as separate surgical pathology

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[3]The statute then provided: "No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in [enumerated sources] unless the action is brought by the Attorney General or the person bringing the action is an original source of the information."

[4]The parties refer to the wrongful death action as "the Steinlage litigation." See Steinlage v. Giannini, No. 03-6067 (D. Minn. 2003).

services. Relators only learned of this practice during the Steinlage litigation from Mayo discovery responses that were never filed in court and therefore may not be considered *public* disclosures. This was a sound argument; § 3730(e)(4)(A) expressly limits the bar to "public disclosure of allegations or transactions in a . . . civil . . . *hearing*." See United States ex rel. McKenzie v. Bellsouth Tel., Inc., 123 F.3d 935, 939 (6th Cir. 1997), and cases cited (public disclosure "includes documents that have been filed with a court"); United States ex rel. Kinney v. Stoltz, 2002 WL 523869, at *5 (D. Minn. 2002), aff'd on other grounds, 327 F.3d 671 (8th Cir. 2003). Mayo did not respond to this argument at the hearing.

The district court, without extended discussion, ruled that it had subject matter jurisdiction over this claim because the court "does not discern a public disclosure of the allegations regarding Mayo's alleged failure to prepare reports in the materials cited." On appeal, Mayo argues the court erred, asserting that Mayo's practice of not preparing written reports was specifically disclosed in the published 1995 medical study, in a 2002 Medicare administrative hearing, and in an affidavit filed in the Steinlage litigation. As the issue is jurisdictional, we must address it first.[5] Relators as the parties invoking federal jurisdiction have the burden of proof on this issue. See Hays v. Hoffman, 325 F.3d 982, 987 (8th Cir.), cert. denied, 540 U.S. 877 (2003).

We have carefully examined the materials cited in Mayo's brief and find no such specific disclosures. Accordingly, reviewing this issue *de novo*, we agree with the district court that Relators satisfied their burden of showing that the public disclosure bar did not deprive the court of jurisdiction over this specific claim. See United States ex rel. Hixson v. Health Mgmt. Sys., Inc., 613 F.3d 1186, 1188 (8th Cir.

[5]As amended in 2010, § 3730(e)(4)(A) now provides that, if the bar applies, "The court shall dismiss an action or claim under this section, unless opposed by the Government." The parties agree that this case is governed by the statute in effect when the action was filed. See Graham Cnty. Soil & Water Conserv. Dist. v. United States ex rel. Wilson, 130 S. Ct. 1396, 1400 n.1 (2010).

2010) (to bar an FCA action, "the disclosure must reveal the critical elements of the fraudulent transaction"); Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp., 276 F.3d 1032, 1044 (8th Cir.) (public disclosures must reveal "both the true state of facts and that the defendant represented the facts to be something other than what they were"), cert. denied, 537 U.S. 944 (2002).

III. Failure To State a Claim

Turning to the merits of the claim at issue, the FCA imposes treble-damage liability on any person who "knowingly presents . . . a false or fraudulent claim for payment" to the government, or who "knowingly makes a false record or statement . . . to get a false or fraudulent claim paid or approved by the government." 31 U.S.C. § 3729(a)(1)(A), (B) (2008).[6] "The FCA attaches liability, not to the underlying fraudulent activity, but to the claim for payment." Costner v. URS Consultants, Inc., 153 F.3d 667, 677 (8th Cir. 1998) (quotation omitted). "Without sufficient allegations of materially false claims, an FCA complaint fails to state a claim on which relief may be granted." United States ex rel. Vigil v. Nelnet, Inc., 639 F.3d 791, 796 (8th Cir. 2011). Therefore, to state a claim "that is plausible on its face," Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009), Relators must plead facts raising more than a speculative possibility that Mayo's claims for Medicare payments were materially false or fraudulent. See United States ex rel. Raynor v. Nat'l Rural Utils., 690 F.3d 951, 956 (8th Cir. 2012).

[6]These provisions were amended and renumbered to § 3729(a)(1) and (a)(2) in 2009; the amendment applies "to all claims . . . pending on or after [June 7, 2008]." Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, § 4(a)(1), 4(f)(1), 123 Stat. 1617, 1621-22. Because we conclude that Relators' claim would fail under either version, we need not address an unresolved retroactivity issue. See United States v. Hawley, 619 F.3d 886, 894 (8th Cir. 2010). All citations to § 3729(a) in this opinion are to the prior version.

Our review of this issue was substantially frustrated by Relators failure to put in the record even one example of a claim Mayo submitted to a Medicare paying agent seeking payment for surgical pathology services. This violated the well-established principle that a relator who "alleges a systematic practice of submitting fraudulent claims . . . must provide some representative examples of the alleged fraudulent conduct." United States ex rel. Roop v. Hypoguard USA, Inc., 559 F.3d 818, 822 (8th Cir. 2009) (quotation omitted). At bottom, we conclude, Relators alleged nothing more than regulatory noncompliance, which fails to state a claim because "the FCA does not encompass those instances of regulatory noncompliance that are irrelevant to the government's disbursement decisions." Vigil, 639 F.3d at 796; accord 31 U.S.C. § 3729(b)(4). Nonetheless, like the district court, we will examine the relevant Medicare regulations to see whether Mayo's alleged practice of submitting claims for Medicare payment for the creation and examination of permanent surgical pathology slides for which Mayo did not prepare a written report necessarily constituted the knowing submission of a false or fraudulent claim or statement within the meaning of 31 U.S.C. § 3729(a)(1)(A) or (B).

Medicare regulations set forth conditions for when the payment of claims for "surgical pathology services" will be made on a fee schedule basis. See 42 C.F.R. § 415.130(b)(1).[7] The Medicare Reimbursement Manual, ch. 12, § 60(B), defines "surgical pathology services" by cross referencing the American Medical Association's "current procedural technology" (CPT) nomenclature for identifying particular medical services:

[7]The regulations establish only three conditions for payment for surgical pathology services: "(1) The services are personally furnished for an individual beneficiary by a physician[;] (2) The services contribute directly to the diagnosis or treatment of an individual beneficiary[; and] (3) The services ordinarily require performance by a physician." 42 C.F.R. §§ 415.102(a), 415.130(b)(1).

> Surgical pathology services include the gross and microscopic examination of organ tissue performed by a physician . . . . Surgical pathology services paid under the physician fee schedule are reported under the following CPT codes: 88300, 88302, 88304, 88305, 88307, 88309, 88311, 88312 . . . .

See generally Michelle Abraham, et al., *Current Procedural Technology: Standard Edition* (Am. Med. Assn. ed., 4th ed. 2010) (the "Codebook"). Mayo used CPT codes 88300 through 88309 in billing Medicare for general surgical pathology services. (The remaining codes refer to specialized additional services, for example, using a special dye to stain the slide.) The Codebook states that "Services 88300 through 88309 include accession [accessing the tissue sample], examination, *and reporting*." Codebook at 298 (emphasis added). The Codebook's Introduction defines "reports" as "the work product" of a physician's interpretation. Codebook at xvi.

Relators argue (i) that use of CPT codes in submitting claims for payment by Medicare represents that the services listed in the codes were provided; (ii) that the "reporting" service included in CPT codes 88300 through 88309 means creating a *written* report for each CPT-coded service that is separately billed; and therefore (iii) that Mayo submitted a false or fraudulent claim within the meaning of the FCA each time it billed Medicare for a permanent slide knowing that a written report of the pathologist's examination of *that slide* would not be prepared. Mayo counters that the proper interpretation of these billing codes as incorporated in the Medicare regulations does not require written reports for each slide; "reporting" has a broader meaning, encompassing whatever medium appropriately communicates the pathologist's conclusions. Creating a single written report for each surgical *case*, regardless of the number of CPT-coded slides created and examined, and supplementing that report with oral communications between doctors regarding individual slides and any needed written amendment, satisfies this requirement. Thus, Mayo argues, it made no false or fraudulent statement, material or otherwise.

We will assume without deciding that Relators are correct in asserting that use of a CPT billing code in submitting a claim for Medicare payment, knowing that the services listed in that code have not been provided, can give rise to "false or fraudulent claim" liability under 31 U.S.C. § 3729(a)(1)(A) or (B).[8] But the elements of an FCA cause of action must still be plausibly alleged. In that regard, we agree with the district court that Relators' claim fell short in numerous respects:

- CPT codes 88300 through 88309 require "reporting" but do not explicitly require a written report for each slide created and examined for a particular surgery. By contrast, the regulation for another category of pathology services, "clinical consultation services," requires that the service "[r]esult in a *written narrative report* included in the beneficiary's medical record." 42 C.F.R. § 415.130(c)(3). This strongly suggests that the regulations do not require a separate written report for each surgical pathology slide.

- Turning to the AMA Codebook, for other CPT codes, such as the code for diagnostic ultrasounds, the Codebook explicitly requires a "*written* report," unlike the general inclusion of "reporting" in the services for codes 88300 through 88309. See Codebook at 365 (emphasis added). This is strong evidence that the Codebook uses the terms "report" and "reporting" broadly; when pathologists are expected to prepare *written* reports, the Codebook makes that requirement explicit.

- Relators submitted no specific evidence that Medicare or paying agents responsible for approving claims for surgical pathology services expect that a separate written report was prepared for each surgical pathology slide that Mayo billed, and no evidence (other than Relators' own interpretation of general

[8]The cases Relators cite in support of that assertion did not squarely address this issue.

authorities) that Medicare considers the existence of a separate written report to be a material condition of paying each separate claim for surgical pathology services.

Turning to extrinsic sources, Relators argue the reporting requirements for laboratory tests performed under Medicare Part B for non-hospital medical care imply that each individual surgical pathology slide must be accompanied by a separate written report. See 42 C.F.R. §§ 493.1291, .1273, .1105; 410.32(d). Mayo argues that these regulations govern laboratories performing diagnostic tests, not physicians performing surgical services. In any event, while these regulations seem to require written rather than oral reports, they do not imply that a written report is required *for each slide*. Mayo prepares written pathology reports for each surgical case, which appears to satisfy the requirements of Part 493 as incorporated by § 410.32.

Finally, Relators argue that pathology "reports" must *always* be written as a matter of standard industry practice, pointing to a recommendation published by the College of American Pathologists. See Jeffrey D. Goldsmith, et al. *Reporting Guidelines for Clinical Laboratory Reports in Surgical Pathology*, 132 Archives Pathology & Laboratory Med. 1608 (Oct. 2008). But this is not evidence that Medicare expects written reports for each permanent slide. The authors considered what must be done in every surgical case, not for each individual specimen considered in a surgical case. They recommended that pathology laboratories use exactly the procedure Mayo uses for cases that involve multiple specimens, namely, attaching an addendum to the initial report *if* there are "results of deeper sections or slides" or "results of additional tissue sections." Id. at 1611, Table 8. If anything, the College of American Pathologists recommendation demonstrates what common sense would suggest -- that it is *not* industry practice to incur the expense of a separate report for each slide when the initial report is accurate and complete.

On this record, all Relators have plausibly alleged is their *desire* that the Medicare regulation and CPT Codebook be interpreted to require a separate written

report for each permanent slide that is billed as a separate surgical pathology service. This fails to state an FCA claim of knowing fraud. See Raynor, 690 F.3d at 956-57. The absence of a clear requirement that a written report must underlie or support each claim for surgical pathology services means that Relators pleaded a claim of regulatory noncompliance, not a plausible claim that Mayo submitted false or fraudulent claims for Medicare payment. Moreover, Mayo's reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud under the FCA. See 31 U.S.C. § 3729(b)(1). An FCA defendant does not act "with the knowledge that the FCA requires before liability can attach" when "the defendant's interpretation of the applicable law is a reasonable interpretation, perhaps even the most reasonable one." Hixson, 613 F.3d at 1190; see Raynor, 690 F.3d at 957.

In sum, nowhere in the Medicare regulations or in the American Medical Association Codebook have we found a requirement that physicians using the CPT codes for surgical pathology services must prepare the additional written reports that Relators claim Mayo fraudulently failed to provide. The FCA may not properly be used to impose an onerous and costly burden on the healthcare system without plausible evidence that Medicare would consider such redundant reports to be a material condition of payment. The judgment of the district court is affirmed.
